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14. ABSTRACT Statistics show that over 66% of American adults, or more than 127 million, are overweight or obese. There is a strong link between obesity and diabetes. As the rates of obesity rise, so will the epidemic of diabetes. Diabetes is the fifth leading cause of death by disease in the United States, and annual costs are $132 billion. Without proper medical care and patient education, individuals with diabetes will experience devastating, costly complications. Research shows that if patients at risk for developing diabetes make lifestyle changes, they can decrease their chance of progressing to diabetes by 59%. For those with diabetes, complications can be prevented and/or delayed with proper treatment and education. Building on previous work done by UPMC and the University of Pittsburgh, the focus of this program was to implement and evaluate comprehensive diabetes prevention and treatment programs disseminated throughout diverse practice settings and communities. In order to test the applicability of prevention and treatment modalities to diverse communities and racial and ethnic groups, we included initiatives targeted to underserved and military populations. To increase reach and access, we incorporated web-based tools and telecommunications technologies into our multi-faceted approach to prevention and treatment. As a result of the program, we were able to provide the AF SGR rationale for the implementation of the diabetes prevention and treatment programs, and assist them with such implementation. The work accomplished through these project years formed the basis of subsequent efforts to further demonstrate cost-effectiveness and sustainability.			
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INTRODUCTION

Diabetes affects approximately 20 million people (54 million with pre-diabetes) in the United States (8% of the population).(1) In 2007, diabetes was estimated to cost the United States $174 billion in medical expenditures and lost productivity.(2) These estimates do not include costs of uncompensated care or decrement in health related quality of life. In addition to care directly associated with diabetes, people with diabetes have an increased incidence of neurological, peripheral vascular, cardiovascular, renal, and ophthalmic co-morbidities and complications.(2) In order to treat both the underlying physiological abnormalities as well as their behavioral and psycho-social antecedents of risk factors, pre-diabetes and diabetes, a combination of medical and self-care is the preferred approach.(3) While both of these components have been well-defined literature, the breadth of required services and their integration are difficult to implement in practice. Efforts of this project have included the development and implementation of comprehensive, evidence-based, multi-faceted approaches that improve outcomes for the following focus areas:

- Primary prevention of diabetes
- Diabetes self-management education (DSME)
- Identification of diabetic retinopathy
- Initiatives specific to the population of veterans
- Inpatient initiatives for improved glycemic control
- Implementation of the chronic care model (CCM) into an integrated health network

Body

UPMC Collaborative Team

In recognition that reduction in the incidence of diabetes and alleviation of its complications have become national public health priorities, UPMC galvanized a partnership that included the University of Pittsburgh Diabetes Institute (UPDI) and the United States Air Force Surgeon General's Modernization Directorate (US AF SGR-M), to study how we can best prevent diabetes and improve diabetes care in both the civilian and military populations. Project evolution and success relied significantly on this collaboration and illuminated elements of the core infrastructure needed to implement a scalable and locally customizable national model for prevention and treatment, with focus on the core areas described above.

UPMC is one of the country's largest non-profit horizontally and vertically integrated healthcare payment and delivery systems. Its 19 hospitals, more than 500 outpatient sites (located in both urban and rural areas), and international operations serve over 4 million patients per year. In

order to support this geographically dispersed model and its diverse populations, UPMC has implemented one of the most advanced electronic medical records in the nation, deployed innovative telemedicine technology to connect its specialists with remote locations, and put into practice unique models of care delivery to address needs of underserved locations and developing countries. As the largest employer in western Pennsylvania, UPMC is also committed to advancing the health of the population and maintaining a productive work force.

UPMC is affiliated with the University of Pittsburgh, a major research institution that is ranked 6th nationally in NIH funding. Drawing on the considerable expertise within its six Schools of the Health Sciences, the university is a recognized leader in diabetes research, having conducted major national trials such as the Diabetes Control and Complications Trial (DCCT) and the Diabetes Prevention Project (DPP) (4, 5).

The University of Pittsburgh Diabetes Institute (UPDI) and UPMC Diabetes Centers leverage the academic expertise of the University with the clinical resources of UPMC, in order to advance research and translate these findings into practice through critical evaluation of new models for care. UPDI has established the largest diabetes registry in the nation, which supports tracking and determination of outcomes. The Diabetes Prevention Support Center offers educational programs and assists primary care physicians throughout the region in providing these services to their patients. In addition, 36 ADA-recognized diabetes self-management centers have been established.

In addition to our local collaboration and with the aid of AFSGR, we have forged a matrix relationship with the active military at Wilford Hall Medical Center (WHMC) to translate our efforts into a military setting. 59 MDW (59th Medical Wing), the Air Force's largest medical facility, is a national resource, providing complete medical care to military health care beneficiaries in the United States, as well as specialized care to patients referred from all over the world. The dynamic healthcare environment provided by WHMC allows for an exceptional research center in expanding our efforts to the military.

DIABETES

Government statistics show that almost 65% of American adults, or more than 120 million people, are overweight or obese. With the rate of obesity on a dramatic rise in the U.S., the incidence of individuals at risk of developing diabetes is expected to continue at epidemic rates. The Center for Disease Control (CDC) recently reported that one in three children born in 2003 will develop diabetes during their lifetime. Diabetes already affects more than 20 million Americans, with an estimated 54 million with pre-diabetes. There is disproportionate prevalence among minority, underserved, and rural populations.

Diabetes is the leading cause of new blindness, end stage renal disease, and non-traumatic amputations (6). Without proper medical care and patient education, individuals with diabetes will experience devastating, costly complications and frequent, extended hospitalizations. Research shows that if patients at risk for developing diabetes make lifestyle changes, they can decrease their chance of developing diabetes by 58% (5). For those with diabetes, complications can be prevented and/or delayed with proper treatment and education (4, 7).

With recognition of the impact of obesity on healthcare costs, prevention and treatment are a priority for both the public and private sectors. The U.S. health care system focuses heavily on a symptom-driven response to acute illnesses and is therefore poorly configured to provide preventive care and to meet the needs of the chronically ill (8). This traditional medical model is

particularly limited in rural, under-served, and geographically distributed environments (such as the U.S. military), in which the availability of both primary care and specialists are limited. New models of care that rely on a variety of health care professionals, tools, and interventions have been proposed to address these issues (8, 9, 10), but have not been systematically and comprehensively evaluated in terms of feasibility of implementation in diverse populations or their impact on a variety of outcomes measures. This project was the first phase of a multi-year program designed to rigorously evaluate new approaches to the prevention and treatment of obesity and diabetes in adult civilian and military populations.

UPMC DIABETES PROJECT

Primary Prevention

There is extensive evidence that both diabetes and cardiovascular disease can be substantially delayed or even prevented. Both lifestyle modification (Finnish Diabetes Prevention Study (11) and Diabetes Prevention Program (DPP) (5)) and pharmacotherapy (DPP (5); Stop-Niddm (12) have been shown to prevent or delay Type 2 diabetes (T2D). Numerous primary prevention and mixed primary/secondary prevention studies have also shown efficacy in preventing cardiovascular disease (CVD), (13, 14, 15, 16). While many factors are responsible for the lack of control of risk factors, the inadequate delivery of prevention services and limited availability of lifestyle modification programs are likely leading components. The key components of the DPP lifestyle intervention have been well described (17), however research examining a feasible practice or community based dissemination is lacking, as well as a national resource or center that can provide clinicians and researchers the most up-to-date information and guidance in the area of diabetes prevention.

Diabetes Self-Management Education (DSME)

Diabetes is a lifestyle disease where patients provide 98% of their own care. Patient-related factors contribute 98% of the effect on glycemic outcomes, while physician-related factors contribute the remaining 2%. (2) Diabetes self-management education (DSME), the foundation for self-management, is defined as the ongoing process of facilitating the knowledge, skill and ability necessary for effective self-management and is guided by evidence-based standards. (3) Research demonstrates that DSME improves self-management skills and adherence by affecting intermediate outcomes such as diabetes knowledge, psychological, and behavioral, which positively affect short-term metabolic outcomes that in turn, would lead to a decrease in diabetes-related complications. Patients with diabetes who do not receive DSME are found to be four times more likely to develop a major complication of diabetes (18) and incur higher diabetes-related hospital costs. (4)

Healthy People 2010 has established a goal of increasing the proportion of individuals reached with diabetes education from 40 to 60% (19-20). However, while the rates of diabetes are increasing, the very programs that help patients to better self-manage are closing and the numbers of certified diabetes educators (CDE) available are shrinking. In a cost-saving environment, nurse and dietitian educators are often the target of budget reduction initiatives when financial stability cannot be demonstrated. This is a particular hardship in underserved communities where budgets are severely restricted.

Access to education has been proposed as a potential barrier, particularly in communities where the closest DSMT program may be miles away (21). Another potential problem may be the traditional way in which education is prescribed and delivered. Currently, physicians are expected

to refer diabetes patients to a hospital-based DSME program. This hospital-based process is consistent with the current system of health care delivery as it applies to acute care where services are provided at a hospital. Although over 90% of patients with diabetes are cared for by primary care physicians (PCPs) (5), education is rarely available in the primary care office (22, 23).

The American Diabetes Association (ADA) provides a Diabetes Self Management Education (DSME) recognition program that assures uniform quality of services and offers the opportunity for Medicare and other third party reimbursement (24). UPMC in collaboration with UPDI has systemically developed a far-reaching network of DSME programs that has increased ADA recognized program sites from 3 in 2001 to 36 in 2009 (the third largest network in the US). Through its network, UPMC has demonstrated that DSME can sustain through reimbursement and can be delivered effectively in primary care.

While the ADA recognition process is widely accepted, there is a paucity of literature on the delivery process, reimbursement practices, and most importantly, hard outcomes. The ADA and the American Association of Diabetes Educators (AADE) collaborated to conduct a survey of DSME programs. Their findings in 122 sites confirmed other studies that indicate that diabetes education is an underutilized service (7, 13-15). More disappointing were the reimbursement practices. Of the sites that bill Medicare, only 57% were collecting the mandated collection fees, while 37% of the respondents didn't even know how often they were collecting these fees (7). Despite attempts to remedy this problem, only 57% reported having a fiscal reporting system. Moreover, despite the fiscal difficulties, this activity received the highest patient satisfaction ranking as compared with all other problem-solving activities. ADA and AADE concluded that processes for monitoring billing and establishing a reporting system specific to DSME were critically important (7).

In an effort to address this national mandate, UPMC collaborated with the AADE to systematically evaluate the AADE National Diabetes Education Outcome System (NDEOS). NDEOS incorporates DSME processes, assessment, patient behavior and educator interventions and outcomes evaluation with unique tools to aid in the achievement of ADA recognition. The NDEOS system was tested in both UPMC and community programs as part of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE).

Diabetic Retinopathy

Diabetic retinopathy is the leading cause of new cases of blindness in Americans between the ages of 20 to 74. (25-30). It has been estimated that blindness from diabetic retinopathy is preventable in at least 65% of cases, if abnormalities are identified through screening, before patients become symptomatic. Although retinal laser therapy has been shown to stabilize visual acuity, there is less success at improving or restoring vision that has already been lost (28). Unfortunately, retinal screening of diabetics is not consistently performed. Data from the Behavioral Risk Factor Surveillance System (BRFSS) has shown that the rate of eye exams in Pennsylvania ranged from 64.8% and 72.4% depending on age group, from 1994 to 1998, and It has also been estimated that only 77% of the 59 MDW enrolled diabetic population receives the annual recommended eye screening examinations with the screening rate for the entire Air Force Medical Service, 66%, is even lower (31). To improve screening rates and decrease ophthalmologic complications, innovative approaches must be introduced to make eye exams and specialty services more accessible, particularly to patients in under-served and geographically isolated locations (32). New technology allows non- dilated examinations to be conducted by personnel within primary care practice sites, with images transmitted electronically to specialists for interpretation. However, further study is needed to determine the effectiveness and accuracy of these methods.

Veteran's Initiative

Within the Veterans Health Administration (VHA), diabetes ranks among the leading causes of morbidity and mortality. Between 500,000 and 730,000 veterans receive care for diabetes within the VHA each year, and diabetes accounts for about 25% of all pharmacy costs (33-35). According to local performance measures at the initiation of this study, 35% of veterans in the VA Pittsburgh Healthcare System (VAPHS) had HbA1c levels in excess of 8%, above the targets recommended by either the American Diabetes Association (ADA; 7.0%) or the VHA (8.0%) for adequate glycemic control. About 50% of local veterans with diabetes had blood pressure (BP) readings above the ADA target of 130/80; 22% had BP greater than 140/90. Participant factors, such as non-adherence to an optimal regimen, and system factors, such as limited frequency and duration of contact with primary care providers (PCPs) and limited access to specialty care are recognized barriers to optimal glycemic, BP, and lipid control. Inadequate control, in turn, is associated with increased morbidity and mortality due to micro- and macrovascular disease (33, 34, 36-38).

Home-based telemedicine is emerging as a tool for chronic disease management, because it enables access to specialty care from distant locations, provides automated education and feedback, and facilitates patient communication with providers. Independent of our study, such a system has been adopted in the VA Healthcare System nationally to improve management of prevalent chronic diseases, including diabetes, for defined high-cost users of the system.

Home telehealth approaches that involve education, counseling, and/or transmission of clinical data uploaded from peripheral measurement devices (e.g. glucose meters, sphygmomanometers, and weight scales) may reduce barriers to self-management and improve outcomes in adults with type 2 diabetes. A number of studies have evaluated the effectiveness of telehealth interventions, including three clinical investigations involving veterans with T2D (39-42). One used telemonitoring for messaging and collection of participant data regarding symptoms and self-management (35), and a second involved bi-weekly automated calls that provided counseling, self-management guidance, and optional education messages (35-36); neither involved peripheral uploads of clinical data. A third reported two telemonitoring initiatives in two different diabetic veteran subpopulations, one in which veterans requiring aggressive wound management were instructed to send weekly photographs of their wounds to a care manager (who referred for further evaluation as needed), and the other in which telemonitoring was used for daily telemessaging, symptom monitoring, and weekly uploads of glucose results and vital signs (with referral as needed) (42). These interventions resulted in reduced utilization of healthcare services (39,42); less depression and bed days due to illness; greater self-efficacy, satisfaction with care, and self-management effort; and better HbA1c levels (40-42). None of these studies targeted veterans with poor glycemic control and none involved real-time nurse practitioner adjustment of the veterans' medication regimens.

Inpatient Initiatives for Improved Glycemic Control

Evidence supporting goal-directed management of hyperglycemia in patients hospitalized with diabetes and hospital related hyperglycemia continues to grow (43-45). The criteria used to diagnose diabetes in the hospital setting is similar to that in the outpatient setting (American Diabetes Association (ADA)), with the recognition that factors exist within the inpatient setting that provoke hyperglycemia (45-47). There is now a consensus that inpatient hyperglycemia poses a major risk factor for adverse outcomes among hospitalized patients (45,47). Increased mortality, frequency of cardiac arrhythmias, infections, fluid and electrolyte abnormalities and a prolonged hospital length of stay (LOS) have all been associated with uncontrolled glucose levels (45,47). Unfamiliarity with ordering and adjusting insulin in the context of the numerous contingencies that

occur in hospitalized patients (e.g., altered caloric intake), and fear of inducing hypoglycemia, which represents the principal impediment to intensive glucose control, perpetuate practices that prevent achievement of glycemic goals. From an institutional perspective, education to established hospital routines by nursing and medical staff, inconsistent meal distribution, and lack of coordination between meals and insulin administration add to difficulties with inpatient glucose control. While it is acknowledged that achieving and maintaining glycemic control in hospitalized patients while avoiding hypoglycemia is undeniably challenging, strategies must be developed to more tightly managed these patients. It is important that the barriers that currently exist be identified and addressed systematically at several levels, including development and implementation of protocols, education of healthcare professionals, and improved patient monitoring.

Chronic Care Model

Effective chronic disease programs support access by providers to decision support systems rooted in evidence-based guidelines and by patients to self-management education and team-based care. Studies have demonstrated, however that providers are often reluctant to rely on management tools such as guidelines (48), consider diabetes difficult to treat, and observe that their patients lack sense of urgency to treat their disease (49-50). Reports also show that patients do not use preventive health care services or educational tools (51) and that team care is rarely available or employed in primary care settings (52). A Chronic Care Model (CCM) is organized around elements shown to improve outcomes, requiring pre-planned care processes and innovative models of delivery system design.

Many prior studies of implementation of the CCM have been performed in small and/or homogenous populations. Implementing and evaluating comprehensive approaches to care are particularly critical in rural communities, which, like other under-served groups, experience increased rates of chronic disease including diabetes (31.6/1000 vs. 26.7/1000, rural Vs urban respectively) (53-54). Rural residents are also known to have a poorer perception of overall health, lower income, and a higher proportion of elderly and children compared to those residing in urban settings (53-54). Since access to diabetes specialists is limited in rural areas, it becomes critical to determine if a process delivery system that includes initiatives to institute ADA Standards of Care and diabetes self-management education are possible. An information support tool designed to support providers in adhering to and tracking guidelines is essential to effective implementation of the CCM in diverse community populations and would permit evaluation of provider behaviors and patient outcomes respective its inclusion of decision support, self-management and delivery system redesign.

Given that over 80,000 people with diabetes in western Pennsylvania receive care at UPMC facilities, the health system has expended considerable resources to deliver more effective care, including implementation of the CCM (53-54), which integrates core elements including decision support, clinical information systems, self-management, and delivery system design (51, 55-56). Decision support has been implemented in a way that monitors provider adherence to practice guidelines. A large repository of clinical information supports tracking of costs and outcomes. Self-management education has been facilitated by a network of 36 sites recognized by the ADA. The infrastructure established by UPMC presents a unique opportunity to critically evaluate the impact of implementation of the CCM.

In an effort to deploy “lessons learned” and evaluate the Chronic Care Model in rural communities outside of the UPMC health system, UPMC organized a regional quality-improvement initiative entitled the Pittsburgh Regional Initiative for Diabetes Education (PRIDE). Diabetes education is referred to in the broadest sense: diabetes education for providers, patients, and the community.

The initiative included: provider education, enhanced reminder and tracking systems, patient self-management education delivered in primary care and public awareness campaigns.

PURPOSE

The purpose of this document is to describe key research accomplishments associated with completion of the FY 04 and 05 Diabetes Project. The report to follow provides a summary of focus area and respective goals outlined in the awarded statement of work(s). All publications and presentations included as appendices in this report were completed, in whole or in part, by UPMC and UPDI Project staff during the course of these funding periods.

The FY 04 and 05 Diabetes Project focused on six sub-projects with each segmented further into goals.

- Primary Prevention

  This effort explored a model to improve the identification of those at high diabetes or cardiovascular risk and the management of their prevention needs. Screening, Training, Education, and Prevention services (STEP UP) were developed in diverse primary care services, with the adaptation of the Diabetes Prevention Program's life style intervention serving as the foundation for translation. In addition to the primary care setting, community-based screening for diabetes and cardiovascular risk and community-based lifestyle intervention were tested in underserved neighborhoods. A centralized resource center, the Diabetes Prevention Support Center, was also developed to support these efforts, as well as provide wide spread training and assistance with prevention services and DPP based services and DPP based Lifestyle Intervention. Translation of these efforts was subsequently commenced at 59 MDW for the benefit of the military population and surrounding communities in San Antonio, Texas.

- Diabetes Self-Management Education (DSME)

  This effort designed and explored the implementation of diabetes self-management education (DSME) in PRIDE sites and primary care offices. Diabetes educators (CDE) were integrated into practices in an effort to explore novel approaches for DSME access. Educators used the AADE NDEOS system to intervention outcomes and collect data for ADA DSME reimbursement to demonstrate program sustainability.

- Diabetes Retinopathy

  This effort developed and explored the implementation of a diabetes tele-ophthalmology program to improve screening rates for diabetic retinopathy. Specifically, the goals of the project were threefold: 1) to enhance awareness of the importance of screening eye exams among the diabetic population, 2) to reinforce the importance of screening eye exams among physicians caring for patients with diabetes, and 3) to provide continued education for ophthalmologists in the evaluation and treatment of diabetic retinopathy.

- Veteran's Initiative

  This effort was a two-phase, randomized clinical trial to evaluate telemonitoring paired with real-time mediation management for veterans with poor glycemic control, hereafter Diabetes Telemonitoring Study (DiaTel). The goal of Phase I was to evaluate the short-term effectiveness of the intervention. Specifically, an Active Care Management (ACM) and home telemonitoring (HT) and less-intensive Care Coordination (CC) interventions were compared for veterans with type 2 diabetes and sub-optimal glycemic control. The goal of Phase II was to examine the nature of contact effectiveness of the intervention over time. Specifically, the intensity of subsequent management required to sustain improvements in glycemic, blood pressure (BP), and lipid control among consenting participants from Phase I of the DiaTel Study.

- Inpatient Initiatives for Improved Glycemic Control

  This effort was developed to improve inpatient medical care for the management of diabetes and glycemic control. A comprehensive Inpatient Diabetes Management Program (IDMP) was developed, implemented, and evaluated for safety and efficacy at UPMC. This program consisted of the development of a series of protocols that addressed specific areas of inpatient glycemic management. Local, regional and national dissemination of this IDMP is ongoing to affiliate hospitals and 59 MDW through education, support, and guidance in developing the infrastructure necessary for successful implementation of the IDMP at these sites.

- Chronic Care Model

  This effort was developed to improve outcomes for diabetes care through the implementation of the Chronic Care Model. Tasks were initiated to commence comprehensive system changes that incorporate all the elements of the Chronic Care Model: decision support, clinical information systems, self-management education, and delivery system design. The goals of this project involved 1) developing and evaluation a web-based patient portal, 2) interfacing medical practice with community efforts, and 3) establish a Diabetes Outreach Clinic at 59 MDW aligned to implement diabetes care practices derived from our studies noted herein.

Project Challenges

Throughout the course of this program, we encountered a series of challenges that often hindered our efforts from both an administrative and programmatic focus. These range from an evolving health care environment to more familiar barriers often encountered when participating in translational research studies. Our challenges are bulleted below.

- The constantly changing dynamic of health care and addressing chronic disease.
- Unanticipated delays with Internal Review Board processes.
- Unanticipated challenges with information technology (IT) security issues, particularly with IT programs being deployed for the military programs.
- Delays in hiring staff, particularly at the Wilford Hall Medical Center. At the start of the project, the US was beginning to experience a shortage of diabetes health care professionals, endocrinologists, primary care physicians, nurses and diabetes educators.

This shortage escalated throughout the course of the project period, making it extremely difficult to recruit clinical and research personnel.
- Staff turn-over, particularly medical team leadership.
- In working with national organizations, like AADE, unpredictable direction with program development and evaluation with annual change of volunteer leadership.
- Lack of clarity regarding reporting strategies and documents.
- Recruitment challenges, particularly in the military setting.
- Active duty engaged and leading projects, deployed or moving to other bases.
- Developing trusting relationships with small community hospitals and clinics threatened by a large health system.
- Inability to gather data from military setting for a long period of time.
- Managing a personnel and clinic in Texas from a long-distance (Pittsburgh).
- Expected challenges of translational research, for example, an intervention established at a primary care office was sold to another group of physicians, a hospital where a project was ongoing was acquired by another health system not interested in maintaining the project, etc.

Evaluation

Since the inception of the diabetes program, the UPDI Data Core has provided services and support for design and evaluation of projects. Instruction and guidance on sound methodologic framework for evaluation and training in systematic data collection methods are provided to all constituents of the diabetes program. Additionally, the primary goals of the Data Core include, yet are not limited to:

- Development and implementation of projects within communities that translate current knowledge into practice.
- Design of projects for both the inpatient and outpatient settings that address patient and healthcare provider needs.
- Development and implementation of projects that monitor quality of care delivered to people with diabetes.
- Development and oversight of all human subjects protocols.
- Training of staff in standardized data collection methods.
- Translation and oversight of research methodologies in the Air Force.

Reportable Outcomes

Immediately below is a listing of peer review publications, abstracts and other presentations accomplished throughout the period of performance of Cooperative Agreement W81XWH-04-2-0030:

PEER REVIEWED PUBLICATIONS

1. DiNardo M, Korytkowski M, Siminerio L. The Importance of Normoglycemia in Critically Ill Patients. *Critical Care Nurse Quarterly.* 27(2):126-134, 2004.

2. DiNardo M. Griffin C. Curll M. Outpatient surgery. A Guide for People With Diabetes. *Diabetes Forecast*. 58(5):50-4, 2005.

3. Curll M. Esposito D. Hospital Food Tips. Practical Advice for Eating Healthy When Hospitalized. *Diabetes Forecast*. 58(9):59-60, 2005.

4. DiNardo M, Donihi A, DeVita M, Siminerio L, Rao H, Korytkowski M. A Nurse-Directed Protocol for Recognition and Treatment of Hypoglycemia in Hospitalized Patients. *Practical Diabetology*. 37-40, 2005.

5. Hess, R, Bryce, CL, McTigue, K, Fitzgerald, K, Olshansky, E, Zickmund, S, Fischer, G, The Diabetes Patient Portal: Patient Perspectives on Structure and Delivery. *Diabetes Spectrum* 92(2):106-10, 2006.

6. McTigue KM, R Hess, C Bryce, K Fitzgerald, E Olshansky, D Sacco, and G Fischer. Perception of "Healthy" Body Weight by Patients with Diabetes. *Diabetes Care*. 29(3):695-7, 2006.

7. Donihi A, DiNardo M, DeVita M, Korytkowski M. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. *Quality and Safety in Health Care*. 15:89-91, 2006.

8. Donihi A, Raval D, Saul M, Korytkowski M. DeVita M. Prevalence and Predictors of Corticosteroid-Related Hyperglycemia in Hospitalized Patients. *Endocrine Practice.* 12(4): 358-362, 2006.

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12. Zgibor J, Peyrot M, Ruppert K, Noullet W, Siminerio L, Peeples M, McWilliams J, Koshinsky J, DeJesus C, Emerson S, Charron-Prochownik D, and the Diabetes Education Outcomes Team. Using the AADE Outcomes System to Identify Patient Behavior Change Goals and Diabetes Educator Responses. *The Diabetes Educator*, v33: 839-842, 2007.

13. Charron-Prochownik D, Zgibor J, Peyrot M, Peeples M, McWilliams J, Koshinsky J, Noullet W, Siminerio L on behalf of AADE/UPMC Diabetes Education Outcomes Project. The Diabetes Self-management Assessment Report Tool (D-SMART®): Process Evaluation and Patient Satisfaction. *The Diabetes Educator*, v33: 833-838, 2007.

14. Peeples M, Tomky D, Mulcahy K, Peyrot M, Siminerio L on behalf of AADE Outcomes Project and AADE/ UMPC Dia betes Education Outcom es Project. Evolution of the American Association of Diabete s Educators' Diabetes Education Outcomes Project. *The Diabetes Educator*, v33: 794-817, 2007.

15. Peyrot M, Peeples M, Tomky D, Charron-Prochownik D, Weaver T on behalf of AADE Outcomes Project and AADE/UPMC Diabetes Education Outcomes Project. Development of the American Associat ion of Diabetes Educ ators' Diabetes Self-management Assessment Report Tool. *The Diabetes Educator,* v33: 818-826, 2007.

16. Siminerio L, Funnell M, Peyrot M, Rubin R. US Nurses' Perceptions of Their Role in Diabetes Care: Results of the Cross-National Diabetes, Attitudes, W ishes and N eeds (DAWN) Study. *The Diabetes Educator* 33(1):152-162, 2007.

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ABSTRACTS AND OTHER PRESENTATIONS

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2005

Piatt G, Zgibor J. Treatment and Control of the "ABCs" of Diabetes: Getting to the Heart of the Matter. American Diabetes Association 65th Scientific Session. San Diego, CA, June 2005. Published Only

Zgibor J, Piatt G, Orchard T. Predicting Cardiovascular Risk in Type 1 Diabetes: Impact of Renal Disease. American Diabetes Association 65th Scientific Session. San Diego, CA, June 2005. Poster

Siminerio L, Piatt G, Zgibor J. Using the Chronic Care Model as a Framework To Develop and Sustain Diabetes Self-Management Training Programs. American Diabetes Association Scientific Session. San Diego, CA, June 2005. Oral Presentation

Emerson S, Piatt G, Solano F, Siminerio L. The Effect of Point of Service Education (POSE) on Glycemic Control. American Diabetes Association 65th Scientific Session. San Diego, CA, June 2005. Poster

Ruppert K, Saul M, Piatt G, Siminerio L, Orchard J, Zgibor J. Development of a Diabetes Registry for a Large Health System. American Diabetes Association 65th Scientific Session. San Diego, CA, June 2005. Published Only

2006

Gretchen Piatt: State of the Art Lecture: Implementing Novel Approaches to Improve Diabetes Care: A Population Perspective – Health Care Delivery and Economics; Washington DC, June 2006. Invited Speaker

Linda Siminerio: Symposium: The Changing Face of Diabetes Care Delivery 2006 – Alternate Care Delivery Systems for Diabetes – Diabetes Education; Washington DC, June 2006. Invited Speaker

Sharlene Emerson: Symposium: Show Me the Money – Payer Policies and Diabetes Education – Sustaining Self-Management Support in Primary Care – Diabetes Education; Washington DC, June 2006. Invited Speaker

Piatt G, Zgibor J. Primary and Secondary Prevention of Cardiovascular Risk Factors in People with Diabetes: Is there a Gender Bias? Session Title: Health Care Delivery and Economics; Washington DC, June 2006. Oral Presentation

Piatt G, Orchard T, Siminerio L, Zgibor J. Sustainability of Clinical and Behavioral Improvements Following a Multi-Faceted Diabetes Self-Management Training (DSMT) Intervention. Session Title: Diabetes Self Management Training: Approaches, Outcomes, and Missed Opportunities; Washington DC, June 2006. Oral Presentation

Peyrot M, Piatt G, Zgibor J, Peeples M, Charron-Prochownik D, Siminerio L. Using the AADE National Diabetes Education Outcomes System (NDEOS) to Identify Patient Behavior Change Needs and Diabetes Educator Responses. Session Title: Diabetes Self Management Training: Approaches, Outcomes, and Missed Opportunities. Washington DC, June 2006. Oral Presentation

Charron-Prochownik, Zgibor J, Peyrot M, Peeples M, Siminerio L. Computer or Telephonic Diabetes Self-Management Assessment Report Tool (D-SMART): Process Evaluation with Patient Satisfaction. Session Title: Diabetes Self Management Training: Approaches, Outcomes, and Missed Opportunities; Washington DC, June 2006. Oral Presentation

Donihi AC, Rea RS, Haas L, Donahoe M, Korytkowski MT. Glycemic Control and Patient Outcomes Before and After Implementation of an IV Insulin Protocol. Washington DC, June 2006. Poster Presentation

Donihi A, Rea R, Haas L, Donahoe M, and Korytkowski M. Safety and Effectiveness of a Standardized 80-150 mg/dL IV Insulin Infusion Protocol in the Medical Intensive Care Unit: >11,000 Hours of Experience. Washington DC, June 2006. Poster Presentation

Korytkowski M, Saul M, Irsiss A, Dinardo M, CRNP Hypoglycemia in the Hospital: A Method for Measuring Frequency and Severity. Washington DC, June 2006. Poster Presentation

Curll M, Dinardo M, Ruppert K, Nochese M, Banks T, Korytkowski M. A Comparison of a Consistent Carbohydrate Diet with a Patient Controlled Diet in Hospitalized Patients with Diabetes Mellitus. Washington DC, June 2006. Poster Presentation

Noschese ML, Ruppert K, Dinardo M, Donihi A, Korytkowski M, Nurse Knowledge and Attitudes Towards CSII in Hospitalized Patients. Washington DC, June 2006. Poster Presentation

Dinardo M, Noschese ML, Ruppert K, Banks TR, Korytkowski MT. An Assessment of Physician Trainee Confidence and Knowledge of Inpatient Diabetes Management. Washington DC, June 2006. Published Only

2007

Emerson S. Moderating Diabetes Education Interest Group session. Chicago, IL 2007

Siminerio L "Using conversation maps for diabetes educatio n". Americ an Diabetes Associatio n 67th Scientific Sessions. Chicago IL, June 2007. Invited Speaker

Siminerio L "The role of diabetes health care professionals in education on advo cacy issues". American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Invited Speaker

Kriska AM. "Can a physically act ive lifestyle really prevent type 2 diabet es"? American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Invited Speaker

Seidel M, Powell R, Piatt G. Translating the diabetes pr evention program (DPP) in an urban underserved community: long term sustainability of positive clinical outcomes. American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Oral Presentation

Emerson S, Piatt GA, Siminerio LM. Expanding diabetes se lf-management education (DSME): A look at access and ch arges for a hospital ba sed and primary care model. Ame rican Diabet es Association 67th Scientific Sessions. Chicago IL, June 2007. Poster Presentation

Kramer K, Miller R, Venditti E, Orchard T. Relationship of risk perce ption to perfo rmance in a modified DPP group lifestyle intervention for i ndividuals with metab olic syndro me. American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Poster Presentation

Noschese M, Calabrese-Donihi A, Ruppert K, DiNardo M, Banks T, Korytkowski M. A guideline for diabetes se lf management in the hospital: ex perience with 50 patients u sing continu ous subcutaneous insulin infusions. American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Poster Presentation

Terry M, Bl ueEye L, Trauth J, Jar os K, Goodm an R, Si minerio L. Community-based diab etes management. American Diabetes Associat ion 67th Scientific Sessions. Chicago IL, June 2007. Poster Presentation

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Korytkowski et al. Freq uency and Severity of Hypoglycemia in Adult Inpatients P rior to and Following Implementation of a Hypoglycemia Treatment Program. American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Published Only

Curll et al. Hospitalization, An Opportunity to Address Medical Nutrition Therapy in Patients With Diabetes. American Diabetes Association 67 th Scientific Sessions. Chicago IL, June 2007 . Published Only

Noschese et al. The Use of an Inpatient Diabetes Order Set Increases the Use of Scheduled Insulin. American Diabetes Association 67 th Scientific Sessions. Chicago IL, June 2007. Published Only

Donihi et al. Comparison of Different Methods of Transitioning MICU Patients from Intravenous to Subcutaneous Insulin. American Diabetes Association 67th Scientific Sessions. Chicago IL, June 2007. Published Only

Stone et al . Diabetes Telemonitoring (DiaTel) Study: 6-Month Results American Diabetes Association 67th Scientific Sessions.Chicago IL, June 2007. Poster Presentation.

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2008

Gretchen Piatt: Meeting Healthy People 2010 Education Goals in Rural Communities. Invited Speaker

Jolynn Gibson, Colleen Lauster, Jeannine Dinella, Monica Dinardo, Mary Korytkowski, Amy C. Donihi. Implementation of Standardized Discharge Instructions for Insulin at Hospital Discharge. Oral Presentation

Laura Bettencourt, Amy Uhler, Kristine Ruppert, Janice Zgibor, Linda M. Siminerio, Gretchen Piatt, Implementing the Chronic Care Model in a Rural Healthcare Setting to Improve the ABCs of Diabetes Author Block. Poster Presentation

Gretchen Piatt, Amy Cook, Carol Harding, Linda Siminerio Financially Sustaining a Comprehensive Diabetes Clinic in Rural Southwestern Pennsylvania through Diabetes Self-Management Education Reimbursement. Poster Presentation

Robert Powell, Mim Seidel, Gretchen Piatt, Does BMI Predict Successful Sustained Weight Loss following a modified Diabetes Prevention Program in an Underserved Urban Community? Poster Presentation

Janice Zgibor, Kristine Ruppert, Janis McWilliams, William Noullet, Mark Peyrot, Linda Siminerio, Denise Charron-Prochownik. Assessing the Role of Diabetes Self-Management Education in Behavior Change Using the AADE Outcome System. Poster Presentation

Monica m. Dinardo, Patrick Forte, Laura Bettencourt, Suzanne Rocks, Mary T. Korytkowski. Use of a Peri-Operative Treatment Protocol Improves Glycemic Management in Same Day Surgery Patients. Poster Presentation

Amy c. Donihi, Jolynn Gibson, Lindsey Fostel, Colleen Lauster, Michelle Noschese, Monica Dinardo, Glory Koerbel, Michelle Curll, Melissa Saul, Mary Korytkowski. Impact of a Targeted Glycemic Management Service on the General Medicine Units of an Academic Medical Center.

Poster Presentation

CDC Division of Diabetes Translation Conference

2005

Zgibor J, Piatt G, Si minerio L., for t he UPDI In vestigators. Diabetes Prevention Programs for Western Pennsylvania: A Large Scale Translat ion Effort by the University of Pittsbu rgh Diabetes Institute (UPDI). CDC Diabetes Translation Conference, Miami, FL, May 2005. Poster

Zgibor J: Diabetes Prevention in the Real Worl d. CDC Diabetes Translation Conference, Miami, FL, May 2005. Plenary Session

2006

M.C. Seidel, J.C. Zgibor, L.M. Siminerio, G.A. Piatt. Screening for Metabolic Syndrome (MS) in an Underserved Urban Community. Oral Presentation

Kramer K, Orchard T. PCP-Based Group Intensive Lifest yle (GILS) I ntervention for Metabolic Syndrome. CDC Diabetes Translation Conference, Denver, CO May 2006. Poster

Kramer K, Orchard T. Evaluation of Recruitment for a Birthday Base d Preventio n Screening Program for Diabetes and CVD. CDC Diabete s Translation Conference, Denver, CO May 2006. Poster

2007

M.C. Seidel, R.O. Powell, G.A. Piatt. Prevention of Diabetes and Cardiovascular Disease (CVD) in an Urban, Underserved Community. Oral Presentation

Piatt G, Harding C, Zgibor J. Improving Diabetes Care Through Systems Change: Implementing a Diabetes Clinic in Rural Pennsylvania. Oral Presentation

Kramer, MK, Miller, RG, Orchard TJ: Healt h-Related Quality-of-Life Foll owing Group Lifestyle Balance Intervention for Metabolic. Poster Presentation

2008

Jan Miller, Pennsylvani a Diabetes Preventio n and Control Program; Pennsylva nia Diabete s Action Partnership members. Building the Pennsylvania Diabetes Action Plan .Oral Presentation

M.C. Seidel; R.O. Powell, G.A. Piatt. Relatio nship betw een Stress and Clinical Outcomes Following a Modified Diabetes Prevention Program. Oral Presentation

American Telemedicine Association Conference

2005

Hess R, Fisher G, Fitzgerald K, Sacco D, Bryce C, McTigue K. Olshansky E: Patient Reaction to a Web-Based Integrated Disease Management Sy stem. American Telemedicin e Association Conference, Denver, CO, April 2005. Oral Presentation

2006

Hess et al. A PAMPHLET'S JUST A PAMPHLET

2007-2008

Ruppert, Faderewski, McDermot, Siminerio. Using Data Inte gration and OLAP to Identify Gaps in Diabetes Self-Management Education (DSME) Services in Western Pennsylvania.

Linda Siminerio. Using Technolog y to Suppo rt and Eval uate Behavior Change in Diabetes Prevention and Treatment

Using Data Integration and OLAP to Identify Gaps in Diabetes Self -Management Educatio n (DSME) Services in Western Pennsylvania

Simkin-Silverman et al. Development and Implementation of a Standardized Online Lifestyl e Intervention Coaching Protocol for Diabetes Prevention

American Association of Diabetes Educators Conference

2005

Emerson S. , Siminerio L. The Chronic Care Model in DSMT: Program and Policy Challenges. American Association of Diabetes Educators Annual Meeting. August 2005. Oral Presentation

McWilliams J. Implementing an Electronic Medical Record in a Diabetes C enter. American Association of Diabetes Educators Annual Meeting. August 2005. Poster

McWilliams J. AADE Outcomes Project: Giving Birth to a Product. American Association of Diabetes Educators Annual Meeting. August 2005. Oral Presentation

D.M.Luther, E.Bowlin, G.A.Piatt ,L.M.Siminerio. Diabetes P revention in the Community Through Hospital Based Education. August 2005. Poster Presentation

2006

Diane M Luther, Gretchen A Piatt , Ellen Bowlin, Linda M Siminerio. Diabetes Educators as Preventionists: Translating a M odified Diabetes Prevention Program (DPP) into the Communit y. August 2006. Poster Presentation

Janice Koshinsky, Janis McWilliams, Janice Zgibor, Mark Peyrot
Symposium: AADE Outc omes System: I mplementation and Evaluation; American Associat ion of Diabetes Educators Meeting, Los Angeles, CA 2006. Invited Speakers

2007-2008

European Association for the Study of Diabetes (EASD)

Piatt et al. Predicting Return for a Long-Term Follow-Up Diabetes Self-Management Education Visit following a Chronic Care Model Based Diabetes Care In tervention. September 2007. Poster Presentation

Siminerio et al. Using th e chronic ca re model as a frame work to improve diabetes care in a large U.S. health system. September 2007. Poster Presentation

Piatt GA, Seidel M, Zgibor JC. A Comparison of Three Indices of Obesity in Individuals at Risk for Diabetes and Cardiovas cular Disea se in an Underserved Community in the United States: Is Measuring BMI a Thing of the Past? September 2008. Poster Presentation

Siminerio et al. Addressing the ga p for diabe tes educat ion services in a rural US community. September 2008. Poster Presentation.

Pre-Diabetes Congress

Piatt et al. Assessing Cardio-metabolic Risk (CMR) in Women from an Underserved Community. Barcelona, Spain, April 2007. Poster Presentation

Society for Medical Decision Making
Hsu et al. Cost-Effectiveness Analyses of Community-Based Efforts to Prevent Diabetes. October 2007. Poster Presentation

Society for General Internal Medicine National Meeting
McTigue et al. Using the Internet to translate an evidence-based lifestyle intervention into clinical practice. April 2007.

Society for Behavioral Medicine Meeting
McTigue et al. Translation of an Intensive Lifestyle Intervention to an Online Setting. March 2008.

Key Research Accomplishments

Primary Prevention

- FY04 Efforts

Creation of the Group Lifestyle Balance (GLB) program.
- Initial adaptation of the Diabetes Prevention Program's intensive lifestyle intervention to the GLB program for translation to the primary care, community, and military settings.
- DPSC (Diabetes Prevention Support Center) develops training criteria and curriculum for implementation of the GLB program.
- DPSC offers GLB training to health professionals.

STEP-UP for Primary Care Services
- Prevention Screening for risk identification for type 2 diabetes and cardiovascular disease is feasible in a primary care setting and is successful in identifying many at risk
- Recruitment rates for the STEP-UP study varied across clinics (34.2% versus 7%) based on internally versus externally assigned preventionists suggesting familiarity and trust affects recruitment, yet not discounting other basis, such as geographic, racial, economic, and time barriers
- Findings substantiated the importance of screenings. Specifically, 64% of individuals screened yielded at least one risk factor warranting further medical follow-up with 41% having new risks noted.
- Each of the identified risks was noted as being clinically billable thereby providing potential source of revenue in support of such prevention services.
- Upon chart review, appropriate follow-up was more prevalent among individuals screened (41%) versus those not screened (36%)
- A computer automated prevention screening program would yield increased efficiency and effectiveness in communicating with the patient, improved time management for the physician and other clinic staff, and an opportunity for patient education
- The GLB program is successful in reducing some parameters of risk for diabetes and cardiovascular disease in individuals with metabolic syndrome. The DPP lifestyle

intervention can be adapted for use in the "real-world" and is feasible to conduct in a primary care practice setting.

Group Lifestyle Balance Program in an underserved community (Braddock)

- The GLB Program was implemented by DPSC trained preventionists.
- Twenty-one community-based screenings yielded 360 people screened with 120 meeting risk criteria: BMI >_ 25 and exhibiting at least metabolic syndrome risk parameters.
- Forty-five percent of eligible adults chose to enroll in the GLB intervention and 78% of those people completed a 12 week re-assessment.
- Non-whites comprised 26.4% of those screened for the program.
- Thirty-one percent and 21.1% of participants met the weight loss goal at three months and six months, respectively.
- Roughly 74 % of participants decreased at least one metabolic syndrome risk parameter at three months and 63% were able to maintain this outcome at six months.
- Translating the national DPP into the community is both feasible and effective although larger numbers and longer follow-up are needed to draw conclusions.

• FY05 Efforts

STEP-UP for Primary Care Services

- The GLB program was successfully expanded to primary care practice settings and subsequently demonstrated the reduction in key components of risk for type 2 diabetes and CVD for participants in these local primary care practice settings.
  - 38.5% met a weight loss goal of 7% at 3 months.
- Research protocols have been approved by respective IRBs and recruitment has commenced and challenges noted.
- Resolve to recruitment challenges have yielded requirements to coordinate IRB modifications, as well as address more intense efforts to facilitate revised program

Group Lifestyle Balance Program in an underserved community (Braddock)

- The FY04 protocol was continued in FY05 in the same underserved community yielding a two-year total of 599 people screened; 192 (32%) eligible; and 96 (50%) participating in the intervention.
- Twenty-four percent of the participants were non-white and 84% were female.
- At 12 week follow-up, 28.1% lost at least 7% of body weight and 50% sustained that weight loss at last follow-up.
- Almost 47% reduced at least one metabolic syndrome parameter at the 12 week follow-up with 70% sustaining that reduction at last follow-up visit.
- Almost 22% reduced at least two metabolic syndrome parameters at the 12 week follow-up with 57.1% sustaining that reduction at last follow-up visit.
- Requiring a fasting (therefore "morning") screening appears to be a barrier to participation in this underserved community. Given that BMI and waist circumference are predictive factors for diabetes and cardiovascular risk, a screening based on these two risk factors without accompanying blood work may increase the program's reach to the at-risk community.

WHMC – Military site

- Efforts to develop, implement, and evaluate a diabetes and cardiovascular risk screening and prevention program at 59 MDW in San Antonio, Texas have

commenced. UPMC, US AF, and HAWC personnel have been trained on the GLB and clinical training measurements
- Prevention staff has been employed by UPMC for WHMC
- A number of strategies have been used to recruit participants, GLB program recruitment remains low

Diabetes Self-Management Education (DSME)

- FY04 Efforts

  - Providing DSME in primary care afforded the opportunity to track outcomes and provided insight into access issues
    - Aggregated data from 8 primary care practices showed that African Americans with diabetes entered the DSME programs with higher A1C values, but with education there was a decline in A1C levels. This same decline was also seen in our Caucasian population, although Caucasians came into the programs with lower A1C values
  - Established a network and clinical information tracking system for charges offered the ability to gain perspective on charges and, reimbursement for program sustainability.
  - A DSME program can cover its costs with appropriate systems to assure compliance with ADA recognition, submission of charges with appropriate codes, and payor follow-up
  - DSME in primary care leads to improvements in A1C similar to what is observed in hospital DSME programs
  - Significantly more patients receive DSME at points of service in primary care sites. This increased access, in part, due to a dedicated diabetes educator determining the best days and frequency for "Diabetes Days"
  - DSME in primary care is feasible, efficient, accessible, and effective
  - The CCM provides an excellent framework for implementing and sustaining DSME
  - Patient-centered, multidisciplinary teams understand process requirements for sustainability of DSME and institute measures to accommodate individual practice needs respective delivery of DSME (individual versus group), record keeping, scheduling, and billing
  - DSME was provided by educators in the DOC and is ongoing with transition to Diabetes Center of Excellence (DCOE)

- FY05 Efforts
  - DSME programs using the AADE NDEOS program were widely disseminated and implemented into 9 diverse practice and community settings
  - Educator use and acceptance differed among practice sites
  - AADE NDEOS was validated, yet was shown to be somewhat cumbersome, necessitated an additional amount of time to complete the tool (minimum 20 minutes), and requires the addition of clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools.
  - A user-friendly educational outcomes system that considers elements of behavior is under development in collaboration with UPMC, AF SGR, PRIDE, and ADA.
  - DSME Sustainability for 59 MDW cannot be presently supported via third-party payor reimbursement. This limitation is not due to in ability to charge a third-party payor for DSME, but rather the in ability to process a charge due to information system interface incompatibility

Diabetes Retinopathy

- FY04 Efforts
    - An eye education video can be a useful tool in an effort to improve patient understanding of eye diseases caused by diabetes
    - Physician education remains paramount in that people with diabetes gain most of their information/education from their physicians
    - Patients learned that diabetes educators serve as an important resource through the education video program
    - A program to study diabetic retinopathy screening utilizing a non-mydriatic fundus camera, transmission of the images over the internet, using a Stentor-like PACS system for image archival, and a novel protocol for interpreting the images was implemented and shown to be effective in diagnosing individuals at risk for diabetic eye disease
    - Inability to adequately image all subjects due to current state of technology remains and inherent limitation. Pupil size must minimally be 4mm in size; as individuals age, his/her pupil tends to become smaller.
    - Study design demonstrated the need for ongoing education and diabetic eye care given various compliance rates

- FY05 Efforts
    - WHMC image collection processes remain cumbersome and have the potential to be improved and further automated via improved connectivity
    - Expected solution for transmitting retinal images from remote clinic locations is to use the Joslin Vision Network (JVN)/Comprehensive Diabetes Management Program (CDMP). Technical requirements for this implementation at WHMC and 37th Wing systems groups are presently being reviewed by Mr. James Mason of AF SGR.
    - Initiatives will move forward with the goal to have all retinal images stored electronically on the WHMC PACS system rather than a portable medium.
    - Educational efforts, both provider and patient, have been successful in patient's actively engaged and willing to participate in the retinal screening program at WHMC.
    - Improved access and screening has enabled the ophthalmologist to focus on patients with disease and defer a large majority of patients presenting with normal readings to annual retinal screening program, thereby increasing efficiency for specialist physician(s) in the military, as well as, permit for a larger through put that may ultimately screen patients otherwise interested and potentially at an unknown risk of clinical eye disease.

Veteran's Initiative

- FY04 Efforts (*Phase I DiaTel*)
    - Improvements in glycemic control can be achieved in an abbreviated (3 month) telemonitoring intervention in which a CRNP (Certified Registered Nurse Practitioner) titrates the medication in response to real-time transmissions of blood glucose meter results.

- FY05 Efforts (*Phase II DiaTel*)

- Glycemic improvements are sustained for at least 6 months after active CRNP medication management is discontinued.
- Patients experience a "burn-out" using the technology over time.
- Improvement in glycemic control can be sustained without continued use of a home telemonitoring device.
- Sustained benefit in improvement of glycemic control when participants are returned to UC after a period of CC.

Inpatient Initiatives

- FY04 Efforts
  - Developed, implemented, and evaluated the following protocols: Hypoglycemia Treatment Protocol (HTP), Inpatient Diabetes Order Set (IDOS), Continuous Insulin Infusion Protocol (CII), and Insulin Pump Protocol
  - Implemented and evaluated peri-operative glycemic management protocols
  - Obtained efficacy and safety data relative to established inpatient diabetes management protocols
  - Developed proactive approach to patients at risk for in patient hypoglycemia and hyperglycemia

- FY05 Efforts
  - Introduced and evaluated standardized order sets including: adult diabetes admission order set, insulin order for – physician order set, guidelines for inpatient diabetes management, insulin (subcutaneous): initiation or modification order set, and oral diabetes medication: initiation or modification order set.
  - Demonstrated improved patient safety by decreasing the frequency of severe hypoglycemia through the use of HTP
  - Demonstrated improved patient safety by the utilization of a targeted management plan (TGMP)
  - Demonstrated the use of standardized order set for CII in a critical care area improved patient outcomes
  - Demonstrated improved patient safety and glycemic control for patients admitted to the hospital with an insulin pump
  - Noted that additional studies must be planned to investigate the contribution of inpatient diabetes education to glycemic control, diabetes self-management practices and Quality of Life (QOL) in the outpatient setting.
  - Demonstrated decrease length of stay with protocol use.

- Cumulative across FY04 and FY05
  - A series of seven diabetes inpatient protocols were developed, implemented, and evaluated for efficacy and safety.
  - Implementation of any one of these protocols requires extensive inservice educational sessions with nursing personnel and existence of an inpatient diabetes protocol does not guarantee use.
  - Institutions adopting the protocols noted above must identify and evaluate the best means for introducing these protocols into their respective hospital culture
  - Continuous quality review is recommended to monitor and evaluate the impact of protocol(s) on overall glycemic control in the hospital setting

Chronic Care Model

- FY04
    - Developed a web-based patient portal (HealthTrak) that enabled patients with diabetes to communi cate directly with their physi cians electronica lly through their person al health record
    - Evaluated HealthTrak in four primary care practices
    - Determined that it was not feasible to explore integration of a patient portal into the military IT system because of DIACAP and security challenges

- FY05 Efforts
    - Developed a web-based virtual lifestyle manager (VLM) program
    - Evaluated VLM in a general internal medical practice
    - Participants using VLM reduced risk factors and continued t o access th e program for as long as 1 year
    - Established Diabetes Outreach Clinic (DOC) at WHMC and office space, procu red equipment, forms, systems support
    - Gained UPMC leadership approval for positions at WHMC
    - Hired clinic staff and clinical research support personnel
    - Created a charter and Memorandum of Understanding
    - Explored best approach to build diabetic patient registry compatible with WHMC CHCS and other patient data bases, tra cking to ols (Periodic h ealth assessment, Annual fitness testing, AF Population Health, and other in-house data bases)
    - Transferred and enrolle d, patients with diabete s (<65 yrs) to DOC fro m other over-enrolled clinics (begin April 2005 and ongoing).
    - Provided team-based care to > 4,000 patients with diabetes
    - Reduced HbA1C levels in total population
    - Improved lipid panels in patients
    - Provided additional serv ices on site to primary c are for diab etics (foot care, eye care, education) June 2005
    - Collected data to obtain recognition from the American Diabetes Association (ADA) for the diabetes self management education program
    - Applied to the Education Recognition Program of the ADA for recog nition of the diabetes self management education program at Wilford Hall. (December 15, 2005)
    - Received training on a diabetes management system to colle ct dat a for enrolled patients and collect baseline data – May 2005
    - Received training and initiated DIGMA (Drop In Group Med ical Appoint ments)– group medical visits
    - Provided DIGMA visits for 126 patients
    - Determined that the DOC needed to be fully imp lemented and tested be fore outreach clinics could be established. Per d irection fro m SGR and AF active duty, outrea ch opportunities were to be explored in 2005.
    - Determined that the DOC should be re-organize d as a Diab etes Center of Excellence (DCOE)

Conclusions

In our effo rts to te st the appl icability of p revention and treatment modalitie s in diverse communities and ra cial and ethnic groups, we focused on several themes: primary prevention of diabetes u sing a modified DPP (mDPP) program, treatment of diabet es using a CCM appro ach, and employi ng rigorous evaluation methods to determine t he impact o f specific pr evention an d treatment strategies and inform deve lopment of new health care delivery paradigms. Throughout

the course of our study, we were able to deploy the mDPP in a variety of settings and implement multiple methodologies, as well as review strategies for the treatment of diabetes. Specifically, we addressed the utilization of multi-disciplinary staff, data management systems, education programs, protocols for inpatients, telemedicine to veterans, and retinal imaging screenings.

Throughout our effort, we recognized that the proposed comprehensive model required robust infrastructure to meet the needs of geographically and culturally diverse communities and constituencies. The project drew on the depth of academic and clinical resources at UPMC and our civilian and military partners to best determine the central resources necessary to maintain continuity of our program efforts. These included the Data Core as described above, as well as other support centers to facilitate research and program efforts. Specifically, we coordinated the following:

- modified and implemented a lifestyle intervention known as Group Lifestyle Balance (GLB) that was proven to be effective in the national DPP through the Diabetes Prevention Support Center (DPSC)
- coordinated the creation of screening tools to identify those at risk, worked with the AF Center for Excellence in Medical Media (CEMM) in the creation of a DPP interactive DVD
- created (in collaboration with University of Pittsburgh experts) a computer-based Virtual Lifestyle Manager (VLM), as well as web-site for Physical Activity Resources (PARC),
- promoted effective patient self management through creation of a patient portal (HealthTrak), and implemented and evaluated an education tool for patients and educators
- deployed telemedicine techniques from the Pittsburgh Veteran's Affairs (VA) to reach homebound veterans
- placed retinal imaging cameras a specialty, internal medicine clinic and a mobile van to expand reach to underserved areas
- demonstrated improvements in both glycemic control and length of stay (LOS). through the use of inpatient management protocols

Additionally, partnerships were established between the UPMC and leaders in communities throughout western Pennsylvania (PA) and the AF, using focus groups to gain insight on local needs and issues related to the prevention and treatment of diabetes (49). We further extended our reach, by way of developing formal partnerships with 4 identified community institutions in other healthcare networks (Conemaugh Health System, Highlands, Indiana Regional Medical Center (IRMC), and Uniontown Hospital), leading to the formation of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE). Elements of the mDPP program and the CCM have been instituted into the PA communities and their local primary care practices.

Our last efforts of this program have been to successfully translate our works to WHMC. We performed a preliminary assessment at WHMC, whereby WHMC DOC staff, physicians, and nurses were interviewed to identify various needs: support of local diabetes prevention and comprehensive treatment programs; data management tools and systems; diabetes education services; alternative methods for endocrinology services; expansion of the roles of non-physician healthcare providers; public awareness campaigns; and partnerships with an academic hub to facilitate awareness, data collection and reporting. Our efforts on this program then focused to commenced to establishing a local infrastructure and clinic in support of future efforts awarded in follow-on years. Specifically, we staffed a multi-disciplinary clinical team serving 700 patients with a total of 5 000 visits since January, 2006. Group medical visits have been established and protocols are being developed to test the effectiveness of this model. The DOC has also performed cross-training of staff to increase access to non-dilated retinal screenings.

In summary, UPMC, in concert with the rural and AF communities, has made significant progress with each cohort recognizing the need to further advance the care and clinical outcomes of the diabetic population. As such, UPMC, AF SGR, WHMC, VAPHS continue to refine existing models of care and note the necessity to continually revise strategic direction to assure effective implementation of national prevention and treatment strategies for diabetes.

APPENDIX A: Glossary of Acronyms

59MDW	59th Medical Wing
AADE	American Association of Diabetes Educators
ACM	Active Care Management
ADA	American Diabetes Association
BP Blood	Pressure
BRFSS	Behavioral Risk Factor Surveillance System
CBOCS	Community Based Outpatient Clinics
CC Care	Coordination
CCM	Chronic Care Model
CDC	Center for Disease Control
CDMP	Comprehensive Diabetes Management Program
CRNP	Certified Registered Nurse Practitioner
CVD Cardiovascular	Disease
DCCT	Diabetes Control and Complications Trial
DCOE	Diabetes Center of Excellence
D-ET	Diabetes Educator Training
DIGMA	Drop In Group Medical Appointments
DOC	Diabetes Outreach Clinic
DPP	Diabetes Prevention Project
DPSC	Diabetes Prevention Support Center
D-SMART	Diabetes Self-Management Assessment Report Tool
DSME	Diabetes self-management education
DSMT	Diabetes Self-Management Training
GLB	Group Lifestyle Balance
GLI	Group Lifestyle Intervention Program
HCI	Health Care Integrators
HCPCS	Health Care Common Procedure Coding System
HT	Home Telemonitoring
IDMP	Inpatient Diabetes Management Program
IT	Information Technology
JVN	Joslin Vision Network
LOS	Hospital Length of Stay
MARS	Medical Archival Retrieval System
NDEOS	National Diabetes Education Outcome System
PACS	Picture Archiving and Communication System
PCP	Primary Care Physicians
PRIDE	Pittsburgh Regional Initiative for Diabetes Education
STEP UP	Screening, Training, Education, and Prevention
TGMP	Targeted Glycemic Management Plan

UC Usual	Care
UPDI	University of Pittsburgh Diabetes Institute
VAPHS	VA Pittsburgh Healthcare System
VHA	Veterans Health Administration
VLM	Virtual Lifestyle Manager or Management
WHMC	Wilford Hall Medical Center

Project 1: Primary Prevention

PREPARED BY:
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This project was designed to develop a centrally organized, locally delivered prevention service utilizing annual birthday reminders to increase the number of patients clinically evaluated for diabetes and/or cardiovascular disease risk. Subsequently, programs were expanded to further assist identified individuals in achieving goal levels respective of the program(s) through the utilization of two centralized sources: Diabetes Prevention Support Center (DPSC) and Physical Activity Resource Center (PARC).

The project had six goals:

1.1 Develop, Implement and Evaluate a Diabetes and Cardiovascular Risk Screening and Prevention Programs
1.2 Modify, Deliver, and Evaluate an Intensive Lifestyle Intervention Program for at Risk Patients Based on the Diabetes Prevention Program (DPP)
1.3 Expand Diabetes Prevention Program (DPP) Translation Activities through Establishment of a Diabetes Prevention Support Center and the Introduction of the STEP-UP Program to Additional Rural Practices
1.4 Develop Centers with resources for nutrition, exercise, DSME, and Access to Specialty Services for Minority-Urban and Rural Populations
1.5 Develop and Implement a Diabetes and Cardiovascular Risk Screening and Prevention Program at 59 MDW in San Antonio, TX
1.6 Modify, Deliver, and Implement a Group Lifestyle Intervention Program (GLI) at 59 MDW for High-Risk and Pre-Diabetic Military Members or Other MHS Eligible Patients, Based on the Diabetes Prevention Program (DPP)

This report serves as a final summary of Project 1 research accomplishments.

Goal 1.1: Develop, Implement, and Evaluate a Diabetes and Cardiovascular Risk Screening and Prevention Programs

As described in deliverable # 124 (Appendix B), *Screening, Training, Education and Prevention Service of the University of Pittsburgh: Final Screening and Chart Review Report*, a screening program was devised to address various barriers to prevention screening and risk identification, specifically a lack of organized prevention screening for risk identification, as well as simplification of prevention guidelines for easier implementation, provision of patient education information regarding individual risk and alleviating time constraints.

A concise, "user-friendly" document summarizing current guidelines was compiled based on the recommendations for prevention screening regarding diabetes, hypertension, dyslipidemia, and obesity (57-62). In addition, a computer-based automated screening program was developed to facilitate the collection of screening information and to provide immediate feedback regarding risk and necessary follow-up.
For project implementation, four primary care practices, two urban and two rural, were identified in the Western Pennsylvania area. Each practice was requested to identify a "preventionist",

possessing a healthcare background, to facilitate the prevention screening program, including screening, recruitment, and delivery of a lifestyle change intervention program. Each preventionist was trained for appropriate prevention screening, collection measures (blood pressure, lipid profiles, height, weight, and waist circumference) and use of an automated computer program to track, screen, and report on targeted patients within the respective practice.

Eligible patients, age 25-74, were recruited from each practice via issuing computer-generated invitation letters to those satisfying a pre-determined data set that addressed age and patient birthdates within one quarter of the year. Upon entry into the study, the patient attended a brief screening visit, and the preventionist reviewed his/her chart for the above named measures. Follow-on chart reviews were conducted to examine the efficacy of the prevention screening.

Efficacy of the computer-assisted prevention screening program was evaluated by documenting the proportion of individuals responding to the following:

- screening invitation by age and gender
- reasons for declining the invitation for screening
- proportion of cases contacted after a reminder from the central coordinating center

Additionally, charts were reviewed for the following data:

- the numbers of patients within the selected quarter that were evaluated for diabetes or CVD risk according to national guidelines
- newly identified to be at risk
- newly identified to be at risk and received appropriate action

Research Accomplishments

Recruitment

- 2,786 computer-generated invitation letters originating from three primary care practices (patient volume range 2,150-2,659) and one urban, primary care center reporting 5,539.
- Various exclusions (re-location and refusal) yielded an n =350 for screening participation, whereby 61.7% self-responded immediately following receipt of invitation. Subsequent follow-up, one phone call and two/three phone calls, yielded additional participation for 14% and 11.4%, respectively.

Screening Results

- Median age of those screened was 49 years old; 26.3% less than age 40, 60% age 40-64, 13.7% 65 and older.
- 72% screened were women.
- 19.4% were from minority ethnic groups (African American (17.2%) and other (2.2%).
- Screening attendance rates varied by clinic with a high of 34.2% and a low of 7.0% ($p=0<0.001$). The two rural clinics, both of whom used internally assigned preventionists had significantly higher rates of screening attendance than the urban clinics with externally identified preventionists (27.9% vs. 10.9%, p=0.00).
- 79.1% had a body mass index (BMI) $\geq$ 25kg/m^2, of whom 27.7% had no reported history of diabetes and met criteria for the metabolic syndrome (based on National Cholesterol Education Program Adult Treatment Panel III) (53)
- 45.3% enrolled in the prevention program, representing a yield of 2.2% from the attempted invitation of 1,963 patients.

Identification of Risk Factors at Screening

- 224 patients (64%) had at least one risk factor meriting further medical evaluation regardless of previous diagnosis.
- 236 new potential risk factor states were identified by examining elevated levels and assessing patient report of previous diagnosis at screening
    - 6% were found to have elevated blood pressure (SBP ≥ 140 and/or DBP ≥ 90) without reporting a previous diagnosis
    - 2.6% and 16% had elevations in glucose at the diabetes and pre-diabetes levels, respectively
    - 22.3% and 20.6% had elevated total cholesterol (≥ 200mg/dl) and triglycerides, respectively
- Almost one-half (n=66, 44.9%) of 147 patients who reported no previous diagnosis with any of the above conditions had at least one risk factor which warranted further follow-up.

Chart Review for Potential New Risk Factors

- 206 potential cases of new hypertension, diabetes, pre-diabetes or hypercholesterolemia were identified at screening, with only 9.2% of those conditions being already noted in the chart.
- 41% of those screened being identified through screening to have one or more potentially new risk states.

Chart Review

- A total of 7,116 chart reviews were completed with 3,765 (2,011target and 1,754 comparison) completed prior to the screening period (primary review) and 3,351 (1,599 target and 1,752 comparison) completed post-screening (secondary review).
- Based on the chart review, the screened/target cohort showed an increased prevalence of clinically diagnosed hyperlipidemia including cholesterol and triglycerides ($p<0.05$) as well as a significant increase in the prevalence of diagnosed pre-diabetes ($p<0.05$); however no such differences were seen in the comparison group. The prevalence of diagnosed hypertension, diabetes and obesity did not change materially in either cohort.
- Including the target and comparison groups for both primary and secondary review, a total of 189 charts were noted to have glucose levels above 125 mg/dl and 682 within the pre-diabetes range of 100 mg/dl-125mg/dl (those with previous diagnosis of diabetes were excluded for both groups); appropriate follow-up action was noted for 95 (50.3%) and 151 (22.1%) charts respectively.
- A total of 1,823 charts were noted to have an elevated blood pressure recorded (≥140 and/or ≥ 90 mmHG); appropriate action was noted for 620 (34%), while 728 were noted to have elevated LDL cholesterol (based on risk), with appropriate action noted for 330 (45.3%). Elevated triglycerides were noted on 901 charts with appropriate action noted for 479 (53%). Obesity (BMI >30kg/m $^{2)}$ was also examined; 1,816 charts were noted to have obesity with appropriate follow-up noted for 541(29.9%).
- The same risk factors and appropriate action were examined for charts of individuals who attended the screening and had a post-screening review completed (n=185 individuals) and are further shown in Table 3, Appendix B, Deliverable #124. A total of 11 charts were noted to have glucose levels at or above 125 mg/dl and 41 within the pre-diabetes range; appropriate follow-up action was noted for 6 (55.5%) and 16 (39%) charts respectively.
- A total of 73 charts were noted to have an elevated blood pressure recorded; appropriate action was noted for 20 (27.4%).
- A total of 49 charts with elevated LDL cholesterol were noted with appropriate action occurring for 23 (46.9%); 46 charts had elevated triglycerides with appropriate action noted

for 24 (52.2%). Obesity was noted on 117 charts with appropriate action noted on 48 charts (41%).

- A significant difference was noted in the secondary chart reviews between those who completed the screening versus those who did not in the target and the comparison groups for appropriate action for pre-diabetes (39% vs. 16.7%, p=0.002) and obesity (41% vs. 30.8%, p=0.03); no significant differences were noted for appropriate action for diabetes, hypertension, elevated LDL or triglycerides. Overall results for appropriate action were significantly higher in the screened versus non-screened group (79.9% vs. 63.1%, p=<0.001).

Goal 1.2: Modify, Deliver, and Evaluate an Intensive Lifestyle Intervention Program for at Risk Patients Based on the Diabetes Prevention Program (DPP)

As described in deliverable # 96 (Appendix C), *DPP and the Real World: Translating the Diabetes Prevention Program Lifestyle Intervention to Primary Care Practice*, UPMC assessed the effectiveness and feasibility of a modified Diabetes Prevention Program (DPP) Lifestyle Intervention delivered in a primary care practice setting.

In consideration of known challenges in translating intervention program(s), including lack of trained personnel, patient recruitment and retention, coordination of care, and availability of quality programs (Reference 8 of Appendix C), UPMC elected to deploy its study in an ideal venue, primary care practice(s). Institutional delivery and reinforcement of prevention intervention within a primary care practice more easily accommodates patient-provider familiarity and ease of access.

Four primary care practices representing moderately low income and ethnically diverse patient populations were invited to participate in a lifestyle change intervention study. 51 participants (42 female) without prior history of diabetes with a body mass index (BMI) >_25kg/m2 and metabolic syndrome (NCEP ATPIII definition) were enrolled in the 12-session Group Lifestyle Balance (GLB) program. The program closely followed the DPP protocol with minor adaptations; weight loss and physical activity goals remained at 7% and 150 min/week respectively. Anthropometric measures were collected before and after the intervention.

Research Accomplishments

- Average weight loss, comparing pre and post-intervention assessments, was 4.6 lbs. (2.2% relative loss, p<0.001) using last observation carried forward methodology for participants who did not complete the intervention
- An average 0.5 pound weight loss per week was estimated (p<0.001) after adjusting for starting weight and clinic.
- Waist circumference, BMI and fasting blood glucose decreased an average of 0.69 in. (1.6%, p=0.003), 0.82 kg/m^2 (2.3%, p<0.001) and 4.63mg/dl (3.7%, p= 0.02) respectively. A positive correlation was noted between total activity minutes and total pounds lost (Spearman's r=0.36, p=0.01).

Goal 1.3: Expand Diabetes Prevention Program (DPP) Translation Activities through Establishment of a Diabetes Prevention Support Center (DPSC) and the Introduction of the STEP-UP Program to Additional Rural Practices

As described in deliverable # 230 (Appendix D), *Final Report on the Implementation of STEP UP at Additional Primary Care Practices*, UPMC expanded the services and support of the Diabetes Prevention Support Center (DPSC) of the UPDI to additional regional primary care practices that provide a universal framework for translation of all aspects of DPP research efforts and readily allows for implementation in a variety of settings.

Translation involved modifying the original DPP lifestyle intervention to the GLB program for group rather than individual delivery. In addition, the intervention sessions were decreased from 16 to 12 throughout the quarter in order to better accommodate a "real-world" schedule. Additional modifications included concentrating on healthy food choices rather than specifically the food pyramid, a focus on calorie as well as fat intake from the beginning of the intervention and an enhanced emphasis on the pedometer, which originally had not been part of the core DPP sessions. The DPSC of the UPDI further developed training for GLB delivery; ten training workshops have been held to date, with over 350 health care professionals completing training.

Research Accomplishments

Attendance

- GLB program was well attended, with 89.1% of the total group (n=46) and 100% of participants in the research group (n=13) attending at least half of the sessions. The mean number of sessions attended was 10. In addition, 11 (85%) research participants attended the six month assessment visit, and 10 (77%) attended the 12 month assessment visit.

Clinical Outcome Measures

- Demographic characteristics of the research group are shown in Table 1, Appendix B, Deliverable #124, with specific results of the baseline and post intervention comparisons for weight, waist circumference and BMI for both the research and the total group including all primary care practices (n=46) shown in Table 2, Appendix B, Deliverable #124. A significant decrease in weight (-9.3 pounds, -4.3%, p<0.0001), waist circumference (-1.4 inches, -3.2%, P<0.0001) and BMI (-1.7 kg/m^2, -4.4%, p=<0.0001) was noted over all.
- Weight loss remained significant at the 6 month (-15.1 pounds, -7.4%, p=0.0002) and 12 month assessment visits (-10.6 pounds, -5.2%, p=0.001), as did BMI, waist circumference, LDL cholesterol, and systolic blood pressure. Total cholesterol remained significantly decreased at the 6 month assessment and marginally decreased at the 12 month assessment. In addition, a significant decrease in diastolic blood pressure from baseline was noted at 6 months and 12 months and a significant increase in HDL cholesterol was noted between baseline and the 12 month assessment visit. Results are shown in Table 3, Appendix B, Deliverable #124.

Goal 1.4: Develop Centers with resources for nutrition, exercise, DSME, and Access to Specialty Services for Minority-Urban and Rural Populations

The process for developing centers with resources for nutrition, exercise, DSME, and access to specialty services for minority-urban and rural populations was multifaceted and spanned across multiple years. Efforts were primarily to establish local capacity and infrastructure to facilitate centers of diabetes education and treatment within the designated populations. Specifically, necessary infrastructure improvements were coordinated at each site, urban and rural, as well as the following services being offered:

- DSME classes
- Modified DPP (mDPP)
- Healthy Lifestyle Program
- Diabetes Support Group
- Gestational Diabetes Care
- One-on-One Diabetes Education
- Community Outreach and Public Awareness

Details pertaining to each sub-goal can be read respective the bulleted Appendix:

Goal 1.4.1: Identify people with metabolic syndrome through community screenings in accessible sites

- Appendix E, Deliverable # 214 *Evaluation Process and Measuring Tools*
- Appendix F, Deliverable # 215 *Evaluation Process and Measuring Tools*

Goal 1.4.2: Assure access in the community to DSME and Develop diabetes data repository for evaluation (rural) or DSMT program implementation

- Appendix G, Deliverable #199 *Final Report to Include Training and Advertising Materials Produced*

Goal 1.4.3: Develop Diabetes Data Repository for Evaluation (rural) or DSMT program implementation

- Appendix H, Deliverable # 216 Final Report on Data Repository

Goal 1.4.4: Determine the demographic characteristics of those people in the community who are screened for metabolic syndrome and of those people in the community with metabolic syndrome, who participate in the intensive lifestyle program, and to examine the relationship with class participation

- Appendix I, Deliverable # 89 *Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community*; including two power point presentations:
    - Deliverable #86 *Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes*

- Deliverable #87 *Prevention of Diabetes and Cardiovascular Disease in Urban Underserved Community*

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Goal 1.4.5: Determine if community members with metabolic syndrome will lose at least 7% of their body weight in 12 weeks and maintain it for at least six months and maintain that weight loss for up to one year

- Appendix I, Deliverable # 89 *Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community*; including two power point presentations:
  - Deliverable #86 *Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes*
  - Deliverable #87 *Prevention of Diabetes and Cardiovascular Disease in Urban Underserved Community*

Goal 1.4.6: Determine if the community members with metabolic syndrome will decrease at least one of their metabolic syndrome parameters in six months and will sustain those changes for up to a one year post-completion of the initial six month period

- Appendix I, Deliverable # 89 *Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community*; including two power point presentations:
  - Deliverable #86 *Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes*
  - Deliverable #87 *Prevention of Diabetes and Cardiovascular Disease in Urban Underserved Community*

Goal 1.4.7: Determine if the community members with metabolic syndrome who were unable to decrease at least one of their metabolic syndrome parameters after completion of the six month Intensive Lifestyle Balance demonstrates a positive change post-six months and/or up to one year post-completion of the Intensive Lifestyle Balance program

- Appendix I, Deliverable # 89 *Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community*; including two power point presentations:
  - Deliverable #86 *Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes*
  - Deliverable #87 *Prevention of Diabetes and Cardiovascular Disease in Urban Underserved Community*

Research Accomplishments

Recruitment

- The targeted community is an underserved, low income community made up of eleven non-homogenous neighborhoods. In total, 24% and 76% participating in the intervention were African-American and Caucasian, respectively.
- 75% participating are part of households with a family income under $ 50,000 and of those, half have an income less than $20,000 (poverty level).
- The majority of participant had less than a college education, but 99 % had at least a high school education with many noting that they had some education or training after high school. Almost 75% of the participants had a family member with diabetes, a fact that the participants stated as their reason for joining the intervention.

- BMI of 25 or greater a nd the presence of three of the fi ve risk para meters for Metabolic Syndrome were the minimal inclusion criteria with a mean BMI of the 36.2 for participants.
- Abdominal obesity wa s the most commonly seen Met abolic Syndrome risk factor in participants with low HDL cholesterol seen second most often. Diagnosed hypertension or an elevated systolic or d iastolic read ing at the scr eening was seen in 68 % of the participants. Half had elevated triglycerides and 43% had elevated glucose.

Clinical Outcomes

- 28% of participants met a weight loss goal of 7 % within a 12 week intervention and 50% of those participants were able to sustain that weight loss at their last follow up visit.
- 50% of par ticipants lost at least 5 % of their starting weight with 66 % of those people sustaining the weight loss over time
- 75% of the participants lost at least 3% of their starting weight at 3 months with 58% of them sustaining that weight loss at last follow up visit.
- 47% of part icipants red uced at lea st one metabolic syndrome risk par ameter after the 12 week intervention and 70% were able to sustain that improvement.
- 22% reduced at least t wo Metabolic Syndrome risk parameters at thre e months with more than half sustaining that reduction at last follow up visit.
- Demographic measures – gender, r ace, age, in come and education – did not diffe r among those participants with positive clinical outcomes compared to those without.
- Class attendance was not a factor. Mean class attendance was 9.2 classes out of 12.

Goal 1.5: Develop and Im plement a Diab etes an d Card iovascular Risk Screening and Prevention Program at 59 MDW in San Antonio, TX

Goal 1. 6: Modify , Deli ver, and Im plement a Group Lif estyle Intervention Program (GLI) at 59 MDW for High-Ri sk and Pr e-Diabetic Military Members or Other MHS Eli gible Patients, Based on the Diabetes Prevention Program (DPP)

As describe d in deliver able # 230 (Appendix J), *Final Re port on the Im plementation of the Diabetes Project*, the in cidence of T2D in military personnel is similar to that of t he civilia n population (1.9 vs 1.6 cases per 1 ,000 persons per year) despite having weight and fitness standards in place (61). Further, heavy de mands of e ver-changing schedule s and stress impose by t ours of dut y in extre mely remote locations, p resent the potential for decreased participation in healthy lifestyle practices.

These cir cumstances le nd themselves to an op timum venue in studying the effect iveness of a mDPP to reduce the risk (as measu red by com ponents of t he metabolic syndrome) of diabete s and cardiovascular disease in an Air Force population.

Challenges and Project Delays
Numerous unanticipated challenges with Institutional Review Board (IRB), as well as challenge s with recruit ment caused delays in the actual implementation of this pro ject with implication tha t affected de livery. As such, eff orts focu sed t o coordinat e and finalize methodology, target population, and criteria with the intent to complete study efforts with follow-on funding.

Research Accomplishments

Methods Determination

- mDPP will be facilitate d at WHMC, San Antonito, Texas using metabolic synd rome to determine p atient eligibility due to p racticality wi thin commu nity setting (62, 63, 64). The following risk factors will be measured for the respective population:
    - Abdominal obesity
    - Fasting triglycerides
    - Low levels of high density lipoprotein (HDL) cholesterol
    - Elevated blood pressure
    - Elevated fasting glucose
    - High body mass index (BMI)
- This method was use d in the mDPP imple mented in the UMPC North urban primary prevention project. Parameters of the MetS include: Abdominal obesit y; fasting triglycerides, low levels of High Density Lipoprotein (HDL) cholester ol; elevated blood pressure; elevated fasting glucose and high Body Mass Index (BMI).

Study Population

The study population will include individuals satisfying the following criteria:

- Retired members of the US military and their adult depen dents as wel ll as adu lt dependents of active duty US military members for MetS risk factors:
    - Abdominal obesity (waist circumference > 102 cm in males or > 88 cm in females)
    - Fasting triglycerides $\geq$ 150 mg/dL
    - Low high density lipopro tein (HDL) cholesterol < 40 mg/dL f or men and < 50 mg/dL for women
    - Blood pressure $\geq$ 130/85
    - Elevated fasting glucose $\geq$ 100 mg/dL < 126 mg/dL
- Those who have a body mass inde x (BMI) of > 25kg/m² an d who test positive for three of five MetS ri sk factor s will be eli gible for a GLB program directed at co ntrolling wei ght and improving physical activity levels. Risk factors for MetS include:

Clinical Outcomes

Clinical end point is to increase the proportion of subje cts who improve the para meters of th e metabolic syndrome and/or meet one of the following clinical outcome goals:

- 50% of peo ple completing at least 8 0% of the curriculum exhibit a weig ht loss of 7% of their body weight in six months, or
- Blood pressure < 130/85, or
- Waist Circumference < 102 cm in males or <88cm in females, or
- Fasting triglycerides <150 mg/dL, or
- Fasting blood sugar < 100 mg/dL, or
- HDL cholesterol greater than or equal to 40 mg/ dL for male s or greater than or equal to 50 mg/dL for women.

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Project 1: List of Appendices

- Appendix B, Deliverable #124, *Screening, Training, Education and Prevention Service of the University of Pittsburgh: Final Screening and Chart Review Report*
- Appendix C, Deliverable #96, DPP and *the Real World: Translating the Diabetes Prevention Program Lifestyle Intervention to Primary Care Practice*
- Appendix D, deliverable #230, *Final Report on the Implementation of STEP UP at Additional Primary Care Practices*
- Appendix E, Deliverable #214, *Evaluation Process and Measuring Tools*
- Appendix F, Deliverable #215, *Evaluation Process and Measuring Tools*
- Appendix G, Deliverable #199, *Final Report to Include Training and Advertising Materials Produced*
- Appendix H, Deliverable #216, Final Report on Data Repository
- Appendix I, Deliverable #89. *Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community*; including two power point presentations:
    - Deliverable #86, *Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes*
    - Deliverable #87, *Prevention of Diabetes and Cardiovascular Disease in Urban Underserved Community*
- Appendix J, Deliverable # 230, *Final Report on the Implementation of the Diabetes Project*,

Project 2: Diabetes Self-Management Education (DSME)

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This project was designed to develop a Diabetes Self-Management Education program to improve access, reach, and sustainability for DSME.

UPMC worked with primary care practices to integrate DSME into the office setting. In partnership with the AADE, the National Diabetes Education Outcome System (NDEOS) which provides tools to support the educator in facilitating data collection promoting patient knowledge and behavior change and reporting tools to achieve ADA recognition was deployed and evaluated. These tools were implemented and tested in five education programs and are available through three technological mediums: web-based, touch screen and telephonic. Follow-on efforts have been to widely disseminate and evaluate in rural, underserved PA communities, as well as establish a sustainable DSME program at 59 MDW.

The project goals are as follows:

2.1 Implement and Evaluate a Theory-Based Self-Management Education Computer Based Touch-Screen Program Based on the American Association of Diabetes Educators (AADE) National Diabetes Outcome Study (NDEOS) Program in Diverse Practice Settings
2.2 Deploy an Education Intervention into Primary Care Practices and Community Settings.
2.3 Establish Sustainable, Cost-Effective DSME Programs for Diverse Practice Settings and Communities.
2.4 Establish Sustainable Diabetes Education Programs for 59 MDW

This report serves as a final summary of Project 2 research accomplishments.

Goal 2.1: Implement and Evaluate a Theory-Based Self-Management Education Computer Based Touch-Screen Program Based on the American Association of Diabetes Educators (AADE) National Diabetes Outcome Study (NDEOS) Program in Diverse Practice Settings

The NDEOS system consists of several components which can be used to validate the value of the system by demonstrating its ability to track the delivery and impact of diabetes interventions. The patient tool (DSMART) tracks patient self-care behavior (as well as patient level determinants of behavior such as intentions to change, barriers to change and outcome efficacy) over time and the educator tool (DET) tracks the delivery of services and a number of clinical parameters (including levels of glycemia, cholesterol, blood pressure, and weight) over time. The Diabetes Self-Management Assessment Report Tool (D-SMART ®), an instrument within the AADE 7 Self-Care Behaviors, was designed to assist diabetes educators to assess, facilitate and track behavior change in the provision of diabetes self-management education (DSME). D-SMART was integrated into computer and telephonic systems at four University of Pittsburgh Medical Center DSME programs. The University of Pittsburgh Diabetes Institute

(UPDI) research team performed all of the analyses for the study. Process evaluation was conducted at the programs among 242 patients with diabetes using the system.

Additional analyses was also conducted to characterize patients' self-identified and mutually-identified or agreed upon (working with diabetes educators) behavior change goals and examine the diabetes educators' response to these goals during the provision of diabetes self-management education. Data from patients and their diabetes educators were obtained from the D-SMART and D-ET. Nine hundred fifty-four individuals with diabetes (type 1 and type 2) using the D-SMART were evaluated.

Research Accomplishments:

- Seventy-six percent reported completing the D-SMART at home, in one attempt (87%) via the internet (57%).
- On average, patients completed the assessment in 29 minutes on the internet, 42 minutes on the telephonic system, and 25 minutes using a touch screen. Seventy five percent felt the questions were easy to understand, and only 22% needed assistance.
- Moreover, 75% felt that the D-SMART helped them to think about their diabetes, and 67% said that it gave the diabetes educator good information about themselves and their diabetes.
- Overall, the D-SMART was easily completed at home in one attempt, content was understandable, patients were generally satisfied with the wording of the questions and the selection of answers, and ease of use.
- Computer-based and telephonic D-SMARTs appear to be feasible assessment methods for diabetes educators.
- Individuals with diabetes using the D-SMART self-identified Healthy Eating=74% and Activity=54% most commonly as behavior change goals.
- From that sample, 527 patients identified goals that were mutually identified or agreed upon with their diabetes educator: Healthy Eating =94%, Activity=59%, Risk reduction=19%, Coping=18%, Monitoring=49%, Problem-solving=18%, and Medications=26%.
- Educators addressed these goals in the following proportions: Healthy Eating=98%, Activity=90%, Risk reduction =80%, Coping=48%, Monitoring=94%, Problem-solving=72%, and Medications=75%.
- These data demonstrate that the most common behavior change goals identified by patients (self-identified or mutually-identified) were Healthy Eating and Activity; and diabetes educators addressed these behaviors the majority of the time.
- The behavior change goal least addressed by patients and educators alike was Coping.
- Mutually-identified goals among educators and patients may improve targeted appropriate educational strategies to support patients in meeting these goals.
- Coping strategies and goal setting to address coping may need further attention.
- These results demonstrate the feasibility of using the NDEOS system for data collection and tracking of patient behavior goals

Goal 2.2: Deploy an Education Intervention into Primary Care Practices and Community Settings

As described in deliverable # 34 (Appendix K), *Final Report on Deployment*, this study utilized an alternate care delivery system focusing on self-management education strategies to effectively deploy a comprehensive self-management education program. Individuals at risk for

diabetes or diagnosed with diabetes are largely responsible for the lifestyle decisions that directly affect their health outcomes. To assist individuals to make appropriate decisions regarding their food choices, activity changes, medication adherence and adjustment, education is critical in laying the foundation.

DSME is an important part of care and there is a body of evidence to support it. Although national standards serve as a tool for benchmarking and the ADA recognition program provides a framework for programs and the Medicare and State rules support reimbursement for DSME, reality dictates that not enough people received adequate education due to cost cutting efforts.

In response to these challenges, UPMC looked to innovative and creative methods to increase reach and access while establishing methods to sustain programs. Such an approach lends itself to the Chronic Care Model that focuses on a more informed activated patient and prepared proactive practice team. Specifically, the provisions of DSME included:

- community resources and policies, such as partnerships with local community hospitals and centers
- health systems that are responsible for providing quality services and establishing policies
- self-management support that is facilitated through DSME
- delivery system redesign - using a planned team approach
- decision support that includes promoting care and education that is evidence-based
- clinical information systems, that assure ready access to key data

Overall objectives were to demonstrate the value of DSME by showing improvements in A1C levels for the health of their patients, financial sustainability, and increased access by expanding the number of programs and reach to primary care practitioners.

Research Accomplishments

- All elements of the CCM were used to expand and support DSME at UPMC with administrative support from the following areas: finance, information systems, and academic and community medicine physician practices.
- Upon expansion to communities and practices external to UPMC, the project coordinated communications to educate external parties with the DSME program and the most timely and relevant clinical information. This initiative is known as the Pittsburgh Regional Initiative for Diabetes Education (PRIDE)
- A central data repository, Medical Archival Retrieval System (MARS), was an informational resource to identify study patient population, as well as a system to track reimbursement and metabolic outcomes for 8 UPMC hospital programs and 4 primary care practices.
- System-wide seminars were designed with objectives that helped educators meet ADA and CDE requirements
- UPMC utilized the above referenced data to establish a coordinating center and submit application for a system-wide ADA recognition; sites increased from 3 to 21 affording increased access to quality and consistent programs and opportunity to bill for services at diverse sites: hospital, adult and pediatric, government, and primary care.
- An annual plan and continuous quality improvement(s) (CQI) were established to assure effectiveness of educator ability, as well as track charging and reimbursement for DSME

Goal 2.3: Establish Sustainable, Cost-Effective Education Programs for Diverse Practice Settings and Communities

As described Appendix L, *Deploying the Chronic Care Model to Implement and Sustain diabetes Self-management Training Programs*, efforts focused to identify process issues that should be considered when implementing DSME programs, as described immediately above, in primary care settings and provide helpful information about the billing and revenue issues associated with such an education program.

Historically, management of diabetes has been viewed primarily as the responsibility of providers, and very recently has become more patient centric with team approaches to care. Patient-centered, multidisciplinary teams that most often include a diabetes educator now must be charged with understanding the process requirements for sustainability, as well as instituting such processes.

Individual versus group visits

- Individualized DSME is supported under certain conditions by the Centers for Medicare and Medicaid Services regulations
- Group education for DSME is the preferred method of delivery, yet most primary practice settings do not have adequate space to hold group classes and practice must consider HIPAA privacy requirements for each participant
- Space and privacy concerns addressed by scheduling group classes during hours when there were no patients in the waiting rooms. Community rooms, senior centers, churches, and libraries are other potential ideal locations for DSME.

Record keeping

- Medical record access and record keeping are important factors to address at the onset of a primary care DSME program.
- Policies for charting and accessing health records must be known and understood.
- Communication with the provider is essential for the diabetes educator to organize an approach to each patient's educational plan and must address all informational system gaps (e.g. delayed record due to dictation)

Scheduling

- The office manager or scheduler is often the initial contact to arrange a DSME appointment in a primary care site and is often done electronically, yet can be done via an appointment book. The scheduler/manager must be kept abreast of scheduling changes and times that must be built into the schedule template for documentation, lunch, or meetings.
- Initial visits with an educator are scheduled for 90 minutes. Return visits take 45 minutes. All attempts are made to stay close to scheduled visit times to prevent acute patient problems associated with delayed meal or medication administration times. At the end of a DSME visit, the patient and educator discuss when the patient will return for further DSME, if warranted. Most patients choose to return for 2–4 visits per year. A few patients wish to return monthly or on some type of ongoing schedule for behavioral support, although these services may not be covered by the health insurer.

Billing

- Infrastructure to support appropriate billing requires the engagement of clinical providers and multiple ancillary administrative departments: finance, compliance, medical management, enrollment, coding/charge processing, compliance, legal, and representatives from third-party payors.
    - Challenges noted while coordinating processes were contractual relations to facilitate payment, capitation, personnel reimbursement, and third-party payor authorization
- Specific attention must be to DSME coding systems. Coding of DSME services is identified by CMS as G0108 (individual DSME) or G0109 (group DSME).
    - Primary practice sites often provide services to members representing many different insurance plans. Not all insurers recognize the "G" codes. Efforts must be coordinated to interface above named codes with those recognized by an entity's internal billing software, as well as the third-party payor's software.

Goal 2.4: Establish Sustainable Diabetes Education Programs for 59 MDW

As described in deliverable # 218-221 (Appendix N), *Final Report on the Implementation and evaluation of the AADE Outcomes Tool at 59 MDW*, systems capable of defining, measuring, and collecting relevant data on education outcomes that specifically include elements of behavior change are yet unavailable to DSME programs and facilitators. Initial collaborations with the American Association of Diabetes Educators (AADE) have been burdened with challenge and only now yield an educational Outcome System that will be available to PRIDE and WHMC under a 10 year license agreement.

AADE Outcome System Project Challenges

As has been reported in a series of program communications to US AF SGR, efforts to execute a reasonable agreement with AADE have not been successful or statisfactory to date. Although efforts prior to this respective project yielded an initial, validated AADE Outcome System, follow-on studies determined the AADE System to be cumbersome, necessitated an extensive amount of time to complete the tool (minimum 20 minutes), and required the addition of clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools.

These process evaluation findings and user-defined challenges severely limited the practicality of the existing tool and suggested the need for a more robust tool. AADE agreed to shorten the tool (based on the process evaluation) and engaged a separate an independent vendor to modify the existing software program.

To date, the revised AADE Outcome System is unavailable. However, UPMC understands that AADE is pursuing the revision of its AADE Outcomes System. In an agreement between AADE and UPMC, the AADE agreed that on completion of the revision, it will be made available to PRIDE and WHMC sites under a license for 10 years.

DSME Sustainability at 59 MDW Project Challenges

As discussed previously, DSME is widely considered to be an important part of diabetes management and national standards for DSME administered through the ADA recognition program provide a framework for delivery and quality. As such, Medicare and other third-party payors reimburse for programs when they meet ADA requirements. Reimbursement is linked to

codes, and charges are typically based on Medicare rates. Medicare requires that in order to bill for DSME, programs must meet the National Standards for DSME and be approved through the American Diabetes Association Recognition Program. Education charges are based on Health Care Common Procedure Coding System (HCPCS) "G" codes.

In a fiscal environment where health care administrators are skeptical of services that do not generate revenue, tracking reimbursement in justifying positions is critically important. Reimbursement is critical in generating operational revenue to support various clinical programs. As noted above, UPMC north efforts demonstrated that a DSME program can more than cover its costs when appropriate measures assure compliance with ADA certification, submittal of charge with appropriate charge code, and payor follow-up.

Although Texas mandates coverage for DSME and UPMC facilitated ADA DSME Recognition for 59 MDW, efforts to bill for such services remain impeded for 59 MDW. Specifically, billing capacity of Tricare and other government agencies (e.g. Veteran's Administration) are limited in their billing information systems to allow charges against a Health Care Common Procedure Coding System (HCPCS) G code for DSME. This limitation is not unlike what had been initially experienced at UPMC. Recommendations have been communicated to Lt. Col Nina Watson (ret) to explore various information system interfaces that would permit for such billing.

Research Accomplishments

In recognition that an educational system tool is essential to DSME and elements of behavior change also remain critically important, UPMC continued to develop system components and review alternatives to improve workflow and complete efforts for this project. Specifically, UPMC developed clinical, medication management, patient snapshot, patient-provider interfaces, and new letter manager tools. Additionally, efforts are currently under way to expand on these components and develop a user-friendly comprehensive Educational Outcomes System in collaboration with PRIDE, AF SGR, and American Diabetes Association (ADA).

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Project 2: List of Appendices

- Appendix K, Deliverable #34, *Final Report on Deployment*
- Appendix L, Deliverable #17, *List of Billing Processes for Future Sustainability*
- Appendix N, Deliverable #218-221, *Final Report on the Implementation and evaluation of the AADE Outcomes Tool at 59 MDW*

Project 3: Diabetes Retinopathy

PREPARED BY:
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This project was intended to improve diabetic eye care through the establishment of a comprehensive retinal screening program that improves access to care and enhances prevention strategies of vision loss. The key components were to provide the clinical resources, appropriate education, and access to an at risk population.

Goal 3.1: Design, Implement and Evaluate an Educational Program on the Importance of Screening for Diabetic Eye Disease to the Diabetic Patient Population and Physicians in Rural Communities

As described in Appendix 0, *Deliverable 209 Final Report Design, Implement, and Evaluate an Educational Program on the Importance of Screening for Diabetic Eye Disease to the Diabetic Patient Population and Physicians in Rural Communites*, a didactic educational video module was developed to be shown and integrated into the current workflow of Diabetic Retinopathy Screening. Educational material on eye care, importance of good glycemic control and sources of diabetes information were each incorporated into the video to be viewed as part of an eye screening program. Two screening sites were selected to pilot the study, Great American Cookout and Healthy 4 Life, each site drawing from a unique population, rural and likely urban, respectively.

Along with the video presentation, two questionnaires were administered pre and post-viewing to determine where individuals received their diabetes information:

- 7-item assessment questionnaire identifying barriers in obtaining quality eye care (*The Diabetes Eye Education Barrier Assessment*)
- 10 questions adapted from a standardized questionnaire available from the National Eye Institute (*Diabetes Eye Education Eye-Q Assessment*)

Research Accomplishments

- Barriers associated with lack of retinal screening did not appear to be associated with patient's report of challenges in receiving quality eye care or locating a provider
- Patient's report lack of support and fear of learning as barriers to seeking retinal imaging, as well as cost
- Majority of patients recognized that good glycemia prevents complications and that diabetic eye disease can be prevented.
- > 25% of the patients tested had not had an eye exam in the past year and almost half didn't know their A1C level
- Pre- and post-eye education survey demonstrated an eye educational program contributes to the improvement in participant's understanding of the concepts of diabetic retinopathy, the importance of glucose control, and the overall self-management of diabetes among people with diabetes.

- Results demonstrated that viewing the educational video improved understanding of the cause of retinopathy, value of diabetes educators, and the use of laser surgery to halt the progression of diabetic retinopathy.

Goal 3.2: Develop a Solution for the Photography, Storing, and Tracking of Eye Images for Diabetes Patients in Outlying Communities

As described in Appendix P, *Deliverable 2.10 Final Report Develop a Solution for the Photography, Storing, and Tracking of Eye Images for Diabetes Patients in Outlying Communities*, a remote system was developed and deployed to detect vision threatening diabetic retinopathy, as well as the establishment of recommendations for the referral to an ophthalmologist for treatment. Specifically, this study investigated a comprehensive educational outreach program to both patients and primary care physicians and its respective impact on screening rates for diabetic retinopathy in a target population. Additionally, awareness was enhanced through educating the target population as to the importance of screening eye examinations among the diabetic population, and access improved via employing digital fundus photography in convenient locations, in conjunction with Tele-Medicine. Lastly, "Laser treatment was recommended to those individuals with threshold disease.

- Patients with a diagnosis of Diabetes Mellitus, for diabetic retinopathy were screened using the Topcon Non-Mydriatic Fundus Camera.
- The clinical study was performed in three different settings. There were two locations within the complex of the University of Pittsburgh Medical Center and a third setting for the photo-screening of diabetic retinopathy held in a number of "health fairs" that were performed in various community locations (Community Health Fairs or CHF). These community events took place in a variety of locations including hospitals, picnics, churches, and a synagogue.
- Maximum of three, 45-degree images were acquired for each eye. Fewer images were acquired if the image(s) were felt to be of acceptable quality. At the completion of each patient, the images were uploaded to a server for archival purposes. The software developed for this purpose was based on a Stentor-like PACS (picture archiving and communication system). After archived in PACS, images are available for interpretation and grading.
- In the community screening events, the camera and computer were transported to the site with a van.

Research Accomplishments

- A program to study diabetic retinopathy screening using a non-mydriatic fundus camera, transmission of the images over the internet, using a Stentor-like PACS system for image archival, and a novel protocol for interpreting the images was implemented in two different out-patient, hospital-based practices, the General Internal Medicine Clinic and in the Center for Diabetes and Endocrinology, UPMC- Presbyterian Hospital.
- Community diabetic retinopathy photo-screening events were held at a variety of health fairs in this region, using a mobile unit. This program showed that 83 to 91% of the images were of adequate quality to grade. Furthermore, 1-2% of the individuals in this study were found to have a level of disease that was considered potentially vision threatening, and were advised to seek eye care within a period of 6 weeks. As noted above, the "Recommendations" for follow-up eye care can be correlated to the level or stage of diabetic retinopathy. One might hypothesize that more advanced disease would be identified in the subspecialty Center for Diabetes and Endocrinology clinic

where patients with complex management issues are treated. On the other hand, perhaps there may be less retinopathy in patients with improved diabetic control as provided by the subspecialists. Results also suggest that people with diabetes are not receiving annual eye exams despite recommendations.

- It is generally accepted that approximately 50% of diabetics receive routine, yearly screening eye exams for diabetes, and these numbers are basically confirmatory.

Goal 3.3: Design, Implement and Evaluate a Telemedicine Pilot Project Using a Mobile Screening for Detection and Treatment of Diabetic Eye Disease

As described in Appendix Q*, Deliverable 126 Final Report Design, Implement, and Evaluate a Telemedicine Pilot Project Using a Mobile Screening for Detection and Treatment of Diabetic Eye Disease*

Goal 3.4: Continuation of Retinal Screening with Digital Fundus Cameras

As described in Appendix R, Deliverable 231 *Copy of image collection process*, a workable image collection process was developed to enable timely and accurate reading of retinal images by a medically trained ophthalmologist. Pre-defined image collection processes were translated into workable collection processes for clinic(s) located in the San Antonio area participating in this retinal imaging study.

Research Accomplishments

- The processes used to transmit and store images to the WHMC reading center to date have been dictated by connectivity limitations. Specifically, images are taken via the Topcon camera, stored on a dedicated CPU directly supporting the Topcon camera, and subsequently copied to a portable medium (e.g. CD, key drive, etc.).
- The images stored on the portable medium are then transferred to another computer networked at WHMC for reading and permanent storage. Upon transfer to the networked computer, the portable medium is securely stored.
- Similarly, images collected at Kelly Clinic are immediately stored to the local CPU supporting the Topcon camera, transferred to a CD and hand carried by the ophthalmology technician at the close of each work day.
- Each set of images is reviewed by the Dr. Waller that yields the respective follow-up for each patient. Potential follow-up includes:

(1) Patient follow-up communicating that there is no additional need to visit specialist and request for follow-on appointment and retinal image within one year
(2) Patient follow-up communicating request to visit specialist whereby visits are prioritized per retinal image findings.

Goal 3.5: Develop Educational Activities

As described in Appendix S, Deliverable 232 *Develop Educational Activities*, providers, patients, and the patients' families were educated with respect to the importance of monitoring patients at risk for diabetic retinopathy via application of a two-tiered approach and using multi-faceted media.

Wilford Hall Medical Ce nter's (WHMC) ophthalmologist, Stephen Waller MD, worked with the UPMC and University of Pittsburgh, and participated with Joslin Diabete s Center to establish a comprehensive knowledge base an d resource dissemination at WHMC Reading Center. He established the educational program by coordinating an infrastructure for provider education, as well as, patient education.

Provider ed ucational ef forts were concentrated in spring and summer 2006 an d continued locally via Dr. Waller ser ving as the lead educat or. Provider education focuses on information dissemination, and part icipation in clin ical do main specif ic summits. Patient educational activities involve communicating with the patie nt at the t ime of their initia l visit, as well as, providing ready access to informational hand- outs. Specifically, the pro viders, both ophthalmologist and ophthalmic technician, educate the pat ient and the ir respective families on the importance of screening, as well as the following salient points:

- Diabetes is the #1 cause of blindness in American adults of working age
- Diabetic retinopathy is directly related to blood glucose
- Hemoglobin A1c having a value of $\leq$ 7 is safe and is the KEY to maintaining one's sig ht for a person at risk
- Nearly every patient ha s the ab ility to maintain their A1c at a level o f $\leq$ 7 with t he appropriate actions:
    - Being co mpliant with medical recomme ndations a nd pharmaceutical prescriptions
    - Losing weight as deemed necessary
    - Exercising 30 minutes daily, five times a week

Additionally, each patient and his/her family can actively consult with the ophthalmologist to gain a better understanding of the reti nal screening process, frequency, and diagnostic capacity. Individuals can also use these discu ssions to learn more of other eye d isease stat es, such as, glaucoma, macular degeneration, etc.

Research Accomplishments

- The educational efforts, both provi der and pat ient, have b een successful in patie nt's actively engaged and willing to participate in the retinal screening program at WHMC.
- Improved a ccess and screening has enabled the ophthalmologist to focus on patient s with disease and defer a large majority of patients presenting with normal readings to the annual retinal screening program, thereby increasing efficiency for specialist physician in the military, as well as, permit for a larger through put that may ultimately screen patients otherwise not interested and potentially at an unknown risk of clinical eye disease.

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Project 3: List of Appendices

- Appendix 0, Deliverable #209, *Final Report Design, Implement, and Evaluate an Educational Program on the Importance of Screening for Diabetic Eye Disease to the Diabetic Patient Population and Physicians in Rural Communites*
- Appendix P, Deliverable #210, *Final Report Develop a Solution for the Photography, Storing, and Tracking of Eye Images for Diabetes Patients in Outlying Communities*
- *Appendix Q, Deliverable #126, Final Report Design, Implement, and Evaluate a Telemedicine Pilot Project Using a Mobile Screening for Detection and Treatment of Diabetic Eye Disease*
- Appendix R, Deliverable #231, *Final Report Develop a Solution for the Photography, Storing, and Tracking of Eye Images for Diabetes Patients in Outlying Communities*
- Appendix S, Deliverable # 232, *Develop Educational Activities*

Project 4: Veteran's Initiative

PREPARED BY:
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Home-based telemedicine is emerging as a tool for chronic disease management, because it enables access to specialty care from distant locations, provides automated education and feedback, and facilitates patient communication with providers. Independent of our study, such a system has been adopted in the VA Healthcare System nationally to improve management of prevalent chronic diseases, including diabetes, for defined high-cost users of the system.

Goal 4.1: Implement a Telemedicine Project with the Overall Goal to Assess the Effectiveness and Acceptability to Veteran Patients of Several Modalities of Chronic Disease Management

The DiaTel Study was a two–phase, randomized clinical trial to evaluate telemonitoring paired with real-time medication management for veterans with poor glycemic control. The goal of Phase I was to evaluate the short-term effectiveness of the intervention. The goal of Phase II was to examine the nature of contact required to sustain effectiveness of the intervention over time. We report Phase I here; Phase II will be reported separately.

Phase I

- Evaluated a 6-month Active Care Management intervention for veterans with poor glycemic control that included home telemonitoring (ACM+HT) combined with intensive medication management by a Certified Registered Nurse Practitioner (CRNP).
- The intervention was compared to a lower intensity Care Coordination (CC) intervention, which consisted of monthly telephone contact with a study registered nurse.
- Secondary analyses examined differences between ACM+HT and CC with regard to satisfaction with care, quality of life, and behavioral factors associated with adherence to the diabetes self-management regimen.
- Changes in medication management were described in both treatment arms over the course of the intervention.
- The following process-oriented factors were described for participants randomized to the ACM+HT
    - frequency of capillary glucose self-monitoring using home glucose meters
    - frequencies of unacceptably low and high capillary glucose readings as defined by the home telemonitoring support system, Viterion 100.

Phase II

- Continuation of the DiaTel Study Phase I trial
- Primary aim was to assess whether glycemic, BP, and lipid control at the end of an additional 6 months of follow-up differed for participants randomized to the four groups
    - ACM+HT-to-Care Coordination plus Home Telemonitoring (CCHT)
    - ACMHT-to- CC

  - CC-to-C C
  - CC-to-Usual Care (UC)
- Participants who completed the 6 month visit of DiaTel Phase I were invited to participate in Phase II study
- Participants were consented and re-randomized to subseque nt management group s as noted immediately above at the same or lower intensity as in Phase I, and followed for an additional 6 months

Details pertaining to each sub-goal can be read respective the bulleted Appendix:

Goal 4.1.1: Design, Implement, and Evaluate a Pilot Diabetes Care Manage ment/Coordination Program Uti lizing Nurses (RNs) or Nurse Practitioners (CRNPs) Supported by Appropriate In-Home Technology (Home Blood Glucose and Blood Pressure (BP) Monitoring Interfaced with a Home Messaging Device Capable of Electronic Data Transmission to VA Pittsburgh Healthcar e System-Based (VAPHS) Providers via a Secure Network.

- Appendix T, Deliverables #77 and #84 *Final report on program*

Goal 4.1.2: Establish Pilot Telem edicine Diabet es Consultative Services Based at VAPHS for the Altoona and Butler VAMCs and Three VA Community Based Outpatient Clinics (CBOCS)

- Appendix U, Deliverable # 172 *Final Report on data analysis*

Goal 4.1.3: Follow Veterans with Diabetes Mellitus and Suboptim al Glycemic Control (HBA1C > 7.5% Who Were Enrolled in a Prospective St udy of Two Interventio ns to Im prove Glycem ic, Blood Pressure (BP), and Lipid Control for an Additional Six Months to Determ ine the Appropriate Level of Subsequent Management Required to Sustain Improved Glycemic Control

- Appendix V, Deliverable # 173 *Final Report and analysis of the study*

Research Accomplishments

Phase I

Compared to CC, ACM+HT particip ants will ex perience gr eater improvements in HbA1c, BP, lipids (tot al cholesterol, HDL, LDL, and triglycer ides) and w eight. We defined improvement in terms of mean differen ces at 3 an d 6 months as well as differential change over time. In addition, we examined change over time within each treatment arm separately.

Phase II

- Short-term ACM+HT intervention for a period of possibly as brief as 3 months, during which most improvement was observed, is an eff ective intervention approach for ach ieving and sustaining g lycemic control for at le ast 12 months in veterans who have been una ble to achieve HbA1c goals after 12 months or more of standard diabetes care.
- After initial improvements in glycemia are achieved with ACM+HT, continued prompting and education via the home telemedicine device used in this study offered no significan t advantage over a monthly phone call from a nurse coordinator.

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Project 4: List of Appendices

- Appendix T, Deliverables #77 and #84, *Final report on program*
- Appendix U, Deliverable #172, *Final Report on data analysis*
- *Appendix V,* Deliverable #173, *Final Report and analysis of the study*

Project 5: Inpatient Initiative

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This project primarily focused to develop and implement a series of protocols that addressed specific areas of inpatient gylcemic management. The protocols were evaluated for efficacy and safety and intended as general guidelines that must be adapted to the specific circumstances of hospitals and institutional providers, physicians and healthcare professionals, and their patients. UPMC Diabetes Protocols to date are as follows:

- Hypoglycemia
  - Hypoglycemia Treatment Protocol
- *Insulin Pump*
  - Continuous Subcutaneous Insulin Pump Order Set
  - Insulin Pump Patient Assessment Form
  - Insulin Pump Log Sheet
  - DPSC Treatment Guidelines – Hospital Management of Patients Admitted with Continuous Insulin Pumps
- *Diabetes Order Set*
  - *Adult Diabetes Admission Order Set*
  - *Insulin Order Form – Physician Order Set*
  - *Guidelines for Inpatient Diabetes Management*
  - *Insulin (Subcutaneous): Initiation or Modification Order Set*
  - *Oral Diabetes Medication: Initiation or Modification Order Set*
- *DKA*
  - Diabetic Ketoacidosis Order Set
- *IV Insulin Infusion*
  - Regular Insulin IV Infusion Protocol: Goal Blood Glucose 80-150, Order Set *(Limited use – through diabetes service only)*
- *Sliding Scale*
  - Regular Humulin Insulin Sliding Scale Physician Order Set
- *Perioperative Order Set*
  - Anesthesiology Management
    - IV Insulin Infusion
    - Subcutaneous Insulin Orders
  - Pre-operative Instructions for Patients with Diabetes

Details and specific research accomplishments pertaining to each goal are included in the previously submitted reports noted below.

Goal 5.1: Develop and Implement a Standardized Approach for Improving Glycemic Control and Clinical Outcomes in Patients Hospitalized with a Diagnosis of Diabetes or Newly Recognized Hyperglycemia

- Deliverable #8 *Copy of efficacy data.*

Goal 5.2: Implement Protocol for Peri -Operative Gl ycemic Managem ent of the Pateint with Diabetes or Newly Recognized Hyperglycemia

- Deliverables #63, 64, 65, 67, 68, 69, 70 *Final report on program.*
- Deliverable #66*, Copy of approved protocols.*

Goal 5.3: Introduce and Impl ement Hyperg lycemia Drip Pr otocol w ithin Critical Care Unit(s) at 59 MDW Intensify Implemen tation and Obtain Efficacy and Safety Data Related to Estbalished Protocols for Inpatient Dia betes Management, Including Hy poglycemia Treatment Protocol (HTP), Use of Sliding Scale Regular (SSR) Insulin, and Order Set for Management of Patients Admitted to the Hospital with Diabetic Ketoacidosis (DKA)

- Deliverables #71, 72, and 73 *Final report on implantation and data collected.*

Goal 5.4: Develop a proactive app roach to patients at risk for inpatient hypoglycemia and hy perglycemia, includi ng assignment of fasting status to patients receiving insulin or oral h ypoglycemic agents, or the initiation of enteral and parenteral nutrition or high dose steroi d therapy to patients w ith and without a prior diagnosis of diabetes

- Deliverables #10, 75, and 76 *Final report to include education materials developed.*

Goal 5.5: Introduce and evaluate a st andardized admission order set that encompasses critical aspects of inpatient glycemic management w ith the goal of improving caregiver know ledge across a ll disciplines and decreasin g adverse events

- Deliverables #101a-d *Copy of Order Set/Guidelines at UPMC-PUH.*
- Deliverable #102 *Copy of UPMC-PUH Diabetes Ketoacidosis (DKA) order set/guidelines*
- Deliverable #103 *Summary report of DKA QI project.*
- Deliverable #104 *Copy of UPMC-PUH Guidelin es and Algorithm s for Management of Hyperglycemia in Patients on High Dose Steroids.*
- Deliverable #105 a, b Summary report of Steroid Project.
- Deliverable #61 *Copy of QI program that will evaluate ph ysician and nurse knowledge and perceived barriers to glycemic control in the hospital.*
- Deliverable #151 *Copy of internet learning modules.*
- Deliverable #106 *Copy of the PDA version of Inpatient DM Management Guidelines.*

Goal 5.6: Improve Patient Safet y by decreasing the frequency of sever e hypoglycemia

- Deliverables #107 a, b *Final report on the evaluation of frequency of mild, moderate and severe hypoglycemia and analysis of related inpatient outcome.*
- Deliverable #152 *Final report on th e dissem ination of the HTP to UPMC affiliates and rural community hospitals.*

Goal 5.7: Improve Patient Safety by decreasing the frequency and severity of hyperglycemia. Development of a targeted glycemic management plan (TGMP) for high risk patients to improve patient safety by decreasing the frequency and severity of hyperglycemia defined as CBG >180 and severe hyperglycemia defined as CBG >300 mg/dl in the hospital setting

- Deliverable #109 *Final analysis and report on implementation of a targeted glycemic management plan (TGMP) for high risk patients.*

Goal 5.8: Improve patient outcomes in critical care areas by increasing the use of the standardized order set for Continuous Intravenous Insulin Infusion targeting BG of 80-150 mg/d

- Deliverables #111 a, b *Summary report of Inpatient Protocol for Transition from Insulin Infusion to Subcutaneous Insulin Injections.*
- Deliverables #112 a-e *Final analysis of outcomes in the Medical ICU and other ICU's within UPMC PUH of the 80-150 and 80-130 mg/dl IV infusion protocol.*

Goal 5.9: Develop and implement a standardized order set for peri-operative glycemic management as a means of reducing peri-operative complications and hospital LOS

- Deliverable #114 *Final analysis and report on per-inoperative glycemic management, evaluation of outcomes and dissemination of protocol to outside facilities.*

Goal 5.10: Improve patient safety and glycemic control for patients admitted to the hospital with an insulin pump

- Deliverables #152 and 155 *Final analysis and report on the implementation of the continuation of the insulin pump QI project including summary of outcomes and dissemination of protocol to outside facilities.*

Goal 5.11: Develop methodologies to assess current dietary practices as they relate to glycemic management of patients with diabetes in the hospital discharge

- Deliverables #152 and 156 *Final analysis and report. Dissemination of information regarding approaches to inpatient nutrition.*

Goal 5.12: Measure the impact of inpatient glycemic management and diabetes education on DSM practices and quality of life following hospital discharge

- Deliverable #127 *Final report on the impact of the unit based diabetes education project on patient satisfaction, diabetes self management practices and quality of life following discharge.*

Goal 5.13: Improve patient outcomes in critical care units at 59 mdw by increasing use of the standardized order set for intravenous insulin administration that targets a blood glucose of 80-150 mg/d

- Deliverable #127 *Final analysis and report of findings related to outpatient metabolic control and frequency of hospitalizations.*

Research Accomplishments

- A series of seven diabetes inpatient protocols were developed, implemented, and evaluated for efficacy and safety.
- Implementation of any one of these protocols requires extensive inservice educational sessions with nursing personnel and existence of an inpatient diabetes protocol does not guarantee use.
- Institutions adopting the protocols noted above must identify and evaluate the best means for introducing these protocols into their respective hospital culture.
- Continual quality review is recommended to monitor and evaluate the impact of protocol(s) on overall glycemic control in the hospital setting.
- Use of protocols reduces hospital length of stay.

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Project 5: List of Appendices

- None included.

Project 6: Chronic Care Model

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This effort was to improve provider processes and patient outcomes for diabetes care through the implementation of the Chronic Care Model. Understanding that instituting system changes to incorporate the elements of the Chronic Care Model (decision support, clinical information systems, self-management education, and delivery system design), this project focused to accomplish four overarching goals.

The project had four overarching goals:

6.1 Develop and evaluate a web-based patient portal that enables patients with diabetes to communicate directly with their physicians electronically and receive diabetes care information

6.2 Interface medical practice and community efforts to improve diabetes care and outcomes

6.3 Establish a Diabetes Outreach Clinic at WHMC

This report serves as a final summary of Project 6 research accomplishments.

Goal 6.1: Develop and evaluate a web-based patient portal that enables patients with diabetes to communicate directly with their physicians electronically and receive diabetes care information

Effective chronic disease programs assure provider access to patient information and to patients for self-management education and team-based care. Self-management is recognized as a critical component of effective chronic care delivery models. The portal was developed in two phases. Phase 1 included the development of the web-based portal. HealthTrak was designed as an interactive patient portal, with a specific focus on diabetes self-management. HealthTrak connects the patient to the physician office Electronic Medical Record (EMR) through a secure portal and allows the patient to view laboratory results, message with the physician office, schedule appointments, receive preventive health reminders (e.g., need to measure A1C), and track diabetes related values, such as blood glucose. Following implementation of HealthTrak in four primary care practices, several evaluation processes were organized.

In Phase 2 based on feedback obtained on HealthTrak, providers and patients expressed a need for the portal to be expanded to include a lifestyle management system. A multi-disciplinary team of researchers hypothesized that an internet-based approach may facilitate the translation of an evidence-based intensive lifestyle counseling curriculum into the clinical setting, and so adapted the DPP Lifestyle Balance Curriculum for online delivery. In Phase 2, the resultant program, Virtual Lifestyle Management (VLM), includes a single in-person orientation session, then 16 weekly and 8 monthly lessons derived from DPP materials. Each

lesson is a utomated and include s interactive workbook exercises. The progra m includes a variety of behavioral tools su ch as email pro mpts for diet, physical activity and weight se lf-monitoring, and automated weekly progress re ports. Each participant was assign ed a life style coach, who regularly reviewed participants' status, self-monitoring efforts, and workbook entries, sends scheduled and a s-needed coaching not es, and mo derates cha t sessions. The progra m incorporates behavioral tools such a s email pro mpts for onl ine self-monitoring of diet, physical activity and weight, and automated weekly progr ess repo rts. Support was also provided vi a electronic counseling. A before-after pilot study of program imple mentation, feasibility and effectiveness was conducted in an academic general internal medicine practice in Phase 2.

Goal 6.1.1: Create a Patient Portal f or Diabetes Mellitus (DM) management for patients to vi ew and annotate their personal health management

Goal 6.1.2: Develop and Implement a technology based delivery of a diabetes self-management program, Virtual Lifestyle Management (VLM)

Research Accomplishments (Phase 1)

Focus grou ps were co nducted to ascertain p atients' vie ws regardin g HealthTrak's value t o them. While the focus group participants appr eciated feat ures of HealthTrak, the y expressed frustration when messages or laboratory tests were not responded to promptly. Fe atures that patients fou nd particularly useful included: electr onic reminders about u pcoming appointments, online sche duling of ap pointments, and email access to t he health care team. Patients also reported a reluctance to assign a value, or willingness to pay for HealthTrak. While men, college graduates, and those recently diagnosed with diabetes ap pear to me more likely to assign a monetary value to HealthTrak, these difference s do not rea ch statistical significance. Reasons cited for reluctance to assign a monetary val ue included the fact th at these se rvices (e.g., diabetes nurse educators and telephone calls with practice) are already provided free of charge, preference for telephon e communication, and potential for t he "system" to realize savings as a result of improvements (so the system should bear the costs).

The impact of HealthTrak on diabetes related process measures (e.g. , having a diabetic foot exam), and intermediate outcomes (e.g., A1C value) has also been e xamined. Patients who participated in HealthTrak achieved more diabe tes related process measures and were more likely to be at goals for diabetes related intermediate outcomes. Ho wever, when HealthTrak participants changes in achieving these process measures and attaining goal values before and after signin g up for He althTrak were compared to a sample of patie nts over the same time period who did not sign up for HealthTrak, ther e was no difference in t he trend. This led to the hypothesis that providing passive a ccess to information and reminders is inadequa te to chang e health outcomes and that future work should test more active self-management systems.

Research Accomplishments (Phase 2)

The VLM was designe d and teste d in Phase 2. Fifty a dults recru ited from a large UPMC General Internal Medicine practice were recruit ed to part icipate in a pilot study to evaluate the use of VLM. Patients with a BMI > _25 kg/m^2, at least one weight-related cardiovascular risk factor and Internet acces s were eligible if the referring physician felt that the lifestyle goals were safe and medically app ropriate. Program use and change s in weight and blood p ressure were assessed. Participants were primarily female (76%), with a n average age of 51.94 (SD 10.82), and BMI of 36.43 (SD 6.78). At 12 months of enrollment, 50% of participants ha d logged in within 30 days. On a verage, completers (n=45) lost 4.79 (SD 8.55) kg. Systolic blood pressure

dropped 7.33 (SD 11.36) mm Hg and diastolic blood pressure changed minimally (+0.44 mm Hg; SD 9.27).

The investigators conclude that an Internet-based lifestyle intervention may facilitate the incorporation of evidence-based lifestyle interventions into primary care. Pilot data suggest that a wide spectrum of primary care patients can successfully use the program for lifestyle change.

Details and specific research accomplishments pertaining to each of the above named sub-goals as well as those listed immediately below are included in previously submitted reports as noted.

Goal 6.1.4: Create secured messaging to enable patients to exchange messages with their providers about their health care and diabetes management.

Goal 6.1.5: Create toolset that provides disease management tools via patient portal.

Goal 6.1.5: Appropriate education sites and content will be identified with links to slected UPMC approved content web sites.

- Deliverables #16, 23, 24, 36, and 37 Final Report on the Diabetes Portal and the DM Patient Portal Outcomes

Goal 6.2: Interface medical practice and community efforts to improve diabetes care and outcomes

Despite agreement with guidelines for diabetes management, providers often fail to enact appropriate care. Patients are often either unaware of, or mistrust, advice about diabetes interventions. Even when patients agree with care goals, they often lack the knowledge, resources, and motivation to take action steps. The UPMC Shadyside Primary Care Institute providers with the faith-based Centers for Healthy Hearts and Souls (CHHS) to develop community-based exercise groups, smoking cessation programs, and diabetes support groups in order to reduce cardiovascular risk in the African American community. This project ties together the medical practice and community programs to improve diabetes care and outcomes. It was our hypothesis that culturally-tailored, community-based programs for diabetes support will improve mastery and outcomes for diabetic patients. Modules to encourage smoking cessation, exercise initiation, and depression awareness used to enhance action steps by diabetics, their family and care takers, and at-risk individuals were designed and implemented. We wanted to determine if community-based :
1. diabetes support groups help patients increase mastery and improve markers for diabetes outcomes.
2. smoking cessation programs help people with diabetes to quit smoking and avoid second hand smoke.
3. exercise groups engage patients with diabetes and family members in activities that reduce cardiovascular risk and improve quality of life.

Support Group: Each group member is trained to take better care of his own diabetes, that of a significant other or his own risk status. Group Structure: Each group of 15 to 30 individuals meets every two weeks at local churches or community centers. The group is led by the Diabetes Nurse and a Lay Advocate with the assistance of the group's Physician. A typical meeting includes a spiritual greeting, introduction and testimony of new members, sharing of

action steps and new problems or questions, stretching and snack, topical presentation or video vignette, an educational handout and spiritual message.

Data Management: Forms used for the program are linked to an ACCESS data base developed and maintained by the Shady Side Primary Care Institute. Data transcription is provided by CHHS for smoking cessation, fitness and diabetes programs. Each month group facilitators review reports on missing data and needed referrals. Patients are encouraged to engage in a partnership with their physicians by the utilization of "My Diabetes Progress Report" form. The physicians are asked to provide patients HbAlc, LDL, HDL, blood pressure and weight, and to set desired goals specific to these categories. There is also a comment section on the form where physicians can give specific advice.

Fitness and Smoking Cessation program
The smoking cessation programs are directed by an experienced community-based registered nurse. Each group of 4-8 individuals meets over a six week period at local churches or community centers. Each group is led by trained community facilitators using an American Cancer Society-approved methodology. Individuals who will not attend a group receive telephone counseling and in some case home visits for counseling. Subsidized nicotine replacement therapy is available through funding from Tobacco Free Allegheny (TFA), and is now provided through commercial and state -supPOlied health plans. Formal assessment includes an initial "Readiness Questionnaire" and "Smoking History"; CO monitoring; self-report; and attendance. A well-organized follow-up program utilizing phone and mail contacts aims to help each person to meet his/her smoking cessation goals.
Research Accomplishments:

- CHHS community-based programs have hosted > 15,000 visits in five sites including > 2000 patients.
- Forty of forty-seven sedentary support group members have met exercise action steps.
- Ninety-seven members of the CHHS diabetes support groups now participate in the special low-impact CHHS exercise program
- 292 persons with diabetes or high-risk for diabetes participated in the exercise and fitness programs.
- Among forty participants with multi-year participation, mean HbAlc levels declined from 7.92 to 6.99%, LDL was reduced from 112.5 to 113, and weight reduction 216.9 to 199.5 lbs.
- Members rated themselves as having made significant changes in activity, diet, self-care, and ability to talk openly about diabetes.
- Successful cultural tailoring of prevention and disease management programs is essential to care
- Utilization of retired community nurses and training of lay advocates provides vital culturally-competent resources in underserved communities.
- Smoking intervention: Outcomes analysis report, Attachment W.

Fitness Intervention: Data gathered at each support group session from each participant. Outcomes analysis report, Attachment W.

Goal 6.3: Establish and Continue a Diabetes Outreach Clinic at WHMC

The AF Medical Service delivers diabetes care to 132,000 beneficiaries. At WHMC 10,000 persons with diabetes (majority Type 2) are “eligible” for care. There are 3,600 persons with type 2 diabetes enrolled at WHMC, including approximately 800 of the most complex cases, as well as 700 persons with type 1 diabetes under age 21. In order to meet the needs of the

increasing populations, in collaboration with US Air Force (USAF) medical partners, it was determined that a model diabetes program should be developed and evaluated. The Air Force Medical Service (AFMS) in partnership with the UPMC established a Diabetes Outreach Clinic within the Wilford Hall Medical Center (WHMC) Internal Medicine Clinic. The DOC is a full-service diabetes clinic that supports the team care approach and primary care services at WHMC. The DOC model was designed based on feedback and direction from AF active duty endocrinologists and representatives from SGR during phase 1 of the project. It was hypothesized that comprehensive, improved disease management for diabetic patients within a model diabetic program for the USAF would result in better control and therefore fewer co-morbidities and complications in diabetic patients.

Project Accomplishments (The DOC)

Staff
The clinic operates under a "one stop shop" concept, which means clinic patients have access to multiple health care providers at one visit. It was anticipated that the DOC would serve as a resource for improvement in diabetes care and in doing so reduce costs. Prior to the clinic opening on January 3, 2006, efforts were targeted toward staff recruitment and setting up the clinic to be fully ready for patient care, with attention to items and processes that include: obtaining furniture, setting up offices and exam rooms, obtaining patient education materials and creating contacts within the hospital.

The UPMC Program Management Office representative Jane Ward, MD, was responsible for hiring the majority of the original staff in September and October 2005 and organizing preparations for opening the clinic. The initial clinic staff included: an Endocrinologist, a Nurse Practitioner, 1 RN, Dietitian, Licensed Professional Counselor, Ophthalmologist, 1 Ophthalmology technician and Medical Receptionist. A second Ophthalmology Technician was hired in January 2006 and a second RN was hired in March 2006. The position of Clinic Manager was approved and added and filled in November 2006. Staffing attrition for the first year included 2 ophthalmology technicians and 1 RN. One ophthalmic technician was replaced in November 2006. After reviewing staffing needs in ophthalmology, it was decided that only one ophthalmology technician would be needed. Initially, total clinic management/oversight was the responsibility of the Medical Director, until the Clinic Manager Position was added later in the year.

Space
The WHMC Internal Medicine clinic provided space for the clinic, which consisted of a check in area, 6-exam rooms and 3-offices. Family Medicine provided space for the Ophthalmology section, which consists of 2-offices and one eye lane, with the eventual goal of 2-fully functional eye lanes in the future. Medical supplies essential to direct patient care are provided by WHMC. Other supplies, i.e. office supplies and educational materials, are purchased through UPMC.

Patient Enrollment
The initial empanelment goal for the DOC was 500 patients, with a long term goal of serving 1500 patients. In servicing and recruiting patients for the DOC, staff worked with the Wilford Hall Health Care Integrators (HCI's). The HCI's were given the following criteria for patient recruitment: (1) patients must have either type 1 or 2 diabetes; (2) patients must be between the ages of 18-62; (3) patients must have a HbA1C > 6.5%. The HCI's then worked with the primary care clinics at both WHMC and Kelly to obtain patient names for recruitment. The initial list of 500 patients was sent to the clinic and an announcement of the DOC services in a

brochure was sent. No other promotional materials were used. In the letter, patients were instructed to call the clinic to schedule an initial visit. When patients were called to schedule the appointment, they were instructed to obtain their laboratory work prior to their visit. The clerk explained to the patient what was to be expected at the visit. The clinic patients are a mix of active duty military, military retirees, and dependent family members of retirees. A second round of empanelment occurred beginning in June 2006, with another group of 500 patients. These patients were phased into the clinic at 100 patient visits per month so that the demand for appointments would not exceed availability.

Patient Visits

Initial (first time) visits were designed as proposed as a "one stop shop" for the patients. Patients would visit their provider, either the M.D. or the Nurse Practitioner for one hour followed by a half hour visit with the dietitian, the RN for education and an eye exam if needed, with the ophthalmologist. Follow up visits were scheduled as necessary. The initial templates for the providers allowed for 3 initial visits per day, 6 follow up visits and 2 acute (same day) appointments. The intent was to have patients follow up more frequently in the DOC than they would in other Primary Care clinics. Most primary care practitioners follow patients every six months to one year. Patients are followed every three months at the DOC once good blood glucose control is reached and are followed more frequently (as determined by their provider) if uncontrolled glucoses or problems are noted.

Group Medical Appointments (DIGMA)

Group medical visits have been shown to be an effective method to provide chronic care services. In September 2006, the clinic held its first "Drop In Group Medical Appointments" (DIGMA). The concept of the DIGMA was developed by Dr. Mark Nofsinger, who trained clinic staff in his model earlier in the year. The intent of the DIGMA is to maximize the number of patients that a provider sees in an abbreviated time slot. DIGMAs helped create greater access to care in the clinic. The DOC providers see between 6-8 patients in the DIGMA over 90 minutes. Patients and people that accompany them to the visit are first consented. They are also given a packet of educational materials. The DIGMA is facilitated by the DOC Counselor. During the first year 126 patients were seen at the DOC using the DIGMA Model. This model of care was effective in increasing access for follow up routine care services. In a usual care model only 27 patients would have been seen in the time frame of record. Using the DIGMA model 126 patients had visits and were seen for a variety of reasons that can be facilitated in a group appointment, e.g. medication titration, acute issues, etc.

Research Accomplishments

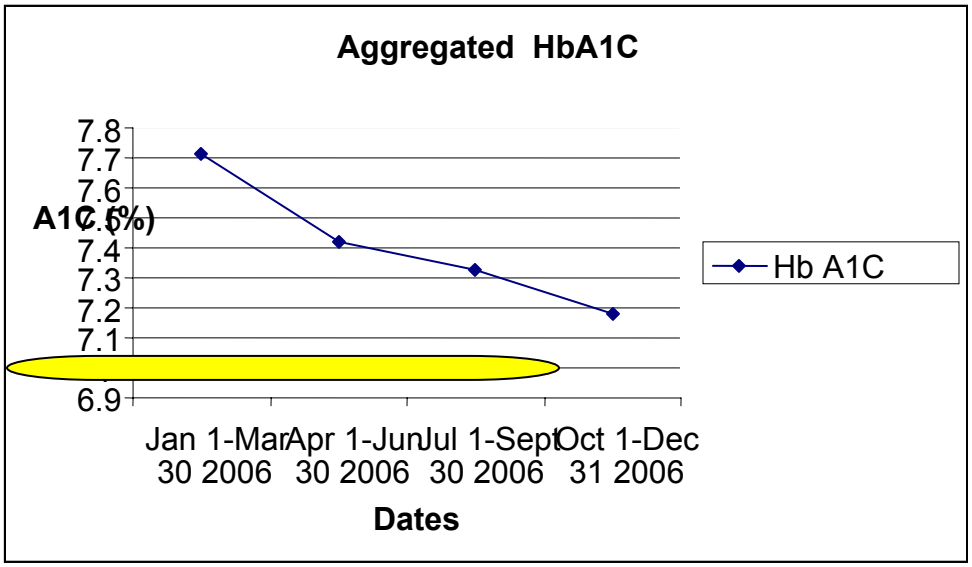
The proposal for the DOC translational research study was developed and approved by both the University of Pittsburgh and Wilford Hall IRBs (Quality Assurance Research). The area of study is ongoing and consists of comparing the health outcomes and costs of providing primary and diabetes care in a disease management forum, to enrolled diabetics. Their previous two years of health status and records of accessing the health care system will be used to establish the level of baseline care. Indices normally used to evaluate diabetes care processes and outcomes include: weight, blood pressure, HbA1C values, cholesterol, renal function, foot health status, and retinopathy assessment. Chronic care visits, education sessions, and acute care episodes as well as use of pharmacy, lab, and critical or emergency care will be documented.

Data Management

We have determined that the Comprehensive Diabetes Management Program (CDMP) was the best method in collecting this clinical data and monitoring patient outcomes. The staff was trained on the CDMP, which is also being used by Walter Reed Army Medical Center in their

diabetes disease management program. Staff worked with AF systems and Estenda to be able to have interface to have CDMP with AF systems, specifically ICDB, which is a lengthy process given DoD security requirements. The interface was not activated until 2007. Although the CDMP, is now activated the data available is reported in aggregate numbers. Currently, staff is working with the CDMP in using the system to be able to identify and monitor individual patients and reports. Clinical baseline data is illustrated below.

FIGURE1: AGGREGATED HBA1C VALUES



The above figure is an aggregate view of the data collected at the DOC over the first year. This data is represented in quarterly time periods. In the first quarter there was over 1, 100 patients represented in the average HgA1C value. The number of patients enrolled at the DOC increased over time therefore, the last quarter represented in the above figure consists of lab values of over 1,400 patients. The American Diabetes Association (ADA) guidelines recommended that individuals with diabetes have an HbA1C < 7%. This graph depicts that there is a trend for the average patient at the DOC to reach the recommended guidelines by the ADA.

TABLE 1:AGGREGATE VIEW OF THE DOC'S LIPID MANAGEMNET:

DATES	TOTAL CHOLESTEROL	TOTAL # CHOL. LABS	LDL	TOTAL # LDL LABS	HDL	TOTAL # HDL. LABS	TRIG	TOTAL # Trig. LABS
JAN 1-MAR 30 2006	176.18	580	88.12	570	50.33	558	172.21	568
APR 1-JUN 30 2006	170.79	507	82.79	498	50.18	493	162.54	549
JUL 1-SEPT 30 2006	170.87	561	86.24	542	49.13	545	165.18	548

OCT 1-DEC 31 2006	171.66	552	86.51	547	50.13	547	165.53	550
GOAL VALUES	<200 mg/dL		<100 mg/dL		>45 mg/dL		<150 mg/dL	

The above table represents the aggregate patient view of the lipid profiles. Lipid values are represented as a numerical value for each as well as the number of patients that were measures during the quarterly timeframe. Target goal values (ADA Standards) are represented at the bottom of the table. These goal values are the values that the ADA recommends for lipid management.

TABLE 2: NUMBER OF PATIENTS SEEN AT THE DOC :

TYPE OF APPOINTMENT	*NUMBER OF PATIENTS*
Scheduled	*4030*
Walk-In	*776*
Total	***4806***

In summary, with the implementation of the DOC there were lessons learned and based on the lessons, future strategies that need to be addressed as next steps, include:

1) Recruitment: The original position postings were advertised as a splash ad in the *San Antonio Express News*, on www.monster.com and on the UPMC website. While most positions were filled through these means, it was difficult to obtain applicants for the remaining open positions and vacated positions. It is recommended that more aggressive recruitment occur for future openings. It is also recommended, that while it must be disclosed that these positions are grant funded, it is recommended that future recruitment ads not reference this in the lead off statement. This modification may add to more qualified individuals responding to the advertisement.

2) Empanelling patients: After the initial round of letters was mailed, it was decided that when the next round of patients were empanelled, a letter would not be used. The letter instructed patients that they were now going to be enrolled in the DOC as their primary care clinic, but they had the option to stay with their current physician. This proved to be a confusing message to patients. Future empanelments are being done by sending the standard letter from Humana. Another lesson learned from empanelling patients is that we found that we could not directly recruit patients from the primary care clinics as initially intended. The procedure at WHMC is to work through HCI's to obtain a pool of patients from Primary Care clinics, approved by the providers in those clinics. Thus, no advertised, active recruitment campaign was carried out.

3) Empanelling patients: After the initial round of letters was mailed, it was decided that when the next round of patients were empanelled, a letter would not be used. The letter instructed patients that they were now going to be enrolled in the DOC as their primary care clinic, but they had the option to stay with their current physician. This proved to be a confusing message to patients. Future empanelments are being done by sending the

standard letter from Humana. Another lesson learned from empanelling patients is that we found that we could not directly recruit patients from the primary care clinics as initially intended. The procedure at WHMC is to work through HCI's to obtain a pool of patients from Primary Care clinics, approved by the providers in those clinics. Thus, no advertised, active recruitment campaign was carried out.

4) Equipment: 2 fax/scanner/copiers were paid for with UPMC funds. It is very difficult to obtain approval for non-AF procured telecommunications equipment to be installed on base due to high security conditions. This somewhat impeded patient care as providers receive and send faxes as a part of patient care on a daily basis. A method for procuring all future telecommunications through AF channels needs to be examined so systems can be installed on a timely basis so clinic functions are not slowed down.

5) DIGMAs: The DOC does not have a dedicated classroom or conference room for the DIGMAs. Not only should space be planned for this in BRAC and other WHMC space planning documents, but future group education should not be started until a committed space is identified for these appointments. Space had to be arranged at locations throughout the hospital, creating confusion for patients and making it difficult to provide all the services that the appointment should provide.

6) Systems: As stated above, CDMP was not ready for use as of the end of calendar year 2006. The AF has strict security requirements and bringing new, non-AF programs into WHMC will carry with it long waits until the program is installed (or interfaced) and operational. When building new programs to the DOC, adequate time should be built into future milestones/deliverables to allow for the delays so these milestones/deliverables can be met.

7) Management/Oversight: The initial staffing plan for the DOC had a Medical Director responsible for all DOC day to day positions, which is adds excessive duties to a practitioner with a full patient load. Adding a Clinic Manager at the start would have been a benefit to the medical director, leaving that position to medical clinical decisions and patient care, but freeing that position of the administrative clinical burden that accompanies the day to day running of a clinic.

8) Diabetes Self-Management Education: We began collecting data to obtain recognition from the American Diabetes Association (ADA) for the diabetes self management education program. The plan was to collect necessary data for application for the Education Recognition Program by the mid 2007.

Diabetes outreach clinic: Small Base Outreach project planning.

Project Accomplishments:
It was determined that the WHMC DOC needed to be established and evaluated before services where expanded to other outreach sites. Over the course of the project, UPMC and AF active duty medical team members determined that with the limited numbers of endocrinologists, services that included primary care delivered by specialists, was an unsustainable model of diabetes care delivery services. It was recommended that the DOC services be reserved for high risk diabetes patients who required special attention from an endocrinologist and team. The DOC was reorganized into a Diabetes Center of Excellence (DCOE), where specialty care for high risk patients is provided and from which a "Go Team" is deployed to support and educate outreach bases. The DCOE was established in 1/09. Focus

group meetings were h osted at ou treach base s, where in formation regarding th eir specific diabetes ca re needs was assesse d. Go teams have been subseque ntly deployed and are actively involved in visiting the outreach bases in disse minating quality care p rograms to educate provider staff and patients.

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Project 6: List of Appendices

- Appendix W, *CHHS Diabetes Support Groups*

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Appendix B

Deliverable #124: Screening, Training, Education and Prevention Service of the University of Pittsburgh: Final Screening and Chart Review Report

Appendix B

Screening, Training, Education and Prevention Service of the University of Pittsburgh: Final Screening and Chart Review Report
Prepared for the Department of Defense October 31, 2007

Often referred to as a "touch of sugar" and frequently perceived by the general population as nothing more than a nuisance requiring a pill, type 2 diabetes has continued to hide behind a wall of ignorance and denial, with the truth often revealed only after an individual is diagnosed with the disease. Currently over 20 million people or about 7% of the US population are estimated to have diabetes, with one-third unaware (1). With rates increasing steadily around the world (2), diabetes is clearly one of the most important public health concerns of our time.

A major complication of diabetes, cardiovascular disease (CVD) is the leading cause of death for those with diabetes in the U.S. Individuals with diabetes are 2-4 times more likely to have heart disease or suffer a stroke than those without diabetes (3). CVD is the most costly complication of diabetes, accounting for more than $17 billion of the $91.8 billion in annual direct medical costs for diabetes in 2002 in the U.S. (4).

CVD risk factors are often present in the interim stages prior to diagnosis with T2D and predict its development (5-14). The clustering of these conditions of risk including insulin resistance, dyslipidemia, obesity and hypertension has been referred to as syndrome X, insulin resistance syndrome and more recently the metabolic syndrome. While definitions of and criteria for inclusion in this disorder have varied (15-20) and even its very existence as a syndrome has been debated (21; 22), research has supported the conclusion that the grouping of these risk factors generally places an individual at increased risk for both type 2 diabetes and CVD (23-28). It seems appropriate therefore, that prevention be directed toward both type 2 diabetes and CVD, a position consistent with the recent American Diabetes Association cardiometabolic

initiative and joint statements form both the U.S. and European diabetes and cardiology associations (21).

Current estimates from the Center for Disease Control indicate that over 54 million people in the US have pre-diabetes (1). In addition, using NCEP ATP III diagnostic criteria, the estimated unadjusted prevalence of the metabolic syndrome in the U.S. was approximately 23% based on NHANES data from 1988-1994 (29), while data from NHANES 1999-2000 showed a significant increase in prevalence to 26.7% (30). The current target group for a joint diabetes/CVD prevention thus likely exceeds a quarter of the adult population.

Fortunately proven strategies exist for the prevention or delay of type 2 diabetes and for the reduction of CVD risk (31-35) in those at risk for diabetes by virtue of impaired glucose tolerance. While most physicians practice some form of prevention screening, many are falling short of recommended prevention guidelines (36-38). When prevention screening does occur it may often be combined with a “sick” visit where other acute medical conditions require attention or the patient may be ill thus rendering risk assessment and counseling difficult. Other reasons for lack of routine prevention assessment may be attributable to multiple and confusing prevention guidelines (39), physician and patient time constraints, patient ignorance concerning screening requirements, cost of testing and both physician and patient attitude and personal characteristics (40).

For these reasons, a systematic birthday-based prevention screening program incorporating national guidelines designed for type 2 diabetes and CVD risk assessment for patients in a primary care practice setting was developed and evaluated. The screening program was devised to address some of the above barriers to prevention screening and risk identification, specifically a lack of organized prevention screening for risk identification, as well as simplification of prevention guidelines for easier

implementation, provision of patient education information regarding individual risk and alleviating time constraints.

Methods

Initially, a concise, "user-friendly" document summarizing current guidelines was compiled based on the recommendations for prevention screening regarding diabetes, hypertension, dyslipidemia, and obesity (41-45). In addition, a computer-based automated screening program was developed to facilitate the collection of screening information and to provide immediate feedback regarding risk and necessary follow-up.

Practice and Preventionist Identification

Four primary care practices, two urban and two rural, were identified in the Western Pennsylvania area. Each practice was asked to identify a "preventionist" to oversee the prevention screening program, including screening, recruitment and delivery of a lifestyle change intervention program. The preventionists were required to have a healthcare background; four were nurses and two were health educators (in one practice the position was split and in one practice the preventionist was replaced when she left the position). In two practices, the preventionists were identified from within the practice; in the other two practices the preventionists were brought in specifically for the position. The preventionists completed clinical measurement certification through the project Coordinating Center for the measures that were collected including blood pressure, height, weight, and waist circumference, as well as training regarding prevention screening and use of the automated computer program.

Automated Computer Screening Program

In collaboration with Flipside Media, Inc. a lap top driven questionnaire and data collection system was developed to track, screen and report on targeted patients within the practices. The system included a study recruitment tool, integrated with the office's existing patient database, which facilitated sending invitation letters to eligible patients

and tracking their progress. The system also generated a patient-specific report. The data was synchronized weekly with a central server, through which progress reports (indicating who needed to be contacted) were generated and emailed to the researchers weekly. The system is based on Flipside's "ScoreMD" screening and data collection platform which is built upon a Unix-based operating system, Apache web server, MySQL database, the PHP scripting language, PDF-based reporting, secure web services for data transfer, and is usable through standard web browsers (like Internet Explorer, Firefox/Mozilla, Safari, and Opera).

Eligibility and Recruitment

Initially, each practice was assisted in preparing a data set which included all practice patients age 25-74 in 2005 that had been seen by a practice physician within the past three years. All patients were assigned a random 8-digit ID number with the link to the patient's identifying information kept in a secure location on site. Within each practice, all patients with birthdates within one quarter of the year (a consecutive 13-week period of time) were identified as eligible for a prevention screening invitation and were sent computer generated invitation letters near their specific birthday. The invitations, which encouraged the recipient to call the preventionist to set up an appointment, were sent out weekly by the preventionists. Up to three subsequent follow-up telephone calls at different time and days of the week were made if no response was received within one month. This prevention screening and chart review project received approval by the University of Pittsburgh Medical Center Quality Assurance Council.

Screening and Data Collection

Patients attended a brief 30 minute screening visit which was conducted at the primary care practice, completing a short interview concerning medical, social and family history. The preventionist reviewed the chart for pre-existing blood glucose and lipid profiles, blood pressure, height, weight, and waist circumference. This information was

subsequently entered into the computer program which determined if and when screening measures needed to be performed according to the guidelines. After completion of the required testing the program also determined the prevention follow up schedule and provided a written summary for the patient, preventionist and physician. The prevention screening was provided at no cost to the patients, however any follow-up lab tests or care that was required as a result of the screening were billed for in the usual manner.

Chart Review

In addition to the collection of patient screening data, a chart review was conducted to examine the efficacy of the prevention screening. Chart reviews were conducted by trained staff members that were independent of the research component of the project. A „pre' screening (primary) chart review which covered the 13 months immediately prior to the 13-week screening period was conducted for those who had the prevention invitation letters sent. Similarly a „post' invitation (secondary) chart review was conducted for the 13 month period forward from the date of the invitation letter. A comparison group consisting of those with birthdates in another quarter of the year and not invited for screening was similarly examined by chart review. All data collected was de-identified by the chart reviewers and uploaded to the Coordinating Center.

Outcome Measures

All clinical measures were obtained by a certified preventionist. Blood pressure was measured in a sitting position in the right arm after resting for five minutes. First appearance and last heard (phase V) Korotkoff's sounds were used to define the pressure readings; the measures were repeated twice with a thirty second wait between each reading. An average of the 2nd and 3rd readings was computed. Height and weight were measured twice without shoes with the average computed; BMI was calculated as average weight divided by average height squared (kg/m^2). Waist circumference was

measured at the midpoint between the lower rib margin and the iliac crest; the measurement was repeated twice and the average computed.

Total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides and glucose were recorded from the patient chart or when necessary, were completed by the practice or referred lab. Type 2 diabetes and global CVD risk assessment (46) was completed automatically by the program, as well as determination of follow-up scheduling.

Evaluation

The efficacy of this computer-assisted screening program was evaluated by firstly documenting the proportion of individuals responding to screening invitation by age and gender, the reasons for declining the screening invitation and the proportion of cases identified that were contacted after a reminder from the central Coordinating Center. These data will be helpful for future operational and costing analysis. Secondly, the numbers of patients within the selected quarter that were 1) evaluated for diabetes/CVD risk according to national guidelines, 2) newly identified to be at risk and 3) newly identified to be at risk and received appropriate action were also documented from the chart review. For the purposes of this evaluation, appropriate action was defined as the reasonable response that would be expected to occur upon the identification and documentation of a risk factor state, i.e., scheduling a repeat test or follow-up visit, beginning a new treatment or changing treatment type or dose, or referral to a specialist. Situations where the time interval following detection of a new risk factor was not sufficient for action within the chart review period were not counted as lack of action. Patient attendance or compliance with recommendations were not required for the action to be considered appropriate; for example if it was documented that a repeat visit was to occur but the patient did not attend, the action was still considered to be appropriate by the clinic.

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The study sample size was based on the ability to detect with 80% power, a 20% increase in the prevalence of known LDL and hypertension between pre and post, assuming no background change in pre-post comparison rates. One of the rural practices was sold prior to the secondary chart review phase and could not provide full reviews and was thus excluded from the analyses of prevalence rates.

Results

Recruitment

Three of the primary care practices reported a similar number of patients (range 2,150-2,659); however the fourth, urban, center was a larger practice with 5,539 patients. Figure 1 shows the planning and recruitment scheme for this project. A total of 2,786 letters were sent out across all practices; those found to have moved away from the area permanently, to have a different primary care physician outside the practice, or found to be deceased were subsequently excluded (n=823). Of the remaining 1,963 patients, 776 (39.5%) were not able to be reached with three phone calls and 837 (42.6%) refused screening. Among refusals, most common known reasons were illness/medical condition (23.1%), scheduling issues (lack of time or out of area-21.9%), felt screening was not necessary (18.8%) and lack of insurance (11.6%). A significantly higher number of males refused the screening invitation compared to females (69.1% vs. 58.1%, p=0.00). Three hundred and fifty (17.8%) of those invited attended a screening assessment.

Of the 350 individuals that attended a screening visit, 216 (61.7%) self-responded after receiving the invitation. Of the remaining group, 45 individuals (12.9%) required one follow-up telephone call to schedule a visit, 49 (14%) and 40 (11.4%) scheduled a visit on the second and third follow-up calls respectively. No significant differences by age were noted for self-response; 68% of whom were female.

Screening Results

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The median age of those screened was 49 years old; 26.3% were less than age 40, 60% were age 40-64, 13.7% were 65 and older. Seventy-two percent of those screened were women. A total of 68 patients (19.4%) were from minority ethnic groups (African American (17.2%) and other (2.2%)). The two urban practices were significantly more ethnically diverse with 51.2% non-white participants compared to 1.4% non-white participants in the rural practices ($p<0.001$); these racial proportions reflect the local community structure. Screening attendance rates varied by clinic with a high of 34.2% and a low of 7.0% ($p=0<0.001$). The two rural clinics, both of whom used internally assigned preventionists had significantly higher rates of screening attendance than the urban clinics with externally identified preventionists (27.9% vs. 10.9%, p=0.00).

Of the 350 individuals who attended screening, 277 (79.1%) were found to have a body mass index (BMI) $\geq$ 25kg/m^2, of whom 97 (27.7%) had no reported history of diabetes and met criteria for the metabolic syndrome (based on National Cholesterol Education Program Adult Treatment Panel III) (42), thus were eligible to participate in a lifestyle change program. A total of 43 patients (45.3%) enrolled in the prevention program, representing a yield of 2.2% from the attempted invitation of 1,963 patients.

Identification of Risk Factors at Screening

Overall, regardless of previous diagnosis, 224 patients (64%) had at least one risk factor meriting further medical evaluation (405 total risk factor states noted) (Table 1). New potential risk factor states were identified by examining elevated levels and assessing patient report of previous diagnosis at screening; 21 patients (6%) attending screening were found to have elevated blood pressure (SBP ≥ 140 and/or DBP ≥ 90) without reporting a previous diagnosis, while elevations in glucose at the diabetes and pre-diabetes levels were seen in 9 (2.6%) and 56 (16%) respectively. Elevated total cholesterol (≥ 200mg/dl) was identified in 78 (22.3%) and elevated triglycerides (≥150 mg/dl) in 72 (20.6%) individuals without previously reported dyslipidemia. Thus a total of

236 cases of potentially new risk states were identified at screening (Table 1). Furthermore, almost one-half (n=66, 44.9%) of 147 patients who reported no previous diagnosis with any of the above conditions had at least one risk factor which warranted further follow-up.

Chart Review for Potential New Risk Factors

Results of the chart review are further shown in Table 1 and revealed that of the 21 individuals with new potential hypertension, 2 (9.5%) had a previous diagnosis of hypertension recorded on the patient chart (2 did not have a chart review completed). Similarly, of the 56 with glucose in the pre-diabetes range, 3 (5.4%) had a diagnosis noted in the chart (2 had not had a chart review completed), while for the 72 with elevated triglycerides, 7 (9.7%) had this noted previously in the chart. No previous diagnoses of diabetes was noted for 8 of those with glucose levels in the diabetes range; however one did not have a chart review completed. Of the 78 with cholesterol levels greater than or equal to 200mg/dl, 7 (9%) had a diagnosis noted on the chart (6 had no chart review completed). Thus excluding those without chart review, 206 potential cases of new hypertension, diabetes, pre-diabetes or hypercholesterolemia were identified at screening, with only 19 (9.2%) of those conditions being already noted in the chart. This translates to 142 patients (41% of those screened) being identified through screening to have one or more potentially new risk states.

Chart Review

A total of 7,116 chart reviews were completed with 3,765 (2,011target and 1,754 comparison) completed prior to the screening period (primary review) and 3,351 (1,599 target and 1,752 comparison) completed post-screening (secondary review). Based on the chart review, the screened/target cohort showed an increased prevalence of clinically diagnosed hyperlipidemia including cholesterol and triglycerides ($p<0.05$) as well as a significant increase in the prevalence of diagnosed pre-diabetes ($p<0.05$);

however no such differences were seen in the comparison group. The prevalence of diagnosed hypertension, diabetes and obesity did not change materially in either cohort. (Table 2)

Overall appropriate follow-up action was examined for each risk factor identified in all charts included in the chart review (Table 3). A risk factor was counted if it was recorded at least once during the chart review period; patients were assumed to be fasting when not specifically noted in the chart as non-fasting. Including the target and comparison groups for both primary and secondary review, a total of 189 charts were noted to have glucose levels above 125 mg/dl and 682 within the pre-diabetes range of 100mg/dl-125mg/dl (those with previous diagnosis of diabetes were excluded for both groups); appropriate follow-up action was noted for 95 (50.3%) and 151 (22.1%) charts respectively. A total of 1,823 charts were noted to have an elevated blood pressure recorded (≥140 and/or ≥ 90 mmHG); appropriate action was noted for 620 (34%), while 728 were noted to have elevated LDL cholesterol (based on risk), with appropriate action noted for 330 (45.3%). Elevated triglycerides were noted on 901 charts with appropriate action noted for 479 (53%). Obesity (BMI >30kg/$m^{2)}$ was also examined; 1,816 charts were noted to have obesity with appropriate follow-up noted for 541(29.9%).

The same risk factors and appropriate action were examined for charts of individuals who attended the screening and had a post-screening review completed (n=185 individuals) and are further shown in Table 3. A total of 11 charts were noted to have glucose levels at or above 125 mg/dl and 41 within the pre-diabetes range; appropriate follow-up action was noted for 6 (55.5%) and 16 (39%) charts respectively. A total of 73 charts were noted to have an elevated blood pressure recorded; appropriate action was noted for 20 (27.4%). A total of 49 charts with elevated LDL cholesterol were noted with appropriate action occurring for 23 (46.9%); 46 charts had

elevated triglycerides with appropriate action noted for 24 (52.2%). Obesity was noted on 117 charts with appropriate action noted on 48 charts (41%).

A significant difference was noted in the secondary chart reviews between those who completed the screening versus those who did not in the target and the comparison groups for appropriate action for pre-diabetes (39% vs. 16.7%, p=0.002) and obesity (41% vs. 30.8%, p=0.03); no significant differences were noted for appropriate action for diabetes, hypertension, elevated LDL or triglycerides. Overall results for appropriate action were significantly higher in the screened versus non-screened group (79.9% vs. 63.1%, p=<0.001).

Discussion

The results of this evaluation demonstrate that prevention screening for risk identification for type 2 diabetes and cardiovascular disease is feasible in a primary care practice setting and can be successful in identifying many at risk so that appropriate action and follow up may occur. It is interesting to note that over 60% of the individuals that attended a screening visit responded to the invitation letter and scheduled a visit without further recruitment contact. This suggests that letter mailing may be a reasonable method to contact patients for prevention screening as well as being time-saving and fairly inexpensive. Although no formal cost-effectiveness evaluation was performed, based on feedback from the preventionists, the authors estimate that on average approximately 5 minutes per individual was spent during the recruitment process. For this project this would translate to about to about 164 hours of time per clinic or about 32% of a full-time employee's annual hours. Much of the time initially was spent in the identification of patients that were actually eligible to be contacted, i.e., alive, still living in the area and listing that primary care physician as their provider. Once a practice has developed and subsequently maintains a database, future time spent on contacting patients would be minimized.

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As noted, recruitment rates varied significantly across the clinics (34.2% versus 7%) , with the two rural clinics who used internally assigned preventionists demonstrating significantly higher recruitment rates than the two urban clinics with preventionists brought in specifically for the position. These results suggest that recruitment for screening may be higher when done by someone the patients already are familiar with and trust, i.e. the internally assigned preventionist. However, other reasons for this discrepancy could certainly exist, for example, both of the externally assigned preventionist clinics were in an urban area with a significantly higher non-white population attending screening. Because these proportions reflect the racial makeup of the communities it is quite conceivable that certain racial barriers related to screening may exist. There may also be some inherent differences between urban and rural responses to health care. It will be important to further evaluate these issues in order to develop appropriate recruitment methods for different settings.

Several key themes emerged from the data concerning refusal of prevention screening: medical illness/health condition, lack of time/out of the area, felt screening was not necessary and lack of insurance were the top rated known reasons for refusal. Medical problems (47) and lack of time/inconvenience are reasons that are often cited for non-participation (48; 49). Further investigation revealed that of those who felt that prevention screening was not necessary, over half (57%) were missing at least one risk assessment measure including weight, glucose, blood pressure or LDL measure within the 13 month primary review period prior to screening. It is interesting to note that lack of insurance was a common reason for refusal even though there was no charge for the screening visit. There were also a fair number of individuals that cited “other” unknown reasons for non-participation. Research has suggested that those who do not participate in health-related research may be at higher risk than those who do (50). Similarly individuals who do not take part in preventive practices may also be at higher

risk; thus it is important to further evaluate reasons for refusal in order to reach out to patients that may not initiate a "healthy" visit with their physician.

Of the 350 individuals that attended a screening assessment visit, 224 (64%) had at least one risk factor warranting further medical follow-up (405 elevated risk factors), with 206 risk factors subsequently determined to not have been previously diagnosed through patient self-report at screening and chart review. This translates to 142 patients (41% of those screened) with potentially new risk states. Thus the importance of screening is once again substantiated, and may be a consideration when planning for financial support for a prevention screening program as all of the risk factors identified are potentially billable in the future as follow up services provided by the practices. The authors estimate based on preventionist feedback that each screening visit took about 30 minutes to complete; when considering a preventionist salary of approximately $50,000, each visit cost approximately $12 in staff time (excluding fringe). It is anticipated that the automated screening program and process could be streamlined in the future to permit the patient to complete a large portion of the information prior to or at the visit, which would allow for a significant reduction in staff time. It is also conceivable that using a program such as this could actually save cost by decreasing physician time spent in reviewing old results, determining risk manually and evaluating the prevention schedule as all of these components would be completed prior to the actual encounter with the patient.

While more than half of those screened were identified as having at least one elevated risk state warranting further follow-up, it is somewhat disturbing to note that overall, for the entire group with chart reviews completed, only 36% of elevated risk factors noted in the charts received appropriate follow-up. The screened group exhibited slightly better follow-up with 41% of elevated risk factors receiving appropriate action in the chart review conducted post-screening. Elevated LDL-C, glucose in the diabetes

range (>125mg/dl), and triglycerides seemed to receive appropriate action most often, occurring in 45-55% of overall and screening group chart reviews, while elevated blood pressure, glucose in the pre-diabetes range (100-125mg/dl), and obesity were not as well addressed ranging from 22-41%. The lack of appropriate follow up for blood pressure is surprising although the lack of clear guidelines and relatively new focus on pre-diabetes and obesity may be reflected in their poor action. It is interesting to note however that appropriate action overall was significantly higher in the screened versus non-screened group, with pre-diabetes and obesity showing significantly higher results individually. This suggests that prevention screening may have increased awareness of and subsequent action overall and specifically for these conditions. When performing the chart review, along with other actions considered appropriate, a follow-up visit scheduled for a patient was counted even if the patient did not actually attend. Because patient non-compliance with return visits is a well-known problem, the actual number receiving appropriate follow-up action may thus be even lower than these results indicate.

The overall prevalence of diagnosed hyperlipidemia (including LDL and triglycerides) and pre-diabetes increased significantly in the target group, while no changes were seen in the prevalence of diagnosed hypertension, diabetes or obesity. No significant changes were noted in any parameters in the comparison group. This again supports the effectiveness of prevention screening; it is possible that changes in the other risk states may have shown a difference if the screening numbers had been larger. These results seem to follow the trend noted for appropriate action noted above, i.e. LDL cholesterol and triglycerides received appropriate follow-up more frequently than some of the other risk parameters. It will be important to continue to evaluate screening programs to determine if certain elements of prevention are more frequently addressed in order to promote all aspect of prevention as equally important.

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Although widely recognized as being essential for prevention of many chronic diseases, organized screening programs for risk factors leading to these conditions are lacking; little progress has been made toward making prevention part of our health care system(51). While other stimuli for preventive services have been examined such as patient satisfaction as a mechanism to prompt physicians to refer for prevention (52) it is generally agreed that in order for preventive service use to increase, prevention must become an integral part of the health care system (40). The results of this project validate the need for prevention screening and describe a means for implementation in a health care system. A computer automated prevention screening program such as described could certainly be integrated into the usual routine of a primary care practice. The program has several advantages: 1) reminder invitation letters may be set up to be sent out on a regular schedule automatically with little time and effort on the part of the primary care staff; 2) the program provides a print-out of the screening information for the patient and physician thus providing an excellent opportunity for patient education about risk, 3) the results, risk assessment and time schedule for prevention measures are completed and available to the physician at the time of visit, thus potentially facilitating better time management for the physician and 4) ongoing screening would be provided on a regular basis with built-in follow-up guidelines, thus making the entire process somewhat less daunting but more effective for practices.

There are some limitations to this project including 1) a smaller than desired sample size responding to and attending screening, thus possibly limiting the observed results and 2) a lack of a formal cost analysis which would be very beneficial in further understanding financial implementation of prevention screening in the health care system. In addition, there will certainly be challenges to implementing a program such as this including a general lack of the existence of patient databases within primary care practices, thus necessitating that this step be completed first, as well as getting

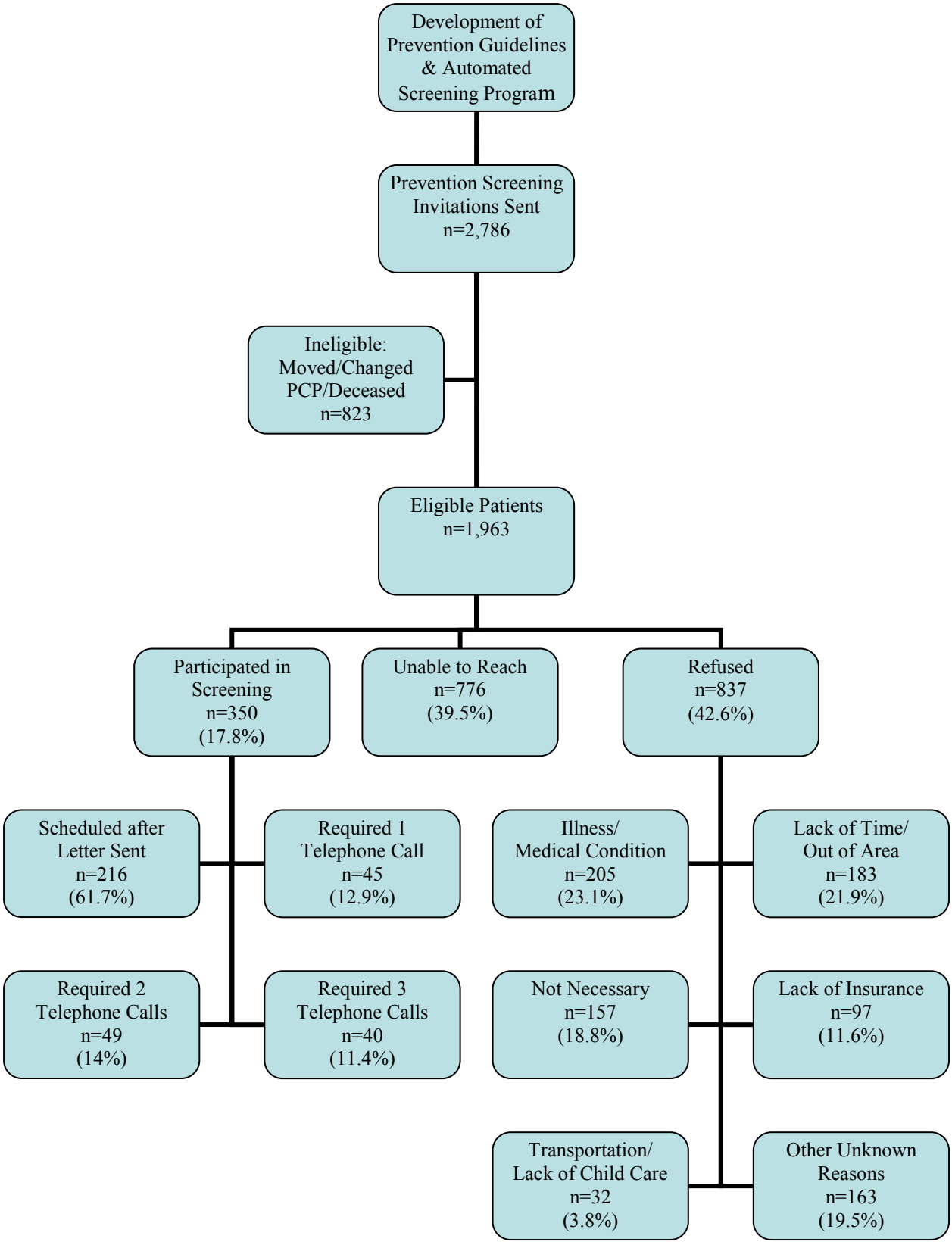
physicians and staff “on-board” with the idea of prevention screening. Ensuring that follow-up action after risk states are identified is completed is another challenge, although this seems to better when risk factors are discovered as part of a structured program as shown here.

Future areas of study should include examination of potential barriers to recruitment for preventive services, including racial, cultural and financial concerns, research to continue to follow post-screening action taken for risk states that are identified and comprehensive cost analysis to help clinicians determine how best to make prevention work in their setting.

While prevention has become the “buzz” word of this century, very few concrete measures have been taken toward one of the most key components of prevention: identification of those at risk. It is hoped that the information provided here will offer an overview of the importance of prevention screening as well as present a roadmap for prevention screening implementation which is rooted in the health care system.

Appendix B

Figure 1 Screening Program Development and Recruitment: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population



Appendix B

Table 1 Potential New Risk Factors Identified at Screening: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Elevated Risk Factors Identified at Screening	**Potential New Risk States at Screening** (Excluding those w/previously reported diagnosis)	**Potential New Risk States Based on Chart Review** (Excluding those w/previous diagnosis on chart review)	
TC ≥ 200mg/dl	139	78	65	7 w/previous diagnosis 6 w/o chart review
Trig ≥ 150mg/dl	114	72	65	7 w/previous diagnosis
SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg	66	21	17	2 w/previous diagnosis 2 w/o chart review
FBG ≥ 126 mg/dl	23	9	8	1 w/o chart review
FBG ≥ 100 mg/dl & ≤ 126 mg/dl	63*	56	51	3 w/previous diagnosis 2 w/o chart review
Total	405	236	206	

* Those with previously reported diabetes excluded

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Table 2 Prevalence of Diagnosed Conditions in Target and Comparison Groups Between Primary and Secondary Chart Review: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Hyperlipidemia		Hypertension		Diabetes		Pre-diabetes		Obesity	
	Primary Review n=1600	Secondary Review N=1606	Primary Review n=1600	Secondary Review N=1606	Primary Review n=1600	Secondary Review N=1606	Primary Review n=1600	Secondary Review N=1606	Primary Review n=1600	Secondary Review N=1606
Target	322 (20%)	367 (22.9%)*	488 (30.4%)	504 (31.5%)	163 (10.1%)	179 (11.2%)	33 (2.1%)	51 (3.2%)*	248 (15.4%)	271 (16.9%)
	Primary Review n=1650	Secondary Review N=1650	Primary Review n=1600	Secondary Review N=1650	Primary Review n=1650	Secondary Review N=1650	Primary Review n=1650	Secondary Review N=1650	Primary Review n=1650	Secondary Review N=1650
Comparison	343 (20.8%)	371 (22.5%)	491 (29.8%)	523 (31.7%)	162 (9.8%)	173 (10.5%)	41 (2.5%)	51 (3.1%)	271 (16.4%)	289 (17.5%)

*Significant at the 0.05 level

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Table 3 Elevated Risk Factors and Appropriate Action Based on Chart Review: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Screened Group Post-Invitation Chart Review		**Whole Group Primary and Secondary Chart Review**	
	Elevated Result	Appropriate Action	Elevated Result	Appropriate Action
Glucose > 125mg/dl	11	6 (55.5%)	189	95 (50.3%)
Glucose 100-125 mg/dl	41	16 (39%)	682	151 (22.2%)
BP >= 140 or 90 mm/Hg	73	20 (27.4%)	1,823	620 (34%)
LDL (based on risk)	49	23 (46.9%)	728	327 (45%)
Triglycerides >= 150 mg/dl	46	24 (52.2%)	1,861	541 (29.9%)
Obesity BMI >30 kg/m^2	117	48 (41%)	901	479 (53%)

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Appendix C

Deliverable # 96: DPP an d the Real World: Translating the Diabetes Prevention Program Lifestyle Intervention to Primary Care Practice

DPP and the Real World: Translating the Diabetes Prevention Program Lifestyle Intervention to Primary Care Practice

Translating the Diabetes Prevention Program

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ABSTRACT

Objective: To assess the effectiveness and feasibility of a modified Diabetes Prevention Program (DPP) Lifestyle Intervention delivered in a primary care practice setting.

Research Design and Methods: Four primary care practices were invited to participate in a lifestyle change intervention study. 51 participants (42 female) without prior history of diabetes with a body mass index (BMI) $\geq$25kg/m2 and metabolic syndrome (NCEP ATPIII definition) were enrolled in the 12-session Group Lifestyle Balance (GLB) program. The program closely followed the DPP protocol with minor adaptations; weight loss and physical activity goals remained at 7% and 150 min/week respectively. Anthropometric measures were collected before and after the intervention.

Results: Using last observation carried forward methodology for participants who did not complete the intervention, average weight loss, comparing the pre and post-intervention assessments, was 4.6 lbs. (2.2% relative loss, $p<0.001$). An average 0.5 pound weight loss per week was estimated ($p<0.001$) after adjusting for starting weight and clinic. Waist circumference, BMI and fasting blood glucose decreased an average of 0.69 in. (1.6%, $p=0.003$), 0.82 kg/m^2 (2.3%, $p<0.001$) and 4.63mg/dl (3.7%, $p=0.02$) respectively. A positive correlation was noted between total activity minutes and total pounds lost (Spearman's $r=0.36$, $p=0.01$).

Conclusions: The results of this translational research suggest that the GLB program was successful in reducing some parameters of risk for diabetes and cardiovascular disease in this group of individuals with metabolic syndrome. The DPP lifestyle intervention can be adapted for use in the "real-world" and is feasible to conduct in a primary care practice setting.

In 2001, the Diabetes Prevention Program (DPP) ended prematurely due to significant results indicating that the intensive lifestyle intervention utilized in the program was highly

successful in reducing risk for type 2 diabetes in all groups regardless of ethnicity, age or gender (1). Other studies have also demonstrated the efficacy of lifestyle intervention and reduction in risk for type 2 diabetes (2-5). In addition, the DPP lifestyle intervention was found to be effective in reducing risk factors for cardiovascular disease (CVD) (6) and components of the metabolic syndrome (7). While it is apparent that type 2 diabetes and CVD risk can be lowered with lifestyle intervention, the translation of these intervention programs in a real-world setting presents a number of challenges.

Some of these challenges include lack of trained personnel, patient recruitment and retention, coordination of care, and availability of quality programs (8). Primary care practices provide an ideal venue for institutional delivery and reinforcement of prevention intervention, long-term, for several reasons. They employ individuals who have the knowledge and background to be trained to deliver a lifestyle intervention. Patients are familiar with their primary care practice staff, routine, and location, which could facilitate participation and retention. Finally, since one of the most important aspects of prevention intervention is continued monitoring regarding lifestyle change, primary care practices are well placed to provide ongoing follow-up care. For these reasons, translation of a modified DPP Group Lifestyle Balance (GLB) intervention for patients with the metabolic syndrome was assessed for effectiveness and feasibility in a variety of moderately low income and ethnically diverse primary care settings.

Research Design and Methods

This prospective study used a one-group design to deliver intervention, incorporating pre and post intervention testing of subjects in four diverse primary care practices in the Western Pennsylvania area (two urban and two rural practices). Each of the participating practices was asked to identify a "preventionist" to be responsible for implementation of the GLB program. The identified preventionists included nurses, a health educator and an exercise physiologist. One practice shared the responsibilities between two nurses. Preventionists were required to attend a two-day training workshop which addressed all aspects of the intervention and was conducted by faculty at the study Coordinating Center. Additionally, preventionists took part in a pilot GLB intervention themselves where they completed all of the components of the program as well as clinical outcomes measurement certification through the study Coordinating Center.

Participant Inclusion and Exclusion Criteria

Inclusion criteria consisted of males and females without previously reported diagnosis of diabetes, age 25-74 years in 2005 with body mass index (BMI) $\geq$ 25kg/m^2 and at least three of five components of the metabolic syndrome (based on National Cholesterol Education Program Adult Treatment Panel III) (9) identified at screening. At the time of study, the NCEP had not yet changed its glucose criterion, although the American Diabetes Association had lowered its criterion for pre-diabetes from a fasting glucose of 110 mg/dl to 100 mg/dl (10). Therefore patients who met the above criteria with only 2 components of the metabolic syndrome with a fasting glucose between 100 mg/dl and 109 mg/dl were also included at their primary care physician's discretion. Exclusion criteria included previously reported diabetes, pregnancy, lack of physician approval and inability to sign informed consent.

Recruitment and Study Population

In order to facilitate screening for diabetes and CVD risk, an automated screening program was developed which provided immediate feedback regarding the patient's risk and determined eligibility for the GLB program. Invitations for prevention screening were sent to all practice patients age 25-74 with birthdays within a specific quarter of the year. The screening assessment included collection of medical and family history, fasting lipid and glucose and clinical measures consisting of blood pressure, height, weight, and waist circumference. A total of 388 patients attended the screenings, with 106 (27%) found to meet eligibility criteria for the intervention.

Eligible patients were invited to take part in the study which included attendance at the 12-session GLB program, as well as pre and post intervention assessments. Of the 106 eligible individuals, 55 declined participation, yielding a study population of 51. Specific reasons for non-participation are not available as the screening component is not part of the research evaluation. This research project was approved by the University of Pittsburgh Institutional Review Board and the University of Pittsburgh Medical Center Quality Assurance Council, as well as the Surgeon General's Office of Review. Eligible and interested patients signed informed consent prior to beginning the study.

Procedures and Outcome Measures

Enrolled participants were asked to attend an assessment to obtain clinical measures prior to beginning and again at the conclusion of the intervention. All clinical measures were obtained by a certified preventionist and/or certified Coordinating Center staff member. Blood pressure was measured in a sitting position in the right arm after resting for five minutes. First appearance and last heard (phase V) Korotkoff's sounds were used to define the pressure readings; the measures were repeated three times with a thirty second wait between each reading (11). An average of the 2nd and 3rd readings was computed. Height and weight were measured twice without shoes with the average computed; BMI was calculated as average weight divided by average height squared (kg/m^2). Waist circumference was measured at the midpoint between the lower rib margin and the iliac crest; the measurement was repeated twice and the average computed.

Total cholesterol, high-density lipoprotein (HDL) cholesterol, non-HDL cholesterol (total cholesterol - HDL cholesterol) and glucose were measured after at least a two-hour fast using the Cholestech LDX System by a certified laboratory assistant. Global CVD risk assessment (12) was estimated and medication use was assessed via participant interview. In addition, weight was recorded weekly at each session.

Intervention

The original DPP Individual Intensive Lifestyle Intervention was developed at the University of Pittsburgh by the DPP Lifestyle Resource Core and has been described in detail elsewhere (13). Members of the original DPP lifestyle team collaborated to adapt the individual intervention to a group-based program and to condense the program from 16 individual sessions delivered over 24 weeks to 12 group sessions delivered over 12-14 weeks. Other modifications included concentrating on healthy food choices rather than specifically the food pyramid, a focus on calorie as well as fat intake from the beginning of the intervention and more emphasis on the pedometer. As in the original DPP lifestyle program, the goals of the GLB intervention were to achieve and maintain a 7% weight loss, and to safely and progressively increase physical activity to 150 minutes per week of moderately intense physical activity similar to a brisk walk.

The GLB curriculum was administered by the trained preventionist(s) in each practice at the primary care practice location. Each participant received a copy of the GLB participant handouts, Fat and Calorie Counter, self-monitoring books for keeping track of food and physical activity, a pedometer with instructions, a set of measuring cups and spoons, and a chart for self-monitoring weekly weights over the course of the program. All subjects were asked to self-monitor weight, food intake and physical activity and were given feedback concerning progress.

Sample Size Estimation and Statistical Analysis

Based on the local DPP weight loss experience and using this variance estimate, we estimated that 21 subjects were needed to detect a 7% weight loss (as per the DPP goal) with α=0.05 and 90% power. The DPP achieved a 7% mean weight loss in the intensive lifestyle (ILS) group after 6 months. In translation to a real-world setting, we assumed the new intervention might achieve only half the DPP goal by 3 months, i.e. a 3.5% mean weight loss, requiring 78 subjects.

Analyses were carried out using the SAS statistical package (version 9.1, SAS Institute, Cary North Carolina, USA). The mean change between pre and post intervention measures was analyzed using the Paired Student's *t*-test when change data was normally distributed (weight, waist circumference and BMI); however, for most measures the non-parametric Wilcoxon Matched-Pairs Signed Rank test was used. Mixed models were used to examine weight change over time (repeated measures per participant) adjusting for weight at study entry and clustering of participants within clinical site; individual participant and clinical sites were random effects in this model. Correlations were calculated using Pearson's or Spearman's correlation coefficient r. Primary analyses were conducted on an intention to treat basis; to handle missing data we used last observation carried forward methodology for participants who did not attend the post assessment visit (n=51). Subjects with changes in medication during the course of the intervention for the condition being evaluated were excluded from the analyses; in addition 8 participants whose glucose results were affected by a laboratory error were excluded from glucose analysis. Secondary (per protocol) analyses were also performed for the group (completers) that attended at least 50% of the intervention sessions and the pre and post intervention assessments (n=28).

Results

The mean age of the participants in this study was 52.9 years; the majority (82%) of participants were female (n=42/51) and approximately 25% of the participants were non-white. Baseline clinical measures for the total group are shown in Table 1. There were no notable differences in baseline measures between gender with the expected exception of a higher HDL cholesterol for females (43.8 mg/dL v. 31.4 mg/dL, $p<0.05$). Average BMI for the group was greater than 30kg/m^2.

A total of 31 participants (61%) attended 6 or more of the 12 intervention sessions, with 81% of those (25 participants) attending 8 or more sessions. Retention rates varied between the clinics ($p<0.05$) with a range of 39%-82%. Attendance at fifty percent or more of the sessions was associated with achieving 3.5% weight loss ($p=0.002$) and reaching the 150 minutes/ week physical activity goal ($p=0.003$).

Table 2 shows the results of the pre and post intervention measure comparisons for the total group (n=51) and those who completed the intervention and the post assessment visit (n=28). Overall weight loss for the total group was significant with an average weight loss of 4.6 pounds (2.2%, $p<0.001$). Using mixed models, participant weight loss was

estimated as 0.5 pound per week ($p<0.001$) after adjusting for starting weight and clinic ($p<0.001$). A significant decrease from pre to post intervention was also found for waist circumference (-0.69 inches, 1.6%, $p=0.003$), BMI (-0.82 kg/m^2, 2.3%, $p<0.001$) and glucose (-4.63 mg/dl, 3.7%, $p=0.02$). No significant changes were noted for systolic or diastolic blood pressure or total, non-HDL or HDL cholesterol. There is no suggestion of heterogeneity between the clinics for any of the measures with the exception of waist circumference, where one center had an increase in contrast to all other centers.

A sub-analysis of "completers" (those who attended at least 50% of the intervention sessions as well as the pre and post assessments, n=28) was also conducted. Significant results were seen in the same variables as for the total population, although mean weight loss was greater in this group (7.22 pounds, 3.5%, $p<0.001$), and a marginally significant decrease in diastolic blood pressure (-2.55 mm/Hg, 2.5%, $p=0.09$) was noted. The change results comparing pre and post intervention measurements were not impacted by age or by gender.

Attainment of the program goals was examined for both the total and "completer" groups (Figure 1). In the total group of 51 participants, four participants reached the weight loss goal of 7% (7.8%), while 11 (21.6%) reached 5% or greater and 17 participants (33.3%) had 3.5% or more weight loss. Of those participants who recorded physical activity minutes (n=21), 12 (57.1%) were successful in reaching the physical activity goal (average of $\geq$ 150 minutes/week) with an overall mean of 242.5 (sd=398.6, range=0-1,914) activity minutes per week observed. For those who recorded both initial and later activity (n=16), a non-significant mean increase of 46.1 (sd=139.6, 28.3%, $p=0.11$) in activity minutes was noted.

Within the "completers" group, 4 of 28 participants reached the 7% weight loss goal (14.3%), while 10 (35.7%) and 15 (53.6%) achieved weight loss of at least 5% and 3.5% respectively. Of the 18 "completers" who recorded physical activity minutes, 12 (66.7%) met the physical activity goal, with an overall mean of 274.88 (sd=423.0) activity minutes per week. Of those completers who recorded activity level for both initial and later weeks (n=15), a significant increase in mean physical activity minutes of 51.13 (sd=142.99, 31.8%, $p=0.04$) was noted.

Overall, a positive correlation was observed between total activity minutes and total pounds lost (Spearman's $r=0.36$, $p=0.01$). Furthermore, a significant association between attainment of the activity and weight loss goals was noted; 25% (n=12) of those who attained activity goal vs. 2.5% (n=39) of those who did not were successful in reaching the weight loss goal ($p=0.03$).

Discussion

The current project is one of the first attempts to take the successful intervention utilized in the DPP, modify it for real-world implementation and evaluate its effectiveness in a primary care setting. The results suggest that the current GLB adaptation of the DPP lifestyle intervention can be successfully delivered by trained healthcare providers in diverse primary care practices, with comparable weight loss to that achieved in DPP itself. As is well known, translation from research to the "real-world" presents a number of challenges, which make the current findings particularly encouraging.

One notable difference between research studies such as the DPP and the real world is the population being examined. Unlike volunteer research, the current program targeted all primary care practice patients found to be at risk, rather than the more selective recruitment of volunteers already willing to participate in a clinical treatment trial. In a recent analysis of the physical activity component of the DPP intervention, investigators found that the level

of reported physical inactivity in the DPP cohort was less than that reported in the NHANES III subgroup with impaired glucose tolerance (14) suggesting that the DPP volunteers were likely healthier and more motivated. In the current study, the primary reasons for non-attendance were related to medical and psychosocial problems.

Retention of enrollees in an intervention program can be difficult in a research environment, however, may be even more challenging in real-world settings operating with limited funds and devoid of monetary rewards or incentives. In the current study, about 60% of participants attended at least half of the sessions. Interestingly, there was a significant difference between retention rates in two clinics (82% vs. 39%, $p<0.05$) although there were no significant differences in age, gender or ethnic distributions in these clinics and both clinics were located in an urban setting. This finding warrants further investigation to determine what factors may contribute to program retention.

Comparisons for retention to similar translational programs are limited; however, one such translational study in a workplace setting exhibited about 95% retention. Participants were encouraged to attend during work hours without loss of pay or personal time and received other small incentives (15). Another lifestyle translation study involving a partnership between a university and a local HMO noted a 92% retention rate; patients were charged an initial commitment fee which was returned in its entirety if the subject met certain attendance requirements (16). These translation attempts suggest that allowing patients to attend sessions during work without loss of pay and offering some incentive and/or reimbursement for attendance may be beneficial in improving retention. Since the current project's evaluation indicated a correlation between attendance and weight loss as well as physical activity, attention to provision of motivational items for attendance should be an important consideration for future translational efforts.

Likewise, levels of interest for primary care staff working in the real world may be dissimilar to those involved in traditional research, with different goals and role expectations. One study examining health care provider attitudes toward the detection and management of those at risk for diabetes found that many have concerns including lack of resources and questionable patient motivation for making lifestyle change (17). It is important to note that the preventionists who were trained to deliver the GLB had no prior experience in behavioral modification, nor specialist diabetes interest and had varied backgrounds. Thus, a large pool of health professionals is potentially eligible to deliver the GLB with appropriate training.

The GLB was successful in reducing certain risk factors for diabetes and CVD including weight, BMI, waist circumference and glucose. Weight loss data from the DPP is only available for the 6 month follow up visit forward, so we are unable to directly compare weight loss in the DPP at 3 months to the GLB weight loss; however, review of the trend in the DPP at 3 months shows a mean weight loss of 3.5%, similar to that achieved by over half of the "completer" group. As it is expected that the effectiveness of an intervention may be reduced when being translated from research to clinical practice (18), thus these findings are encouraging.

Strengths of this study include a prospective follow-up design in one of the first efforts to translate the DPP lifestyle intervention to a real-world health care setting. In addition, we were able to collect measures of change in risk parameters for subjects in both rural and urban primary care settings. Data were analyzed according to the principle "intention to treat" as well as for those that actually completed the program and follow-up assessment.

Limitations of this study include: 1) a lower number of participants enrolled than originally anticipated, thus not permitting practice specific comparison analyses, 2) the attrition of participants and subsequent lack of evaluation of those who did not complete the intervention and 3) the limited period of study (3 months) due to funding considerations.

We have successfully adapted the individual lifestyle intervention utilized in the DPP for group implementation in a "real-world" setting while maintaining the fundamental aspects of the original intervention. The current evaluation suggests that the GLB program delivered by trained health professionals was feasible and effective in reducing some parameters of risk for type 2 diabetes and CVD in this group of individuals with the metabolic syndrome. It will be important to evaluate the GLB program in larger populations and other venues over time. Additional future areas of study should address methods of delivery of GLB versus standard care, as well as in-depth cost analysis. It will also be important for future evaluations to consider longer follow-up.

In the "real-world", patients with risk factors for diabetes and CVD are often told to "lose weight and increase activity". It is hoped that this, and similar programs will enable physicians to write a "prescription" for lifestyle change (and insurers to cover the costs) with the assurance that tangible health benefits will ensue.

Acknowledgements

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Table 1 Baseline Characteristics of Study Population: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Female (n=42) Mean (sd)	Male (n=9) Mean (sd)	Overall (n=51) Mean (sd)
Weight (pounds)	212.8 (44.7)	231.0 (24.8)	216.0 (42.3)
Total Cholesterol (mg/dL)	194.5 (31.3)	176.2 (28.7)	191.3 (31.4)
HDL Cholesterol* (mg/dL)	43.8 (11.1)	31.4 (5.7)	41.6 (11.4)
Non-HDLC (mg/dL)	150.7 (32.1)	144.8 (28.2)	149.7 (31.2)
Blood Glucose (mg/dL)	98.4 (18.4)	100.6 (17.6)	98.8 (17.9)
Systolic Blood Pressure (mm Hg)	122.9 (19.1)	130.1 (19.3)	124.2 (19.1)
Diastolic Blood Pressure (mm Hg)	77.8 (12.6)	80.4 (8.3)	78.3 (11.9)
Waist (inches)	42.8 (5.9)	44.8 (3.9)	43.2 (5.6)
Body Mass Index[1]	36.9 (7.9)	35.2 (3.9)	36.6 (7.4)

Data are means (standard deviation)

*$p<0.05$, statistically significant difference between genders

[1]n=50, height missing for 1 participant

Table 2 Pre and Post Intervention Comparisons: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Total Group n=51						Completers n=28					
Variable	n	Pre-Mean (sd)	Post-Mean (sd)	Mean Change (sd)	Mean % Change	p-value	n	Pre-Mean (sd)	Post-Mean (sd)	Mean Change (sd)	Mean % Change	p-value
Weight (pounds)	51	216.0 (42.3)	211.4 (43.0)	-4.60 (7.2)	-2.2%	<0.001	28	213.98 (46.9)	206.76 (47.8)	-7.22 (8.1)	-3.5%	<0.001
Total Cholesterol* (mg/dL)	47	190.57 (31.4)	190.74 (32.4)	0.17 (23.9)	0.8%	0.92	25	194.0 (30.2)	195.52 (33.1)	1.52 (32.0)	1.96%	0.69
HDL* (mg/dL)	47	42.11 (11.5)	42.77 (11.7)	0.66 (7.1)	2.2%	0.32	25	44.56 (13.1)	45.48 (13.2)	0.92 (9.63)	3.45%	0.41
Non-HDL* (mg/dL)	47	148.47 (31.2)	147.98 (32.8)	-0.49 (22.6)	-0.51%	0.84	25	149.44 (29.9)	150.04 (33.7)	0.6 (30.0)	1.8%	0.92
Glucose** (mg/dL)	43	99.09 (15.7)	94.46 (15.5)	-4.63 (16.7)	-3.7%	0.02	21	102.28 (16.1)	95.28 (18.9)	-7.0 (19.4)	-5.9%	0.03
SBP* (mm Hg)	45	122.41 (17.9)	124.23 (19.9)	1.82 (9.31)	1.6%	0.29	22	124.73 (16.2)	126.50 (20.2)	1.77 (12.0)	1.5%	0.71
DBP* (mm Hg)	45	77.59 (11.8)	76.58 (10.9)	-1.00 (5.39)	-0.08%	0.22	22	79.09 (8.3)	76.55 (5.9)	-2.55 (7.0)	-2.5%	0.09
Waist (inches)	51	43.16 (5.58)	42.46 (5.67)	-0.69 (1.61)	-1.6%	0.003	28	42.85 (5.3)	41.63 (5.5)	-1.21 (2.0)	-2.8%	0.003
BMI (kg/m^2)	50	36.55 (7.35)	35.74 (7.45)	-0.82 (1.18)	-2.3%	<0.001	28	36.85 (8.8)	35.62 (9.0)	-1.23 (1.3)	-3.53%	<0.001

*Patients with med changes excluded

**n=43 due to lab error

Figure 1 Weight Loss Attainment for Total Group and Completers: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

Legend:

Black:	Weight loss ≥ 7%
Light gray:	Weight loss ≥ 5%
Dark gray:	Weight loss ≥ 3%

A Guideline for Diabetes Self- Management in the Hospital: Experience with 50 Patients using Continuous Subcutaneous Insulin Infusions

University of Pittsburgh DIABETES INSTITUTE

Michelle Noschese, Amy Calabrese Donihi, Kris Ruppert, Monica DiNardo, Tracey Banks, Mary Korytkowski

ABSTRACT

Patients using Continuous Subcutaneous Insulin Infusions (CSII) as outpatients are candidates for inpatient diabetes self management. Essential components of self management include appropriate patient selection, physician orders for infusion rates, and documentation of capillary blood glucose (CBG) and boluses. The absence of information regarding inpatient outcomes and clinician unfamiliarity with CSII contribute to inconsistencies in hospital management. To address this, an inpatient CSII guideline and order set were developed and implemented at the University of Pittsburgh Medical Center by a multidisciplinary Diabetes Patient Safety Committee. We report the experience in 50 consecutive inpatients using CSII, between November 2004 and August 2006, grouped as follows: I: No guideline or Diabetes Service Consultation (DSC); II: Guideline only; III: Guideline & DSC.

	n	Age	LOS* (days)	CSII Use (days)	% CBG <70 mg/dl	% CBG 70-180 mg/dl	% CBG >180 mg/dl
Group I	4	36 12	3 1.5	3 1.5	7.1	33.3	59.6
Group II	12	51 16	5.2 6.2	3.2 2.9	6.4	41.8	51.8
Group III	34	48 15	9.8 15.4	5.4 7.1	5.7	51.4	42.9
p value	--	0.19	0.16	0.67	0.70	0.17	0.26

*Length of Stay

There was one pump malfunction and one infusion site problem; no DKA or hypoglycemia with loss of consciousness was reported. A high degree of satisfaction with hospital CSII management was expressed in 13/15 patients in Groups II and III who responded to a patient survey. All surveyed patients reported adequate knowledge regarding pump settings and adjustments at discharge. These results suggest that alert patients using CSII as outpatients can safely continue this in the hospital with adequate clinical support. The high percentage of CBG > 180 mg/dl in all groups suggests the need for continued efforts toward improving glycemic control in hospitalized patients.

INTRODUCTION

- Patients who have been well controlled with CSII prior to hospitalization are candidates for diabetes self management in the hospital.
- Essential components of hospital self-management include an assessment of a patient's ability to perform pump functions and deliver insulin doses accurately. Additional requirements include a physician order for diabetes self management; the recording of basal, bolus and correctional insulin doses in the medication record; and documentation of all capillary blood glucose (CBG) results as well as site changes.
- Personnel knowledgeable in CSII therapy who are able to support these patients by making indicated adjustments to basal and bolus infusion rates, and assist with trouble-shooting of mechanical problems can contribute to the success of an inpatient insulin pump program.
- Currently, there are no standardized guidelines for use of CSII therapy in the inpatient setting, in part due to the lack of information regarding outcomes in patients who use CSII therapy in the hospital.
- The paucity of outcomes data and a lack of familiarity with CSII technology among nurses and physicians has created variability in how these patients are managed in the hospital.

OBJECTIVES

The purposes of this quality assurance project were to:

- Report the safety and effectiveness of CSII self-management in the hospital
- Compare glycemic control in hospitalized patients managed with a standardized CSII Guideline alone or together with consultation from the Inpatient Diabetes Service with patients who are managed with usual care.
- Measure patient satisfaction with CSII self-management in the hospital

PROTOCOL DEVELOPMENT & IMPLEMENTATION

A Guideline for CSII use in the hospital was developed and implemented by the hospital Diabetes Patient Safety Committee. Key features of this guideline included:

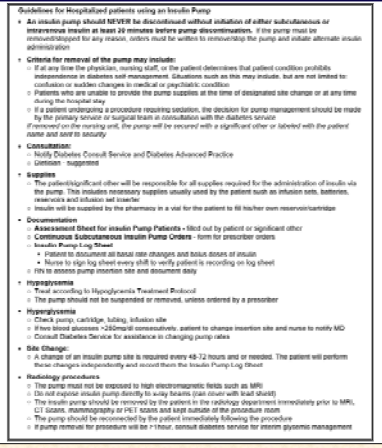
- Evaluation of a patient's physical and mental ability to self-manage CSII in the hospital
- Recommendation for consultation with the Inpatient Diabetes Service to assist with management.

A CSII Protocol was developed to accompany the Guideline. Components include:

- Patient Self-Assessment and Attestation Statement
- Standardized Order Set
- Bedside Patient Logbook
- Medical Administration Record

Educational sessions were conducted for nursing staff prior to implementation of the protocol

INPATIENT CSII GUIDELINE



Guidelines for Hospitalized patients using an Insulin Pump

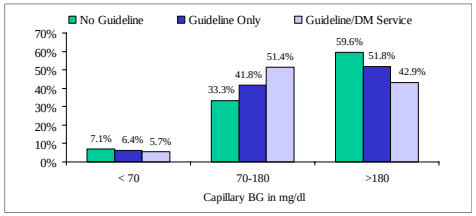
- An insulin pump should NEVER be discontinued without initiation of either subcutaneous or intravenous insulin at least 2/ minutes before pump discontinuation. If the pump must be removed/stopped for any reason, orders must be written to remove/stop the pump and initiate alternate insulin administration
- Criteria for removal of the pump may include:
  - If at any time the physician, nursing staff, or the patient determines that patient condition prohibits independence in diabetes self-management. Situations such as this may include, but are not limited to: confusion or sudden changes in medical or psychiatric condition
  - Patients who are unable to provide the pump supplies at the time of designated site change or at any time during the hospital stay
  - If a patient undergoing a procedure requiring sedation, the decision for pump management should be made by the primary service or surgical team in consultation with the diabetes service
  - If removed on the nursing unit, the pump will be secured with a significant other or labeled with the patient name and sent to security
- Consultation:
  - Notify Diabetes Consult Service and Diabetes Advanced Practice
  - Dietician - suggested
- Supplies
  - The patient/significant other will be responsible for all supplies required for the administration of insulin via the pump. This includes necessary supplies usually used by the patient such as infusion sets, batteries, reservoirs and infusion set inserter
  - Insulin will be supplied by the pharmacy in a vial for the patient to fill his/her own reservoir/cartridge
- Documentation
  - Assessment Sheet for insulin Pump Patients - filled out by patient or significant other
  - Continuous Subcutaneous Insulin Pump Orders - form for prescriber orders
  - Insulin Pump Log Sheet
    - Patient to document all basal rate changes and bolus doses of insulin
    - Nurse to sign log sheet every shift to verify patient is recording on log sheet
  - RN to assess pump insertion site and document daily
- Hyperglycemia
  - Treat according to Hypoglycemia Treatment Protocol
  - The pump should not be suspended or removed, unless ordered by a prescriber
- Hyperglycemia
  - Check pump, cartridge, tubing, infusion site
  - If two blood glucoses >280mg/dl consecutively, patient to change insertion site and nurse to notify MD
  - Consult Diabetes Service for assistance in changing pump rates
- Site Change:
  - A change of an insulin pump site is required every 48-72 hours and or needed. The patient will perform these changes independently and record them the Insulin Pump Log Sheet
- Radiology procedures
  - The pump must not be exposed to high electromagnetic fields such as MRI
  - Do not expose insulin pump directly to x-ray beams (can cause with lead shield)
  - The insulin pump should be removed by the patient in the radiology department immediately prior to MRI, CT scans, mammography or PET scans and kept outside of the procedure room
  - The pump should be reconnected by the patient immediately following the procedure
  - If pump removal for procedure will be > 1 hour, consult diabetes service for interim glycemic management

METHODS

- This project was approved as a Quality Improvement Initiative by the UPMC Total Quality Council
- Retrospective chart review was performed on 50 consecutive inpatients identified as continuing CSII therapy in the hospital between November 2004 and August 2006.
- Patients were grouped as follows:
  - 4 were managed without the Guideline or Diabetes Service
  - 12 were managed with the CSII Guideline only
  - 34 were managed with the CSII Guideline in consultation with Diabetes Service
- Age, LOS, number of days of CSII use, all CBG values during CSII therapy, mechanical pump problems
- Patients identified as using CSII while still hospitalized were invited to complete a survey at the time of discharge to determine satisfaction with CSII management in the hospital.

RESULTS

Bedside Glucose in Inpatients Using CSII



Patient Satisfaction with CSII Therapy

	Agree	Neutral	Disagree
I was satisfied with my insulin pump diabetes management during my hospital stay.	86%	0	14%
While I was on my pump in the hospital, my diabetes was managed just as well or better than as at home.	50%	33%	17%
Hospital staff understood my insulin pump.	57%	29%	14%
I had control over my diabetes management in the hospital.	57%	0	43%
The hospital staff supported the use of my insulin pump in the hospital.	83%	0	17%
I had the information I needed to be able to take care of my diabetes during my hospital stay.	71%	29%	0
The meals that I received in the hospital were adequate for maintaining blood sugar control.	67%	33%	0
The insulin adjustments made while I was in the hospital were appropriate for keeping my blood sugar under control.	86%	0	14%
I had the supplies that I needed to maintain my insulin pump while in the hospital.	86%	14%	0
I know what to do with my pump settings after I am discharged from the hospital.	100%	0	0

Problems Related to CSII Use in Hospitalized Patients

All Groups	Device Malfunction	CBG < 40 mg/dl	DKA	CSII removed/ SQ or IV insulin required	Infusion Site problems	% CBG >300 mg/dl
50	1	0	0	11	1	8%

CONCLUSIONS/FUTURE DIRECTIONS

- Alert patients who use CSII as an outpatient can safely self-manage CSII in the hospital with support from clinical staff.
- Use of a standardized CSII Guideline and Order Set helps guide inpatient use of CSII therapy
- Inpatients who continue to use CSII require vigilant blood glucose monitoring and insulin dose adjustments to maintain blood glucose levels in a desired range

This research was sponsored by funding from the United States Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland, Award Number W81XWH-04-2-0030.

Diabetes

Appendix D

Deliverable #230: Final Report on the Implementation of STEP UP at Additional Primary Care Practices

UPMC

University of Pittsburgh Diabetes Institute

Contract #:	W81XWH-04-2-0030
Deliverable #:	230
Funding Year:	2004/2005
Goal/Initiative:	Primary Prevention, Goal 1
Submitted By:	Kaye Kramer, PhD
Submission Date:	04/15/2009
Description:	Final Report on the Implementation of STEP UP at Additional Primary Care Practices

UPMC

University of Pittsburgh Diabetes Institute

Table of Contents

Introduction

Approximately 314 million people worldwide are estimated to have impaired glucose tolerance and are therefore at increased risk for developing type 2 diabetes and cardiovascular disease (CVD) [1]. The metabolic syndrome, a clustering of risk factors including insulin resistance, dyslipidemia, obesity and hypertension has also been associated with elevated risk for both of these conditions [2-6].

Lifestyle intervention clearly reduces the risk for type 2 diabetes [7-10]. In the United States, the Diabetes Prevention Program (DPP) demonstrated that intensive lifestyle intervention was highly successful in reducing risk for type 2 diabetes in all groups regardless of ethnicity, age or gender [11]. In addition, the DPP lifestyle intervention was effective in reducing risk factors for CVD [12] and components of the metabolic syndrome [13]. Recent research has focused on translating the DPP intervention to a variety of settings including local YMCAs [14], primary care practice settings [15], and hospital-based locales [16, 17]. These successful projects focused on lifestyle intervention delivery in their respective settings; however, did not address a model for training and support that could be applied to health professionals in other settings. The challenge for public health is to devise a universal framework for translation of all aspects of the DPP research effort (from training and support to the intervention program and materials) in order to be readily implemented in a variety of settings.

Objective

The objective of this project was to expand the services and support of the Diabetes Prevention Support Center of the University of Pittsburgh Diabetes Institute to additional regional primary care practices.

Methods

Intervention Adaptation

The original DPP Individual Intensive Lifestyle Intervention was developed at the University of Pittsburgh by the DPP Lifestyle Resource Core (LRC) and has been described in detail elsewhere [18]. For translation, based on analysis from the DPP which suggested that group delivery could be cost-effective [19], several members of the DPP LRC modified the original DPP lifestyle intervention to the Group Lifestyle Balance (GLB) program for group rather than individual delivery. In addition, the translation team adapted the intervention to be more compatible with a real world schedule by decreasing the number of sessions from 16 to 12 in order for the program to be delivered on a quarterly basis. Other modifications included concentrating on healthy food choices rather than specifically the food pyramid, a focus on calorie as well as fat intake from the beginning of the intervention and an enhanced emphasis on the pedometer, which originally had not been part of the core DPP sessions. Major modifications are summarized in Table 1.

GLB program participants receive handouts for each session, a fat and calorie counting book, self-monitoring books for keeping track of food and physical activity, a pedometer with instructions, and a chart for self-monitoring weight over the course of the program. All

subjects were asked to self-monitor their own weight, food intake, and physical activity levels and received feedback concerning their progress.

Training and Support System

A major component of the successful DPP intervention revolved around the training and support provided to the interventionists delivering it [20]. In an effort to mirror the successful DPP model, the Diabetes Prevention Support Center (DPSC) of the University of Pittsburgh Diabetes Institute (https://diabetesprevention.upmc.edu) was established in 2006. Members of the DPSC faculty developed a two-day training workshop for health care professionals in order to provide a complete, standardized overview of the GLB program and its implementation. Ten training workshops have been held to date, with over 350 health care professionals completing training, including the preventionists providing the intervention for this present evaluation. Figure 1 shows the breakdown of attendee locale, as well as the proportion of those trained who are involved in Department of Defense projects. In addition, military personnel from Wilford Hall are shown (TX). Figure 2 depicts the professional affiliation of those attending workshops to date.

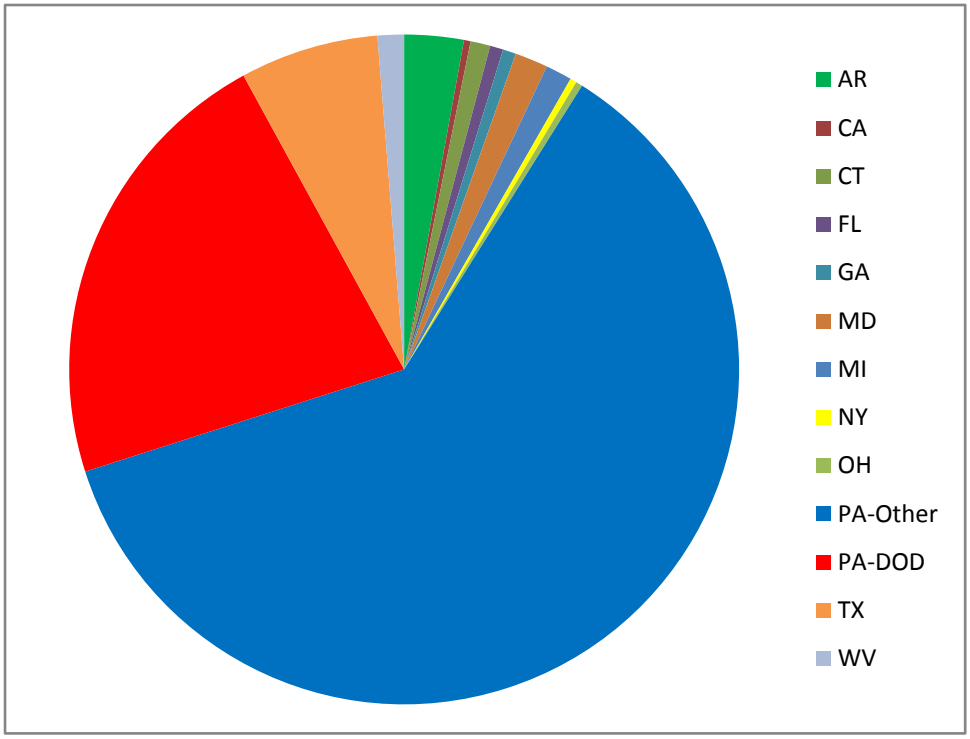


Figure 1: Group Lifestyle Balance Training Workshop Attendee Locale

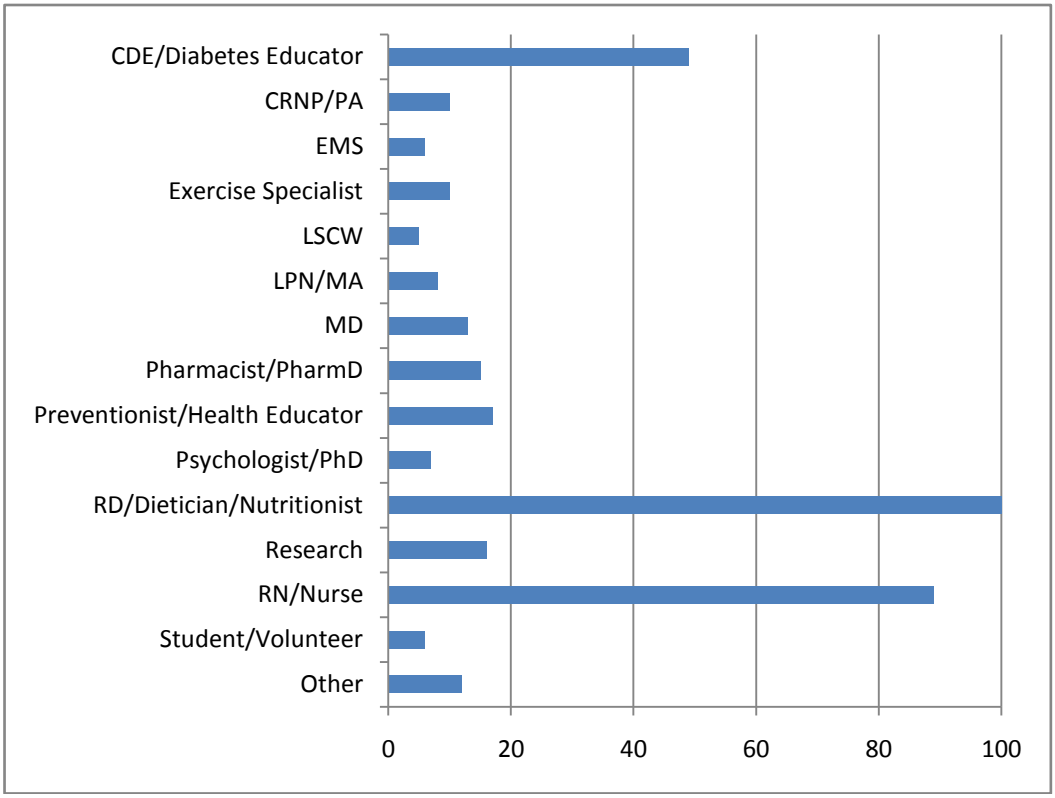


Figure 2: Group Lifestyle Balance Training Workshop Attendee Professional Affiliation

The workshops provide an overview of the background and results of the DPP, the rationale for the nutrition and physical activity goals of the program, and a thorough summary regarding teaching the basic components of each intervention session. In addition, one section of the workshop is devoted to instruction in conducting group sessions and also provides time to help attendees "brainstorm" how they might implement the program in their setting. Training closely follows the GLB manual of operations, which includes a leader's guide for teaching each session as well as a complete set of participant handouts; the manual has thus been designed to be a one-stop resource for implementation of the GLB program.

In addition to receiving initial training, interventionists in the DPP also received ongoing support from the DPP Lifestyle Resource Core (LRC) as they implemented the program. Support was provided via monthly conference calls or as needed calls for specific assistance with any problems that arose. In order to replicate this support structure, the DPSC is

available to all preventionists who have attended the GLB training workshop including those who have participated in this current effort. During this past year, the DPSC also completed a "train the trainer" for our military partners so that these training workshops may be conducted onsite within the military framework.

Expansion of the DPSC to Additional Primary Care Practices

A non-randomized prospective one-group design was chosen for this effectiveness evaluation as it is a design often used in translation efforts. The primary care practice setting was chosen initially for translation because it provides an ideal venue for institutional delivery and reinforcement of prevention intervention, as well as the provision of ongoing follow-up care. Working with Dr. Francis Solano of the University of Pittsburgh Medical Center, 6 primary care practices were identified and approached to take part in this evaluation. The primary care practices that agreed to participate were located in Aspinwall, Cranberry Township, Monroeville, Murrysville, New Kensington, and Pittsburgh. Two practices, Aspinwall and Monroeville, agreed to take part in formal research evaluation. One practice (Murrysville) later withdrew their participation as they had other competing demands in the office such that they were not able to direct attention to this project. One of the research practices had a patient base of approximately 5,000, and the other approximately 10,000.

Subjects age 18 and older without diabetes, a body mass index (BMI) $\geq$25kg/m2 and the metabolic syndrome (NCEP ATPIII definition)[21] and/or pre-diabetes (fasting glucose 100-125) [22] were invited to take part. Potential participants learned about the GLB program through flyers posted in primary care practices or directly from their physician. A physician referral documenting eligibility as well as permission for physical activity was required.

Procedures and Outcome Measures

After completion of informed consent, participants completed assessments at baseline and at the conclusion of the intervention. Subjects had blood pressure, height, weight and waist circumference measured following a standard protocol. Total cholesterol, high-density lipoprotein (HDL) cholesterol, non-HDL cholesterol and glucose were measured after at least an eight-hour fast using the Cholestech LDX System by a certified laboratory assistant. Global CVD risk assessment [23] was also estimated and medication use was assessed via participant interview. In addition, weight was recorded weekly at each session. After completion of the 12 core sessions, participants attended monthly maintenance meetings to report their weight and activity minutes.

Complete outcomes data were collected for the two research practices (N=13) with limited quality assurance data available (weight, BMI and waist circumference) for the total primary care practice group (N=46) at baseline and 3 months post-intervention.

Sample Size Estimation and Statistical Analysis

Based on previous local DPP weight loss experience and using this variance estimate, we estimated that for paired analysis 21 subjects were needed to detect a 7% weight loss with α=0.05 and 90 % power. Analyses were carried out using the SAS statistical package (version 9.1, SAS Institute, Cary North Carolina, USA). The mean change between pre and post intervention measures was analyzed using the Paired Student's *t*-test when change data were normally distributed (weight, waist circumference and BMI); however, for most measures the non-parametric Wilcoxon Matched-Pairs Signed Rank test was used. Mixed models were used to examine weight change over time (repeated measures per participant) adjusting for weight at study entry and clustering of participants within clinical site; individual participant and clinical sites were random effects in the model. Correlations were calculated using Pearson's or Spearman's correlation coefficient r. Analyses were conducted on an intention to treat basis; to handle missing data we used last observation carried forward methodology for participants who did not attend the post assessment visit. Subjects with changes in medication use during the course of the intervention for the condition being evaluated were excluded from appropriate specific analyses.

Results

Attendance

The Group Lifestyle Balance program was well attended, with 89.1% of the total group (n=46) and 100% of participants in the research group (n=13) attending at least half of the sessions. The mean number of sessions attended was 10. In addition, 11 (85%) participants attended the six month assessment visit, and 10 (77%) attended the 12 month assessment visit.

Clinical Outcome Measures

Demographic characteristics of the research group (N=13) are shown in Table 1, with specific results of the baseline and post intervention comparisons for weight, waist circumference and BMI for both the research and the total group including all primary care practices (n=46) shown in Table 2. A significant decrease in weight (-9.3 pounds, -4.3%, p<0.0001), waist circumference (-1.4 inches, -3.2%, P<0.0001) and BMI (-1.7 kg/m^2, -4.4%, p=<0.0001) was noted over all.

Table 1: Demographic Characteristics: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	N=13
Female/Total Group (%)	11/13 (85%)
Non-Caucasian (%)	0 (0%)

Mean age (sd)	57.4 (sd=10.9)
Age Range	37-73

Table 2: Baseline and Post-Intervention Comparisons for Weight, Waist and BMI in Total and Research Groups: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

Variable	**n**	**Pre-Mean (sd)**	**Post-Mea (sd)**	**Mean Change(sd)**	**Mean % Change**	**p-value**
Weight (lbs)	46	220.1 (47.1)	210.9 (47.7)	-9.3 (9.1)	4.3%	**<.0001**
	13	204.0 (40.9)	192.6 (40.7)	-11.3 (7.9)	-5.6%	**0.0002**
Waist (inches)	44*	42.0 (6.1)	40.6 (6.0)	-1.4 (1.9)	3.2%	**<.0001**
	13	40.8 (6.8)	39.0 (6.1)	-1.8 (2.5)	-4.4%	**0.01**
BMI (kg/m^2)	44*	37.5 (7.4)	35.9 (7.6)	-1.7 (1.6)	4.4%	**<.0001**
	13	34.7 (6.2)	32.7 (6.2)	-1.9 (1.4)	-5.7%	**0.0002**

* Waist and height not measured on 2 participants

The remaining outcome measures for the research group at the 3 month post-intervention assessment are shown in Table 3, with significant decreases noted in total cholesterol (-28.3 mg/dL, -15.3%, p=0.006), LDL cholesterol (-21.5 mg/dL, -20.3%, p=0.005) and systolic blood pressure (-9.7 mm/Hg, -7.5%, p=0.005) at the 3 month post-intervention assessment. No significant changes were noted for diastolic blood pressure, HDL cholesterol, triglycerides, glucose, or HbA1c.

Weight loss remained significant at the 6 month (-15.1 pounds, -7.4%, p=0.0002) and 12 month assessment visits (-10.6 pounds, -5.2%, p=0.001), as did BMI, waist circumference, LDL cholesterol, and systolic blood pressure. Total cholesterol remained

significantly decreased at the 6 month assessment and marginally decreased at the 12 month assessment. In addition, a significant decrease in diastolic blood pressure from baseline was noted at 6 months and 12 months and a significant increase in HDL cholesterol was noted between baseline and the 12 month assessment visit. Results are shown in Table 3 to follow.

Table 3: Baseline and Post-Intervention Comparisons for Clinical Outcome Measures: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Baseline		3 Months (n=13)				6 Months (n=11)					12 Months (n=10)			
Variable	**n**	**Mean (sd)**	**Mean (sd)**	**Mean Change (sd)**	**Mean % Change**	**p**	**Mean (sd)**	**Mean Change (sd)**	**Mean % Change**	**p**	**n**	**Mean (sd)**	**Mean Change (sd)**	**Mean % Change**	**p**
Weight (lbs)	13	204.0 (40.9)	192.6 (40.7)	**-11.3 (7.9)**	**-5.6%**	**0.0002**	188.9 (41.7)	**-15.1 (10.5)**	**-7.4%**	**0.0002**	10	193.3 (43.1)	**-10.6 (10.6)**	**-5.2%**	**0.001**
Waist (inches)	13	40.8 (6.8)	39.0 (6.1)	**-1.8 (2.5)**	**-4.4%**	**0.01**	37.7 (6.0)	**-3.1 (2.5)**	**-7.5%**	**0.0005**	10	37.2 (6.3)	**-3.6 (2.5)**	**8.7%**	**0.0005**
BMI (kg/m^2)	13	34.7 (6.2)	32.7 (6.2)	**-1.9 (1.4)**	**-5.7%**	**0.0002**	32.1 (6.4)	**-2.6 (1.8)**	**-7.7%**	**0.0003**	10	32.8 (6.5)	**-1.9 (1.8)**	**-5.6%**	**0.0007**
Total Chol. (mg/dl)*	13	187.3 (24.2)	159.0 (37.5)	**-28.3 (29.2)**	**-15.3%**	**0.006**	161.5 (36.1)	**-25.8 (25.5)**	**-14.2%**	**0.004**	10	177.3 (31.5)	-10.0 (18.0)	-5.6%	0.07
HDL Chol.l (mg/dl)*	13	46.2 (6.9)	43.9 (9.2)	-2.3 (5.6)	-5.2%	0.25	46.7 (8.2)	+0.5 (5.9)	+1.4%	0.84	10	51.2 (6.4)	**+4.9 (5.8)**	**+11.6%**	**0.01**
LDL Chol. (mg/dl)*	13	108.2 (26.4)	86.7 (31.1)	**-21.5 (23.2)**	**-20.3%**	**0.005**	86.8 (29.5)	**21.4 (21.9)**	**-20.0%**	**0.004**	9	95.3 (27.6)	**-14.2 (18.4)**	**-12.7%**	**0.02**
Triglycerides (mg/dl)*	13	162.7 (73.6)	147.5 (62.1)	-15.2 (47.9)	-9.3%	0.27	139.7 (59.3)	-23.0 (38.8)	-13.9%	0.08	9	160.1 (71.9)	-2.6 (44.5)	-2.4%	0.98
Glucose (mg/dl)*	13	98.9 (12.0)	103.2 (5.6)	+4.3 (10.1)	+4.5%	0.15	93.4 (5.4)	-5.5 (12.3)	-4.3%	0.12	10	95.0 (17.1)	-3.9 (18.4)	0.84	0.70
HbA1c (%)	13	5.7 (0.4)	5.8 (0.4)	+0.07 (0.3)	+1.2%	0.33	5.8 (0.32)	+0.07 (0.32)	+1.4%	0.27	10	5.9 (0.4)	+0.16 (0.31)	+2.9%	0.26
SBP (mmHg)*	12	122.9 (10.7)	113.3 (6.6)	**-9.7 (8.6)**	**-7.5%**	**0.005**	113.5 (8.7)	**-9.4 (8.1)**	**-7.4%**	**0.001**	8	112.6 (11.5)	**-11.3 (12.2)**	**-8.8%**	**0.03**
DBP (mmHg)*	12	80.3 (4.5)	7.7 (6.2)	-3.7 (7.1)	-4.4%	0.10	75.0 (5.5)	**-5.3 (6.4)**	**-6.4%**	**0.01**	8	73.1 (5.4)	**-7.4 (6.7)**	**-9.0%**	**0.004**

* Participants with any medication changes excluded

Achievement of Goals

Results for weight loss achievement are shown in Figure 3 below. When examining weight loss, 9 of 13 participants (69.2%) reached a weight loss of at least 3.5%, 8 of 13 (61.5%) had weight loss of at least 5%, and 5 of 13 (38.5 %) reached the 7% weight loss goal. At the 6 month follow up assessment visit, 77% (10/13) reached 3.5% weight loss, 69% (9/13) reached 5% weight loss, and 46% (6/13) reached the 7% goal. In addition, 100% of those who achieved 3.5%, 5% and 7.5% weight loss at the 3 month post intervention assessment maintained that weight loss at the 6 month assessment visit. At the 12 month assessment visit, 7 of the 13 participants (53.9%) had weight loss greater than or equal to 3.5%, 38.5% (5/13) had weight loss greater than or equal to 5% and 30.8% (4/13) had weight loss greater than or equal to 7%; 80%, 63% and 77% respectively maintained those weight loss levels at one year

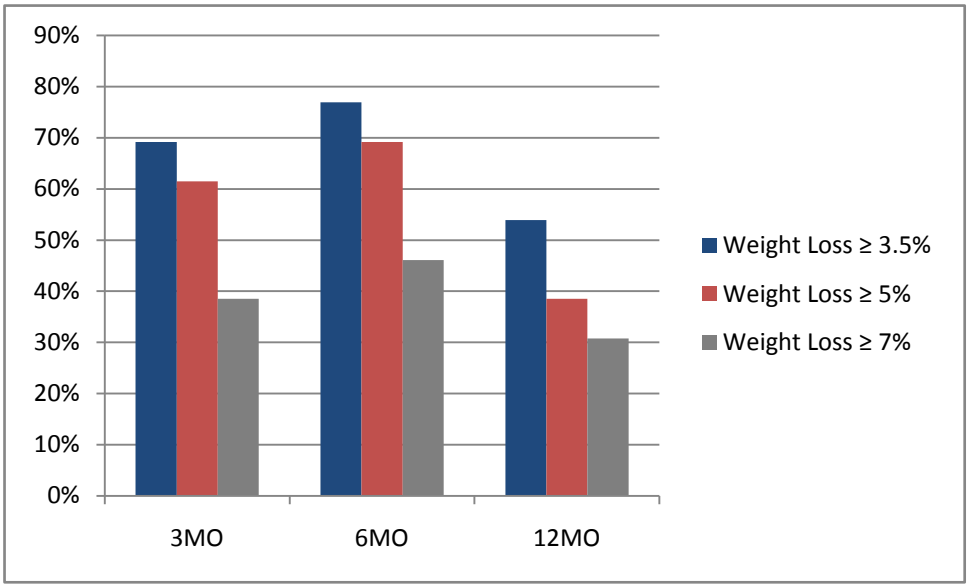


Figure 3: 3, 6 and 12 Month Post-Intervention Weight Loss: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

Of the 7 (53.8%) participants that recorded activity minutes, 2 (28.6%) successfully reached the physical activity goal (average of 150 minutes per week). Additionally, the mean number of activity minutes completed per week was positively correlated with weight loss in Phase 2 (r=0.71, p=0.07). Based on information collected during participant interview, a significant increase in the median self-reported activity minutes was noted between baseline and the 3 month post-intervention assessment (30 versus 150 minutes, p=0.001) and a marginally significant increase noted between baseline and the 6 month post-intervention visit (30 versus 120 minutes, p=0.08). Reported activity minutes remained increased at the 12

month assessment when compared to baseline; however, this difference was not significant (30 versus 59 minutes, NS).

Discussion

The findings of this project provide further evidence that this diabetes prevention model was successfully expanded to these UPMC Primary Care Practices. The Group Lifestyle Balance program was successfully administered to preventionists who, in turn, received their training and support from the DPSC. The program reduced key components of risk for type 2 diabetes and CVD for participants in these local primary care practice settings. In the DPP, 49% of lifestyle participants reached the 7% weight loss goal by the completion of the core intervention at the end of six months [24]; in the current project, 38.5% met a weight loss goal of 7% at 3 months. The GLB program was also recently implemented by DPSC trained preventionists in an urban medically underserved community setting subjects with the metabolic syndrome; 26.1% reached the 7% weight loss goal at the conclusion of the 3 month intervention and over one-third reduced at least one component of the metabolic syndrome [25].

We expected that the effectiveness of our translation effort might be reduced relative to that administered in a controlled research setting like the DPP [26], however, 69.2% achieved weight losses of at least 3.5% at 3 months in the current group which appears somewhat similar that the trend for weight loss seen in the DPP at 3 months. In addition, 100% of participants that achieved 7%, 5% and 3.5% weight loss maintained that weight loss at the 6 month assessment, with 80%, 63% and 77% respectively maintaining those weight loss levels at one year. Furthermore, significant decreases in weight and several other parameters of risk were successfully maintained through the 6 and the 12 month assessment visits, demonstrating the long-term impact of the intervention.

Achievement of the physical activity goal was limited in this group; however, only a little more than half of the participants actually recorded activity minutes. This may reflect a problem in tracking and reporting of physical activity since self-reported activity minutes increased significantly between baseline and the 3 month assessment. This trend continued at the 6 month assessment and activity minutes remained increased from baseline at the 12 month assessment, however the difference was no longer significant. In moving forward with prevention intervention it will be important to determine more effective methods to encourage tracking and recording of physical activity was well as general measures of physical activity.

Retention of participants in an intervention program can prove difficult in the most supportive research environment; this is even more challenging in a real-world setting that must operate with limited staffing and funds, devoid of monetary rewards or incentives. For this project, we demonstrated excellent retention of participants. It is likely that by fine-tuning the types of

motivators that are introduced, participant engagement strategies have improved as we move forward with translation. In the current project, preventionists in earlier projects learned which tools were effective and were able to share that knowledge in planning for later implementations. Preventionists reported positive participant response to providing samples of low fat/calorie foods for taste-testing in appropriate sessions, individual participation in providing favorite healthy recipes or cookbooks, and small incentives such as a food scale or certificate of achievement for completing the program. These translation attempts demonstrate that creativity is necessary for participant retention, and that a small budget for healthy lifestyle enablers and incentives should be considered during planning. Since poor treatment outcome for weight loss has been shown to be related to poor program attendance [27, 28] and the current project's evaluation indicated a correlation between attendance and weight loss, attention to provision of motivational items for attendance is an important consideration for future translational efforts.

Strengths of this project include the development of a framework for training and support for lifestyle intervention implementation, as well as prospective follow-up design in the initial evaluation of this modified DPP lifestyle intervention for translation to real-world settings. In addition we collected measures of change in risk parameters for subjects in both urban and rural environments, in two phases, with data analyzed according to the intention to treat principle.

Limitations of this study include the modest sample size, thus not permitting sub-group analysis. In addition, only a small number of males participated, and the cohort consisted of only Caucasians, thus it will be important for future translational efforts to determine strategies to engage other groups.

Future translation steps will address the development of a recognition program that will further enhance program delivery expertise and standardization, thus providing third-party payers with confidence that the program meets a prescribed level of quality for reimbursement.

By mirroring the successful intervention training and support scheme utilized in the DPP, we have further expanded our translation model for diabetes prevention and CVD risk reduction. At the core is the modified lifestyle intervention utilized in the DPP which has been adapted for implementation in real world settings, while maintaining the fundamental aspects of the original intervention. The GLB program has now been successfully implemented in several health care locales, and a medically underserved community setting, and is currently in process within the military. By providing a central training center for intervention delivery via workshops as well as provision of subsequent post-training support, it is hoped that this model will provide a framework for large-scale prevention dissemination in expanded civilian and military settings.

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Appendices E, F

Deliverable #214, #215: Evaluation Process and Measuring Tools

Appendices E and F

Title: Diabetes Prevention and Treatment Programs for Western PA

Contract No. W81XWH-04-2-0030

Sub-project Title: Rural & Minority Outreach – Johnstown

Goal: Identify people with metabolic syndrome through community screenings in accessible sites

Deliverable: Evaluation process and measurement tools.

Submission Date: November 19, 2008

Deliverable No: 214 and 215

BACKGROUND

Implementing and evaluating diabetes interventions with comprehensive approaches is particularly critical in rural communities as this population experiences increased rates of chronic disease, including diabetes (31.6/1000 vs. 26.7/1000, rural vs. urban respectively) and in minority populations who are at increased risk for developing diabetes and its complications (1) . The efficacy of lifestyle change to prevent or delay type 2 diabetes in at-risk adults has been demonstrated nationally in the Diabetes Prevention Program (2). Subsequently, we demonstrated the effectiveness of implementing a modified Diabetes Prevention Program (DPP) entitled Group Lifestyle Balance (GLB) in a high risk urban community (3). It is equally important to test a similar intervention in a rural site since rural residents are known to have a poorer perception of overall health, lower income, lower use of preventive services and a higher proportion of elderly and children compared to those residing in urban settings (1). This arm of the Diabetes Prevention and Treatment Program project was designed to target people with metabolic syndrome who are at increased risk for diabetes and cardiovascular disease who live in an underserved rural community and facilitate the GLB in a community-based clinic.

Appendices E and F

METHODS

Setting

The Johnstown community with its lower socioeconomic and aging population serves as the site for the project. Through this program, the Conemaugh Diabetes Institute (CDI) was established as part of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) network. At the heart of CDI is a comprehensive clinic located in downtown Johnstown. While much of the clinic's activity revolved around the treatment of persons already diagnosed with diabetes, the staff embarked on providing a Group Lifestyle Balance program to persons with metabolic syndrome, and at high risk for developing diabetes.

Population profile

The Johnstown community, with approximately 23,906 residents, is located in rural Cambria County, 100 miles east of Pittsburgh. Johnstown has suffered economic hardship with the closing of the steel and mining industry. The population is largely elderly and of lower socioeconomic status made up of 86% Caucasians, 45% > 45 years of age, and a per capita personal income of $13,236 in 1999 (4). According to the Pennsylvania Department of Health's 2004 Behavioral Risk Factor Surveillance Survey, 9% of adults in Cambria County have diabetes compared to 8% with diabetes in Pennsylvania (,5).

Screening

People at risk for diabetes and cardiovascular disease often have a cluster of symptoms that are characterized as metabolic syndrome (6). The causes of metabolic syndrome are usually related to improper nutrition and inadequate physical activity.

The risk factors for metabolic syndrome include:

1. Abdominal obesity (waist circumference > 102 cm in males or > 88 cm in females

2. Triglycerides ≥ or equal to 150mg/dL
3. Low high-density lipoprotein (HDL) cholesterol<40mg/dL for men and <50 mg/dL for women
4. BP ≥ or equal to 130/85
5. High fasting glucose≥ or equal to 100 mg/dL

People living in the PRIDE Johnstown community were screened for metabolic syndrome in the community service area. Participants were eligible for the study if they were overweight (BMI of at least 25) and had at least three of five risk factors for the metabolic syndrome. Participants were recruited by posting flyers in physicians' offices and through community advertisements (Appendices A and B). The majority of patients were self referrals

Intervention - The Group Lifestyle Balance Program (GLB)

Three nurses and 1 dietitian were trained to be the GLB preventionists. Ten groups of participants, for a total of 105 at-risk adults, enrolled in the GLB program. . The GLB program began with a 12-week nutrition and activity curriculum adapted from the National Diabetes Prevention Program's 16-week curriculum. Morning, afternoon and evening classes were offered during the 12-week period. Participants were told of all exercise opportunities available to them in the local area. All GLB classes took place at the Conemaugh Diabetes Institute.

Support Groups

Initially, support groups were offered quarterly for those participants who completed the 12 week GLB. However, participants requested monthly support groups and beginning with the third set of participants, support groups became available on a monthly basis. The support group meetings were offered in the afternoons and evenings with 7 - 10 participants usually attending the sessions.

Appendices E and F

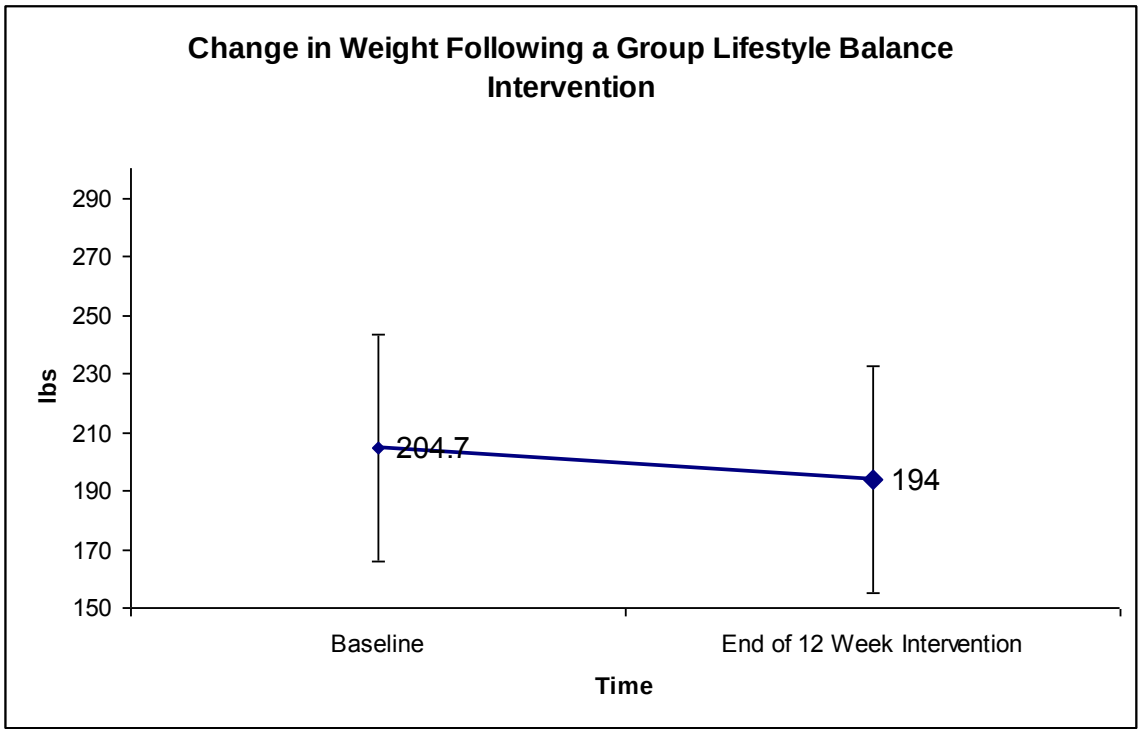
RESULTS

Results are available for the 76 participants who completed clinical measurements at the end of the 12 week GLB.

Weight Loss

The average participant weight loss was 10 pounds, a significant weight loss ($p < 0.0001$).

Baseline	12 Week Post Intervention
204.7 lbs	194 lbs.

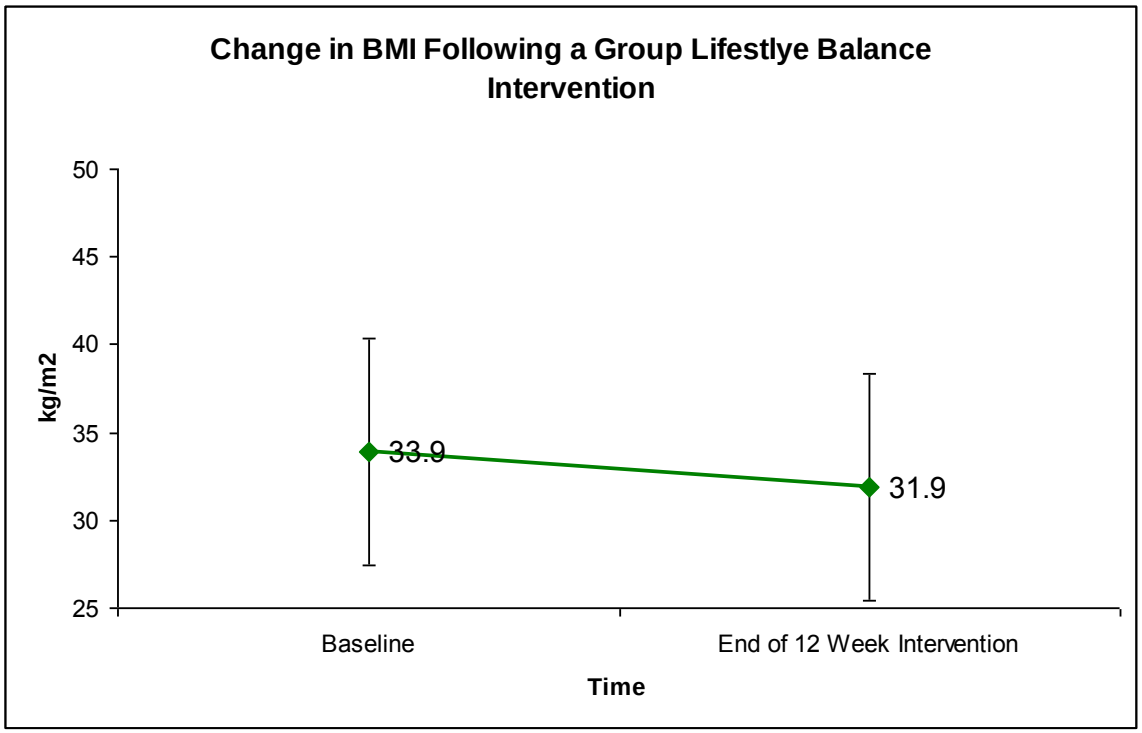


Appendices E and F

Body Mass Index (BMI)

On average, BMI dropped 2 units, a significant reduction in BMI ($p < 0.0001$).

Baseline	12 Week Post Intervention
BMI 33.9	BMI 31.9

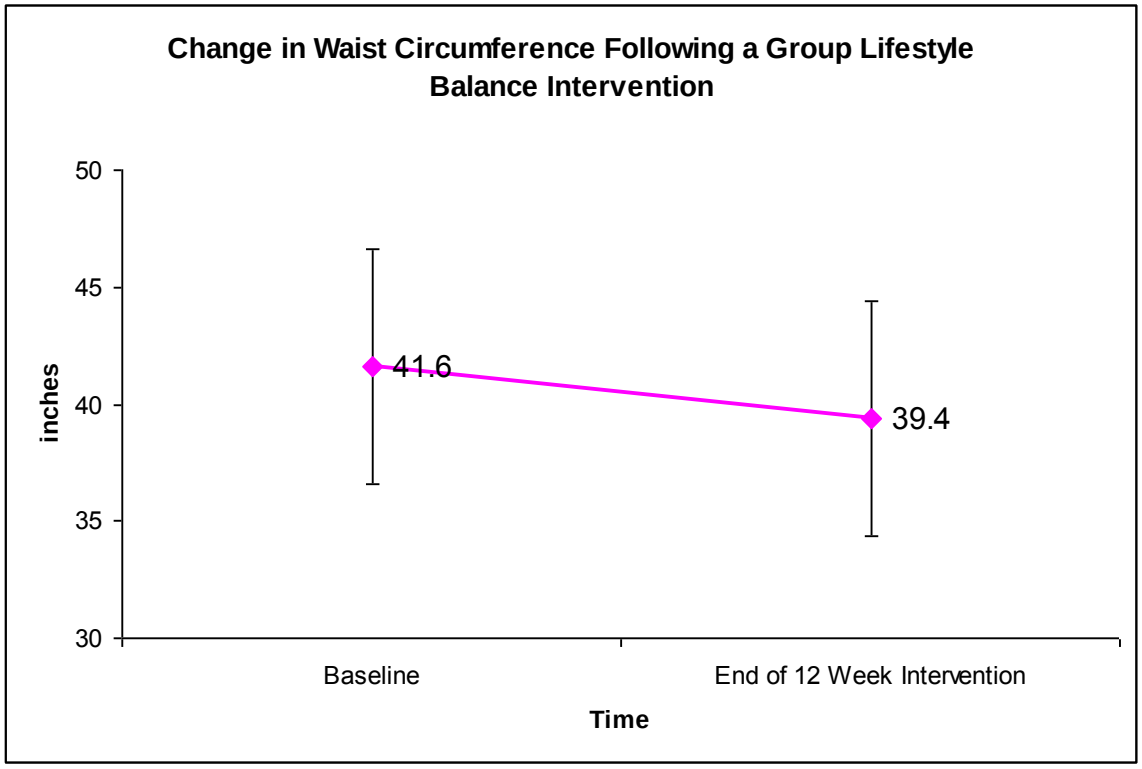


Waist Circumference (WC)

On average, just over two inches was lost in waist circumference (WC), a significant reduction ($p< 0.0001$).

Baseline	12 Week Post Intervention
41.6 inches	39.4 inches

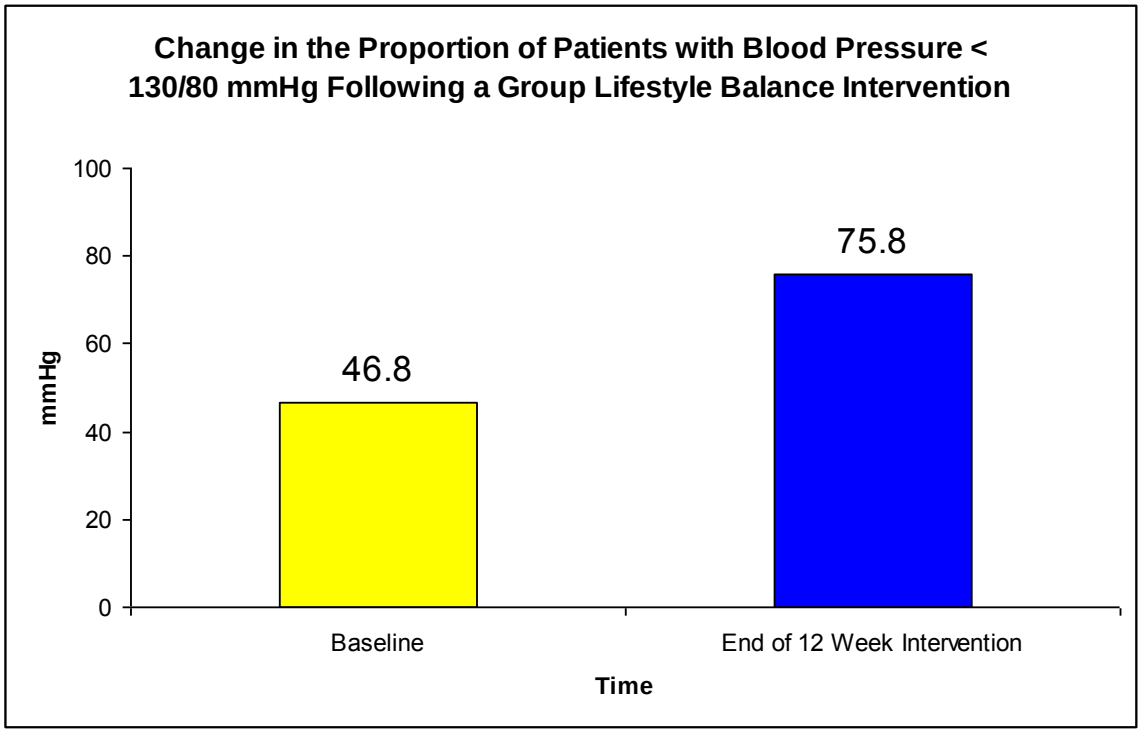
Appendices E and F



Appendices E and F

Blood Pressure

At baseline, less than half of participants met the blood pressure recommendation of <130/85. After the 12 week intervention, 75% met the blood pressure recommendation, a significant improvement ($p < 0.0007$).



Attendance and Adherence to Behavioral Recommendations

The majority of participants attended 85% of the classes. Of those attending the classes, approximately 97% tracked their calorie and fat intake as well as their time spent exercising. According to the "Keeping Track" records the majority of participants used walking or swimming as their choice of physical activity. Some participants added strength training by lifting weights or using exercise bands.

Program Challenges

We consider recruitment and program participation reasonable, despite challenging community dynamics that occurred during this project. When this project was initiated, the Conemaugh Diabetes Institute was part of UPMC Lee Hospital. Shortly after project implementation, the Conemaugh Memorial Health System assumed administrative

responsibility for the Conemaugh Diabetes Institute and became the major medical institution and host for the diabetes treatment and diabetes prevention programs. With the hospital leadership transition, personnel and community trust needed to be attended to and re-established.

CONCLUSIONS

Implementing a community-based diabetes clinic in an underserved, rural area that facilitates an evidence-based diabetes prevention program appears to be feasible and effective. Attendance and active participation was high. More than one hundred adults participated in the lifestyle intervention to reduce or delay type 2 diabetes and 76 fully completed the program. Statistically significant reductions in weight, BMI, waist circumference and blood pressure were demonstrated.

REFERENCES

1. U. S. Congress. (Office of Technology Assessment). Health Care in Rural America. Report No.: OTA-H-434.23

2. The Diabetes Prevention Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine 2002:346(6):393.

3. Seidel MC, Powell RO, Zgibor JC, Siminerio LM, Piatt GA. Translating the diabetes prevention program into an urban medically underserved community. Diabetes Care 2008; 31(4):684.

4. http://censtats.census.gov/data/PA/1604238288.pdf

5. www.health.state.pa.us/stats

6. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), National Heart, Lung and Blood Institute, NIH, 2002.

Approval Date: April 4, 2005
Renewal Date: April 3, 2006
University of Pittsburgh
Institutional Review Board
IRB #0502153

Appendix A - Flyer,
General

We're Happy To Announce The Opening Of The New UPMC Lee Regional Diabetes And Heart Disease Prevention Program –a Research Study for eligible adults-

If eligible for this Research Study, you will receive:

- classes to help you prevent diabetes and heart disease
- opportunities to exercise in different, convenient locations
- follow-up health screenings to see how you are doing
- personal help from a professional, caring staff.

Appendices E and F

We are offering a series of free Health Screenings in many community locations

Find out if you are eligible for this research study - Get Screened!

For more information about the ***UPMC Lee Regional Diabetes And Heart Disease Prevention Program***
and a list of Screening Dates and Sites, contact Carol Harding, Director, At 814-533-0594.

A Program Of UPMC Lee Regional and the University of Pittsburgh Diabetes Institute

Approval Date: April 4, 2005

Renewal Date: April 3, 2006
University of Pittsburgh
Institutional Review Board
IRB #0502153

Appendix B - Flyer,
Specific

Worried About Getting Diabetes Or Heart Disease?

Find out if you're at risk at a Free Health Screening

Date
Time
Place
Address

The Free Screening Includes:

- ✓ *Fasting Blood Test for HDL Cholesterol, Blood Fats and Blood Sugar (Do not eat for **3 hours** or **8 hours** before the Screening – Refreshments will be served at the Screening.)*
- ✓ *Height, Weight, and Body Measurements*
- ✓ *Blood Pressure*

For information about the ***UPMC Lee Regional Diabetes and Heart Disease***

Prevention Program - a Research Study for eligible adults

and a list of additional screening dates and sites,
contact Carol Harding, Director, at 814 533-0594.

Reminder: You must not eat for at least 3 hours. Or, you may do an "overnight" 8 hour fast before the Screening. You may have water and medicine. Refreshments will be served.

A Program Of UPMC Lee Regional and the University of Pittsburgh Diabetes Institute

Appendix G

Deliverable # 199: Final Report to Include Training and Advertising Materials Produced

Title:	Diabetes Prevention and Treatment Programs for Western PA
Contract No.	W81XWH-04-2-0030
Sub-project Title:	Rural and Minority Outreach -- Johnstown
Goal:	Develop centers with resources for nutrition, exercise, DSME and access to specialty services.
Deliverable:	Final report to include training and advertising materials produced.
Submission Date:	June 30, 2008
Deliverable No:	199

Background

The goal of the Rural and Minority Outreach component of the 2004 Diabetes Treatment and Prevention Program proposal was to develop centers with resources for nutrition, exercise, DSME and access to specialty services in rural and minority communities. The focus of the effort for rural outreach was Johnstown, Pennsylvania.

At the time of the project's inception, there were two major health providers in the greater Johnstown area, UPMC Lee Regional and Conemaugh Health System. In order to build local capacity for the treatment of persons with diabetes, renovations were planned to the UPMC Lee Regional Main Medical Building in downtown Johnstown to establish a diabetes center for education and treatment. Nearly six months into the project it was learned that UPMC planned to sell the UPMC Lee Regional business unit to Conemaugh Health System. As of August 1, 2005, the sale of UPMC Lee Regional to Conemaugh Health System was official. At that point, plans were made to incorporate this project into the Conemaugh Health System by establishing the Conemaugh Diabetes Institute (CDI).

The Conemaugh Diabetes Institute opened on March 22, 2006 (Appendix A). Services offered at the Institute at the time of inception and continuing through the present day are:

- Diabetes Self Management Education (DSME) classes
- Modified Diabetes Prevention Program (mDPP)
- Healthy Lifestyles Program
- Diabetes Support Group
- Gestational Diabetes Care

- One-on-One Diabetes education
- Community Outreach and Public Awareness

Throughout its 2-year existence the CDI educated persons with diabetes, health professionals and the community. The attached appendices are education materials, presentations and information on various publicity agents used to train, educate and advertise the services of the Conemaugh Diabetes Institute. The materials are those used in treatment and education. Materials for diabetes prevention are included in another deliverable.

Appendices

A. Conemaugh Diabetes Institute Grand Opening press coverage

B. Education presentations used in delivering Diabetes Self Management Education

C. Diabetes Self Management Education Assessment

D. Healthy Nutrition Program presentation given to schools

E. School Nurse program – Students with Diabetes

F. DSME Program for Nursing Home professionals

G. Education delivered to Meyersdale Hospital

H. Community Awarenss

   a. Dining Out Program

   b. Diabetes Phone Bank

   c. Diabetes Health Fair 2006

   d. Boscov's Diabetes Awareness event

   e. Diabetes Health Fair 2007

CONEMAUGH HEALTH SYSTEM

News Release

Contact: Helene Gleason, Public Affairs Coordinator, Memorial Medical Center
Phone: 814-534-3903

FOR IMMEDIATE RELEASE:

Congressman John Murtha celebrates grand opening of Conemaugh Diabetes Institute highlighting UPMC & Conemaugh Health System community partnership

Johnstown, PA (March 22, 2006)- At a press conference today, Congressman John P. Murtha joined administrators from Conemaugh Health System's Memorial Medical Center, Children's Hospital of Pittsburgh and the University of Pittsburgh Diabetes Institute (UPDI) to mark the grand opening of the new Conemaugh Diabetes Institute, located at Memorial Medical Center's Downtown Campus.

"Diabetes has emerged as one of the most serious health problems in Pennsylvania, particularly in rural areas," said Congressman Murtha. "Working together, leaders from the University of Pittsburgh Diabetes Institute, the Conemaugh Health System and other community partners will create systems to improve outcomes for people in this region who are living with diabetes and for those at high risk for developing diabetes. It is our expectation that in the future these initiatives will serve as models that can be replicated throughout the United States and applied to our military."

In Cambria, Somerset and Bedford counties alone, more than 13,000 people have been diagnosed with diabetes. The Institute, which is funded by the U.S. Department of Defense, will take a comprehensive approach to managing diabetes, incorporating prevention, education, treatment and research initiatives. Some of the various programs offered at the Institute will include:

- Diabetes Self Management Education (DSME) classes
- Diabetes Prevention Program (DPP)
- Healthy Lifestyles Program
- Diabetes Support Group
- Mount Aloysius/Memorial Medical Center Diabetes Foot Study
- Gestational Diabetes care
- One-On-One Education

"With the tremendous support of Congressman Murtha and the new community partnership forged with UPMC, those affected by diabetes can now get comprehensive care close to home," says Scott Becker, CEO, Conemaugh Health System. "We are very excited to see the kind of positive impact the Conemaugh Diabetes Institute will have not only on those already diagnosed with the disease, but our goal is also to educate those at risk for diabetes, in an effort to stop the disease before it starts."

-more-

"The diabetes epidemic creates challenges that require a comprehensive approach to prevention and treatment," said Linda Siminerio, PhD, Director, UPDI. "To be effective in the fight against diabetes, team work and partnerships are critical. The job is too big and complex to handle it alone. The Conemaugh Diabetes Institute is a prime example of how the collaboration of two entities such as the University of Pittsburgh Diabetes Institute and the Conemaugh Health System can build a bridge to bring the latest research, cutting edge treatments and quality care to a community in need."

One of the missions of the community partnership is to create a system to monitor and support the needs of people affected by diabetes. To accomplish this goal, UPMC's community partners such as Memorial Medical Center's Conemaugh Diabetes Institute, Uniontown Hospital, Highlands Hospital and Indiana Regional Medical Center will track diabetes information.

Eight percent of Pennsylvanians-1.1 million people* have diabetes, and experts estimate that 1.5 million new cases are diagnosed each year in the United States. In fact, newly released statistics from the Centers for Disease Control and Prevention (CDC) note that the incidence of diabetes has increased by more than 14 percent in the past two years. Diabetes accounts for about $7.7 billion in total health care costs every year in Pennsylvania-and $132 billion nationwide. Nationally, diabetes is the fifth leading cause of death, according to the American Diabetes Association. In Pennsylvania more than 11,500 people die each year from the disease. Diabetes is also the leading cause of new blindness, end-stage renal disease and non-traumatic amputations in Pennsylvania.

*720,500 diagnosed and 379,500 undiagnosed

-30-

University of Pittsburgh
DIABETES INSTITUTE
in partnership with University of Pittsburgh Medical Center

CONTACT: Michele Baum
PHONE: (412) 647-3555
FAX: (412) 624-3184
E-MAIL: BaumMD@upmc.edu

MEDIA ADVISORY/PHOTO OPPORTUNITY: CONGRESSMAN JOHN MURTHA CELEBRATES OPENING OF DIABETES CENTER HIGHLIGHTING PITTSBURGH-JOHNSTOWN PARTNERSHIP

WHO: **U.S. Rep. John Murtha, D-12th District,** administrators and officials from the **University of Pittsburgh Diabetes Institute, Children's Hospital of Pittsburgh** and **Conemaugh Memorial Medical Center.**

WHAT: Press conference and grand opening ceremony of the **Conemaugh Diabetes Institute** clinic, a joint venture between Johnstown's **Conemaugh Health System, Children's Hospital of Pittsburgh** and the **University of Pittsburgh Diabetes Institute.**

WHEN: 11 a.m. ET Wednesday, March 22, 2006.

WHERE: **Conemaugh Diabetes Institute,** Conemaugh Memorial Medical Center, Downtown Campus, 320 Main St., Johnstown, Pa.

WHY: Diabetes has become one of the most serious health problems in Pennsylvania, particularly in rural areas. In Cambria, Somerset and Bedford counties alone, more than 13,000 people have been diagnosed with diabetes. Working together, leaders from the University of Pittsburgh Diabetes Institute, the Conemaugh Health System and other community partners will create systems to improve outcomes for people in the Johnstown region who are living with diabetes, and for those who are at high risk for developing diabetes. In the future, these initiatives will serve as models that can be adapted throughout the United States. The **Conemaugh Diabetes Institute** is being funded by the U.S. Department of Defense and will take a comprehensive approach to diabetes management.

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Daily American
Somerset County's Newspaper
America's Coun
Vol. 77, No. 223 Thursday, March 23, 2006 50 Cents

Diabetes institute opens

By SANDY WOJCIK
Daily American Correspondent

A dream became a reality on Wednesday, said Memorial Medical Center President Steve Tucker at the grand opening of the Conemaugh Diabetes Institute, located at Memorial Medical Center's Downtown Campus

Rep. John P. Murtha (D-Johnstown), who joined the administrators from Conemaugh Health System's Memorial Medical Center, Children's Hospital of Pittsburgh and the University of Pittsburgh Diabetes Institute (UPDI) for the grand opening of the facility, echoed Tucker's enthusiasm, saying, "this has been the most important project that I've been involved with."

Murtha said he knew there was a problem with the diabetes epidemic when he asked the surgeon general just how many people in the Air Force are affected by the disease and said he was shocked with the reply.

"He said there were 140,000 people."

By opening facilities like the one in Johnstown, "you could reduce the military budget" by saving money on health care. "Mentally we have to change, we have to educate people," Murtha said.

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"Diabetes has emerged as one of the most serious health problems in Pennsylvania, particularly in rural areas," said Congressman Murtha. "Working together, leaders from the University of Pittsburgh Diabetes Institute, the Conemaugh Health System and other community partners will create systems to improve outcomes for people in this region who are living with diabetes and for those at high risk for developing diabetes. It is our expectation that in the future these initiatives will serve as models that can be replicated throughout the United States and applied to our military."

The director of UPDI, Linda Siminerio, Ph.D., said a facility such as the new Institute takes learning and working on the disease from the universities into the community. "Everything is based on science", she said and because of this funding "we have the opportunity to take the science out to where it belongs.

"The diabetes epidemic creates challenges that require a comprehensive approach to prevention and treatment," said Siminerio. "To be effective in the fight against diabetes, team work and partnerships are critical. The job is too big and complex to handle it alone. The Conemaugh Diabetes Institute is a prime example of how the collaboration of two entities such as the University of Pittsburgh Diabetes Institute and the Conemaugh Health System can build a bridge to bring the latest research, cutting edge treatments and quality care to the community in need."

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Because there are an ever increasing amount of children being diagnosed with the disease, Memorial will be working with Children's Hospital in Pittsburgh, said Amy Sullivan RD, LDN, CDE from the hospital.

She said when a child is diagnosed, "this puts a strain on family."

"This beautiful, state of the art facility, kids in this region will get the best care that they can."

Photo by Sandy Wojcik

A ribbon was cut to symbolize the opening of the new Conemaugh Diabetes Institute in Johnstown Wednesday. Taking part in the ribbon cutting were Carol Harding, director of the Institute, Mrs. Joyce Murtha, Rep. John P. Murtha, Linda Siminerio, Ph.D. Director, UPDI, Amy Sullivan, RD, LDN, CDE from Children's Hospital in Pittsburgh; and Mike Lauf, vice president and business director of Conemaugh Health Systems.

Officials tout new diabetes institute

By RANDY GRIFFITH
THE TRIBUNE-DEMOCRAT

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But the Conemaugh Diabetes Institute represents an army of health-care professionals and scientists, leaders said Wednesday at dedication ceremonies.

"Our job is to bring the science – to leave the ivory tower and bring it to the communities," said Dr. Linda Siminerio, executive director of the University of Pittsburgh Diabetes Institute.

The Conemaugh Diabetes Institute is a collaboration between Conemaugh Health System, the University of Pittsburgh Diabetes Institute and Children's Hospital of Pittsburgh.

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Education and intervention are at the heart of Johnstown's program, which will serve as a support and information center for primary-care doctors.

Using the latest research, the institute's doctors, nurses and dietitians will design individualized programs for diabetes patients referred by those family doctors.

"The most important part of what we are doing here is looking at the statistics and finding out what that means to individual patients," Murtha said. "I'm just thrilled with what is happening here."

Siminerio said the institute hopes to track patients' success with diabetes control.

"We will provide patient reports and physician reports to see how the patient has done, and what he needs to do," Siminerio said.

Diabetes control is vital, Antoinette Franke said after the ceremony. As a nurse and diabetes educator, Franke helps patients understand the importance of nutrition and physical activity.

She meets with newly diagnosed patients to provide 10 hours of training on how to control their diabetes and prevent life-threatening complications.

"If they learn self-management, they are less likely to land in the hospital with a stroke or heart attack," Franke said.

A grant-funded diabetes-prevention program will work with those at risk of developing diabetes.

Those with at least three risk factors who are referred by their doctors are eligible for the free 12-week course, Program Manager Carol Harding said.

Regular physical activity, weight loss and healthy nutrition can delay or even prevent diabetes, Harding said.

Randy Griffith can be reached at 532-5057 or rgriffith@tribdem.com.

TODD BERKEY/THE TRIBUNE-DEMOCRAT

Dr. Linda Siminerio (left), executive director of the University of Pittsburgh Diabetes Institute, talks about a diabetes-screening assessment tool with U.S. Rep. John Murtha, D-Johnstown, his wife, Joyce, and J. Brad Ummer of Flipside Media Inc. on Wednesday at the Conemaugh Diabetes Institute.

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Daily American 3/23/00

CONEMAUGH HEALTH SYSTEM

Open House

Conemaugh Diabetes Institute

Wednesday, March 22 • Noon - 4 p.m.
Memorial Medical Center, Downtown Campus, First Floor

Memorial
Medical Center
Member Conemaugh Health System

+.27 | GeneWyo s ... 32.19 +.71 | McClatchy .72d48.41 +.07 | QwestCm
+.99 | GlaxoSKln1 57a54.00

BUSINESS

THE TRIBUNE-DEMOCRAT ■ THURSDAY, MARCH 23, 2006

Officials tout new diabetes institute

By RANDY GRIFFITH
THE TRIBUNE-DEMOCRAT

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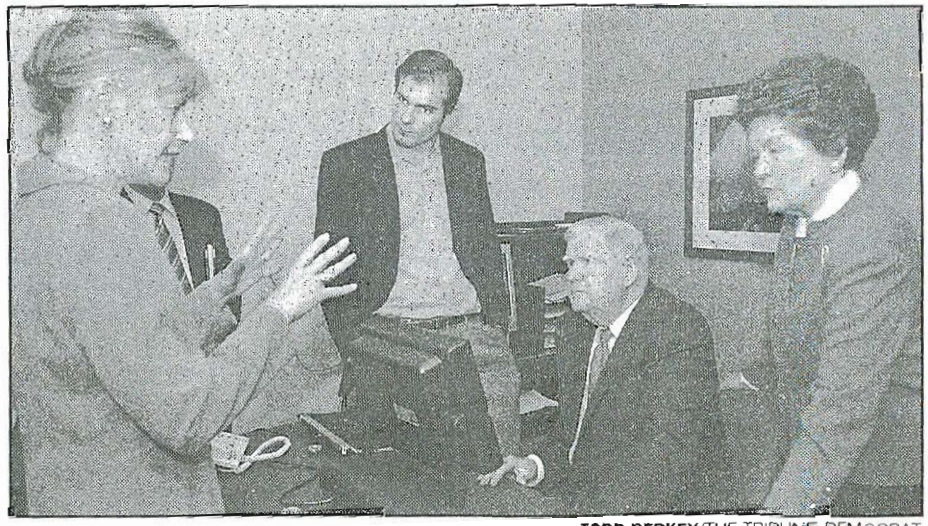

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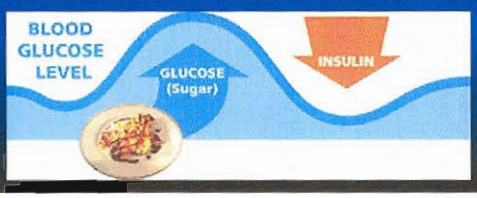
Diabetes Self Management: An Overview

Conemaugh Diabetes Institute

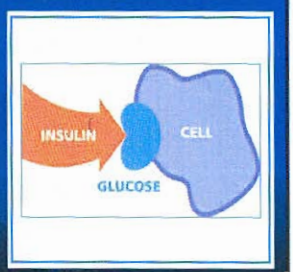
What is Diabetes?

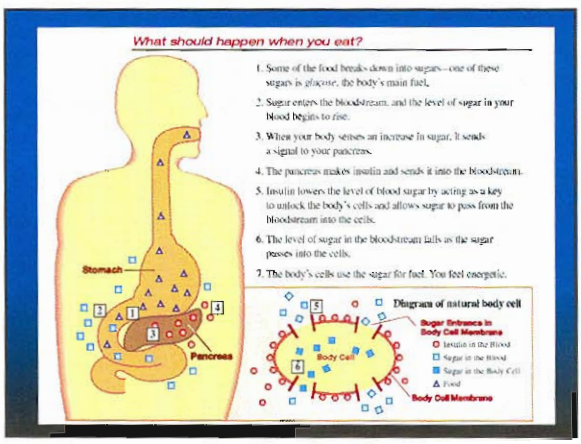
– Diabetes is a chronic progressive condition of impaired glucose metabolism characterized by insulin absence, deficiency and/ or resistance.

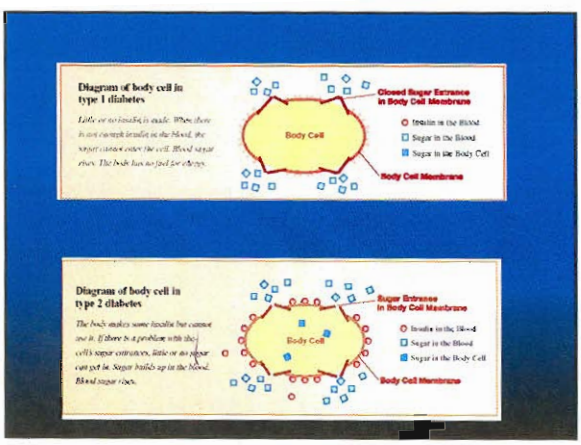


The Basics: Glucose and Insulin

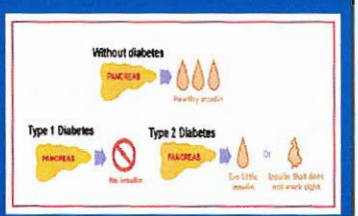
- Glucose comes from food we eat, also the liver and muscles
- Glucose = energy for body
- Blood carries glucose to cells
- Insulin helps glucose into cells







Types of Diabetes



Type 1
Type 2
Gestational
Pre-diabetes/insulin resistance

Blood Glucose Values

- 70-100 mg/dl normal blood sugar
- 100-125 mg/dl pre-diabetes
- >126 mg/dl diabetes

Type 1 Diabetes

-Insulin dependent

-Usually occurs in young people, but can occur in older persons

-Normal body weight

-Prone to ketoacidosis

Symptoms of Type 1

Increased thirst
Increased passing of urine
Increased hunger
Sudden weight loss
Dehydration
Extreme tiredness

Causes of Type1

Family history

Viruses

Body's own white blood cells have destroyed the insulin-making cells in the pancreas

Type 2 Diabetes

Insulin resistant -makes it but can't use it

Over 40 years old

Overweight

Family history

Given birth to a baby over 9 pounds

Symptoms of Type 2 Diabetes

- Dry itchy skin
- Feeling tired
- Frequent infections
- Frequent passing of urine
- Blurry vision/slow healing
- Increased thirst
- Increased hunger





Treatment Tools

Education
Meal planning
Exercise
Medicines
Monitoring
Diabetes tests

Diabetes Self Management Education

- Balance is the key to diabetes self management

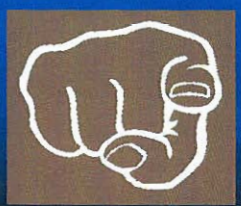
You Need To Balance

- Diet
- Physical activity
- Medication
- Support of:
  - family
  - friends
  - community
  - health care team

Goals of Management

- Maintain blood glucose to near normal
- Achieve and maintain healthy weight
- Integrate diabetes with lifestyle
- Prevent or delay progression of complications

YOU ARE IN CHARGE!!!



DCCT Study Findings

- Lowering blood sugar reduces the risk for:
  - Eye disease
    - 76%
  - Kidney disease
    - 50%
  - Nerve disease
    - 60%
  - Cardiovascular disease
    - 35%

Important tests to have done…

Hemoglobin A1C	every 3 months
Blood Pressure	every visit
Lipid panel	ever year
Urine test (microalbumin)	every year
Eye exam	every year
Flu shot	every year

Pneumonia shot- if given before the age of 65, need a booster if 5 years passed since the 1st dose if given at age 65 or older only one dose needed

What is an A1C?

- A blood test that measures the average blood sugar over the last three months
- Normal 4-6%
- Diabetic goal
  - ACE goal < 6.5
  - ADA goal < 7
- For every 1% decrease in A1C, complication risk drops at least 25%

The Good, The Bad, and The Ugly about Cholesterol

What is Cholesterol??

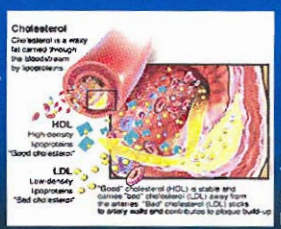
- Type of fat that comes from the food we eat
- It also is produced by the liver

- Cholesterol in moderate amounts is essential for good health
- It's the excess found in foods that get us in trouble

What is Cholesterol made of?

- Three types of cholesterol

HDL- High Density lipoproteins also known as "good cholesterol."



LDL- Low density lipoproteins also known as "bad cholesterol."

Triglycerides- a form of fat in the blood stream that is used for energy.

Do you know what your cholesterol goal is?

<200

High Density Lipoproteins H=Healthy

- HDL is referred to as good cholesterol
- Clears the LDL out of the blood vessels when they are clogged.
- Unwanted LDL is transported to the liver where it is removed from the body.

What should my HDL level be?

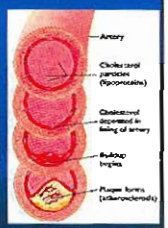
- *The HIGHER the better !*
- For women an HDL level > 55
- For men an HDL level > 45

What should I do when my HDL level is to low?

- If your HDL level is low there are a few things you can do:
  - » Exercise
  - » You must exercise regularly for it to make a difference.
  - » Drink a glass of wine- preferably red

Low Density Lipoproteins L=Lousy

- LDL is also known as bad cholesterol
- LDL sticks to the walls of arteries where it combines with other substances to form plaque
- Excessive amounts of plaque in your blood stream can cause your arteries to block.



What should my LDL level be?

- High LDL levels can lead to serious health risk.
- Goal:
  - < 100
  - For people with heart disease < 70

Triglycerides

- A form of fat that is stored in artery walls.
- Stored for later use as energy.
- The extra calories you eat are stored as triglycerides.

What is your Triglyceride goal?

<150

Ways to lower your lipids

Lifestyle changes:

- •diet modification
- •exercise
- •weight management

Drug therapy

Drugs That Lower Your Lipids

"Statins"

Simvastatin- Zocar
Pravastatin- Pravachol
Lovastatin- Mevacor
Fluvastatin- Lescol
Rosuvastatin- Crestor
Atorvastatin- Lipitor

- Side effects-muscle aches

Drugs that lower your lipids

Bile acids- Questran, Colestid, Welchol

- Side effects- GI upset

Niacin

- Side effects- flushing, GI upset, liver damage

Zetia- new class called cholesterol absorption inhibitors

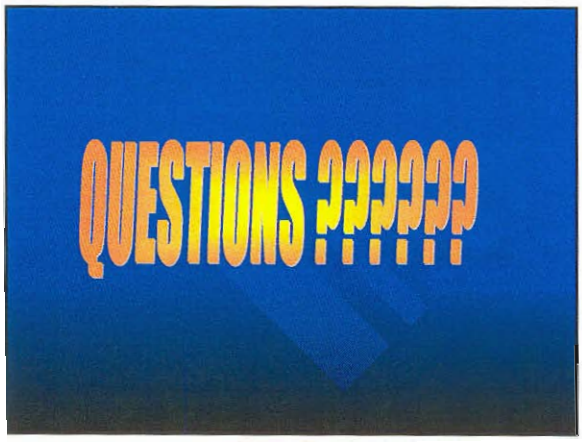
Drugs to Lower Triglycerides

•Fibrates

Lopid- Gemfibrozil
Tricor- fenofibrate
-Side effects- GI Upset

•Omega fatty acids

Fish oil
Flax seed oil


QUESTIONS ¿¿¿¿¿¿¿

Blood Glucose Monitoring

What do the numbers mean?

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Blood Glucose Targets

- Blood glucose levels recommended by the ADA / AACE
  - Before meals 80-110 mg /dl
  - 2 hours after a meal -less than 140mg/dl
  - at bedtime - 100-140 mg/dl

Factors That Affect Blood Sugar Levels :

- Food/beverages
- Medicine
- Exercise
- Stress
- Timing of food/meds
- Time of day test is performed
- Related to testing device:
  - Outdated strips
  - Technique error
  - Meter malfunction
  - Spoiled materials

Event	Effect on sugar	When to test
Eating/drinking	increases	before meals 2hrs after meals bedtime
Exercise	decreases	before and after exercise
Meds	decrease	before meals
Stress/illness	increase	during/after If S/S of high blood sugar

Alternative Site Testing

NOT recommended when your blood sugar is rapidly rising or falling

When To Test?
Based on treatment & BG Goals

- There are many options:
  - 1-8 times per day
  - Before meals and bedtime
  - Fasting and 2 hours after meals
  - Before and after meals
  - Once a day- at varying times
  - Fasting and once more at different times of the day
  - Daily before breakfast

Ask Yourself WHY?

- Look for patterns, not just one glucose result. Then ask yourself,
  - Did I change my meal plan?
  - Did I change my exercise routine?
  - Did I forget to take my medicine?
  - Was I stressed?
  - Am I getting sick?

How to Use Your Results

- Keep Accurate records
- Look for patterns in your results
- Try to closely follow your diabetes plan
- Meet with your diabetes team to discuss your results
- Continue to learn
- **ALWAYS** take your log book to your doctor appointments

When to call the Doctor

- Two or more high results in 24 hour period
- Two or more low results in a 24 hour period
- Ketones in urine
- Illness
- Vomiting

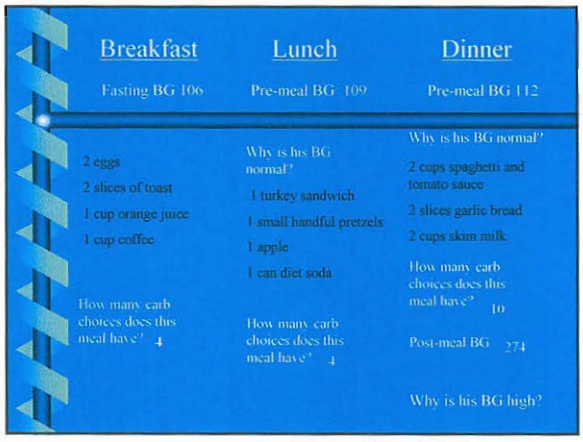
Patterns

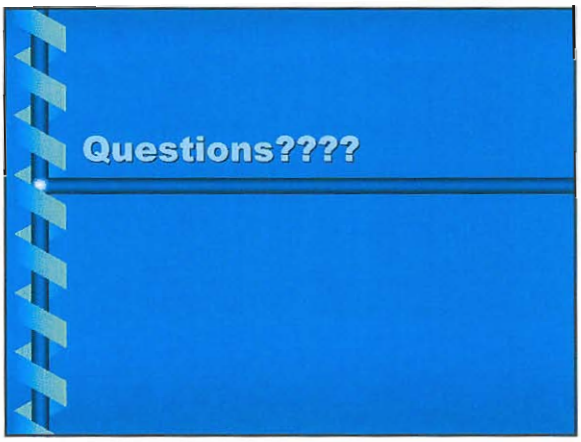
7am	11 am	4pm	9 pm
230	120	100	140
193	115	126	147
188	135	85	129
158	100	125	132

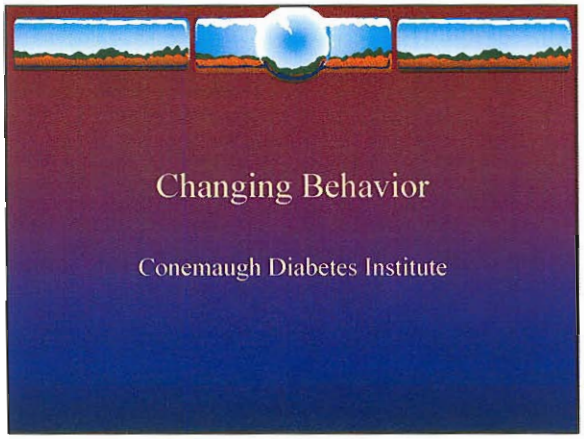
Patterns

7am	11 am	4pm	9pm
107	185	145	132
125	203	128	133
115	197	117	141
103	215	113	124

Breakfast	Lunch	Dinner
Fasting BG 91	Pre-meal BG 247	Pre-meal BG 110
1 1/2 cups dry cereal	Why is his BG high?	Why is his BG Normal?
2 slices of toast with margarine	1 hamburger on bun	6oz. sirloin steak
12 oz. orange juice	1 small french fry	1/2 cup mashed potatoes
1 cup skim milk	medium diet soda	1 cup green beans
		1 cup salad with low-fat dressing
How many carb choices does this meal have? 8	How many carb choices does this meal have? 4-5	How many carb choices does this meal have? 1-2
		Post-meal BG 55
		Why is his BG low?


Breakfast
Fasting BG 106
2 eggs
2 slices of toast
1 cup orange juice
1 cup coffee
How many carb choices does this meal have? 4
Lunch
Pre-meal BG 109
Why is his BG normal?
1 turkey sandwich
1 small handful pretzels
1 apple
1 can diet soda
How many carb choices does this meal have? 4
Dinner
Pre-meal BG 112
Why is his BG normal?
2 cups spaghetti and tomato sauce
2 slices garlic bread
2 cups skim milk
How many carb choices does this meal have? 10
Post-meal BG 274
Why is his BG high?


Questions????


Changing Behavior
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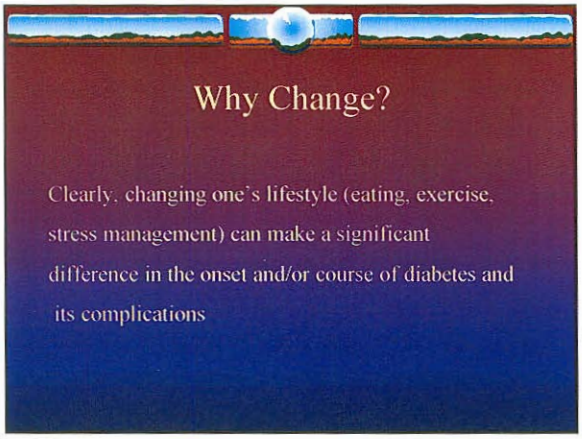
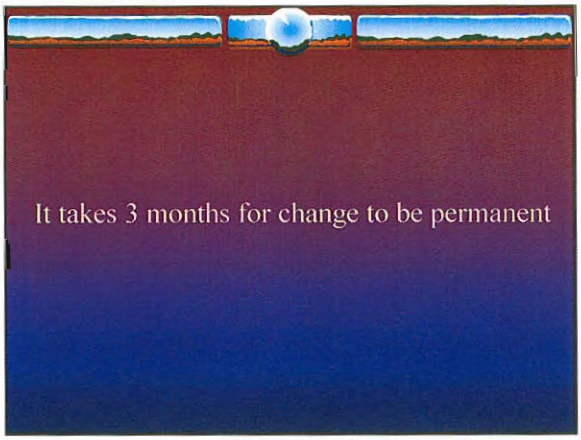
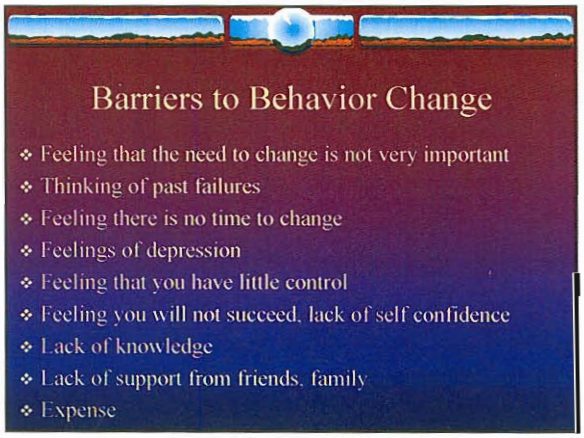
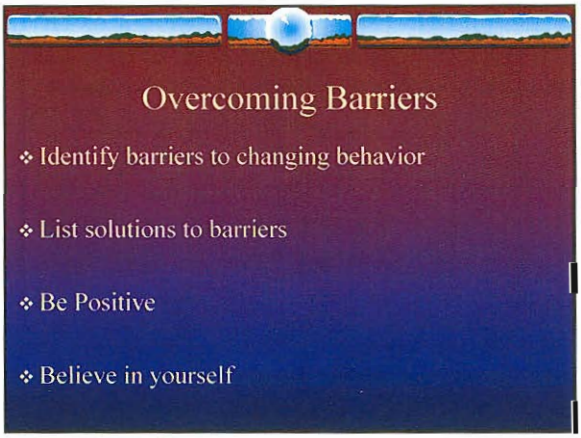
What is Change?
Change is replacing old ways of doing things with a new way
Change requires that YOU choose to change
You replace old habits with new more healthy habits


Why Change?
Clearly, changing one's lifestyle (eating, exercise, stress management) can make a significant difference in the onset and/or course of diabetes and its complications


It takes 3 months for change to be permanent


Barriers to Behavior Change
Feeling that the need to change is not very important
Thinking of past failures
Feeling there is no time to change
Feelings of depression
Feeling that you have little control
Feeling you will not succeed, lack of self confidence
Lack of knowledge
Lack of support from friends, family
Expense


Overcoming Barriers
Identify barriers to changing behavior
List solutions to barriers
Be Positive
Believe in yourself

Examining Your Feelings

- Problem- blood sugar is 240
- Negative thoughts= 240 BS! I am doomed! My diabetes is out of control!
- Positive thoughts= Ok its higher than I want but a walk should help it, I can take care of this. I will do better!

How to change behavior

- Make a list of areas you want to change related to your diabetes(diet, exercise etc.)
- Pick ONE area you want to work on first
- State the problem
- Set the goal

Goal Setting

- Goals should be SMART
  - Specific
  - Measurable
  - Achievable
  - Realistic
  - Time frame

Goal Setting

- Writing down your goals has been scientifically proven to more than **double** your chances of achieving them
- Examples:
  - I will lose 10 pounds in three months
  - I will test my blood sugar twice a day

Achieving Your Goals

- Identify ways you can meet the goal
- Reward your self when you meet your goals
- Plan ahead
- Be prepared
- Avoid making excuses
- Avoid "all or none" behavior
- Think positive

Stay Away From Those Old Habits

- **Do not** stop a new habit
- If you backslide ask yourself:
  - What caused me to go back to my old habit?
  - How can I prevent this in the future?
  - How can I get back and stay on track?

Positive thinking

- Have faith in yourself
- If you "slide" pick yourself up and start again
- Your good health depends on YOU.

Empowerment

Health care professionals are experts in diabetes care

But...

You are the expert on your own life

Empowerment

•My role is to help you make informed decisions to achieve your goals

•Your role is to be well informed and active in planning your care

Goal Setting: 7 Self-Care Behaviors

- Healthy Eating
  - Make better food choices
  - Reduce portion sizes
  - Follow meal plan
- Being Active
  - Start to exercise
  - Exercise longer
  - Exercise more often
  - Follow exercise plan

Goal Setting: 7 Self-Care Behaviors

- Monitoring
  - Follow monitoring schedule
  - Monitor more often
  - Monitor health status
- Taking Medication
  - Take medication on time
  - Miss fewer medications
  - Take medications as prescribed

Goal Setting: 7 Self-Care Behaviors

- Problem Solving
  - Identify potential problems
  - Plan problem situation treatment
  - Prevent problem situations
- Healthy coping
  - Cope with diagnosis of diabetes
  - Adapt to lifestyle changes
  - Get support from family friends
  - Attend Support Group

Goal Setting: 7 Self-Care Behaviors

- Reducing Risks
  - Stop smoking
  - Get health checkups
  - Perform daily self-care activities

Case Study

- John is 60 pounds overweight, smokes,rarely exercises and doesn't test his glucose levels. He eats in restaurants everyday at lunch time and doesn't follow his diet.
- What are areas might he consider changing?
- What might be some barriers?
- How can he overcome these barriers(solutions)?
- Rewards???

The Ultimate Reward

- Prevent/delay complications
- Improved quality of life

Diabetes : Nutrition Component

Eileen T. Fiorina, RD, CNSD LDN
Conemaugh Diabetes Institute

Main Topics

- Healthy Eating
- Carbohydrate Counting/Exchange Lists
- Food Label Reading
- Meal Planning
- Measuring Tips
- Eating Out/Special Occasions
- Sick Day Management
- Other DM resources

Diabetes is Managed by:

- Diet – food what & how much is eaten
  - Increases Blood Glucose Levels (BGL)
- Medication
  - May decrease or increase BGL depending on medications
- Exercise
  - Decreases BGL
- Stress
  - Increases BGL
- Infection/illness
  - Increases BGL

Healthy Eating

- Dietary Guidelines for Americans
  - Whole grains vs. white flours
  - More fruits and vegetables to increase fiber
  - Low fat milks or yogurts
  - Healthy kinds of fat
    - Monounsaturated fats
  - Less salt
  - Exercise

What are Nutrients?

- Carbohydrates
- Protein
- Fat
- Vitamins & Minerals
- Fluids

Where should calories come from??

- Carbohydrate
  - 50-55%
  - 4 calories/gram
- Protein
  - 10-20%
  - 4 calories/gram
- Fat
  - 25-30%
  - 9 calories/gram

What percentage of foods are converted to blood sugar?

- Carbohydrate - glycogen
  - 100%
- Protein - muscle
  - 50%
- Fat - ketones
  - Less than 10%

What are Carbohydrates?

- Starches
- Starchy Vegetables
- Fruits & Juices
- Milk & Yogurt
- Sweet Snacks
- Most Salty Snacks

What are Proteins?

- Animal Sources
  - beef, pork, poultry, fish, cheese, eggs
- Vegetable Sources
  - peanut butter, tofu, dried beans & peas

What are fats?

- Monounsaturated – help HDL's remain high
- Polyunsaturated – remain the same
- Saturated – lower HDL, increase LDL

The goal is to reduce saturated fats and replace with unsaturated

Water is needed for:

- Needed to form digested juices
- To carry nutrients
- Lubricated joints & muscles
- Regulates body temperature
- ¾ of body fluid is water
- Encourage 4-6 (8oz.) glasses daily

Fiber

- Indigestible part of plant food
- Provides bulk
- Reduces BGL
- Can help reduce blood fat & cholesterol levels
- Diet should include 20-35 grams of fiber daily
- Major sources are whole grains (bread, cereals, vegetables, fruits, nuts & seeds)

Carbohydrate Counting

- Magic Number =

15 grams

Total Carbohydrate

- 1 starch
- 1 fruit
- 1 milk

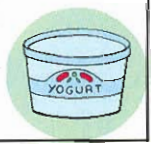
**All of these are equal to 1 carb exchange.

Carbohydrate Counting

- The following all equal =

1 Carbohydrate Serving:

- 1 carb serving
- 1 starch
- 1 fruit
- 1 milk
- 15 grams total carbohydrate



Label Reading

- Serving size/ per- container
- Total calories
- Total carbohydrates
  - Sugar
  - Dietary fiber
- Total Fat
  - Monounsaturated
  - Unsaturated
  - Trans
  - Saturated

Nutrition Facts

Serving Size ½ cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 90 Calories from Fat 30

	% Daily Value*
Total Fat 3g	**5%**
Saturated Fat 0g	**0%**
Cholesterol 0mg	**0%**
Sodium 300mg	**13%**
Total Carbohydrate 13g	**4%**
Dietary Fiber 3g	**12%**
Sugars 3g	
Protein 3g	

Vitamin A 80% • Vitamin C 60%
Calcium 4% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

What is Meal Planning?

- It is knowing:
  - What to Eat
  - When to Eat
  - How much to Eat

Meal Planning- Basic Guidelines

- Eat at least 3 meals
- Eat regularly throughout the day
- Eat even amounts of high carb foods throughout the day
- Use nonstarchy veggies and free foods as fillers & snacks
- Test BGL regularly!!

When to eat

- Eat at the same time every day
- Eat every 4-5 hours
- Do no skip meals
- Time meals to synchronized diabetes medications with peak times
- Some may need a snack between meals
- Snack at bedtime daily (carb & protein)

How much to eat?

- **Balance food intake with activity**
- **Measure foods - monitor portion size**
- **Eat the correct carbohydrate servings per meal**

Sample Breakfast: 4 Carbs

• ½ Cup Oatmeal	Or	2 whole wheat toast
• 1 Cup Skim milk		1 egg scrambled
• 1 Whole wheat toast		½ Cup OJ
• 1 T. Peanut butter		1 Cup Skim milk
• 1 small banana		1 Cup coffee/tea
• 1 Cup coffee/tea		

Eating Out

- **Possible Barriers**
  - Temptation to overeat
  - How to fit foods into a meal plan
  - Food preparation methods
  - Mealtimes
- **Solutions??**

Tips for Eating Out: All foods can fit!!

- **Plan ahead**
  - Call restaurants or go on line for menus, prep. methods, or specials
- **Focus on PORTIONS**
- **Count carbs**
- **Fill up on free foods**
  - Non-starchy veggies, diet sodas, water
- **Ask server to remove bread from table**
  - Unless counting as a carb

Tips for Eating Out: All foods can fit!!

- **Ask for items or for the item to be prepared differently**
- **Skip fried foods and buffets**
- **Special requests:**
  - Ask for items to be on the side (dressings, butter, etc.)
  - Ask for items to be served without sauces, butter, etc.
  - Low calorie salad dressing
  - Fruit for dessert

More Restaurant Eating Tips…

- **Choose More Often**
  - Broth soups
  - Fresh fruits and veggies
  - Baked, broiled, grilled items
  - Small portions
  - Light desserts (share)

Alcohol

- Not a food- no nutritional value
- Provides 7 calories/gram – converted into fat
- Depressant
  - May lower BGL
- Reacts with medications
- Stimulates appetite
  - Could make weight control more difficult

Counting Alcohol

- Beer (12 oz.)
  - Regular = 1 serving carb, 2 fats
  - Light = .5 serving carb, 2 fats
- Liquor (1 ½ oz.)
  - Gin, rum, scotch, vodka, whiskey = 0 carb, 2 fats
- Wine (4 oz.)
  - Dry white, red, Champagne = 2 gm carb, 2 fats
  - Light wine = 1 fat
  - Sweet wine = ½ serving carb + 1 1/2 fats
  - Wine cooler = 1 serving carbs + 2 fats

Areas of Interest

- Sugar substitutes
- Sugar Alcohols
- Low carb items –may contain more fat
- Sugar free items – may still contain carbohydrates

Special Occasions

- Weekends, Holidays, Vacations
- Plan ahead
- Take snacks
- Stick to some eating schedule
- Account for more activity or specialty foods

Sick Days

- Everyone gets sick: cold, flu, fever & ect.
- Interrupt diabetes control – elevated BGL
- Everyone's illness is different & adjustment must be personalized

What should be done during illness?

- Maintain Adequate hydration
  - Drink 8 oz of calorie containing fluids if on liquids
    - Drink 8 oz of carb free fluids if on regular diet to maintain fluid balance
  - Consume caffeine free liquids
  - Caffeine acts as a diuretic and should be avoided
  - Drink electrolyte beverages to replace electrolytes
    - Bouillon, broth, clear canned soups, sports drinks

What should be done during illness?

- Continued
- Substitute clear liquids or soft foods if unable to tolerate regular foods
- Patients should have 200 grams of carbs per day evenly divided
- If unable to keep food down – sipping diet-
  - 15 grams of carbs every 1-2 hours

15 Gram of Carbohydrate Foods:

- ½ C regular soda
- 1 regular popsicle
- 5 lifesavers
- 1/3 C milkshake
- ½ C cooked cereal
- 1/3 c frozen yogurt
- ½ C regular ice cream
- ¼ C regular pudding
- 1 slice toast
- ½ C regular jello
- 1 C yogurt
- ½ C Apple Juice
- 6 saltines
- 1 C Gatorade
- ¼ C Sherbet

Other Issues:

- Constipation – increase fiber, increase fluids, and encourage mobility
- Poor appetite – replace meals with liquid supplements, offer other high calorie carbohydrates, may need to adjust diabetic medications according to calorie intake
- Food Intolerances – especially to lactose, add alternate carbohydrates

Other DM Resources

- Diabetic cookbooks, magazines
- Websites
  - www.diabetes.org
  - www.eatright.org
  - www.splenda.com
  - Any fast food website- check nutrition facts
- TV
- Books
- Support Groups

Exercise

Benefits of Exercise

- Reduced blood glucose and glycosylated hemoglobin levels.
- Improved glucose tolerance.
- Increase strength, flexibility, balance and coordination
- Improved peripheral and insulin sensitivity.
- Improved blood lipid levels.
- Decrease blood pressure in hypertensives.

More Exercise Benefits

- Regularity
- Increased caloric expenditure resulting in reduction in or maintenance of body weight.
- Reduction in body fat and preservation of lean body mass.
- Improved psychological well being including enhanced quality of life and increased self-esteem.

How Do I Get Started?

- Consult with your physician before starting any exercise program
- Set realistic goals:
  - What do you want to achieve?
  - Short & long term exercise goals

Components of an Exercise Program

- Warm-up
- Weight-bearing aerobic exercise
- Strength training
- Cool down

Before starting any exercise program, contact an Exercise Physiologist or Physical Therapist who is familiar with diabetes.

Guidelines for an Exercise Program

- *Always* perform 10 minute warm-up and 10 minute cool down using a low intensity activity and stretching exercises
- Work up to 20-30 minutes of weight-bearing aerobic exercise
- Incorporate a strength training program designed for all limbs, trunk and back muscles

Exercise

Caution!

- If you have been diagnosed with retinopathy, neuropathy or or nephropathy, you should consult with physician before starting strength training.)

HealthPLACE/HOPE Program

Exercise

Warm-up

- Slowly perform your choice of aerobic exercise to warm-up large muscles (for example: walk slowly)
- Conduct a stretching program using all major muscle groups
- Include range of motion exercises (for example: arm circles, rolling shoulders and shoulder touches)

HealthPLACE/HOPE Program

Exercise

Benefits of Warm-Up

- Increase and maintain full range of motion, balance and agility
- Decrease muscle soreness
- Reduce the risk of injury
- Increase blood flow to the working muscles

HealthPLACE/HOPE Program

Exercise

American College of Sports Medicine Recommendations for Stretching

- Stretch 5-7 days a week
- Hold for 15-30 seconds
- Repeat 3-5 times

Guidelines:

- Slowly stretch each muscle group to the point of slight discomfort
- Stretching should not cause pain
- Never bounce or hold your breath while stretching

HealthPLACE/HOPE Program

Exercise

Aerobic Exercise

- **Definition** – activities that utilize large muscle groups and are rhythmic in nature
- Focus should be on ***Weight-Bearing Aerobic Exercise*** which places a healthy demand on the bones causing them to work against gravity .
- Non –weight bearing best choice for those at risk for orthopedic injury.

HealthPLACE/HOPE Program

Exercise

Examples of Weight-Bearing and Non Weight-Bearing Aerobic Exercise

Weight-Bearing	Non Weight-Bearing
Walking	Swimming
Hiking	Water aerobics
Dancing	Chair aerobics
Stair climbing	Cycling

Non weight-bearing exercise may be appropriate for individuals with arthritis, severe osteoporosis, fractures, or other orthopedic limitations.

HealthPLACE/HOPE Program

Exercise

American College of Sports Medicine Recommendations for Aerobic Exercise

- Exercise for 20-30 minute sessions
- Perform at least 3-7 days a week (Daily if on insulin therapy).
- Goal of 150 minutes for the whole week

Individuals may start exercising in multiple 10 minute intervals and increase the time in small increments until one 20-30 minute session is achieved.

HealthPLACE/HOPE Program

Exercise

Activity vs. Exercise

Inactivity	*Activity*	*Exercise*
Watching TV	Gardening	Biking
Reading	Golf	Hiking
Computer	Shopping	Walking
	Cooking	Aerobic class
	House cleaning	Jogging
	Basketball	Rowing
	Doubles tennis	Strength training

HealthPLACE/HOPE Program

Exercise

Exercise Intensity

The purpose of monitoring your exercise intensity is to ensure that you are receiving the benefits of the exercise session without experiencing injury of discomfort.

- Target Heart Rate (THR) Scale
- Rate of Perceived Exertion (RPE) Scale

It is important to exercise at a level that you are comfortable with and is consistent with your goals.

HealthPLACE/HOPE Program

Exercise

Metabolic Control Before Exercise

- Monitor blood sugar before and after exercise.
- Avoid exercise if fasting glucose levels are >250mg/dl and/or ketones are present.
- Eat extra carbohydrates or carry carbohydrate containing food or beverage if glucose levels are <100 mg./dl.
- Identify when changes in insulin or food intake are necessary.
- Learn the glycemic response to different exercise conditions.

Exercise

Benefits of Strength Training

- Increase muscle strength of arms, shoulders, legs, hips and back
- Maintain bone mass
- Improve balance, coordination and flexibility
- Maintain functional independence (reduce risk of falls)
- Increases resting metabolic rate.

HealthPLACE/HOPE Program

Exercise

Types of Strength Training Exercises

- Exercise bands (Thera-Band®)
- Weight machines
- Dumbbells

It is recommended that a person starts out with light resistance and gradually increases resistance or weight over time.

HealthPLACE/HOPE Program

Exercise

American College of Sports Medicine Recommendations for Strength Training

- Strength train 3 days a week with one day rest between sessions
- Perform 2-3 sets of 8-10 repetitions of each exercise
- Utilize proper body mechanics to reduce risk of injury

HealthPLACE/HOPE Program

Exercise

Always Use Proper Breathing

- When performing aerobic or strength training exercises, it is ***VERY*** important to breathe…
  - for strength training exercises, exhale on exertion
  - for aerobic exercises, remember to breathe evenly and NEVER hold the breath!

HealthPLACE/HOPE Program

Exercise

Benefits of Cool Down

- Decrease dizziness
- Increase flexibility
- Reduce muscle soreness
- Allow heart rate to return back to resting levels

Always complete a 10-15 minute cool down consisting of low intensity activity and stretching.

HealthPLACE/HOPE Program

Exercise

Stop Exercise If You Experience… and call your Physician

- Chest pain/pressure
- Sweating with cold/clammy skin
- Persistent pain
- Dizziness
- Nausea
- Fainting
- Confusion
- New or increased chest, jaw, back or arm pain that does not go away with rest
- Severe shortness of breath
- Excessive fatigue
- Poor recovery

HealthPLACE/HOPE Program

Exercise

Precautions

- Cotton-polyester socks to prevent blisters
- Proper Footwear
- Diabetes education bracelet or shoe tag.
- Proper Hydration
- Dress for the weather.

Exercise

Review of Exercise Guidelines

- Start slow
- Progress gradually
- Remember to have proper body alignment
- Stay hydrated (drink plenty of fluids)
- Dress appropriately wearing comfortable shoes and clothing
- Perform **3** days strength training and **150 minutes** of weight-bearing aerobic exercise per week

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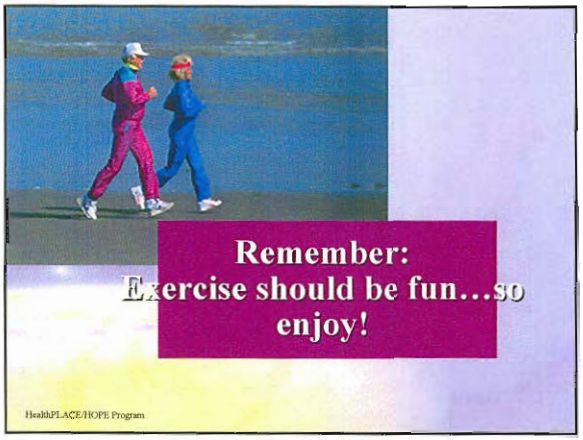

Remember:
Exercise should be fun…so
enjoy!
HealthPLACE/HOPE Program

Diabetes Self Management Education

Eileen T. Fiorina, RD, CNSD, LDN
Conemaugh Diabetes Institute

Topic Overview

- Living with Diabetes
- Stress

Living with Diabetes

- Diabetes is a life long condition
- Diabetes effects many aspects of a persons life

What effect has diabetes had on your life??

Diabetes effects a person's life.

- Need for a regular schedule
- Change in eating habits
- Daily medication and monitoring
- Possible changes in relationships
- Fear of future effects on life and health

Living with Diabetes

- Identification of self as person with diabetes
  - Who have you told?
  - Who needs to know? Why?
- How have others reacted when you told them you have diabetes?
- How would you like others to respond?

Feelings related to diabetes

- Everyone has feelings/thoughts
  - What were your feeling at first?
  - What are your feelings now?
  - What are your fears/concerns?
  - What is the worst thing about diabetes for you?

Feelings related to diabetes

- Fear/worry about long-term effects of diabetes
- It is common to go through the stages of the grieving process:
  - Denial
  - Anger
  - Depression
  - Adaptation

Feelings related to diabetes

- Feelings/stress levels affect BGL and your BGL affect your mood and your ability to cope with stress
- It is important to acknowledge feelings and reasons for them
- Thoughts influence feelings which influence motivation and behavior

How do you view diabetes???

- CHALLENGE
- OPPORTUNITY
- DISASTER
- BURDEN

Support Network

- Important to recognize the need for a support person:
  - Family, friend, healthcare team, others with diabetes (support group)
  - Living with diabetes is difficult but help and support are available

Support with your healthcare team

- The role of the healthcare team is to provide
  - Information
  - Strategies to help you change behavior
  - Support

Stress

Defining Stress

- Stress is the way you react – physically and emotionally to change
- Stress is defined by our perceptions of a situation, not necessarily the reality
- Stress can be positive or negative

Positive Stress

- Short term
- Can help you concentrate, focus, perform
- When the challenge is met, time is taken to relax
- The relaxation phase allows you to build up physical and emotional reserve to meet the next challenge

Negative Stress

- Stress becomes negative when you stay geared up
- Don't or can't relax after meeting the challenge
- When stress becomes a constant ongoing cycle, your health and well-being can suffer

Negative Stress

- You can stop the cycle of negative stress by becoming aware of your stress, practicing relaxation techniques and developing a positive attitude and lifestyle.

Fight or Flight: How the body responds to stress

- The body releases high levels of stress hormones (catecholamines, glucogon, cortisol, growth hormone)
- These hormones increase your heart rate, blood pressure, and BGL

Fight or Flight: How the body responds to stress

- An increase in BGL provides extra energy to fight off stress or run away from it
- If this extra energy is not used it can leave you feeling tense and tired or cause a headache

Physical Signs of Stress

- Back pain
- Chest pain
- Cold hands
- Constipation
- Diarrhea
- Headaches
- Indigestion
- Muscle tension
- Racing heart
- Shortness of breath
- Changes in BGL

If these symptoms are sudden or severe, or if they persist, contact your doctor.

Psychological Signs of Stress

- Anxiety
- Trouble thinking clearly
- Forgetfulness
- Frustration
- Trouble making decisions
- Sleeping poorly
- Short temper
- Nervousness

Some of these signs are similar to signs of hypoglycemia. If you experience these symptoms, check your blood glucose and see if it is low.

Awareness of Stress

- You need to be aware of the things that make you feel stressed (stressors) and the way you feel when under stress
- What is stressful for you?
- How do you feel when you are stressed?

Major Life Stresses

- Any changes positive or negative that can affect your lifestyle
- What are major stresses in your life?

Minor Life Stresses

- Daily annoyances that are part of day to day life
- What are minor stresses in your life?

Top **10** Daily Hassles

A survey of middle-aged adults revealed the top ten daily hassles:

1. Concerns about wt.
2. Health of a family member
3. Rising prices
4. Home maintenance
5. Too many things to do
6. Misplacing or losing things
7. Yard work or outside home maintenance
8. Property, investments, or taxes
9. Crime
10. Physical appearance

Coping Strategies

- Problem-focused coping
  - Going to the source of the problem to fix it
- Emotion-focused coping
  - Learning to live with the stress by changing the way you respond to it
  - How do you cope with stress?
  - How do you usually act before, during and after a stressful situation?

Coping Strategies

- You can break the cycle of negative stress by learning ways to help yourself relax

Relaxation Techniques

- Deep Breathing
  - Breathing slowly and deeply is one way you can "turn off" your stress reaction and "turn on" your relaxation response
- Clearing your mind
  - Concentrate on one pleasant thought, word or image
- Autogenics
  - Mind over matter

Relaxation Techniques

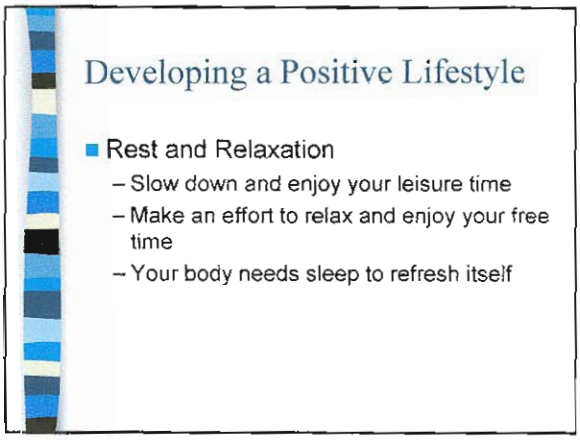
- Visualization (mental vacation)
  - Unlike clearing your mind, where you focus on one single image – this allows your imagination to run free
- Progressive Muscular
  - Can help you feel difference between tension and relaxation
- Stretching
  - Loosen up tight muscles

Coping with Positive Thinking

- Positive thinking is giving yourself the go-ahead to succeed
- Develop a positive attitude
  - Self talk
  - Rehearsal
  - Develop an action plan

Developing a Positive Lifestyle

- Exercise
  - Physically fit people handle stress more easily than those who are not
- Nutrition
  - Eating well and limiting your use of salt, sugar, caffeine and alcohol can promote health and help reduce stress

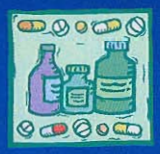

Developing a Positive Lifestyle
Rest and Relaxation
– Slow down and enjoy your leisure time
– Make an effort to relax and enjoy your free time
– Your body needs sleep to refresh itself

Diabetes Medications

Conemaugh Diabetes Institute

Classes of Medications

- Sulfonylureas
- Meglitinides
- Biguanides
- Alpha Glucosidase Inhibitors
- Thiazolidinediones-TZD's
- Incretin Mimetics



Sulfonylureas

Most common drugs in this class:

- •Glipizide (Glucotrol, Glucotrol XL)
- •Glyburide (Micronase, Diabeta, Glynase)
- •Glimepiride (Amaryl)

How do they work?

- •Stimulate the pancreas to make more insulin
- •Work for up to 24 hours
- •Lowers fasting and post prandial blood sugar

Sulfonylureas

Advantages:

- •May decrease AIC 1.5-2%
- •Inexpensive

Side effects:

- •Weight gain (4.5-11 lbs.)
- •Low blood sugar

How to take:

- •Take glipizide 30 min before the first meal of the day
- •All others take with first meal of the day

Meglitinides

Drugs in this class:

- Repaglinide(Prandin)
- Nateglinide (Starlix)

How do they work?

- •Stimulate the pancreas to make more insulin
- •Work only for about 4 hours after meals
- •Only effects post prandial sugars – NOT FASTING!

Meglitinides

Advantages:

- May decrease A1C by 1-2%

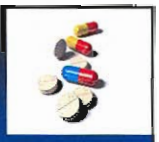
Side effects:

- Weight gain
- Low blood sugar

How to take:

- Take up to 30 minutes before meals
- No meal= No pill

Biguanides



Drug in this class:

- •Metformin (Glucophage, Glucophage XR)
- •Liquid Form (Riomet)

How does it work?

- •Helps your body produce less glucose from the liver
- •Helps insulin work better
- •Reduces glucose absorption in the intestines
- •Takes up to 2 weeks to see maximum effect

Biguanides

Advantages:

- •Can decrease AIC 1.5-2%
- •Does not cause low blood sugar or weight gain
- •May also lower triglycerides and cholesterol

Side effects:

- • Nausea and Diarrhea

How to take:

- •Take with breakfast and supper

Biguanides

Precautions:

- DO NOT use when having a heart cath or x-ray procedure involving dye (48˚ or until creatinine normal)
- DO NOT use if you drink excessive amounts of alcohol
- DO NOT use if kidneys are impaired (serum creatinine >1.4 F, 1.5 M)

Alpha Glucosidase Inhibitors

Drugs in this class:

- •Acarbose (Precose)
- •Miglitol (Glyset)

How do they work?

- •Slows the digestion of carbs in the small intestine thus decreasing the post prandial blood sugar spike

Alpha Glucosidase Inhibitors

Advantages:

- •May decrease A1C by 0.5 to 1%
- •Do not cause low blood sugar or weight gain

Side effects

- •Gas and diarrhea

How to take:

- •Take with first bite of food of 3 largest meals of the day

Alpha Glucosidase Inhibitors

- Precautions:
  - If low blood sugar occurs, food will NOT increase it
  - Must use glucose tablets to treat!!!!

Insulin Sensitizers-TZD'S

Drugs in this class:

- Rosiglitazone (Avandia)
- Pioglitazone (Actos)

How do they work?

- Help insulin work better
- Enhances glucose uptake by the muscle tissue
- Reduces glucose production by the liver
- Takes up to 3 months to see maximum effect

Insulin Sensitizers

Advantages:

- May decrease A1C by 0.5-1%
- Does not cause low blood sugar
- May decrease triglycerides and increase HDL

Side effects:

- Swelling in legs and weight gain (caution in heart failure)
- If on oral contraceptive, may increase risk of pregnancy
- Liver damage (<1% chance)
  - Liver function is monitored every 2 months for the first year

Combination Drugs

Glucovance (glyburide/metformin)

Metaglip (glipizide/metformin)

Avandamet (avandia/metformin)

New Ones:

Fortamet (metformin SR)

Glumetza (metformin SR)

Actoplus (actos/metformin)

Avandryl (avandia/glimepiride)

Special Points

- Do not use over the counter medicines or alcohol without checking with your doctor.
- If you have several doctors, be sure all of them know about your diabetes medications.
- Bring a list of all medications to your doctor visits and hospital admissions

Incretin Mimetics "Gut Hormones"

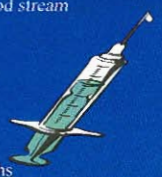
- Drugs in this class
  - Byetta (Exenatide) approved for type 2
  - Symlin (Pramlintide) approved for type 1 and type 2 using mealtime insulin

Byetta

- Approved for type 2 using a sulfonylurea, metformin, or both without achieving glycemic goals

How does it work?

- Prevents stored sugar from entering the blood stream
- Stimulates insulin release
- Slows gastric emptying
  - Lowers post prandial blood sugar spike
  - Makes you feel full
  - Reduces food intake and appetite



Advantages:

- May decrease A1C by 1% after 6 months
- Promotes weight loss (5-6 lbs)

Dosing

Given by injection:

- Comes in a prefilled pen that lasts one month
- 5 mcg twice a day for 1 month, then increase to 10mcg twice a day
- Give within 60 minutes of morning and evening meal
- Do NOT give after a meal
- If you miss a meal, skip the dose

Side effects

- Nausea (will go away with time and dose titration)
- Vomiting and diarrhea
- Low blood sugar
  - May need to decrease dose of sulfonylurea to avoid low blood sugar

Tips for Byetta

- Keep in the refrigerator
- Discard 30 days after opening
- Not to be used in:
  - type 1 diabetes
  - kidney failure
  - Severe stomach diseases including gastroparesis
- Cost - $230 for 1 month supply

Symlin

- Synthetic analog of the human hormone amylin (first isolated in the Gila Monster)
  - This hormone is absent in type 1's and decreased in type 2's
- Approved for type 1 and type 2 diabetics on insulin who failed to achieve desired blood glucose control with insulin

Symlin

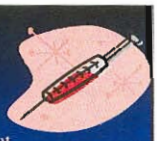
How does it work?

- Slows gastric emptying
  - Lowers the post prandial blood sugar spike
  - Makes you feel full
  - Reduces food intake and appetite
- Slows production of glucose from liver

Advantages:

- May lower A1C by 0.6% in Type 2 after 6 months
- Promotes weight loss (4 lbs)

Dosing



- Given by injection right before you eat
- Type 1 start 15mcg before meals
  - If no side effects after 1 week increase by 15mcg to max dose of 60mcg
- Type 2 start at 60 mcg before meals
  - Titrate to max dose 120mcg
  - May need to take rapid acting insulin at end of your meal due to delayed gastric emptying

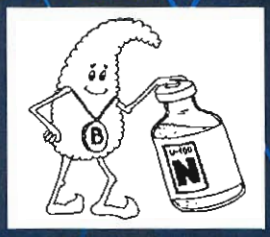
Side Effects

- Nausea (will decrease over time)
- Loss of appetite
- Vomiting
- Hypoglycemia (3 hours after dose)
  - Decrease amount of rapid acting insulin by 50%

Tips for Symlin

- Not to be used in:
  - Children
  - Gastroparesis
- Cannot be mixed in syringe with insulin
- Unopened vials should be stored in the refrigerator
- Open vials can be refrigerated or kept at room temperature
- Discard 28 days after opening
- Cost: $190 for one month supply

Insulin



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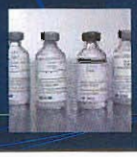
Insulin

Insulin is a hormone produced in the beta cells of the pancreas

It's job is to:

- Get glucose into the cells
- Decrease release of glucose from liver and muscles



Who uses insulin?

- Type 1 to survive
- Type 2 when orals no longer keep blood sugar at goal
  - during surgery
  - DKA
  - HHNS
  - when receiving parenteral nutrition
  - severe illness/ infection
  - when not able to eat
- Women with gestational diabetes

Types of Insulin

- Rapid acting
  - Novolog, Humalog, Apidra
- Short acting
  - Regular
- Intermediate acting
  - NPH
- Long acting
  - Lantus, Detemir
- Combination
  - Novolog 70/30, Humulin 70/30, Humulin 50/50, Novolin 70/30, Humalog Mix 75/25, Humalog 50/50
- Inhaled insulin
  - Exubera

Insulin Therapy

- Each person has unique requirements
- Single and multiple injection schedules
- Insulin pump

Insulin Therapy

- Basal (background)
  - Long acting insulin to cover your normal body functions. (NPH, Lantus)
- Bolus- (meal coverage)
  - Shorter acting insulin (Novolog, Humalog, Exubera, Apidra, Regular insulin)

Insulin delivery systems

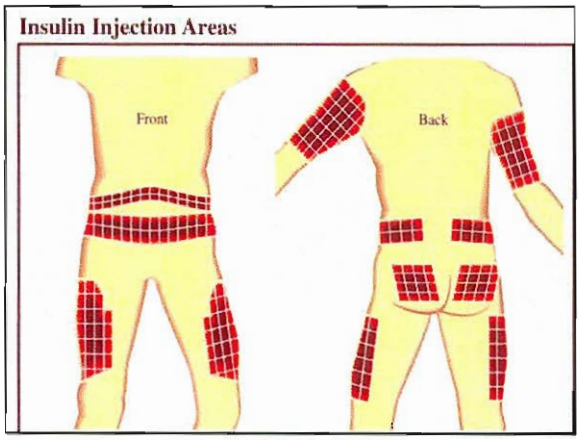
- Vial and syringe
- Insulin pens
- Disposable dosers
- Inhaled Insulin

Insulin: How and Where to Inject

- Clean the site with soap and water
- NPH (cloudy) must be rolled at least 10 times.
- Accurately measure the amount of insulin, making sure no air bubbles are in the syringe
- Rotation of sites
  - Abdomen, arm, leg, and hip sites
  - Do not inject at the same spot more than once a month

Insulin: Routine Insulin Injection

- Subcutaneous tissue
  - 90 degree angle - most adults
  - 45 degree angle – children/thin adults
- Rotation of sites
  - Abdomen, arm, leg, and hip sites
- Examine injection site for:
  - Bruising, redness, infection, and lumps



Insulin:When to Inject

- Basal insulin (long acting)
  - Inject at the same time everyday
- Bolus insulin (short acting)
  - Short acting insulin (Regular)
    - 30 – 60 minutes before eating
  - Rapid acting insulin (Novolog, Humalog, Apidra)
    - at least 15 minutes before eating
  - Inhaled insulin (Exubera)
    - no more than 10 minutes before eating

Insulin: Tips for Taking Insulin

- Take your insulin even when you are ill and unable to eat
- AVOID
  - Giving insulin over a muscle you will be using within 30 minutes
  - Rubbing the sites
  - Long hot baths after injecting
- Check expiration dates before use
- Examine insulin vial for crystals and discoloration
- Wear identification

Insulin: Tips for Storage

- After opening a vial it does not need to be refrigerated
  - Injecting insulin that is room temp is less painful
- Avoid extreme temperatures
  - direct sunlight
  - glove compartments
  - bathroom

	Insulin	Onset	Peak	Duration of Action	Administration with regards to meals	Special Precautions
Rapid-acting						
Short-acting						
Intermediate-acting						
Long-acting						
Pre-Mixed						

Recommended Insulin Storage

Recommended Insulin Storage	Refrigerated (36°F - 46°F)		Room Temp. (56°F - 85°F)	
Vial	**Opened**	**Unopened**	**Opened**	**Unopened**
Humalog, novolog, humulin, novolin	28 Days	until expiration date	28 Days	28 Days
Novalog (release pending)		until expiration date		
Lantus (10mL)	28 Days	until expiration date	28 Days	28 Days
Lantus (5mL)	28 Days	until expiration date	14 Days	14 Days
Pens/Cartridges	**Not in use**		**In use**	
Humalog	Until expiration date		28 Days	
Humulin R (cartridge)	Until expiration date		28 Days	
Humulin N	Until expiration date		14 Days	
Humulin 70/30	Until expiration date		10 Days	
Humalog Mix 75/25	Until expiration date		10 Days	
Novolog	Until expiration date		28 Days	
Novolin R (prefilled and 1.5-mL cartridge	Until expiration date		30 days	
Novolin R (3-mL cartridge)	Until expiration date		28 Days	
Novolin N (prefilled and 1.5-mL cartridge	Until expiration date		7 Days	
Novolin N (3-mL cartridge)	Until expiration date		14 Days	
Novolin 70/30 (prefilled and 1.5-mL cartri	Until expiration date		7 Days	
Novolin 70/30 (3-mL cartridge)	Until expiration date		10 Days	
Lantus™	Until expiration date		28 Days	
Self-filled syringes	14 days*		7 Days*	

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*Suggested, not clinically established

Side Effects of Insulin

- Hypoglycemia
  - Sweating
  - Confusion
  - Hunger
  - Impaired vision
  - Headache
  - Rapid heart beat
- Injection site reactions
  - Itching
  - Redness
  - Swelling
  - Stinging

Inhaled Insulin: Exubera

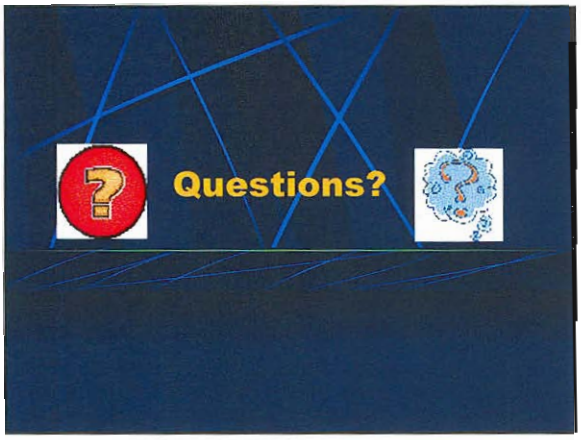
- Available summer 2006
- Not for kids!
- Its onset, duration, and peak are similar to the rapid acting insulin
- Contraindicated in
  - Smoker or those who have smoked within last 6 months
  - Lung problems
- Check pulmonary function test after 6 months then yearly

Inhaled Insulin: Exubera

- Side effects
  - No local site reactions
  - Dry mouth, pharyngitis
  - Cough
- Storage:
  - Room temp do not freeze or refrigerate
  - Inhaler keep at room temp may use up to 1 year
- Expiration:
  - Use unit dose blister within 3 months after opening foil over wrap

Traveling with Insulin

- Keep out of extreme temperatures
- When flying
  - Do not store in luggage that will pass through airport surveillance equipment
  - If a dose of insulin is due, inject half the air into the vial that you normally would
  - Foreign or long distance travel (time change)
    - Change the time on your pump
    - Basal insulin dose may need adjusted
      - Eastward may need less insulin
      - Westward may need more insulin



Acute Complications

Conemaugh Diabetes Institute

Hypoglycemia (low blood sugar)

- A blood glucose below 70 would be considered low and a dangerous level for most people.

Low Blood Sugar Causes

- -Too much insulin or medication
- -Missing or delaying a meal
- -More exercise than usual
- -Drinking alcohol on an empty stomach

Low Blood Sugar (Hypoglycemia)

Mild	Moderate	Severe
Shakiness	Confusion	Seizure
Sweating	Behavior	Coma
Fast heartbeat	Impaired	
Blurry Vision	Motor	
Dizziness	Function	
Hunger		

Rule of 15

- **Feeling low??**
- **Check your blood sugar**
- **If 70 or less - eat/drink 15 grams of carbohydrate**
- **Wait 15 minutes & recheck blood sugar**
- **If less than 70, repeat the above**
- **If you aren't going to eat in 1 hour, have a snack – 1/2 peanut butter sandwich & milk**

Low Blood Sugar - Treatment

- 3 - 4 glucose tablets
- 1/2 cup of regular soda
- 6 - 7 small candies
- 1/2 cup of juice
- 1 Tablespoon of sugar

Followed by milk/crackers/sandwich

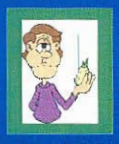
Glucagon

- Glucagon is a hormone that will raise the blood sugar.
- It is given by injection when the person with diabetes is unable to take treatment (food or drink) orally
- Only side effect may be nausea/vomiting
- If still unresponsive after 15 minutes call EMS

Things to Remember

- Always wear identification
- Always carry sugar with you
- Check your glucose before driving
- Do not give an unconscious person something by mouth, use Glucagon
- Take your meds as directed
- Follow your meal plan
- Monitor your blood sugar as directed

Some Signs and Symptoms of High Blood Sugar


Always hungry

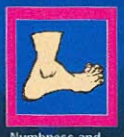

Crave extra liquid

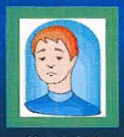

Frequent urination


Unexplained weight loss

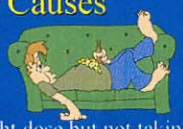

Wounds that won't heal


Blurred vision


Numbness and tingling of feet


Always tired

High Blood Sugar Causes



- Eating more food
- Being less active
- Meds- forgot to take, wrong dose, right dose but not taking it at the proper time, or meds are expired
- Stress- emotional and physical (injury, illness, infection, surgery)
- Hormones- menstruation (blood sugar rises one week prior to starting menses)
- Not using insulin or lower dose to let blood sugar stay high for weight loss or maintenance

High Blood Sugar Treatment

Drink sugar free fluids

Watch diet

Do not exercise if >240mg/dl

Take your meds

Check blood sugar and urine ketones every 4 hours

Why blood sugar may go higher with exercise

•When you exercise your liver pumps out extra glucose to fuel the muscles

•If your body has too little insulin circulating in the blood stream to allow the cells to use this extra glucose your blood sugar will rise

Ketone Testing

- Test your urine for ketones if
  - Your blood sugar is greater than 240 mg for more than 24 hours
  - You are ill
  - You have symptoms of high blood sugar
    - » thirst, frequent urination , tiredness etc
  - Vomiting/abdominal pain
  - Before you exercise
  - **Do not** exercise if ketones are present

When To Contact Your Healthcare Team:

- Fasting blood sugar >160 for more than 1 week
- Symptoms of high blood sugar persist
- Moderate to large ketones
- 2 consecutive blood sugars >300
- Vomiting
- Confusion
- Severe dehydration

Avoid high and low blood sugars by:

- Following your meal plan
- Taking your medication as prescribed
- Test your glucose levels frequently
- Don't skip or delay meals
- Compensate for exercise with increased food intake
- Don't let special occasions upset your diabetes control- practice stress management

Case Study

- Joan is a 25 year old secretary who skipped lunch today but had a diet Coke and crackers. While playing tennis at 4pm she complains of shakiness, sweating, and dizziness.
- What is wrong with Joan?
- Why did this happen?
- What should she do?

Case Study

- Bill is a 62 year old recently retired construction foreman. He is complaining about dry mouth, thirst,frequent urination and tiredness. In fact he hasn't felt well since his daughter's wedding 3 days ago.
- What is wrong with Bill?
- Why did this happen?
- What should he do?

Complications of Diabetes

Conemaugh Diabetes Institute

Breakfast	Lunch	Dinner
Fasting BG 91	Pre-meal BG 247	Pre-meal BG 110
1 1/2 cups dry cereal 2 slices of toast with margarine 12 oz. orange juice 1 cup skim milk	Why is his BG high? 1 hamburger on bun 1 small french fry medium diet soda	Why is his BG Normal? 6oz. sirloin steak 1/2 cup mashed potatoes 1 cup green beans 1 cup salad with low-fat dressing
How many carb choices does this meal have? 8	How many carb choices does this meal have? 4-5	How many carb choices does this meal have? 1-2
		Post-meal BG 55
		Why is his BG low?

Breakfast	Lunch	Dinner
Fasting BG 106	Pre-meal BG 109	Pre-meal BG 112
2 eggs 2 slices of toast 1 cup orange juice 1 cup coffee	Why is his BG normal? 1 turkey sandwich 1 small handful pretzels 1 apple 1 can diet soda	Why is his BG normal? 2 cups spaghetti and tomato sauce 2 slices garlic bread 2 cups skim milk
How many carb choices does this meal have? 4	How many carb choices does this meal have? 4	How many carb choices does this meal have? 10
		Post-meal BG 274
		Why is his BG high?

Long-term Complications of Diabetes

- Large blood vessel disease
  - Cardiovascular
    - –Heart Attack
    - –Stroke
    - –Circulation Problems

Small blood vessel disease

- Retinopathy - eye
- Nephropathy - kidney
- Neuropathy - nerve damage

Diabetic Retinopathy is the

leading cause of new blindness

How does diabetes damage your eyes???

Retinopathy

- Over time high blood sugar, high blood pressure, and high cholesterol damage the blood vessels in the retina.
  - Vessels swell and become blocked
  - New weaker vessels grow and leak
  - Retina may detach
- More prone to cataracts- clouding of the lens
- Glaucoma- increased fluid pressure

Treatment

Laser surgery-

Will not restore vision already lost

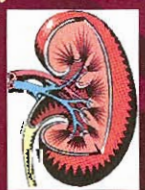
May need low vision aids

Finding and treating diabetic retinopathy EARLY can protect your vision!

Retinopathy Prevention

- Yearly dilated eye exams by an ophthalmologist
- Keep glucose and blood pressure under control
- Do not smoke or use tobacco

Diabetes is the **single leading** cause of chronic kidney failure in the United States



Kidney Disease

- High blood sugar + high blood pressure increase the chances of developing kidney disease
- Kidney disease is a silent process
- Symptoms appear when kidney function has decreased to less than 25%

Kidney Disease

- 70% of people with chronic kidney disease have diabetes, high blood pressure, or both
- High blood sugar damages the filtering system of the the kidneys.
- In early stages - small amounts of protein leak into the urine
- In late stages -kidneys leak large amounts of protein and can lead to kidney failure and need for dialysis.

Taking care of your kidneys

- Yearly urinalysis for microalbumin
- Control blood pressure
- Control blood sugar
- Control cholesterol
- Report signs of urinary tract infections
- Always ask about x-ray dyes- they can be harmful to the kidneys

Medications for kidney disease

- ACE inhibitors/ARB's can delay clinical nephropathy

ACE	ARB'S
Captopril	Cozaar
Lisinopril	Diovan
Enalapril	Benicar

Kidney Disease

- Microalbumin is a protein that leaks into the urine
- This tells us that the kidneys are not working well.
- Need to have a yearly urinalysis for microalbumin

Neuropathy-disease of nerves

- Diabetic Neuropathy is a nerve disorder caused by diabetes
- Factors that contribute to this disorder
  - High blood sugar
  - Poor blood circulation to nerves
  - Accumulation of sorbitol in nerves, which blocks the impulse

Symptoms of Peripheral Neuropathy

- Numbness, burning and tingling in feet
- Can cause pain and insensitivity at the same time
- Sharp pains or cramps
- Extreme sensitivity to touch

Neuropathy Tips

- Examine your feet daily
- Remove your shoes and socks at every doctor visit
- Yearly monofilament exam
- Control blood sugar, lipids, and blood pressure
- Do not smoke

Things that endanger your feet

Neuropathy- nerve damage

Blood vessel- narrowing

Foot bone- deformities (corns and calluses)

Dry crack skin- infection

Relief of Pain of Peripheral Neuropathy

- Medications
  - Amitriptyline
  - Neurotonin
  - Capsaicin cream-Zostrix, ArthriCare, Axsain
  - Ibuprofen
  - Cymbalta
  - Lyrica

Neuropathy Treatment

- Non-Medicine
  - Massage
  - Acupuncture
  - Tens unit

Autonomic Neuropathy

- Affects internal organs
  - Heart- no chest pain
  - Digestive tract- gastro paresis
  - Urinary tract- infections, incontinence
  - Sex organs- impotence, vaginal dryness

Control These Risk Factors

- Smoking
- Obesity
- Inactivity
- Stress
- High blood glucose levels
- High cholesterol levels
- High blood pressure

Dental Care

- High blood glucose changes normal composition of saliva and makes the mouth and teeth susceptible to various microorganisms.
- More prone to cavities, and gingivitis

Good Skin Care

- The skin is our first defense against infections
- Bathe daily
- Protect your skin from sunburn, frostbite blisters etc. (wear gloves, use sunscreen.)

Clinical Trials

- Diabetes Control and Complication Trial (DCCT) 1993
  - studied type 1
- United Kingdom Prospective Diabetes Study (UKPDS) 1993
  - studied type 2

Results: near normalization of blood sugar will reduce complications and mortality in both type 1 and type 2

Trial Results

- Retinopathy-decreased by 76%
- Nephropathy-decreased by 50%
- Neuropathy- decreased by 60%
- Cardiovascular- decreased by 35%

Questions???

Foot Care/Hygiene

Importance of Good Health

- Good health habits are very important to good health for everyone, with or without DM
- Good health habits include:
  - Adequate sleep
  - Nutrition
  - Exercise

Infections- Problems

- Infections raise BGL
- Occur more often when BGL are high
- More common and more serious in people who have DM
- Can occur without open cuts or injuries
- Signs:
  - Pain, redness, warmth of area, swelling, discharge and fever
- The first sign may be elevated BGL

Importance of Foot Care

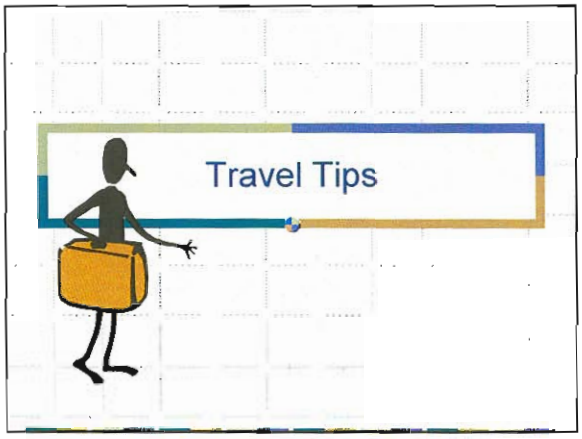
- Decreased circulation causes slow healing of injuries
- Peripheral neuropathy causes decreased sensation
- Early treatment of food injuries can prevent serious complications
- Most amputations from DM are preventable with appropriate care

Prevention of Foot Problems

- Wear shoes and socks that fit
- Shop for shoes in the afternoon when feet are largest.
- Break in new shoes slowly
- When taking shoes off look for areas of redness
- Check inside shoes for foreign objects before putting them on
- Avoid heating pads, hot water bottles, or microwaveable warmers
- Avoid going barefoot indoors or outdoors
- Take shoes off at Dr. office- check for sensation

Daily Inspection/ Care of Feet

- Wash daily with with mild soap and warm water/dry completely
- Look at tops, bottoms, between toes for cracks, cuts, calluses, red spots, bruises, etc.
- If skin is dry use lanolin-based lotion
- If feet sweat a lot—use powder
- Remove calluses by gently rubbing with emery board or pumice stone
- Treat corns or bunions by padding
- Cut toenails straight across—softer after a bath



Travel Tips

- Protect test strips from extremes of heat and cold
- Keep food and some form of fast-acting sugar handy
- Plan ahead for changes in mealtimes (especially when crossing 2 or more time zones

Travel Tips

- From your doctor:
  - Get a letter about your DM care and what to do in an emergency
  - Get prescriptions for all your medications and DM supplies
  - Get names and phone numbers of the doctor or DM center near where you will be
- You may need to test BG more frequently

Travel Tips

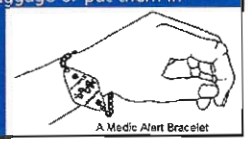
- If driving in a car:
  - Test BG before starting and regularly
  - Stop and take a short break every 2-3 hours
  - Keep extra food with you

Travel Tips

Conemaugh Diabetes Institute

Travel Tips

- Carry and wear your DM identification
- Stay as close as you can to your usual meal, exercise, and medication routine
- Make sure you have enough DM supplies for your whole trip, plus an extra week
- Keep your supplies with you in a carry-on
  - Do not check them with your luggage or put them in a trunk
- Keep insulin as cool as possible



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Travel Tips

- If driving in a car:
  - Test BG before starting and regularly
  - Stop and take a short break every 2-3 hours
  - Keep extra food with you

Travel Tips

- If flying:
  - Check with airline for their most current recommendations

Managing Sick Days

Sick days

- Flu
- Common cold
- Infection
- Sore throat
- Toothache
- Nausea/ vomiting

What will the effect be on your blood sugar?

- It will make it go up
- May go out of control

Should you take your medicine or insulin?

Yes

Sick Day Rules

- Always take your insulin and diabetic pills.
- Drink the right fluids.
  - -If blood sugar is high, drink **sugar free** fluids like water, broth, tea, coffee, and diet soda.
  - -If blood sugar is low, drink fluids with sugar like fruit juice, regular cola, seven-up, or a popsicle.
  - -Recommendation is 8oz/hr while awake
  - *Avoid caffeine (it is a diuretic)*
- Check your blood sugar every 2-4 hours.

Sick Day Rules

- Check for ketones if blood sugar is greater that 240 and continue to check every 4 hours until negative.
- Call doctor if:
  1. Moderate to large ketones are present in 2 tests in a row.
  2. If you are unable to eat for more than 6 hours.
  3. Blood sugar is greater than 240 mg/dl for 24 hours.
  4. Vomiting or have diarrhea for more than 6 hours

Diabetes Support Group
Sign In

Please Print **Date** _____

Name _____

Address _____
(street)

_____
(city) (zip code)

Phone _____

Last eye exam (date) _____

How often do you inspect your feet? _____

Date and result of your last A1c _____
BP _____ Weight _____

CONEMAUGH DIABETES INSTITUTE
DIABETES ASSESSMENT FORM

Patient Demographics

Patient Name: _____ Date: _____

Date of Birth: _____ *Medical Record #*: _____

Home Phone: (_____) _____ Work Phone: (_____) _____

Height: _____ Feet _____ Inches / Weight: _____ Pounds *[Actual _____]*

Type of Diabetes (if known): ☐ Type 1 ☐ Type 2 ☐ Gestational ☐ Pre-Diabetes

Year Your Diabetes was Diagnosed: _____

Do You Live Alone? ☐ Yes ☐ No

Marital Status: ☐ Married ☐ Single ☐ Widowed ☐ Divorced
☐ Significant Other

Smoking Status: ☐ Non-Smoker ☐ Ex-Smoker (Quit Date: _____)
☐ Current Smoker

Employment Status

☐ Working full time, 35 hours or more per week ☐ Homemaker ☐ In school

☐ Working part time, less than 35 hours a week ☐ Retired ☐ Disabled, not able to work

☐ Unemployed or laid off and looking for work ☐ Something else?

☐ Unemployed and not looking for work Please specify: _____

Educational Goal

What do you hope to gain from this educational program?

_____

_____

Health Information

Primary Care Physician: _____

Address: _____

Phone: _____

Do you see your Primary Care Physician regularly? ☐ Yes ☐ No

If yes, how often? _____

List any allergies you may have: _____

What physician referred you to the Conemaugh Diabetes Institute?

Name: _____

Address: _____

Do you see a specialist to treat your diabetes? ☐ Yes ☐ No

If yes, who? _____

Number of Emergency Department visits (within last 3 months): _____

Days of hospitalization (within last 3 months): _____

Exams

How do you describe your vision? ☐ Good ☐ Poor

Do you wear glasses? ☐ Yes ☐ No

Have you had an electrocardiogram (EKG)? ☐ Yes ☐ No

Have you had your blood pressure checked recently? ☐ Yes ☐ No

If yes, what is your most recent values? _____ SBP (Top #) _____ DBP (Bottom #)

Do you take medication for high blood pressure? ☐ Yes ☐ No

Do you take medication for high cholesterol? ☐ Yes ☐ No

Have you had a flu vaccine in the previous year? ☐ Yes ☐ No

Have you had a pneumonia vaccine in the previous year? ☐ Yes ☐ No

How would you describe your hearing?

☐ Good ☐ Poor Right ☐ Poor Left ☐ Both Poor

Do you wear a hearing aid? ☐ Yes ☐ No

Do you exercise? ☐ Yes ☐ No Type of exercise: _____

How often do you exercise? ☐ Daily ☐ 1- 3 times per week ☐ > 3 times per week

For Men Only

Are you experiencing any sexual problems? ☐ Yes ☐ No

☐ Erectile Dysfunction Other: _____

For Women Only

Contraceptive Method: _____

Are you currently pregnant? ☐ Yes ☐ No ☐ Not Applicable

Do you plan to get pregnant in the future? ☐ Yes ☐ No ☐ Not Applicable

Are you experiencing any sexual problems? ☐ Yes ☐ No ☐ Not Applicable

Please state: _____

This Section to be completed by staff of the Conemaugh Diabetes Institute

Date of Current Clinic Visit: _____ *Primary CDE:* _____

Clinical Lab Information and Standards of Care

Laboratory Measures

HbA1C

Date: _____ *Value:* _____ ☐ *See attached*

Date: _____ *Value:* _____ ☐ *See attached*

Fasting Blood Glucose

Date: _____ *Value:* _____ ☐ *See attached*

Lipid Profile

Date: _____ ☐ *See attached*

Total Cholesterol _____ *mg/dl* *Triglycerides* _____ *mg/dl*

HDL _____ *mg/dl* *LDL* _____ *mg/dl*

Urinalysis for Proteinuria / Microalbuminuria

☐ *Yes* ☐ *No* *If yes, type:* _____ ☐ *See attached*

Serum Creatinine:

☐ *Yes* ☐ *No* *Value:* _____ ☐ *See attached*

Complications / Comorbidities / Quality of Life Indicators

Comorbidity Conditions: ☐ *Coronary Heart Disease* ☐ *Congestive Heart Failure*

☐ *Cerebrovascular Disease* ☐ *Depression*

Complications: ☐ *Coronary Artery Disease* ☐ *Cerebrovascular Disease / TIA*

☐ *Peripheral Vascular Disease* ☐ *Retinopathy* ☐ *Neuropathy*

☐ *Nephropathy* ☐ *Gastroparesis* ☐ *Erectile Dysfunction*

☐ *Other* _____

Medication List
(Do NOT complete if you brought a list of your medications.)

Insulin

Date Started	Type	Dose	How Often

Oral Diabetes Medications

Date Started	Name	Dose	How Often

Other Medications

Date Started	Name	Dose	How Often

Date: _____

Dear Dr. _____

Your patient listed below has attended a comprehensive Diabetes Self Management Education program (10 hours) sponsored by the Conemaugh Diabetes Institute of Memorial Medical Center. This program was presented by a team of Health Care Professionals.

Your patient received the following information:			
___ Diabetes Overview	___ Meal Planning	___ Medications – Oral / Insulin	___ Long Term Complications
___ Blood Glucose Monitoring	___ Fiber	___ Exercise	___ Hyperglycemia
	___ Food Labeling	___ Stress Management	___ Hypoglycemia
	___ Food Exchange Lists	___ Psychosocial Adjustment	___ Sick Day Management
	___ Carb Counting		___ Travel
	___ Restaurant Eating		___ Foot Care
			___ Set Goals

To help improve overall diabetes management, your patient selected the following behavior change goal to work on over the next 6 months.	
Goal	

Comments

Follow-up is planned with this individual within the next three to six months. Please feel free to communicate with the Diabetes Educator any questions or information regarding this patient or the diabetes classes.

_____ Educator

_____ Educator

_____ Educator

Patient Name: _____

DOB: _____ MR#: _____

CONEMAUGH DIABETES INSTITUTE
MEMORIAL MEDICAL CENTER
1 DAY FOOD DIARY

Please record one day of meals and snacks consumed prior to your scheduled appointment.
See sample meal below. Please bring this paper with you to your appointment.

Sample Meal: Breakfast	**EXAMPLE**	Time: 7:30 am
How Much	What Kind	
1 cup	Shredded wheat cereal	
1 cup	Skim milk	
½	Banana	
½ cup	Orange juice	

Date:

Breakfast	Time:
How Much	What Kind

Lunch	Time:
How Much	What Kind

Dinner	Time:
How Much	What Kind

Snacks (List time eaten next to food.)	
How Much	What Kind

Conemaugh Diabetes Institute - Outpatient Diabetes Documentation Form

Medical Record #: _____
Account #: _____

Patient Name: _____ **Date:** _____
DOB: _____ **Patient Phone:** _____
Physician: _____

The following was discussed and /or demonstrated:	Initials
Overview of diabetes / definition / overall management of blood sugar	
Blood Glucose Monitoring _____ Importance _____ Coding the meter and running controls _____ Return demonstration _____ Alternate test sites _____ Testing schedule _____ Blood sugar target ranges	
Oral Medications _____ Action of specific oral diabetes medication	
Insulin _____ Start, peak, and duration _____ Sites to use and importance of rotating sites _____ Procedure for preparing injection and injecting of insulin / pens _____ Self-injection _____ Proper disposal of lancets, syringes, and needles _____ Storage _____ Pre-pump training _____ Saline start _____ Pump start-up	
Gestational Diabetes Due Date _____ _____ Definition _____ Causes / risks _____ Relationship between diabetes and pregnancy	
Hypoglycemia - signs / symptoms / treatment	

Patient Name: _____ **Date:** _____

Outpatient Diabetes Documentation Form

Medical Nutrition Therapy _____ Carbohydrate counting _____ Label reading _____ Meal planning	
Overall management of blood sugar to include meal plan and exercise	
Made aware of DSME classes, if needed	
Made aware of Diabetes Support Group(s)	

Comments: _____

Educator Signature: _____ Date: _____

Educator Signature: _____ Date: _____

Memorial
Medical Center
Member Conemaugh Health System

Date Sent: _____

Patient: _____

Date of Visit: _____

Type of Visit: _____

Dear Dr. _____:

Thank you for referring your patient to the Conemaugh Diabetes Institute. Your patient was seen on the date stated above as an outpatient for diabetes education. Enclosed is a copy of the documentation of that visit for your files.

We hope we can be of assistance to you and your patients in the future.

Sincerely,

Janice Albert, RN, CDE _____

Laura DiGiorgio, MS, RD, LDN, CDE _____

Eileen Fiorina, RD, LDN, CNSD _____

Antoinette Franke, RN, CDE _____

Bonnie Pepon, RN, BSN, CDE _____

Enclosure

Conemaugh Diabetes Institute
Toll Free: 1 (866) 641-382
Phone: (814) 534-6800
Fax: (814) 534-6937

1086 Franklin Street
Johnstown, PA 15905-4398
814-534-9000
www.conemaugh.org

AADE 7™
Self-Care Behaviors

Patient name: _____

Addressograph/Stamp Area

Goal Setting Date / Goal	Follow Up Date / Achievement	Goal Review Documentation
Date: ☐ **Healthy eating** ☐ Make better food choices ☐ Reduce portion size ☐ Follow meal plan Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified
Date: ☐ **Being active** ☐ Exercise longer ☐ Exercise more often ☐ Follow exercise plan Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified
Date: ☐ **Monitoring** ☐ Follow monitoring schedule ☐ Monitor more often ☐ Monitor health status Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified
Date: ☐ **Taking medication** ☐ Increase taking medications on time ☐ Miss fewer medications ☐ Take medications as prescribed Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified
Date: ☐ **Problem solving** ☐ Identify potential problems ☐ Plan problem situation treatment ☐ Prevent problem situations Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified
Date: ☐ **Healthy coping** ☐ Cope with diagnosis of disease ☐ Adapt to lifestyle changes ☐ Get support from family/friends Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified
Date: ☐ **Reducing risks** ☐ Stop smoking ☐ Get health checkups ☐ Perform daily self care activities Goal individualization: _____	**Date:** _____ ☐ 1 mo. ☐ 3 mo. ☐ 6 mo. ☐ 12 mo. Rate 0-10 _____	☐ Achieved ☐ Continued ☐ Modified

Diabetes Educator Name and Initial Index:

Name: _____ Initial: _____

Name: _____ Initial: _____

Name: _____ Initial: _____

Name: _____ Initial: _____

100 W. Monroe, 4th floor, Chicago, IL 60603 www.diabeteseducator.org (800) 338-3633

DIABETES SELF MANAGEMENT EDUCATION
EVALUATION

Thank you for participating in the educational program. Please take a few minutes to complete this evaluation so that we may continue to improve the quality of class. Please rate the following by putting a check mark in the appropriate box.

	Strongly Disagree	**Disagree**	**Indifferent**	**Agree**	**Strongly Agree**
The **instructors** were knowledgeable and prepared for class.					
The **instructors** were friendly and helpful					
Instructors answered questions in a helpful way.					
I was able to understand the information presented in ***class***.					
The ***class*** was at a day and time convenient for me.					
The ***class*** lasted an appropriate amount of time					
This ***class*** helped me to better understand and manage my diabetes.					
I will recommend this ***class*** to others.					
What additional material would you like to see covered in this class?					
What suggestions do you have to improve this class?					
Other comments					

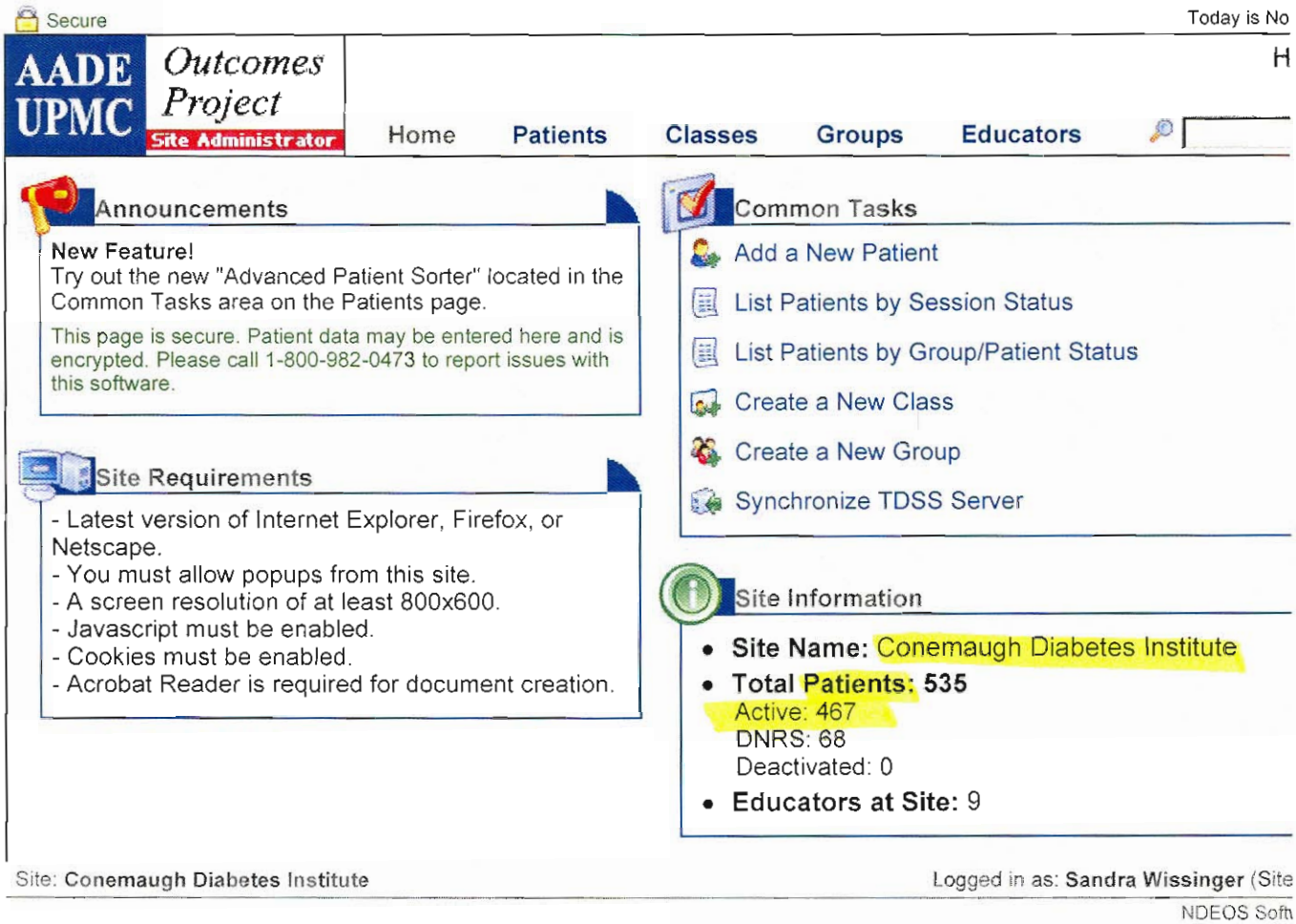
How did you hear about this program?

Physician Referral _____ Family/Friend _____

Other (specify) _____

Name (optional) _____

Date of class _____


Secure
Today is No
AADE UPMC
Outcomes Project
Site Administrator
H
Home
Patients
Classes
Groups
Educators
Announcements
New Feature!
Try out the new "Advanced Patient Sorter" located in the Common Tasks area on the Patients page.
This page is secure. Patient data may be entered here and is encrypted. Please call 1-800-982-0473 to report issues with this software.
Site Requirements
- Latest version of Internet Explorer, Firefox, or Netscape.
- You must allow popups from this site.
- A screen resolution of at least 800x600.
- Javascript must be enabled.
- Cookies must be enabled.
- Acrobat Reader is required for document creation.
Common Tasks
Add a New Patient
List Patients by Session Status
List Patients by Group/Patient Status
Create a New Class
Create a New Group
Synchronize TDSS Server
Site Information
Site Name: Conemaugh Diabetes Institute
Total Patients: 535
Active: 467
DNRS: 68
Deactivated: 0
Educators at Site: 9
Site: Conemaugh Diabetes Institute
Logged in as: Sandra Wissinger (Site
NDEOS Soft

Carol - Eileen
School
Special
Kids

You and Healthy Eating

Eileen T. Fiorina, RD, CNSD, LDN
Conemaugh Diabetes Institute

TOPICS:

- Healthy Eating
- "Carb" Counting
- Meal Planning
- Food Label Reading
- Healthy Fast Foods

Healthy Lifestyle is Managed by:

- Diet
- Exercise
- Stress Reduction

Healthy Eating

Dietary Guidelines:
- Whole grains
- More vegetables & fruits
- Low fat milk
- Healthy fats
- Less salt

Calories Come From:

- Carbohydrates
- Proteins
- Fats

Other Nutrients Needed

- Minerals
- Vitamins
- Water

Exercise

- **Types of Exercise:**
  - Aerobic (increases heart & breathing rate)
  - Strengthening (builds strong bones & muscle)
  - Stretching (helps joints be flexible)
- **Exercise Makes:**
  - You feel more alert
  - You have more energy
  - You feel better about yourself
  - You increase muscle
  - You burn more calories (lose weight)
  - You reduce stress

Exercise

- Be physical active 150 minutes per week
- Start slowly
- Exercise with a friend
- Choose activities you enjoy
- Make it FUN!

Stress

- **Defining Stress**
  - It is the way you react both physically & emotionally to change

What are stressors in your life?

- Parents
- School
- Friends
- Weight
- Too many things to do
- Losing things
- Physical appearance
- Crime

Stress

- **Physical Signs of Stress**
  - Headaches
  - Upset stomach
  - Shortness of breath
  - Cold hands
  - Back & chest pain
  - Diarrhea

Stress

- **Emotional Sign of Stress:**
  - Trouble thinking
  - Forgetfulness
  - Easily frustrated
  - Unable to sleep
  - Short temper
  - Nervousness

Stress

- **How to deal with stress:**
  - Learn to relax
    - Deep breathing
    - Clear your mind
  - Exercise
  - Positive attitude & thinking
  - Get needed sleep
  - Slow down & enjoy your free time

"Carb" Counting:

- Magic Number is 15 grams of Carbohydrates (Carbs)

= 1 carbohydrate serving
- starch
- fruit
- milk

Starches

- Bread
- Pasta
- Milk
- Fruit
- Sweet snacks
- Salty snacks
- Starchy vegetables
  - Corn
  - Peas
  - Lima Beans
  - Potatoes

How many fruits can you name?

- 1 – 3
- 4 – 6
- 7 - 9
- 10 – 13
- 14 - 16

How many fruits do you eat per day?

- 1
- 2
- 3
- 4
- 5

How many vegetables can you name?

- 1 – 3
- 4 – 6
- 7 - 9
- 10 – 13
- 14 - 16

How many vegetables do you eat per day?

- 1
- 2
- 3
- 4
- 5

Meal Planning:

- **IS:**
  - **What to Eat**
    balanced meals
    (proteins, carbohydrates, fats)
  - **When to Eat**
    at regular times (every 3-4 hours)
  - **How much to Eat (ages 12-18)**
    2.5 cups of vegetables
    2.0 cups of fruits
    6.0 ounces of grains
    3.0 cups of milk
    5.5 ounces meat & beans

Meal Planning & Snacks Guide

- Eat 3 meals - breakfast, lunch, dinner, & snacks at same times
- Eat free foods as snacks
- Balance food eaten with activity
- Eat same number of snacks at each meal
- Eat 3 meals per day
  - Remember breakfast is the most important meal of the day!

Snacking Tips

- **Smart Snack Ideas:**
  - Fresh or canned unsweetened fruit
  - Raw vegetables & fat free dip
  - Baked tortilla chips & salsa
  - Rice & popcorn cakes & low fat peanut butter
  - Celery stuffed with peanut butter or cream cheese
  - Air popcorn with butter spray & seasoning
  - Cereal & non fat milk
  - Low fat frozen yogurt

Label

Nutrition Facts
Serving Size ½ cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 90	Calories from Fat 30
	% Daily Value*
Total Fat 3g	5%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 300mg	13%
Total Carbohydrate 13g	4%
Dietary Fiber 3g	12%
Sugars 3g	
Protein 3g	
Vitamin A 80% •	Vitamin C 60%
Calcium 4% •	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Label Reading

- **Raise a finger if the food has:**
  - 10% or more vitamin A
  - 10% or more vitamin C
  - 10% or more Calcium
  - 10% or more Iron
  - 10 or less Carbohydrate
  - 10% or more Fiber
  - 10% or more Protein

Lower a finger if:
10% or more Total Fat or
200 Calories or more per serving

If any finger remains up it is a HEALTHY Food for you!

Label

Nutrition Facts
Serving Size ½ cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 90	Calories from Fat 30
	% Daily Value*
Total Fat 3g	5%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 300mg	13%
Total Carbohydrate 13g	4%
Dietary Fiber 3g	12%
Sugars 3g	
Protein 3g	
Vitamin A 80% •	Vitamin C 60%
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Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Fast Food Tips

- Say no to combo meals
- Portions (swap super-size for smart size)
- Share a "biggie" size with friend
- Save money & calories with kid meals
- Substitute soft drinks & shakes with low fat milk, juice & diet drinks
- Skip fried foods and have it fresh

Menu

Menu Item	Calories	Food Exchanges
Hamburger	250	2 carbohydrate, 1.5 medium fat meat
Cheeseburger	300	2 carbohydrate, 2 medium fat meat, 0.5 fat
Double Cheeseburger	440	2 carbohydrate, 4 medium fat meat, 1 fat
Quarter Pounder	410	2 carbohydrate, 3 medium fat meat, 1 fat
Big Mac	540	2 carbohydrate, 4 medium fat meat, 1 fat

MENU

Desserts/Shakes

Fruit 'n Yogurt Parfait	160	2 carbohydrate
Fruit 'n Yogurt Parfait (without granola)	130	1.5 carbohydrate
Apple Dippers	35	0.5 carbohydrate
Low Fat Caramel Dip	70	1 carbohydrate
Vanilla Reduced Fat Ice Cream Cone	150	1.5 carbohydrate, 1 fat
Small (Kiddie) Cone	45	0.5 carbohydrate, 0.5 fat

MENU

Sides

Small French Fries	250	2 carbohydrate, 2 fat
Medium French Fries	380	3 carbohydrate, 3 fat
Large French Fries	570	4.5 carbohydrate, 5 fat
Ketchup Packet	15	free
Salt Packet	0	free
Side Salad	20	0.5 carbohydrate
Ranch Dressing	170	1 carbohydrate, 3 fat
Low Fat Italian Dressing	60	.5 carbohydrate, 0.5 fat
Fruit & Walnut Salad	210	2 carbohydrate, 1.5 fat

MENU

Beverages

Chocolate Triple Thick Shake (12 ounces)	440	4.5 carbohydrates 2 fats
1% Milk (8 ounces)	100	1 carbohydrate, 0.5 fat
1% Chocolate Milk (8 ounces)	170	2carbohydrate, 0.5 fat
OJ (12 Ounces)	180	2.5 carbohydrate
Coke (12 Ounces)	210	4 carbohydrate

Fast Food Tips

- Say no to combo meals
- Portions (swap super-size for smart size)
- Share a "biggie" size with friend
- Save money & calories with kid meals
- Substitute soft drinks & shakes with low fat milk, juice & diet drinks
- Skip fried foods and have it fresh

Review

- Eat Healthy
- Count Your Carbs
- Meal and Snack Planning
- Reading Food Labels
- Healthy Fast Foods

Healthy Lifestyle

- Diet
- Exercise
- Controlling Stress

All lead to a happy healthy you!

Students with Diabetes

Conemaugh Diabetes Institute
Jan Albert RN, CDE
Eileen Fiornia RD, CNSD, LDN
Antoinette Franke RN, CDE
Bonnie Pepon RN, BSN, CDE

Conflict of Interest

- The Staff of the Conemaugh Diabetes Institute receive no significant financial benefits or gifts from the pharmaceutical, blood glucose meter, or insulin pump companies

Objective :

To educate you – the staff - about diabetes so you will be able to provide a safe learning environment for your students with diabetes.

WRITTEN PLANS

- Educational needs:
  - 504 plan
  - IEP
- Health care needs:
  - Diabetes Medical Management Plan (DMMP)

Diabetes

- Diabetes is one of the most common chronic diseases in school-aged children.
- One out of every 400-500 kids under age 20 is diagnosed with Type 1 Diabetes.
- Unfortunately with the rising obesity rates, we now are seeing more and more kids and teens diagnosed with Type 2.

What is Diabetes?

- A chronic, progressive disease that NEVER goes away, but can be controlled
- There are 2 main types
- May also occur during pregnancy

Types of Diabetes

- **Type 1**
- No insulin being made
- Usually occurs in children and young adults
- Need insulin to survive

- **Type 2**
- Pancreas does not make enough insulin

or

- Your body does not use insulin correctly

Symptoms of Type 1

- Increased thirst
- Increased passing of urine
- Increased hunger
- Sudden weight loss
- Dehydration
- Extreme tiredness

Causes of Type 1

- Family history
- Viruses
- Body's own white blood cells have destroyed the insulin-making cells in the pancreas.

Type 2 Diabetes

- Insulin resistant - makes it but can't use it.
- More common in adults.
- Becoming more common in kids due to: overweight
  inactivity.

Symptoms of Type 2 Diabetes





- Dry itchy skin
- Feeling tired
- Frequent infections
- Frequent passing of urine
- Blurry vision/slow healing
- Increased thirst
- Increased hunger

Blood Glucose Monitoring

- Enables maintenance of blood glucose levels within target range for safety;
- promotes long term health and optimal academic performance
- Identifies factors that affect blood glucose

Any Time, Any Place Monitoring

For students who can self-check:

- Better blood glucose control
- Safer for student
- Student gains independence
- Less stigma
- Less time out of class
- Assists decision making in response to result

Know the Meter

- Features vary:
  - Ease of use
  - Sample size needed
  - Wait time
  - Alternate-site testing capacity
  - Ability to reapply, if insufficient sample

- Many meters available on market. Work with parent to become familiar with operation of student's particular meter.
- 1-800 number on back of meter.

Hypoglycemia- Low Blood Sugar

- Blood sugar less than 70.
- Not always preventable.
- Does impair cognitive and motor function.
- Early recognition and intervention can prevent an emergency.

Low Blood Sugar Causes

- Too much insulin or medication.
- Missing or delaying a meal.
- More exercise than usual.

Low Blood Sugar (Hypoglycemia)

Mild	Moderate	Severe
Shakiness	Confusion	Seizure
Sweating	Behavior	Coma
Fast heartbeat	Impaired	
Blurry Vision	Motor	
Dizziness	Function	
Hunger		

Behavior Change

- If a student with diabetes exhibits a **change** in their behavior example:
- Becomes aggressive/agitated/belligerent
- Confused
- Not focused/blank stare
- Unable to respond to directions
- THINK LOW - CHECK BLOOD SUGAR - TREAT

Treatment of Hypoglycemia

This will differ among students and should be addressed in the students individual plan.

Rule of 15

- **Is student "feeling low"??**
- **Check blood sugar.**
- **If 70 or less – student should eat/drink 15 grams of carbohydrate.**
- **Wait 15 minutes & recheck blood sugar.**
- **If less than 70, repeat the above.**
- **If student is not going to eat in 1 hour, they need a snack – 1/2 peanut butter sandwich & milk.**

Low Blood Sugar - Treatment

- **3 - 4 glucose tablets**
- **1/2 cup of regular soda**
- **6 - 7 small candies**
- **1/2 cup of juice**
- **1 Tablespoon of sugar**

Followed by milk / crackers / sandwich

Glucagon

- Glucagon is a hormone that will raise the blood sugar.
- It is given by injection when the person with diabetes is unable to take treatment (food or drink) orally.
- Person may experience nausea / vomiting.
- If still unresponsive after 15 minutes, call EMS.

Glucagon

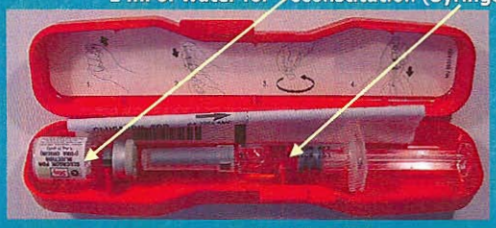
- Can save a life.
- Cannot harm a student - they can't overdose.

Glucagon Kit Storage

- Place: As designated in DMMP accessible to school personnel.
- Store at room temperature
- Expiration date: Monitor
- After mixing, dispose of any unused portion within one hour.

Emergency Kit Contents:

1 mg of freeze-dried glucagon (Vial)
1 ml of water for reconstitution (Syringe)



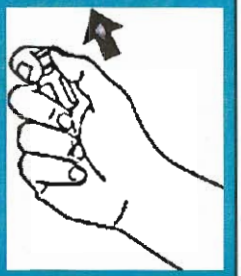
Combine immediately before use

When to Give?

- Needs to be authorized on the students plan of care. Usually given when student is:
  - unconscious or unresponsive
  - is having seizures
  - is not able to eat or drink.

Preparation

1. Flip cap off glass vial containing dry powder
2. Remove cap from syringe



Mixing Solution

3. Inject entire fluid in syringe into the bottle containing powder

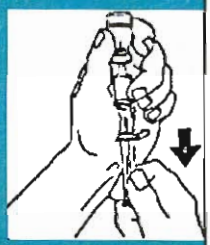
4. Shake gently or roll to mix until all powder is dissolved and solution is clear.

Drawing Out

5. Inspect. Solution should be clear and colorless.
6. Draw prescribed amount of glucagon back into syringe.

½ vial = if < than 45 lbs.

entire vial = if > than 45 lbs



After Injecting

9. Give sips of fruit juice or regular soda, once person is awake and able to drink.
10. Check blood sugar.
11. May take 10-20 minutes for the person to regain consciousness.
12. Advance diet as tolerated.

Don't Be Surprised If. . .

- person does not remember being unconscious, incoherent
- has a headache.
- blood sugar becomes very high (over 200).
- nausea or vomiting occurs.

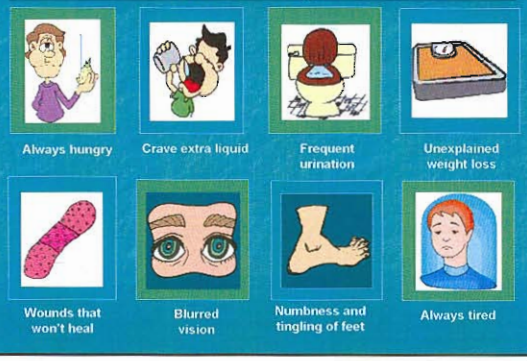
Hyperglycemia- High Blood Sugar

- Due to not enough insulin - can lead to diabetic coma.
- Interferes with students ability to learn and participate.
- Causes the serious complications of diabetes.
- Usually slow to develop but can occur rapidly for those on insulin pumps.
- Treatment should be individualized on students plan.

High Blood Sugar Causes

- Eating more food.
- Being less active.
- Meds - forgot to take, wrong dose, right dose but not taking it at the proper time, or meds are expired.
- Stress - emotional and physical (injury, illness, infection, surgery).
- Hormones - menstruation (blood sugar rises one week prior to starting menses).
- Not using insulin or lower dose to let blood sugar stay high for weight loss or maintenance.

Some Signs and Symptoms of High Blood Sugar



High Blood Sugar Treatment

- Goal is to normalize blood sugar.
  Follow student plan.
- Drink sugar free fluids.
- Watch diet.
- No exercise if greater than 240mg/dl.
- Medications should be taken.
- Blood sugar and urine ketones need checked every 4 hours

Ketone Testing

- Urine should be tested for ketones if:
  - Blood sugar is greater than 240 mg for more than 24 hours
  - Student is ill.
  - Student has symptoms of high blood sugar
    - thirst, frequent urination, tiredness, etc.
  - Vomiting / abdominal pain is present.
  - Before exercise.
  - **No** exercise if ketones are present.

How to Check for Ketones

Treatment of Ketones

Generally:

- free use of bathroom
- sugar free liquids
- insulin as per student plan
- no physical activity
- if vomiting or lethargic, call the parents.

Ketoacidosis

- Occurs in people with type 1
- "Diabetic Coma"
- Body can't use glucose for energy due to lack of insulin
- Body burns fat for energy, produces ketones or "acids " in the blood
- Very dangerous condition

Symptoms of Ketoacidosis

- Onset is gradual
- Extreme thirst-dehydration
- Glucose levels over 250mg/dl
- Nausea / vomiting
- Abdominal pain/fruity breath
- Shortness of breath-rapid breathing

Treatment of Ketoacidosis

- Call your doctor immediately or go to the Emergency room
- Take additional insulin as prescribed
- You may need hospitalization to correct this

Insulin in Schools Today

- Many students need to take insulin in school.
- Insulin regimens vary with each student and over time.
- Need for assistance will vary as the student progresses in self-management.
- GOAL: Maintenance of blood glucose target range.

Insulin

Insulin is a hormone produced in the beta cells of the pancreas

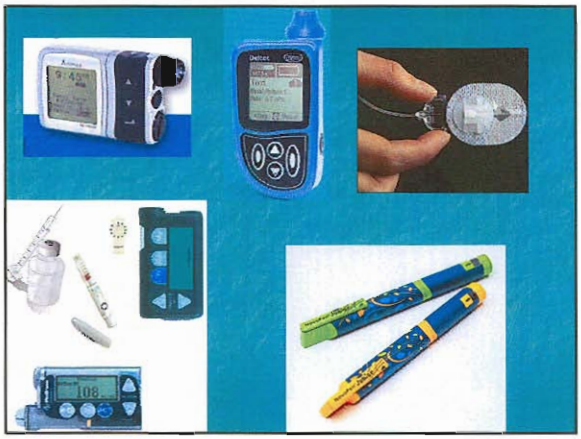
It's job is to:

- Get glucose into the cells
- Decrease release of glucose from liver and muscles

Types of Insulin

- Rapid acting
  - Novolog, Humalog, Apidra
- Short acting
  - Regular
- Intermediate acting
  - NPH
- Long acting
  - Lantus, Detemir
- Combination
  - Novolog 70/30, Humulin 70/30, Humulin 50/50, Novolin 70/30, Humalog Mix 75/25, Humalog 50/50
- Inhaled insulin
  - Exubera

Insulin Delivery Options



Insulin: Tips for Storage

- After opening a vial it does not need to be refrigerated
  - Injecting insulin that is room temp is less painful
- Avoid extreme temperatures
  - direct sunlight
  - glove compartments
  - bathroom

Insulin Therapy

- Basal (background)
  - Long acting insulin to cover your normal body functions. (NPH, Lantus)
- Bolus- (meal coverage)
  - Shorter acting insulin (Novolog, Humalog, Exubera, Apidra, Regular insulin)

Insulin Pump Delivery

- Uses rapid acting insulin alone.
- Automatically releases small amounts of insulin continuously through the day / night (basal rate of insulin).
- The user enters the amount of insulin needed to cover the food eaten and/or to lower a high blood glucose (bolus of insulin).

How is Patient Attached?

- The pump is "attached" by an "infusion set" with a thin catheter that is inserted into skin.
- The pump attempts to mimic a normal pancreas' release of insulin, BUT patient must tell the pump how much insulin.

Infusion Sets

Comfort, Tender™/Silhouette™

Inset

Meal Plan

- Usually, there is no forbidden food.
- Many utilize carb counting to determine insulin dose.
- Lunch should be at same time - not necessary if on insulin pump.
- Some students depending on their insulin may need to have scheduled snacks- a missed snack could result in a low blood sugar

School Meals

- School menus should be provided to families in advance.
- May need to monitor food intake if on student plan - especially newly diagnosed.
- Work with the school nutrition director to determine the carb content in the menus.

Physical Activity / Gym Class / Sports

- Students with diabetes are not restricted and are, in fact, encouraged to participate in all of these.
- May need to make adjustments in their insulin and / or food intake.
- Will need to check blood sugar more frequently during activity.

Exercise Tips

Need quick acting source of glucose available, their BG meter, plenty of H2O.

"Pumpers" may adjust their rates during activity.

Why Blood Sugar may go Higher with Exercise

- **When you exercise, your liver pumps out extra glucose to fuel the muscles.**
- **If your body has too little insulin circulating in the blood stream to allow the cells to use this extra glucose, your blood sugar will rise.**

Parties / Field Trips / Extracurricular Activities

- If possible, give parents advanced notice so they can incorporate food into meal plan or adjust insulin dose.
- Remember, no foods are forbidden but encouraging more nutritious snacks will be healthier for everyone.
- Parents may wish to attend field trip but if not, someone must assume this role (usually spelled out in 504 or IEP).

Why is Effective Diabetes Management in School Crucial ?

- For the immediate safety of students with diabetes.
- For long term health.
- To ensure that they are ready to learn and participate fully in school activities.
- To minimize diabetes related emergencies that can disrupt class room activities.

Recommendations to Get Started

- Administration needs to provide leadership and support in the development and implementation of the district policy.
- Arrange both initial and ongoing training.
- Develop a system for ongoing training and monitoring.
- Understand Federal and State laws related to students with diabetes.
- Respect and protect students privacy.

Recommendations Continued...

- Develop a process for notification of the health team of new students with diabetes.
- Communication to the different buildings as students progress through school.
- Annual meeting with health team.
- Ongoing communication between family and staff.

It's the Law

Three Federal laws address the school's responsibilities to help students with diabetes:

- Section 504 of the Rehabilitation Act of 1973 (Section 504)
- American Disabilities Act of 1990 (ADA)
- Individuals with Disabilities Education Act (IDEA).

Diabetes Management Training for School Personnel

Two Levels:

Level #1

Training for school staff members who have primary responsibility for the student with diabetes:

- Teachers
- Coaches
- Bus drivers

But who do not perform diabetes care task i.e. BGM, Insulin or Glucagon Injection

Training Includes:

1. Overview of diabetes and typical healthcare needs of the student.
2. Recognition of high and low blood sugar.
3. How and who to contact for help.

Level #2

2nd level is for school personnel who will perform routine and emergency care.

- School Nurse
- Staff who received proper training

This Training Includes:

- General overview of typical health care needs of a student with diabetes and how these needs are addressed in the student's written care plans.
- Explanation / overview of Type 1 and Type 2 diabetes.
- The effect of balancing insulin, food, and exercise upon a student's blood glucose levels.
- Procedures for routine care of individual students including blood glucose monitoring, insulin administration, urine ketone testing, and recording results.

Training Continued...

- Signs and symptoms of hypoglycemia and hyperglycemia and the short- and long-term risks of these conditions.
- Treatment of hypoglycemia and hyperglycemia.
- Glucagon administration.
- Tools, supplies, and equipment required for diabetes care and their storage.
- Legal rights and responsibilities of schools and parents / guardians.

Student Emergency Kit

- Enough supplies for 72 hours -
- Blood glucose meter, testing strips, lancets, and batteries for meter
- Urine ketone strips
- Insulin and supplies
- Insulin pump and supplies, including syringes
- Other medications
- Antiseptic wipes or wet wipes
- Fast-acting source of glucose
- Carbohydrate-containing snacks
- Hypoglycemia food supplies (enough for 3 episodes): quick-acting sugar and carbohydrate/protein snacks
- Glucagon emergency kit

Hints

- Student must have access to a quick acting form of glucose
  - Juice box
  - Glucose tabs/gel
  - Regular soda

Communication/Communication/ Communication!!!!

Remember

The health, safety, and educational progress of a student with diabetes depends on cooperation and collaboration between the family and school staff.

What RN's Needs to Know about Diabetes Care at School Carbohydrate Counting & Exercise

Eileen T. Fiorina, RD, CNSD, LDN
Conemaugh Diabetes Institute
Memorial Medical Center

Overall goal: Optimal student health and learning

- Managing nutrition and exercise are critical to student success.
- But these are just two pieces of a comprehensive management plan

Monitoring BGL	Ketones	Hypoglycemia Hyperglycemia
Glucagon	Sick day Management	Legal Rights
Insulin & Oral Medication	Nutrition	Exercise

Learning Objectives

- Participants will learn:
  - Basic meal plan for students with diabetes
  - Carbohydrate Counting
  - Exercise benefit for students with diabetes
  - Exercise guidelines for students with diabetes

Nutrition

- Good Nutrition is important for everyone
- Nutrition planning is essential for good diabetes control
  - Maintain BGL within target range
  - To prevent or delay complications
  - To aid children & teens grow & develop properly

School Nutrition Management

- Student's family & health care team determine an individualized meal plan
- Meals & snacks need to be carefully timed to balance exercise & insulin/ medications
- Encourage healthy eating for all students

Basic Meal Plan

- Key: Balance insulin/medications with carb intake

Most students have flexibility in WHAT to eat
by using Carb Counting

Some students have flexibility in WHEN to eat
More precise insulin delivery (pumps, pens)
New insulins

Carbohydrate Counting Advantages

- Helps improve blood glucose
  - A1C goal: Less than 7%

  - Blood glucose goals (plasma)
    - **Before meals:** 80-110
    - **2 Hours after meals:** less than
    - **Bedtime:** 110-140

Carbohydrate Counting Advantages

- Easier - you only count carbohydrates
- Allows you more flexibility in food choices
  - Virtually any food can be worked into your meal plan

What is Carbohydrate Counting?

- Keeping track of the amount of carbohydrates eaten at meals and snacks
- Keeping carbohydrate intake consistent at meals from day to day
- Matching insulin injections to carbohydrate intake (for some)

Why Count Carbohydrate?

Carbohydrate is the nutrient in food that raises blood glucose the most

Why Count Carbohydrate?

- Amount of carbohydrates eaten determines how high blood glucose will rise after a meal
- Carbohydrates begins to raise blood glucose within 15 minutes of eating

Who Should Count Carbohydrate?

People wanting to improve diabetes control who manage their diabetes with:

- Balanced food intake
- Regular physical activity
- Diabetes pills
- Insulin injections

Nutrients in Foods

- Carbohydrate
- Protein
- Fat

(Vitamins, minerals, water)

What are Carbohydrates?

Starches

bread, rice, cereal, potatoes, pasta, corn, peas, butter beans, milk

Sugars

fruit, regular sodas, candy, juices

Combination Foods That Contain Carbohydrates

- Pizza
- Spaghetti
- Sandwiches
- Casseroles
- Soups
- Stews

Which Contain Carbohydrate?

- Stew
- Brussels sprouts
- Sugar-free jello
- Skim milk
- Fat-free frozen yogurt
- Baked chicken
- Rice
- Orange juice
- Diet soda
- Oreos

Which Contain Carbohydrate?

- Stew
- Brussels sprouts
- Sugar-free jello
- Skim milk
- Fat-free frozen yogurt
- Baked chicken
- Rice
- Orange juice
- Diet soda
- Oreos

Carbohydrates are Healthy

- Most foods containing carbohydrates are among the healthiest foods to eat:
  - grains, fruits, vegetables, low-fat milk and yogurt
- Carbohydrates are the foundation of a healthy eating plan
  - contain many essential vitamins, minerals, and fiber

Does the Type of Carbohydrate Matter?

- Various carbohydrates have slightly different effects on blood glucose
  - processing, cooking, fiber, mixed meals with with fat or protein effect glucose response

The Amount of Carbohydrate is More Important Than the Type

1 (2") frosted brownie = 2 slices bread

1 cup ice-cream = 2 slices bread

or

(30 grams carbohydrate)

Use of Sugar in the Meal Plan

- Can be used in moderation
  - share desserts in restaurants
  - ask for child-sized portions of ice-cream
  - keep large portions of sweets out of the house
- Substitute for other carbohydrate in the same meal
- Check effect on your blood glucose

Use of Sugar in the Meal Plan

Many high-sugar foods:

- are also high in fat, increase triglycerides
- provide very little nutritional value (empty calories)
- may replace healthier foods

2 Ways to Count Carbohydrate

- **Carbohydrate Choices**
  Food Exchanges or Servings
- **Carbohydrate Grams**
  Specific number of grams of carbohydrate per meal or snack

Carbohydrate Choices (servings)

- Each food: fruit, starch, milk group contains about 15 grams carbohydrate
- One carbohydrate serving = 15 grams carbohydrate

Carbohydrate Choices

- Lunch:

Exchanges		Carbohydrate Choices
2 starch	=	2 carb servings
1 fruit	=	1 carb serving
1 milk	=	1 carb serving
3 meat	=	0 carb serving
2 fat	=	0 carb serving

Each Carbohydrate Choice
= 15 grams Carbohydrate

Example:

- Breakfast: 3 carb serving = 45 grams
- Lunch: 2 carb serving= 30 grams
- Snack: 1 carb serving= 15 grams
- Dinner: 3 carb serving= 45 grams
- Evening Snack: 1 carb serving = 15 grams

How Much Carbohydrate are needed ?

- Depends on your:
  - calorie needs
  - height
  - weight
  - physical activity
  - level of fat in your blood (triglycerides)
  - usual food habits and schedule

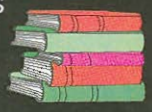
Carbohydrate Needs (Example)

1500 Calories: 188 grams/day = 12.5 carb servings

- 3 carb choices at breakfast
- 4 carb choices at lunch
- 4 carb choices at dinner
- 1 carb choice at bedtime

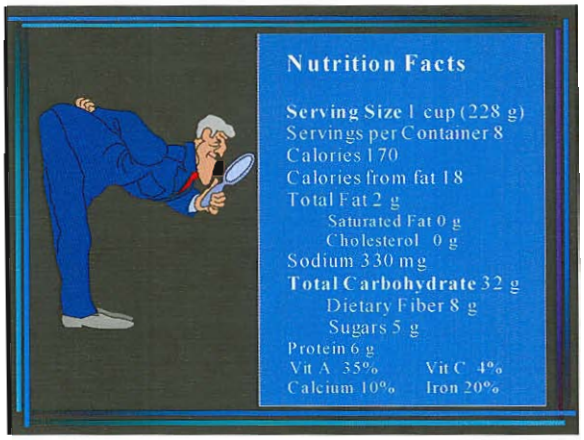
Resources for Counting Carbohydrate

- Food package labels
- Carbohydrate counting books
- Food Exchange booklets



Nutrition Facts Label

- Best resource for carbohydrate counting
- Pay attention to:
  - Serving Size
  - Total Carbohydrate



Food Label (Example 1)

- Your meal plan: **2 carb choices (30 grams carb)**
- Food label (ice-cream):
  Serving size = 1/2 cup
  Total carbohydrate = 15 grams

How much ice-cream should you have?

Food Label (Example 2)

If your meal plan at breakfast is:
45 grams carbohydrate, 1 oz. protein

Food label:	Cereal	Milk
Serving size:	1/2 cup	1 cup
Total Carb:	15 grams	12 grams

How much cereal, milk should you have?
What type of protein should you have?

Carbohydrate Counting Books

- Use for foods without a Nutrition Facts Label
  - Fresh fruits
  - Fresh vegetables
  - Breads from a bakery or farmer's market
  - Restaurant foods

Food Exchange Booklet

- Gives average carbohydrate values for many foods
- Pocket Guide available

Practice Counting Carbs #1

Breakfast	Choices	Grams
1 large bagel (4 oz)		
1 tsp. margarine		
1 scrambled egg		
1/2 cup orange juice		
1 cup skim milk		




Practice Counting Carbs #2

Dinner	Servings	Grams
Spaghetti noodles		
1 cup, 3 meatballs		
Spaghetti sauce, ½ cup		
Tossed salad with lettuce, tomato & dressing		
Garlic bread, 2 slices (2 oz)		
Diet Coke		




School Meals & Snacks

- Provide school menus & nutrition info to students & families in advance
- Provide sufficient time for eating
- Monitor actual food intake per meal plan
  - young, or new diagnosed
  - picky eaters
- Respect, encourage independence

School Meals

- The approximate carbohydrates content of school meals can be determined in advance by the school nutrition director & can be indicated on the school menu for each item.

School Parties

- Provide parent /guardian with advance notice of parties / special events
- Follow the student's meal plan and 504 Plan or IEP
- Some students may prefer to bring their own lunch
- Provide nutritious party snacks to encourage healthy eating habits for all

Field Trips

- Brink plenty of snacks to treat hypoglycemia
- Bring appropriate lunch
- Check with parent/guardian about food and/or insulin adjustment for extra activity level
- Bring diabetes equipment & supplies
- Bring list of emergency contacts

Matching Insulin to Carbohydrate Intake

- Useful for student taking at least 3-4 insulin injections per day or on insulin pump
- Carbohydrate to insulin ratio is determined
  - Example: Ratio of 15:1 means that 1 unit of insulin needed for every 15 grams carbohydrate
- Insulin dose depends on planned carbohydrate intake at meal

Write down:

- Carbohydrate eaten
- Times of meals
- Blood glucose results
- Diabetes oral medications or insulin
- Physical activity/exercise

What Else Affects Your Blood Glucose?

- **Portions sizes**
  - Large portions of carbohydrate increase blood glucose

What Else Affects Your Blood Glucose?

- **Timing of food intake**
  - Space food throughout day
  - Eat at regular times
  - Don't skip meals

Measuring and Weighing Foods

- You can't accurately count carbohydrate without weighing and measuring
- Weigh at least once a week
- Practice, practice, practice!

What to Weigh and Measure

- **Weigh**: Bread, rolls, bagels, some fruits, baked potatoes
- **Measure**: mashed potatoes, popcorn, pasta, rice, vegetables, fruit juice

Mixed Foods Containing Carbohydrate

- Macaroni & Cheese
- Soups
- Casseroles
- Lasagna
- Subs
- Beef Stew
- Spaghetti and Meatballs

Restaurant Dining

- Dining Out in Restaurants
  - Use books on restaurant eating
  - Estimate carbohydrate content
    - Check blood glucose 2 hours after meal
- Take-out (Example: Chinese)
  - Measure food at home to determine carbohydrate content

Fast Foods

Get carbohydrate information from:

- Web site or toll-free number for chain restaurants
  - i.e. www.mcdonalds.com
- Extension web site for fast foods
- Carbohydrate counting books

Fast Food Restaurants #1

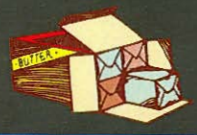
Subway®	Carb	Exchanges
Classic Italian	**43 g**	2 1/2 starch 2 meat,1 veg, 1 fat
Tuna - 6"	**42 g**	2 1/2 starch 1 meat, 1 veg 5 fat

Fast Food Restaurants #2

McDonalds®	Carb	Exchanges
Hamburger	**34 g**	2 starch, 1 meat 1/2 fat
6-pc Chicken McNuggets	**15 g**	1 starch, 2 meat, 1 1/2 fat
French Fries medium	**57 g**	4 starch, 3 fat

Other Factors to Consider

- **Fat**
  - Slows down time your stomach takes to empty
  - Delays rise in blood glucose
  - High in calories



Other Factors to Consider

- **Protein**
  - Slows down time your stomach takes to empty
  - Usually combined with fat

Weight Gain and Carbohydrate Counting

You can gain weight if you:

- Count carbohydrate, but ignore content of foods
- Eat more high-calorie foods
- Need increase insulin to control BGL, higher carb intake

Fiber and Carbohydrate Counting

- Included in total carbohydrate
- Does not convert to glucose
- For more than 3 grams insoluble fiber per serving: subtract amount of fiber from the Total Carbohydrate

Fiber and Carbohydrate Counting

- For example:

1 cup cereal = 30 gm Total Carbohydrate
- 7 gm insoluble dietary fiber
23 grams

Count as 23 grams carbohydrate

Exercise & Diabetes

- Everyone benefits from exercise & physical activity
  Students with diabetes should fully participate
- In general, exercise lowers BGL
  - May need to make adjustments to insulin/meds & food intake
  - A quick-acting source of glucose, glucose monitor, & water should be available
  - PE teachers & coaches must be familiar with symptoms of both high & low BGL

Exercise & BGL

- Check before, during & after exercise per
  - Especially a new activity or sport
  - If blood glucose starts to fall, student should stop & have a snack
  - Students with pumps may disconnect or adjust the basal rate down, instead of snacking

Type of Exercise	If Blood Sugar Is:	Increase Carb. Intake by:	Suggested Food
• Short Duration or Moderate intensity	Less than 80-100 mg/dl	10-15 grams	1 fruit & 1 protein or 1 bread
	100 mg/dl or above	Not necessary	—
• Moderate intensity	Less than 80-100 mg/dl	25-50 grams before exercise then 10-15 grams/hr. if necessary	½ meat sandwich + milk or fruit
	80-170 mg/dl	10-15 grams	1 fruit & 1 protein or 1 bread
	180-300 mg/dl	Not necessary	—
	300 mg/dl or greater	Don't exercise	—
• Strenuous activity or exercise	Less than 80-100 mg/dl	50 grams	1 meat sandwich + milk or fruit
	180-300 mg/dl	10-15 grams/hr	1 fruit & 1 protein or 1 bread
	300 mg/dl or greater & ketones present	Don't exercise	—

Treating Hypoglycemia

Blood Glucose	Amount of Carbohydrate Recommended
51-70 mg/dl	15 grams
41-50 mg/dl	20 grams
<40 mg/dl	30 grams

Amount of Carbohydrates	Apple or Orange Juice	Grape juice	Skim Milk	Cola/ Sprite
15 grams	4 oz.	3 oz.	8 oz.	4 oz.
20 grams	5 oz.	4 oz.	10 oz.	5 oz.
30 grams	8 oz.	6 oz.	16 oz.	8 oz.

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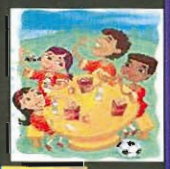
Exercise & Insulin/ Meds

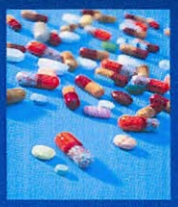
- Physical activity can raise BGL if there is insufficient insulin
  - Follow the student's plan for exercise restrictions when ketones are present
- Work with parents/ guardians to determine the best times for physical activity and to adjust snacks, insulin, or timing of activity to prevent low or high BGL.

So, enjoy the increased variety and flexibility with Carb Counting & exercise...



..but watch the fat and calories!

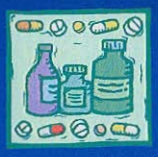
Diabetes Medications



Conemaugh Diabetes Institute

Classes of Medications

Sulfonylureas
Meglitinides
Biguanides
Alpha Glucosidase Inhibitors
Thiazolidinediones-TZD's
Incretin Mimetics
DPP 4's



Sulfonylureas

Most common drugs in this class:

- Glipizide (Glucotrol, Glucotrol XL)
- Glyburide (Micronase, Diabeta, Glynase)
- Glimepiride (Amaryl)

How do they work?

- Stimulate the pancreas to make more insulin
- Work for up to 24 hours
- Lowers fasting and post prandial blood sugar

Meglitinides

Drugs in this class:

Repaglinide(Prandin)
Nateglinide (Starlix)

How do they work?

- Stimulate the pancreas to make more insulin
- Work only for about 4 hours after meals
- Only effects post prandial sugars – NOT FASTING!

Biguanides

Drug in this class:

- Metformin (Glucophage, Glucophage XR)
- Liquid Form (Riomet)

How does it work?

- Helps your body produce less glucose from the liver
- Helps insulin work better
- Reduces glucose absorption in the intestines
- Takes up to 2 weeks to see maximum effect

Alpha Glucosidase Inhibitors

Drugs in this class:

- Acarbose (Precose)
- Miglitol (Glyset)

How do they work?

- Slows the digestion of carbs in the small intestine thus decreasing the post prandial blood sugar spike

Insulin Sensitizers-TZD'S

Drugs in this class:

- •Rosiglitazone (Avandia)
- •Pioglitazone (Actos)

How do they work?

- •Help insulin work better
- •Enhances glucose uptake by the muscle tissue
- •Reduces glucose production by the liver
- •Takes up to 3 months to see maximum effect

Combination Drugs

Glucovance (glyburide/metformin)

Metaglip (glipizide/metformin)

Avandamet (avandia/metformin)

Janumet(januvia/metformin)

Actoplus (actos/metformin)

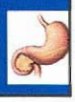
Avandryl (avandia/glimepiride)

New Extended Release Drugs

- Fortamet ER
- Glumetza ER
- Both extended release Metformin

Non Insulin Injectables:

- Byetta (Exenatide) Incretin Mimetic "gut hormone"
  - approved for type 2
  - mimics the effects of GLP-1
  - Works on
    - liver
    - stomach
    - pancreas
    - brain



Non Insulin Injectables

- Symlin(Pramlintide) synthetic analog of amylin which is cosecreted with insulin by the pancreatic beta cells
  - Approved for type 1
  - Same action as Byetta except it <u>does not</u> stimulate the pancreas

DPP 4 Inhibitors

- Drugs in this class
  - Sitagliptin(Januvia)
  - Others under FDA review

How does it work?

Slows the inactvation of the "gut hormones"-GLP1 and GIP which are diminished in type 2's

Insulin

Jan Albert RN, CDE

Insulin

Insulin is a hormone produced in the beta cells of the pancreas

It`s job is to:

- Get glucose into the cells
- Decrease release of glucose from liver and muscles

Types of Insulin

- Rapid acting
  - Novolog, Humalog, Apidra
- Short acting
  - Regular
- Intermediate acting
  - NPH
- Long acting
  - Lantus, Detemir
- Combination
  - Novolog 70/30, Humulin 70/30, Humulin 50/50, Novolin 70/30, Humalog Mix 75/25, Humalog 50/50
- Inhaled insulin
  - Exubera

Insulin Therapy

- Each person has unique requirements
- Single and multiple injection schedules
- Insulin pump

Insulin Therapy

- Basal (background)
  - Long acting insulin to cover your normal body functions. (NPH, Lantus,Detemir)
- Bolus- (meal coverage)
  - Shorter acting insulin (Novolog, Humalog, Exubera, Apidra, Regular insulin)

Insulin delivery systems

Vial and syringe

Insulin pens

Disposable dosers

Inhaled Insulin

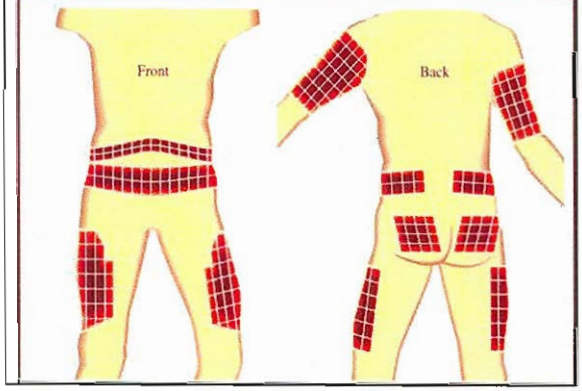
Insulin: How and Where to Inject

- Clean the site with soap and water
- NPH (cloudy) must be rolled at least 10 times.
- Accurately measure the amount of insulin, making sure no air bubbles are in the syringe
- Rotation of sites
  - Abdomen, arm, leg, and hip sites
  - Do not inject at the same spot more than once a month

Insulin: Routine Insulin Injection

- Subcutaneous tissue
  - 90 degree angle - most adults
  - 45 degree angle – children/thin adults
- Rotation of sites
  - Abdomen, arm, leg, and hip sites
- Examine injection site for:
  - Bruising, redness, infection, and lumps

Insulin Injection Areas



Insulin:When to Inject

- Basal insulin (long acting)
  - Inject at the same time everyday
- Bolus insulin (short acting)
  - Short acting insulin (Regular)
    - 30 – 60 minutes before eating
  - Rapid acting insulin (Novolog, Humalog, Apidra)
    - at least 15 minutes before eating
  - Inhaled insulin (Exubera)
    - no more than 10 minutes before eating

Insulin: Tips for Taking Insulin

- Take your insulin even when you are ill and unable to eat
- AVOID
  - Giving insulin over a muscle you will be using within 30 minutes
  - Rubbing the sites
  - Long hot baths after injecting
- Check expiration dates before use
- Examine insulin vial for crystals and discoloration
- Wear identification

Inhaled Insulin: Exubera

- Not for kids!
- Its onset, duration, and peak are similar to the rapid acting insulin
- Contraindicated in
  - Smoker or those who have smoked within last 6 months
  - Lung problems
- Check pulmonary function test after 6 months then yearly

Pump Therapy

Jan Albert RN, CDE, CPT

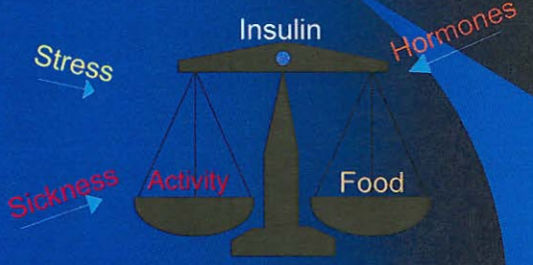
Diabetes

- Diabetes is one of the most common chronic diseases in school-aged children.
- One out of every 400-500 kids < age 20 is diagnosed with Type 1 diabetes.
- Unfortunately with the rising obesity rates, we now are seeing more and more kids and teens diagnosed with Type 2 diabetes.

Objectives

- Understand the principles of pump therapy
- Discuss the benefits and limitations of pump therapy
- To be able to assist student with meal bolusing

A Balancing Act



Healthy Pancreas

- Produces enough insulin to maintain blood sugar levels while fasting.
- The liver releases stored glucose to help with energy needs during fasting.
- A burst of insulin is automatically released when food is eaten.

Unhealthy Pancreas Needs

- 1) Basal or background insulin --
  Automatically releases small amounts of insulin continuously through the day / night.
- 2) Bolus insulin --
  The user enters the amount of insulin needed to cover the food eaten and/or to lower a high blood glucose.

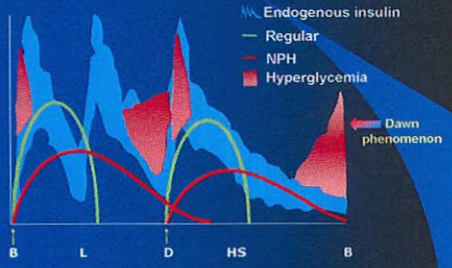
Intensive Therapy

Multiple Daily Injections

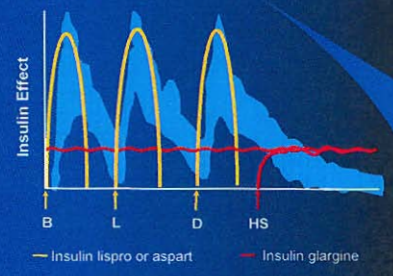
vs.

Insulin Pump

Twice-Daily Split-Mixed Regimens



Basal-Bolus Insulin Therapy: Insulin Glargine at HS and Mealtime Lispro or Aspart

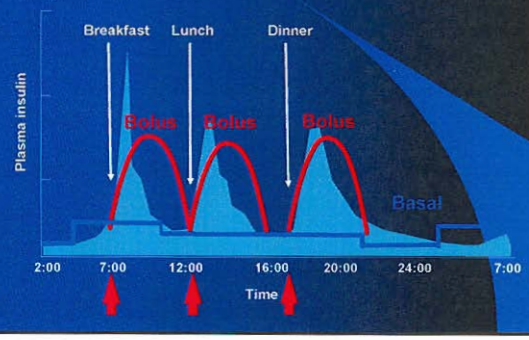


Adapted with permission from Leahy J. In: Leahy J, Cefalu W, eds. *Insulin Therapy*. New York, NY: Marcel Dekker Inc.; 2002:87.

Insulin Absorption

- Long-acting insulin absorption may vary 10 - 52%
  - **Unpredictable.**
  - **Tight control very difficult.**
- Fast-acting insulin absorption varies less than 3%
  - **Very predictable.**
  - **Allows for tighter control.**

Basal And Bolus In Pumps



Current Typical Diabetes Routines

Type 1 on injections	Type 1 on a pump
4-6 BG checks per day	o One injection every 2-3 days
2 – 4 shots per day	o 6-10 BG checks per day
Scheduled meals	o Meals and snacks at your convenience
Planned exercise	o Spontaneous exercise / activity

Pumps Offer More Normal Lifestyle

- Liberalization of diet – timing and amount.
- Increased control with exercise.
- Able to work shifts and through lunch.
- Less hassle with travel and time zones.
- Less anxiety in trying to keep on schedule.

Insulin Pump Delivery

- Uses rapid acting insulin alone.
- Automatically releases small amounts of insulin continuously through the day / night (basal rate of insulin).
- The user enters the amount of insulin needed to cover the food eaten and/or to lower a high blood glucose (bolus of insulin).

How is Patient Attached?

- The pump is "attached" by an "infusion set" with a thin catheter that is inserted into skin.
- The pump attempts to mimic a normal pancreas' release of insulin, BUT patient must tell the pump how much insulin.

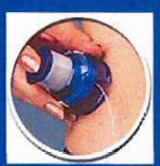
Infusion Sets

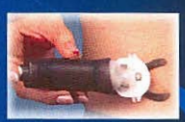
- Infusion sets come in different cannula and tubing lengths.
- If patient is very thin, 6mm or possibly an angled one.
- If heavy, a longer 9mm cannula.
- Must change every 2 - 3 days

Infusion Sets

Comfort, Tender™/Silhouette™

Inset





Benefits

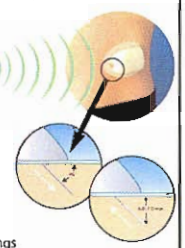
OmniPod Insulin Management System

Automated cannula insertion

- Provides consistent cannula insertion (angle and depth) with each and every OmniPod
- Minimizes errors and variability commonly associated with manual insertion and insertion devices

Rated virtually pain-free by patients'

A closer look at the OmniPod System's Automated Cannula Insertion



Smart, easy to use Personal Diabetes Manager

- Features intuitive, menu-driven programming

Suggests personalized bolus dosages based on individual settings

- Puts a reference food library and complete diabetes management records at the fingertips

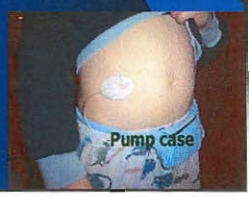
1. Data on file at Insulet Corporation.

Insulet Corporation MyOmniPod.com

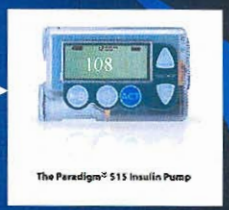
OmniPod

How to Wear A Pump?

- Clip it--similar to a beeper.
- Sleeping--under pillow, special clothing, special cases...
- Exercise--clip it to shorts, Sport Pac.
- Accessories —
  - Belter
  - Clip 'n Go
  - Colorful Covers
  - Bra Band
  - Waist-it.



Meter Talks to Pump



The Paradigm® 515 Insulin Pump

Pump is Meter

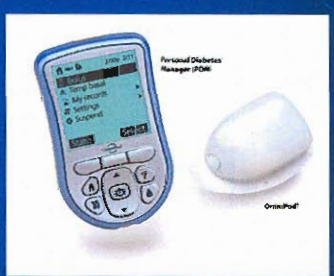
Take the guesswork out of counting carbs

- Create a food database on your pump using CalorieKing
- Choose up to 500 foods from a list of 7,000
- Add family favorites
- Enter up to 9 food items for any one meal -- the IR 1250 totals the carbs and calculates the insulin dose

Pump Is Carb Counter

- Pump or external controller contains user-selected food list for accurate carb counting.

No strings attached ! Omni pod



Accu Chek d-tron and Spirit

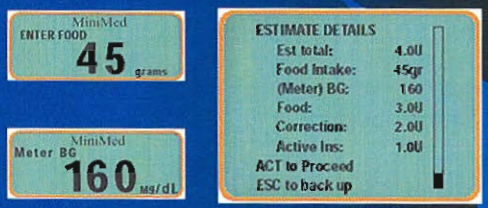
Smart Pumps

Now have smart pumps.

They do all of the math.

"Carb Smart", Bolus Wizard

Carb Bolus Assistance



Carbohydrates… What are They?

- When eaten, cause a rise in blood glucose.
- ALL carbohydrates (starches and sugars) eventually turn into glucose in the blood.
- Your insulin bolus dose should be matched to the amount of carbohydrate eaten.

Food Sources That Affect Blood Glucose

- *Carbohydrates*
  (Starches, fruits, vegetables, milk, and sugars)
  Constitutes most of the glucose that enters the bloodstream between 15 minutes to 2 hours after eating.
- *Protein and Fats*
  Glucose from protein and fat appears hours after eating, not *immediately* after the meal; proteins and fats can potentially slow down the rate at which accompanying carbohydrates turn to glucose.

Two Methods of Counting Carbohydrates

- *Carbohydrate Gram Counting*
  Adds up the exact number of grams of carbs for each meal and snack. Food labels, food lists, and meal planning books are useful tools.
- *The Carbohydrate Exchange System*
  Uses food 'exchange' groups. One exchange or serving of food containing carbs has approximately 15 grams of carbs.

Nutrition Labels

- *Total Carbohydrate*
  Includes grams of sugar, sugar alcohol, starch, and dietary fiber.
- *Serving Size*
  Grams of total carbohydrates, multiplied by number of servings = total grams of carbs.

Nutrition Labels

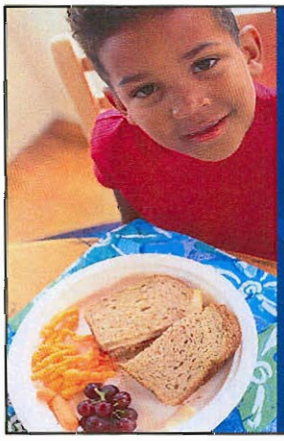
If using the Exchange Method, divide the total grams of carbohydrate by 15 for the number of carb exchanges in a food.

This food label describes one serving as 1 cup containing 31 grams of carb or 2 carb exchanges.

Tools for Carbohydrate Counting

Nutrition Labels

Measuring Tools



Calculating a meal bolus dose

Insulin-to-Carbohydrate Ratio

- Individually determined, for example:
  - Kate: 1.0 unit of insulin for 15g carbs
  - Luis: 1.0 unit of insulin for 7g carbs
  - Tim: 1.0 unit of insulin for 75g carbs

Estimating an Insulin-to-Carbohydrate Ratio

Use the 500 Rule:
500 divided by total daily insulin dose

Example:
500 / 50 = 10
Insulin to carb ratio = 1u for 10g

Calculating a correction bolus dose

Using Insulin Sensitivity
to Determine a Correction Dose

Insulin sensitivity (correction factor) determines the estimated BG reduction for every 1.0 unit of insulin.

Your HCP calculates this information for you.

Insulin Sensitivity: The 1700 Rule

1700 Rule says:

Take 1700 and divide by your total daily insulin dose to determine your insulin sensitivity (correction factor)

Example:
50 units insulin/day
1700/50 = 34
1 unit lowers BG 34 mg/dl

Correction Bolus Formula

$$\frac{\text{Current BG} - \text{Ideal BG}}{\text{Correction Factor}}$$

Example:
Current BG: 220 mg/dl
Ideal BG: 100 mg/dl
Correction Factor: 30 mg/dl

$$\frac{220 - 100}{30} = 4.0u$$

Glucagon

- Can save a life.
- Cannot harm a student - they can't overdose.

Glucagon Kit Storage

- Place: As designated in DMMP accessible to school personnel
- Store at room temperature
- Expiration date: Monitor
- After mixing, dispose of any unused portion within one hour

Causes of Hyperglycemia

- If pump delivery is interrupted, blood sugar will start to rise 90 minutes later.
- DKA can develop within 4 - 5 hours.
- Infusion site and set problems are the most common cause of DKA. Problems can also occur as a result of outdated insulin or incorrect programming.

Pump Perks

- Pumps, when set up correctly and used correctly, will allow for a more consistent, flexible, and precise delivery of insulin that keeps your blood sugar in target range
- A well trained "pumper" whose settings are correct can skip meals, eat late, and cover variations in carb intake without losing control.

Disconnecting From the Pump

You can remove pump for 1 hour without taking insulin

- **If removed for more than one hour you have 2 options:**
  - **Bolus with needle and syringe**
  - **Reconnect and take a bolus**
- **It's recommended that you take an injection or bolus every 4 hours**
  - **Include: 1. missed basal units**
    2. missed meal bolus
    3. correction bolus

Sports and Pumps

- Usually removed during contact sports.
- Many have protected cases.
- Do not remove pumps for longer than 1 - 2 hours without a plan for insulin replacement.

Exercise and Pumping

- Usually no adjustment is needed if 30 minutes or less.
- Use temporary basal rate if exercises causes you to drop low. Start rate 1 hour before starting to exercise, the entire time you exercise, and 1 hour after you are done exercising.

Draw Backs of Pump Therapy

- Risk of DKA
- Infection
- Attachment to an external device

Myths About Pump Therapy

- Injections will never be needed again.
- Can have anything you want to eat, at any time, and in any amount.
- A pump causes weight gain.
- Must be admitted to a hospital to start pump therapy .
- A pump is a constant, visible reminder of having diabetes.
- A person is too young or too old to get a pump.

Cost and Insurance

- A pump typically lists for close to $6000.
- Pump supplies average $1,200 to $1,600 per year.
- Most insurance companies cover all or most of these costs.

Questions???

Case Study

Conemaugh Diabetes Institute

- JJ is a 15 year old with Type 1 Diabetes. He has final exams today. During lunch he studied. He ate an apple. Half way through the test he began to become verbal and loud. When the teacher approached him he became more aggressive.
- What is happening?
- How should the teacher respond?

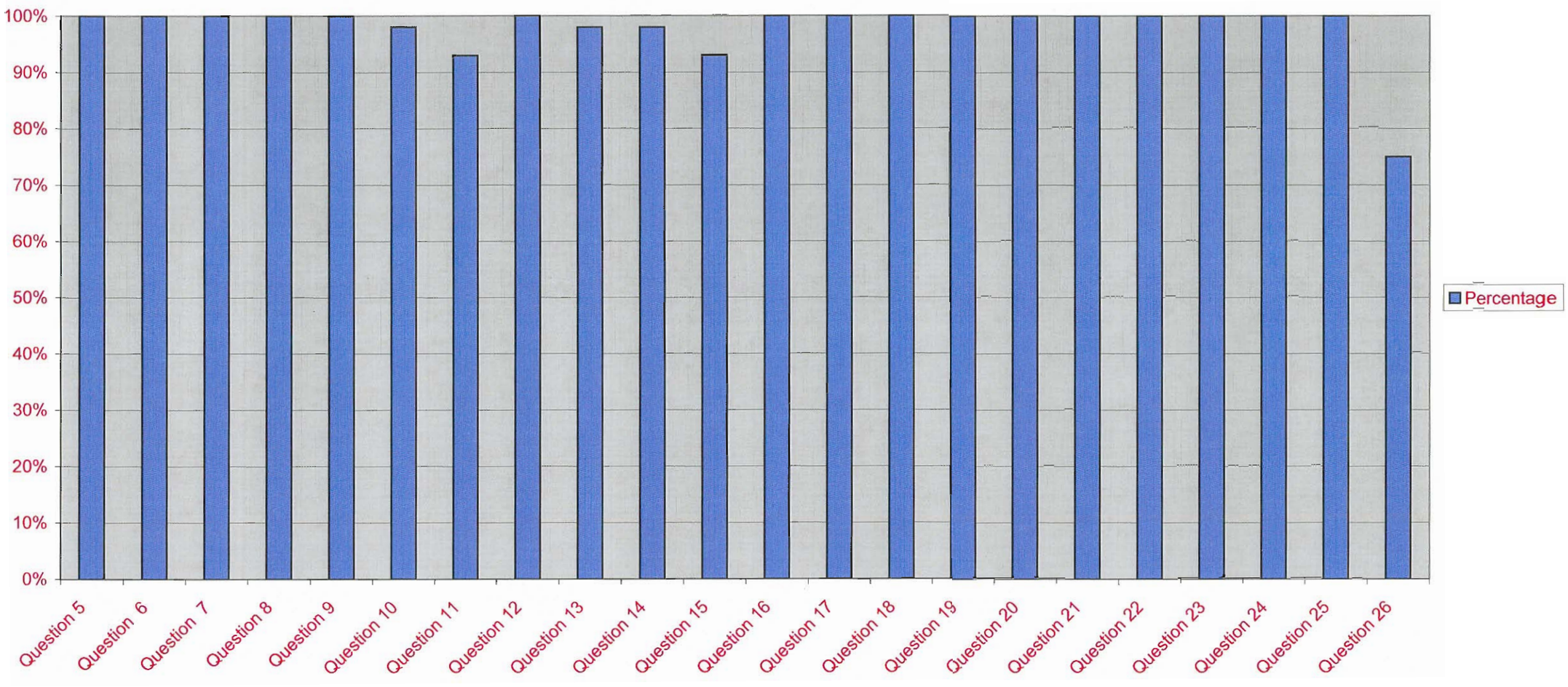
- AJ is a 16 year old with Type 1 Diabetes. She uses an insulin pump to manage her BS. Her morning BS was 110. When she checked her BS prior to lunch it was 210. She gave herself a bolus to cover the BS and number of carbs she ate. After lunch her BS was 300 and she had moderate ketones in her urine.
- What is happening?
- How should you respond?

- MS is a 16 year old with Type 1 Diabetes. She is in gym and they are playing basketball. MS is unable to walk and follow directions. You suspect her BS is low. MS does not have her meter with her. It is in her locker.
- How would you respond?

Diabetes Education in High Schools
2007 Program Comments

1. The session on meds was particularly helpful, I was way outdated!
2. Excellent presentation.
3. Will connect Conemaugh Diabetes Institute for future programs for faculty.
4. Handouts were great!
5. Would appreciate blank pages in binder for note taking.
6. The part on carb counting was good.
7. Would like more info on the carb counting and the exchange system.

Diabetes Education in High Schools Program



Diabetes Education in High School 2007 Program

Question	Percentage
Question 5	100%
Question 6	100%
Question 7	100%
Question 8	100%
Question 9	100%
Question 10	98%
Question 11	93%
Question 12	100%
Question 13	98%
Question 14	98%
Question 15	93%
Question 16	100%
Question 17	100%
Question 18	100%
Question 19	100%
Question 20	100%
Question 21	100%
Question 22	100%
Question 23	100%
Question 24	100%
Question 25	100%
Question 26	75%

Diabetes Self Management: An Overview

Jan Albert RN, CDE

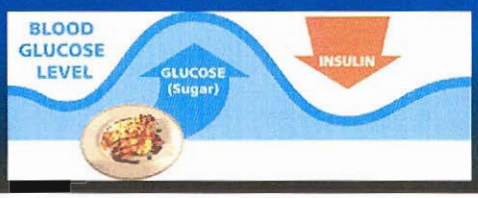
Eileen Fiorina, RD, CNSD, LDN

Antoinette Franke, RN, CDE

Bonnie Pepon, RN, BSN, CDE

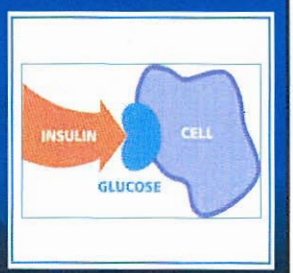
What is Diabetes?

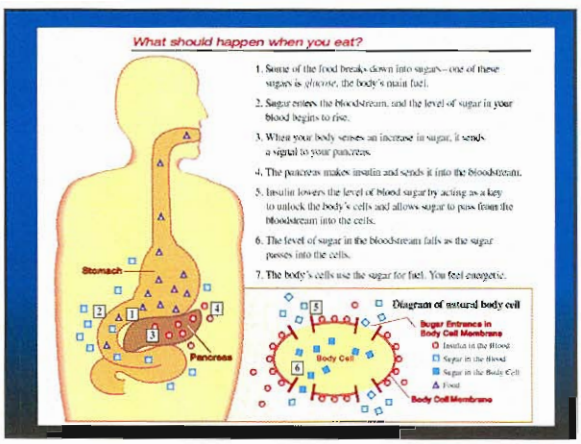
– Diabetes is a chronic progressive condition of impaired glucose metabolism characterized by insulin absence, deficiency and/ or resistance.

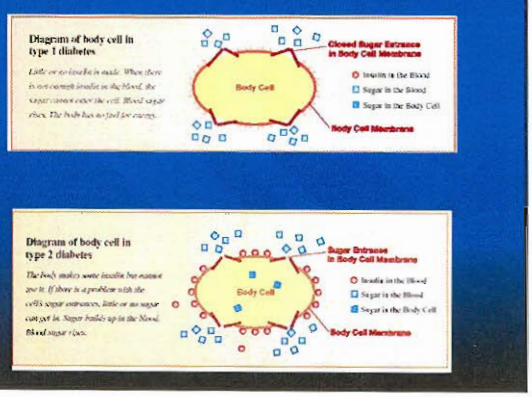


The Basics: Glucose and Insulin

- Glucose comes from food we eat, also the liver and muscles
- Glucose = energy for body
- Blood carries glucose to cells
- Insulin helps glucose into cells







Types of Diabetes

Type 1
Type 2
Gestational
Pre-diabetes/insulin resistance

Blood Glucose Values

- 70-100 mg/dl normal blood sugar
- 100-125 mg/dl pre-diabetes
- >126 mg/dl diabetes

Type 1 Diabetes

-Insulin dependent

-Usually occurs in young people, but can occur in older persons

-Normal body weight

-Prone to ketoacidosis

Symptoms of Type 1

Increased thirst
Increased passing of urine
Increased hunger
Sudden weight loss
Dehydration
Extreme tiredness

Causes of Type1

Family history
Viruses
Body's own white blood cells have destroyed the insulin-making cells in the pancreas

Type 2 Diabetes

Insulin resistant -makes it but can't use it
Over 40 years old
Overweight
Family history
Given birth to a baby over 9 pounds

Symptoms of Type 2 Diabetes

- Dry itchy skin
- Feeling tired
- Frequent infections
- Frequent passing of urine
- Blurry vision/slow healing
- Increased thirst
- Increased hunger





Treatment Tools

Education
Meal planning
Exercise
Medicines
Monitoring
Diabetes tests

Diabetes Self Management Education

- Balance is the key to diabetes self management

Goals of Management

- Maintain blood glucose to near normal
- Achieve and maintain healthy weight
- Integrate diabetes with lifestyle
- Prevent or delay progression of complications

DCCT Study Findings

- Lowering blood sugar reduces the risk for:
  - Eye disease
    - 76%
  - Kidney disease
    - 50%
  - Nerve disease
    - 60%
  - Cardiovascular disease
    - 35%

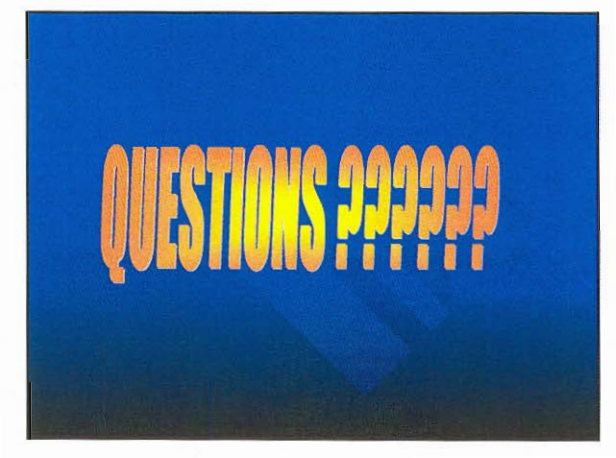
Important tests to have done…

Hemoglobin A1C	every 3 months
Blood Pressure	every visit
Lipid panel	ever year
Urine test (microalbumin)	every year
Eye exam	every year
Flu shot	every year

Pneumonia shot- if given before the age of 65, need a booster if 5 years passed since the 1st dose if given at age 65 or older only one dose needed

What is an A1C?

- A blood test that measures the average blood sugar over the last three months
- Normal 4-6%
- Diabetic goal
  - ACE goal < 6.5
  - ADA goal < 7
- For every 1% decrease in A1C, complication risk drops at least 25%


QUESTIONS ¿¿¿¿¿¿

Diabetes : Nutrition Component

Eileen T. Fiorina, RD, CNSD LDN
Conemaugh Diabetes Institute

Main Topics

- Healthy Eating
- Carbohydrate Counting/Exchange Lists
- Meal Planning
- Measuring Tips
- Food Label Reading
- Eating Out/Special Occasions
- Sick Day Management
- Other DM resources

Diabetes is Managed by:

- Diet – food what & how much is eaten
  - Increases Blood Glucose Levels (BGL)
- Medication
  - May decrease or increase BGL depending on medications
- Exercise
  - Decreases BGL
- Stress
  - Increases BGL
- Infection/illness
  - Increases BGL

Healthy Eating

- Dietary Guidelines for Americans
  - Whole grains vs. white flours
  - More fruits and vegetables to increase fiber
  - Low fat milks or yogurts
  - Healthy kinds of fat
    - Monounsaturated fats
  - Exercise
  - Less salt

Where should calories come from??

- Carbohydrate
  - 50-55%
  - 4 calories/gram
- Protein
  - 10-20%
  - 4 calories/gram
- Fat
  - 25-30%
  - 9 calories/gram

What are Nutrients?

- Carbohydrates
- Protein
- Fat
- Vitamins & Minerals
- Fluids

What are Carbohydrates?

- Starches
- Starch Vegetables
- Fruits & Juices
- Milk & Yogurt
- Sweet Snacks
- Most Salty Snacks

What percentage of foods are converted to blood sugar?

- Carbohydrate - glycogen
  - 100%
- Protein - muscle
  - 50%
- Fat - ketones
  - Less than 10%

What are Proteins?

- Animal Sources
  - beef, pork, poultry, fish, cheese, eggs
- Vegetable Sources
  - peanut butter, tofu, dried beans & peas

What are fats?

- Monounsaturated – help HDL's remain high
- Polyunsaturated – remain the same
- Saturated – lower HDL, increase LDL

The goal is to reduce saturated fats and replace with unsaturated

Water is needed for:

- Needed to form digested juices
- To carry nutrients
- Lubricated joints & muscles
- Regulates body temperature
- ¾ of body fluid is water
- Encourage 4-6 (8oz.) glasses daily

Fiber

- Indigestible part of plant food
- Provides bulk
- Reduces BGL
- Can help reduce blood fat & cholesterol levels
- Diet should include 20-35 grams of fiber daily
- Major sources are whole grains (bread, cereals, vegetables, fruits, nuts & seeds)

Carbohydrate Counting

- Magic Number =

  15 grams

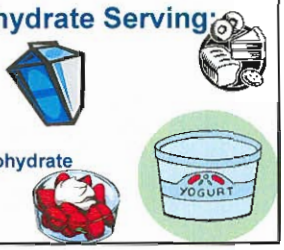
  Total Carbohydrate
- 1 starch
- 1 fruit
- 1 milk

**All of these are equal to 1 carb exchange.

Carbohydrate Counting

- The following all equal =

  1 Carbohydrate Serving:
  - 1 carb serving
  - 1 starch
  - 1 fruit
  - 1 milk
  - 15 grams total carbohydrate



What is Meal Planning?

- It is knowing:
  - What to Eat
  - When to Eat
  - How much to Eat

Meal Planning- Basic Guidelines

- Eat at least 3 meals
- Eat regularly throughout the day
- Eat even amounts of high carb foods throughout the day
- Use nonstarchy veggies and free foods as fillers & snacks
- Test BGL regularly!!

When to eat

- Eat at the same time every day
- Eat every 4-5 hours
- Do not skip meals
- Time meals to synchronized diabetes medications with peak times
- Some may need a snack between meals
- Snack a bedtime daily

How much to eat?

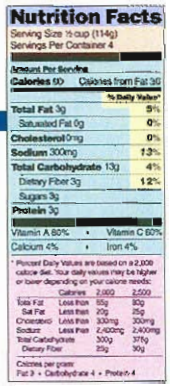
- Balance food intake with activity
- Measure foods - monitor portion size
- Eat the correct carbohydrate servings per meal

Sample Breakfast: 4 Carbs

• ½ Cup Oatmeal	Or	2 whole wheat toast
• 1 Cup Skim milk		1 egg scrambled
• 1 Whole wheat toast		½ Cup OJ
• 1 T. Peanut butter		1 Cup Skim milk
• 1 small banana		1 Cup coffee/tea
• 1 Cup coffee/tea		

Label Reading

- Serving size/ per- container
- Total calories
- Total carbohydrates
  - Sugar
  - Dietary fiber
- Total Fat
  - Monounsaturated
  - Unsaturated
  - Trans
  - Saturated



Areas of Interest

- Sugar substitutes
- Sugar Alcohols
- Low carb items –may contain more fat
- Sugar free items – may contain still contain carbohydrates

Tips for Eating Out: All foods can fit!!

- Plan ahead
  - Call restaurants or go on line for menus, prep. methods, or specials
- Focus on PORTIONS
- Count carbs
- Fill up of free foods
  - Non-starchy veggies, diet sodas, water
- Ask server to remove bread from table
  - Unless counting as a carb

Tips for Eating Out: All foods can fit!!

- Ask for items or for the item to be prepared differently
- Skip fried foods and buffets
- Special requests:
  - Ask for items to be on the side (dressings, butter, etc.)
  - Ask for items to be served without sauces, butter, etc.
  - Low calorie salad dressing
  - Fruit for dessert

More Restaurant Eating Tips…

- Choose More Often:
  - Broth soups
  - Fresh fruits and veggies
  - Baked, broiled, grilled items
  - Small portions
  - Light desserts (share)

Special Occasions

- Weekends, Holidays, Vacations
- Plan ahead
- Take snacks
- Stick to some eating schedule
- Account for more activity or specialty foods

Sick Days

- Everyone gets sick: cold, flu, fever & ect.
- Interrupt diabetes control – elevated BGL
- Everyone's illness is different & adjustment must be personalized

What should be done during illness?

- Maintain Adequate hydration
  - Drink 8 oz of calorie containing fluids if on liquids
    - Drink 8 oz of carb free fluids if on regular diet to maintain fluid balance
  - Consume caffeine free liquids
  - Caffeine acts as a diuretic and should be avoided
  - Drink electrolyte beverages to replace electrolytes
    - Bouillon, broth, clear canned soups, sports drinks

What should be done during illness?

- Continued
- Substitute clear liquid or soft foods if unable to tolerate regular foods
- Patients should have 200 grams of carbs per day evenly divided
- If unable to keep food done – sipping diet-
  - 15 grams of carbs every 1-2 hours

15 Gram of Carbohydrate Foods:

- ½ C Apple Juice
- ½ C regular soda pudding
- 1 regular popsicle
- 5 lifesavers
- 1 slice toast
- ½ C cooked cereal
- 1/3 c frozen yogurt
- ½ C regular ice cream
- ¼ C Sherbet
- ¼ C regular
- ½ C regular jello
- 1 C yogurt
- 1/3 C milkshake
- 6 saltines
- 1 C Gatorade

Other Issues Facing the Elderly

- Constipation – increase fiber, increase fluids, and encourage mobility
- Poor appetite – replace meals with liquid supplements, offer other high calorie carbohydrates, may need to adjust diabetic medications according to calorie intake
- Food Intolerances – especially to lactose, add alternate carbohydrates

Other DM Resources

- Diabetic cookbooks, magazines
- Websites
  - www.diabetes.org
  - www.eatright.org
  - www.splenda.com
  - Any fast food website- check nutrition facts
- TV
- Books
- Support Groups

Blood Glucose Monitoring

What do the numbers mean?

Jan Albert RN, CDE
Eileen Fiorina, RD, CNSD, LDN
Antoinette Franke, RN, CDE
Bonnie Pepon, RN, BSN, CDE

Blood Glucose Targets

- Blood glucose levels recommended by the ADA / AACE
  - Before meals 80-110 mg /dl
  - 2 hours after a meal -less than 140mg/dl
  - at bedtime - 100-140 mg/dl

Factors That Affect Blood Sugar Levels :

- Food/beverages
- Medicine
- Exercise
- Stress
- Timing of food/meds
- Time of day test is performed
- Related to testing device:
  - Outdated strips
  - Technique error
  - Meter malfunction
  - Spoiled materials

Event	Effect on sugar	When to test
Eating/drinking	increases	before meals 2hrs after meals bedtime
Exercise	decreases	before and after exercise
Meds	decrease	before meals
Stress/illness	increase	during/after If S/S of high blood sugar

Alternative Site Testing

NOT recommended when your blood sugar is rapidly rising or falling

When To Test?
Based on treatment & BG Goals

- There are many options:
  - 1-8 times per day
  - Before meals and bedtime
  - Fasting and 2 hours after meals
  - Before and after meals
  - Once a day- at varying times
  - Fasting and once more at different times of the day
  - Daily before breakfast

Ask Yourself WHY?

- Look for patterns, not just one glucose result. Then ask yourself,
  - Did I change my meal plan?
  - Did I change my exercise routine?
  - Did I forget to take my medicine?
  - Was I stressed?
  - Am I getting sick?

How to Use Your Results

- Keep Accurate records
- Look for patterns in your results
- Try to closely follow your diabetes plan
- Meet with your diabetes team to discuss your results
- Continue to learn
- **ALWAYS** take your log book to your doctor appointments

When to call the Doctor

- Two or more high results in 24 hour period
- Two or more low results in a 24 hour period
- Ketones in urine
- Illness
- Vomiting

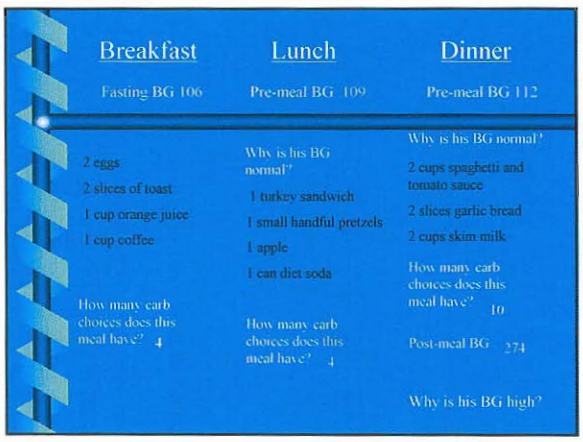
Patterns

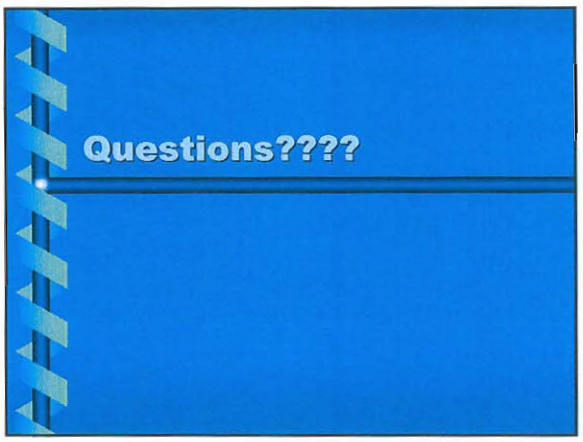
7am	11 am	4pm	9 pm
230	120	100	140
193	115	126	147
188	135	85	129
158	100	125	132

Patterns

7am	11 am	4pm	9pm
107	185	145	132
125	203	128	133
115	197	117	141
103	215	113	124

Breakfast	Lunch	Dinner
Fasting BG 91	Pre-meal BG 247	Pre-meal BG 110
1 1/2 cups dry cereal	Why is his BG high?	Why is his BG Normal?
2 slices of toast with margarine	1 hamburger on bun	6oz. sirloin steak
12 oz. orange juice	1 small french fry	1/2 cup mashed potatoes
1 cup skim milk	medium diet soda	1 cup green beans
		1 cup salad with low-fat dressing
How many carb choices does this meal have? 3	How many carb choices does this meal have? 4-5	How many carb choices does this meal have? 1-2
		Post-meal BG 55
		Why is his BG low?


Breakfast
Fasting BG 106
2 eggs
2 slices of toast
1 cup orange juice
1 cup coffee
How many carb choices does this meal have? 4
Lunch
Pre-meal BG 109
Why is his BG normal?
1 turkey sandwich
1 small handful pretzels
1 apple
1 can diet soda
How many carb choices does this meal have? 4
Dinner
Pre-meal BG 112
Why is his BG normal?
2 cups spaghetti and tomato sauce
2 slices garlic bread
2 cups skim milk
How many carb choices does this meal have? 10
Post-meal BG 274
Why is his BG high?


Questions????

Acute Complications

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Hypoglycemia (low blood sugar)

- A blood glucose below 70 would be considered low and a dangerous level for most people.

Low Blood Sugar Causes

- -Too much insulin or medication
- -Missing or delaying a meal
- -More exercise than usual
- -Drinking alcohol on an empty stomach

Low Blood Sugar (Hypoglycemia)

Mild	Moderate	Severe
Shakiness	Confusion	Seizure
Sweating	Behavior	Coma
Fast heartbeat	Impaired	
Blurry Vision	Motor	
Dizziness	Function	
Hunger		

Rule of 15

- •Feeling low??
- •Check your blood sugar
- •If 70 or less - eat/drink 15 grams of carbohydrate
- •Wait 15 minutes & recheck blood sugar
- •If less than 70, repeat the above
- •If you aren't going to eat in 1 hour, have a snack – 1/2 peanut butter sandwich & milk

Low Blood Sugar - Treatment

- 3 - 4 glucose tablets
- 1/2 cup of regular soda
- 6 - 7 small candies
- 1/2 cup of juice
- 1 Tablespoon of sugar

Followed by milk/crackers/sandwich

Things to Remember

- Always wear identification
- Always carry sugar with you
- Check your glucose before driving
- Do not give an unconscious person something by mouth, use Glucagon
- Take your meds as directed
- Follow your meal plan
- Monitor your blood sugar as directed

Glucagon

- Glucagon is a hormone that will raise the blood sugar.
- It is given by injection when the person with diabetes is unable to take treatment (food or drink) orally
- Only side effect may be nausea/vomiting

When to Give Glucagon

when a person is:

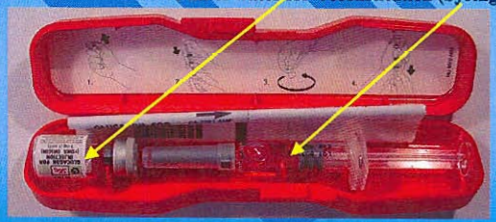
- Unconsciousness, unresponsiveness
- Having convulsions (seizures)
- Not able to safely eat or drink

Glucagon Kit Storage

- Store at room temperature
- Monitor expiration date
- After mixing, dispose of any unused portion within one hour.

Emergency Kit Contents:

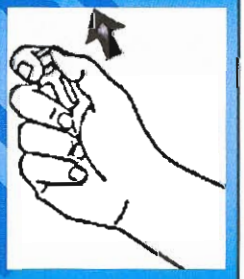
1 mg of freeze-dried glucagon (Vial)
1 ml of water for reconstitution (Syringe)



Combine immediately before use

Preparation

1. Flip cap off glass vial containing dry powder
2. Remove cap from syringe



Mixing Solution

3. Inject entire fluid in syringe into the bottle containing powder

4. Shake gently or roll to mix until all powder is dissolved and solution is clear.

Drawing Out

5. Inspect. Solution should be clear and colorless.

6. Draw prescribed amount of glucagon back into syringe.

Dosing & Injecting

7. Clean site if possible.

8. Inject at 90° into the tissue under cleansed area
   - buttocks
   - thigh
   - arm

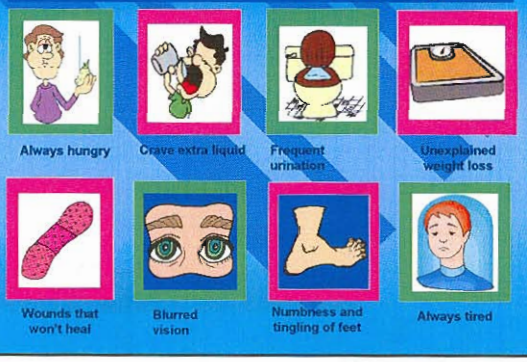
After Injecting

9. May take 10-20 minutes for the person to regain consciousness.
10. Check blood sugar.
11. Give sips of fruit juice or regular soda, once person is awake and able to drink.
12. Advance diet as tolerated.

Don't Be Surprised If. . .

- person does not remember being unconscious, incoherent
- has a headache.
- blood sugar becomes very high (over 200).
- nausea or vomiting occurs.

Some Signs and Symptoms of High Blood Sugar



High Blood Sugar Causes

- Eating more food
- Being less active
- Meds- forgot to take, wrong dose, right dose but not taking it at the proper time, or meds are expired
- Stress- emotional and physical (injury, illness, infection, surgery)
- Hormones- menstruation (blood sugar rises one week prior to starting menses)
- Not using insulin or lower dose to let blood sugar stay high for weight loss or maintenance

High Blood Sugar Treatment

Drink sugar free fluids

Watch diet

Do not exercise if >240mg/dl

Take your meds

Check blood sugar and urine ketones every 4 hours

Why blood sugar may go higher with exercise

•When you exercise your liver pumps out extra glucose to fuel the muscles

•If your body has too little insulin circulating in the blood stream to allow the cells to use this extra glucose your blood sugar will rise

Ketone Testing

- Test your urine for ketones if
  - Your blood sugar is greater than 240 mg for more than 24 hours
  - You are ill
  - You have symptoms of high blood sugar
    - thirst, frequent urination , tiredness etc
  - Vomiting/abdominal pain
  - Before you exercise
  - **Do not** exercise if ketones are present

Avoid high and low blood sugars by:

- Following your meal plan
- Taking your medication as prescribed
- Test your glucose levels frequently
- Don't skip or delay meals
- Compensate for exercise with increased food intake
- Don't let special occasions upset your diabetes control- practice stress management

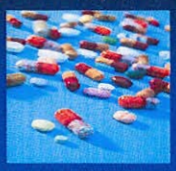
Case Study

- Joan is a 25 year old secretary who skipped lunch today but had a diet Coke and crackers. While playing tennis at 4pm she complains of shakiness, sweating, and dizziness.
- What is wrong with Joan?
- Why did this happen?
- What should she do?

Case Study

- Bill is a 62 year old recently retired construction foreman. He is complaining about dry mouth, thirst,frequent urination and tiredness. In fact he hasn't felt well since his daughter's wedding 3 days ago.
- What is wrong with Bill?
- Why did this happen?
- What should he do?

Diabetes Medications



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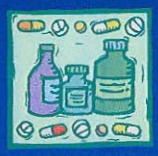
Classes of Medications

Sulfonylureas
Meglitinides
Biguanides
Alpha Glucosidase Inhibitors
Thiazolidinediones-TZD's
Incretin Mimetics



Sulfonylureas

Most common drugs in this class:
- •Glipizide (Glucotrol, Glucotrol XL)
- •Glyburide (Micronase, Diabeta, Glynase)
- •Glimepiride (Amaryl)

How do they work?
- •Stimulate the pancreas to make more insulin
- •Work for up to 24 hours
- •Lowers fasting and post prandial blood sugar

Sulfonylureas

Advantages:
- •May decrease AIC 1.5-2%
- •Inexpensive

Side effects:
- •Weight gain (4.5-11 lbs.)
- •Low blood sugar

How to take:
- •Take glipizide 30 min before the first meal of the day
- •All others take with first meal of the day

Meglitinides

Drugs in this class:
- Repaglinide(Prandin)
- Nateglinide (Starlix)

How do they work?
- •Stimulate the pancreas to make more insulin
- •Work only for about 4 hours after meals
- •Only effects post prandial sugars – NOT FASTING!

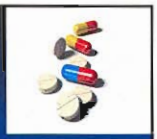
Meglitinides

Advantages:
- May decrease A1C by 1-2%

Side effects:
- Weight gain
- Low blood sugar

How to take:
- Take up to 30 minutes before meals
- No meal= No pill

Biguanides



Drug in this class:

- •Metformin (Glucophage, Glucophage XR)
- •Liquid Form (Riomet)

How does it work?

- •Helps your body produce less glucose from the liver
- •Helps insulin work better
- •Reduces glucose absorption in the intestines
- •Takes up to 2 weeks to see maximum effect

Biguanides

Advantages:

- •Can decrease AIC 1.5-2%
- •Does not cause low blood sugar or weight gain
- •May also lower triglycerides and cholesterol

Side effects:

- • Nausea and Diarrhea

How to take:

- •Take with breakfast and supper

Biguanides

Precautions:

- DO NOT use when having a heart cath or x-ray procedure involving dye (48˚ or until creatinine normal)
- DO NOT use if you drink excessive amounts of alcohol
- DO NOT use if kidneys are impaired (serum creatinine >1.4 F, 1.5 M)

Alpha Glucosidase Inhibitors

Drugs in this class:

- •Acarbose (Precose)
- •Miglitol (Glyset)

How do they work?

- •Slows the digestion of carbs in the small intestine thus decreasing the post prandial blood sugar spike

Alpha Glucosidase Inhibitors

Advantages:

- •May decrease A1C by 0.5 to 1%
- •Do not cause low blood sugar or weight gain

Side effects

- •Gas and diarrhea

How to take:

- •Take with first bite of food of 3 largest meals of the day

Alpha Glucosidase Inhibitors

- Precautions:
  - If low blood sugar occurs, food will NOT increase it
  - Must use glucose tablets to treat!!!!

Insulin Sensitizers-TZD'S

Drugs in this class:

- Rosiglitazone (Avandia)
- Pioglitazone (Actos)

How do they work?

- Help insulin work better
- Enhances glucose uptake by the muscle tissue
- Reduces glucose production by the liver
- Takes up to 3 months to see maximum effect

Insulin Sensitizers

Advantages:

- May decrease A1C by 0.5-1%
- Does not cause low blood sugar
- May decrease triglycerides and increase HDL

Side effects:

- Swelling in legs and weight gain (caution in heart failure)
- If on oral contraceptive, may increase risk of pregnancy
- Liver damage (<1% chance)
  - Liver function is monitored every 2 months for the first year

Combination Drugs

Glucovance (glyburide/metformin)

Metaglip (glipizide/metformin)

Avandamet (avandia/metformin)

New Ones:

- Fortamet (metformin SR)
- Glumetza (metformin SR)
- Actoplus (actos/metformin)
- Avandryl (avandia/glimepiride)

Special Points

- Do not use over the counter medicines or alcohol without checking with your doctor.
- If you have several doctors, be sure all of them know about your diabetes medications.
- Bring a list of all medications to your doctor visits and hospital admissions

Incretin Mimetics "Gut Hormones"

- Drugs in this class
  - Byetta (Exenatide) approved for type 2
  - Symlin (Pramlintide) approved for type 1 and type 2 using mealtime insulin

Byetta

- Approved for type 2 using a sulfonylurea, metformin, or both without achieving glycemic goals

How does it work?

- Prevents stored sugar from entering the blood stream
- Stimulates insulin release
- Slows gastric emptying
  - Lowers post prandial blood sugar spike
  - Makes you feel full
  - Reduces food intake and appetite

Advantages:

- May decrease A1C by 1% after 6 months
- Promotes weight loss (5-6 lbs)

Dosing

Given by injection:

- Comes in a prefilled pen that lasts one month
- 5 mcg twice a day for 1 month, then increase to 10mcg twice a day
- Give within 60 minutes of morning and evening meal
- Do NOT give after a meal
- If you miss a meal, skip the dose

Side effects

- Nausea (will go away with time and dose titration)
- Vomiting and diarrhea
- Low blood sugar
  - May need to decrease dose of sulfonylurea to avoid low blood sugar

Tips for Byetta

- Keep in the refrigerator
- Discard 30 days after opening
- Not to be used in:
  - type 1 diabetes
  - kidney failure
  - Severe stomach diseases including gastroparesis
- Cost - $230 for 1 month supply

Symlin

- Synthetic analog of the human hormone amylin (first isolated in the Gila Monster)
  - This hormone is absent in type 1's and decreased in type 2's
- Approved for type 1 and type 2 diabetics on insulin who failed to achieve desired blood glucose control with insulin

Symlin

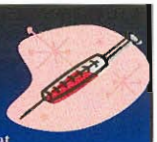
How does it work?

- Slows gastric emptying
  - Lowers the post prandial blood sugar spike
  - Makes you feel full
  - Reduces food intake and appetite
- Slows production of glucose from liver

Advantages:

- May lower A1C by 0.6% in Type 2 after 6 months
- Promotes weight loss (4 lbs)

Dosing



- Given by injection right before you eat
- Type 1 start 15mcg before meals
  - If no side effects after 1 week increase by 15mcg to max dose of 60mcg
- Type 2 start at 60 mcg before meals
  - Titrate to max dose 120mcg
  - May need to take rapid acting insulin at end of your meal due to delayed gastric emptying

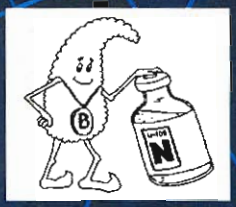
Side Effects

- Nausea (will decrease over time)
- Loss of appetite
- Vomiting
- Hypoglycemia (3 hours after dose)
  - Decrease amount of rapid acting insulin by 50%

Tips for Symlin

- Not to be used in:
  - Children
  - Gastroparesis
- Cannot be mixed in syringe with insulin
- Unopened vials should be stored in the refrigerator
- Open vials can be refrigerated or kept at room temperature
- Discard 28 days after opening
- Cost: $190 for one month supply

Insulin



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Insulin

Insulin is a hormone produced in the beta cells of the pancreas

It's job is to:

- Get glucose into the cells
- Decrease release of glucose from liver and muscles

Who uses insulin?

- Type 1 to survive
- Type 2 when orals no longer keep blood sugar at goal
  - during surgery
  - DKA
  - HHNS
  - when receiving parenteral nutrition
  - severe illness/ infection
  - when not able to eat
- Women with gestational diabetes

Types of Insulin

- Rapid acting
  - Novolog, Humalog, Apidra
- Short acting
  - Regular
- Intermediate acting
  - NPH
- Long acting
  - Lantus, Detemir
- Combination
  - Novolog 70/30, Humulin 70/30, Humulin 50/50, Novolin 70/30, Humalog Mix 75/25, Humalog 50/50
- Inhaled insulin
  - Exubera

Insulin Therapy

- Each person has unique requirements
- Single and multiple injection schedules
- Insulin pump

Insulin Therapy

- Basal (background)
  - Long acting insulin to cover your normal body functions. (NPH, Lantus)
- Bolus- (meal coverage)
  - Shorter acting insulin (Novolog, Humalog, Exubera, Apidra, Regular insulin)

Insulin delivery systems

- Vial and syringe
- Insulin pens
- Disposable dosers
- Inhaled Insulin

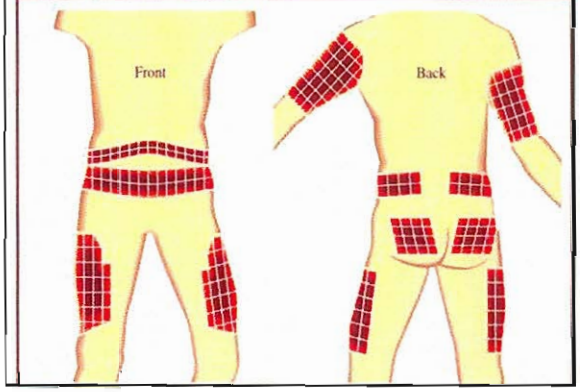
Insulin: How and Where to Inject

- Clean the site with soap and water
- Rotation of sites
  - Abdomen, arm, leg, and hip sites
  - Do not inject at the same spot more than once a month

Insulin: Routine Insulin Injection

- Subcutaneous tissue
  - 90 degree angle - most adults
- Rotation of sites
  - Abdomen, arm, leg, and hip sites
- Examine injection site for:
  - Bruising, redness, infection, and lumps

Insulin Injection Areas



Insulin:When to Inject

- Basal insulin (long acting)
  - Inject at the same time everyday
- Bolus insulin (short acting)
  - Short acting insulin (Regular)
    - 30 – 60 minutes before eating
  - Rapid acting insulin (Novolog, Humalog, Apidra)
    - at least 15 minutes before eating
  - Inhaled insulin (Exubera)
    - no more than 10 minutes before eating

Insulin: Tips for Taking Insulin

- Take your insulin even when you are ill and unable to eat
- AVOID
  - Giving insulin over a muscle you will be using within 30 minutes
  - Rubbing the sites
  - Long hot baths after injecting
- Check expiration dates before use
- Examine insulin vial for crystals and discoloration
- Wear identification

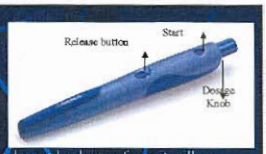
Insulin: Tips for Storage

- After opening a vial it does not need to be refrigerated
  - Injecting insulin that is room temp is less painful
- Avoid extreme temperatures
  - direct sunlight
  - glove compartments
  - bathroom

Side Effects of Insulin

- Hypoglycemia
  - Sweating
  - Confusion
  - Hunger
  - Impaired vision
  - Headache
  - Rapid heart beat
- Injection site reactions
  - Itching
  - Redness
  - Swelling
  - Stinging

Using the OptiClik Pen



Inserting a Cartridge

- Hold pen with release button facing up. Push the dosage knob in as far as it will go. The cartridge will not go in if the knob is not in place.
- Insert the cartridge straight into the pen, turn cartridge until it clicks. Do not force cartridge in.
- Wipe the edge of the cartridge with an alcohol swab. Screw on the new needle without removing any caps.
- Remove outer needle cap.

Before using the OptiClik perform a test run

- Press the start button.
- 00 will appear on the screen. Turn the knob to the right until it clicks and reads 01.
- Remove the inner needle cap.
- Hold the OptiClik with the release button facing up and push the dosage knob in all the way. One droplet should appear, repeat if not seen.

Now you may begin to give yourself an injection.

- Press the start button.
- Turn the dosage knob to the right until you reach your desired dosage.
- Clean injection area with rubbing alcohol.
- Inject the needle.
- Press the dosage knob in slowly all the way until it locks into place.
- Count to 10 and remove needle.
- Replace outer needle cap, remove needle and discard.

Replacing an empty cartridge

- Push dose knob in.
- Press release button.
- Remove cartridge and follow the above.

Questions?

Complications of Diabetes

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Long-term Complications of Diabetes

- Large blood vessel disease
  Cardiovascular
  - Heart Attack
  - Stroke
  - Circulation Problems

Small blood vessel disease

- Retinopathy - eye
- Nephropathy - kidney
- Neuropathy - nerve damage

Diabetic Retinopathy is the

leading cause of new blindness

Retinopathy

- Over time high blood sugar, high blood pressure, and high cholesterol damage the blood vessels in the retina.
  - Vessels swell and become blocked
  - New weaker vessels grow and leak
  - Retina may detach
- More prone to cataracts- clouding of the lens
- Glaucoma- increased fluid pressure

Treatment

Laser surgery-

Will not restore vision already lost

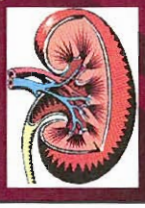
May need low vision aids

Finding and treating diabetic retinopathy EARLY can protect your vision!

Retinopathy Prevention

- Yearly dilated eye exams by an ophthalmologist
- Keep glucose and blood pressure under control
- Do not smoke or use tobacco

Diabetes is the **single leading** cause of chronic kidney failure in the United States



Kidney Disease

- High blood sugar + high blood pressure increase the chances of developing kidney disease
- Kidney disease is a silent process
- Symptoms appear when kidney function has decreased to less than 25%

Taking care of your kidneys

- Yearly urinalysis for microalbumin
- Control blood pressure
- Control blood sugar
- Control cholesterol
- Report signs of urinary tract infections
- Always ask about x-ray dyes- they can be harmful to the kidneys

Neuropathy-disease of nerves

- Diabetic Neuropathy is a nerve disorder caused by diabetes
- Factors that contribute to this disorder
  - High blood sugar
  - Poor blood circulation to nerves
  - Accumulation of sorbitol in nerves, which blocks the impulse

Symptoms of Peripheral Neuropathy

- Numbness, burning and tingling in feet
- Can cause pain and insensitivity at the same time
- Sharp pains or cramps
- Extreme sensitivity to touch

Neuropathy Tips

- Examine your feet daily
- Remove your shoes and socks at every doctor visit
- Yearly monofilament exam
- Control blood sugar, lipids, and blood pressure
- Do not smoke

Things that endanger your feet

Neuropathy- nerve damage

Blood vessel- narrowing

Foot bone- deformities (corns and calluses)

Dry crack skin- infection

Autonomic Neuropathy

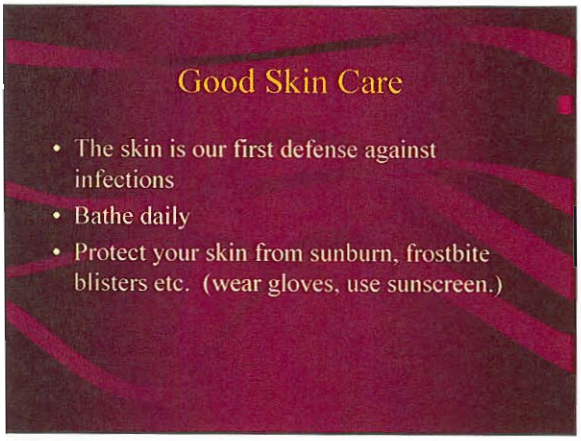
- Affects internal organs
  - Heart- no chest pain
  - Digestive tract- gastro paresis
  - Urinary tract- infections, incontinence
  - Sex organs- impotence, vaginal dryness

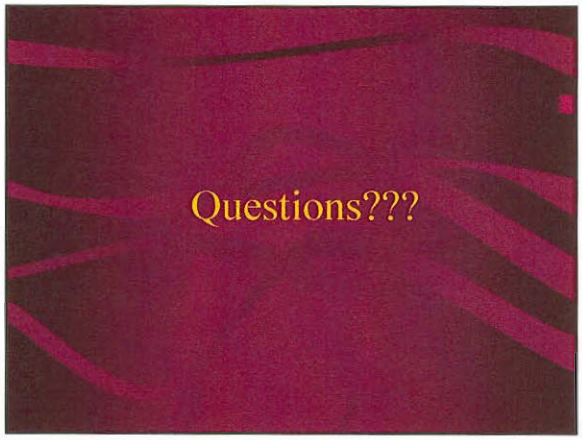
Control These Risk Factors

- Smoking
- Obesity
- Inactivity
- Stress
- High blood glucose levels
- High cholesterol levels
- High blood pressure

Dental Care

- High blood glucose changes normal composition of saliva and makes the mouth and teeth susceptible to various microorganisms.
- More prone to cavities, and gingivitis


Good Skin Care
• The skin is our first defense against infections
• Bathe daily
• Protect your skin from sunburn, frostbite blisters etc. (wear gloves, use sunscreen.)


Questions???

Nursing Home - Diabetes Programs - Pre Post Tests Results

Date	Location	Presenters	Participants	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8	Question 9	Question 10	Average
3/21/2007	Arbus Manor	A, E	8											
4/3/2007	Saulbury PCH	B, E	8											
			Pre-Test	100%	50%	50%	13%	75%	88%	75%	100%	88%	38%	67%
			Post Test	100%	63%	100%	50%	63%	100%	100%	100%	88%	88%	85%
4/17/2007	Martins PCH	B, E	5											
			Pre-Test	100%	80%	60%	80%	60%	60%	60%	80%	80%	20%	68%
			Post Test	100%	100%	100%	100%	80%	80%	80%	100%	100%	100%	96%
4/26/2007	Confluence AM	B, E	12											
			Pre-Test	92%	50%	75%	92%	92%	75%	92%	100%	92%	33%	68%
			Post Test	100%	92%	83%	100%	100%	83%	92%	100%	100%	83%	96%
4/26/2007	Confluence PM	B, E	12											
			Pre-Test	100%	80%	42%	67%	50%	58%	92%	83%	83%	25%	68%
			Post Test	100%	100%	100%	100%	80%	80%	80%	100%	100%	100%	96%
4/30/2007	Luthern Home	A, E	27											
			Pre-Test	100%	81%	62%	74%	58%	81%	88%	83%	83%	44%	77%
			Post Test	100%	100%	100%	100%	80%	80%	80%	100%	100%	100%	96%
5/10/2007	Laurel Wood	B, E	7											
			Pre-Test	85%	71%	57%	57%	71%	71%	85%	85%	85%	42%	68%
			Post Test	100%	100%	100%	100%	85%	85%	85%	100%	100%	100%	96%
5/30/2007	Rest Assure	A, E	11											
			Pre-Test	73%	27%	64%	82%	55%	100%	82%	100%	73%	18%	67%
			Post Test	82%	67%	73%	91%	91%	100%	100%	100%	82%	91%	97%

Nursing Home - Diabetes Programs - Evaluations

	Sec I (1)	Sec 1 (2)	Sec 1 (3)	Sec 1 (4)	Sec II (1)	Sec II (2)	Sec III (1)	Sec IV (1)	Sec IV (2)	Sec IV (3)	Sec IV (4)	Sec IV (5)	Sec IV (6)	Average %
3/21/2007	93%	88%	85%	85%	83%	83%	75%*	95%	83%	80%	90%	90%	90%	**86%**
4/3/2007	98%	98%	99%	93%	99%	100%	88%*	98%	98%	100%	100%	98%	98%	**98%**
4/17/2007	100%	80%	100%	100%	80%	100%	60%*	100%	100%	100%	100%	100%	100%	**94%**

Program Comments
March 20, 2007
Beaverdale Christian Church

ıt was the most valuable aspect of this program?

1. **Learning about sodium**
2. **Learning about healthy eating**
3. **Learning how to plan my meals so I can eat things I like**
4. **Learning about diabetes**
5. **I've been a diabetic since 1994 and received answers to meal planning**
6. **Learning what Carb Counting is & how to use it**

ıt recommendations do you have to improve this program?

1. **Nothing X 6**
2. **Very well done X 4**

Nursing Home Program Comments
March 21, 2007
Arbutus Manor

ıt was the most valuable aspect of this program?

1. **Learning about different insulins & meds**
2. **Learning more about diabetes**

ıt recommendations do you have to improve this program?

1. **Very well done**
2. **Speak louder due to intercom X 2**
3. **None**
4. **More interactive**
5. **Too long**

rall, what is your opinion of this course?

1. **Very help with my home life & work**
2. **Great**
3. **Speakers very well informed X2**
4. **Well presented**
5. **Very informative**
6. **Boring – too much talking X 2**

April 3, 2007
Saulsbury - Nursing Home

t was the most valuable aspect of this program?

1. It was all good
2. Learning about carbs
3. Learning about diets & meal planning
4. 2 X Learning about taking care of the residents with diabetes
5. None
6. Learning that individuals with diabetes can live a normal, good life
7. Different types of diabetes
8. Instructors presented very well, therefore, learning was easy

t recommendations do you have to improve this program?

1. 7 X None
2. Handouts on medical testing needed for an individual with diabetes
3. Handout of diabetic terminology
4. Have staff do a mock insulin injection

all, what is your opinion of this course?

1. 2 X Very interesting
2. Very informative
3. Instructors well informed
4. Great job by the instructors
5. Technical – a bit much for Personal Care Homes.
6. Very educational
7. It was a good course

Nursing Home's Diabetes Program Comments
Laurel Wood PCH
05/10/07

1. What was the most valuable aspect of this program?

X 2 Teachers themselves

Feeling better about my knowledge of diabetes

Learned that nutrition plays a major role in diabetes

Learned the importance of eating protein & fiber at the same meal

2. What recommendations do you have to improve this program?

It was perfect

Excellent job we need to have the same instructors present other topics

X 2 None

3. Overall, what is your opinion of this course?

It was a great learning experience, I learned a lot

Excellent – Thank you, thank you

X 2 Very good I learned a lot

X 2 Very informative

Speakers very pleasant & knowledgeable

Nursing Home's Diabetes Program Comments
Lutheran Home, Westmont, PA
05/30/07

1. What was the most valuable aspect of this program?

X 3	Everything
	Learned a lot that I did not know
X 2	Latest insulin devices
X 2	Update on diabetes drugs

2. What recommendations do you have to improve this program?

	Have a 2 day class so much to learn
	Program was well prepared
X 3	None
	Program very effective

3. Overall, what is your opinion of this course?

X 2	Good information, Very informative
	Very organized
X 6	Excellent
X 2	Very well presented

Nursing Home's Diabetes Program Comments
Confluence
04/26/07 (Morning Session)

1. What was the most valuable aspect of this program?

X 6	Everything
	Learning what diabetic individuals should eat

2. What recommendations do you have to improve this program?

X 7	None
X 2	Longer session so much to learn

1. Overall, what is your opinion of this course?

X 4	Very informative
X 3	Very good I learned a lot
	Very organized
	Speakers very pleasant
	Everything was valuable
	Good teachers

Nursing Home's Diabetes Program Comments
04/26/07 (Afternoon Session)

1. What was the most valuable aspect of this program?

- X 4 Everything
- X 2 Learning about carbohydrates & proteins
- Very organized & informative
- Understanding treatment for a diabetic resident
- Learning about the dietary needs of the resident

2. What recommendations do you have to improve this program?

- X 5 None
- X 2 Showing & demonstrating how to give insulin

2. Overall, what is your opinion of this course?

- X 8 Very informative & learned a lot
- Good
- Very organized
- It was very helpful on a personal & professional level as I am an individual with diabetes

What is Diabetes Mellitus?

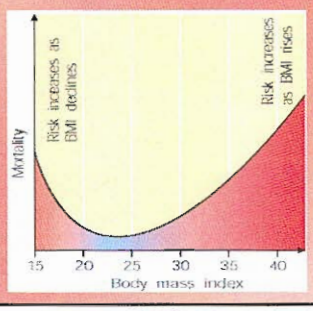
Diabetes is.....

- A disease that occurs when your body cannot produce enough insulin to control the amount of glucose in your blood or if your body is resistant to your own insulin
- When there is not enough insulin, glucose cannot get into your cells where it is needed for energy
- **A treatable and manageable disease**

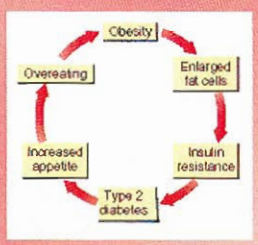
Diabetes Prevalence in U.S.

- 20.8 million people have diabetes (7% of the population)
- 14.6 million are diagnosed
- 6.2% are undiagnosed

Type II Diabetes



Insulin Resistance



Obesity Trends Among U.S. Adults between 1985 and 2002

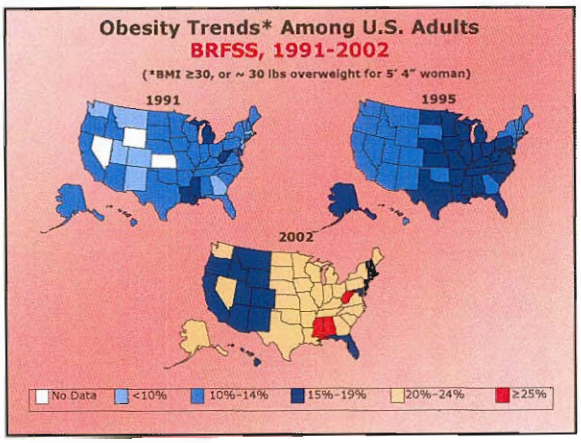
Definitions:

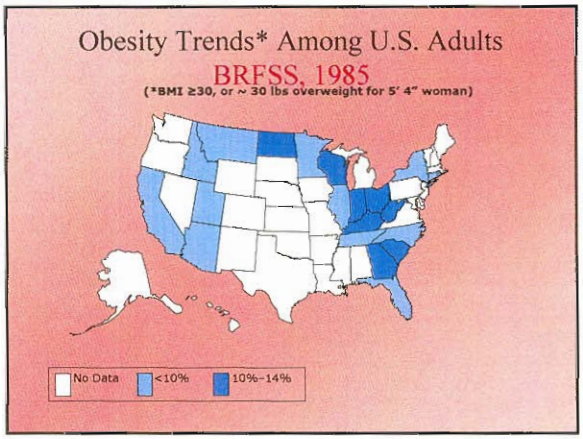
- **Obesity: having a very high amount of body fat in relation to lean body mass, or Body Mass Index (BMI) of 30 or higher**
- **Body Mass Index (BMI): a measure of an adult's weight in relation to his or her height, specifically the adult's weight in kilograms divided by the square of his or her height in meters**

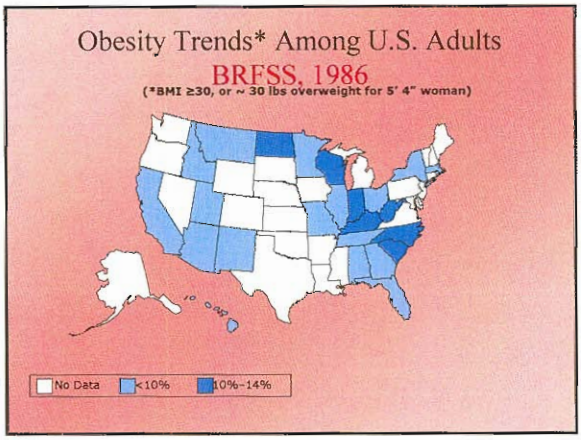
Obesity Trends Among U.S. Adults between 1985 and 2002

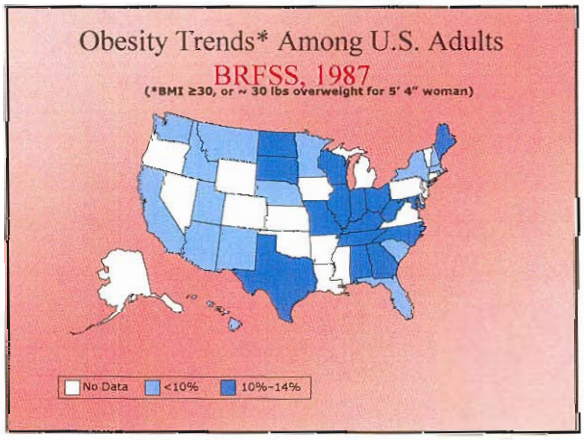
Source of the data:

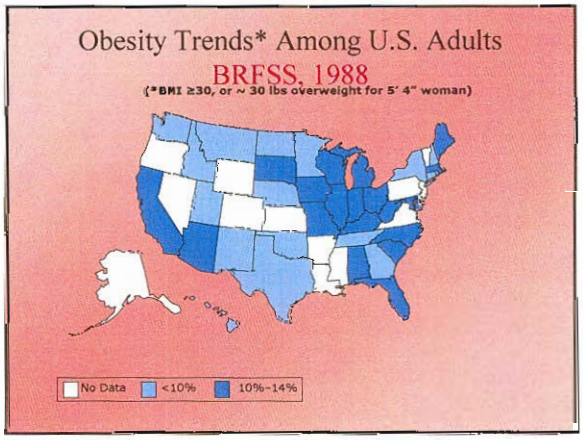
- The data shown in these maps were collected through CDC's Behavioral Risk Factor Surveillance System (BRFSS). Each year, state health departments use standard procedures to collect data through a series of monthly telephone interviews with U.S. adults
- Prevalence estimates generated for the maps may vary slightly from those generated for the states by BRFSS (http://aps.nccd.cdc.gov/brfss) as slightly different analytic methods are used.

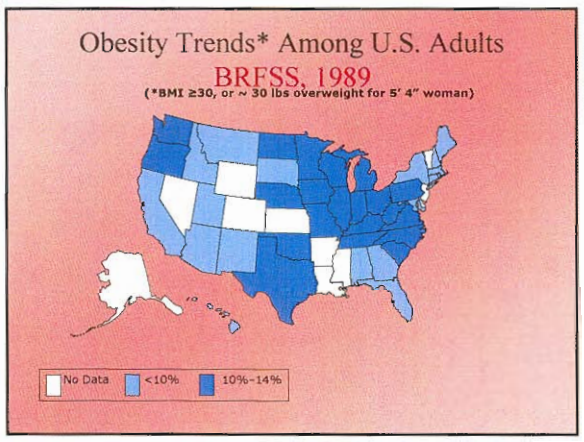


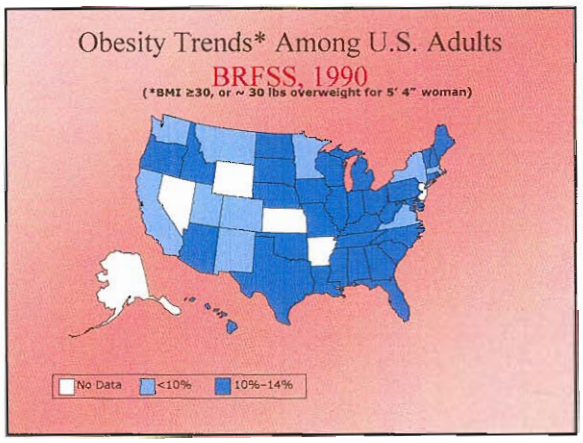









Obesity Trends* Among U.S. Adults
BRFSS, 1989
(*BMI ≥30, or ~ 30 lbs overweight for 5' 4" woman)
No Data
<10%
10%-14%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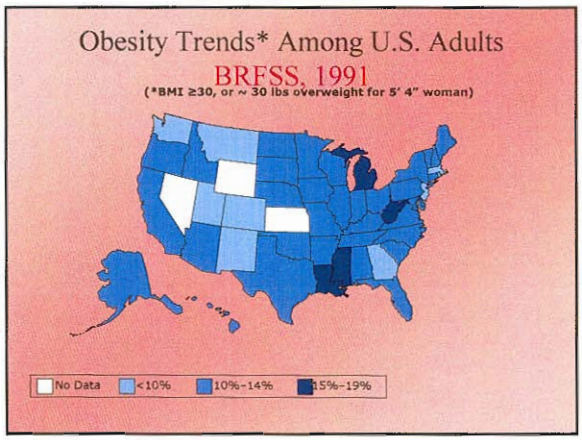
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BRFSS, 1991
(*BMI ≥30, or ~ 30 lbs overweight for 5' 4" woman)
No Data
<10%
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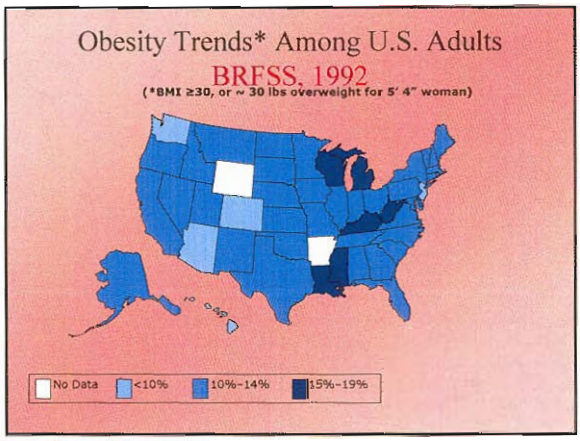
15%-19%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BRFSS, 1992
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<10%
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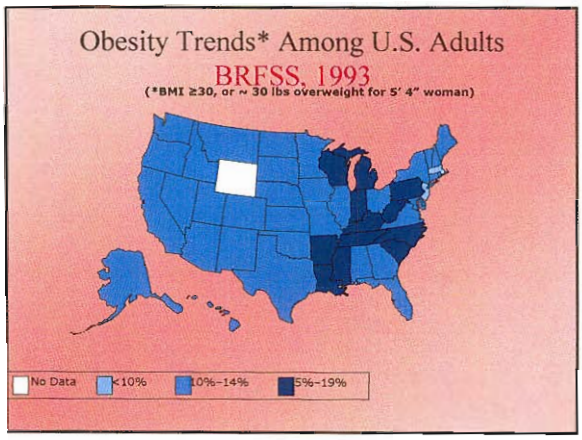
15%-19%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BRFSS, 1993
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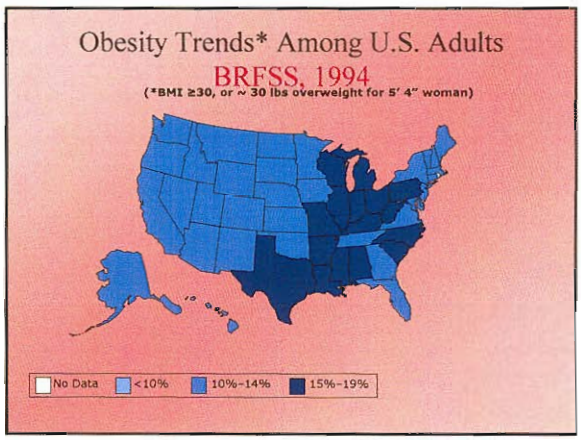
10%-14%
15%-19%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BRFSS, 1994
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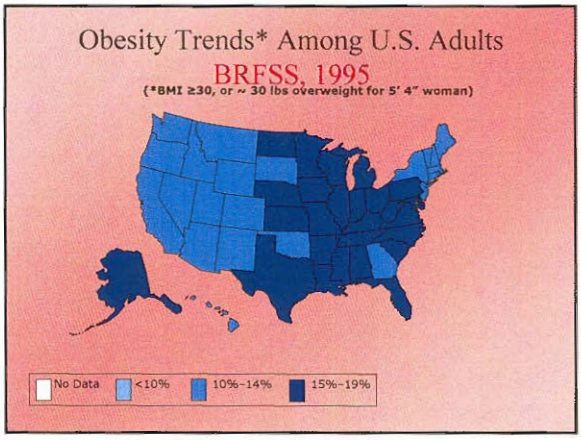
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BRFSS, 1995
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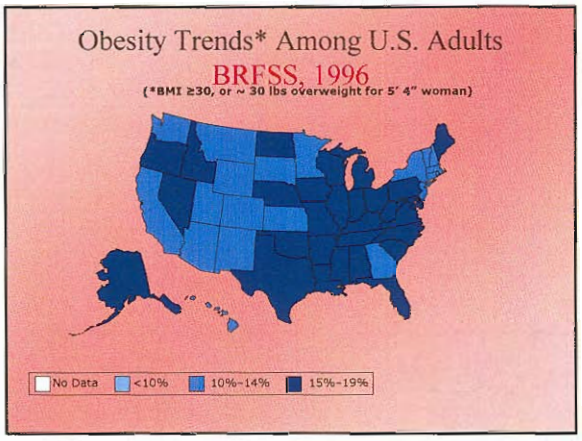
Obesity Trends* Among U.S. Adults
BRFSS, 1996
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No Data
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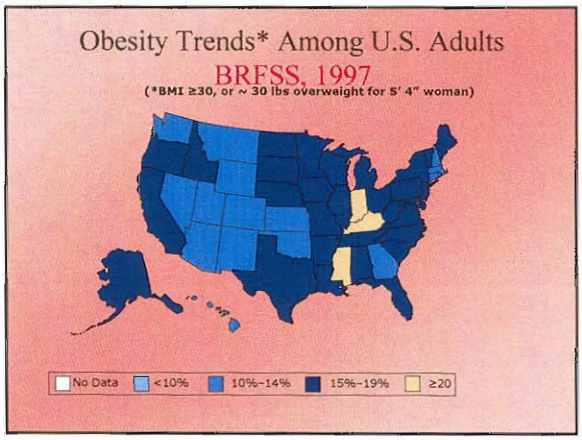
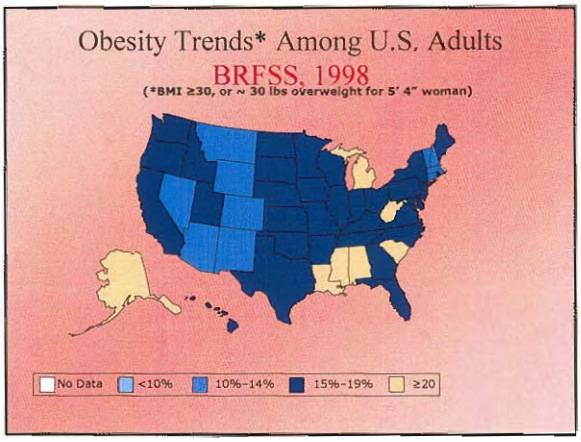
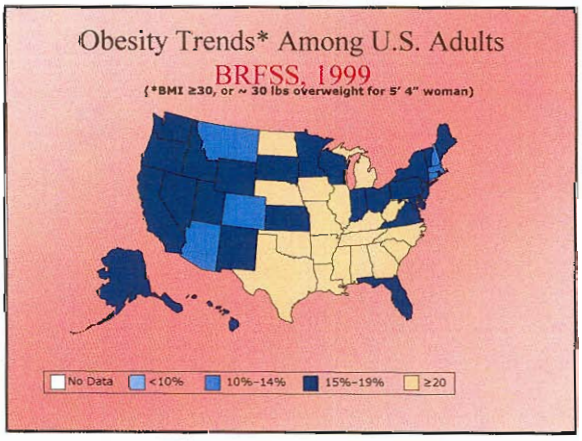
15%-19%


Obesity Trends* Among U.S. Adults
BRFSS, 1997
(*BMI ≥30, or ~ 30 lbs overweight for 5' 4" woman)
No Data
<10%
10%-14%
15%-19%
≥20


Obesity Trends* Among U.S. Adults
BRFSS, 1998
(*BMI ≥30, or ~ 30 lbs overweight for 5' 4" woman)
No Data
<10%
10%-14%
15%-19%
≥20


Obesity Trends* Among U.S. Adults
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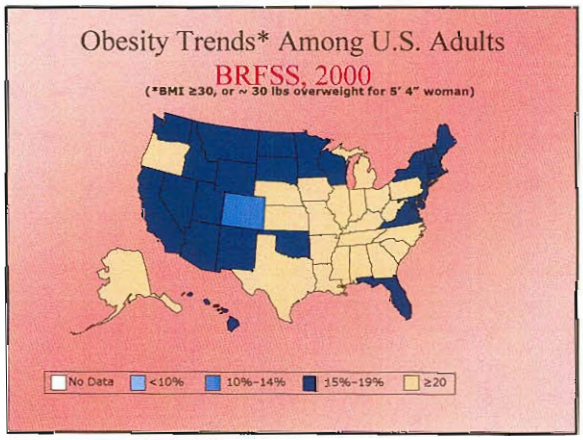
15%-19%
≥20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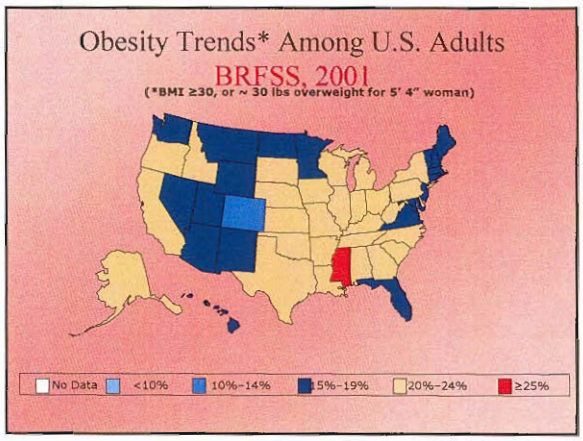
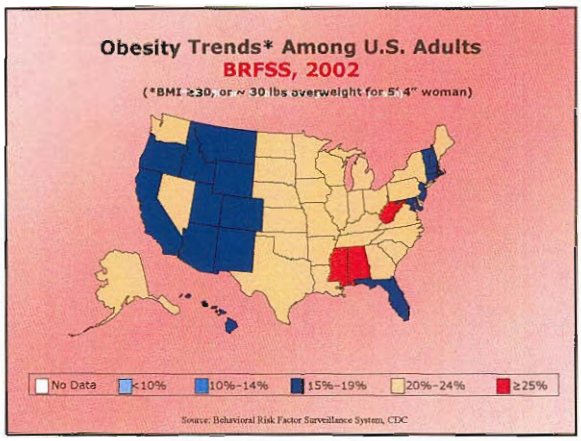
<10%
10%-14%
15%-19%
≥20





Let's Do The Diabetes Risk Test

I am under 65 years of age and I get little or no exercise during a usual day

Yes-5 points

No-0 points

I am between 45 and 64 years of age

Yes-Score 5 points
No-Score 0 points

I am 65 years or older

Yes-Score 9 points
No-Score 0 points

I am a woman who has had a baby weighing more than 9 pounds

Yes-Score 1 point
No-Score 0 points

I have a sister or brother with diabetes

Yes-Score 1 point
No-Score 0 points

I have a parent with diabetes

Yes-Score 1 point
No-Score 0 points

At Risk Weight Chart

Height in Feet and Inches (Without Shoes)	Weight in Pounds Without Clothing
4'10"	129
4'11"	133
5'0"	138
5'1"	143
5'2"	147
5'3"	152
5'4"	157
5'5"	162
5'6"	167
5'7"	172

Height in Feet and Inches (Without Shoes)	Weight in Pounds (Without Clothing)
5'8"	177
5'9"	182
5'10"	188
5'11"	193
6'0"	199
6'1"	204
6'2"	210
6'3"	216
6'4"	221

Overweight

- **Add 5 Points!**
- **Greater than 10 points puts you at high risk for diabetes.**

Risk Factor Review

- Activity
- Age

- Gestional Diabetes
- Heredity

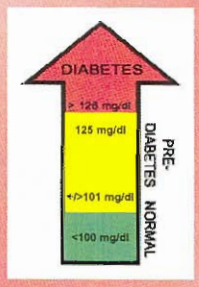
- Weight

Individuals without Diabetes

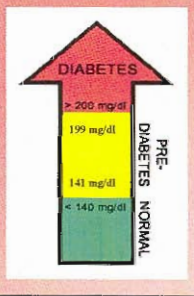
Normal Fasting Blood Sugar Level: Less than 100

How to Determine Diabetes

Fasting Plasma Glucose Test



Oral Glucose Tolerance Test

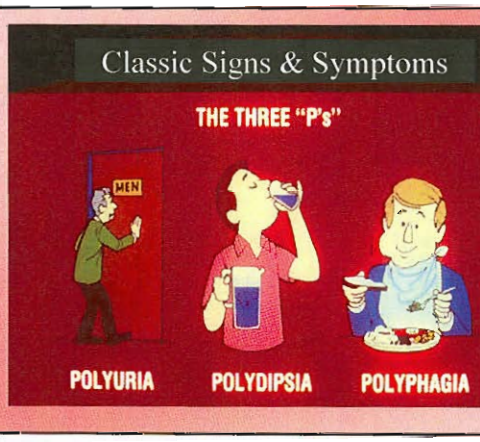


How does Type 1 diabetes differ from Type 2 diabetes?

What are the Signs & Symptoms of Diabetes?

Classic Signs & Symptoms

THE THREE "P's"



Signs & Symptoms Cont…

- Tiredness
- Blurred vision
- Numbness or tingling of hands or feet
- Frequent infection
- Slow healing of cuts and sores
- Sudden weight loss
- Impotence

Or None AT All!!!!!

ADA Targets for Glycemic Control

Biochemical Index	Goal	Action Suggested
Pre-prandial	90-130	<80 >180
Bedtime	100-140	<100 >160
HgA1c (%)	<6.5%	>8%

The American Association of Clinical Endocrinologists

Biochemical Index	Goal
Pre-prandial glucose (mg/dl)	less than 100 mg/dl
Post-meal glucose	Less than 140 mg/dl
Hemoglobin A_{1c}(%)	Less than 6.5%

High Blood Sugar

Hyperglycemia - Blood glucose ≥ 240 mg/dl

Causes:

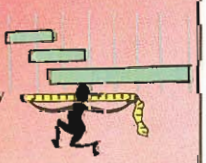
- Too little medication
- Too much food
- Not enough exercise
- Exercise when blood glucose ≥ 240 mg/dl
- Too much stress-(physical & emotional)
- Illness
- Sometimes it just happens!!!

Low Blood Sugar

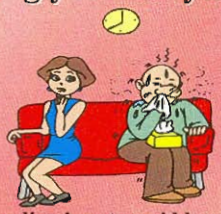
Hypoglycemia –Blood glucose < 70

Causes:

- –Too much Medication
- –Skipping or delaying meals
- –Not enough food
- –Too much exercise
- –Exercise when sugar too low



Hypoglycemia Symptoms



- Shakiness, pounding heart, rapid heart rate, tingling in extremities & lips, sweating, heavy breathing, cold clammy skin
- Hunger, headache, nausea, weakness, general feeling of something not right

Hypoglycemia Treatment

- 4 oz of fruit juice
- 4-6 oz of regular (non-diet) soft drink
- 3 glucose tablets (1 tube glucose gel)
- 1 cup skim milk
- 8-10 jelly beans
- 1 tablespoon of honey
- 1 small tube cake (gel) icing
- 2 tablespoons of raisins
- 6-7 hard candies (NOT sugar free), such as Lifesavers

Hypoglycemia Treatment

Poor Food Choices!

Chocolate(candy bar), donuts, potato chips, cookies,cheese, whole milk, ice cream

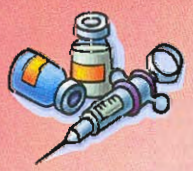
All contain fat and are not fast acting

How do we manage diabetes?

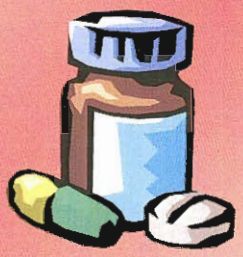
The 5 Elements of Diabetes Control

- Education
- Diet
- Exercise
- Medication
- Monitoring

Diabetes Medications
Orals & Injections



Diabetes Medications



What is the next step?

Insulin Therapy

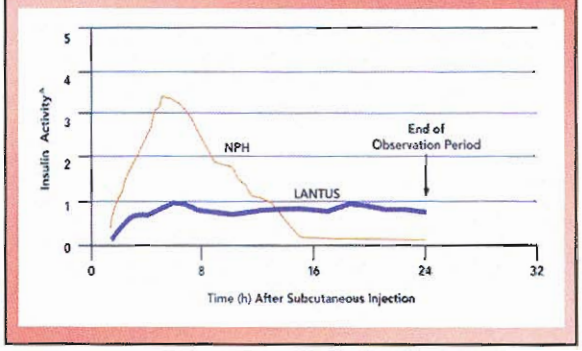
Types of Insulin

Insulin Type	Onset	Peak	Duration	Appearance
Rapid Acting Humalog, Novalog, Apidra	5 –15 min	30' to 1.5 hr	<5 hrs.	Clear
Short Acting Regular	30 min	2-4 hrs	6-8 hr.	Clear
Intermediate NPH	1-4 hrs	4-12 hrs	12-18 hrs	Cloudy

Types of Insulin

Insulin Type	Onset	Peak	Duration	Appearance
Long-Acting Levemir *(Detemir)*	1 hr	None Flat	24 hours	Clear
Lantus *(Glargine)*	1 hr	None Flat	24 hours	Clear

Lantus vs. NPH Insulin



Exubera-Inhaled Insulin

Exubera is an insulin inhaled into the lungs, which has recently been approved for use.

Insulin Injection Sites

Insulin injected into different areas will reach the blood at different times.

- **Abdomen - Fastest**
- **Outer arm - Fast**
- **Outer thigh - Slow**
- **Buttocks - Slowest**

- ***Inject at least 1 inch apart & 1 inch away from scars and naval***

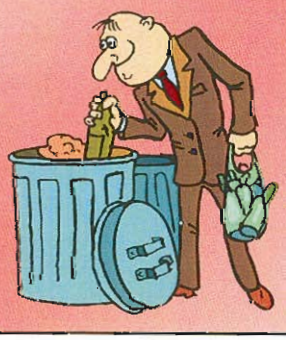
&

- ***Remember to rotate the injection site!***

Insulin Special Considerations

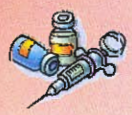
- **Not a cure**
- **Used to help control blood sugars**
- **Check with pharmacist or doctor before taking over the counter medications and alcohol**
- **Remind patient to wear identification**
- **Know symptoms of hypo/hyperglycemia**

Disposing of insulin needles/lancets



Medication Reminders…

- **Patient's should always carry a list of their medications.**
- **Know the onset, peak and durations of medication.**
- **Wear diabetes identification.**
- **When traveling carry extra supplies.**
- **If patient Can't remember if took medication wait for next scheduled time.**



Blood Glucose Monitoring

Importance of Blood Glucose Monitoring

- To achieve and maintain blood sugar goals
- Identifying and treating hypoglycemia
- Avoidance of severe hypoglycemia
- Aids physician in medication adjustment

How to use results!!!!

- Identify and treat hypoglycemia
- Make decisions regarding food intake or medication adjustment when exercising
- Determine effect of food choices and portion sizes on blood glucose levels
- Pattern management
- Managing sick days
- Managing hypoglycemia unawareness

When to Monitor

- Suggested monitoring times before meals and at bedtime for individuals out of control
- Controlled individuals twice daily

ADA Standards of Care

Test or Exam	Frequency
Routine physical exam	Yearly
Blood pressure	Every routine exam
Cholesterol	Yearly;Low risk-every 2 yr
Foot exam	Yearly
Eye exam	Yearly-Ophthalmologist
Urine test	Yearly
HbA1c	Every 3 months

Section IV – Comments

Thanks to Miners & Pfizer for sponsoring this program to us!

What was the best part of the program?

1. Meal Planning /Nutrition X 4
2. Very Informative X 4
3. Everything – very helpful X 2
4. Learning about carbs & proteins X 2
5. Signs of disease
6. New meds
7. Learning about blood sugars
8. Learning more about diabetes X 2
9. Speakers spoke on our level
10. Everything X 2
11. I would like to attend more diabetes sessions
12. Very well presented
13. Very good foot care presentation X 2
14. The nutrition quiz
15. Information on BGL & blood sugar education
16. Making us more aware of our eating habits
17. Answering questions
18. Learning about the possibility of future programs in our area
19. Presented an overall picture of diabetes
20. How to control my blood sugar

What recommendations do you have to improve this program?

1. Continue – would like programs in the Ebensburg area
2. Great X 2
3. More information about diets & their impact on blood sugars
4. Hold questions till the end of entire presentation
5. Nothing X 4
6. Dinner was greatly appreciated
7. Excellent program X 2
8. More information on foot care & neuropathy

9. More information on nutrition
10. Some difficulties hearing the last speaker due to others talking
11. More time to cover more areas & to answer questions
12. Continue to obtain high quality speakers
13. Advertise more
14. Develop a data base to keep us informed of suture programs & classes
16. Meal Planning

Section IV – Comments

Thanks to Meyersdale Medical Center for sponsoring this program!

What was the best part of the program?

1.	Very good presentations & speakers	X 5
2.	Everything – very helpful	X 7
3.	Eating & carb counting	X 12
4.	Dr. Thomas was great spoke in layman's terms	X 1
5.	Learning about exercise	X 3
6.	The diversification of the presentations was great	X 2
7.	My husband said he was going to start exercising due to the presentation	X 1
8.	The program was well planned and informative	X 3
9.	The lunch was not only good but demonstrated how to carb count	X 1
10.	The importance of taking care of ourselves to prevent complications	X1
11.	How to read labels	X2
12.	Discovered that there is a lot more to learn	X2
13.	How to regulate the sugar	X1

What recommendations do you have to improve this program?

1.	Very good presentations & speakers	X3
2.	Keep up the great work	X1
3.	More information about counting carbs	X3
4.	Thank –you everything was great	X1
5.	Nothing	X6
6.	More stretching breaks	X1
7.	Excellent program	X 2
8.	Good interaction with crowd	X 1
9.	More information on nutrition	X 1
10.	Nutrition test was effective & interesting	X 1

Presentation
Minus
meyersdale

What's Your Nutrition IQ?

Eileen T. Fiorina RD, CNSD, LDN
Conemaugh Diabetes Institute
Memorial Medical Center

Quiz Rules

- 29 questions
- 15-20 seconds to answer
- Answers are given after each question
- Score your own "Nutritional IQ" at the end

10 9 **Ready...** 8 7 6 **get set...** 5 4 **Go!** 3 2 1

Question 1

A "calorie" is a measure of _____?

A. Fat
B. Sugar
C. Carbohydrate
D. Energy
E. I don't know

Question 1

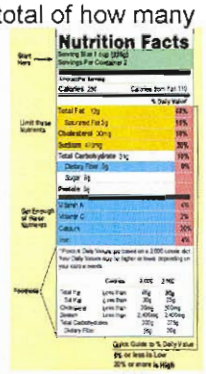
A "calorie" is a measure of _____?

A. Fat
B. Sugar
C. Carbohydrate
D. Energy
E. I don't know

Question 2

An average adult needs a total of how many calories a day?

A. 2000
B. 2500
C. I don't know
D. 1500
E. 1000



Question 2

An average adult needs a total of how many calories a day?

A. 2000

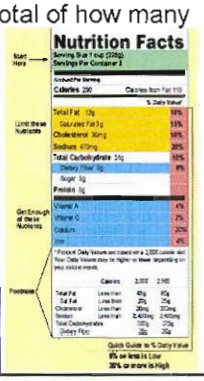
B. 2500

C. I don't know

D. 1500

E. 1000

Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:



Question 3

A pound of fat is equal to HOW MANY EXTRA calories?

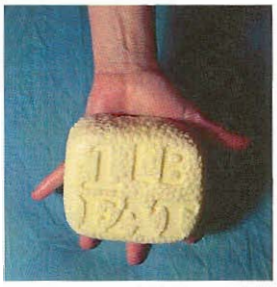
A. 1500

B. 2000

C. 3500

D. 5000

E. I don't know



Question 3

A pound of fat is equal to HOW MANY EXTRA calories?

A. 1500

B. 2000

C. 3500

D. 5000

E. I don't know

Question 4

A 20 ounce regular soda pop has HOW MANY servings in it?

A. 2½

B. 2

C. 1½

D. 1

E. I don't know

Question 4

A 20 ounce regular soda pop has HOW MANY servings in it?

A. 2½

B. 2

C. 1½

D. 1

E. I don't know

Question 5

How many calories are in a McDonald's Big Mac hamburger?

A. 230

B. 340

C. 420

D. 590

E. I don't know

Question 5

How many calories are in a McDonald's Big Mac hamburger?

A. 230
B. 340
C. 420
D. 590
E. I don't know

Question 6

True or False: 12 ounces of regular Sprite has the same calories as 12 ounces of Dr. Pepper

A. True
B. False
C. I don't know

Question 6

True or False: 12 ounces of regular Sprite has the same calories as 12 ounces of Dr. Pepper

A. True
B. False
C. I don't know

Question 7

One gram of fat contains HOW MANY calories?

A. 4
B. 7
C. 9
D. 12
E. I don't know

Question 7

One gram of fat contains HOW MANY calories?

A. 4
B. 7
C. 9
D. 12
E. I don't know

Question 8

A single serving of fruit juice is:?

A. 4 ounces
B. 8 ounces
C. 12 ounces
D. 16 ounces
E. I don't know

Question 8

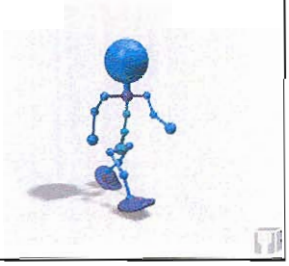
A single serving of fruit juice is:?

A. 4 ounces
B. 8 ounces
C. 12 ounces
D. 16 ounces
E. I don't know

Question 9

The average person (child or adult) should try to take HOW MANY foot steps in a normal day?

A. 2000
B. 5000
C. 10,000
D. 15,000
E. I don't know



Question 9

The average person (child or adult) should try to take HOW MANY foot steps in a normal day?

A. 2000
B. 5000
C. 10,000
D. 15,000
E. I don't know

Question 10

Which of the following is the best fat burning activity?

A. Swimming
B. Running
C. Walking briskly
D. Weight lifting
E. I don't know

Question 10

Which of the following is the best fat burning activity?

A. Swimming
B. Running
C. Walking briskly
D. Weight lifting
E. I don't know

Question 11

How many hours does the typical individual watch television each day?

A. 2 hours
B. 4 hours
C. 6 hours
D. 8 hours
E. I don't know

Question 11

How many hours does the typical individual watch television each day?

A. 2 hours
B. 4 hours
C. 6 hours
D. 8 hours
E. I don't know

Question 12

How many FOOD ADS does the average adult watch on TV each year?

A. 5,000
B. 10,000
C. 15,000
D. 20,000
E. I don't know

Question 12

How many FOOD ADS does the average adult watch on TV each year?

A. 5,000
B. 10,000
C. 15,000
D. 20,000
E. I don't know

Question 13

Which of the following is the most commonly eaten vegetable by an adult in American ?

A. Green beans
B. Carrots
C. Broccoli
D. French fries
E. I don't know

Question 14

How many EXTRA calories are we overfeeding American babies under 1 year of age?

A. 50 calories
B. 100 calories
C. 150 calories
D. Over 200 calories
E. I don't know

Question 14

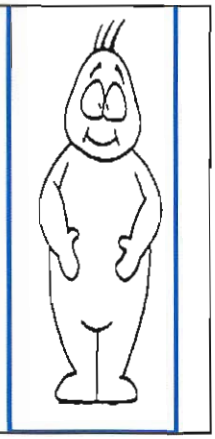
How many EXTRA calories are we overfeeding American babies under 1 year of age?

A. 50 calories
B. 100 calories
C. 150 calories
D. Over 200 calories
E. I don't know

Question 15

If a person (or child) drinks one 12 ounce Regular soda pop each day, how many **EXTRA POUNDS** will be gained each year?

A. 4 pounds
B. 8 pounds
C. 16 pounds
D. 24 pounds
E. I don't know



Question 15

If a person (or child) drinks one 12 ounce Regular soda pop each day, how many **EXTRA POUNDS** will be gained each year?

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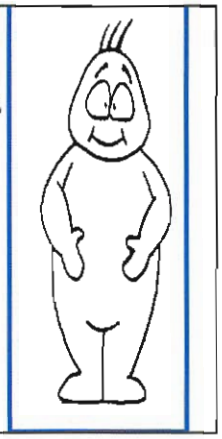
B. 8 pounds
C. 16 pounds
D. 24 pounds
E. I don't know



Question 16

The term "sugar free" on a food label or advertisement refers to which of the following ONLY?

A. Lactose
B. Fructose
C. Sucrose
D. Glucose
E. I don't know

Question 16

The term "sugar free" on a food label or advertisement refers to which of the following ONLY?

A. Lactose
B. Fructose
C. Sucrose
D. Glucose
E. I don't know

Question 17

On a list of ingredients for a typical food product label, IN WHAT ORDER are the ingredients listed ?

A. Alphabetically
B. From LEAST amount to most in the food product
C. From MOST amount to least in the food product
D. I don't know

Question 17

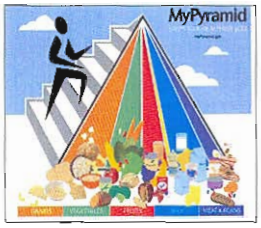
On a list of ingredients for a typical food product label, IN WHAT ORDER are the ingredients listed ?

A. Alphabetically
B. From LEAST amount to most in the food product
C. From MOST amount to least in the food product
D. I don't know

Question 18

What percentage of adults in the United States eat a balanced diet according to the USDA's Food Guide Pyramid?

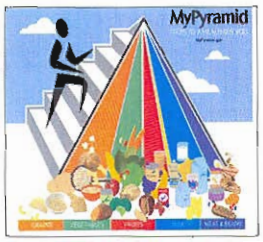
A. 1%
B. 15%
C. 50%
D. 75%
E. I don't know



Question 18

What percentage of adults in the United States eat a balanced diet according to the USDA's Food Guide Pyramid?

A. 1%
B. 15%
C. 50%
D. 75%
E. I don't know



Question 19

What percentage of adults in the United States have a television set in their bedroom ?

A. 24%
B. 37%
C. 65%
D. 83%
E. I don't know

Question 19

What percentage of adults in the United States have a television set in their bedroom ?

A. 24%
B. 47%
C. 65%
D. 83%
E. I don't know

Question 20

What is the primary (main) sweetener used in Regular soda pop and many other sweet foods in the United States?

A. Sucrose
B. Glucose
C. High fructose corn syrup
D. Lactose
E. I don't know

Question 20

What is the primary (main) sweetener used in Regular soda pop and many other sweet foods in the United States?

A. Sucrose
B. Glucose
C. High fructose corn syrup
D. Lactose
E. I don't know

Question 21

What percent of adults get the minimum recommended amount (RDA) of calcium in their everyday diets?

A. 3%
B. 10%
C. 33%
D. 43%
E. I don't know

Question 21

What percent of adults get the minimum recommended amount (RDA) of calcium in their everyday diets?

A. 3%
B. 10%
C. 33%
D. 43%
E. I don't know

Question 22

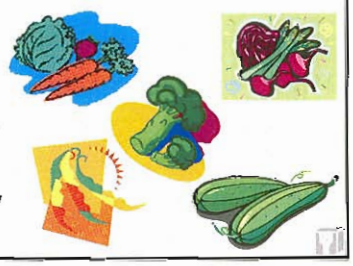
How many times should a toddler be offered a new vegetable food choice BEFORE giving up?

A. 3-5 times
B. 6-9 times
C. 10-15 times
D. 16 times
E. I don't know

Question 22

How many times should a toddler be offered a new vegetable food choice BEFORE giving up?

A. 3-5 times
B. 6-9 times
C. 10-15 times
D. 16 times
E. I don't know



Question 23

How many calories are in a "super size" order of McDonald's French Fries?

A. 210
B. 320
C. 450
D. 610
E. I don't know

Question 23

How many calories are in a "super size" order of McDonald's French Fries?

A. 210
B. 320
C. 450
D. 610
E. I don't know

Question 24

True or False: In-between meal snacks don't add extra weight

A. True
B. False
C. I don't know

Question 24

True or False: In-between meal snacks don't add extra weight

A. True
B. False
C. I don't know

Question 25

How many 8 ounce glasses of water should we drink each day?

A. 3
B. 4
C. 5
D. 8
E. I don't know

Question 25

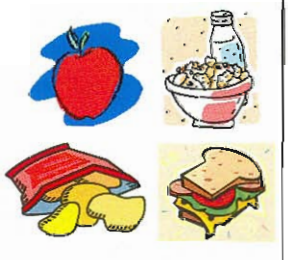
How many 8 ounce glasses of water should we drink each day?

A. 3
B. 4
C. 5
D. 8
E. I don't know

Question 26

Which would be a healthy snack choice?

A. Apple
B. Bowl of cereal
C. Sandwich
D. Chips
E. I don't know



Question 26

Which would be a healthy snack choice?

A. Apple
B. Bowl of cereal
C. Sandwich
D. Chips
E. I don't know

Question 27

Which beverage is best to use during sports?

A. Gatorade
B. Powerade
C. Water (plain or with lemon)
D. 100% fruit juice
E. I don't know

Question 27

Which beverage is best to use during sports?

A. Gatorade
B. Powerade
C. Water (plain or with lemon)
D. 100% fruit juice
E. I don't know

Question 28

How many calories are in the entire container of doughnuts?

A. 110
B. 200
C. 400
D. 800
E. I don't know

Nutrition Facts
Glazed
Serving Size 1 Doughnut (52g)
Servings Per Container 2

Amount Per Serving	
Calories 200	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Cholesterol 5mg	1%
Sodium 95mg	4%
Total Carbohydrate 22g	7%
Dietary Fiber less than 1g	2%
Sugars 10g	
Protein 2g	
Vitamin A 0% •	Vitamin C 2%
Calcium 6% •	Iron 4%

Question 28

How many calories are in the entire container of doughnuts?

A. 110
B. 200
C. 400
D. 800
E. I don't know

Nutrition Facts
Glazed
Serving Size 1 Doughnut (52g)
Servings Per Container 2

Amount Per Serving	
Calories 200	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Cholesterol 5mg	1%
Sodium 95mg	4%
Total Carbohydrate 22g	7%
Dietary Fiber less than 1g	2%
Sugars 10g	
Protein 2g	
Vitamin A 0% •	Vitamin C 2%
Calcium 6% •	Iron 4%

Question 29

For how long after eating ANY calorie containing food or drink is the body making fat?

A. 30 minutes
B. 1 hour
C. 2 hours
D. 4 hours
E. I don't know

Question 29

For how long after eating ANY calorie containing food or drink is the body making fat?

A. 30 minutes
B. 1 hour
C. 2 hours
D. 4 hours
E. I don't know

Now…grade your answers!

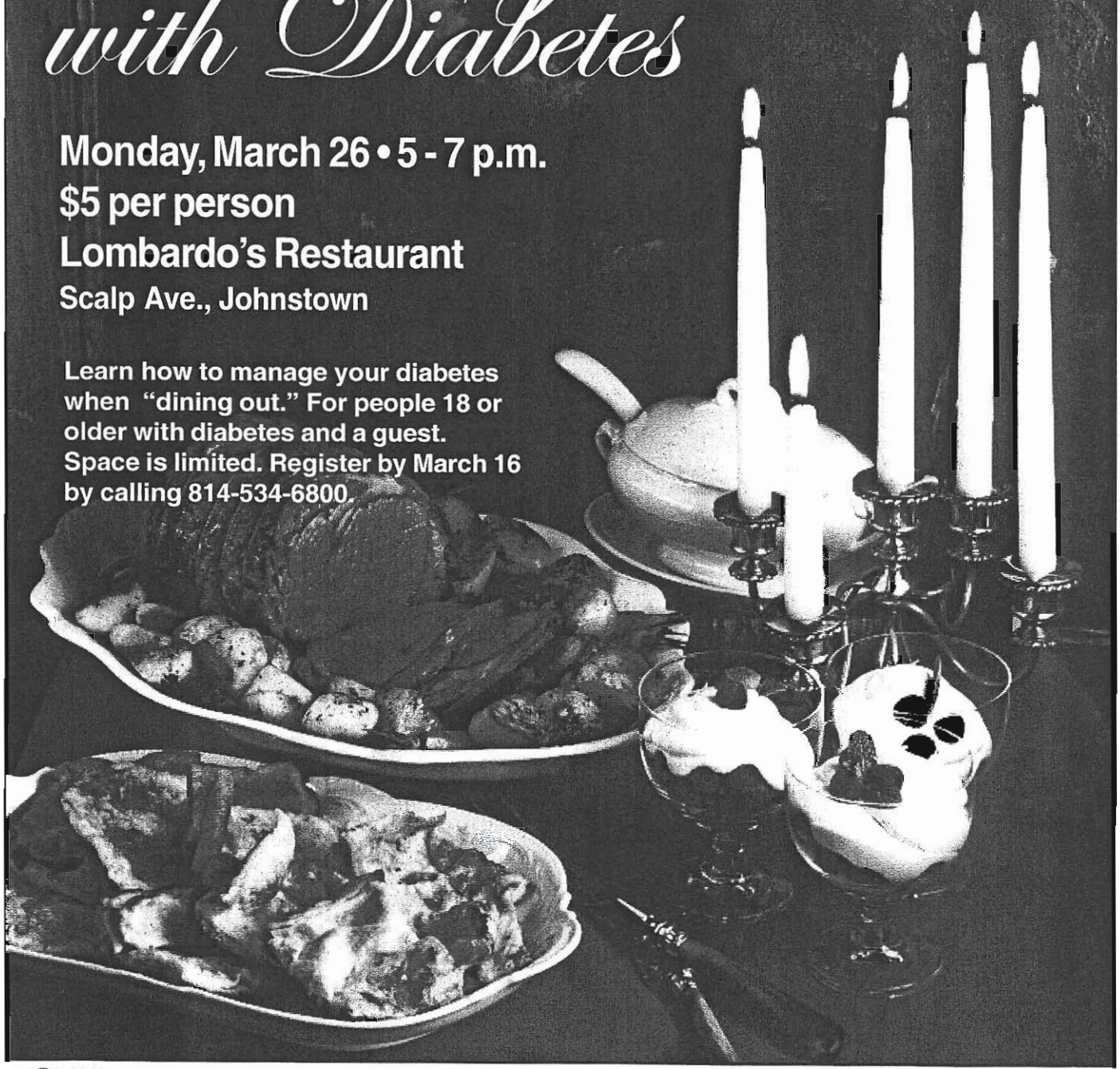
- ✓25-29 correct: Food Genius
- ✓20-24 correct: Nutritionally-gifted
- ✓15-19 correct: Average American
- ✓10-14 correct: Nutritionally-challenged
- ✓9 or less: Checked your weight lately?

CONEMAUGH HEALTH SYSTEM

Dining Out with Diabetes

Monday, March 26 • 5 - 7 p.m.
$5 per person
Lombardo's Restaurant
Scalp Ave., Johnstown

Learn how to manage your diabetes when "dining out." For people 18 or older with diabetes and a guest. Space is limited. Register by March 16 by calling 814-534-6800.



novo nordisk®

In conjunction with Lombardo's Restaurant, Novo Nordisk, Inc. & Conemaugh Diabetes Institute

Conemaugh Diabetes Institute
Affiliate Conemaugh Health System

Dining Out with Diabetes

Recently the Conemaugh Diabetes Institute held a dining out program in conjunction with Nordisk & a local Italian restaurant, Lambardo's. The evening's program goals were to:

1. demonstrate the importance of blood glucose monitoring
2. provide meal-planning education
3. demonstrate that the amount of carbohydrate selections effect blood glucose levels
4. maintaining good eating habits when dining out is possible for the individual with diabetes.

The primary nutrition goal of the individual with diabetes, which is to restore and maintain blood glucose levels to as near normal as possible can be achieved by following the above goals.

The dietitian from the Conemaugh Diabetes Institute met with the owner/chef to choose an appropriate menu. A nutritional analysis of each menu item was formulated. After the meal this analysis was provided to the participants for calculating the number of carbohydrates consumed at the meal.

The 50 participants pre-registered for the evening and were informed to bring their blood glucose monitors. After the guests were welcomed at the restaurant, they were requested to take and record their blood glucose levels. Hors d'oeuvres were available while the guest made their dinner selections. A nutritional meal planning presentation was presented when dessert was served. At the conclusion of the meal and after calculating their carbohydrate selection a postprandial blood glucose level was done.

Some guests were very surprised but were able to determine why there was an increase in their 1.5 – 2 hour post prandial levels. The

top three underlying food habits identified by the participants for the increase in their post prandial blood glucose levels were:

1. ate too many slices of bread before dinner was served
2. chose entrées', sides and desserts that were very high in carbohydrates
3. ate all my meal instead of observing the portion size.

Other guests were in the normal ranges and their correct carbohydrate meals choices confirmed the last two of the listed evenings' goals. (Please refer to participants blood glucose levels chart below.)

Foods that contain carbohydrates will affect blood glucose the most, because they are mostly digested to glucose, which is absorbed from the intestine straight into the blood stream 15 minutes to two hours after eating. Blood glucose is the main sugar found in the blood and the body's main source of energy. How quickly and how much glucose levels rise depends on food composition, portion size, and timing. Remember that proteins and fats in the diet also affect the blood glucose levels. Too much fat and cholesterol may lead over the long run to weight gain, heart disease, stroke and other cardiac diseases. Also if your blood glucose levels stays high (hyperglycemia) too much of the time, the other complications of diabetes are eye, foot, kidney problems in addition to heart. You may also have problems if your blood glucose gets too low (hypoglycemia)

Blood glucose levels are affected differently depending on whether foods that are consumed contains carbohydrates, protein, fats or a combination of the three. Carbohydrates will causes the blood glucose to rise the most and the most quickly. Liquids that contain carbohydrates (milk, & juice) will cause glucose to rise faster than solids that contain carbohydrates (bread & pasta). Because of the impact they have on blood glucose levels, carbohydrates are the most important macronutrient for peoples with diabetes to monitor.

The amount of food that is consumed, eating more food or larger portions, also impact blood glucose levels. Since carbohydrates affect the blood glucose levels the most, the amount of carbohydrates eaten is very important in controlling blood glucose levels. To determine how many carbohydrates to consume at each meal one must be familiar with the carbohydrate counting system, and serving size.

Carbohydrate Counting method is similar to the old diabetic Exchange List method in that they both use food groups. However, Carbohydrate Counting keeps track or " counts" servings equal to 15 grams or 1 unit of carbohydrates. The food groups that have carbohydrates and are counted are: starches, starchy vegetables group, fruit group, and the milk group. One serving from any of these groups counts as one carbohydrate serving.
Proteins & fat are <u>not</u> counted as a carb in the Carb Counting system. When proteins & fats are eaten at the same time as carbs, they actually have a positive effect on blood glucose levels. The blood glucose levels do not rise as quickly. But most individuals consume more protein & fat than needed for good health. Foods high in protein include meat, cheese, eggs & dried beans. Too many servings of foods high in fat increase risk of cardiac disease, cancer & can lead to weight gain. Limit your intake of high fat foods such as cream sauces, gravy, butter, stick margarine, salad dressing, and of course fried foods

Blood glucose levels are also affected by the timing of meals and snacks. Eating 3 meals and 1-2 snacks at the same time of the day and consuming the same amount of carbohydrates at each meal and snack will aid in keeping your blood glucose levels consistent.

Studies show that as people eat out their calorie consumption goes up. This is probably not just due to what was ordered but also how much is consumed. New research shows that restaurant portions sizes have grown markedly, with amounts two to five or more times larger than the standard serving size.

The following 10 tips are for individuals with diabetes when dining out; to aid in selecting healthy meals that are part of their overall diabetes meal plan.

1. **Choose restaurants that serve healthy food**
2. **Include appetizers and cocktails consumed into your meal plan (carb servings)**
3. **Read menu descriptions or ask for details on the food's preparation**
4. **Make special requests or substitutions**
5. **Choose variety of foods**
6. **Avoid fried foods & buffets**
7. **Ask for dressings or sauces on the side**
8. **Count carb servings**
9. **Watch portion sizes**
10. **Eat on time and slowly**

Whether eating at home or dining out, remember the principles of diabetes nutrition. Eat a variety of healthy foods, stick to correct carbohydrate servings, portion size and monitor blood glucose levels. By working with your health care team enjoy eating out without jeopardizing your meal plan or your blood glucose levels. Following these simple guidelines may have the potential to reduce the harmful effects of diabetes purely by making some changes to your lifestyle!

Now you have the tools needed to sit down to a meal in a restaurant. Look at the menu, choose a balance meal, and then ask yourself "is there a better choice?" All the hard work is done before the meal, so that once the food arrives, you can sit back, relax and ENJOY your meal!

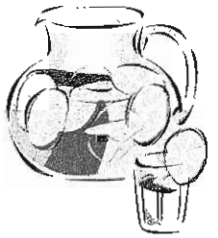
MENU

Entrées

Chicken Piccata
Boston Scrod
Beef Tips
Egg Plant Parmigiana

Beverages

Diet Soda
Unsweetened Ice Tea
Coffee
Tea



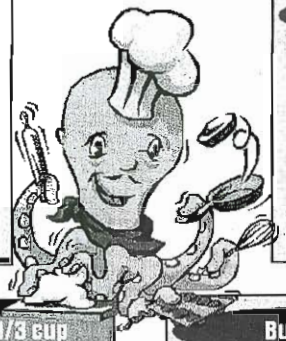
Sides

Baked Potato
  Sour Cream or Butter
Pasta with Marinara Sauce
Green Beans
Broccoli
Salad
  House or Ranch dressing

Dessert

Tiramisu
Cannolli
Spumoni

Sides



Baked Potato

Calories	322
Protein	8.6 gm
Fat	0.4gm
Carbohydrate	46.6gm
Cholesterol	omg
Sodium	34mg

Sour Cream — 1 tbsp

Calories	
Protein	0.4 gm
Fat	2.5 gm
Carbohydrate	0.5 gm
Cholesterol	5 mg
Sodium	6 mg

Pasta (with sause) — 1 1/3 cup

Calories	255
Protein	11.3 gm
Fat	2.9 gm
Carbohydrate	50.5 gm
Cholesterol	17 mg
Sodium	173 mg

Butter — 1 tbsp

Calories	102
Protein	0.1 gm
Fat	2.9 gm
Carbohydrate	50.5 gm
Cholesterol	17 mg
Sodium	173 mg

Green Beans — 1 cup

Calories	63
Protein	2 gm
Fat	8.4 gm
Carbohydrate	8.7 gm
Cholesterol	31 mg
Sodium	36 mg

Broccolli

Calories	71
Protein	2.9 gm
Fat	8.3 gm
Carbohydrate	4.9 gm
Cholesterol	31 mg

Salad — 1.5 cups

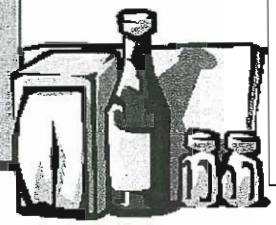
Calories	38
Protein	2.66 gm
Fat	0 gm
Carbohydrate	8.2 gm
Cholesterol	0 mg
Sodium	33.29 mg

Dressing — 2 tbsp

	House	Ranch
Calories	88	230
Protein	0 gm	1 gm
Fat	18 gm	48 gm
Carbohydrate	1 gm	4 gm
Cholesterol	0mg	22mg
Sodium	61 mg	244 mg

Hors d'oeuvres

Stuffed Celery	1 Serving
Calories	19
Protein	1.5 gm
Fat	11.7 gm
Carbohydrate	0.9 gm
Cholesterol	6 mg
Sodium	11 mg



Bruchetta	
Calories	101
Protein	1.4 gm
Fat	6 gm
Carbohydrate	3.6 gm
Cholesterol	0 mg
Sodium	14 mg

Mushroom	Serving
Calories	36
Protein	3 gm
Fat	1 gm
Carbohydrate	5 gm
Cholesterol	0 mg
Sodium	13 mg

Cheeseball	1 tsp
Calories	114
Protein	4.7 gm
Fat	6 gm
Carbohydrate	2.5 gm
Cholesterol	16 mg
Sodium	176 mg

Entree Menu

Chicken Piccata	
Calories	318
Protein	35 gm
Fat	5 gm
Carbohydrate	16gm
Cholesterol	82 mg
Sodium	68 mg

Boston Scrod	7 oz.
Calories	382
Protein	35 gm
Fat	1.5 gm
Carbohydrate	17 gm
Cholesterol	71 mg
Sodium	74 mg

Beef Tips	8 oz.
Calories	257
Protein	35 gm
Fat	5.0 gm
Carbohydrate	25 gm
Cholesterol	27 mg
Sodium	123 mg

Egg Plant	9 oz.
Calories	670
Protein	23 gm
Fat	32 gm
Carbohydrate	75 gm
Cholesterol	130 mg
Sodium	550 mg

Presents

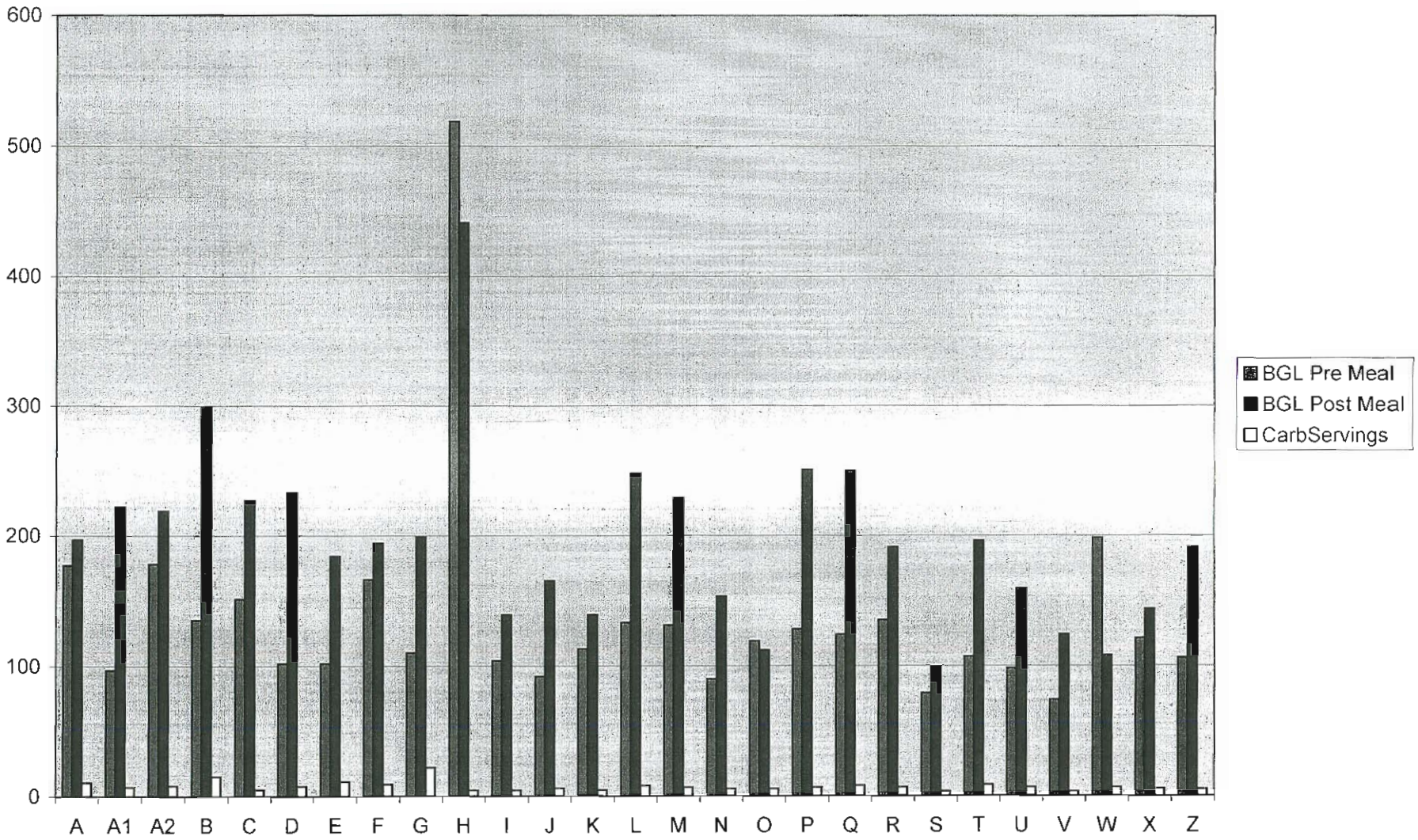
Dining out With Diabetes

In Conjunction with:
Lombardo's

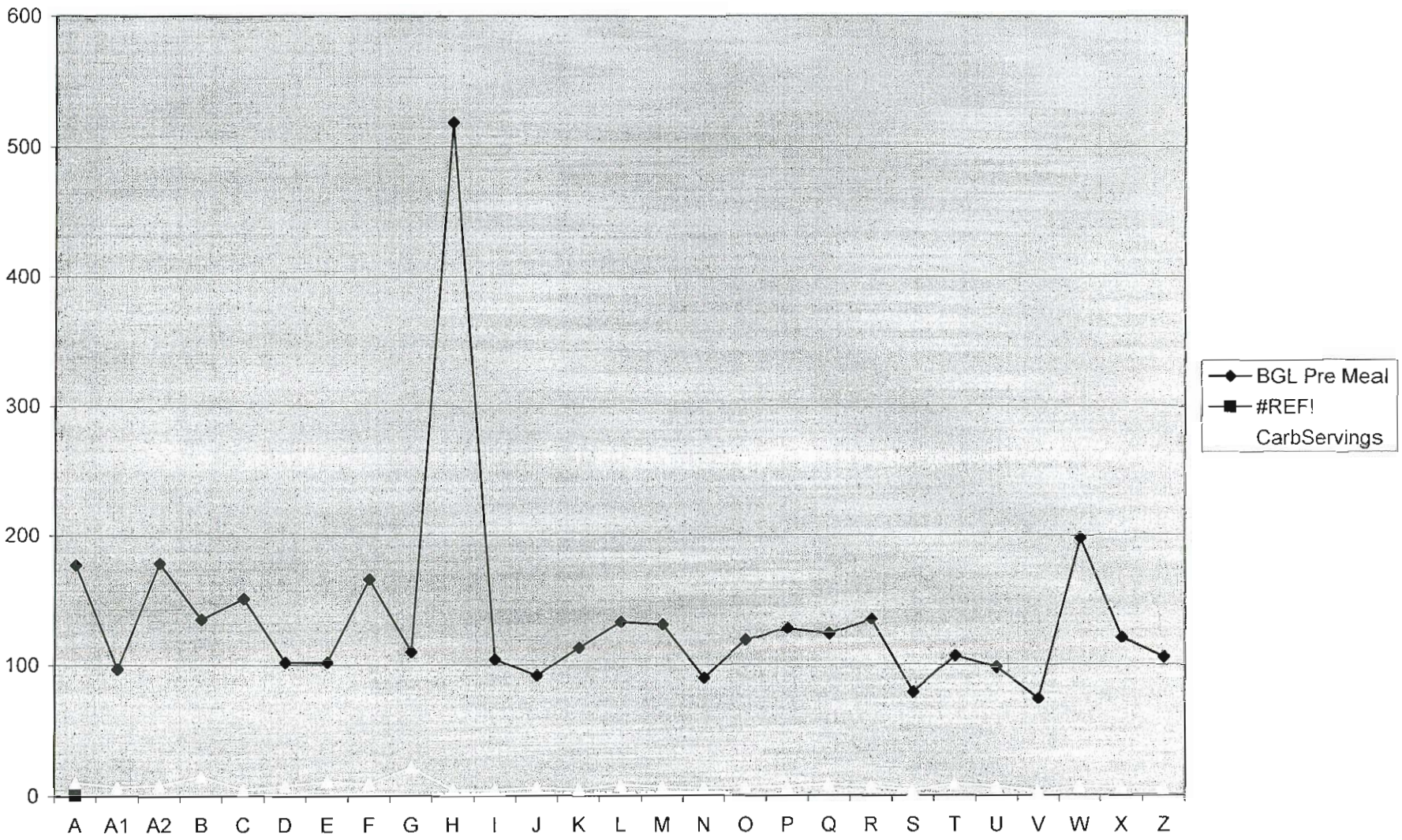
Sponsored by: Novo Nordisk

Conemaugh
Diabetes Institute

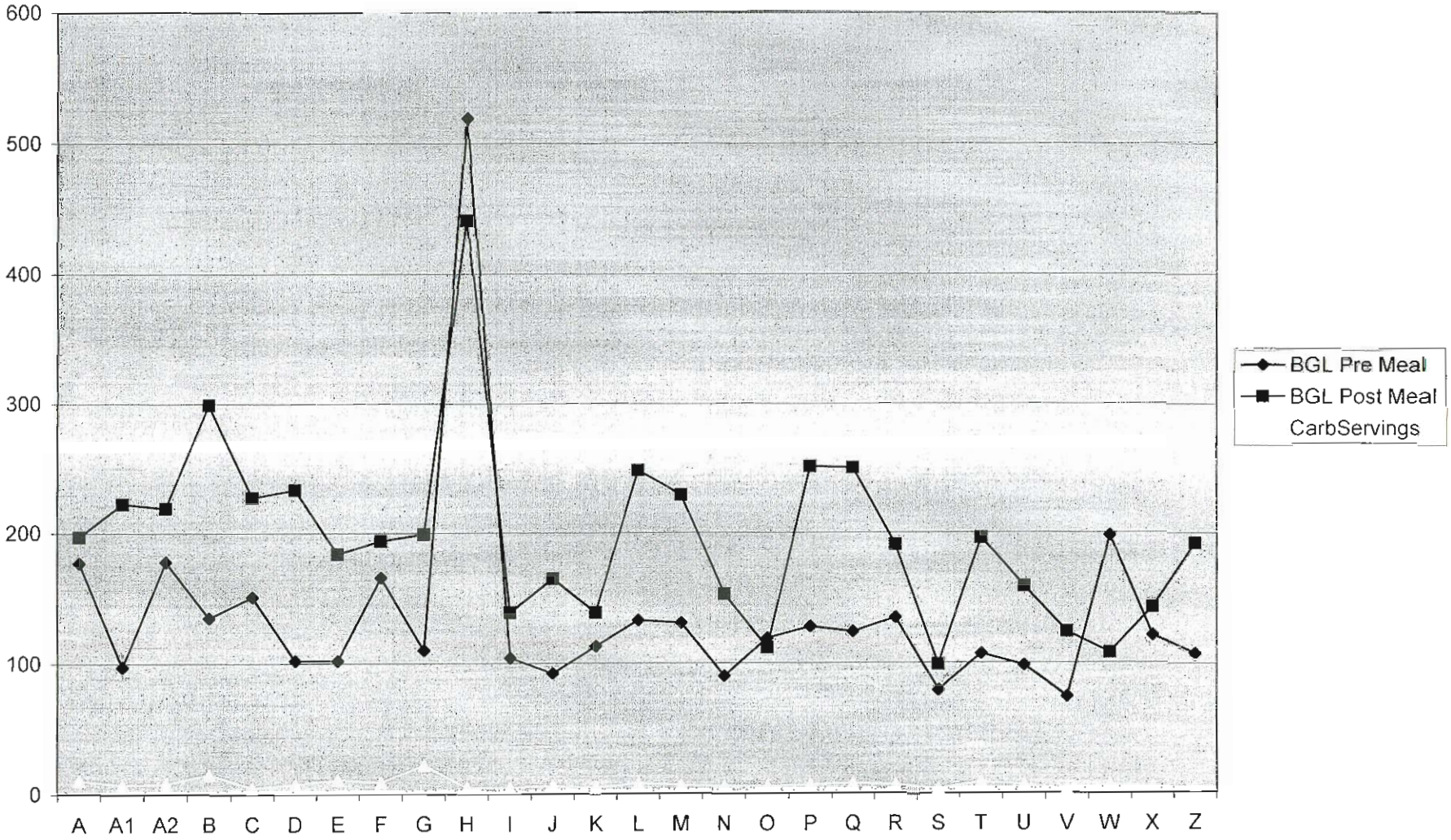
DIABETES & DINING OUT 03/26/07



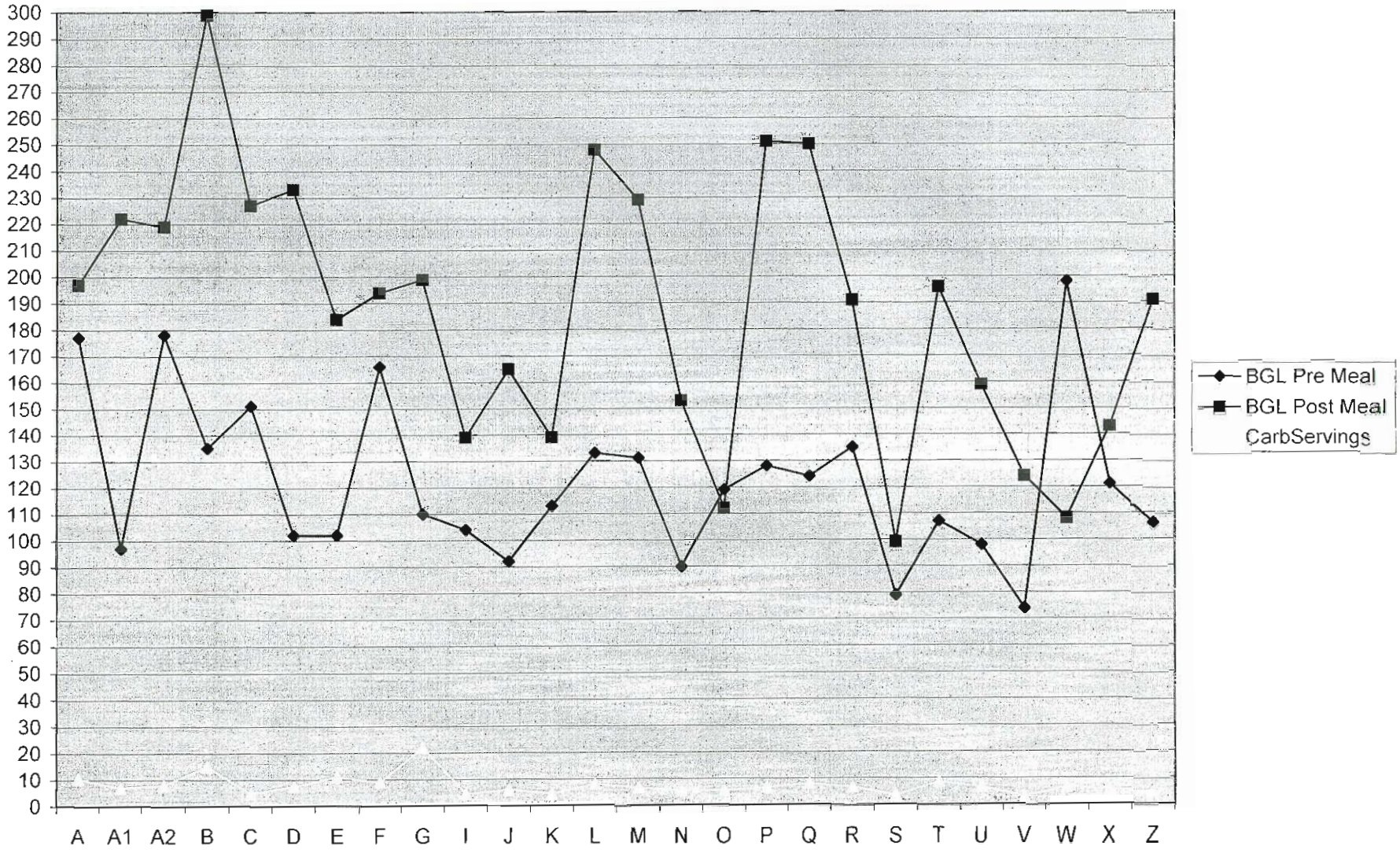
DINING OUT 3/26/07



Dinning Out - Pre - Post BGL- Carbs Consumed



Dining Out
BGL Pre - Post - Carbs
March 26, 2007



Dining Out Program 3/26/07

Individual	BGL Pre Meal	BGL Post Meal	CarbServings
A	177	197	10.5
A1	97	222	7
A2	178	219	8
B	135	299	15
C	151	227	4.8
D	102	233	7.5
E	102	184	11
F	166	194	9
G	110	199	22
I	104	139	4.5
J	92	165	6
K	113	139	4.5
L	133	248	8
M	131	229	6.5
N	90	153	5.5
O	119	112	5.5
P	128	251	6.5
Q	124	250	8
R	135	191	6.5
S	79	99	3.5
T	107	196	8.5
U	98	159	6.5
V	74	124	3
W	198	108	6.5
X	121	143	5.5
Z	106	191	5

Dining Out Program 3/26/07

Individual	BGL Pre Meal	BGL Post Meal	CarbServings
A	177	197	10.5
A1	97	222	7
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B	135	299	15
C	151	227	4.8
D	102	233	7.5
E	102	184	11
F	166	194	9
G	110	199	22
H	519	441	4.5
I	104	139	4.5
J	92	165	6
K	113	139	4.5
L	133	248	8
M	131	229	6.5
N	90	153	5.5
O	119	112	5.5
P	128	251	6.5
Q	124	250	8
R	135	191	6.5
S	79	99	3.5
T	107	196	8.5
U	98	159	6.5
V	74	124	3
W	198	108	6.5
X	121	143	5.5
Z	106	191	5

Broadcast Report
WJAC-TV Diabetes Phone Bank
August 15 &16

North American Markets

Demographics
5:00 – 6:00 PM: 39,000 viewers 18+
6:00 – 6:30 PM: 56,000 viewers 18+

[CC] 00:07:16 It' s a growing epidemic in America **diabetes** and more than a million children are affected by it. Tonight we take an indepth look at their daily battle. Retirement it' s o minds of many baby boomers why your concerns could put you at risk for fraud. 00:08:57

[CC] 00:18:09 --**Diabetes** is a disease that has touched many'pppp Americans in one <a few thunders otherwise partly cloudy. Lows in the low 60s. Sunshine returns tomorrow, and continues for the rest of the week. Highs in the mid to upper 70s tomorrow through Thursday, and in the low 80s by Friday. > <For accurate and dependable forcasting 24/7 check out wjac TV weahter plus on digital channel 6-point-2 or check your local listings. > More than 150 firefighters are battling a wildfire in Los Angeles county that' s burned nearly 15 hundred acres so far. The blaze are only about 15 percent contained. It' s knocked out a power facility and electricity has been shut down to 45 hundred homes in the area. Right now no structures are in nger. The cause of t fire is now under investigation. 00:19:49

[CC] 00:22:34 Imagine being a kid --And told you have a disease --That will require daily shots. You won' t be able to eat all the good stuff your friends eat. And you' ll have to live this way --For the rest of your life. Juvenile-onset **diabetes** --Or type-1 **diabetes** --Affects about a million Americans --Many of them children or adolescents. And as tough as it is for an adult to hear they have **diabetes** --For a kid --It can seem like the end of the world. Lisa stofko reports, <8:00 nat sot, 5, 6, 7 -- --A summer camp? Not quite. Try a summer meeting of the Indiana regional medical center' s juvenile **diabetes** support group. While it' s good for kids to see they' re not alone, doctors say increasing numbers here, reflect a disturbi trend. -- 00:23:21

[CC] 00:23:27 --1:08 jabir "unfortunately, we are seeing more and more **diabetes** in the younger population and more type 2 **diabetes**." 08) -- ---People with type-1 **diabetes** can' t make insulin. Without it, sugar builds up in the blood. It' s a lifelong condition with no cure, and no known cause. In te 2 **diabetes**, typically seen in adults, the body produces insulin, but not enough. Genetics and lifestyle, being overweight and inactive, increase the risk. -- --- 10:55 nat sot "and i' m going to give everybody the recipe, it' s called a sunshine salad." 03) or 12:02, cu blender. 02) -- ---In this group, kids learn ways to cope with their disease and the changes they' ve made as a result. They can socialize with other kids just like them, and even parents can share lessons learned. - ---27:18 lori "we' ve had in the course of our support group, parents come in who their children were just recently diagnosed and they')re pairing up with some parents that have been dealing with **diabetes** for years." 00:24:09

[CC] 00:24:10 11) -- ---Sharon henry' s two daughters, both have **diabetes**. Initially shocked by 12-yr-old casey' s diagnosis three ars ago, the family adjusted. 4-Yr-old emily found out she had **diabetes** last year. - -- --25:10 sharon "you know what you have to do, and you deal with it one day at a time, and she' s doing good, and emily, I think handled it well cause she knew what casey was going through." 13) -- -- --17-yr-old roman sulkosky, a support group alumni, was here today to talk about his insulin pump. Diagnosed at 13, it took him 2 years

to realize he could still treat his disease, play sports and live a normal life. - -- --19:06 roman "a doctor told me, you' re not a **diabetic**, 00:24:54

[CC] 00:25:05 you' re a person with **diabetes** and what I got from that was i' m just like everyone else, but this is something I have to deal with that other people don' t." 16) -- --Ls ch6 news. > The group meets twice a year and is designed with fun in mind. Always in a non-clinical setting --Summer get-togethers are usually held in a park or some other outdoor setting. The winter meetings often include some activity --Like bowling or swimming. Channel 6 is partnering with experts from conemaugh health system and Indiana regional medical center to answer your questions about **diabetes**. Tomorrow and Wednesday --They' ll be here in our studios to take your calls from 5 to 6:30. And for even more information about **diabetes** --Log onto wjactv-dot-com and go to the health page --Where you can take a **diabetes** risk test learn where screnings are being held in your area --And learn about controlling your sugar.

2. Channel 6 News At 5 **DMA: 98**

WJAC-TV CH 6 (NBC) Johnstown/Altoona

08/14/2006 **05:00 PM - 05:30 PM**

Available formats: DVD, CD, , videotape, transcript

[CC] 00:15:08 --On channel 6 news news at 5:30. It' s becoming an American epidemic -- **Diabetes** --Tonight we take an in depth look at kids dealing with the disease.

North American Markets

1. Channel 6 News At 6

WJAC-TV CH 6 (NBC) Johnstown/Altoona

08/16/2006 **06:00 PM - 06:30 PM**

Available formats: DVD, CD, , videotape, transcript,

[CC] 00:06:11 covering cambria county nichelle mckelvey channel 6 news. After several alcohol related problems last year, this time around volunteer fire fighters aren' t taking any chances at the annual firemen' s convention. At last year' s convention in nanty glo, neptune fire chief, ray stringer, was killed in a bar fight. Another fire fighter, john smoter, killed an 83 year old man in a dui crash after the convention. Now organizers are taking a proactive approach to control alcohol consumption. <6.30-6.44 I had one fire fighter ask did you ban beer all together? No we didn' t ban it, that' s going to eliminate all our problems. > Anyone who shows up with alcohol or is intoxicated will not be allowed into the convention. Also, designated drivers will be available. The lily volunteer fire department has contacted local taverns, asking them to stay alert as well. A plan to crack down on illegal immigrants could land the altoona city council in legal trouble. The ordinance is modeled after one adopted in hazelton Pennsylvania. That city is now facing a lawsuit. Altoona' s proposal is slightly different-it would penalize businesses that hire illegal immigrants and landlords who re to them without checking documentation. Council will vote on the ordinance in September. <Dr lltz> And don' t forget our live **diabetes** phone bank continues tonight until 6:30. **Diabetes** experts from **conemaugh** health system and Indiana regional are waiting to answer your questions. The number for the hotline is 1-800-952-2462 I keep putting food out, but they just won' t eat. I' ve got an idea. [Animal sounds] wendy' s cheddar lovers' bacon cheeseburger. Announcer: even burgervores get tired of the same burger. 00:09:40

2. Channel 6 News At 5 **DMA: 98**

WJAC-TV CH 6 (NBC) Johnstown/Altoona

08/16/2006 **05:00 PM - 05:30 PM**

Available formats: DVD, CD, , videotape, transcript,

[CC] 00:00:21: > Do you or a loved one suffer from **diabetes**? The phone lines are now open local experts are here in our studios --Ready to answer your questions. The number: 1-888-952-2462. Representatives from **conemaugh** health system and Indiana regional medical center will be manning the phones --From now until 6:30. Again the number to dial is 1-888-952-2462 passed along as to the kinds of things we should be looking for 6:33:14> Bradley says gang violence is not+ something they' ve had problems with in the past, but the district would rather be pro-active, than re-active. 00:02:20

[CC] 00:12:26 And **diabetes** is a disease that affects millions according to the American **diabetes** association, more than 20 million children and adults in the US Have **diabetes**. It' s a life-altering diagnosis that can leave many people asking, why me, and, what next? But as lisa stofko reports tonight, many sufferers find both answers. And strength, in numbers. <A blood pressure check, weigh in, and a little Q-And-a. All part of the routine at each month' s **diabetes** support group meeting at memorial medical center in johnstown. It' s a tool many diabetics and pre-diabetics have come to rely on. -- ---19:26 antoinette "it' s a way for them

to come, to get information, ask questions, to get reinforced, I know I should be doing this but I need someone to give me that extra push." 12) -- ---For some, education classes, atlhough helpful, aren' t enough. People have trouble sticking to their treatment. For them, 00:13:10

[CC] 00:13:14 the accountability of a group helps them stay on top of their disease. -- ---5:33 Virginia "well, it' s kind of like a pep rally, it gets you hepped up about doing the right thing to control your **diabetes.**" 11) -- ---And then there' s the networking. -- -- --Nat sot laughing -- -- --Sharing common experiences with others who truly understand. Does it help? -- ---2:50 diana "yes, it does. You know you' re not alone, because there are other people who struggle with the same things you do." 04) -- ---And for many, learning that they have **diabetes**, -is-A struggle. There are feelings of anger and fear. 00:13:50

[CC] 00:13:53 Mary jane beam was diagnosed about 10 years ago, long before groups like this were an option. - -- --8:25 mary jane "i got very depressed, thinking this was it. But through the years, I learned I can live with it." 08) ---And live well. -- the group invites a variety of speakers in throughout the year to provide patients with the very latest information on medication and other resources that can help them reclaim their lives, by learning how to contr their **diabetes**, instead of it, controlling them. Ls ch6 news. > **Diabetes** is the seventh leading cause of death in the US. An estimated 22-hundred people are diagnosed each day. This week channel 6 is working with two local hospitals to help you learn more about **diabetes**. **Conemaugh** health system and Indiana regional medical center have become part of a new regional program called the pride' program aimed at helping both docotrs and patients. <00:49 Its education. Education for health care professionals physicians nurses dieticians and its education for patients so that people with **diabetes** learn to self-manage and 00:14:59

[CC] 00:15:12 people who at risk for **diabetes** learn how to prevent **diabetes** 1:05> **Diabetes** experts from Indiana regional and **conemaugh** health system are waiting to answer your **diabetes** questions. 1-800-952-2462 Is the number the line will be open until 6:30. In tonight' s medical alert a cup of joe could lead to a heart attack within an hour of drinking it. A recent study found the risk of heart attack quadrupled among occasional coffee drinkers during the hour after they had a cup. Regular and moderate drinkers had a much lower risk. Coffee might not be all bad previous studies have shown that it can lower your risk for **diabetes** and certain cancers. And here' s something you can drink to new evidence that white wine could be just as heart healthy as red wine. Previous studies has shown that the heart helping antioxidant were found in the skin of grapes used to make red wine. In most white wines the grape pulp is separated from the skin. New study now show that the amount of antioxidant in grape pulp is similar to the skin. The total costs of dealing with a stroke in the US Was about 53 billion dollars in 2004. Now experts say by 20-50 that number could quadruple. The estimated dollar amount included ambulance and hospital services, drugs and potential earning losses. You can prevent a stroke by quitting smoking, losing weight and keeping a healthy blood pressure. More news from where you live on channel 6 news news at 5:30. Your kids might not want to hear this but school is just around the corner tonight we put the newest backpacks to the test. But first one of the most famous spots to get ice cream moves and adds something new. And could we get some new neighbors? 00:16:31

[CC] 00:22:07. And here' s another live look at our phone bank where experts are standing from **conemaugh** health system and Indiana regional medical center ready to answer any question you might have about **diabetes**. Just call the number on your screen 1-888-952-2462 the lines are open until 6-30. 00:22:47

08/15/2006 05:00 PM - 05:30 PM

Available formats:, DVD, CD, , videotape, transcript,

[CC] 00:00:01 Sot 5-34-08. Do you or a loved one suffer from **diabetes**? The phone lines are now open local experts are here in our studios --Ready to answer your questions. The number: 1-888-952-2462. Representatives from **conemaugh** health system and Indiana regional medical center will be manning the phones --From now until 6:30. They' ll also be here tomorrow to take your calls. Again the number to dial is 1-888-952-2462 **conemaugh** health system and the Indiana regional medical center are part of a new partnership --With the university of Pittsburgh **diabetes** institute-aimed at providing comprehensive **diabetes** care throughout western Pennsylvania. It' s called "the pride program" --The Pittsburgh regional initiative for **diabetes** education. The program focuses on ihelping people manage and control **diabetes** --While imporving their quality of fe. Coming up a little bit later --We' ll tell you more about **diabetes**. Lisa stofko takes a look at how it can affect pregnant women. 00:01:26

[CC] 00:08:08? And tonight a look at one of the most common health problems facing pregnant women and how it could affect your children' s risk of **diabetes**.

[CC] 00:12:02 Gestational **diabetes** is one of the most common health problems during pregnancy --Affecting about four-percent of expectant mothers. While the usually-temporary-Condition increases the chances a mother will develop **diabetes** later in life --Most women do go on to deliver healthy babies. Lisa stofko has more. <Lynn mitasky is seven months pregnant with her second child. Over 30, overweight, and with a family history of **diabetes**., lynn was at increased risk for developing gestational **diabetes**. Although her first pregnancy was fine, glucose in a standard urine test two months ago flagged a problem. -- ---10:43 lynn "and then they got a little concerned, they did a fastg blood sugar and it was 171, they do not want it over 110." 08) -- ---(gfx expectant mothers are routinely screened for gestational **diabetes** between their 24th and 28th weeks. - -- --4:19 lori "what happens during pregnancy, the placenta produces extra hormones. The problem is, in these women, 00:12:56

[CC] 00:13:05 The pancreas which normally produces insulin is not producing enough to cover these excess needs, that then causes blood sugar to be elevated." 20) -- ---:47 nat sot "the sugar that they list on the label is what' s been added or what occurs naturally." 05) -- --- Gestational **diabetes** can be managed, most often with diet and exercise. At the center for **diabetes** care at Indiana regional medical center, lynn learned how to adopt a meal plan that brought her blood sugar within a normal range. She also uses a glucometer to regularly monitor her blood sugar. - ---Gfx as for the baby, if left untreated, gestational **diabetes** can result in a large birth weight, newborn jaundice, hypoglycemia or low blood sugar, low calcium, and respiratory distress syndrome. - -- --And while most women with gestational **diabetes** do not remain diabetic, they have a two in three chance of having it again in future pregnancies and up to 50-percent may velop type 2-**diabetes** themselves, within five years. -- 00:13:55

[CC] 00:14:01 ---13:11 lynn "i am very worried about that, being that my brother is an insulin diabetic, and has been for 10 years, but I will adapt to it, and I will deal with it." 14) -- ---Ls ch6 news. > There are things women can do to reduce the risk of developing type-2 **diabetes**. Losing weight --Making healthy food choices --And exercising on a regular basis can make a big difference. And here' s another live look at our phone bank tonight --Where you can ll and speak with experts from **conemaugh** health system and the Indiana regional medical center about **diabetes**. Just dial 1-888-952-2462. In tonight' s medical alert breast cancer patients who are on the drug herceptin could have a higher incidence of heart damage. That' s according to the latest study from M-D Anderson cancer center. They

Phone Bank Script

Thank you for calling WJAC TV, this is the PRIDE Program's Diabetes Information Line, how may I help you?

Conemaugh Information

Conemaugh Connection (answers 24 hours):	800-587-5875
Website:	www.conemaugh.org

Indiana Regional Medical Center Information

Diabetes Center:	724-357-7164
	800-607-9923
Website:	www.indianahospital.org

WJAC Website

www.wjactv.com

Upcoming Diabetes Events

Friday, August 25 10:00 AM – 1:00 PM
Diabetes Day at Indiana Regional Medical Center
Free health information, screenings, cooking demonstrations and activities focusing on diabetes education, monitoring, nutrition and stress management.
Indiana Regional Medical Center (835 Hospital Road, Indiana)

Saturday, August 26 from 11:00 AM – 3:00 PM
Diabetes Day at Boscov's Galleria Mall in Johnstown, PA – Event sponsored by the Conemaugh Diabetes Institute.
Free foot screenings, consultations with diabetes educators, exercise instruction, game for kids and more. Stop by the Diabetes Day registration table to register to win a free treadmill and Dance Dance Revolution video game.

Saturday, September 9 from 10:00 AM – 3:00 PM
Conemaugh Health System Diabetes Fair at the Frank J. Pasquerilla Conference Center in Johnstown, PA. The event will be a "one-stop shop" complete with diabetes screenings; speakers and demonstrations on nutrition, exercise and lifestyle choices; a children's corner; various vendor booths; and visits from local celebrities.

CONEMAUGH HEALTH SYSTEM

What's Happening

Stage Area

Chair Exercises
Food & Nutrition for Kids
Ray Hornyak, PhD
Joel Bezek, MD
Cooking Demonstration
Exercise Presentation

Kids' Area

UPJ Ladies Basketball Team • 10 - 11 a.m.
"Fun Fruit Faces"
Healthy Life Styles
Classic Clowns • Noon - 2 p.m.
"Dance, Dance"
KidShape®Highmark
Children's Exercise

Autograph Table

UPJ Ladies Basketball Team
FROGGY 95 - Live • 10:30 a.m. - 12:30 p.m.
Local Celebrities

Conemaugh Diabetes Institute

Ask the...Dietitian, Pharmacist & Diabetes Educator
Blood Pressure Screenings
Futrex – Body Fat Analysis
LifeStyle Balance
Foot Screening • 10 a.m. - Noon
Dale Goughnour, DPM

The staff of the Conemaugh Diabetes Institute is excited to present this comprehensive event for people with diabetes, their families, and those at-risk for developing the disease.

On behalf of the Connumach Lions Club, we would like to thank you for donating your used eye glasses to assist in their efforts to prevent blindness and diabetes.

CONEMAUGH HEALTH SYSTEM

Conemaugh Diabetes Institute

Special Thanks

Joel Bezek, MD
Dale Goughnour, DPM
Ray Hornyak, PhD
Stephanie Miller, PharmD, BCPS
Ashley Weinzierl

Thank you to our Volunteers.

Without you, this event would not be possible.

Josephine LoScudo
Kay Cooper
Starr Durham
Bill Maher, NSCA, CPT-RKC
Cambria County Foster Grandparents Program
Classic Clowns
Conemaugh School of Nursing Students
Penn Highlands Community College Hospitality Committee
St. Francis University School of Nursing Students
Seton Hill University School of Dietetic Interns
UPJ Ladies Basketball Team
West End Ambulance
Melissa Radovonic and staff at the Frank J. Pasquerilla Conference Center

University of Pittsburgh
DIABETES INSTITUTE
in partnership with University of Pittsburgh Medical Center

Conemaugh
Diabetes Institute
Affiliate Conemaugh Health System

Memorial Medical Center
Lee Campus, 320 Main Street
Johnstown, PA 15901
1-866-641-3828
814-534-6800

CONEMAUGH HEALTH SYSTEM

Conemaugh Diabetes Institute

DIABETES FAIR

September 9, 2006
10 a.m. - 3 p.m.

Frank J. Pasquerilla Conference Center
Downtown Johnstown

HIGHMARK.
Blue Cross Blue Shield

Stage Area Presentations

10:15 a.m. **Couch Potato Exercises**
YWCA Staff

10:45 a.m. **Me and My Snacks**
Katie Steinkamp, MHPE, CHES

11:30 a.m. **Diabetes and Your Mood - Chicken or Egg**
Ray Hornyak, PhD

12:15 p.m. **Diabetes and the Eye**
Joel Bezek, MD

1 p.m. **Cooking for Health**
Amanda Hoffman, RD, LDN

2 p.m. **Increase Your Metabolism: Strength Training with Exercise Bands**
Laurie DiGiorgio, MS, RD, LDN, CDE

Memorial Medical Center
Participating Departments
7 Ashman
Conemaugh Health Foundation
Conemaugh Home Health
Office of Community Health
KidShape® Highmark
Imaging Department
School of Nursing
Sleep Disorders Center
Weight Management

Special thanks to Congressman John P. Murtha for his continuing support of diabetes research and education.

Thank You to our Vendors

Abbott Diabetes Care
American Diabetes Association
Animas Corporation (a Johnson & Johnson Company)
Bayer Health Care
CERMUSA
Center for Medicare & Medicaid Services
Children's Hospital of Pittsburgh
Conemaugh Home Medical Equipment
Connumach Lions Club
Dr. Dean Ornish Program at Windber Medical Center
Edgepark Surgical
Eli Lilly and Company
Flipside Media, Inc.
Galliker Dairy Company
GlaxoSmithKline
Highmark Blue Cross Blue Shield
Indiana Regional Medical Center
Medical Nutrition USA, Inc.
MedXpress
Mount Aloysius College
Novo Nordisk, Inc.
Penn State Cooperative Extension
Pennsylvania Department of Health
Pfizer, Inc.
Rezk Medical Supply
Sanofi-Aventis
SeniorLIFE Johnstown
Somerset County Blind Center
Somerset Hospital
The InforMedx Group
UMWA Health & Retirement Funds
University of Pittsburgh Diabetes Institute
Walnut Medical Services
Weight Watchers
Yankee Shoe Repair Factory, Inc.
YMCA
YWCA of Greater Johnstown

Sponsors

Platinum
Highmark Blue Cross Blue Shield
University of Pittsburgh Diabetes Institute

Silver
Concurrent Technologies Corporation
The InforMedx Group

Bronze
AmeriServ Financial
Penn Highlands Health Plan

Gift
Conemaugh Township Rotary Club
Ross Products

Health Screenings

Vestibule
Conemaugh Home Health – Blood Pressure
Conemaugh Imaging Department – Osteoporosis
Conemaugh Weight Management – Weight and BMI (Body Mass Index)
Somerset Blind Center – Vision and Hearing

Vendor Area
Children's Hospital of Pittsburgh
BMI (Body Mass Index) for Children
The InforMedx Group
Diabetes Risk Assessment
Conemaugh Diabetes Institute
Futrex – Body Fat Analysis
Blood Pressures
Foot Screening • 10 a.m. - Noon
Dale Goughnour, DPM

Conemaugh Health System

News Release: Conemaugh Diabetes Institute sponsoring Diabetes Fair

Conemaugh Diabetes Institute sponsoring Diabetes Fair

Johnstown, PA (08/31/2006) - Memorial Medical Center's Conemaugh Diabetes Institute, along with HighMark Blue Cross Blue Shield and UPMC Diabetes Institute, is sponsoring a comprehensive diabetes event Saturday, September 9, from 10 a.m.-3 p.m. at the Frank J. Pasquerilla Conference Center for people with diabetes, their families and those at-risk for developing the disease.

The Diabetes Fair will be a "one-stop shop" complete with diabetes screenings; speakers and demonstrations on nutrition, exercise and lifestyle choices; a children's corner; various vendor booths; and even visits from local "celebrities."

"Our goal with this event is to combine important diabetes education with fun activities," says Carol Harding, Manager, Conemaugh Diabetes Institute. "We want to cover information concerning the many different components of diabetes including fitness, nutrition and lifestyle all under one roof."

A $2 suggested donation per family will be collected to benefit children with diabetes. For more information contact the Conemaugh Diabetes Institute at 534-6800. See attached brochure for a complete schedule.

In Cambria, Somerset and Bedford counties alone, more than 13,000 people have been diagnosed with diabetes. In Pennsylvania more than 11,500 people die each year from the disease. Diabetes is also the leading cause of new blindness, end-stage renal disease and non-traumatic amputations in Pennsylvania.

The Conemaugh Diabetes Institute, which is funded by the U.S. Department of Defense, will take a comprehensive approach to managing diabetes, incorporating prevention, education, treatment and research initiatives. Some of the various programs offered at the Institute include:

·Diabetes Self Management Education (DSME) classes ·Lifestyle Balance ·Diabetes Prevention Program (DPP) ·Healthy Lifestyles Program ·Diabetes Support Group ·Mount Aloysius/Memorial Medical Center Diabetes Foot Study ·Gestational Diabetes care ·One-On-One Education

Daily American
Somerset County's Newspaper

Print Page

TUESDAY SEPTEMBER 5, 2006 Last modified: Saturday, September 2, 2006 12:57 AM EDT

Diabetes Event

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For more information contact the Conemaugh Diabetes Institute at 534-6800. See attached brochure for a complete schedule.

Daily American
Somerset County's Newspaper

Print Page

MONDAY AUGUST 28, 2006 Last modified: Friday, August 25, 2006 2:40 AM EDT

Diabetes Day

The Conemaugh Diabetes Institute and UPMC's Pride Program are sponsoring Diabetes Day Saturday at the Boscov's department store in the Galleria Mall.

The event will be held from 11 a.m. to 3 p.m. at the mall in Richland Township.

Participants will have the opportunity to visit health professionals on both floors, including educators, a dietitian and an exercise physiologist. The event is a chance to learn more about diabetes and find out if you are at risk, organizers said in a news release.

Children participating have the chance to win a Sony PlayStation interactive dance game. Adults can register to win a treadmill.

Eight percent of Pennsylvanians, some 1.1 million people, have diabetes, and experts estimate that 1.5 million new cases are diagnosed each year in the United States.

The Conemaugh Diabetes Institute, which is funded by the U.S. Department of Defense, takes a comprehensive approach to managing diabetes, incorporating prevention, education, treatment and research initiatives.

Full-page advertisement
The Tribune-Democrat

JOIN BOSCOV'S AS WE HELP RAISE FUNDS FOR CONEMAUGH DIABETES INSTITUTE CHILDRENS PROGRAM

SATURDAY, AUGUST 26, 2006 • 11 AM TO 3 PM • BOSCOV'S GALLERIA MALL

Fun for the Kids
Toy and Candy Departments
- Cookie decorating
- Kids back-to-school craft
- Free face painting
- Free balloon animals

Child ID
Richland Township Police Department will have FREE childrens DNA sampling kits available. *While supplies last.*

Conemaugh Diabetes Institute Kid Shape Program
Stop by and pick up your passport to be stamped at various locations throughout Boscov's and you'll be registered to win a complete Sony PlayStation with dance mat and game (Value $400).

Highmark Caring Foundation with Children's Health Insurance Program (CHIP) Information
Free or low-cost health insurance plan for uninsured kids. A representative will be available to answer your questions.

Conemaugh Diabetes Institute Adult Passport Sites
Pick your passport up and visit these sites located throughout Boscov's and register to win a treadmill (Value $600).

FIRST FLOOR:
- Futrex - Risk Assessment for Diabetes and Heart Disease and Check-Out
  First Floor Mall Entrance
- Foot Care Video
  Cosmetics Department at bottom of escalator
- Podiatrist or CDE-Filament Checks
  Shoe Department
- Abbott Dietary Game and Giveaways
  Mens Clothing Department

SECOND FLOOR:
- Dietitian with Healthy Snacks
  Small Appliances/Housewares
- Conemaugh Diabetes Institute Information
  Domestics at top of escalator
- Passport Kiosk - Mall Entrance
- Exercise Demonstration - Sporting Goods

Boscov's
Galleria Mall

CONEMAUGH DIABETES INSTITUTE - CHILDREN'S PROGRAM
Join Boscov's as we help raise funds for Conemaugh Diabetes Institute - Children's Program whose mission statement is to improve the lives of all affected by diabetes.

Purchase a paper pin-up for $1 at Boscov's Courtesy Desk and all proceeds go directly to Conemaugh Diabetes Institute Children's Programs.

Purchase Buddy Bear and $6 from each bear purchased will go directly to Conemaugh Diabetes Institute Children's Programs.

IT'S POOH'S 80TH ANNIVERSARY
Boscov's and Disney are proud to support the Make-A-Wish Foundation's mission to grant the wishes of children with life-threatening medical conditions and to enrich the human experience with hope, strength and joy. When you "make a wish" on these special wishbands with a friend you are helping to make wishes come true. To find out more, please visit www.wish.org or www.DisneyHand.com, or www.Boscovs.com.

Be a star in the life of a child!

Purchase a set of Pooh Friendship Wishbands  for $2.

"Make a wish" and share your friendship.

75% of the sale of each set of wishbands benefits the Make-A-Wish Foundation.

Purchase a paper pin-up for $1 at Boscov's Courtesy Desk.
All proceeds go to the Make-A-Wish Foundation.

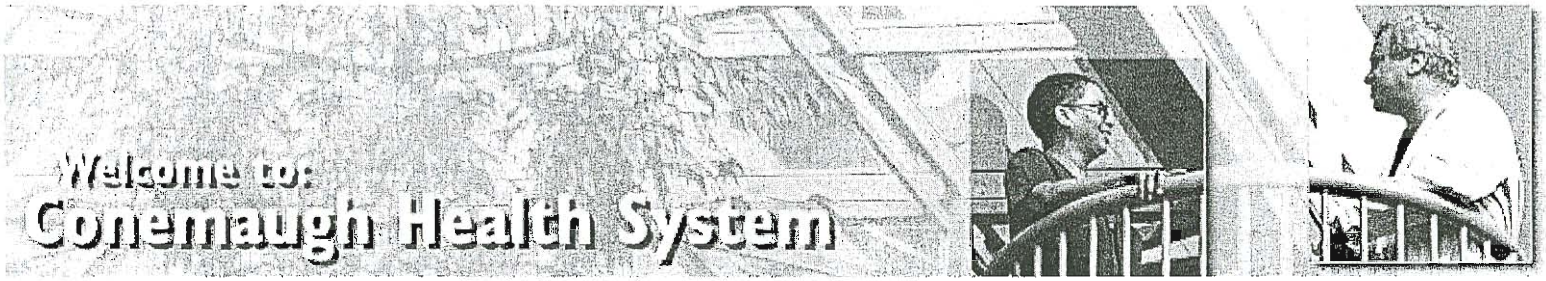
MAKE-A-WISH.

©Disney Based on the "Winnie the Pooh" works, by A.A. Milne and E.H. Shepard

REGISTER TO WIN A 2GB IPOD NANO (Value 199.99) OR ONE OF THESE FABULOUS SHOPPING SPREES:
- $100 Boys Shopping Spree
- $100 Girls Shopping Spree
- $100 Juniors Shopping Spree
- $100 Young Mens Shopping Spree
- $100 Toy Shopping Spree

The following organizations will be available with information for you and your children: Make-A-Wish, Conemaugh Diabetes Institute, Futrex - Risk Assessment for Diabetes and Heart Disease and Abbott Dietary.

Conemaugh Health System



News Release: Diabetes Day at Boscov's

Diabetes Day at Boscov's

Johnstown, PA (08/25/2006) - Diabetes Day at Boscov's The Conemaugh Diabetes Institute and UPMC's PRIDE Program are sponsoring Diabetes Day at Boscov's!

Saturday, August 26, 11 a.m. to 3 p.m., at Boscov's in the Galleria Mall will be a fun-filled day for the entire family. Visit health professionals located in several departments on both floors, such as an educator in footwear, a dietician in appliances and an exercise physiologist in the exercise equipment. Pick up a "passport" at any Boscov's entrance to log your path. Learn more about diabetes, including if you're at risk and how to prevent it. The following is a complete list of diabetes stations:

First Floor ·Skin Care Product ·Shoes ·Men's Clothing ·Mall Entrance Second Floor ·Small Appliances ·Domestics ·Entrance (near food court) ·Children's toys ·Exercise Equipment

Children participating have the chance to win a Sony Play Station interactive dance game (a $400 value) while adults can register to win a treadmill (a $600 value.)

In Cambria, Somerset and Bedford counties alone, more than 13,000 people have been diagnosed with diabetes.

Eight percent of Pennsylvanians-1.1 million people* have diabetes, and experts estimate that 1.5 million new cases are diagnosed each year in the United States. In fact, newly released statistics from the Centers for Disease Control and Prevention (CDC) note that the incidence of diabetes has increased by more than 14 percent in the past two years.

The Conemaugh Diabetes Institute, which is funded by the U.S. Department of Defense, takes a comprehensive approach to managing diabetes, incorporating prevention, education, treatment and research initiatives.

Some of the various programs offered at the Institute will include:

·Diabetes Self Management Education (DSME) classes ·Diabetes Prevention Program (DPP) ·Healthy Lifestyles Program ·Diabetes Support Group ·Mount Aloysius/Memorial Medical Center Diabetes Foot Study ·Gestational Diabetes care ·One-On-One Education

For more information contact the Conemaugh Diabetes Institute at 814-534-6800

As always, thank you for your consideration.

For More Information, Please Contact:
Amy Bradley, Director of Public Affairs
Phone: (814) 534-3121
Email: **abradle@conemaugh.org**

1086 Franklin Street · Johnstown, PA 15905 · Phone:(814)534-9000
Conemaugh Nurse Connection: (800)587-5875 · Email: **emailus@conemaugh.org**

Conemaugh Health System

You must visit **at least three** destinations including the kiosk at the **second floor Mall Entrance** to qualify for grand prize.
Grand Prize – Electronic Treadmill ($600 value)

Name

_____

Address

_____

Phone

_____

All Passports must be dropped off in Women's Clothing. Drawing at 3 p.m. Winner need not be present.

Conemaugh Diabetes Institute
Affiliate Conemaugh Health System

www.conemaugh.org

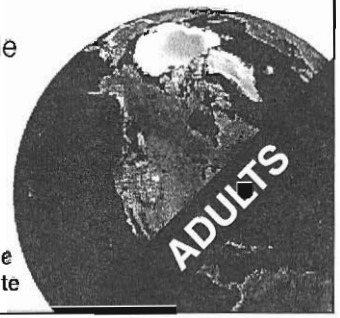
CONEMAUGH HEALTH SYSTEM

PASSPORT

Diabetes Day at Boscov's

August 26, 2006

Travel the **"world"** inside Boscov's and discover what you need to know about preventing and living with diabetes.



Sponsored by Boscov's & the Conemaugh Diabetes Institute

Diabetes Destinations

First Floor

____ Cosmetics
Skin care/foot care

____ Shoes
Filament check for sensitivity

____ Men's Clothing
Diabetes game

____ Mall Entrance
Futrex/Body Mass Index
(Age 18 and older only)

Second Floor

____ Small Appliances
Healthy snacks

____ Domestics
Diabetes educator

____ Exercise Equipment
Exercise physiologist

____ **Mall Entrance**
Diabetes screening kiosk

see back

Boscov's Evaluation Comments

August 26, 2006

Positive

Customers were satisfied with the event
Customers liked the snack station best
Information was good
Boscov's staff was wonderful
Helen Z. was wonderful
Liked the information & the booklets
Everything was great!
Would not change a thing
Customers like getting the information & the give aways items
Free gifts & information
Enjoyed the time talking with people
The event was very well received
Liked the education materials
Wonderful newspaper ads
Good lay out and flow at Boscov's
Overall I feel the day went very well & people seemed to be quite appreciative
Liked the video
Customers were glad we were here to give advice (samples appreciated)
Very pleased to be a part of this service
AV a good attention getter
Liked the info
Fun day – an eye opener
The program was well planned
A very worth while program
Dee Dee could not have been more accommodating
Volunteers were excellent & interacted well with the customers
Received only positive comments regard the newspaper ads
Tremendous success & great PR for the CDI!

Opportunity areas for improvement

Boscov's needs to add internet connections
Somewhat crowded
Too much in a small area
It was difficult to get people to consider every option at the same time
The process of filling out the passport was too involved;
some of the statements were difficult for the customer to understand what they were to do
More of an explanation needed as to which destination must be visited
Disliked too much walking for a few people
More prizes with less expense
Tables set too close to the walkways
Kiosk had technical difficulties
Tables too close the walkways in some areas
Tables seemed to be in the way
Could have used more handouts
More handouts needed in my area
Traffic flow was never ending
Increase display area would be appreciated
Suggest information available for classes & support groups available At each area
Need bigger display tables
My area was hidden by a shoe display

Presented At 2007 FAHC Adult Presentation

Carbohydrate Counting

Eileen T. Fiorina, RD, CNSD, LDN
Conemaugh Diabetes Institute
Memorial Medical Center

What is Diabetes?

Glucose unable to leave the blood & enter the cell
Glucose is the body's major energy source

3 Types of Diabetes
- Type 1 = pancreas produces no insulin – 5-10 %
- Type 2 = pancreas produces little insulin
  cells insulin resistant
  90-95%
- Gestational = shortage of insulin, cells insulin resistant
  or due to high hormones of pregnancy – 3-8%

Purpose of Presentation

- To explain the carbohydrate counting approach and to demonstrate ways for applying it in diabetes nutrition and to explain the importance of exercise in blood glucose management.

What Is A Carbohydrate Serving?

Serving of carbohydrate (carb) = 15 grams of carb

- A carbohydrate is a carbohydrate is a carbohydrate
  - Starch
  - Fruit
  - Milk
  - Sweets
  - Salty starch

Meal Plan – Carb Counting Or Gram Counting

0-5 gm	Do not count
6-10 gm	½ carb serving
11-20 gm	1 carb serving
21-25 gm	1 1/2 carb serving
26-35 gm	2 carb serving

Topics of Discussion

1. Defining Level I of carbohydrate counting approach and highlighting reasons behind popularity
2. Explaining the goals and objectives for level I of carbohydrate counting
3. Presenting recommended aids
4. Effect of exercise on blood glucose levels (BGL)

Definition and Reasons Behind Carbohydrate Counting Popularity

- Definition
  - Carbohydrate Counting is a meal planning approach based on the following ideas:
    - Carbohydrates is the main nutrient affecting blood glucose levels
    - **Total amount** of carbohydrates is more important than **source** of carbohydrates
- Reasons behind popularity
  - Effectiveness
  - Flexibility
  - Ease of implementation

The Three Levels of Carbohydrate Counting

- Level 1: Getting Started: Carbs used to regulate BGL
- Level 2: Moving On: Improve BGL by managing glucose, food, diabetes medication and physical activity
- Level 3: Using Insulin:Carbohydrate Ratios

Level 1 Goals

- Goals of Level 1 of carbohydrate counting
  - Regulate blood glucose by balancing carbohydrate intake with the diabetes medication and physical activity
  - Achieve and maintain consistency of carbohydrate intake at meals and snacks at similar times each day

Level 1 Objectives

- Objectives of Level 1 of carbohydrate counting
  - Identify carbohydrate as the primary nutrient affecting blood glucose levels (BGL)
  - Determine what foods contain carbohydrates, protein, and fat
  - Estimate accurately portion sizes
  - Define 1 carbohydrate serving as 15 grams carbohydrate (1 bread, or 1 fruit, or 1 milk exchange)
  - Count carbohydrate in meal plan
  - Determine time and carbohydrate goals for meals and snacks

The Exchange Lists

Groups/ Lists	Carb.	Protein	Fat	Calories
Carbohydrate Group				
Starch	15	3	1 or less	80
Fruit	15	—	—	60
Milk				
Skim	12	8	0-3	90
Low-fat	12	8	5	120
Whole	12	8	8	150
Other carbohydrates	15	varies	varies	varies
Vegetables	5	2	—	25
Meat and Substitute Group				
Very lean	—	7	0-1	35
Lean	—	7	3	55
Medium-fat	—	7	5	75
High-fat	—	7	8	100
Fat Group	—	—	5	45

Carbohydrate Choices

Foods that Contain Carbohydrates	One Carbohydrate Choice
Bread, cereals, pasta, and grains	15 grams of carbohydrate
Rice, beans, and starchy vegetables: potatoes, corn, peas	1 slice of bread
Fruit and fruit juices	⅓ cup pasta / rice
Milk and yogurt	1 small potato (3 oz)
Sugars foods: regular soda, fruit drinks, jelly beans	½ cup legumes
Sweets: cake, cookies, chocolate candy	½ cup cooked cereal
	¾ cup cold cereal
	1 fruit
	1 cup milk

Label Reading

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 3g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Potassium 700mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Fiber and Carbohydrate Counting

For example:

1 cup cereal = 30 gm Total Carbohydrate
- 7 gm dietary fiber
23 grams

Count as 23 grams carbohydrate

Impact of Fiber

Breakfast Meal	Total Carbohydrate (grams)	Fiber (grams)	Available Carbohydrate (grams)
Breakfast A			
1 scrambled egg	0	0	0
½ grapefruit	15	1.7	15
1 oz bran cereal (1/2 cup)	22	10.0	12
1 oz slice whole-wheat bread	15	1.5	15
Total	52	13.2	42
Breakfast B			
½ c orange juice	15	0.4	15
1 oz corn flakes (1 cup)	24	1.0	24
1 oz slice white bread	15	0.5	15
½ cup cottage cheese	0	0	0
Total	54	1.9	54

15

Factors Influencing BGL

High-fiber Meal

- Subtract from total carbohydrate content the amount of fiber in foods and meals containing more than 3 grams of carbohydrate.

High-protein and/or High-fat Meal

- For individuals taking rapid-acting insulin after, rather than before, the meal
- Split the dose of rapid-acting insulin and take half before the meal and half after the meal.

16

Carbohydrate Counting for Foods Containing Sugar Alcohols (Polyols)

Conditions	Recommendation
• Total carbohydrate comes from polyols • There are less than 10 grams of carbohydrates per serving	• Do not count if three or less servings are eaten per day
• Total carbohydrate comes from polyols • There are more than 10 grams of carbohydrates per serving	• Divide total carbohydrate in half then count it
• Polyols are just one source of carbohydrates	• Divide grams of polyols in half and subtract the amount from total carbohydrate

17

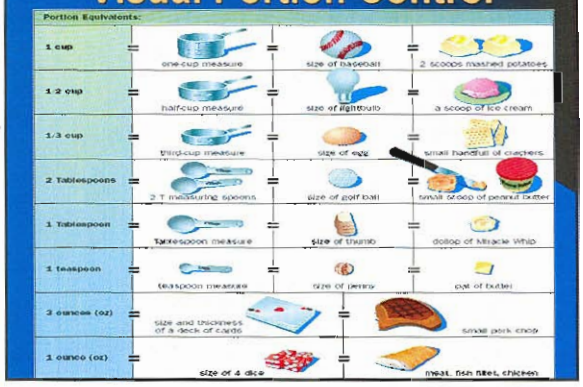
Estimating Portion Sizes and Carbohydrate Choices

Hand Guide	Example
4 dice = 1 oz	1 serving cheese
Card deck = 3 oz	1 serving cooked meat
Light bulb = ½ cup	1 serving frozen yogurt
Egg = 1/3 cup	1 serving pasta

Carbohydrate Choices	Target Total Grams of Carbohydrate	Range of Total Grams of Carbohydrate
1	15	8-22 grams
2	30	23-37 grams
3	45	38-52 grams
4	60	53-65 grams

18

Visual Portion Control



Calculating Carbohydrates in Recipes

Food	Amount	Weight	Carb.	Serving
White flour	1 cup	113 g	87 g	6
Whole wheat flour	1 cup	111 g	77.7 g	5
Oatmeal (uncooked)	1 cup	84	55.2g	4
White sugar	1 cup	200 g	199 g	13
Honey	1 cup	336 g	277 g	17
Raisins	2/3 cup	100 g	79.1 g	5
Cocoa	1/3 cup	28 g	12.8 g	1
Chocolate chips	¼ cup	43 g	31.3g	2

What Increases Blood Glucose?

Portions sizes

– Large portions of carbohydrate increase blood glucose

Hyperglycemia

Definition	Causes	Symptoms	Treatment
High plasma glucose (blood sugar) Untreated may produce ketoacidosis, coma	Excess glucose intake Lack or inadequate insulin	Excess urine Excess thirst Excessive hungry	Insulin Hydrate/ water

How Much Carbohydrate is Needed

Calorie level	~ 1200	~1400	~1600	~1800	~2400	~2800
Calorie range	1200-1500	1300-1600	1400-1700	1600-1900	1800-2300	2200-2800
Carbohydrate grams	180	180	195	210	240	300
Carbohydrate choices	**12**	**12**	**12-13**	**13-14**	**15-16**	**18-20**
Grains, beans, & starchy vegetables	6	6	6	7	9	11
Vegetables	3	3	3	4	4	5
Fruits	3	3	3	3	3	4
Milk	2	2	2-3	2-3	2-3	2-3
Meats	2 (4oz)	2 (4oz)	2 (5oz)	2 (5oz)	2 (6oz)	3 (7oz)
Fats g/servings	40/4	47/5	54/6	60/7	74/9	93/12

Hypoglycemia

Definition	Causes	Symptoms	Treatment
Low levels plasma glucose (blood sugar) Untreated may produce brain damage & even death	Insulin excess Inadequate glucose intake	Sweating Tremors Anxiety Hungry Headache Abnormal behavior	Glucose intake Glucagon

Treating Hypoglycemia

Blood Glucose	Amount of Carbohydrate Recommended
51-70 mg/dl	15 grams
41-50 mg/dl	20 grams
<40 mg/dl	30 grams

Amount of Carbohydrates	Apple or Orange Juice	Grape juice	Skim Milk	Cola/ Sprite
15 grams	120 cc	90 cc	240 cc	120 cc
20 grams	160 cc	120 cc	320 cc	160 cc
30 grams	240 cc	180 cc	480 cc	240 cc

Setting Carbohydrate Goals

Example: 1300 Kcal/day diet

1300 Calories ÷ 2 (½ calories as carbohydrates) = 650 ÷ 80 = 162 grams carbohydrates = 10 - 11 servings of carbs

Meal	Grams of Carbohydrates	Carbohydrate Choices
Breakfast	30 grams	2 choices
Snack	15 grams	1 choice
Lunch	45 grams	3 choices
Snack	15 grams	1 choice
Dinner	45 grams	3 choices
Snack	15 grams	1 choice
Total	**165 grams**	**11 choices**

Guidelines for Illness

- To replace 15 grams of carbohydrates

Food	Quantity
Carbonated beverage containing sugar	½ cup (4 oz.)
Popsicle	½ twin bar
Corn syrup or honey	2 tsp
Sweetened gelatin (Jell-O)	½ cup

- To replace 15 grams of carbohydrates

Food	Quantity	Food	Quantity
Ice cream	½ cup	Saltine crackers	6
Cooked cereal	½ cup	Toast (plain)	1 slice
Milk shake	¼ cup	Sherbet	¼ cup
Orange or grapefruit juice	½ cup	Jell-O	1/2 cup
Grape juice	1/3 cup	Cream soups or broth based	1 cup
Custard	½ cup	Yogurt, plain	1 cup

Applying Pattern Management

Day/Date	Time	BG	Food	Serving Size	Carbohydrate	Activity
Sun 10/7	18:00	99	steak	4 oz	0g	Watch TV
			baked potato	8 oz	40g	
			corn	1 cup	30g	
			Total		**70g**	
	20:00	201				
Mon 10/8	18:30	105	Spaghetti	2 cups	90g	Read
			Marinara sauce	½ cup	15g	
			Total		**105g**	
	20:30	221				
Tues 10/9	18:20	117	Grilled chicken	3 oz	0g	Computer work
			Bun	2 oz	30g	
			French fries	9 oz	45g	
			Diet drink	12 oz	0g	
			Total		**75g**	
	20:30	215				

Weight Gain and Carbohydrate Counting

You can gain weight if you:

Count carbohydrate, but ignore fat content of foods

Eat more high-calorie foods

Need increase insulin to control BGL, higher carb intake

Recommended Aids
from American Diabetes Association (ADA)

The Exchange Lists
Carbohydrate Choices
Estimating Portion Sizes and Carbohydrate Choices
How Much Carbohydrate is Needed
Carbohydrate Counting for Foods Containing Sugar Alcohols
The Actions of Insulin
Insulin: Carbohydrate Ratio
Calculating Carbohydrates in Recipes
Treating Hypoglycemia
Exercise Guidelines
Guidelines for Illness

Exercise & Diabetes

Everyone benefits from exercise & physical activity

Individuals with diabetes should fully participate

In general, exercise lowers BGL

- May need to make adjustments to insulin/meds & food intake
- A quick-acting source of glucose, glucose monitor, & water should be available
- The individual with diabetes must be familiar with symptoms of both high & low BGL

Exercise & Insulin/ Meds

Physical activity can raise BGL if there is insufficient insulin

- Follow the plan for exercise restrictions when ketones are present

Determine the best times for physical activity and adjust snacks, insulin, or timing of activity to prevent low or high BGL.

Exercise & BGL

Check before, during & after exercise

- Especially a new activity or sport
- If blood glucose starts to fall, stop & have a snack
- Individuals with insulin pumps may disconnect or adjust the basal rate down, instead adding a snacking

Exercise Guidelines

Type of Exercise	If Blood Sugar Is:	Increase Carb. Intake by:	Suggested Food
• Short Duration or Moderate intensity	Less than 80-100 mg./dl	10-15 grams	1 fruit & 1 protein or 1 bread
	100 mg./dl or above	Not necessary	
• Moderate intensity	Less than 80-100 mg./dl	25-50 grams before exercise then 10-15 grams/hr. if necessary	½ meat sandwich + milk or fruit
	80-170 mg./dl	10-15 grams	1 fruit & 1 protein or 1 bread
	180-300 mg./dl	Not necessary	
	300 mg./dl or greater	Don't exercise	
• Strenuous activity or exercise	Less than 80-100 mg./dl	50 grams	1 meat sandwich + milk or fruit
	180-300 mg./dl	10-15 grams/hr	1 fruit & 1 protein or 1 bread
	300 mg./dl or greater & ketones present	Don't exercise	

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Individuals with diabetes can enjoy the increased variety and flexibility with Carb Counting & Exercise

FAHC 2007 Kids Presentation

What's Your Nutrition IQ?

Eileen T. Fiorina RD, CNSD, LDN
Conemaugh Diabetes Institute
Memorial Medical Center

Quiz Rules

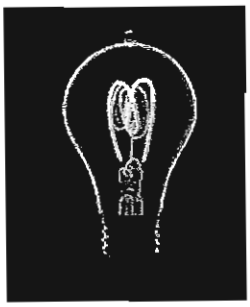
- 30 questions
- 15-20 seconds to answer
- Answers are given after each question
- Score your own "Nutritional IQ" at the end

10
9 **Ready...**
8
7
6
get set... 5
4 **Go!**
3
2
1

Question 1

A "calorie" is a measure of _____?

A. Fat
B. Sugar
C. Carbohydrate
D. Energy
E. I don't know

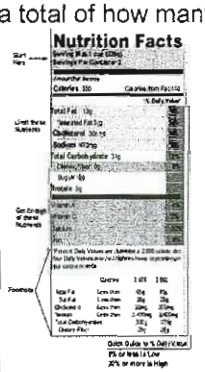


Question 2

An average adult needs a total of how many calories a day?

A. 2000
B. 2500
C. I don't know
D. 1500
E. 1000

Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:



Question 3

A pound of fat is equal to HOW MANY EXTRA calories?

A. 1500
B. 2000
C. 3500
D. 5000
E. I don't know

Question 4

A 20 ounce regular soda pop has HOW MANY servings in it?

A. 2½
B. 2
C. 1½
D. 1
E. I don't know

Question 5

How many calories are in a McDonald's Big Mac hamburger?

A. 230
B. 340
C. 420
D. 590
E. I don't know

Question 6

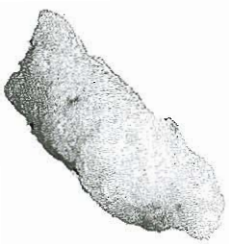
True or False: 12 ounces of regular Sprite has the same calories as 12 ounces of Dr. Pepper

A. True
B. False
C. I don't know

Question 7

One gram of fat contains HOW MANY calories?

A. 4
B. 7
C. 9
D. 12
E. I don't know



Question 8

A single serving of fruit juice is:?

A. 4 ounces
B. 8 ounces
C. 12 ounces
D. 16 ounces
E. I don't know

Question 9

The average person (child or adult) should try to take HOW MANY foot steps in a normal day?

A. 2000
B. 5000
C. 10,000
D. 15,000
E. I don't know

Question 10

Which of the following is the best fat burning activity?

A. Swimming
B. Running
C. Walking briskly
D. Weight lifting
E. I don't know

Question 11

How many hours does the typical child watch television each day?

A. 2 hours
B. 4 hours
C. 6 hours
D. 8 hours
E. I don't know

Question 12

How many FOOD ADS does the average child watch on TV each year?

A. 5,000
B. 10,000
C. 15,000
D. 20,000
E. I don't know

Question 13

Which of the following is the most commonly eaten vegetable in American toddlers?

A. Green beans
B. Carrots
C. Broccoli
D. French fries
E. I don't know

Question 14

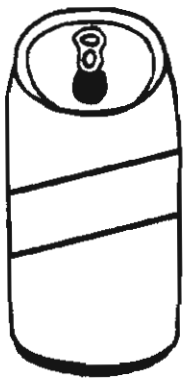
How many EXTRA calories are we overfeeding American babies under 1 year of age?

A. 50 calories
B. 100 calories
C. 150 calories
D. Over 200 calories
E. I don't know

Question 15

If a person (or child) drinks one 12 ounce Regular soda pop each day, how many **EXTRA POUNDS** will be gained each year?

A. 4 pounds
B. 8 pounds
C. 16 pounds
D. 24 pounds
E. I don't know



Question 16

The term "sugar free" on a food label or advertisement refers to which of the following ONLY?

A. Lactose
B. Fructose
C. Sucrose
D. Glucose
E. I don't know

Question 17

On a list of ingredients for a typical food product label, IN WHAT ORDER are the ingredients listed ?

A. Alphabetically
B. From LEAST amount to most in the food product
C. From MOST amount to least in the food product
D. I don't know

Question 18

What percentage of children in the United States eat a balanced diet according to the USDA's Food Guide Pyramid?

A. 1%
B. 15%
C. 50%
D. 75%
E. I don't know

Question 19

What percentage of children in the United States have a television set in their bedroom ?

A. 24%
B. 37%
C. 65%
D. 83%
E. I don't know

Question 20

What is the primary (main) sweetener used in Regular soda pop and many other sweet foods in the United States?

A. Sucrose
B. Glucose
C. High fructose corn syrup
D. Lactose
E. I don't know

Question 21

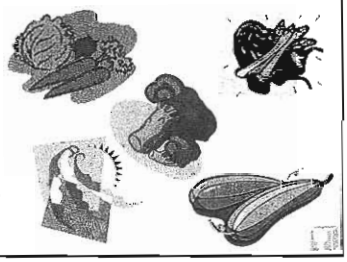
What percent of teenage girls get the minimum recommended amount (RDA) of calcium in their everyday diets?

A. 3%
B. 13%
C. 33%
D. 43%
E. I don't know

Question 22

How many times should a toddler be offered a new vegetable food choice BEFORE giving up?

A. 3 times
B. 8 times
C. 15 times
D. 24 times
E. I don't know



Question 23

How many calories are in a "super size" order of McDonald's French Fries?

A. 210
B. 320
C. 450
D. 610
E. I don't know

Question 24

True or False: In-between meal snacks don't add extra weight

A. True
B. False
C. I don't know

Question 25

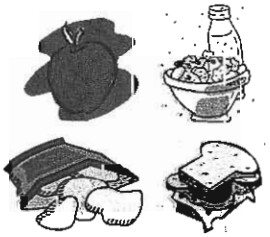
How many 8 ounce glasses of water should we drink each day?

A. 3
B. 4
C. 5
D. 8
E. I don't know

Question 26

Which would be a healthy snack choice?

A. Apple
B. Bowl of cereal
C. Sandwich
D. Chips
E. I don't know



Question 27

Which beverage is best to use during sports?

A. Gatorade
B. Powerade
C. Water (plain or with lemon)
D. 100% fruit juice
E. I don't know

Question 28

How many calories are in the entire container of doughnuts?

A. 110
B. 200
C. 400
D. 800
E. I don't know

Nutrition Facts
Glazed
Serving Size 1 Doughnut (52g)
Servings Per Container 2

Amount Per Serving	
Calories 200	Calories from Fat 110
	% Daily Value*
Total Fat 12g	**18%**
Saturated Fat 3g	**15%**
Cholesterol 5mg	**1%**
Sodium 95mg	**4%**
Total Carbohydrate 22g	**7%**
Dietary Fiber less than 1g	**2%**
Sugars 10g	
Protein 2g	
Vitamin A 0% •	Vitamin C 2%
Calcium 6% •	Iron 4%

Question 29

For <u>how long</u> after eating ANY calorie containing food or drink is the body making fat?

A. 30 minutes
B. 1 hour
C. 2 hours
D. 4 hours
E. I don't know

Now…grade your answers!

✓25-29 correct: Food Genius
✓20-24 correct: Nutritionally-gifted
✓15-19 correct: Average American
✓10-14 correct: Nutritionally-challenged
✓9 or less: Checked your weight lately?

Memorial Medical Center
Member Conemaugh Health System

DIABETES FAIR
CONEMAUGH DIABETES INSTITUTE
November 3, 2007

MEMORIAL MEDICAL CENTER PARTICIPANT'S EVALUATION

FAIR OBJECTIVES

1. Introduce and reinforce the importance of diabetes education
2. Introduce new products
3. Describe the various diabetes medications
4. Provide information and application of exercise to assist in maintaining normal blood glucose
5. Introduce various snacks for the individual with diabetes.
6. Provide information and testing to demonstrate the importance of foot care in diabetes.
7. Make available resources available for the patient with diabetes
8. Provided information on the risk factors of diabetes
9. Provide information on the amount of exercise that is needed to burn various foods eaten
10. Provide information on the importance of dental care for those diagnosed with diabetes

Please circle the number that indicates your level of agreement with the statements below:

SECTION I - OBJECTIVES

	STRONGLY DISAGREE			STRONGLY AGREE		NOT APPLICABLE
				5	17	
1. I was able to achieve one or more of the Fair objectives.	1	2	3	4	5	0
2. The tables were appropriately arranged to provide an optimal				3	19	
location for the exhibitor.	1	2	3	4	5	0

SECTION III - FACILITIES

1. Environment of the area was conductive to interacting with				4	18	
the participants.	1	2	3	4	5	0
				3	19	
2. Overall conditions and cleanliness meet my expectations.	1	2	3	4	5	0
			1	2	19	
3. Convenience and accessibility of the location was favorable.	1	2	3	4	5	0

SECTION V - COMMENTS:

1. **What was the most valuable aspect of this program?**

   _____
   _____
   _____

2. **What recommendations do you have to improve this program?**

   _____
   _____
   _____

3. **Do you have any other comments or suggestions?**

   _____
   _____
   _____

Thank you very much for participating in this educational program and evaluation process!

NAME _____

PHONE: _____ **E-MAIL ADDRESS:** _____

Memorial Medical Center
Member Conemaugh Health System

DIABETES FAIR - CONEMAUGH DIABETES INSTITUTE
November 3, 2007

PARTICIPANTS' EVALUATION

Thank you for attending the Diabetes Fair. Please take a few minutes and fill out this evaluation to provide us with your comments and suggestions so we may strive to improve the quality of our programs. Please one evaluation per family. By completing this evaluation form you are eligible for a **$50.00** gift certificate to the Galleria. You need not be present to win; the gift certificate will be mailed to you.

Please circle the answer/number that indicates your level of agreement with the statements below:

SECTION I - PROGRAM

1. How did you learn of the Diabetes Fair? Newspaper 51 TV 1 Bill Boards 0 Word of Month 13 Flyer 7

	STRONGLY DISAGREE			STRONGLY AGREE		NOT APPLICABLE
1. The Fair provided an opportunity for increasing my knowledge.	1	2	3	4	5	0
			3	18	51	

SECTION II – REGISTRATION

1. The staff at the registration area was courteous and customer focused.	1	2	3	4	5	0
			2	9	61	
2. The brochure was informative and easy to use.	1	2	3	4	5	0
	3		2	9	58	

SECTION III – PROGRAM PRESENTATIONS

1. 1 2 3 1 4 5 59 0 12

TOPIC	Information Useful	Presentation Organized	Length of Presentation	Questions Answered Satisfactory
Foot Care				
Diabetic Foods (Eileen)				

2. The audio visual used for the presentation was good.	1	2	3	4	5	0
Kids area received 1 & 2		1	2	7	31	29

SECTION IV – CHILDRENS AREA				1	18	55
1. My child had fun.	1	2	3	4	5	0
				1	18	55
2. The activities maintained my child's interest.	1	2	3	4	5	0
SECTION V – VENDORS				17	51	4
1. The vendors provided new information and answered my questions.	1	2	3	4	5	0
				13	55	4
2. The vendors were courteous and customer focused.	1	2	3	4	5	0
SECTION VI – CONEMAUGH DIABETES INSTITUTE			1	10	61	
1. The information presented was informative and helpful.	1	2	3	4	5	0
2. The blood pressures, foot exam, and the body fat analysis provided				6	55	11
helpful Information.	1	2	3	4	5	0
				7	58	7
3. The staff in this area was courteous and customer focused.	1	2	3	4	5	0
SECTION VII - FACILITIES:			3	11	58	
1. The layout of the Fair was well designed.	1	2	3	4	5	0
			1	9	62	
2. The facility conditions and cleanliness meet my expectations.	1	2	3	4	5	0
			1	10	61	
3. Convenience and accessibility of the location was favorable.	1	2	3	4	5	0

SECTION VIII - COMMENTS:

1. What was the most valuable aspect of this program?

   _____

2. What recommendations do you have to improve this program?

   _____

   Do you have any other comments or suggestions?

   _____

Thank you very much for participating in this educational program and evaluation process!

NAME _____ PHONE NUMBER: _____

STREET: _____ STATE: _____ ZIP: _____

Memorial Medical Center
Member Conemaugh Health System

DIABETES FAIR
CONEMAUGH DIABETES INSTITUTE
November 3, 2007

VENDORS' PROGRAM EVALUATION

FAIR OBJECTIVES

1. Introduce and reinforce the importance of diabetes education
2. Introduce new products
3. Describe the various diabetes medications
4. Provide information and application of exercise to assist in maintaining normal blood glucose
5. Introduce various snacks for the individual with diabetes.
6. Provide information and testing to demonstrate the importance of foot care in diabetes.
7. Make available resources available for the patient with diabetes
8. Provided information on the risk factors of diabetes
9. Provide information on the amount of exercise that is needed to burn various foods eaten
10. Provide information on the importance of dental care for those diagnosed with diabetes

Please circle the number that indicates your level of agreement with the statements below:

SECTION I - OBJECTIVES

	STRONGLY DISAGREE				STRONGLY AGREE	NOT APPLICABLE
				6	8	
1. I was able to achieve one or more of the Fair objectives.	1	2	3	4	5	0
2. The tables were appropriately arranged to provide an optimal			2	2	10	
location for the vendor.	1	2	3	4	5	0

SECTION II – PROGRAM MATERIALS/ACTIVITIES

				3	11	
1. The materials for the vendors were well-organized,	1	2	3	4	5	0
clear and free of errors.			1	2	11	
2. The registration form was organized and informative.	1	2	3	4	5	0

	STRONGLY DISAGREE			STRONGLY AGREE		NOT APPLICABLE
SECTION III - FACILITIES:						
1. Environment of the area was conductive to interacting with the participants.	1 1	2	3	4 4 2	9 5 12	0
2. Overall conditions and cleanliness met my expectations.	1	2	3	4 4	5 10	0
3. Convenience and accessibility of the location was favorable.	1	2	3	4	5	0

SECTION V - COMMENTS:

1. What was the most valuable aspect of this program?

_____
_____
_____

2. What recommendations do you have to improve this program?

_____
_____
_____

3. Do you have any other comments or suggestions?

_____
_____
_____

Thank you very much for participating in this educational program and evaluation process!

NAME _____ Company: _____

PHONE: _____ E-MAIL ADDRESS: _____

Memorial Medical Center
Member Conemaugh Health System

DIABETES FAIR
CONEMAUGH DIABETES INSTITUTE
November 3, 2007

VOLUNTEER'S PROGRAM EVALUATION

FAIR OBJECTIVES

1. Introduce and reinforce the importance of diabetic education
2. Introduce new products
3. Describe the various diabetic medications
4. Provide information and application of exercise to assist in maintaining normal blood glucose
5. Introduce various snacks healthy snacks for diabetics.
6. Provide information and testing to demonstrate the importance of foot care in diabetes.
7. Make available resources available for the patient with diabetes
8. Provided information on the risk factors of diabetes
9. Provide information on the amount of exercise that is needed to burn various foods eaten
10. Provide information on the importance of dental care for those diagnosed with diabetes

Please circle the number that indicates your level of agreement with the statements below:

SECTION I - OBJECTIVES

	STRONGLY DISAGREE				STRONGLY AGREE	NOT APPLICABLE
				2	4	
1. The objectives of the Fair were met.	1	2	3	4	5	0
2. The Fair provided an opportunity for increasing the participant's knowledge.	1	2	3	4	6 5	0

SECTION II – PROGRAM MATERIALS / ACTIVITIES

				1	5	
1. The volunteer's materials and information was well organized.	1	2	3	4	5 6	0
2. The activities for the participants was informative and helpful.	1	2	3	4	5	0

SECTION III – FACILITIES

				1	5	
1. The layout of the Fair was well designed.	1	2	3	4	5	0
				1	5	
2. The facility conditions and cleanliness meet my expectations.	1	2	3	4	5	0
				2	4	
3. Convenience and accessibility of the location was favorable.	1	2	3	4	5	0

SECTION IV – PROGRAM PRESENTATIONS

1. STRONGLY DISAGREE 1 2 3 4 5 6 STRONGLY AGREE; NOT APPLICABLE 0

TOPIC	Information useful	Presentation Organized	Length of Presentation	Questions Answered Satisfactory
Exercise Demo				
Wound Healing				
Diabetes & you now				

2. The audio – visual used for the presentations was good. 1 2 3 4 5 6 0

SECTION V – OPINIONS - COMMENTS

1. I was made to feel welcomed and was treated courteously. STRONGLY DISAGREE 1 2 3 4 5 6 STRONGLY AGREE; NOT APPLICABLE 0

2. What recommendations do you have to improve this program?

_____

_____

_____

3. Do you have any other comments or suggestions?

_____

_____

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Thank you very much for participating in this educational program and evaluation process!

NAME _____ PHONE NUMBER: _____

STREET: _____ STATE: _____ ZIP: _____

Appendix H

Appendix H, Deliverable # 216 Final Report on Data Repository

Title:	Diabetes Prevention and Treatment Programs for Western PA
Contract No.	W81XWH-04-2-0030
Sub-project Title:	
Goal:	**Final report on data repository development**
Deliverable:	
Submission Date:	**12/15/2008**
Deliverable No:	**216**

Final report on data repository development (Rural Community)

Background

Timely, useful data about individual patients and populations of patients from clinical information systems is a critical feature of effective programs using the Chronic Care Model. The first step is to develop a repository to serve as a mechanism for practitioners to gain information on performance and results [1, 2]. Both the American Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE) have concluded that a reporting system specific to DSME is critically important [3]. We implemented systems to evaluate and satisfy these recommendations. The ***Delphi Diabetes Manager®*** and ***AADE Outcomes System*** were implemented in the Conemaugh Diabetes Institute (CDI), Johnstown PRIDE community, and served as the repository for clinical and education data. Through the data repository, clinicians and the University of Pittsburgh Diabetes Institute (UPDI) research team had the opportunity to monitor patient clinical and behavior changes and characterize populations for targeted interventions.

Methods

Delphi Diabetes Manager®

The first step included a PRIDE community wide assessment of diabetes data management systems occurred throughout 2004. Several programs that included: the Chronic Disease Management Program (CDMP), DECS, Imetrikus, and *Delphi Diabetes Manager®* were presented to the project investigators and community representatives. Demonstrations and on-site meetings (at national diabetes conventions) took place to help to identify the best system (available at the time) for the PRIDE communities. Ease of use, company support and training, opportunity for sustainability (costs), etc. were considered during the review of the programs available at the time. The principal investigator, Linda Siminerio, also validated the decision in a call to the ADA Medical Director who had extensive experience with using *Delphi*. He confirmed that *Delphi Diabetes Manager®* was a flexible system that provided good information and timely support to clinicians.

To meet the needs of rural providers who often lack access to sophisticated technical resources, the *Delphi Diabetes Manager®* which integrates ADA Medical Standards [4] into an office-based electronic medical record was implemented and an outcomes database developed for PRIDE communities. Sites were added in a stepped approach as training and staff opportunities were made available. *Delphi* and the University of Pittsburgh Diabetes Institute provided training on the Chronic Care Model, the ADA standards [4], and technical skills needed to use *Delphi*. Physicians, nurses, hospital administrators, dietitians and office staff participated in the trainings. The *Delphi Diabetes Manager®* system was implemented into PRIDE Conemaugh in April 2005.

The UPDI evaluation and administrative and UPMC Information Technology staff closely monitored the processes. Routine calls were arranged between *Delph*i staff and the UPDI evaluation team. The UPDI has demonstrated experience in building and

evaluating data bases [5]. De-identified data was collected from the *Delphi* system and forwarded to the UPDI evaluation core for analysis.

AADE Outcomes System

Assessing patient behavior change is a key component in determining the effectiveness of diabetes self-management education (DSME). As a result of this need, the American *Association of Diabetes Educators (AADE) Outcome System* was created. The Diabetes Self-Management Assessment Report Tool (D-SMART®) and the Diabetes Educator Tool (D-ET®) were developed to capture patient diabetes self-management behavior, as well as provide the educator with information regarding patient behavior change.

In an effort to evaluate the effectiveness of the *AADE Outcome System*, both the D-SMART and the D-ET tools were installed in the Conemaugh site. All data included was obtained through the first session of a patient's visit to the program (the forms are intended to be completed multiple times throughout patient visits to the clinic).

Results

Delphi Diabetes Manager®

Several types of data were collected in the *Delphi Diabetes Manager®*, including patient demographics, clinical lab values (relevant to the ADA Medical Standards of Care) [4], rates of reported complications and co-morbidities. These data were captured and reported in order to characterize the community populations in planning targeted clinical and education programs.

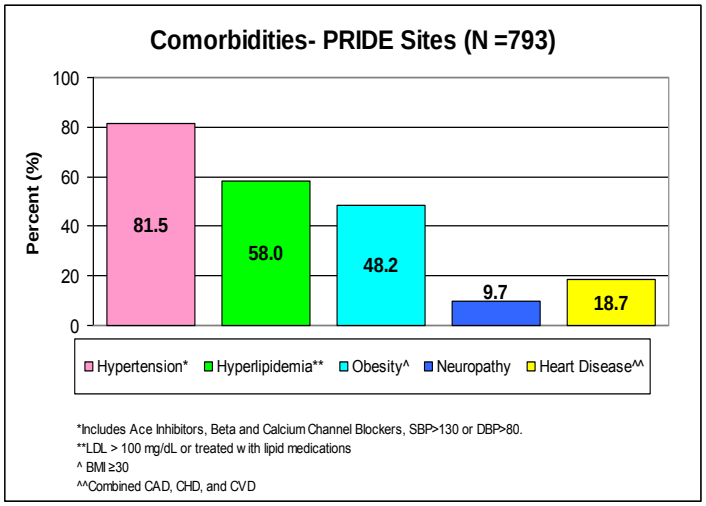
Demographic information on the population entered and monitored in the *Delphi System* is presented in table 1.

Table 1 – Demographics for Conemaugh Diabetes Institute vs. PRIDE Community

	Conemaugh Diabetes Institute	**PRIDE Community**
% Female	70.0%	55.0%
Mean age	55.3	58.6
Mean # of visits per person	3.2	3.5

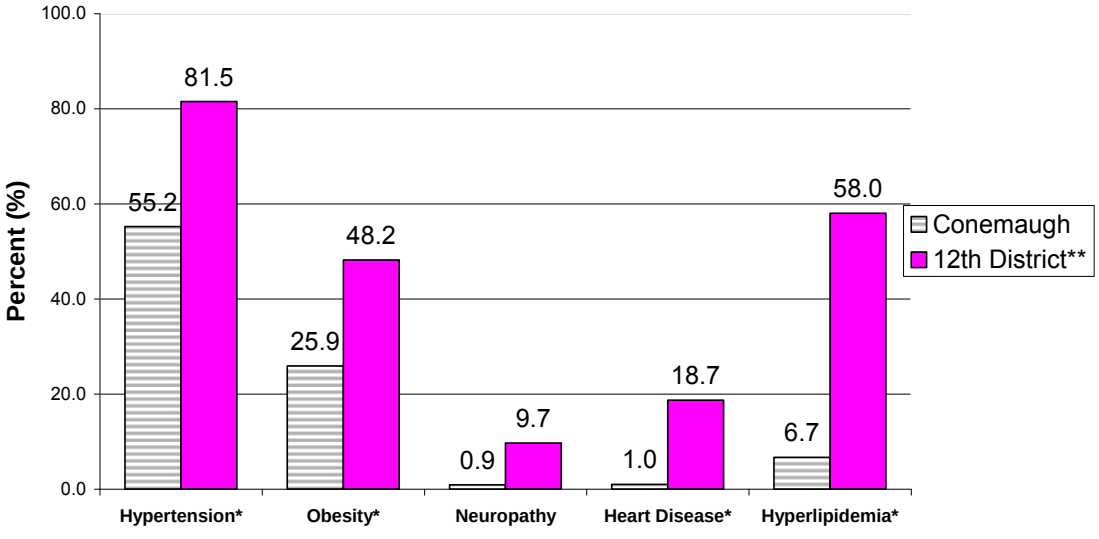
An overview of all PRIDE community site rates (n=793) of co-morbidities and complications are illustrated in Figure 1.

Figure 1



Comparative rates of complications, obesity neuropathy, heart disease and hyperlipidemia in the CDI versus all PRIDE sites are illustrated in Figure 2. As shown in Figure 2 the CDI community had lower rates of all co-morbidities and complications.

Figure 2. Delphi Data System, Conemaugh N = 105



* Definitions:
- Hypertension: Includes Ace Inhibitors, Beta and Calcium Channel Blockers, SBP>130 or DBP>80.
- Heart Disease: Combined CAD, CHD, and CVD
- Obesity: BMI > 30
- Hyperlipidemia:LDL > 100 mg/dL or treated with lipid medications

** 12th Congressional District Population-PRIDE Community Partners (N=793)

AADE Outcome System

The AADE System was implemented in the CDI and was used to evaluate patient behavioral and clinical outcomes and educator teaching processes. A full description of the findings has been reported and published [6-9]. Data in the CDI represents 901 patients.

Population Characteristics

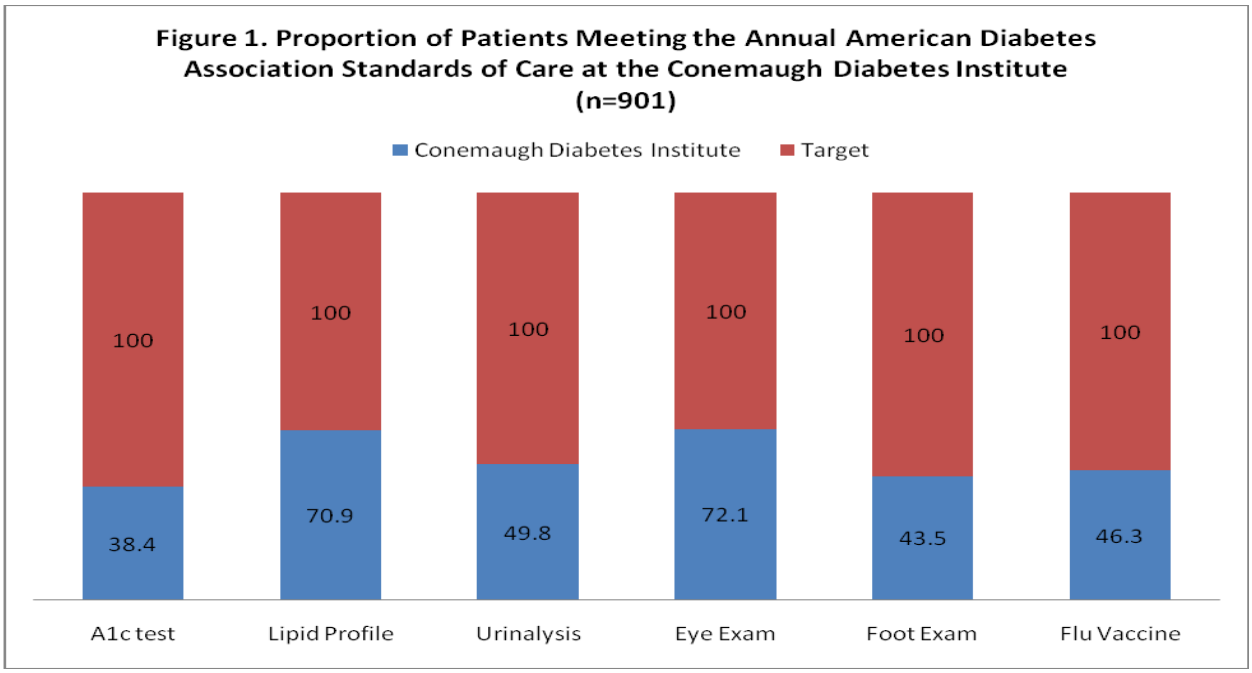
Baseline demographic and clinical characteristics of the 901 patients who were seen for diabetes education services at CDI are presented in Table 2. The mean age was 57.6 years and the majority of the patients were white (91.5%) females (65%). Nearly three-fourths of the patients had a family history of diabetes (72.5%); however, only 27.2% of patients attended diabetes self-management education classes prior to seeking care at CDI. Table 1 also characterizes the patients' weight and diabetes "ABCs" (A1c, blood pressure, and cholesterol). The average weight of patients was 202.4 pounds. Mean A1c levels were 8.7%. Mean LDL, systolic, and diastolic blood pressure levels met target goals at 99.6 mg/dL, 126.5 mmHg, and 74.9 mmHg respectively (Table 2).

Table 2. Baseline Characteristics of the Patients Seen for Diabetes Education Services at Conemaugh Diabetes Institute (n=901)

	% (n) or mean (S.D.)
Age (years)	57.6 (15.3)
Race (% white)	91.5 (806)
Gender (% male)	35.0 (315)
Smoker (% no)	81.2 (665)
Family History of Diabetes (% yes)	72.5 (593)
Previously attended DSME classes	27.2 (245)
Weight (lbs)	202.4
A1c (%)	8.7 (4.4)
LDL (mg/dL)	99.6 (36.8)
Systolic blood pressure (mmHg)	126.5 (15.9)
Diastolic blood pressure (mmHg)	74.9 (9.7)

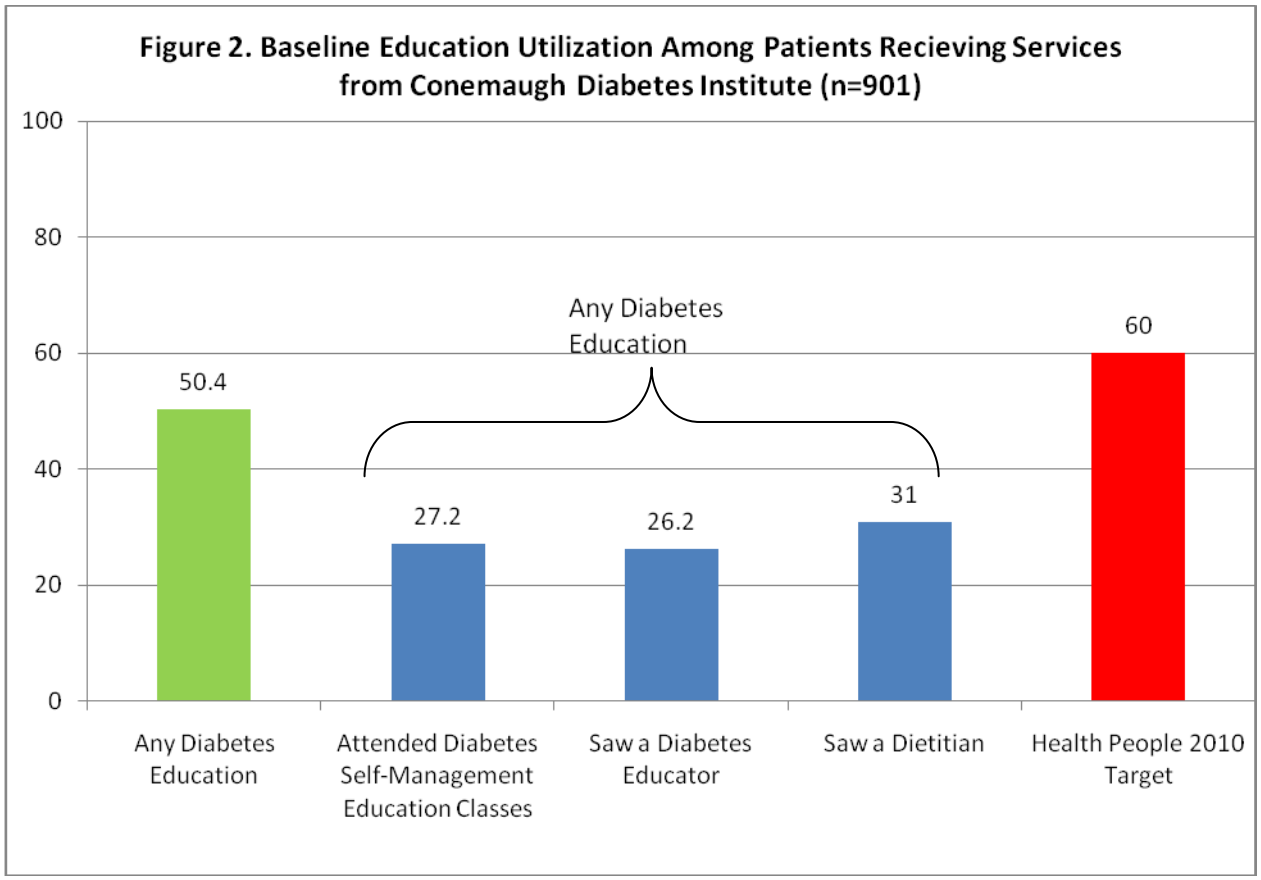
American Diabetes Association (ADA) Standards of Care

The proportion of patients who met the ADA Standards of Care varied by each standard at baseline. Less than half of all patients received an annual A1c test (38.4%), urinalysis for protein (49.8%), foot exam (43.5%), or flu vaccine (46.3%) before seeking care at CDI (Figure 1). Approximately three-fourths of patients received a lipid profile (70.9%) and eye exam (72.1%).



Diabetes Education Services

When the proportion of patients who received diabetes education services, prior to their care at CDI, was examined, approximately half of patients (50.4%) received some type of diabetes education previously (Figure 3). When broken down further, less than a third attended formal diabetes self-management education classes (27.2%), or saw a diabetes educator (26.2%), or saw a dietitian for nutrition counseling (31.0%) (Figure 3). None of these groups met the Healthy People 2010 goal of 60% for diabetes education [10]. However, as the CDI has grown, the number of patients attending diabetes self-management education classes increased three-fold from 245 patients to 901 patients.



Conclusions

Having comprehensive data repository systems are critically important in assessing patients at the individual level and characterizing populations for addressing targeted initiatives for improvements. For example, the baseline information afforded the UPDI investigators to determine which of the PRIDE community partners were at highest risk for co-morbidities and complications and affording the opportunity for prioritization of services. In using the *AADE Outcome System*, rates of poor clinical care and education services provided the necessary feedback to the local clinicians for improvement in their services. In capturing and analyzing the data, community risk and co-morbidities have been presented to the community sites. This data has characterized their populations, so that targeted interventions (monitored through the replacement data system) can be developed and implemented.

CDI and all of the PRIDE community partners recognized and appreciated the opportunity to monitor outcomes and receive feedback for quality improvements. Unfortunately at the time of this project, the development and implementation of data management systems was in the embryonic stage. As a result, both systems were cumbersome and had flaws that posed problems for the community users and researchers.

During the course of the implementation, PRIDE partners reported that using the *Delphi Diabetes Manager*® was cumbersome and disrupted work flow. The UPDI evaluation core had questions about the validity of the data. For example, on careful examination of the results, patient demographic information did not correlate with disease state. In the CDI data an 85 year old with type 2 diabetes was characterized as being pregnant with gestational diabetes. On numerous occasions when the UPDI staff organized calls to vet challenges and discrepancies, the *Delphi* staff missed the calls.

In collaboration with UPMC Information Technology, an audit (supported by UPMC) was performed on the Delphi system (audit report previously submitted). Thus, after implementation, for a variety of reasons, poor technical support and connectivity to existing systems including inaccuracy and inconsistency of patient data, inadequacy of data and reports delivery, and poor user satisfaction, the *Delphi* system license was not renewed.

Although the *Delphi Diabetes Manager*® license was not renewed, UPDI investigators manually downloaded data from all PRIDE sites into a hub database located at the UPDI in order to preserve the sites' active data.

During the evaluation process in UPMC and PRIDE communities, it was determined that the *AADE Outcome System* was cumbersome, necessitated that the patient spend an extensive amount of time completing the tool (minimum 20 minutes) and required the addition of clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools. The findings of the process evaluation and the challenges for users of the tool were communicated to AADE. AADE leadership and UPMC agreed that without the additions, the *AADE Outcome System* was not robust and would not be useful in helping the diabetes educator in capturing necessary and relevant data. In recognition that these components were critically important to the development of any diabetes education system tool, UPMC developed these systems (clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools) for use by educators serving both civilian and military populations.

To date, the revised AADE Outcome System is unavailable. However, it is UPMC's understanding that AADE is pursuing the revision and in an agreement between AADE and UPMC, the AADE agreed that on completion of the revision of the AADE Outcome System, it will be made available to PRIDE sites under a license for 10 years.

In discussions (and through demonstrations) with the PRIDE and WHMC teams, it was agreed that the numerous challenges and delays in using the AADE System were unacceptable. There is a critical need for an education system tool and relying on the final development and release of the AADE System was affecting workflow and completing important efforts on the project.

Recommendations

Thus, it was agreed that a system that included the identified relevant clinical and educational be developed for implementation into all PRIDE communities, including CDI

in Johnstown. The UPMC team is actively developing the comprehensive management system that includes a data repository with input from PRIDE partners that meets the needs of clinicians participating in the Chronic Care Model program. This system is being created in collaboration with the American Diabetes Association. A beta version will be available in Jan. 2009.The projected date for completion of this Data Management System is Feb. 2009.

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Appendix I

Deliverable #86: Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes

Deliverable #87: Prevention of Diabetes and Cardiovascular Disease in an Urban Underserved Community

Deliverable #89: Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community

Translating the DPP in an Urban Underserved Community: Long Term Sustainability of Positive Clinical Outcomes

Mim Seidel, MS, RD, LDN
Robert Powell, BS, CSCS
Gretchen Piatt, MPH, PhD

University of Pittsburgh
DIABETES INSTITUTE
in partnership with UPMC

June 24, 2007

Background

- Results of the National DPP demonstrated the efficacy of an intensive lifestyle program in preventing diabetes compared to medication and placebo
- There is a paucity of literature regarding the sustainability of clinical improvements following lifestyle interventions in community settings

Objectives

- To understand if a community-based diabetes prevention program is effective in decreasing risk for diabetes and CVD in urban, underserved community
- To determine sustainability of improvement of clinical outcomes at long-term follow-up

Study Setting

- Underserved urban community
- 11 neighborhoods near Pittsburgh
- Former steel town – victim of industrial downsizing and out-migration of youth with skills $\rightarrow$ more elderly with more chronic disease
- Local community hospital is base of study

Eligibility Criteria

To be determined "at risk" and eligible for the Intensive Lifestyle Intervention, must have:

BMI ≥ 25 AND

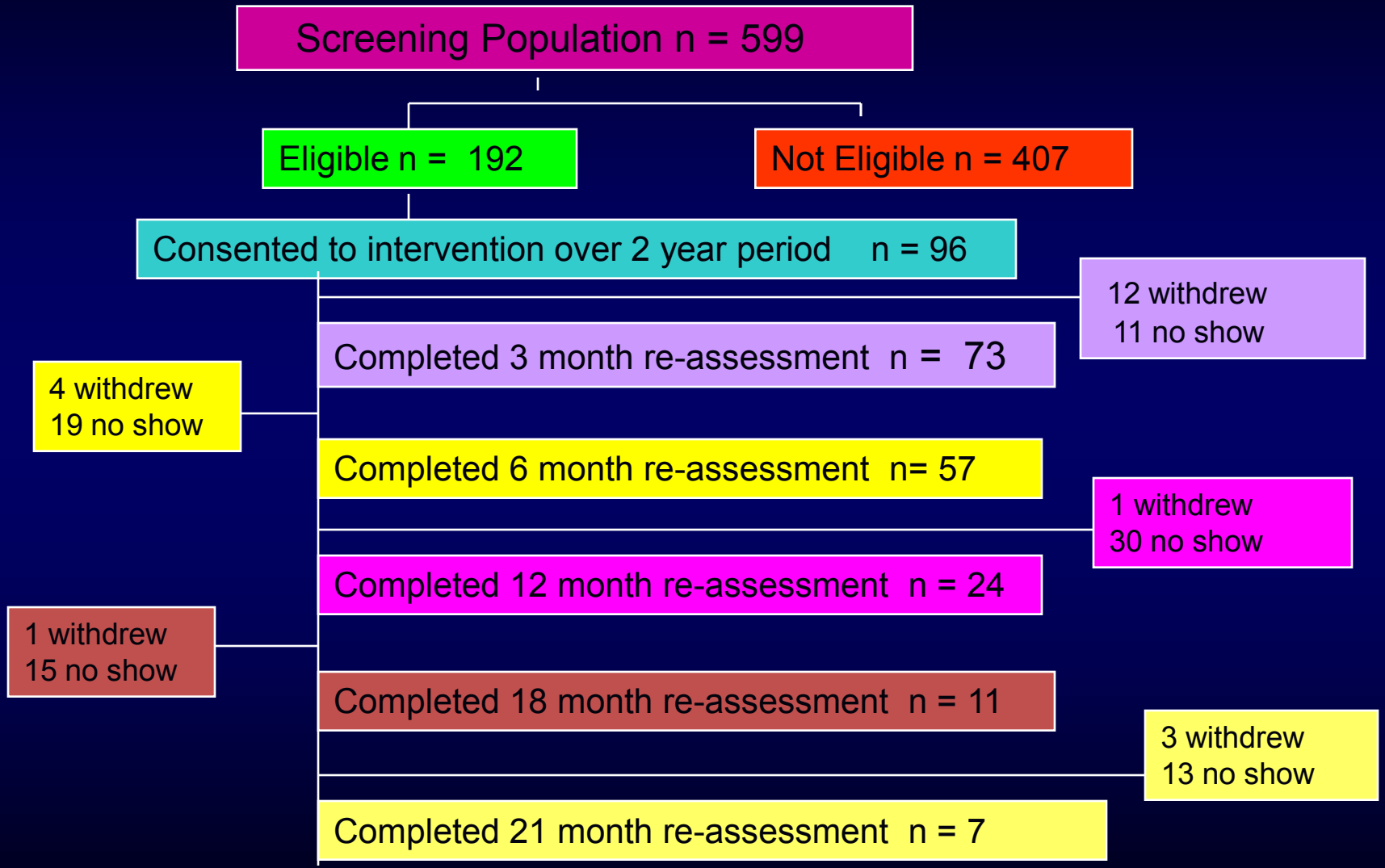
At least 3 of the 5 parameters:

1. Abdominal Obesity (M ≥ 40 inches; F ≥ 35 inches)
2. Abnormal HDLc (M <40 mg/dL, F <50 mg/dL)
3. Hypertension (BP ≥130/85 mmHg)
4. Triglycerides > 150 mg/dL
5. Glucose ≥ 100 < 126 mg/dL

Program

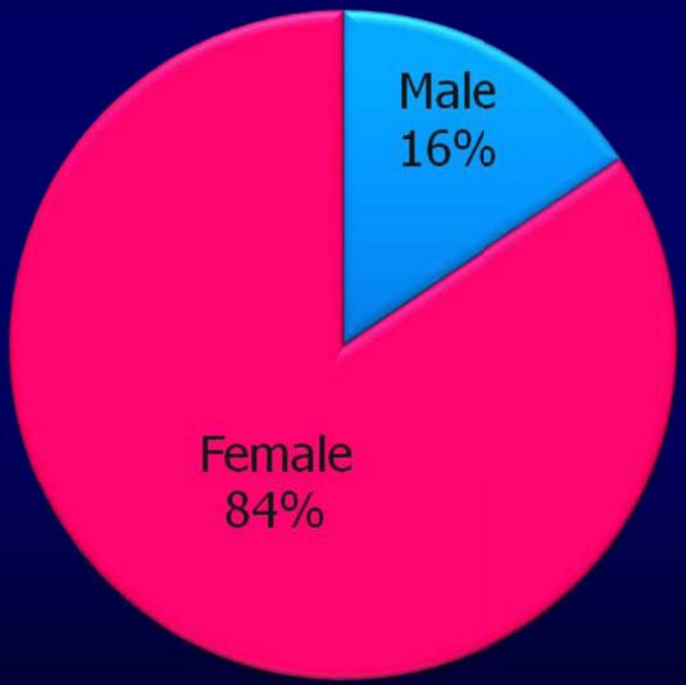
- Community-based screening for BMI and Metabolic Syndrome
- At-risk residents invited to participate in intervention
  - Intensive Lifestyle Balance Program (ILBP) modified from national DPP
  - 12 week curriculum
  - 90 minute weekly sessions
  - Facilitators: RD and Exercise Specialist
  - Lay Health Coach participation

Study Design

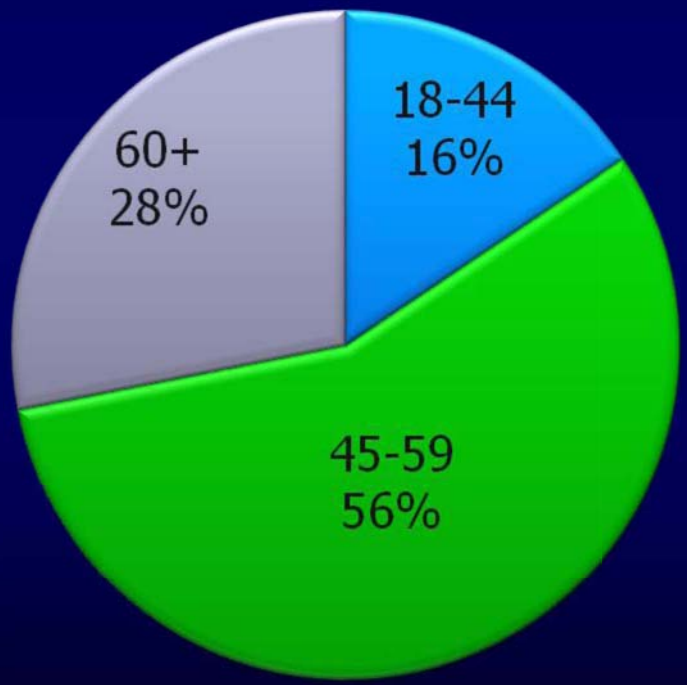


Demographic Characteristics (n=96)

Gender Distribution

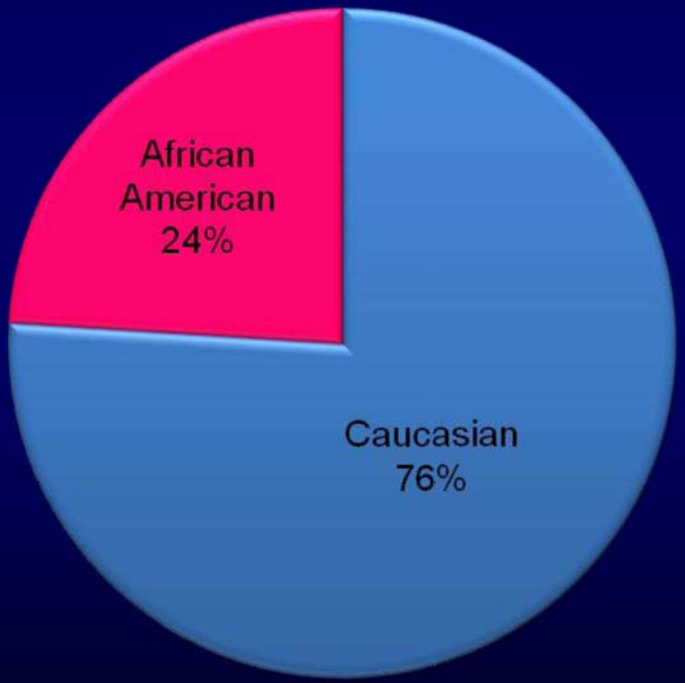


Age Distribution

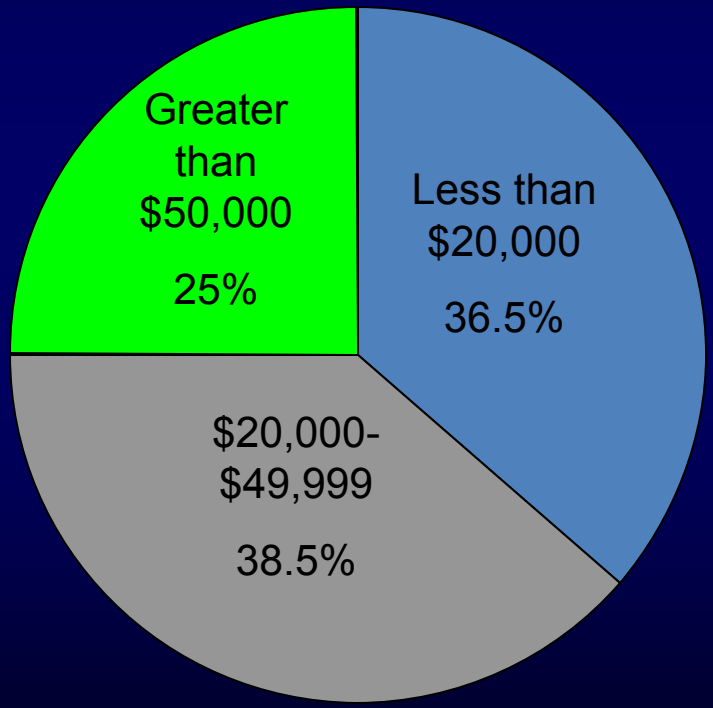


Demographic Characteristics

Race Distribution

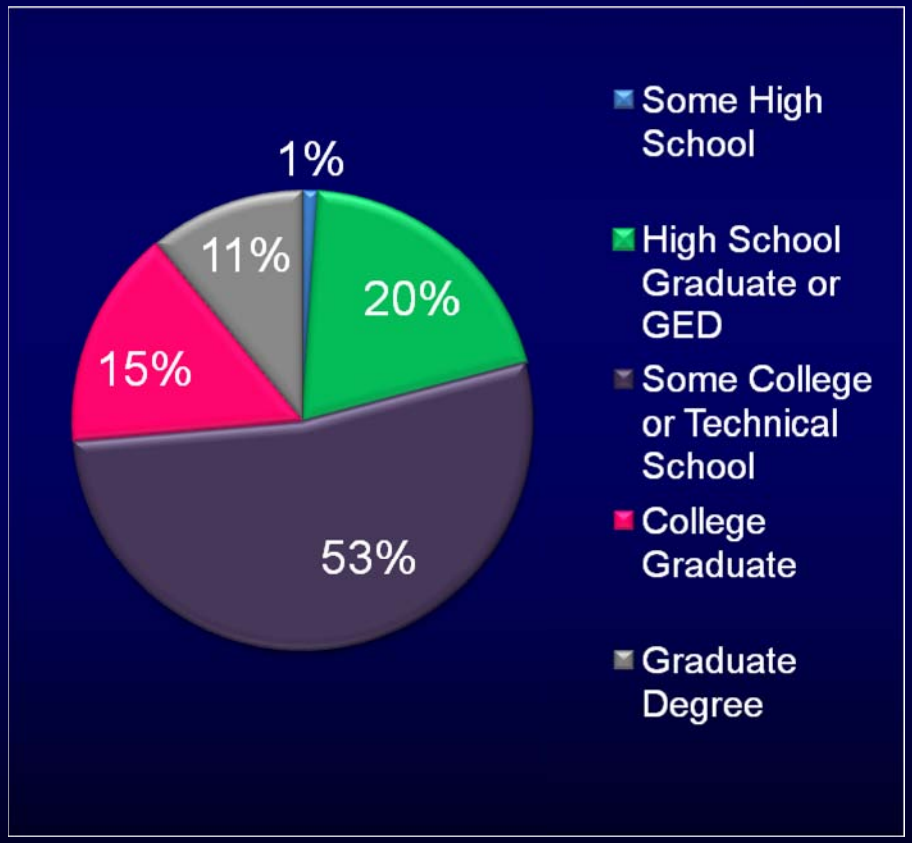


Income Distribution

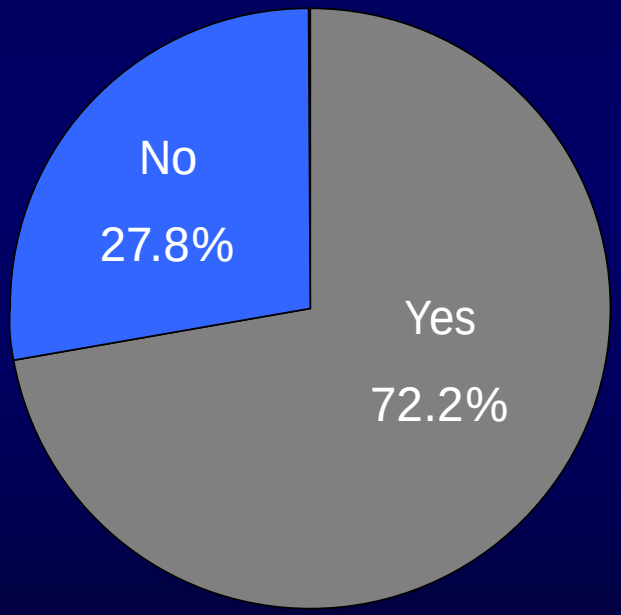


Demographic Characteristics

Education Distribution



Family History

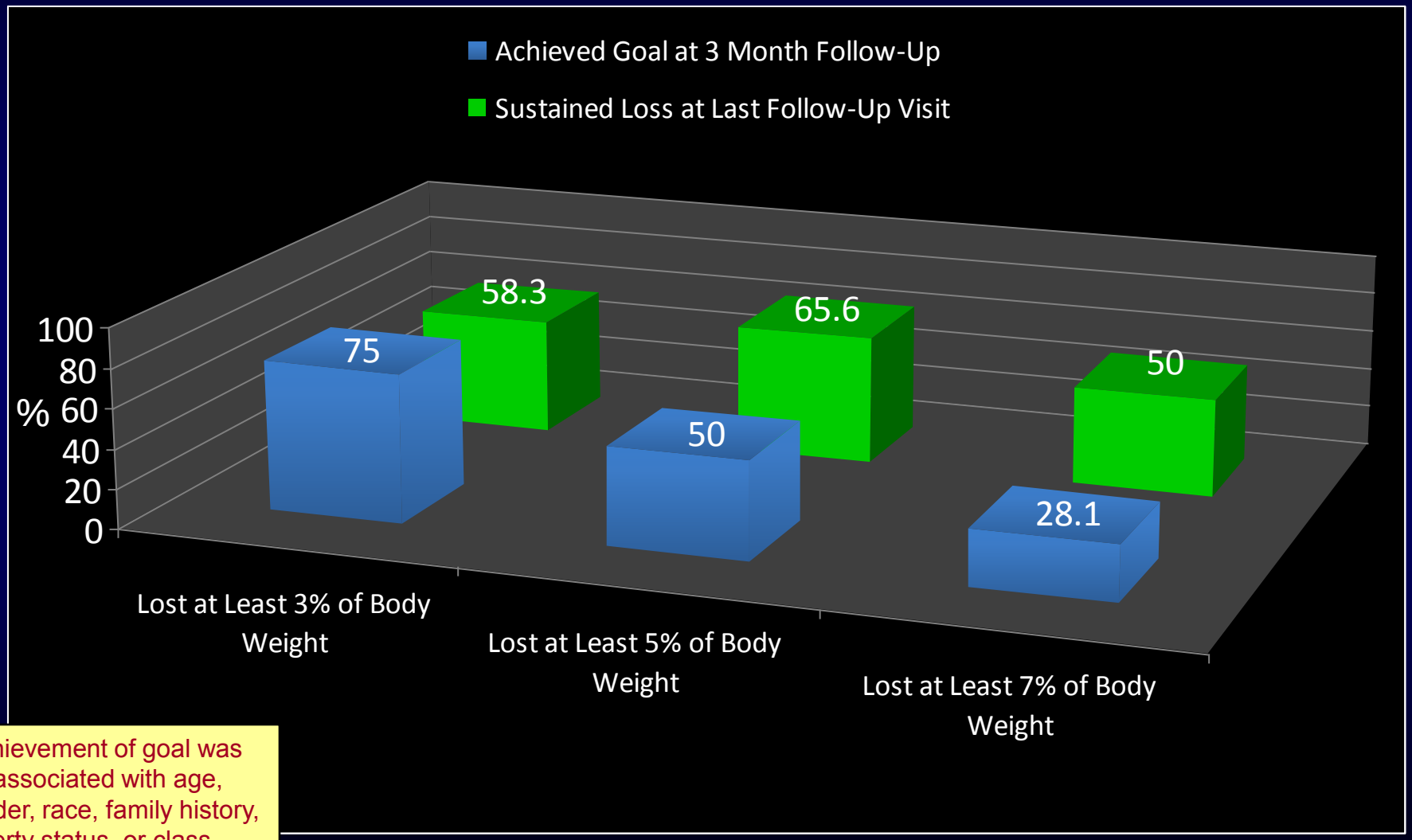


Baseline Clinical Characteristics

Characteristic	n=96
Weight (lbs)	215.6
BMI	36.2
Abdominal Obesity (Males: ≥ 40 inches, Females: ≥ 35 inches)	93.8 (90)
Abnormal HDLc	84.4 (81)
Hypertension (Blood Pressure ≥ 130/85 mmHg	67.7 (65)
Triglycerides ≥ 150 (mg/dL)	51.0 (49)
Glucose ≥ 100 (mg/dL)	42.7 (41)

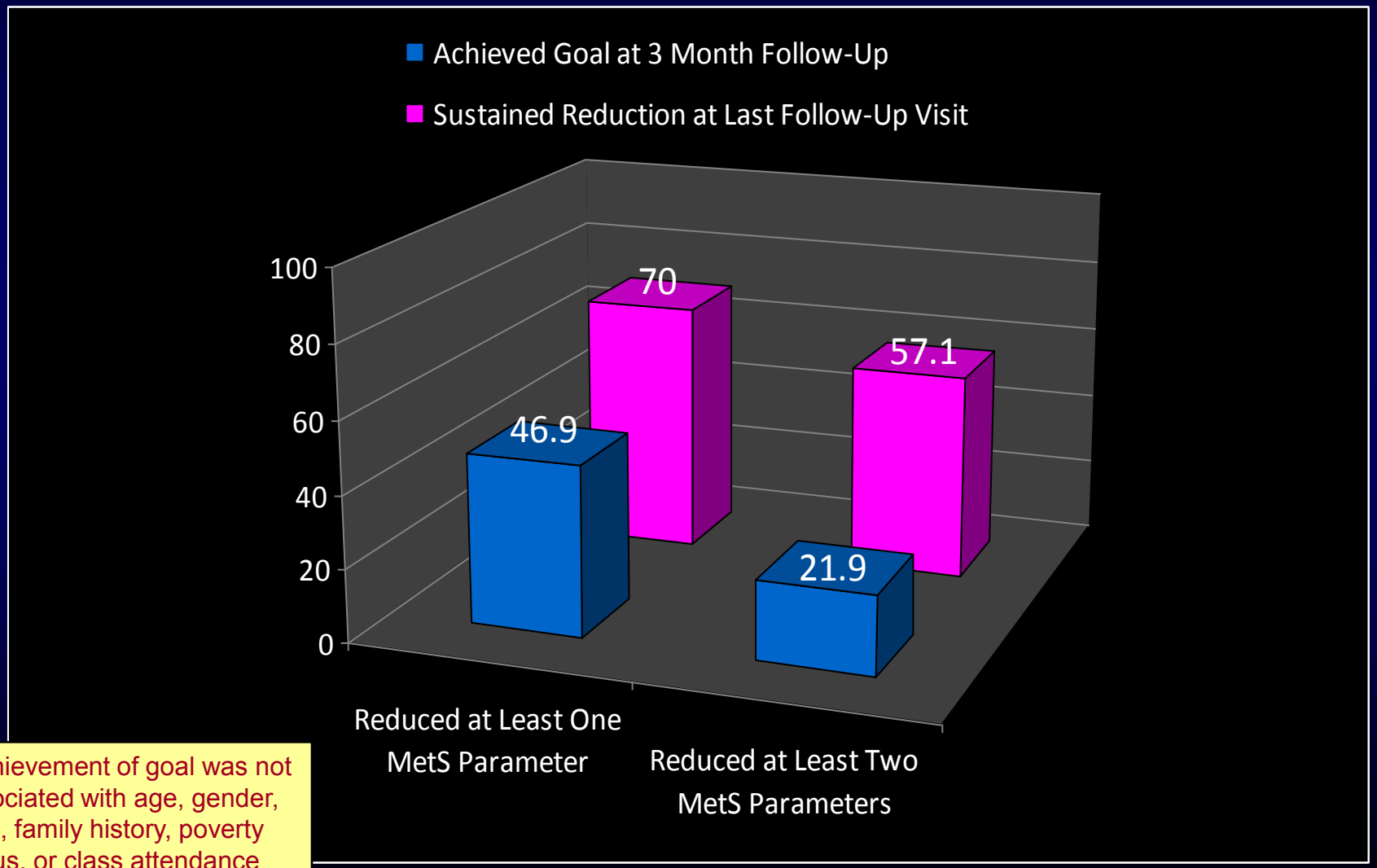
*Data are mean (S.D.) or % (n)

Sustained Weight Loss



*Achievement of goal was not associated with age, gender, race, family history, poverty status, or class attendance

Sustained Reduction in MetS Parameters



*Achievement of goal was not associated with age, gender, race, family history, poverty status, or class attendance

Summary

- 28% of subjects lost at least 7% of their body weight at the 3 month follow-up. At the last follow up half of those subjects had sustained that weight loss.
- 47% of subjects decreased at least 1 metabolic syndrome parameter at 3 months and 70% of those subjects sustained that improvement at the last follow up.

Limitations

- Volunteer bias -- Fasting/timing/working
- Small sample size
- Incomplete data on calories/exercise
- Community screenings as the only method of recruitment limits the pool of possible participants – multi-pronged approaches are needed
- Measurement of abdominal obesity and BMI may be a more efficient as a 1st step screening method than screening for all parameters of the metabolic syndrome

Conclusion

- Adults living in an underserved community can decrease their risk factors for metabolic syndrome through participation in an Intensive Lifestyle Balance Program.
- Long term sustainability is feasible.
- Follow-up of these subjects is continuing

Thank you

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Epidemiologist: Gretchen A. Piatt, PhD
Exercise Specialist: Robert Powell, CSCS
Lay Health Coaches: Rhonda Lee and Helen Tomasic

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DIABETES INSTITUTE
in partnership with UPMC

Prevention of Diabetes and Cardiovascular Disease in an Urban Underserved Community

Mim Seidel, MS, RD, LDN
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Background

- Results of the National DPP demonstrated the efficacy of an intensive lifestyle program in preventing diabetes compared to medication and placebo
- The effectiveness of an intensive lifestyle program implemented in a group setting in an underserved community is unknown
- Additionally, there is a paucity of literature on the sustainability of this type of community-based prevention intervention

Objectives

- To understand if a community-based diabetes prevention program is effective in decreasing risk for diabetes and CVD in urban, underserved community
- To determine sustainability of improvement of clinical outcomes at six month follow-up

Study Setting

- Underserved urban community
- 11 neighborhoods about 8 miles east of Pittsburgh
- Former steel town – victim of industrial downsizing and out-migration of youth with skills $\rightarrow$ more elderly with more chronic disease
- Local community hospital is base of study

Recruitment Methods

- Advertising the screenings:
  - Flyers to churches, MD offices, worksites, community agencies, community partnerships; storefronts, several areas of the hospital for staff and visitors
  - Local cable television
  - Announcements at church; church bulletins; health ministry helped recruit
  - Local newspaper
  - Word of mouth

Eligibility Criteria

To be determined “at risk” and eligible for the Intensive Lifestyle Intervention, must have:

BMI ≥ 25 AND

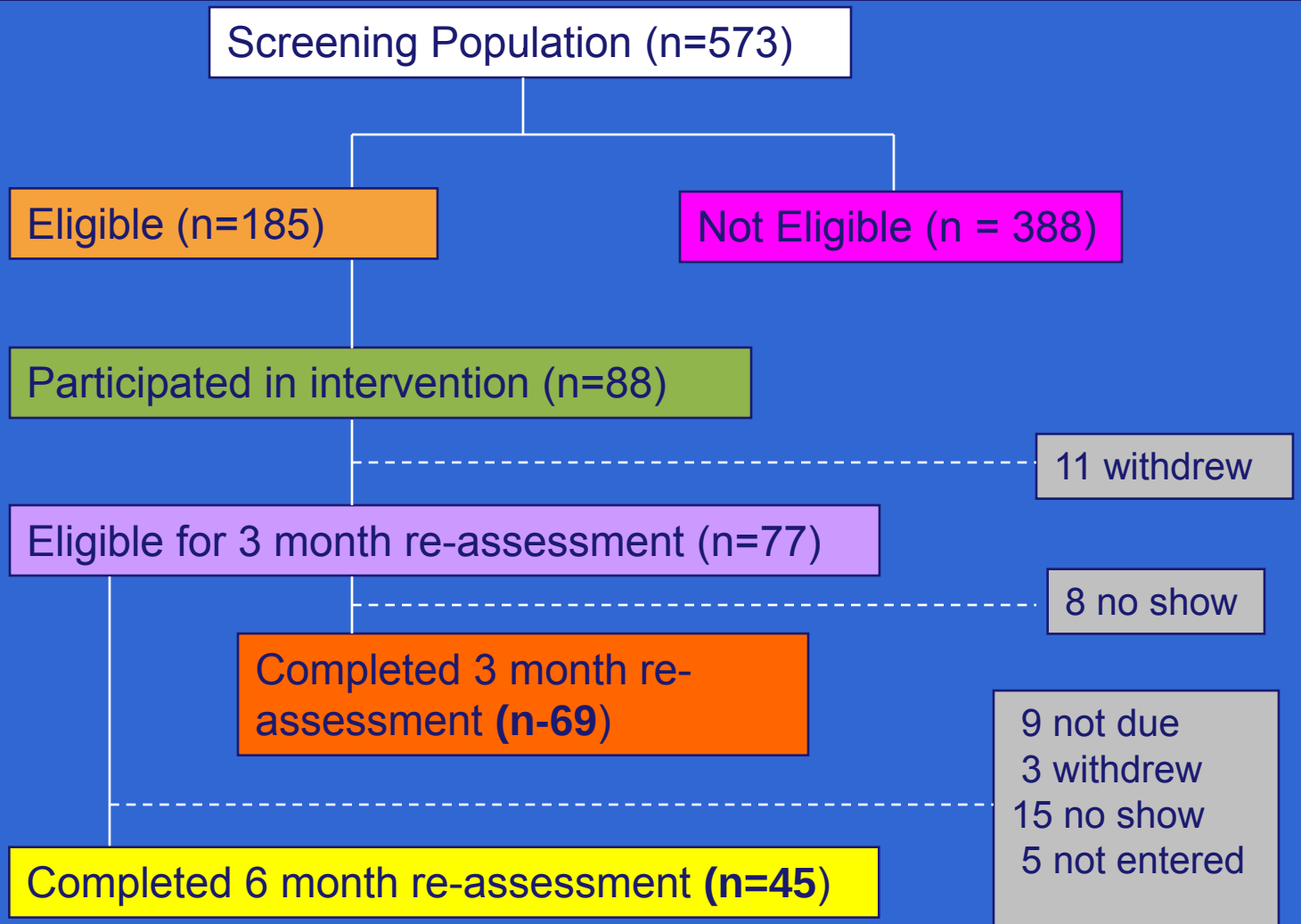
At least 3 of the 5 parameters:

1. Abdominal Obesity (M ≥ 40 inches; F ≥ 35 inches)
2. Abnormal HDLc (M <40 mg/dL, F <50 mg/dL)
3. Hypertension (BP ≥130/85 mmHg)
4. Triglycerides > 150 mg/dL
5. Glucose ≥ 100 < 126 mg/dL

Intervention

- Intensive Lifestyle Balance Program (ILBP) modified from national DPP
- 12 week curriculum
- 90 minute weekly sessions
- Facilitators: RD and Exercise Specialist
- Lay Health Coach participation

Study Design



Demographic Characteristics

Characteristic	Screening (n = 573)	Intervention (n=88)
Age (years)	53.7 (15.6)	54.0 (10.5)
Race (% non-white)	27.7 (157)	27.3 (24)
Gender (% female)	75.2 (430)	77.3 (68)
> High school education (% yes)	N/A	77.4 (65)
Poverty (% < $20,000/year)	N/A	22.7 (17)
Family history of diabetes (% yes)	N/A	71.1 (59)
Weight (lbs)	186 (46.4)	216.8 (40.7)

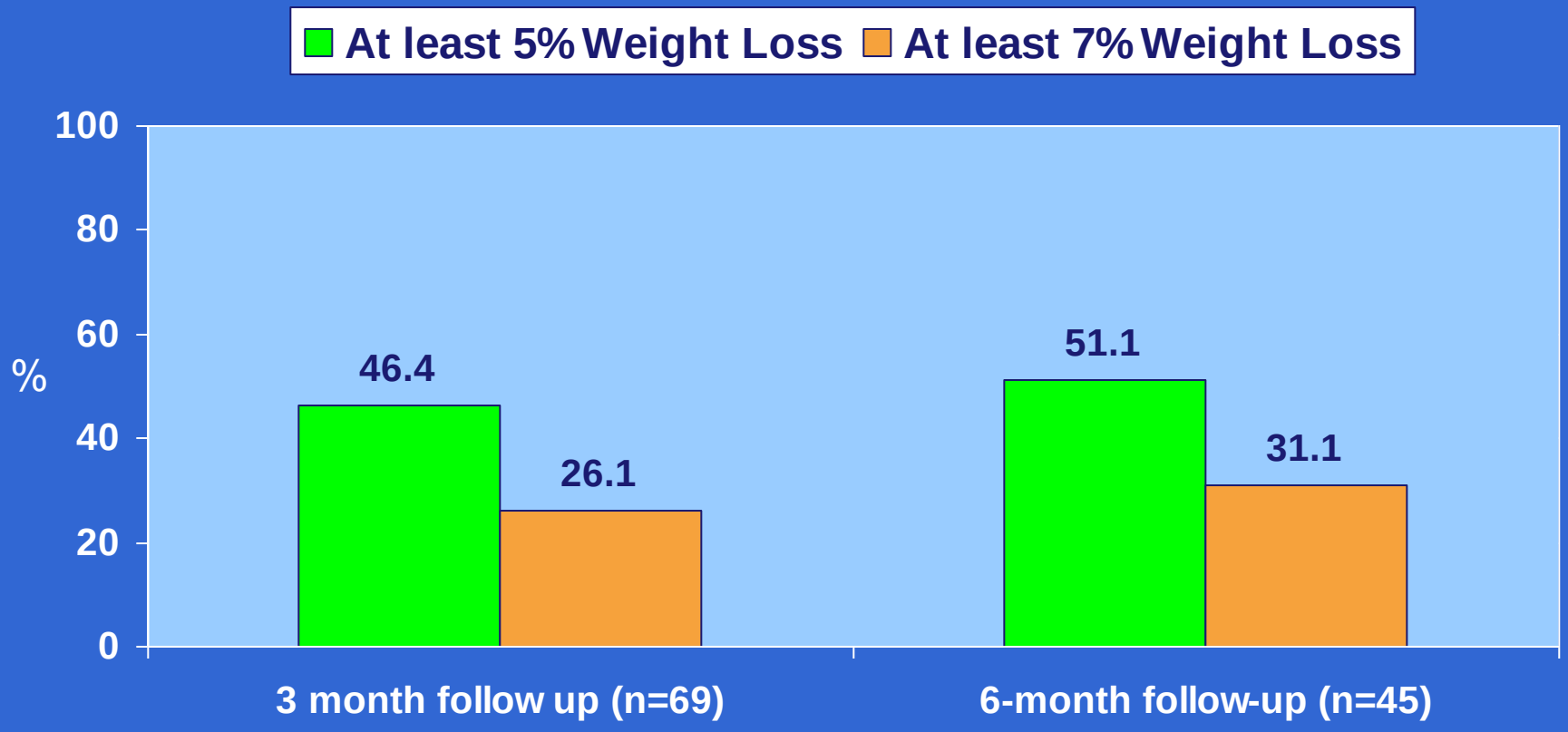
***Data are %(n) or mean (SD)**

Components of the Metabolic Syndrome

Baseline Characteristic	**Intervention (n=88)**
Abdominal Obesity (Males: ≥ 40 inches in males, Females: ≥ 35 inches)	92.1 (81)
Abnormal HDLc (Males: <40 mg/dL, Females: <50 mg/dL)	79.6 (70)
Hypertension (BP ≥130/85 mmHg)	68.2 (60)
Triglycerides > 150 mg/dL (% yes)	47.7 (42)
Glucose ≥ 100 < 126 mg/dL (% yes)	40.9 (36)

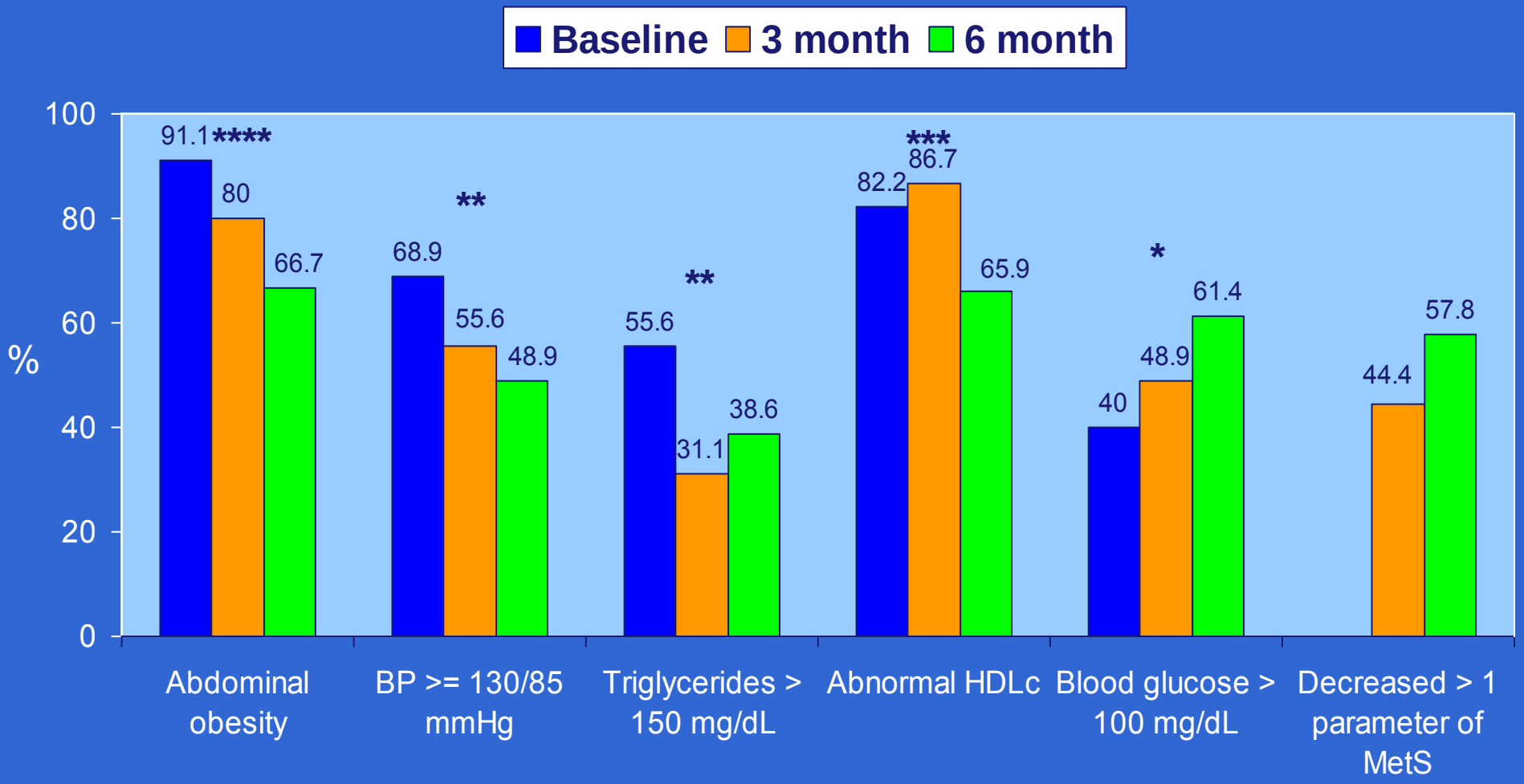
***Data are %(n)**

Proportion of Subjects who Lost Weight at 3 and 6 Month Follow-Up



- Of those who lost at least 5% of their body weight at 3 month follow-up, 82% kept the weight off at 6 month follow-up
- Of those who lost at least 7% of their body weight at 3 month follow-up, 64% kept the weight off at 6 month follow-up

Change in the proportion of subjects with each of the MetS parameters over Time (n=45)



*p<0.1, **p<0.05, ***p<0.01, ****p<0.0001

Summary

- 26% of subjects lost at least 7% of their body weight at the 12 week follow-up. At the six month follow up, 31% of subjects demonstrated at least a 7% weight loss
- 44% of subjects decreased at least 1 metabolic syndrome parameter at 12 weeks and 58% of subjects did so at 6 month follow-up

Limitations

- Volunteer bias -- Fasting/timing/working
- Small sample size
- Incomplete data on calories/exercise
- Community screenings as the only method of recruitment limits the pool of possible participants – multi-pronged approaches are needed
- Measurement of abdominal obesity and BMI may be a more efficient as a 1st step screening method than screening for all parameters of the metabolic syndrome

Conclusion

- Adults living in an underserved community can decrease their risk factors for metabolic syndrome through participation in an Intensive Lifestyle Balance Program.
- Short term (outcomes at 6 months) sustainability is feasible.
- Long term follow-up of these subjects is currently happening.

Thank you

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Appendix I

Deliverable #89: Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community

Appendix I

Diabetes and Cardiovascular Risk Reduction Program for an Underserved Community

UPMC Diabetes Institute Grant Number: W81XWH-04-2-0030.
Principal Investigator: Mim Seidel, MS, RD, LDN
2005 Deliverables
Submitted: 07/2007

Final Report

Abstract

Diabetes is a chronic disease affecting 20.8 million people nationwide (14.6 million diagnosed; 6.2 million undiagnosed (1). In persons 20 years or older, 9.6% have diabetes; in those age 60 or older, 20.9% have diabetes (1). In Pennsylvania, 1.1 million individuals have diabetes and approximately half of those diagnosed are over the age of 65, reflecting the relatively older age of the state's population (2). The Braddock community is at high risk for diabetes. According to the 2000 US Census, the Braddock community has approximately 4,682 residents, 70% of which are African American, 57.4% greater than 45 years of age, 21.7% greater than 65 years old and a mean household income per capita of $13,135. The national Diabetes Prevention Program used the results of an Oral Glucose Tolerance Test (OGTT) to determine pre-diabetes in potential research subjects (8).

Screening for metabolic syndrome in the community is more practical than using an oral glucose tolerance test to diagnose risk for developing type 2 diabetes (6, 7). The term "metabolic syndrome" describes individuals who may be close to but have not yet reached the diagnostic values for high blood pressure, diabetes or hyperlipidemia thus putting them at risk for diabetes, heart disease and stroke. The national Diabetes Prevention Program found that people at-risk for diabetes can minimize this risk through weight loss and exercise (8). Given the relationship between weight, metabolic syndrome and the future development of diabetes and/or cardiovascular disease, initiatives to address weight and metabolic syndrome in low-income, high risk communities may be a cost-effective route to deal with the epidemic of diabetes.

Introduction and Key Literature

Diabetes is a chronic disease affecting 20.8 million people nationwide (14.6 million diagnosed; 6.2 million undiagnosed (1). In persons 20 years or older, 9.6% have diabetes; in those age 60 or older, 20.9% have diabetes (1). In Pennsylvania 1.1 million individuals have diabetes and approximately half of those diagnosed are over the age of 65 reflecting the relatively older age of the state population (2). Diabetes is also problematic in minority populations where, nationwide, 13.3% of non-Hispanic blacks age 20 or older have diabetes (1). The Braddock community is at high risk for diabetes. In the UPMC Braddock service area, African Americans are twice as likely to have diabetes as Caucasian-Americans (3). The prevalence of diabetes is also higher among those of lower socioeconomic status (4, 5). According to the 2000 US Census by zip code, the Braddock community has approximately 4,682 residents, 70% of which are African American, 57.4% greater than 45 years of age, 21.7% greater than 65 years old and a mean household income per capita of $13,135.

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Metabolic syndrome, a term describing individuals who may be close to but have not reached the diagnostic values for high blood pressure, diabetes or hyperlipidemia, is common in the nation and is a precursor to diabetes and cardiovascular disease (6). The national Diabetes Prevention Program (DPP) used the results of an OGTT to determine pre-diabetes and demonstrated that people with an impaired glucose tolerance (IGT) could prevent diabetes if they lost 7% of their body weight and exercised 150 minutes per week for at least six months (7, 8, 9). However, the OGTT is not a practical screening tool in a community setting (10). The parameters measured for metabolic syndrome are a practical surrogate for predicting risk for diabetes and cardiovascular disease (11).

The researchers hypothesized that the elimination of one or more of these risk factors along with (or due to) a minimal weight loss of only 7% of body weight and an increase in physical activity would decrease risk for diabetes and could be achieved in the same manner that the national DPP decreased conversion to diabetes in people with an impaired glucose tolerance.

It is the experience of UPMC Braddock that the people in low-income communities have a host of barriers keeping them from participating in healthy lifestyle practices such as eating right and exercising more. The challenges to eating right, losing weight and exercising were addressed by the successful use of professional health coaches working individually with subjects in the national DPP (12). It is not known if the type of Intensive Lifestyle Program (ILS) used in the national DPP will achieve the same results when some changes are made: a group setting instead of individual encounters; use of professional and *lay* health coaches; intervening with subjects with lower income and education levels than those who participated in the nDPP. Ascertaining if using lay health coaches can increase successful participation in a chronic disease prevention program is important for planning future targeted interventions that attempt to prevent lifestyle related diseases in minority and low- income populations. .

The overall objective of this study was to address health care needs of those individuals living in the communities served by UPMC Braddock through implementation of a model of chronic disease prevention focused on patient empowerment in the areas of food choices and physical activity. Specifically, in this community, we aimed to:

1. Determine the demographic characteristics of those people in the community who were screened for metabolic syndrome and of those people in the community with metabolic syndrome, who participated in the intensive lifestyle program, and to examine the relationship with class participation.
2. Determine if community members with metabolic syndrome could lose at least 7% of their body weight in 12 weeks and maintain it for at least six months and maintain that weight loss for up to one year.
3. Determine if the community members with metabolic syndrome could decrease at least one of their metabolic syndrome parameters in six months and could sustain those changes for up to a one year post-completion of the initial six month period.
4. Determine if the community members with metabolic syndrome who were unable to decrease at least one of their metabolic syndrome parameters after completion of the six month Intensive Lifestyle Balance demonstrated a positive change

post-six months and/or up to one year post-completion of the Intensive Lifestyle Balance program.

Research Design and Methods

The protocol was for a study of the effectiveness of an intensive lifestyle intervention (ILS) aimed at low- income adults in an underserved community who were overweight (as ascertained by BMI) and exhibited metabolic syndrome. The purpose of the lifestyle intervention was to encourage people to lose weight and to decrease at least one of the metabolic risks exhibited by the participants through proper diet and consistent exercise. The study looked at three questions: 1) Will this population join and then remain engaged in the program – a 12 week curriculum with an additional three months of practicing positive nutritional and physical activity behavior change? 2) For the people who complete at least six months of the program, will they be able to lose 7% of their body weight and negate at least one of their metabolic syndrome risk factors? 3) Will those people who made at least one positive change be able to sustain that change and/or make further positive changes? 4) Will those people who demonstrated no clinical changes related to metabolic syndrome during the first six months exhibit at least one positive change subsequently?

There were three phases to the study. Phase I was recruitment/screening; Phase II was intervention and Phase III was follow-up of original participants with additional but limited recruitment/screening.

Phase I, recruitment/screening. The study population was be drawn from UPMC Braddock's Primary Target Area: Braddock, North Braddock, Rankin, East Pittsburgh, Duquesne, Homestead, West Homestead, West Mifflin, North Versailles, Whitaker and Munhall as well as from UPMC Braddock employees. We recruited participants through intensive case finding using referrals from local physicians and the local Family Health Center; the hospital's Emergency Department; local work sites; the many and various social and community service agencies and churches in the targeted area; flyers and advertisements in area work sites, including the hospital, and word of mouth from outreach workers. The advertising stated that we were looking for adults (ages 18 years+) who were at risk for diabetes and cardiovascular disease. We described what "at risk" encompassed and invited interested people to be screened. All interested adults recruited from the aforementioned neighborhoods were provide informed consent and had a blood sample (approximately 15ml) drawn after an 8 hour fast and analyzed at the UPMC Braddock laboratory to measure blood glucose, triglycerides and HDL cholesterol. In addition, waist circumference; blood pressure and height and weight (to ascertain BMI) were measured using accepted research protocol for anthropometric measurements. We looked for the following indicators of metabolic syndrome: Abdominal obesity (waist circumference > 102 cm in males or >88 cm in females); Fasting triglycerides $\geq$ 150 mg/dl (in people who fasted eight or more hours); Low levels of High Density Lipoprotein (HDL) cholesterol < 40 mg/dl for men and < 50 mg/dl for women; Blood pressure $\geq$ 130/85; Elevated fasting glucose $\geq$ 100 mg/dl < 126 mg/dL (6). Eligible subjects met at least three of the five above listed parameters of metabolic syndrome and had a BMI of at least 25. Results were sent to both the subject and the subject's physician. Adults were deemed ineligible for the study if it was determined they had diabetes or if they were pregnant by self-report. The ineligible adults were referred to programs and support as needed.

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Phase II, intervention. Interested and eligible adults were enrolled in the Intensive Lifestyle (ILS) program of the DPP at UPMC Braddock following informed consent. This program began with a 12 week nutrition and activity curriculum adapted from the National DPP's 16 week curriculum (10). Day time and evening classes were offered during each 12 week period and consisted of not more than 20 participants. As with the national DPP, the Intensive Lifestyle Program was facilitated by professional health coaches (a dietitian and an exercise specialist). However, unlike the national DPP, we also used lay health coaches to provide peer support and help identify barriers and solutions to keep the participants engaged in the program. All professionals and lay staff were trained in the DPP methods. Participants were also be told of all exercise opportunities that were available to them at no cost as participants in the study. A health questionnaire was administered at baseline (first day of the 12 week ILS), and at 3 months (last day of the 12 week ILS) along with a re-assessment of clinical measurements. Three months later (six months after baseline), the health questionnaire was again administered along with a re-assessment of clinical measurements. These questions included identification of co-morbidities and prescription medications; self-assessment of "health" and feelings of well being; a few questions regarding dietary and exercise habits as well as demographic questions regarding income and education.
A repeat of the clinical assessment as well as the health questionnaire was offered every six months after the six month re-assessment.

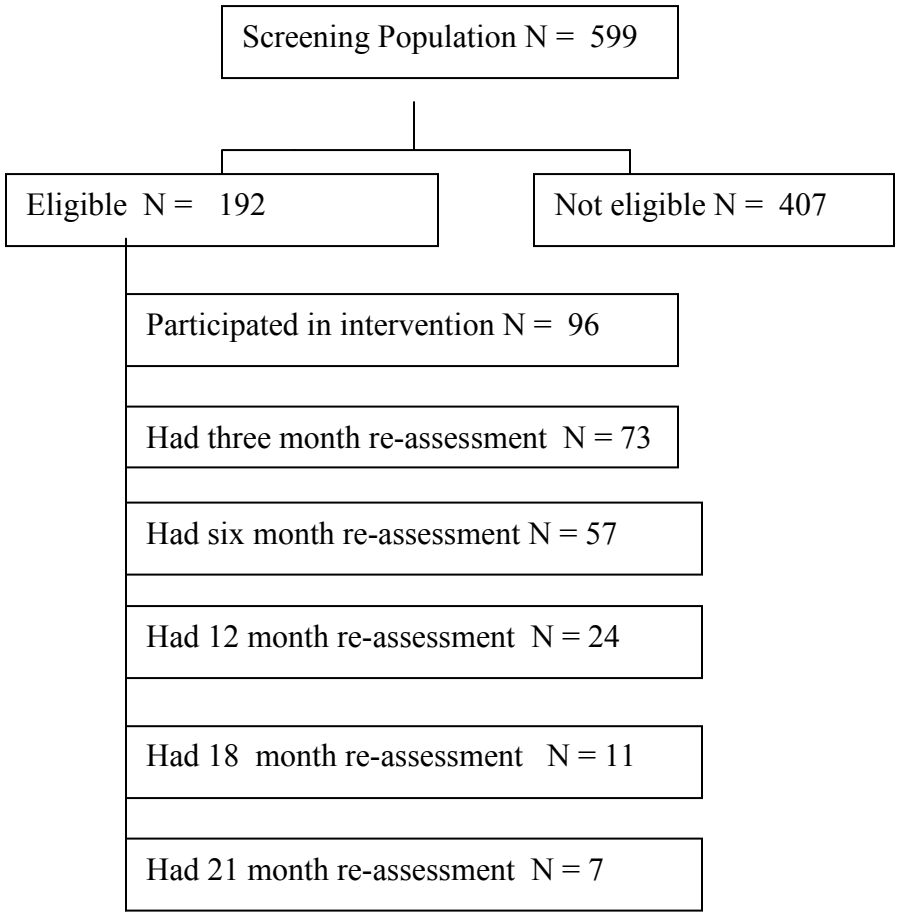
During Phase III, people who completed the Intensive Lifestyle Program were contacted and invited to return for re-assessments of the same parameters described above at least every six months, plus or minus two weeks until the end of the program. All participants were offered a $20 incentive to return for each re-assessment beginning with the 6 month re-assessment (6 months after the ILS class ends). Results of this re-assessment(s) were sent to the person and physician.

Appendix I

Results

Between May 2005 and May 2007, 599 were screened for program eligibility and 192 were determined eligible for the intervention. See Figure 1.

Figure 1



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There was no significant difference between the demographics of the screening and intervention populations. The charts and table below reflect the intervention population.

Chart 1

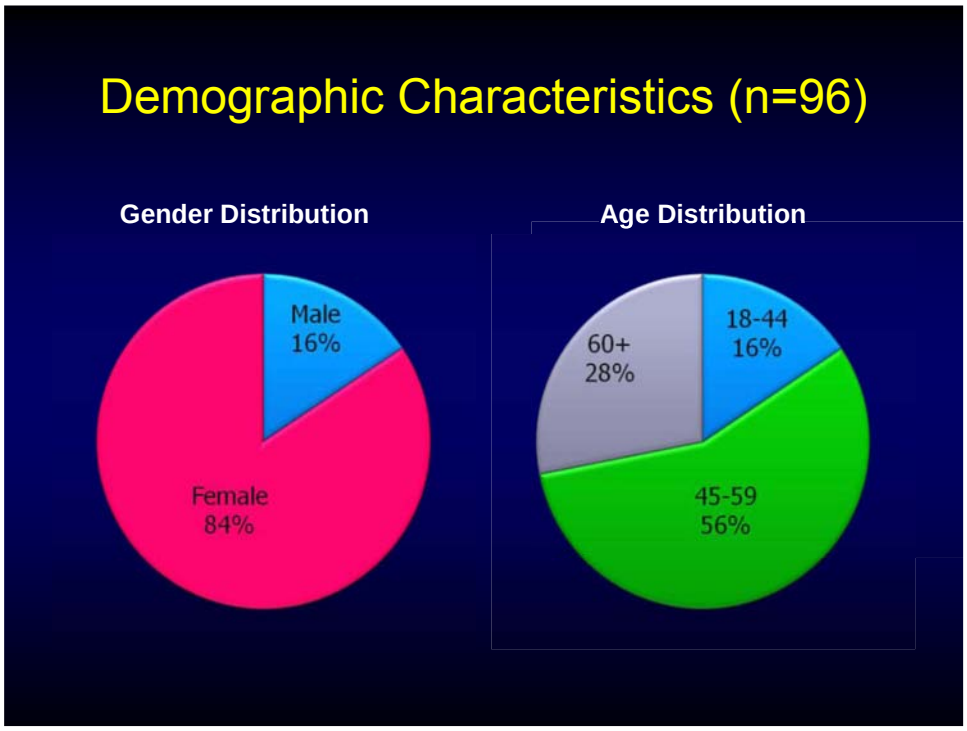

Chart 2

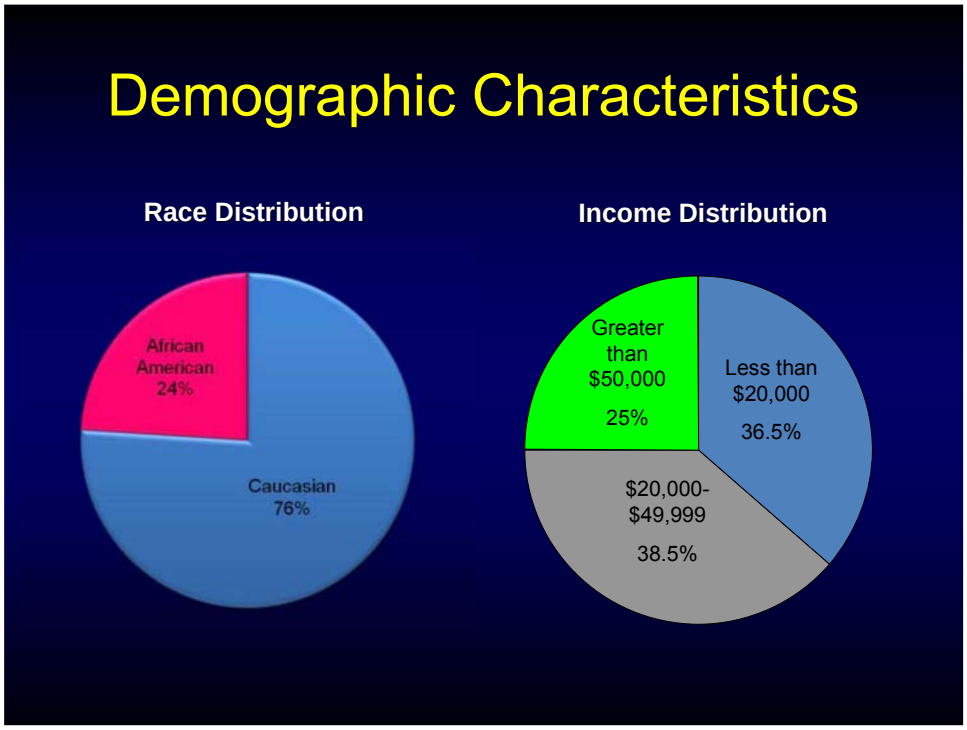

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Chart 3

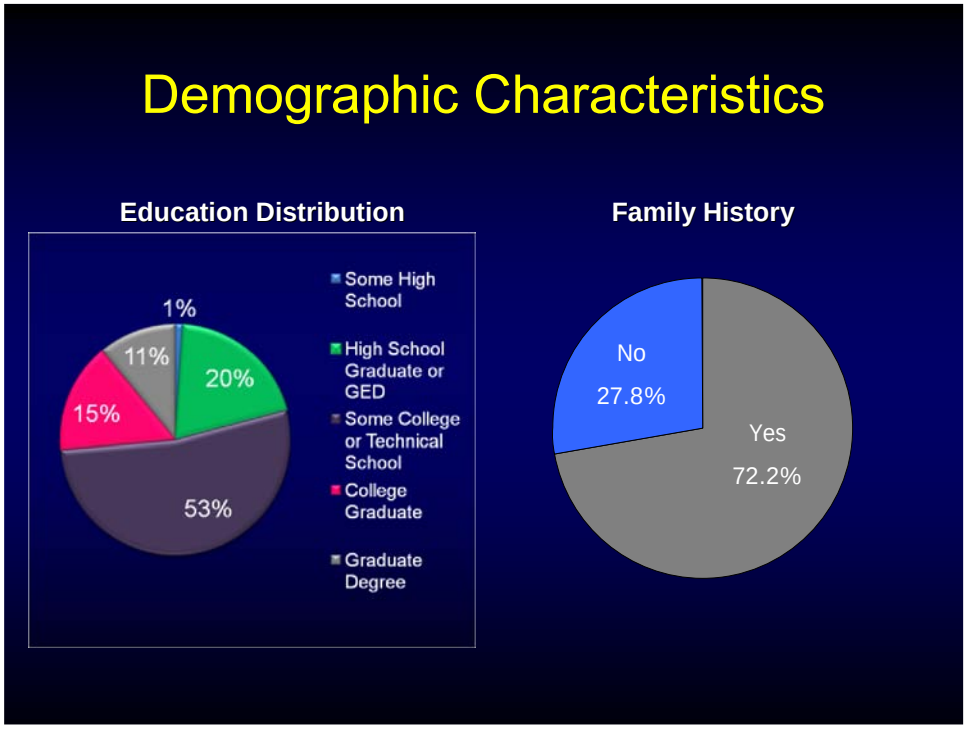

Table 1

Baseline Clinical Characteristics

Characteristic	n=96
Weight (lbs)	215.6
BMI	36.2
Abdominal Obesity (Males: ≥ 40 inches, Females: ≥ 35 inches)	93.8 (90)
Glucose ≥ 100 (mg/dL)	42.7 (41)
Triglycerides ≥ 150 (mg/dL)	51.0 (49)
Abnormal HDLc (Males: > 40 mg/dL, Females: > 50 mg/dL)	84.4 (81)
Hypertension (Blood Pressure ≥ 130/85 mmHg)	67.7 (65)

*Data are mean (S.D.) or % (n)

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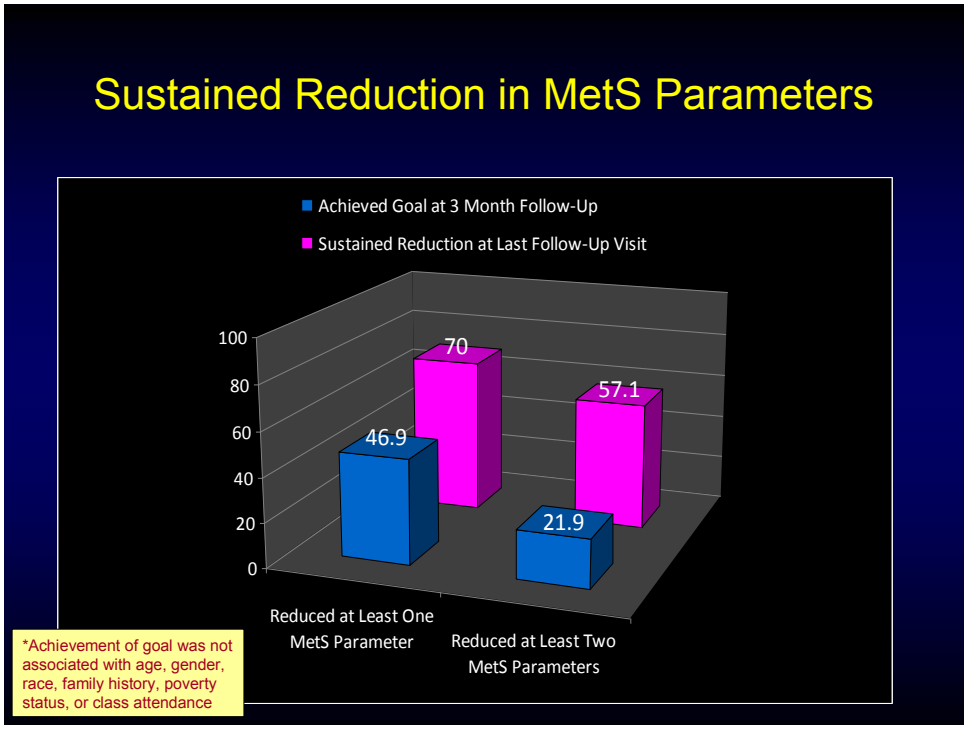
Chart 4

Chart 5



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Discussion

As is common in community interventions, more women than men participated in the screening as well as the intervention. The majority of participants were under age 60.

The targeted community is an underserved, low income community made up of eleven neighborhoods. These neighborhoods are not homogeneous, however. The three smallest neighborhoods have a predominately African American population. The largest neighborhood is predominately Caucasian. In total, twenty-four percent of those participating in the intervention were African-American and 76% were Caucasian. Seventy-five percent of the participants are part of households with a family income under $50,000 and of those, half have an income less than $20,000 (poverty level).

The majority of participant had less than a college education, but 99% had at least a high school education with many noting that they had some education or training after high school. Almost 75% of the participants had a family member with diabetes, a fact that the participants stated as their reason for joining the intervention.

Inclusion criteria for the intervention were a BMI of 25 or greater and the presence of three of the five risk parameters for Metabolic Syndrome. As noted in Table 1, the mean BMI of the participants was 36.2. Abdominal obesity was the most commonly seen Metabolic Syndrome risk factor in participants with low HDL cholesterol seen second most often. Diagnosed hypertension or an elevated systolic or diastolic reading at the screening was seen in 68% of the participants. Half had elevated triglycerides and 43% had elevated glucose.

As with the NDPP, the weight loss goal was to lose at least 7% of initial body weight at the end of the 12 week intervention – noted as “three month follow up” on Chart 4. As noted, 28% of participants met that goal and 50% of those participants were able to sustain that weight loss at their last follow up visit. The literature demonstrates that a 5% and even a 3% weight loss can have clinical significance for preventing diabetes and cardiovascular disease (15, 16). Chart 4 shows that 50% of participants lost at least 5% of their starting weight with 66% of those people sustaining the weight loss over time; 75% of the participants lost at least 3% of their starting weight at 3 months with 58% of them sustaining that weight loss at last follow up visit.

Chart 5 demonstrates reduction in Metabolic Syndrome risk parameters. 47% of participants reduced at least one parameter after the 12 week intervention and 70% were able to sustain that improvement. Twenty-two percent reduced at least two Metabolic Syndrome risk parameters at three months with more than half sustaining that reduction at last follow up visit.

Demographic measures – gender, race, age, income and education – did not differ among those participants with positive clinical outcomes compared to those without. Class attendance was also not a factor. Mean class attendance was 9.2 classes out of 12.

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Conclusions

To identify people at risk for diabetes, community screenings were offered. Because a fasting blood test was necessary to identify Metabolic Syndrome, screenings were only offered in the morning. Morning screenings appear to be a barrier to some people: those who work early, inflexible shift (for example, a bus driver who must be on his route by 7:00 a.m.); those who swing shift; those who take the bus to work or have limited capability of making a detour to a screening; those with sole responsibility for childcare or eldercare. The literature notes that BMI and waist circumference are independent risk factors for diabetes. Using both together is a stronger predictor of risk. In the next phase of the study, only BMI and waist circumference will be used to determine risk to provide greater flexibility in screening times. Fasting blood work will be done for those who consent to the intervention.

It appears that adults living in an underserved community can decrease their risk factors for Metabolic Syndrome through participation in a Healthy Lifestyle Program emphasizing moderate weight loss and physical activity. Long term sustainability of positive clinical outcomes is feasible. Continued follow up of subjects will demonstrate sustainability of positive outcomes over a longer time. Further analysis is needed to define and differentiate the clinically successful from unsuccessful participants.

Appendix I

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Appendix J

Deliverable #230: Final Report on the Implementation of the Diabetes Project

UPMC

University of Pittsburgh Diabetes Institute

Contract #:	W81XWH-04-2-0030
Deliverable #:	230
Funding Year:	2004/2005
Goal/Initiative:	Primary Prevention, Goal 1
Submitted By:	Kaye Kramer, PhD
Submission Date:	04/15/2009
Description:	Final Report on the Implementation of STEP UP at Additional Primary Care Practices

UPMC

University of Pittsburgh Diabetes Institute

Table of Contents

Introduction

Approximately 314 million people worldwide are estimated to have impaired glucose tolerance and are therefore at increased risk for developing type 2 diabetes and cardiovascular disease (CVD) [1]. The metabolic syndrome, a clustering of risk factors including insulin resistance, dyslipidemia, obesity and hypertension has also been associated with elevated risk for both of these conditions [2-6].

Lifestyle intervention clearly reduces the risk for type 2 diabetes [7-10]. In the United States, the Diabetes Prevention Program (DPP) demonstrated that intensive lifestyle intervention was highly successful in reducing risk for type 2 diabetes in all groups regardless of ethnicity, age or gender [11]. In addition, the DPP lifestyle intervention was effective in reducing risk factors for CVD [12] and components of the metabolic syndrome [13]. Recent research has focused on translating the DPP intervention to a variety of settings including local YMCAs [14], primary care practice settings [15], and hospital-based locales [16, 17]. These successful projects focused on lifestyle intervention delivery in their respective settings; however, did not address a model for training and support that could be applied to health professionals in other settings. The challenge for public health is to devise a universal framework for translation of all aspects of the DPP research effort (from training and support to the intervention program and materials) in order to be readily implemented in a variety of settings.

Objective

The objective of this project was to expand the services and support of the Diabetes Prevention Support Center of the University of Pittsburgh Diabetes Institute to additional regional primary care practices.

Methods

Intervention Adaptation

The original DPP Individual Intensive Lifestyle Intervention was developed at the University of Pittsburgh by the DPP Lifestyle Resource Core (LRC) and has been described in detail elsewhere [18]. For translation, based on analysis from the DPP which suggested that group delivery could be cost-effective [19], several members of the DPP LRC modified the original DPP lifestyle intervention to the Group Lifestyle Balance (GLB) program for group rather than individual delivery. In addition, the translation team adapted the intervention to be more compatible with a real world schedule by decreasing the number of sessions from 16 to 12 in order for the program to be delivered on a quarterly basis. Other modifications included concentrating on healthy food choices rather than specifically the food pyramid, a focus on calorie as well as fat intake from the beginning of the intervention and an enhanced emphasis on the pedometer, which originally had not been part of the core DPP sessions. Major modifications are summarized in Table 1.

GLB program participants receive handouts for each session, a fat and calorie counting book, self-monitoring books for keeping track of food and physical activity, a pedometer with instructions, and a chart for self-monitoring weight over the course of the program. All subjects were asked to self-

monitor their own weight, food intake, and physical activity levels and received feedback concerning their progress.

Training and Support System

A major component of the successful DPP intervention revolved around the training and support provided to the interventionists delivering it [20]. In an effort to mirror the successful DPP model, the Diabetes Prevention Support Center (DPSC) of the University of Pittsburgh Diabetes Institute (https://diabetesprevention.upmc.edu) was established in 2006. Members of the DPSC faculty developed a two-day training workshop for health care professionals in order to provide a complete, standardized overview of the GLB program and its implementation. Ten training workshops have been held to date, with over 350 health care professionals completing training, including the preventionists providing the intervention for this present evaluation. Figure 1 shows the breakdown of attendee locale, as well as the proportion of those trained who are involved in Department of Defense projects. In addition, military personnel from Wilford Hall are shown (TX). Figure 2 depicts the professional affiliation of those attending workshops to date.

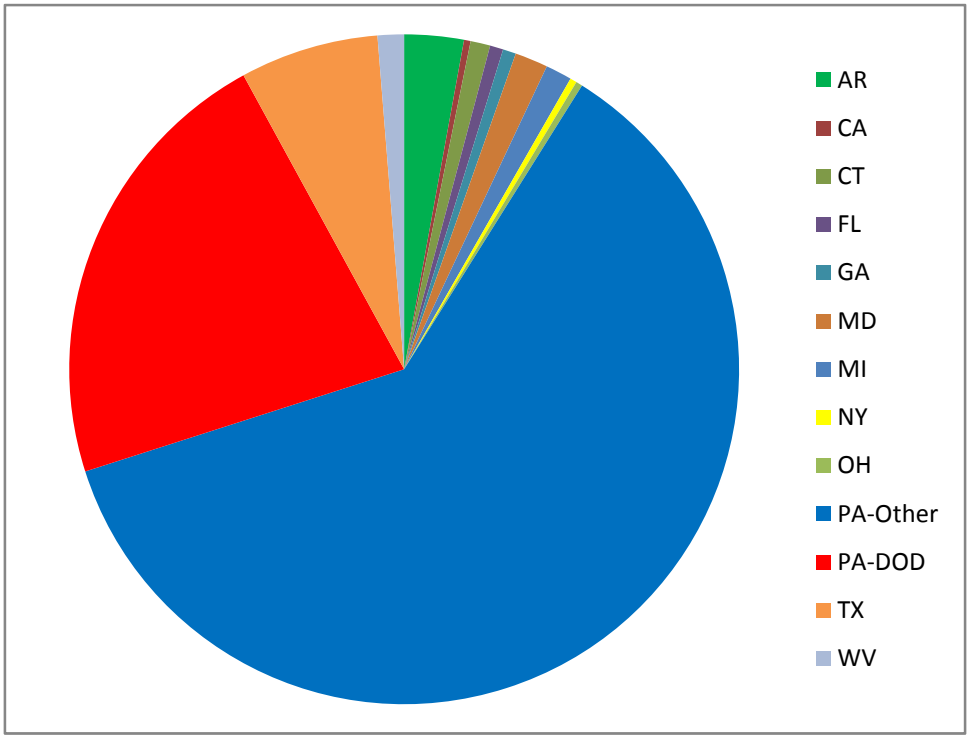

Figure 1: Group Lifestyle Balance Training Workshop Attendee Locale

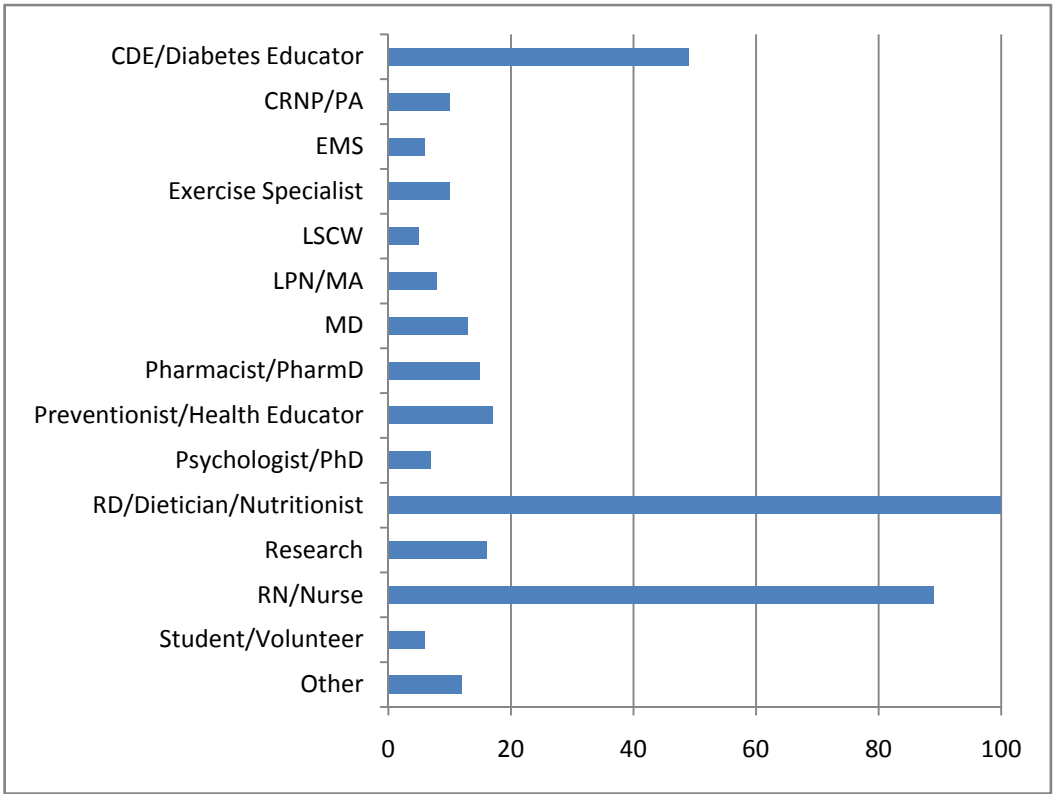

Figure 2: Group Lifestyle Balance Training Workshop Attendee Professional Affiliation

The workshops provide an overview of the background and results of the DPP, the rationale for the nutrition and physical activity goals of the program, and a thorough summary regarding teaching the basic components of each intervention session. In addition, one section of the workshop is devoted to instruction in conducting group sessions and also provides time to help attendees "brainstorm" how they might implement the program in their setting. Training closely follows the GLB manual of operations, which includes a leader's guide for teaching each session as well as a complete set of participant handouts; the manual has thus been designed to be a one-stop resource for implementation of the GLB program.

In addition to receiving initial training, interventionists in the DPP also received ongoing support from the DPP Lifestyle Resource Core (LRC) as they implemented the program. Support was provided via monthly conference calls or as needed calls for specific assistance with any problems that arose. In order to replicate this support structure, the DPSC is available to all preventionists who have attended the GLB training workshop including those who have participated in this current effort. During this past year, the DPSC also completed a "train the trainer" for our military partners so that these training workshops may be conducted onsite within the military framework.

Expansion of the DPSC to Additional Primary Care Practices

A non-randomized prospective one-group design was chosen for this effectiveness evaluation as it is a design often used in translation efforts. The primary care practice setting was chosen initially for translation because it provides an ideal venue for institutional delivery and reinforcement of prevention intervention, as well as the provision of ongoing follow-up care. Working with Dr. Francis Solano of the University of Pittsburgh Medical Center, 6 primary care practices were identified and approached to take part in this evaluation. The primary care practices that agreed to participate were located in Aspinwall, Cranberry Township, Monroeville, Murrysville, New Kensington, and Pittsburgh. Two practices, Aspinwall and Monroeville, agreed to take part in formal research evaluation. One practice (Murrysville) later withdrew their participation as they had other competing demands in the office such that they were not able to direct attention to this project. One of the research practices had a patient base of approximately 5,000, and the other approximately 10,000.

Subjects age 18 and older without diabetes, a body mass index (BMI) $\geq$25kg/m2 and the metabolic syndrome (NCEP ATPIII definition)[21] and/or pre-diabetes (fasting glucose 100-125) [22] were invited to take part. Potential participants learned about the GLB program through flyers posted in primary care practices or directly from their physician. A physician referral documenting eligibility as well as permission for physical activity was required.

Procedures and Outcome Measures

After completion of informed consent, participants completed assessments at baseline and at the conclusion of the intervention. Subjects had blood pressure, height, weight and waist circumference measured following a standard protocol. Total cholesterol, high-density lipoprotein (HDL) cholesterol, non-HDL cholesterol and glucose were measured after at least an eight-hour fast using the Cholestech LDX System by a certified laboratory assistant. Global CVD risk assessment [23] was also estimated and medication use was assessed via participant interview. In addition, weight was recorded weekly at each session. After completion of the 12 core sessions, participants attended monthly maintenance meetings to report their weight and activity minutes.

Complete outcomes data were collected for the two research practices (N=13) with limited quality assurance data available (weight, BMI and waist circumference) for the total primary care practice group (N=46) at baseline and 3 months post-intervention.

Sample Size Estimation and Statistical Analysis

Based on previous local DPP weight loss experience and using this variance estimate, we estimated that for paired analysis 21 subjects were needed to detect a 7% weight loss with α=0.05 and 90% power. Analyses were carried out using the SAS statistical package (version 9.1, SAS Institute, Cary North Carolina, USA). The mean change between pre and post intervention measures was analyzed using the Paired Student's *t*-test when change data were normally distributed (weight, waist circumference and BMI); however, for most measures the non-parametric Wilcoxon Matched-Pairs Signed Rank test was

used. Mixed models were used to examine weight change over time (repeated measures per participant) adjusting for weight at study entry and clustering of participants within clinical site; individual participant and clinical sites were random effects in the model. Correlations were calculated using Pearson's or Spearman's correlation coefficient r. Analyses were conducted on an intention to treat basis; to handle missing data we used last observation carried forward methodology for participants who did not attend the post assessment visit. Subjects with changes in medication use during the course of the intervention for the condition being evaluated were excluded from appropriate specific analyses.

Results

Attendance

The Group Lifestyle Balance program was well attended, with 89.1% of the total group (n=46) and 100% of participants in the research group (n=13) attending at least half of the sessions. The mean number of sessions attended was 10. In addition, 11 (85%) participants attended the six month assessment visit, and 10 (77%) attended the 12 month assessment visit.

Clinical Outcome Measures

Demographic characteristics of the research group (N=13) are shown in Table 1, with specific results of the baseline and post intervention comparisons for weight, waist circumference and BMI for both the research and the total group including all primary care practices (n=46) shown in Table 2. A significant decrease in weight (-9.3 pounds, -4.3%, p<0.0001), waist circumference (-1.4 inches, -3.2%, P<0.0001) and BMI (-1.7 kg/m^2, -4.4%, p=<0.0001) was noted over all.

Table 1: Demographic Characteristics: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	N=13
Female/Total Group (%)	11/13 (85%)
Non-Caucasian (%)	0 (0%)
Mean age (sd)	57.4 (sd=10.9)
Age Range	37-73

Table 2: Baseline and Post-Intervention Comparisons for Weight, Waist and BMI in Total and Research Groups: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

Variable	**n**	**Pre-Mean (sd)**	**Post-Mea (sd)**	**Mean Change(sd)**	**Mean % Change**	**p-value**
Weight (lbs)	46	220.1 (47.1)	210.9 (47.7)	-9.3 (9.1)	4.3%	**<.0001**
	13	204.0 (40.9)	192.6 (40.7)	-11.3 (7.9)	-5.6%	**0.0002**
Waist (inches)	44*	42.0 (6.1)	40.6 (6.0)	-1.4 (1.9)	3.2%	**<.0001**
	13	40.8 (6.8)	39.0 (6.1)	-1.8 (2.5)	-4.4%	**0.01**
BMI (kg/m^2)	44*	37.5 (7.4)	35.9 (7.6)	-1.7 (1.6)	4.4%	**<.0001**
	13	34.7 (6.2)	32.7 (6.2)	-1.9 (1.4)	-5.7%	**0.0002**

* Waist and height not measured on 2 participants

The remaining outcome measures for the research group at the 3 month post-intervention assessment are shown in Table 3, with significant decreases noted in total cholesterol (-28.3 mg/dL, -15.3%, p=0.006), LDL cholesterol (-21.5 mg/dL, -20.3%, p=0.005) and systolic blood pressure (-9.7 mm/Hg, -7.5%, p=0.005) at the 3 month post-intervention assessment. No significant changes were noted for diastolic blood pressure, HDL cholesterol, triglycerides, glucose, or HbA1c.

Weight loss remained significant at the 6 month (-15.1 pounds, -7.4%, p=0.0002) and 12 month assessment visits (-10.6 pounds, -5.2%, p=0.001), as did BMI, waist circumference, LDL cholesterol, and systolic blood pressure. Total cholesterol remained significantly decreased at the 6 month assessment and marginally decreased at the 12 month assessment. In addition, a significant decrease in diastolic blood pressure from baseline was noted at 6 months and 12 months and a significant increase in HDL cholesterol was noted between baseline and the 12 month assessment visit. Results are shown in Table 3 to follow.

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Table 3: Baseline and Post-Intervention Comparisons for Clinical Outcome Measures: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

	Baseline		**3 Months (n=13)**				**6 Months (n=11)**					**12 Months (n=10)**			
Variable	**n**	**Mean (sd)**	**Mean (sd)**	**Mean Change (sd)**	**Mean % Change**	**p**	**Mean (sd)**	**Mean Change (sd)**	**Mean % Change**	**p**	**n**	**Mean (sd)**	**Mean Change (sd)**	**Mean % Change**	**p**
Weight (lbs)	13	204.0 (40.9)	192.6 (40.7)	**-11.3 (7.9)**	**-5.6%**	**0.0002**	188.9 (41.7)	**-15.1 (10.5)**	**-7.4%**	**0.0002**	10	193.3 (43.1)	**-10.6 (10.6)**	**-5.2%**	**0.001**
Waist (inches)	13	40.8 (6.8)	39.0 (6.1)	**-1.8 (2.5)**	**-4.4%**	**0.01**	37.7 (6.0)	**-3.1 (2.5)**	**-7.5%**	**0.0005**	10	37.2 (6.3)	**-3.6 (2.5)**	**8.7%**	**0.0005**
BMI (kg/m^2)	13	34.7 (6.2)	32.7 (6.2)	**-1.9 (1.4)**	**-5.7%**	**0.0002**	32.1 (6.4)	**-2.6 (1.8)**	**-7.7%**	**0.0003**	10	32.8 (6.5)	**-1.9 (1.8)**	**-5.6%**	**0.0007**
Total Chol. (mg/dl)*	13	187.3 (24.2)	159.0 (37.5)	**-28.3 (29.2)**	**-15.3%**	**0.006**	161.5 (36.1)	**-25.8 (25.5)**	**-14.2%**	**0.004**	10	177.3 (31.5)	-10.0 (18.0)	-5.6%	0.07
HDL Chol.l (mg/dl)*	13	46.2 (6.9)	43.9 (9.2)	-2.3 (5.6)	-5.2%	0.25	46.7 (8.2)	+0.5 (5.9)	+1.4%	0.84	10	51.2 (6.4)	**+4.9 (5.8)**	**+11.6%**	**0.01**
LDL Chol. (mg/dl)*	13	108.2 (26.4)	86.7 (31.1)	**-21.5 (23.2)**	**-20.3%**	**0.005**	86.8 (29.5)	**21.4 (21.9)**	**-20.0%**	**0.004**	9	95.3 (27.6)	**-14.2 (18.4)**	**-12.7%**	**0.02**
Triglycerides (mg/dl)*	13	162.7 (73.6)	147.5 (62.1)	-15.2 (47.9)	-9.3%	0.27	139.7 (59.3)	-23.0 (38.8)	-13.9%	0.08	9	160.1 (71.9)	-2.6 (44.5)	-2.4%	0.98
Glucose (mg/dl)*	13	98.9 (12.0)	103.2 (5.6)	+4.3 (10.1)	+4.5%	0.15	93.4 (5.4)	-5.5 (12.3)	-4.3%	0.12	10	95.0 (17.1)	-3.9 (18.4)	0.84	0.70
HbA1c (%)	13	5.7 (0.4)	5.8 (0.4)	+0.07 (0.3)	+1.2%	0.33	5.8 (0.32)	+0.07 (0.32)	+1.4%	0.27	10	5.9 (0.4)	+0.16 (0.31)	+2.9%	0.26
SBP (mmHg)*	12	122.9 (10.7)	113.3 (6.6)	**-9.7 (8.6)**	**-7.5%**	**0.005**	113.5 (8.7)	**-9.4 (8.1)**	**-7.4%**	**0.001**	8	112.6 (11.5)	**-11.3 (12.2)**	**-8.8%**	**0.03**
DBP (mmHg)*	12	80.3 (4.5)	7.7 (6.2)	-3.7 (7.1)	-4.4%	0.10	75.0 (5.5)	**-5.3 (6.4)**	**-6.4%**	**0.01**	8	73.1 (5.4)	**-7.4 (6.7)**	**-9.0%**	**0.004**

* Participants with any medication changes excluded

Achievement of Goals

Results for weight loss achievement are shown in Figure 3 below. When examining weight loss, 9 of 13 participants (69.2%) reached a weight loss of at least 3.5%, 8 of 13 (61.5%) had weight loss of at least 5%, and 5 of 13 (38.5 %) reached the 7% weight loss goal. At the 6 month follow up assessment visit, 77% (10/13) reached 3.5% weight loss, 69% (9/13) reached 5% weight loss, and 46% (6/13) reached the 7% goal. In addition, 100% of those who achieved 3.5%, 5% and 7.5% weight loss at the 3 month post intervention assessment maintained that weight loss at the 6 month assessment visit. At the 12 month assessment visit, 7 of the 13 participants (53.9%) had weight loss greater than or equal to 3.5%, 38.5% (5/13) had weight loss greater than or equal to 5% and 30.8% (4/13) had weight loss greater than or equal to 7%; 80%, 63% and 77% respectively maintained those weight loss levels at one year

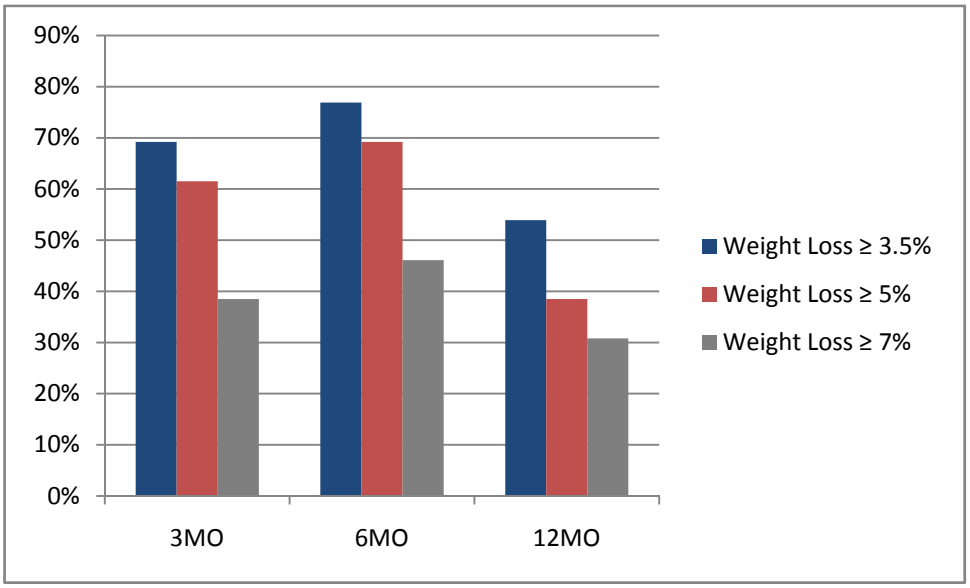

Figure 3: 3, 6 and 12 Month Post-Intervention Weight Loss: Group Lifestyle Balance Program-University of Pittsburgh Primary Care Practice Population

Of the 7 (53.8%) participants that recorded activity minutes, 2 (28.6%) successfully reached the physical activity goal (average of 150 minutes per week). Additionally, the mean number of activity minutes completed per week was positively correlated with weight loss in Phase 2 ($r=0.71$, $p=0.07$). Based on information collected during participant interview, a significant increase in the median self-reported activity minutes was noted between baseline and the 3 month post-intervention assessment (30 versus 150 minutes, $p=0.001$) and a marginally significant increase noted between baseline and the 6 month post-intervention visit (30 versus 120 minutes, $p=0.08$). Reported activity minutes remained increased at the 12 month assessment when compared to baseline; however, this difference was not significant (30 versus 59 minutes, NS).

Discussion

The findings of this project provide further evidence that this diabetes prevention model was successfully expanded to these UPMC Primary Care Practices. The Group Lifestyle Balance program was successfully administered to preventionists who, in turn, received their training and support from the DPSC. The program reduced key components of risk for type 2 diabetes and CVD for participants in these local primary care practice settings. In the DPP, 49% of lifestyle participants reached the 7% weight loss goal by the completion of the core intervention at the end of six months [24]; in the current project, 38.5% met a weight loss goal of 7% at 3 months. The GLB program was also recently implemented by DPSC trained preventionists in an urban medically underserved community setting subjects with the metabolic syndrome; 26.1% reached the 7% weight loss goal at the conclusion of the 3 month intervention and over one-third reduced at least one component of the metabolic syndrome [25].

We expected that the effectiveness of our translation effort might be reduced relative to that administered in a controlled research setting like the DPP [26], however, 69.2% achieved weight losses of at least 3.5% at 3 months in the current group which appears somewhat similar that the trend for weight loss seen in the DPP at 3 months. In addition, 100% of participants that achieved 7%, 5% and 3.5% weight loss maintained that weight loss at the 6 month assessment, with 80%, 63% and 77% respectively maintaining those weight loss levels at one year. Furthermore, significant decreases in weight and several other parameters of risk were successfully maintained through the 6 and the 12 month assessment visits, demonstrating the long-term impact of the intervention.

Achievement of the physical activity goal was limited in this group; however, only a little more than half of the participants actually recorded activity minutes. This may reflect a problem in tracking and reporting of physical activity since self-reported activity minutes increased significantly between baseline and the 3 month assessment. This trend continued at the 6 month assessment and activity minutes remained increased from baseline at the 12 month assessment, however the difference was no longer significant. In moving forward with prevention intervention it will be important to determine more effective methods to encourage tracking and recording of physical activity was well as general measures of physical activity.

Retention of participants in an intervention program can prove difficult in the most supportive research environment; this is even more challenging in a real-world setting that must operate with limited staffing and funds, devoid of monetary rewards or incentives. For this project, we demonstrated excellent retention of participants. It is likely that by fine-tuning the types of motivators that are introduced, participant engagement strategies have improved as we move forward with translation. In the current project, preventionists in earlier projects learned which tools were effective and were able to share that knowledge in planning for later implementations. Preventionists reported positive participant response to providing samples of low fat/calorie foods for taste-testing in appropriate sessions,

individual participation in providing favorite healthy recipes or cookbooks, and small incentives such as a food scale or certificate of achievement for completing the program. These translation attempts demonstrate that creativity is necessary for participant retention, and that a small budget for healthy lifestyle enablers and incentives should be considered during planning. Since poor treatment outcome for weight loss has been shown to be related to poor program attendance [27, 28] and the current project's evaluation indicated a correlation between attendance and weight loss, attention to provision of motivational items for attendance is an important consideration for future translational efforts.

Strengths of this project include the development of a framework for training and support for lifestyle intervention implementation, as well as prospective follow-up design in the initial evaluation of this modified DPP lifestyle intervention for translation to real-world settings. In addition we collected measures of change in risk parameters for subjects in both urban and rural environments, in two phases, with data analyzed according to the intention to treat principle.

Limitations of this study include the modest sample size, thus not permitting sub-group analysis. In addition, only a small number of males participated, and the cohort consisted of only Caucasians, thus it will be important for future translational efforts to determine strategies to engage other groups.

Future translation steps will address the development of a recognition program that will further enhance program delivery expertise and standardization, thus providing third-party payers with confidence that the program meets a prescribed level of quality for reimbursement.

By mirroring the successful intervention training and support scheme utilized in the DPP, we have further expanded our translation model for diabetes prevention and CVD risk reduction. At the core is the modified lifestyle intervention utilized in the DPP which has been adapted for implementation in real world settings, while maintaining the fundamental aspects of the original intervention. The GLB program has now been successfully implemented in several health care locales, and a medically underserved community setting, and is currently in process within the military. By providing a central training center for intervention delivery via workshops as well as provision of subsequent post-training support, it is hoped that this model will provide a framework for large-scale prevention dissemination in expanded civilian and military settings.

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Appendix K

Appendix K, Deliverable # 34 *Final Report on Deployment*

"Alternate Care Delivery Systems for Diabetes"

Linda Siminerio, RN, PhD, CDE
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School of Medicine
School of Nursing

University of Pittsburgh
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The Facts

- 73.3 million Americans have diabetes or IFG
- Daily decisions made by patient
- Diabetes self-management education (DSME) is important
- 90% diabetes care provided by PCPs
- Education rarely available in the office

Diabetes Self-Management Education (DSME)

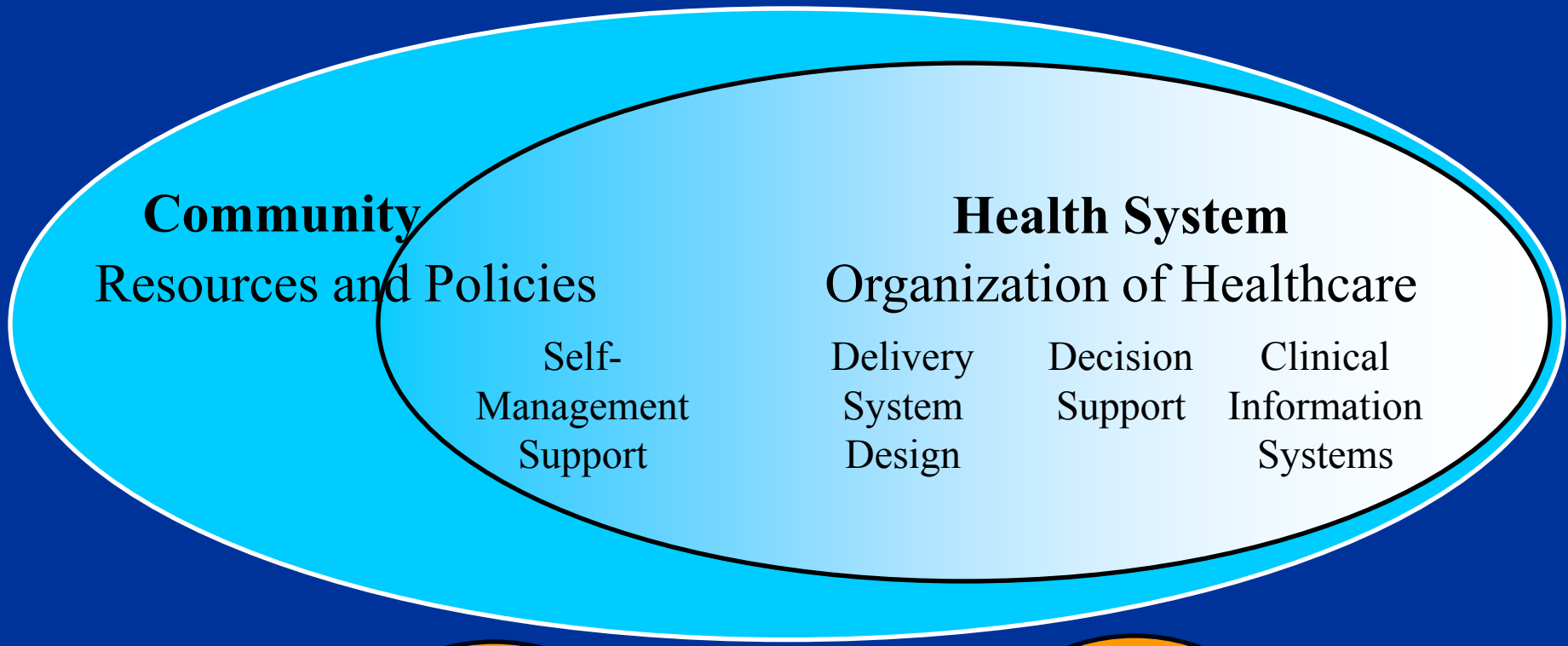
- DSME is an important part of clinical management
- Nat'l. Standards & ADA recognition
- Expanded coverage for diabetes outpatient self-management (Medicare final rule)
- Numbers of patients who receive education and program closings are disappointing
- Educators report frustration with the logistics implementing reimbursement practices

Barriers

- Lack of reporting outcomes (including reimbursement)
- Access
- Traditional Model (Hospital-based programs)
- Poor direct communication with physicians
- Sustainability

Siminerio L, Piatt G, Zgibor J. "*The Diabetes Educator*, Vol 31 (2): 225-234, 2006.
Siminerio, L., et al "The Diabetes Educator, Vol , 2006.
Piatt, G. et al Diabetes Care,

Chronic Care Model

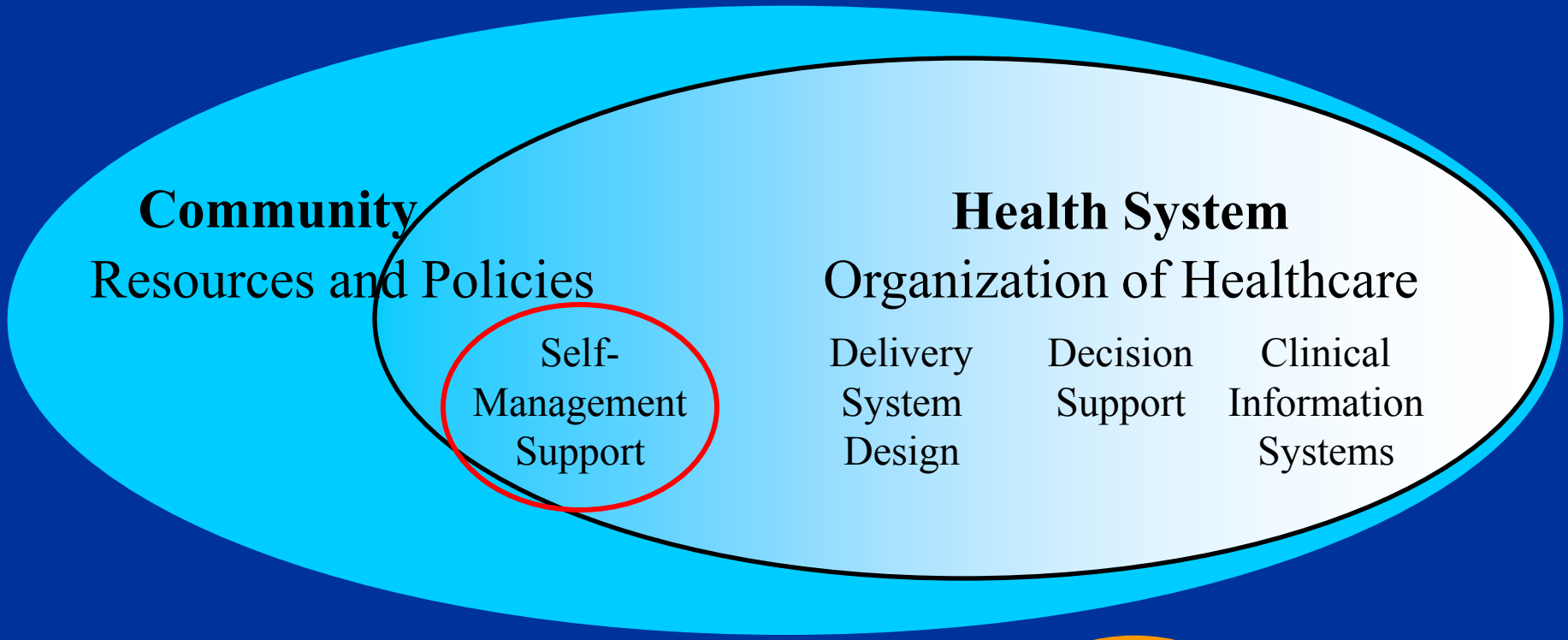


improving chronic illness care

Objective

- By implementing the CCM we could:
  - Gain health system support
  - Demonstrate improvements in A1C
  - Demonstrate reimbursement for services
  - Expand number of programs in communities

The Chronic Care Model



improving chronic illness care

Health System & Community

- UPMC board initiative
- Support from all departments
  - Finance
  - Information systems
  - Physician practices
- Presentations to top leadership
- Corporate Communications
- Pittsburgh Regional Initiative for Diabetes Education (PRIDE)

UPMC Diabetes Repository

- ICD-9 Code for diabetes, A1c, Glucose > 200 mg/dl, Diabetes Medication (oral hypoglycemic or insulin)
- MARS data in 8 DSME sites
- Used to describe target population
- Tracked A1C, charges & reimbursement

Nat'l. Standards for DSME Decision Support

- Established a centralized core
- Sponsored a system-wide ADA application
- Appointed a system coordinator (appointed coordinator at each site)
- Assured qualified staff
- Formed an advisory board, who:
  - Developed an annual program plan
  - Identified continuous quality improvement (CQI) : reimbursement & A1C

Prior to 2000…

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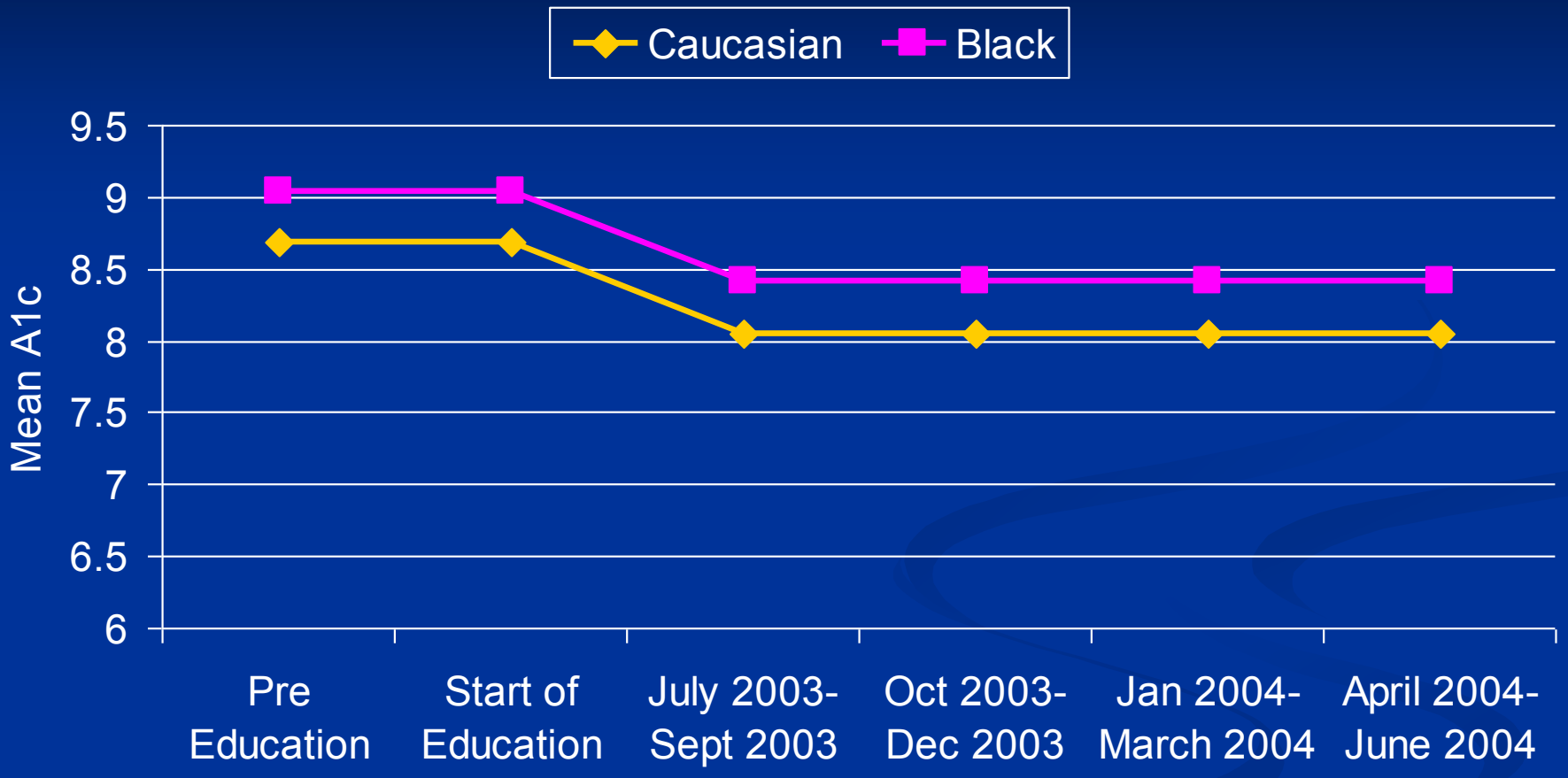
Trends in Glycemic Control by Race Over Time

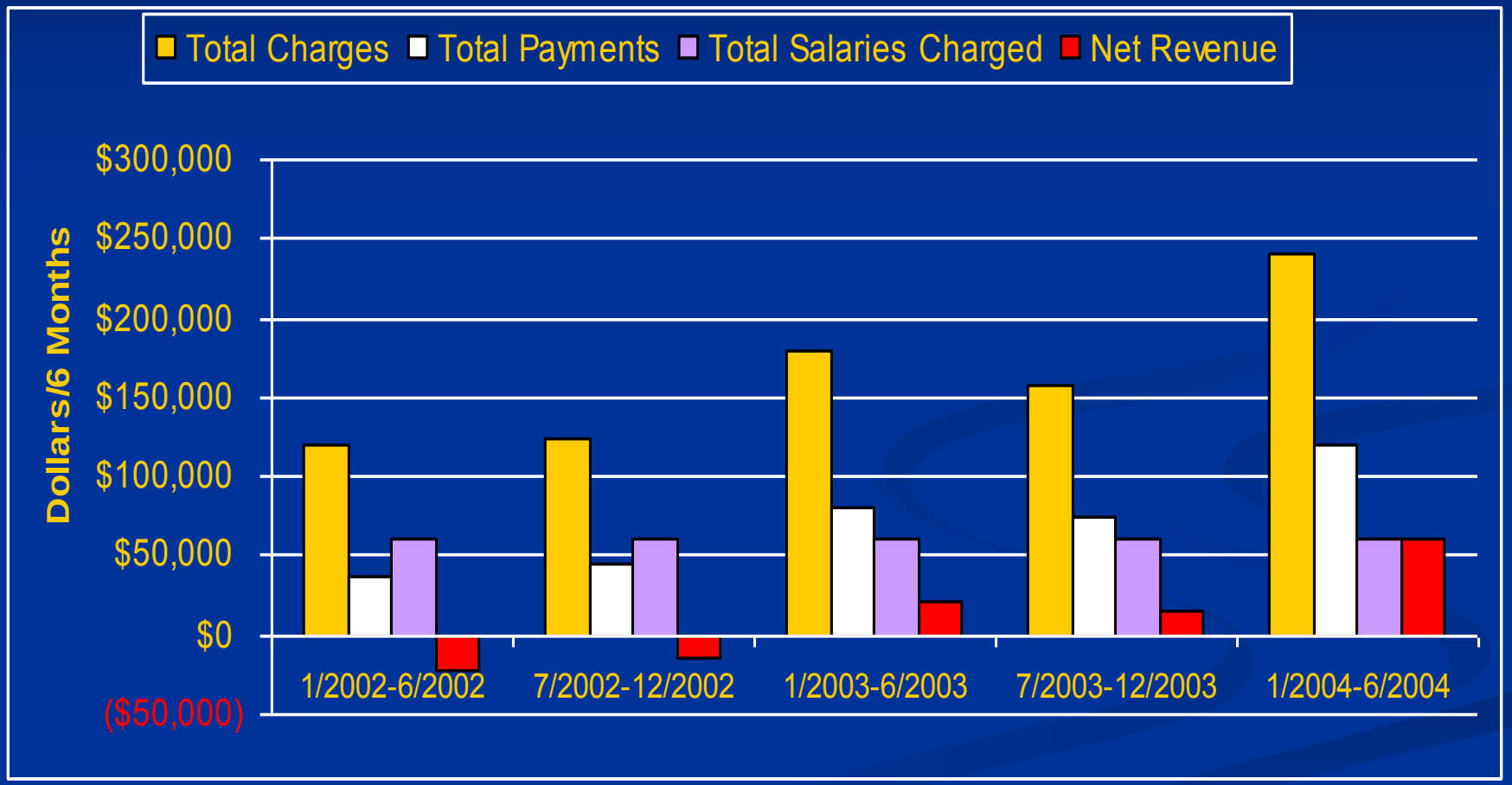


Reimbursement Challenges

- Missing certificates
- Staff neglected to submit charges
- Wrong codes were entered
- Billing on 1 hour frames instead of 30 min.
- Insurers ignored charges

Siminerio L, Piatt G, Emerson S, Ruppert K, Saul M, Solano F, Stewart A, Zgibor J. "Deploying the chronic care model to implement and Sustain diabetes self-management training programs." *The Diabetes Educator*, volume 32 (2): 1-8, 2006.

Figure 23 - *DSME Reimbursement and Educator Salary at 8 UPMC ADA Recognized Programs (January 2002-June 2004)*



Siminerio L, et al . *The Diabetes Educator*, volume 32 (2): 1-8, 2006.

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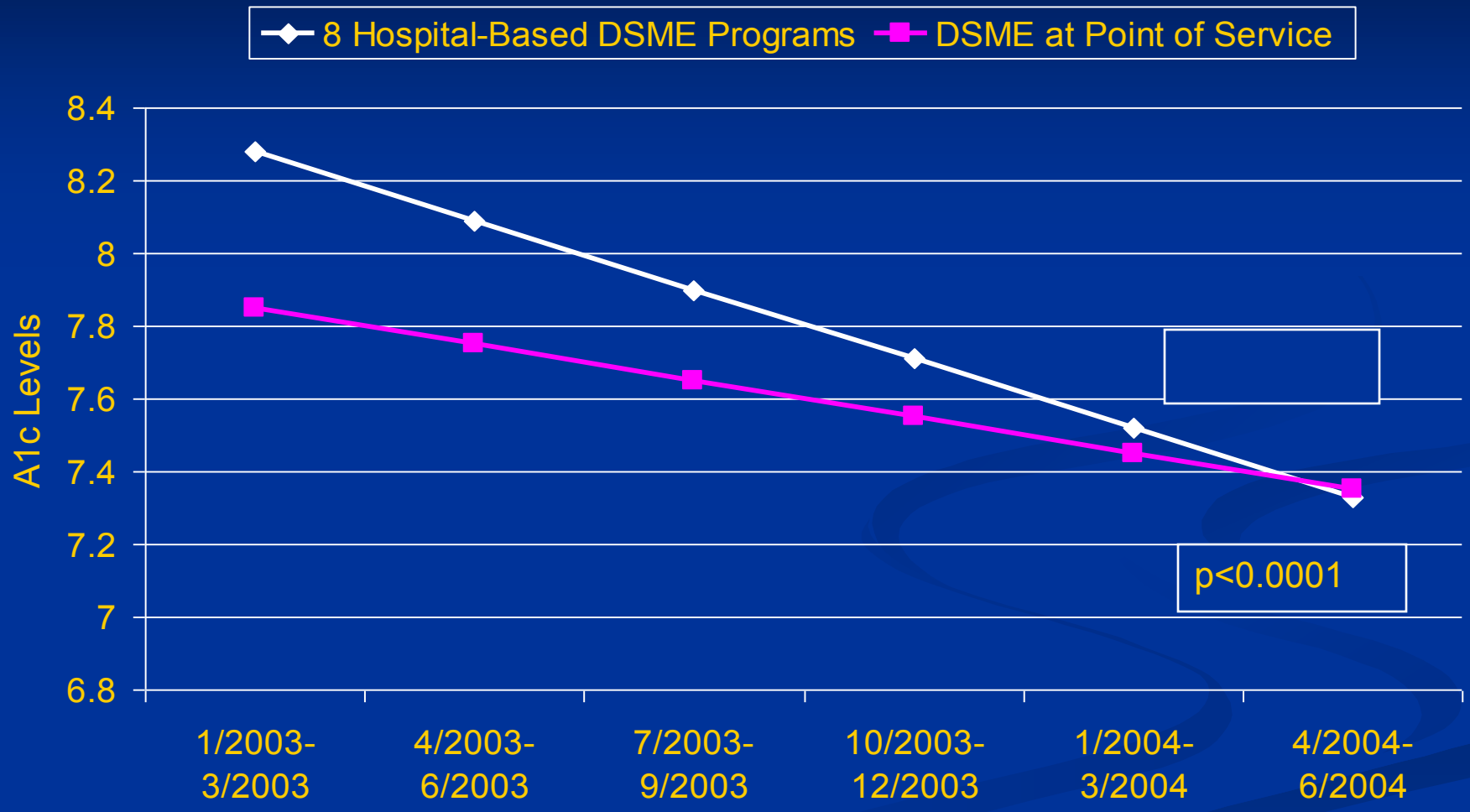
Objective

- By implementing DSME in Primary Care
  - Demonstrate improvements in A1C
  - Increase number of patients reached

- “Diabetes Days” were scheduled

Age Adjusted Trends in Glycemic Control Over Time



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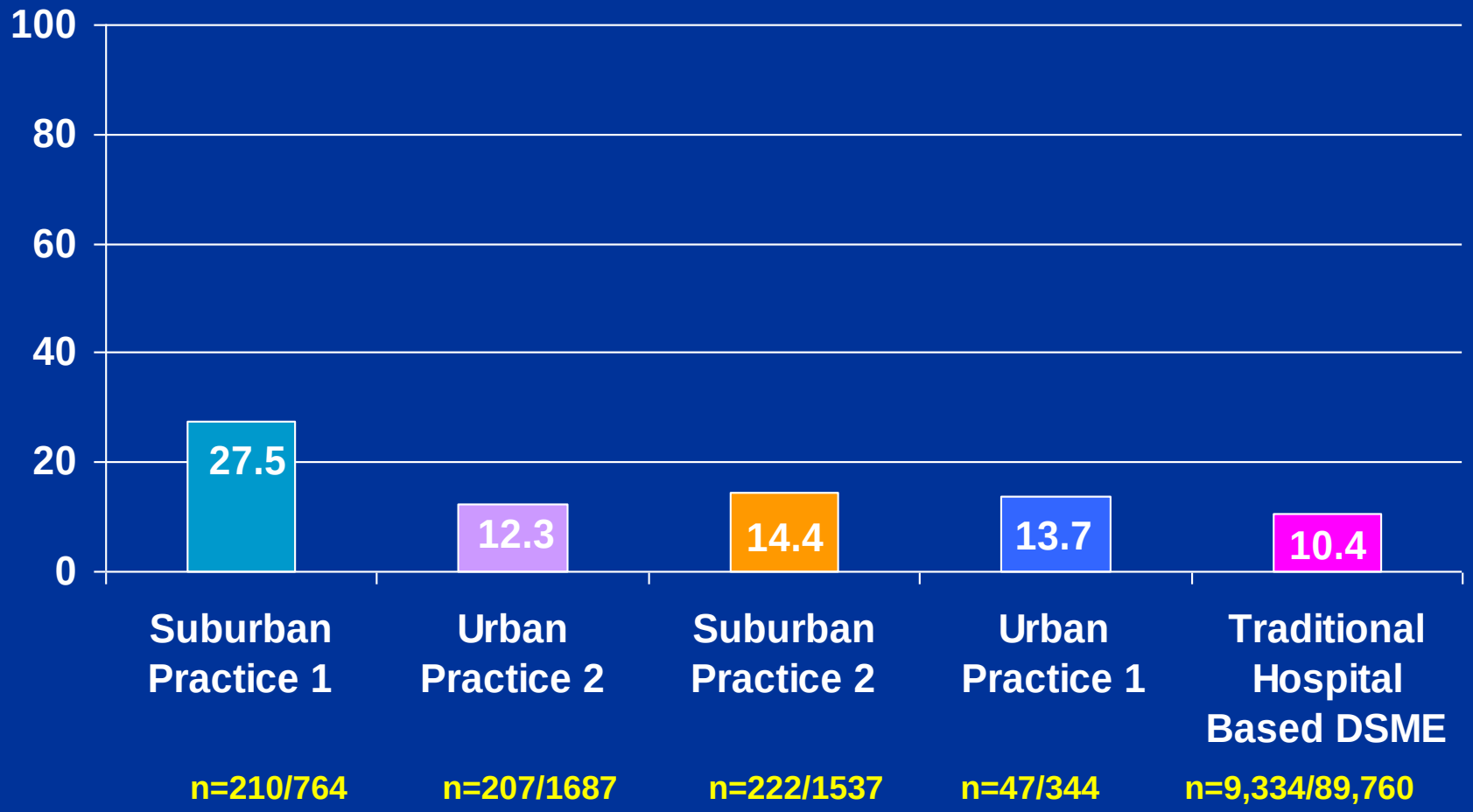
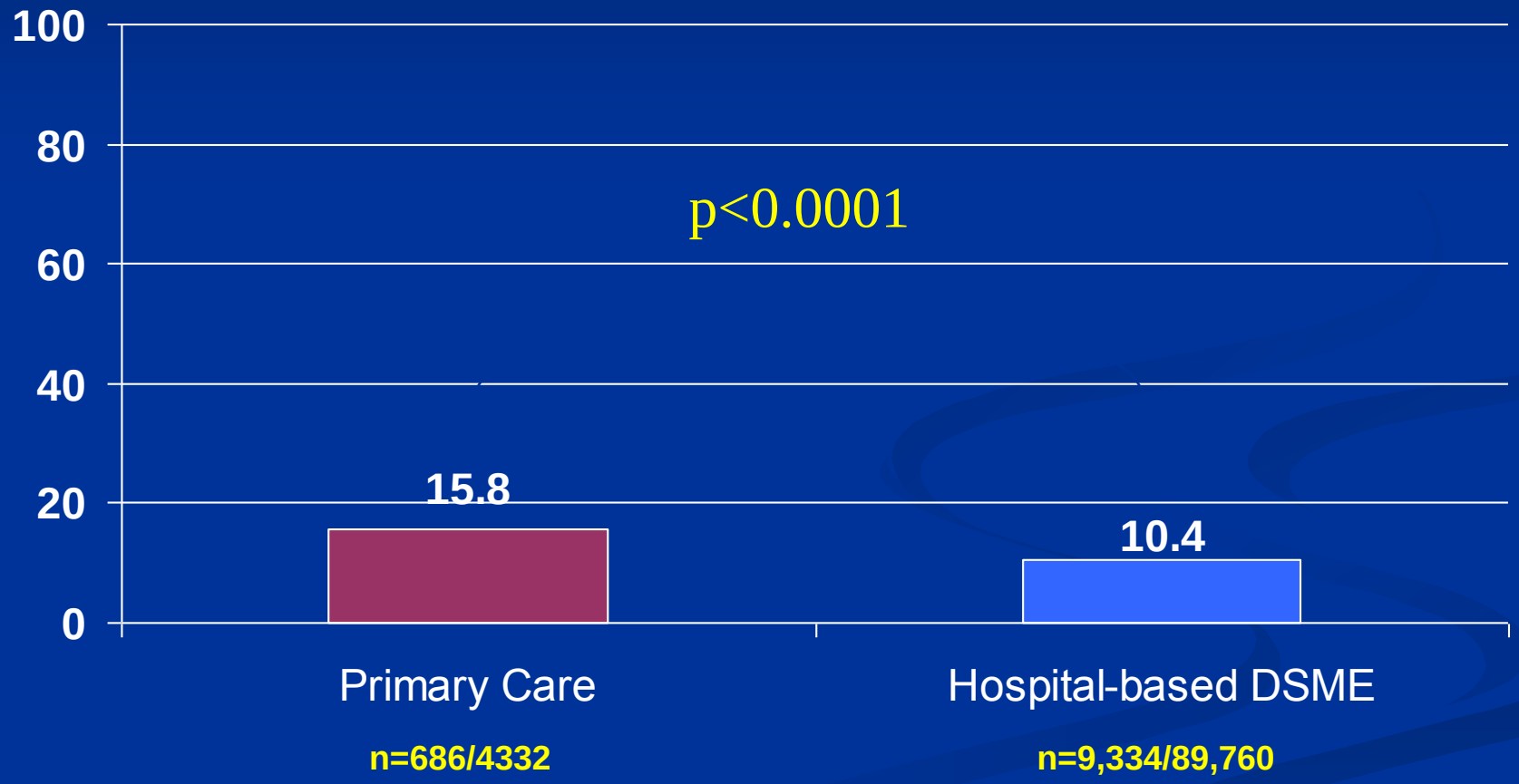
Proportion of People with Diabetes who were Seen for DSME in Primary Care Practice Settings Compared to those Seen for Traditional Hospital-Based Education



Proportion of People Educated at PCP Office Compared to Hospital Based Outpatient DSME



Summary
DSME in Primary Care is:

- Feasible
- Efficient
- Accessible
- Effective

Conclusions

- The CCM provided a good framework for implementing and sustaining DSME
  - Gained health system and community attention
  - Increased number of DSME sites
- Clinical information systems afforded the opportunity for tracking populations & reimbursement
- Reimbursement can be achieved if approached in a systematic way
- System redesign
  - Improved access
  - Physicians and patients reported increased communication and satisfaction.

Limitations

- Lack of long term follow up
- Measures limited to A1C
- Preliminary reports of reimbursement in primary care
- Individual visits at primary care vs. group visits in hospital programs

Future Direction

- Monitor metabolic, behavioral, psychosocial and costs
- Track educator practice, e.g. medication prescribing, dose adjustments, etc.
- Integrate and evaluate educator practice with primary prevention
- Evaluate physician and patient satisfaction

Special Acknowledgement

- Project team
  - Janice Zgibor, RPh, PhD
  - Sharlene Emerson, CRNP, CDE
  - Gretchen Piatt, PhD, CHES
  - Janis McWilliams, MSN, CDE
  - Kristine Ruppert, DrPH
  - Francis Solano, MD

- University of Pittsburgh Diabetes Institute
- University of Pittsburgh Division of Endocrinology and Metabolism
- University of Pittsburgh Medical Center

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Appendix L

Appendix L, Deploying the Chronic Care Model to Implement and Sustain Diabetes Self-management Training Programs

Deploying the Chronic Care Model to Implement and Sustain Diabetes Self-management Training Programs

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Purpose

The purpose of this project was to evaluate the utility of using the 6 elements of the chronic care model (CCM; health system, community, decision support, self-management support, clinical information systems, and delivery system design) to implement and financially sustain an effective diabetes self-management training (DSMT) program.

Methods

The University of Pittsburgh Medical Center (UPMC) uses all elements of the CCM. Partnerships were formed between UPMC and western Pennsylvanian community hospitals and practices; the American Diabetes Association DSMT recognition program provided decision support. A clinical data repository and reorganization of primary care practices aided in supporting DSMT. The following process and patient outcomes were measured: number of recognized programs, reimbursement, patient hemoglobin A1C levels, and the proportion of patients who received DSMT in primary care practices versus hospital-based programs.

Results

Using elements of the CCM, the researchers were able to gain administrative support; expand the number of recognized programs from 3 to 21; cover costs through increased reimbursement; reduce hemoglobin A1C lev-

els ($P < .0001$), and increase the proportion of patients receiving DSMT through delivery in primary care (26.4% suburban; 19.8% urban) versus hospital-based practices (8.3%; $P < .0001$).

Conclusions

The CCM serves as an effective model for implementing and sustaining DSMT programs.

Diabetes self-management training (DSMT) is widely considered to be an important part of diabetes management.[1,2] One of the goals of the US Health and Human Services' *Healthy People 2010* is to increase the number of people who receive diabetes education from 40% (1998) to 60% (2010).[3]

The national standards for DSMT[4] administered through the American Diabetes Association (ADA) recognition program[5] provide a framework for delivery and quality. Medicare and other third-party payers reimburse for programs when they meet ADA requirements. Reimbursement is linked to codes, and charges are typically based on Medicare rates.[6] Reimbursement is critical in generating revenue to support nurse and dietician educators who provide DSMT. Educators can be the target of cost-cutting initiatives when financial stability cannot be demonstrated.[7]

The numbers of patients who receive diabetes education are disappointingly small.[8,9] Access to education has been proposed as a barrier, particularly in communities in which the closest DSMT program may be miles away.[10] Another potential problem may be the traditional way in which education is prescribed and delivered. Currently, physicians are expected to refer diabetes patients to a hospital-based DSMT program. This process is consistent with the current system of health care delivery as it applies to acute care where services are provided at a hospital. Although more than 90% of patients with diabetes are cared for by primary care physicians (PCPs),[11] education is rarely available in the primary care office.[12,13]

Patients and physicians at University of Pittsburgh Medical Center (UPMC) identified education as a barrier to the promotion of quality diabetes care.[10] In an effort to provide education for physician practices and outlying hospitals, the UPMC Endocrine Division supported a certified diabetes educator (CDE). This provided an immediate solution, but a long-term strategy was needed for the UPMC system.

In contrast to traditional methods, the chronic care model (CCM) provides a framework for a systematic approach and has been shown to improve processes and outcomes.[14-16] The CCM is based on the premise that effective chronic disease programs are delivered in partnership with health systems and communities.[14-16] Although the CCM has been used in diabetes improvement projects, it has never been tested in facilitating DSMT programs.[10,17,19] The CCM identifies key elements that are critical to success: (1) health system, to serve as the foundation by providing structure and goals; (2) community, to link with community resources; (3) decision support, to ensure that providers have access to evidence-based guidelines; (4) self-management support, to help patients acquire skills and confidence to self-manage; (5) clinical information systems, to provide timely access to data about patients and patient populations using clinical information systems; and (6) delivery system design, to restructure medical practices to facilitate team care.

It was the objective of this study to evaluate the benefits of using all of the elements of the CCM to expand and support DSMT. The researchers hypothesized that introducing the components of the CCM would lead to increased administrative support along with improved reimbursement for services and A1C levels. By increasing the number of programs and providing DSMT in primary care, it was hoped that some of the barriers to DSMT could be curtailed, including access.

Methods

Setting

UPMC is an integrated health system that includes 19 hospitals and a physician division with 166 primary care and 1400 academic physicians providing services for approximately 90 000 people with diabetes in western Pennsylvania. Implementation of the CCM involved a stepped approach and changes at multiple levels from 2000 to 2004. This project was referred by the

Table 1

Implementation of the Chronic Care Model (CCM)

CCM Component	Activity
Community and health system	UPMC provided educators access to resources in Finance
	Information systems
	Physician practices
	Administration in community hospitals and practices
Self-management support	Nurses and dietitians educators agreed to
	Use consistent forms, educational materials, and a curriculum
	Meet the qualifications for recognition
	Facilitate DSMT to meet the ADA recognition requirements
	Monitor and report CQI processes
Decision support	UPMC supported
	The implementation of national standards for DSMT
	Fee for ADA recognition application
	A central coordinating center to support the educators
	Seminars for training and certification
	A central advisory committee with representation from physician practices, communities, and hospital sites
Clinical information systems	MARS was used to track
	Reimbursement
	Rates of DSMT services
	A1C levels by race
Delivery system design	DSMT delivered in primary care offices was facilitated by
	A CDE who worked with office staff to schedule DSMT
	A CDE who served as a clinical resource available by telephone to physicians, office staff. and patients
	Office staff who reorganized the practices to host “diabetes days”
	Physicians who made direct referrals to the CDE

UPMC = University of Pittsburgh Medical Center; DSMT = diabetes self-management training; ADA = American Diabetes Association; CQI = continuous quality improvement; MARS = Medical Archival Retrieval System; CDE = certified diabetes educator.

University of Pittsburgh Institutional Review Board to the UPMC Quality Council, where it was approved as a quality improvement project.

The CCM implemented at UMPC is outlined in Table 1. The CCM differs from traditional approaches in that it emphasizes self-management support and training.[14,15] The ADA recognition program provided the framework to implement the evidence-based DSMT standards[5] and served as the decision support. In compliance with ADA requirements, an Advisory Committee was established and became responsible for developing an annual plan, assessing the target population, and determining methods for continuous quality improvement (CQI). The Advisory Committee realized a dual purpose could be served if reports on reimbursement, access to DSMT, and A1C levels were available. These reports would serve as important CQI measures and would give UPMC

administration the feedback necessary to gain continued support.

Elements of the CCM

In 2000, the UPMC health system designated diabetes as its quality initiative and agreed to administratively support implementation of the CCM in its network of community hospitals and practices.[17]

The Medical Archival Retrieval System (MARS), a repository of information forwarded from the UPMC electronic clinical, administrative, and financial databases, was used to provide data to the educators and served as the clinical information system. MARS has been refined and validated so that diabetes patients are accurately identified by a combination of diabetes criteria, A1C levels, glucose >200 mg/dL (11 mmol/L), medications, and International Classification of Diseases, ninth revision, codes. At the time of the initiative, only 8 of 21 hospital programs had complete data that were accessible in MARS. This report includes information from those 8 hospitals and 2 primary care practices programs.

When reports of limited access were brought to the attention of the Advisory Committee, UPMC addressed delivery system design and began to implement DSMT in primary care offices in August 2003. A CDE provided DSMT at 1 suburban and 1 urban practice identified as having large populations of diabetes patients. A CDE was available on "diabetes days," when office staff scheduled DSMT appointments. Because of space constraints in the office, DSMT was delivered on an individual basis at the start of the initiative. Group visits were facilitated later on in the project when space was available.

Population

During the tracking period between January 2, 2003, and June 30, 2004, a total of 31 150 people were identified in MARS to have diabetes in the 8 hospitals with DSMT programs (Figure 1). During this time frame 4190 people were identified as having received DSMT at those hospital programs documented by a charge for service generated in MARS. To be eligible for the A1C component of this study, a person had to have their initial education session during this time frame and have at least 2 A1C levels (1 before and 1 after the initial session). Of the 4190 people receiving DSMT, 382 (9%) were eligible for tracking A1C levels. In the suburban and urban practices, 1306 patients were identified as having diabetes using the MARS criteria.

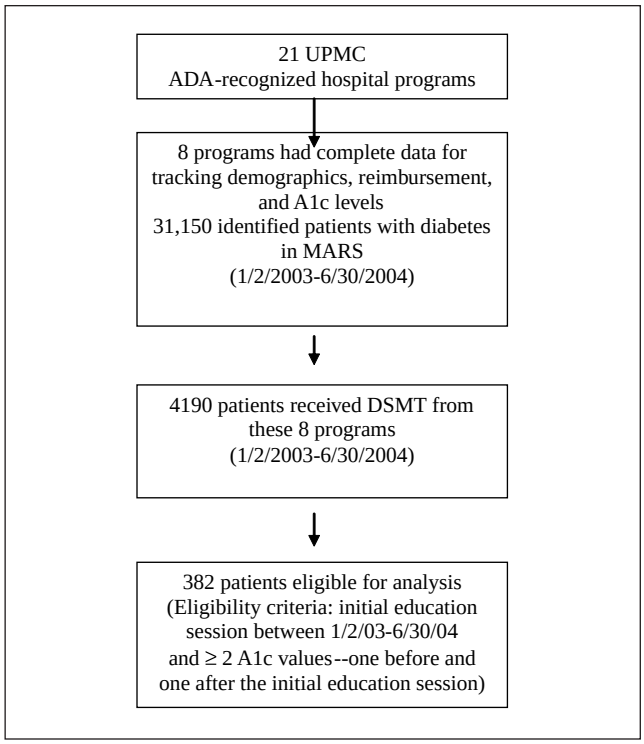

Figure 1. Monitored program populations. UPMC = University of Pittsburgh Medical Center; ADA = American Diabetes Association; MARS = Medical Archival Retrieval System; DSMT = diabetes self-management training.

Program Outcomes

Number of sites. At the start of the initiative, only 3 UPMC hospital programs had ADA recognition. Applications for additional sites were submitted throughout the initiative.

CQI Measures

Reimbursement and patient A1C levels. The tracking of reimbursement was initiated when a program received ADA recognition and bills for service could be generated. A subset of the reimbursement population was used to analyze the effect DSMT had on A1C level trends. At the time of the tracking period, the PCP offices had not

received ADA recognition and therefore could not bill for services.

Patient reach. The proportion of patients who received DSMT at 1 urban and 1 suburban primary care practice was compared to the proportion who received DSMT at the 8 hospital-based programs where DSMT services were available during the same time period (July 2003-December 2004).

Analyses. The statistical analyses incorporated both descriptive and inferential techniques. Measures of central tendency (e.g., proportions, means, standard deviations, medians, etc) were used for all descriptive analyses. In univariate analyses, Student *t* tests for continuous data and Pearson's χ^2 tests for categorical data were used to determine differences in means and proportions. In addition, for each outcome of interest, analysis of variance was used to test for differences in means between more than 2 groups, and χ^2 tests for trends were used to test for differences in proportions between more than 2 groups. To analyze the effect that education had on A1C values, a multilevel model for change was used. This type of analysis allows one to measure change over time while allowing the individuals to be their own controls. All models considered were adjusted for age.[18]

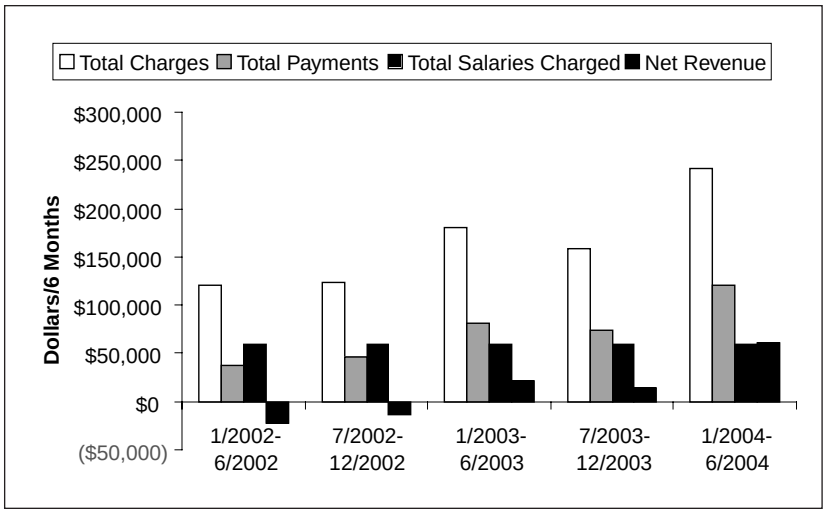

Figure 2. DSMT reimbursement and educator salary at 8 University of Pittsburgh Medical Center American Diabetes Association–recognized programs (January 2002-June 2004).

Results

Decision Support

Between 2000 and 2004, the number of ADA-recognized programs grew from 3 to 21 including pediatric, rural, academic, and 2 primary care practices.

Clinical Information Systems

MARS afforded the opportunity to track reimbursement and A1C levels. As shown in Figure 2, at the 8 DSMT hospital programs where revenue was captured, total charges in 6-month intervals increased from the beginning of the tracking period in January 2002 from $120 846.00 to $241 472.00 in June 2004. Total payment per 6 months increased from $37 192.00 to $120 572.00 over the same period. Interestingly, efficiency of collection increased from approximately 25% to 50%. Most important, diabetes educator effort was covered by the third 6-month period. Thus, at the initiation of this project, DSMT services were a loss leader. In contrast, by the conclusion, educators were more than self-supporting their efforts devoted to DSMT.

When examining patient data from the hospital programs, the mean age was 57.2 years. Patients who received DSMT at the point of service in a suburban office were significantly older than those at the urban PCP office (age: suburban = 66.2 years vs urban = 54.7 years, $P < .0001$). Patients entered the hospital DSMT programs with higher mean A1C values did those in the primary care practices (8.28% vs 7.83%). Figure 3 shows the analysis of the A1C values through 1 year after the initial education session. A mean age-adjusted decrease in A1C values in those in hospital programs (0.95%) versus primary care (0.48%) was achieved ($P = .0001$). A longer follow-up period would be necessary to determine the effects of DSMT over time.

Delivery System Design

In tracking numbers of patients who received DSMT from July 2003 through December 2004, it was found that a 2- to 3-fold greater proportion of patients were reached when DSMT was made available in PCP offices

(26.4% suburban; 19.8% urban) as compared to 8.3% of the population who were referred to hospital-based programs. Of 31 000 patients identified as having diabetes in MARS, only 13% (4190) received DSMT at hospital-based programs during the time period. Of 1306 identified diabetes patients in both the suburban and urban practices combined, 24.7% received DSMT in their PCP's office.

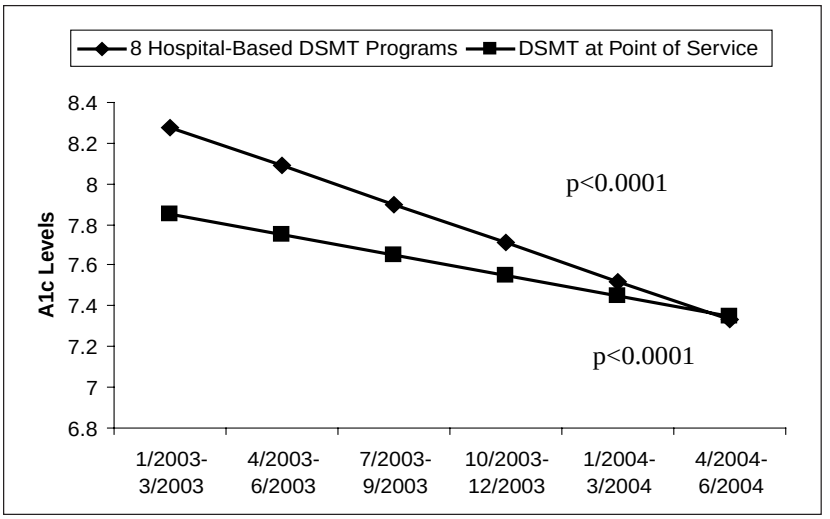

Figure 3. Age-adjusted trends in glycemic control after initial education session. DSMT = diabetes self-management training.

Discussion

In this report, it is demonstrated that the CCM is an effective framework to support DSMT, results in improved program and patient outcomes, and is fiscally self-supporting. With reliable clinical information systems, educators were able to demonstrate the benefits of DSMT delivered in different settings on A1C levels. In a fiscal environment in which hospital administrators are skeptical of services that do not generate revenue, tracking reimbursement in justifying positions was also important.

While the ADA recognition process is widely accepted, there is a paucity of literature on the delivery process, reimbursement practices, and, most important, hard outcomes. Educators in both the ADA and the American Association of Diabetes Educators (AADE) report program closings and express frustration with the implementation of Medicare benefits and receiving appropriate reimbursement.[7] The AADE and ADA collaborated to conduct a survey of DSMT programs. Their findings in 122 sites confirmed the findings of other studies that indicate that diabetes education is an underutilized service.[7-10] Nearly half of the sites reported an average visit volume of fewer than 50 visits per month, and 19% reported only 51 to 100 visits per month. More disappointing were the reimbursement practices. Of the sites that bill Medicare, only 57% were collecting the mandated collection fees, while 37% of the respondents did not even know how often they were collecting these fees.[7] Despite attempts to remedy this problem, only 57% reported having a fiscal reporting system. The ADA and AADE concluded that processes for monitoring billing and establishing a reporting system specific to DSMT were critically important.[7]

The authors took this message seriously and created a system to explore and satisfy these recommendations. Through the repository, educators had the opportunity to monitor reimbursement. UPMC education and billing staff members collaborated and reviewed monthly reports to determine payment practices. Although Pennsylvania mandates coverage for education, compensation for services was not always provided. As reported by others,[7] in addition to external reimbursement difficulties, numerous internal problems were identified throughout the system that precluded reimbursement. Education charges based on Health Care Common Procedure Coding System codes were inaccurately entered, recognition certificates were missing, and charge-entry staff neglected to enter charges. Once these problems were identified, internal efforts to correct the problems and capture reimbursement were implemented.

The authors were also eager to increase their DSMT services and realized that they needed to improve access. An important innovation was that they went beyond traditional models of DSMT delivery as a result of their system redesign; by integrating educators directly into offices, access to DSMT increased. It was demonstrated that DSMT delivered in the office has a positive effect on A1C levels along with PCPs and educators reporting other advantages that included increased communication

on management plans and CDE involvement in medication initiation and adjustments. Patients reported greater comfort with location and easy access to the educator for questions and problem solving. The intent is not to suggest that hospital-based programs be replaced or eliminated but that opportunities to support education and follow up in other settings are investigated.

To the best of the authors' knowledge, this project is the first to systematically develop a DSMT network using all of the elements of the model and report on ADA recognition and reimbursement practices. The CCM has been tested and shown to improve outcomes.[14,15] However, much of the research has focused on specific components of the CCM model, and evaluations of an overall plan are less frequent. More recently, Wagner et al[20] performed a survey and site visits of 72 chronic disease management programs that were considered to be innovative and effective. Only 1 program had instituted all 6 components of the model.

The limitations of the project are recognized. The UPMC diabetes initiative is in its infancy. As the project evolves, each of the components of the CCM continues to be developed and refined. For example, not all of the DSMT programs were linked to the data repository during the initiative.

Another weakness is that the researchers were unable to effectively track all hemoglobin A1C levels throughout the project. Patients may have had laboratory tests done elsewhere. It is recognized that factors other than DSMT may have influenced improvements in glycemic control and that A1C levels are not the only indicator for quality.[21] Other medical interventions and outcomes must be controlled for and captured in future studies.

It is recognized that reimbursement needs to increase to fully support an educator's salary. Now that billing practices have been remedied and new avenues for access have been identified, UPMC will move more educators into primary care practices, increase group visits, and begin an aggressive DSMT promotional campaign in its communities.

Although this study was performed in a large health system with access to many resources, it serves as a model for others to explore creative solutions. It provides a template for educators to explore collaboration with heretofore unlikely partners in administration, finance, and information systems and to create opportunities outside of traditional roles, such as the development of business models for sustainability. Smaller and independent facilities may seek opportunities to share data systems or form consortia to organize systemwide recognition applications. Hospital-based educators could partner with primary care practices to provide follow-up education in an office and seek creative methods for billing for services. Innovative technological methods, virtual teams, and community-based education afford other exciting opportunities that need to be tested. First and foremost, educators and physicians need to be open-minded to consider areas for change.

Developing systems that promote accessible, sustainable DSMT programs that affect metabolic outcomes have large- scale public health implications. Organizing efforts to support the facilitation of DSMT is critical in meeting the *Healthy People 2010* education objectives.

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Appendix N

Deliverables #218-221: Final Report on the Implementation and Evaluation of the AADE Outcomes Tool at 59 MDW

Appendix N

Title: Diabetes Prevention and Treatment Programs for Western PA
Contract No. W81XWH-04-2-0030

Sub-project Title: 59th Medical Wing Diabetes Outreach Clinic (DOC)

Goal:
1. To deploy and evaluate a theory-based, education program based on the American Association of Diabetes Educators (AADE) Outcome program

3. To establish sustainable diabetes education programs for 59 MDW

Deliverable: 1.2 Diabetes Self-Management Education

Submission Date: Dec. 11, 2008

Deliverable No: **218, 219, 220, 221**

Appendix N

1.2 Diabetes Self-Management Education

Goal 1 To deploy and evaluate a theory-based, education program based on the American Association of Diabetes Educators (AADE) Outcome program

Final report on the implementation and evaluation of the AADE Outcomes Tool at 59 MDW

Background

Although diabetes self-management education (DSME) is recognized as a critical component of diabetes care [1], systems that help to define, measure and collect relevant data on education outcomes, that specifically include elements of behavior change are not available. Educators in the American Association of Diabetes Educators (AADE) (of which both UPMC and military educators are members) determined that comprehensive efforts in defining, measuring, collecting, and reporting of diabetes education outcomes for advancing the practice of diabetes self-management education (DSME) were needed. Both external environmental influences and organizational efforts converged in guiding the activities that resulted in the AADE Outcomes Project. A description of the project activities, the components developed and their application to diabetes education practice are described in the attached AADE/UPMC publication: *Evolution of the American Association of Diabetes Educator (AADE): Diabetes Education Outcomes Project* [2].

Project History

As has been reported in a series of communications, there have been challenges in executing a reasonable agreement with the American Association of Diabetes Educators (AADE). The content development for the AADE Outcome System was under a separate agreement between the AADE and UPMC prior to the DOD award. After the content was developed, in our previous efforts the AADE System was evaluated and validated by UPMC and reported. National publications and presentations (attached) summarize the findings of the evaluation and have been previously submitted [2-5].

During the evaluation process in UPMC and PRIDE communities, UPMC determined that the AADE System was cumbersome, necessitated that the patient spend an extensive amount of time completing the tool (minimum 20 minutes) and required the addition of clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools. The findings of the process evaluation and the challenges for users of the tool were communicated to AADE. AADE leadership and UPMC agreed that without the additions, the System was not robust and would not be useful in helping the diabetes educator in capturing necessary and relevant data. AADE agreed that they would shorten the tool (based on the process evaluation) on a separate agreement with another vendor. In recognition that these components were critically important to the development of any diabetes education system tool, UPMC developed these systems (clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools) for use by educators serving both civilian and military populations.

To date, the revised AADE Outcome System is unavailable. However, it is UPMC's understanding that AADE is pursuing the revision and in an agreement between AADE and UPMC, the AADE agreed that on completion of the revision of the AADE Outcome System, it will be made available to PRIDE and WHMC sites under a license for 10 years.

Appendix N

In discussions (and through demonstrations) with the PRIDE and WHMC teams, it was agreed that the numerous challenges and delays in using the AADE System were unacceptable. There is a critical need for an education system tool and relying on the final development and release of the AADE System was affecting workflow and completing important efforts on the project.

Recommendations and Status

Thus, it was agreed that a system that included the already developed clinical management, medication and UPMC assessment, goal setting, and educator documentation be expanded and developed into a user-friendly comprehensive system. The UPMC team is actively developing the education tool with input from PRIDE and AF educators that meets the needs of both civilian and military populations requiring education. This system is being created in collaboration with the American Diabetes Association. WHMC staff has been apprised of the developments. A beta version will be available in Jan. 2009.The projected date for completion of this Education System is Feb. 2009.

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Appendix N

Goal 2 -removed

Goal 3 To establish sustainable diabetes education programs for 59 MDW

Background

Diabetes self-management education (DSME) is widely considered to be an important part of diabetes management [1]. Among the goals of *Healthy People 2010*, one is to increase the number of people who receive diabetes education from 40% (1998) to 60% (2010) [2]. The National Standards for DSME [3] administered through the ADA recognition program [4] provide a framework for delivery and quality.

Medicare and other third-party payers reimburse for programs when they meet ADA requirements. Reimbursement is linked to codes, and charges are typically based on Medicare rates [5]. Medicare (requires that in order to bill for DSME, programs must meet the National Standards for DSME and be approved through the American Diabetes Association Recognition Program. Education charges are based on Health Care Common Procedure Coding System (HCPCS) "G" codes.

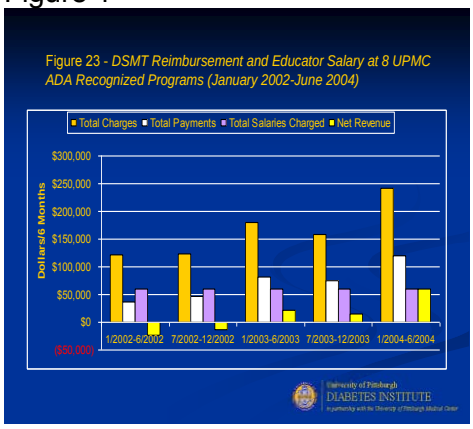
In a fiscal environment where health care administrators are skeptical of services that do not generate revenue, tracking reimbursement in justifying positions is critically important. Reimbursement is critical in generating revenue to support nurse and dietician educators who provide DSME. Educators can be the target of cost-cutting initiatives when financial stability cannot be demonstrated.

The American Association of Diabetes Educators (AADE) and ADA collaborated to conduct a survey of DSME programs. Their findings in 122 sites were disappointing in regards to reimbursement practices. Of the sites that bill Medicare, only 57% were collecting the mandated collection fees, while 37% of the respondents didn't even know how often they were collecting these fees [6]. Despite attempts to remedy this problem, only 57% reported having a fiscal reporting system. ADA and AADE concluded that processes for monitoring billing and establishing a reporting system specific to DSME were critically important [6].

In our previous work at UPMC, we responded to the AADE and ADA call to action and monitored and reported reimbursement practices [7]. Most states, including Pennsylvania and Texas, mandate coverage for diabetes self-management education (DSME). We demonstrated that UPMC diabetes educators were able to use a reporting system to monitor reimbursement. UPMC education and billing staff collaborated and reviewed monthly reports to determine payment practices. As reported UPMC educators were able to demonstrate their ability to generate revenue to the health system. At the 8 DSME programs included in the project where revenue was captured, total charges increased from the beginning of the tracking period in January, 2002 from $120,846.00 to $241,472.00 in June, 2004. Total reimbursement increased from $37,192.00 to $120,572.00 over the same period (Figure 1). Furthermore, each of the 8 sites had one educator who estimated that 25% of his/her time was spent on outpatient DSMT. Educators often had other duties that included inpatient education, clinical responsibilities and staff development. At the time of the initiative, UPMC educator salaries were approximately $60,000 (including benefits). This equates to $120,000/year ($60,000/monitored six month period) for educator salaries (.25 Full Time Exempt) devoted to DSMT in the 8 programs. As shown in Figure 1, at the initiation of

this program DSMT services were a lost leader. In contrast by the conclusion, diabetes educators were entirely covering their costs [7].

Figure 1



We attempted to apply these principles and lessons learned to the 59 MDW Diabetes Education Program. The first essential step was to apply for ADA DSME Recognition. ADA approval for WHMC was received May, 2007. (Certificate attached)

Lt. Col. Nina Watson (ret) WHMC and Janis McWilliams, UPMC explored opportunities to bill for DSME services. In their investigation, they have learned that Tricare (and other government agencies like the Veteran's Administration) do not have the capabilities in their respective billing systems to charge against a HCPCS G code for DSME. Inability to charge against G codes prohibits charging for the service.

Summary report on the billing processes implemented for diabetes self-management education to assure future reimbursement (UPMC and 59 MDW)

As indicated in above, billing processes cannot occur without the related coding. Lt Col Watson and Janis McWilliams continue to explore charging capabilities and opportunities.

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Appendix N

Copy of the CV of the Pediatric Diabetes Educator hired for 59 MDW

As reported in numerous communications, UPMC has been unsuccessful in retaining the services of a pediatric diabetes educator. A number of recruitment strategies that include publishing notices in professional journals, job fairs, posting in facilities that attract recent military retired health professionals, seeking outside service agencies, newspaper advertisements have been used with no success. A number of reasons for the inability to attract/recruit candidates for this position have been speculated that include: a national nursing shortage, a limited number of diabetes educators available in the US (particularly those with a pediatric specialty), low pay grade. Subsequent meetings with pediatric AF medical team have included discussions regarding potential abandonment of this requiring this position with the years of unsuccessful attempts. The USAF has asked that UPMC continue efforts. UPMC is continuing efforts by exploring other agencies that service recruitment for military bases.

Appendix N

Copy of assessment of market reach and expansion opportunities for the DSME program at 59 MDW

Within the application for the American Diabetes Association Recognition Program for Diabetes Self-Management Education (DSME), an assessment for market reach is required. Documentation of market reach must be included in DSME Advisory Board minutes. Attached is the Advisory Board minutes from WHMC (highlighted area of market reach report) that were submitted and approved by the ADA.

In subsequent "Go Team" assessments, education expansion opportunities were identified for Randolph, Kelly, Goodfellow and Laughlin bases. Education needs will be supported by hub services provided through the WHMC Center of Excellence. Complete description of focus group interactions are in a previously submitted report (Small Base Outreach Project Planning Deliverable submitted 10-08).

Evolution of the American Association of Diabetes Educators' Diabetes Education Outcomes Project

Malinda Peeples, Donna Tomky, Kathy Mulcahy, Mark Peyrot, Linda Siminerio and on behalf of AADE Outcomes Project and AADE/UMPC Diabetes Education Outcomes Project

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DOI: 10.1177/0145721707307615

Purpose

This is the initial article in a series that describes a multi-year project of a professional membership organization to define, standardize, collect, and report the outcomes of diabetes self-management education. The purpose of this article is to describe and summarize the contributions of each phase of the project: determining a conceptual framework, developing and testing measurement instruments, defining outcome standards for diabetes self-management education, and implementing a technology approach to capturing the outcomes.

Methods

Association archives, project participants, presentation slides, and published articles provide the historical information that is presented in this article.

Results

Evidence for diabetes education as an intervention has been demonstrated, but key questions remain about what settings and which interventions, provided by whom and over what period of time, produce what outcomes. This project integrated diabetes education outcomes reporting into a system of diabetes care through the development of measurement methods and a data collection system for patients and educators at the point of service.

Conclusions

The AADE7™ Outcomes System supports educators in collecting and reporting on program design, patient self-care behaviors, and educational, behavioral, and clinical interventions and outcomes.

The American Association of Diabetes Educators (AADE) has led a comprehensive effort in defining, measuring, collecting, and reporting of diabetes education outcomes for advancing the practice of diabetes self-management education (DSME). Both external environmental influences and organizational efforts converged in guiding the activities that resulted in the AADE Outcomes Project. The purpose of this article is to reflect on the project's activities, describe the components developed, and highlight the contribution to diabetes education practice.

Health Care Environment

Diabetes education has long been cited as a cornerstone of effective diabetes care, and self-management education is seen as an essential aspect to any chronic care model.[1-3] The National Standards for Diabetes Self-management Education were first developed and published in 1986.[4] Revisions and updates to these standards have occurred in the years 1995,[5] 2002,[6] and 2007.[7] Yet in 1997, when the diabetes community was challenged by the Health Care Financing Administration, now the Centers for Medicare and Medicaid Services, to demonstrate the effectiveness of DSME programs, there were no national outcomes data to present. Nor was AADE able to provide specific measures of effective diabetes education in response to the Balanced Budget Act of 1997, which mandated reimbursement for diabetes self-management training. Lack of standardized measurements, data collection tools, and effective reporting systems had resulted in a paucity of outcomes data.

AADE Organizational Issues and Leadership

In 1997, AADE leaders recognized the critical importance of establishing a unique measurement set for diabetes education and thus established the Outcomes Task Force (OTF). Based on expert consensus and a comprehensive review of the literature, the OTF recommended that health-related self-care behavior changes be considered the unique and measurable outcomes of diabetes education.[8] Recognizing that DSME is one component within a complex diabetes health care delivery system, the task force recommended capturing additional clinical and program outcome measures when feasible.

In 1998 to 1999, the expanded OTF included researchers, educators, clinicians, and measurement and quality consultants, as well as representatives from the American Diabetes Association and the National Certification Board for Diabetes Educators. The OTF was charged by AADE leadership to

1. establish standardized outcome measures that can be used across a variety of educational practice settings by individual diabetes educators,
2. support the evolution of diabetes education from a content-driven practice to an evidence-based practice that focuses on behavior rather than curriculum, and
3. develop a system to support the educator in the collection and reporting of the outcomes. These outcome reports should contribute to quality improvement activities and data collection for demonstrating the value of diabetes education and diabetes educators.

Task force participants represented the various disciplines, practice settings, and geography of the AADE national membership. The work of the OTF became the foundation for the National Diabetes Education Outcomes System (NDEOS).

Project Overview and Phases

The AADE Outcomes Project's timeline began in 1997 and continues today with ongoing research, development, and evaluation. The overarching purpose of the project is to facilitate the collection of standardized outcome measures across a variety of educational practice settings as well as to support the evolution of the practice of diabetes education from a content-driven to an evidence-based practice.

The Outcomes Project, supported by AADE and industry allies, was developed, implemented, and evaluated by diabetes educators, researchers, and patients in real-life diabetes education practices. All testing integrated written protocols, with evaluations performed at

each phase of the project. This article summarizes activities and key lessons learned from each of the 4 phases of the project:

1. conceptual framework,
2. instrument development and testing,
3. diabetes education outcomes standards, and
4. technology implementation.

In Appendix A, the project phases and timeline are described in detail. Appendix B lists the diabetes education programs that participated in each phase of the testing and development. Appendix C acknowledges the many volunteers who contributed to the project work.

Phase 1: Conceptual Framework

The project integrated the theoretical constructs of systems theory and Donabedian's[9] quality assurance framework of structure, process, and outcomes to support the perspective that diabetes education and educators are part of the diabetes care system. To effectively measure DSME activities and outcomes, data must be collected that captures program characteristics (structure), describes the interaction between the patient and educator (process), and measures the impact of the intervention through clinical and patient-centered outcomes (outcomes).

Diabetes program evaluation is challenging because the educational intervention varies based on program design, the frequency of patient contact is not standardized, and educators have varying degrees of responsibility in clinical management of patients. The Outcomes Project team addressed this complexity through a structured systems analysis of the diabetes care system from the perspectives of the diabetes educator, the patient, and the education program. The NDEOS components for patient, educator, and program were identified as a result of this analysis process. Using a behavioral framework, which would later become the AADE7™ Self-Care Behaviors, and incorporating the processes of diabetes education, clinical management, and patient self-management, instruments were developed for the NDEOS.[10]

Phase 2: Instrument Development and Testing

After defining the conceptual framework and process for outcomes measurement, it became apparent there was a lack of consistently used measures and instruments/tools for capturing outcomes. Defining a uniform, basic, and minimum data set for DSME outcome measures was critical in developing instruments and collecting standardized data.[11]

The conceptual framework of structure, process, and outcomes as well as multiple behavioral theories informed the instrument design. Taking the outcomes framework one step further by defining the Diabetes Outcomes Continuum provided more detail for developing instruments and reports (see Figure 1). Three instruments were developed for collecting, measuring, analyzing, and reporting on patient self-management (D-SMART®), educator interventions (D-ET®), and program structure (SRF®).

The Diabetes Self-management Assessment Report Tool (D-SMART®) was developed to assess behavior change and to develop an individualized patient DSME plan. The instrument has a dual purpose: gathering information regarding (1) patient-reported behavior and behavior change goals and (2) health history and demographics. See the "Development of the American Association of Diabetes Educators' Diabetes Self-management Assessment Report Tool" in this issue of *The Diabetes Educator* for a full description of the instrument and its development.[12]

The Diabetes Educator Tool (D-ET®) was developed to document the process for delivering DSME. This instrument captures the identity of the persons delivering DSME (personal identifier and discipline) as well as the dose (visit number, time) of DSME and the specific services delivered (content area, behavioral/educational strategies, group/individual format, etc). The D-ET is designed to capture the services delivered in response to patient behavioral self-reports and behavior change goals, organized in terms of the domains of the AADE7 Self-Care Behaviors. In addition, the D-ET provides an opportunity for the educator to record medical information about the patient (medications, allergies, laboratory and examination test results) and the educator's assessment of the patient's needs and progress. Educator contributions to clinical co-management such as ordering of tests, referral of patient for appropriate examinations, and adjusting of medications per protocol are captured.

The Site Registration Tool (SRF®) is completed by the program director, manager, or person responsible for the diabetes education services. The SRF is designed to obtain information about the structure of the program, which can be used in providing reports to external

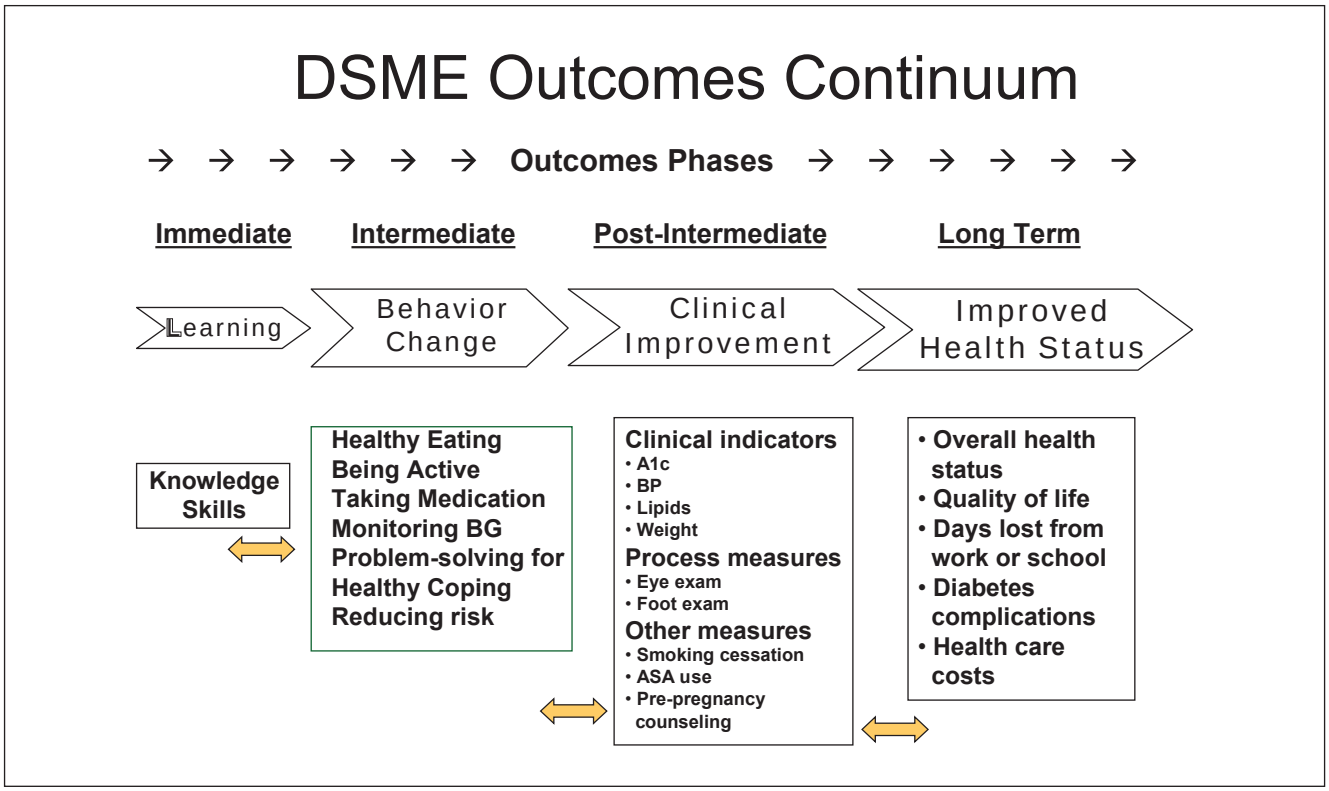

Figure 1. Diabetes Self-management Education Outcomes Continuum (BG indicates blood glucose; BP, blood pressure; and ASA, aspirin)

Based on Mulcahy K, Maryniuk M, Peeples M, Peyrot M, Tomky D, Weaver T, Yarborough P. Diabetes self-management education core outcome measures. Diabetes Educ. 2003;29:768-803.

constituencies (eg, funding organizations, regulatory agencies, certification bodies). Eventually, it will be possible to use this information in selecting benchmarks for comparison.

All 3 tools are integral for defining and developing meaningful reports. The Outcome Project Team defined and developed outcome reports to address 3 levels of reporting: individual, program, and cross-program levels.

The individual-level report represents data that are collected, analyzed, and reported at the point of service. Those reports inform (1) patients about their health status, goals, and behavior change; (2) educators about patient assessment information to guide interventions, serve as a documentation tool, and enable communication with the team; and (3) referring providers who receive communication regarding patient and educator activities.

The program-level report aggregates individual outcomes on a real-time or periodic basis to help the educator understand how the program operates and what population is served and to facilitate continuous quality improvement efforts. At this level, reports inform (1) patients about how their data compare with the local population of people with diabetes, (2) program directors about operational functions and what enhancements or changes could benefit patient outcomes, and (3) internal and external customers about operational and patient data as required by the customer (eg, data requirements of the Health Plan Employer Data and Information Set, Diabetes Quality Improvement Project, Joint Commission on Accreditation of Healthcare Organizations).

The national-level report (across programs or regions) aggregates and analyzes data from multiple diabetes centers to improve diabetes education and care. At this level, reports provide (1) patients with a view of their data compared with the national population with diabetes; (2) program directors with benchmarked data for comparison with other programs at the state, regional, or national level to improve quality of care at

the local level; and (3) evidence-based outcomes that will drive effective advocacy with policy makers for integrating diabetes education as a critical component of diabetes care.

Phase 3: AADE Standards Development for Outcome Measurement

Standards for diabetes self-management programs in existence since 1986 have directed outcomes collection, but there has been little specificity to the process. In 2002, as a growing national awareness of the value of outcomes was developing, a core group of educators developed the AADE Standards for Outcome Measurement of Diabetes Self-management Education using information gained through testing of the NDEOS tools, educator feedback, and an extensive review of the literature. These standards were reviewed by a representative group of diabetes experts and published in 2003.[13]

The outcomes standards consist of 5 standards that direct educators to measure behavior change as well as clinical and health status outcomes at regular intervals:

- Standard 1: Behavior change is the unique measurement for diabetes self-management education.
- Standard 2: Seven self-care behaviors determine the effectiveness of diabetes education at the individual and population participant levels.
- Standard 3: Diabetes self-care behaviors should be evaluated at baseline and then at regular intervals after the educational program.
- Standard 4: The continuum of outcomes including learning, behavioral, clinical, and health status should be assessed to demonstrate the interrelationship between DSME and behavior change in the care of individuals with diabetes.
- Standard 5: Individual patient outcomes are used to drive the intervention and improve care for the patient. Aggregate population outcomes are used to guide programmatic services and for continuous quality improvement activities for the DSME and the population services.

The standards direct baseline and repeated measurements to assess the impact of DSME for individual patients as well as programs or populations. DSME program design varies widely, and the use of standardized measures provides a framework for evaluating practice consistently. The full publication of the AADE Outcome Standards is included in this journal, but 3 concepts need to be highlighted: the outcomes continuum, the AADE7™ Self-Care Behaviors, and integration with the National Standards for DSME.

Outcomes continuum: learning, behavior, clinical, and health outcomes. The AADE Standards for Outcome Measurement for DSME specify behavior as the primary outcome. However, the standards acknowledge the importance of other outcomes and conceptualize these outcomes as part of a continuum from immediate to long term (see Figure 1). Prior to the development of the standards, learning outcomes were often thought of as primary outcome of diabetes education. With the identification of behavior as the primary educational outcome, learning goals were reconceptualized as important only to the degree that they contribute to behavior change; learning that does not help patients better manage their diabetes is irrelevant. Clinical and health outcomes also had been proposed in the past as primary outcomes of diabetes education. The national outcome standards acknowledge the importance of these goals but regard them as a consequence of achieving the primary outcome; patients who improve their self-care behavior should experience improved clinical and health outcomes. However, these outcomes can be influenced by factors that are not subject to the direct impact of diabetes education (eg, prescribed medication regimens, lack of financial resources to purchase medication, equipment, and supplies).

AADE7™ Self-Care Behaviors. Evolving from the work of the AADE Outcomes Project, the framework of the AADE7 Self-Care Behaviors was incorporated into the outcomes standards. The 7 behaviors were identified by the Outcomes Task Force in 1997 and resulted from mapping with the 15 content areas from the 1995 National Standards for DSME, a review of literature, and expert consensus. See Table 1 for the link between the standards and the behaviors.

Many research instruments traditionally measured 1 to 3 behaviors,[14] but the expert group identified that addressing all 7 behaviors was important as part of the patient assessment and educator's intervention skill set. While all should be assessed, educator interventions should be tailored to self-care behaviors identified through shared decision making with the patient and educator.

Table 1

Mapping of the 1995 National Standards for DSME, 2003 AADE Outcomes Standards, AADE7 Self-Care Behaviors™, and 2007 National Standards for DSME

1995 DSME Content Areas (15)	2003 DSME Behavioral Outcome Areas (7)	AADE7 Self-Care Behaviors	2007 DSME Content Areas (9)
Exercise/activity	Physical activity (exercise)	Being active	Incorporating physical activity into lifestyle
Nutrition	Food choices (eating)	Healthy eating	Incorporating nutritional management into lifestyle
Monitoring	Monitoring of blood glucose	Monitoring	Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making
Medication (oral and/or insulin)	Medication administration	Taking medication	Using medication(s) safely and for maximum therapeutic effectiveness
Prevention, detection, and treatment of acute complications	Problem solving for blood glucose: highs, lows, and sick days	Problem solving	Preventing, detecting, and treating acute complications
Appropriate monitoring and use of results			
Benefits, risk, and management options for improving glucose control			
Stress and psychosocial adjustment	Psychosocial adaptation	Healthy coping	Developing personalized strategies to address psychosocial issues and concerns
Family involvement and social support			
Prevention, detection, and treatment of chronic complications	Risk-reduction activities	Reducing risks	Preventing detecting, and treating chronic complications
Foot, skin, dental care			NOTE: These 2 content areas are present with each self-care area:
Preconception care			
Use of health care systems and community resources			Describing the diabetes disease process and treatment options
Risk factor reduction			Developing personalized strategies to promote health and behavior change

Abbreviations: AADE, American Association of Diabetes Educators; DSME, diabetes self-management education.

The standards provided a definition of each patient self-care behavior, the importance of the specific behavior to diabetes self-management, and optional measurement approaches. Over time, the behavior domains have evolved into the AADE7 Self-Care Behaviors and have become a common, standardized language for talking about measurement for patient-centered self-management (Figure 2).

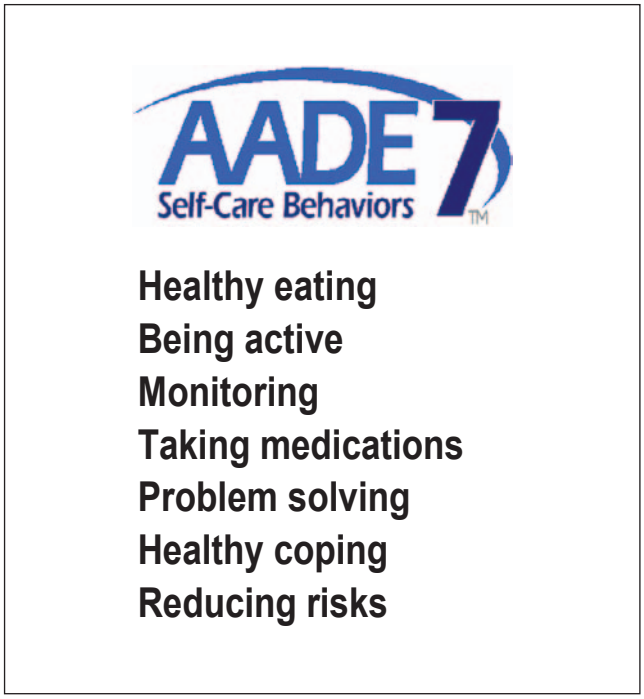

Figure 2. AADE7™ Self-Care Behaviors.

AADE outcomes standards complement the National Standards for DSME. As the work of the AADE Outcomes Project evolved over time, various diabetes organizations participated and provided a review of the project. The outcomes standards were developed as an extension of the 2000 National Standards for DSME (Standard 10), "the DSME entity will utilize a continuous quality improvement (CQI) process to evaluate the effectiveness of the education experience provided, and determine opportunities for improvement." Figure 3 depicts the relationship of the outcomes standards to the 2000 National Standards for DSME.

Program evaluation is a process that leads to the identification of issues that should be addressed as part of a quality improvement effort within the program.[15] Central to measuring quality improvement is the ability to have variables that are measured consistently, longitudinally, and at appropriate intervals. The outcome standards direct educators to capture consistent measurements at specific time intervals and use these to guide or support interventions at an individual level as well as aggregate data and begin to build an evidence base for best practices in diabetes education.

Phase 4: Technology and System Design

During the development and testing of the instrument, information technology was considered a part of the solution to supporting the educator in the collection and reporting of outcomes. While many educators used the pencil-and-paper method to record patient and program activity, it was not efficient nor would it ever support any level of benchmarking or program comparison reporting. As the project moved forward, guiding principles included the recognition that to serve educators effectively, the outcomes system should support data collection at the point of service and serve as the documentation for the intervention, avoiding the need for redundant data entry. In addition, patient self-assessment prior to the educational intervention could provide data for education planning and intervention at the time of the visit.

During the past 10 years, technology has become ubiquitous, and educators and patients have become quite skilled in its use. As the project phases have evolved, different types of technology have been tested and integrated into the project. The pilot testing of the D-SMART®, the initial validity testing of the D-SMART®, and field testing of the patient and educator tools used scan technology. While this data acquisition method was acceptable for instrument testing, it was not user friendly for patients and educators or efficient for program reporting.

Technology implementation. Since the fall of 2004, an academic partner has been collaborating with AADE to advance the technology development and implementation of the AADE7™ Outcomes System, previously known as the National Diabetes Education Outcome System (NDEOS). Educators, researchers, and technology vendors are collaborating to implement the system in 5 stand-alone DSME programs.

The AADE7 Outcomes System is a complete Web-based system of standardized measures, measurement tools, and reporting for individual, program, and national level outcomes of diabetes education. Patient information is gathered via a number of methods, including Web-based forms, an automated phone system, touch-screen kiosks, or optical scan forms. All of the gathered data are consolidated to the central data repository (SQL database) via Health Insurance Portability and Accountability Act–compliant, secure Web services, where it can be reviewed and used. Patient information

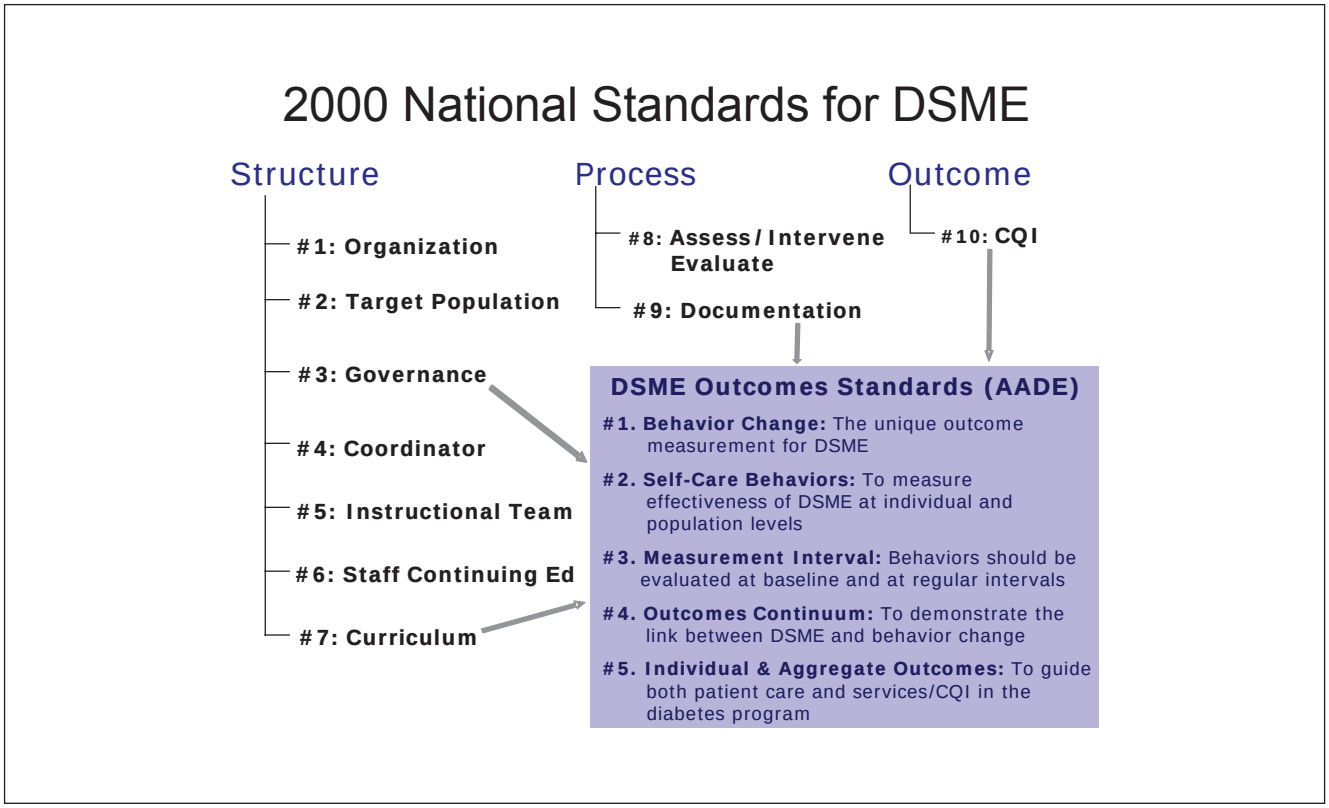

Figure 3. 2000 National Standards for Diabetes Self-management Education (DSME) and 2003 DSME outcome standards. CQI indicates continuous quality improvement; AADE, American Association of Diabetes Educators; and DSMT, diabetes self-management training.

is gathered at baseline from the patient, with all data being date stamped for future reference. Educators enter information post intervention to augment the patient's record and document the intervention. To streamline data entry, class/group education sessions can be entered once and applied across all of the attending patients. Subsequent data are added to the record by the patient and educator through follow-up sessions. The vision of the system, which is currently being implemented, is to acquire longitudinal data on diabetes education programs and ultimately benchmark diabetes education program characteristics, educator delivery methods, and patient and program outcomes. See Figure 4 for a schematic of the system.

As with any information technology project, technical, workflow process integration, people, and organizational issues had to be addressed to move the system to implementation. The evaluation of the system and tools is guiding project revisions and will be detailed in forthcoming articles.

Current and Future Applications

As this project has developed over the past decade, AADE and the participants have identified and developed various applications using the project framework at the association level, for diabetes education practice, and in diabetes education research (Figure 5).

Association Level

At AADE national, the AADE7™ Self-Care Behavior framework has been adopted as a nomenclature for talking about self-care behavior and the role of the educator in supporting patients to consider behavior change. In

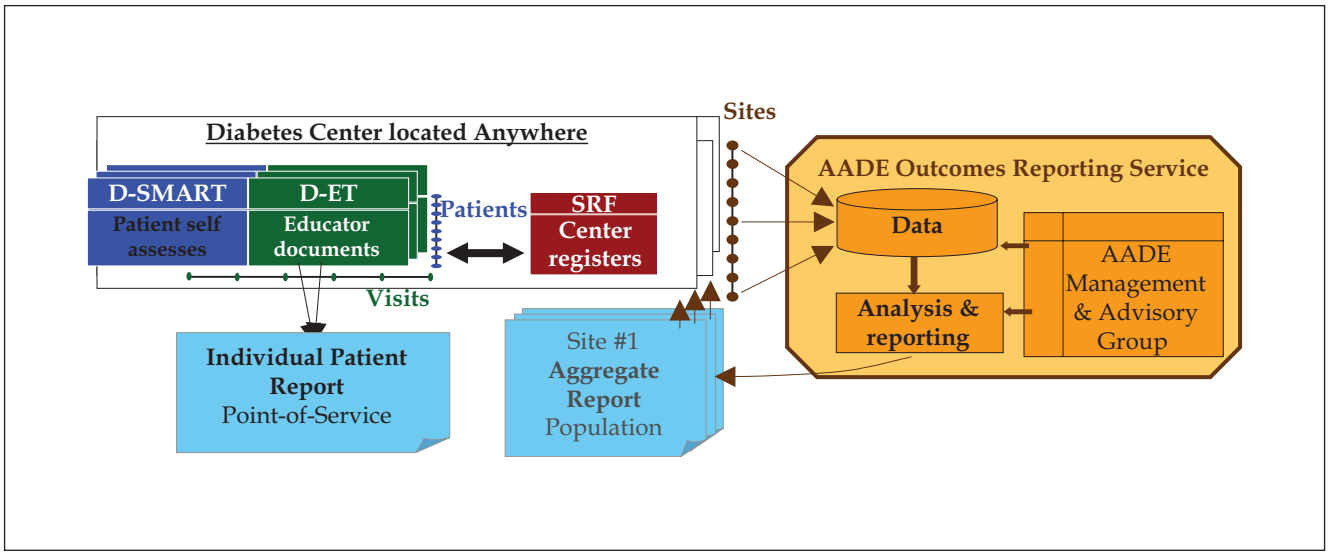

Figure 4. AADE7™ Diabetes Outcomes System. This is an American Association of Diabetes Educators (AADE) service for supporting educators in collecting data at the point of care. Participants in the outcomes system will collect data at the diabetes education program site and transmit it in a standardized data format through a variety of Health Insurance Portability and Accountability Act–compliant, secure technologies to a centralized database/repository. The data are then analyzed using sophisticated statistical methods. Program, population, and outcomes reports will be generated and available to the program site and for cross-program comparisons. D-SMART indicates the Diabetes Self-management Assessment Report Tool; D-ET, Diabetes Educator Tool; and SRF, Site Registration Tool.

2006, AADE adopted the chronic care model[16] and is using this as a foundation for integrating self-management education into chronic care. Using the AADE7 Self-Care Behaviors as a common language for talking about self-management not only for diabetes but also for related conditions supports improving chronic disease care.

The publication of the Diabetes Education Outcome Standards in 2003 positioned the organization as a key voice nationally and internationally in discussions about diabetes education outcomes. In 2006, as the National Standards for DSME were being revised by the diabetes community, the AADE Diabetes Education Outcomes Standards were incorporated into the 2007 National Standards for DSME: Standards 9 and 10.[17]

One component of the AADE7 Outcomes System (the Site Report Tool™) was used to form the basis for the National Practice Survey, the first national survey to describe diabetes education programs. In June 2005, July 2006, and June 2007, the National Practice Survey was administered and information gathered on the evolving practice of diabetes education among the AADE members.[18]

In 2006, AADE determined that educators had sufficient access to technology and that there was a perceived need for educators to have some Web-based tools for use. To validate this and to provide a market test for the feasibility of making the suite of AADE7 Outcomes System tools available to educators, AADE launched AADE7 IMPACT™ at the 2006 AADE annual meeting. AADE7 IMPACT is a Web-based service that supports behavioral goal setting and provides templates for communication with patients and providers.

Practice Level

Diabetes educators are adopting the DSME outcomes framework in daily practice. Most notably embraced are the AADE7 Self-Care Behaviors for assessing current behaviors, identifying barriers, and facilitating problem solving. This allows for targeted behavioral interventions and goal setting with patients. On follow-up visits, measuring and monitoring of behavior change and clinical indicators support the educator's evaluation of outcomes. A simple method of tracking, measuring, and documenting AADE7 Self-Care Behavior goals is available in paper format (www.aadenet.org). The AADE7 Outcomes System supports measuring, monitoring, and tracking behavioral

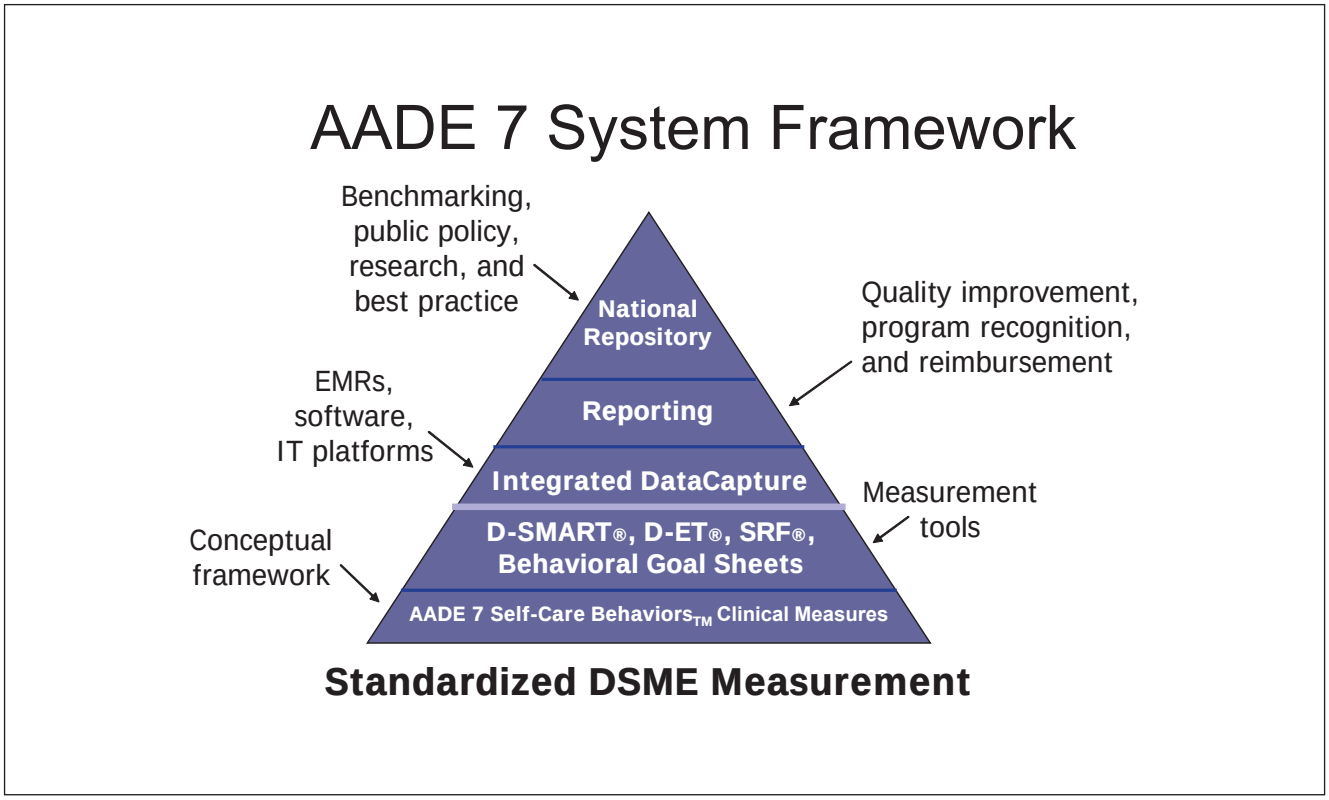

Figure 5. Framework for standardized diabetes self-management education (DSME) measurement. AADE indicates the American Association of Diabetes Educators; EMR, electronic medical record; IT, information technology; D-SMART, the Diabetes Self-management Assessment Report Tool; D-ET, Diabetes Educator Tool; and SRF, Site Registration Tool.

and clinical outcomes needed for program evaluation and reporting for regulatory purposes. At a program level, benchmarking data will support refinement of program design including frequency of patient visits, follow-up, and other support for patient self-management.

A future approach for tracking program DSME outcomes is integrating the AADE Outcomes Project tools into electronic medical records. Learning from this project about the challenges of collecting clinical data as part of the care process will be useful in achieving this goal. Providing a standardized approach to integrating behavioral assessments and interventions into the existing clinical record will better support chronic disease care. Defining required and desired reports will be important for understanding interventions that can be identified and applied to appropriate populations and for outcomes that are critical to various customers.

Research Level

Over time, the AADE7™ Outcomes System has evolved as a standardized approach to diabetes education outcome measurement and is providing a foundation for the building of an evidence base for diabetes education practice. In this regard, the AADE Research Committee has coordinated the systematic reviews of each of the AADE7™ Self-Care Behaviors to document the current evidence for interventions in each behavior area and identify the gaps in research to drive further research efforts. The results will be published in winter 2007.

With the successful implementation of the full outcomes system at the academic site, patient and educator data are being collected at the point of service from more than 2000 patients and 30 educators. Initial data are being gathered about educator interventions, patient behaviors,

and clinical outcomes. The analysis of this data will be the subject of additional articles in this journal.

However, further investigation of the link between educator interventions and self-care behavior changes needs to be conducted. Diabetes education and behavioral interventions are effective in improving short-term outcomes.[19,20] Exactly what interventions, provided by whom and for what population, are not well understood at this time. Definitive answers to these questions will require extensive randomized clinical trials. However, tracking actual DSME practices and outcomes using the AADE7™ Outcomes System can help generate and focus research questions and provide guidance regarding which randomized clinical trial should receive higher priority.

Finally, with a fully operational technology system, the vision continues of developing a national repository for diabetes education program benchmarking, research, and building the evidence base for diabetes education practice. As more sites and educators start participating in the repository, it will be possible to describe and promote best practices in diabetes education and advocate for policy and practice initiatives. Using these outcomes, the association can further define the role of education as an essential health care intervention and diabetes educators as essential to improving patient outcomes.

Appendix A

Description of the AADE Outcomes Project in Phases, With Identification of Diabetes Education Issues, AADE's Response to the Issues, and Results of the Activities

Phase(s)	AADE Years	Diabetes Education Issues	AADE's Response	Results
Conceptual framework	1997-1998	In 1997, AADE was challenged to provide evidence that diabetes education makes a difference in health outcomes for people with diabetes (Balanced Budget Act 1997; HCFA) No specified outcome measurements linked to DSME, only metabolic outcomes collected DSME focused on knowledge and skill acquisition and content completion	Appointment of AADE Outcomes Task Force Performed an extensive review of existing literature, standards, and measurement sets	AADE Task Force established that behavior change is the unique outcome from DSME Initial identification of 7 behavioral areas as outcomes of diabetes education, which later became branded as the AADE7 in 2004 (see Table 1) Recommended that AADE submit to HCFA the 7 behavioral areas as outcome measures for DSMT Publication: Peeples and Mulcahy[8]
Conceptual framework Instrument development and testing	1998-1999	No uniform or minimum data set for measuring DSME outcomes No DSME outcomes measurement instrument of all 7 self-care behaviors No framework or process for measuring DSME outcomes Identify who are customers of DSME Diabetes education interventions not well understood Could the differences of multidisciplines' delivery of care be better understood? Unanswered questions -Who delivered the care, what intervention, and how much time did it take?	AADE Outcomes Task Force expanded to represent diversity of disciplines, practice settings, and membership geography Instrument design and testing began Developed conceptual framework that incorporated systems theory and Donabedian concepts of structure, process, and outcomes Concurrently, AADE Diabetes Educational and Behavioral Research Summit met May 1999 in Chicago AADE Outcomes Task Force expanded to represent diversity of disciplines, practice settings, and membership geography	Framework and process for outcomes measurement established Tools and instruments developed and tested 70-item patient self-report instrument was designed (D-SMART) and pilot tested with 579 patients Educator tool proof of concept tested Site tool developed to allow benchmarking capability Defined a uniform and minimum data set for DSME Performed customer mapping for regulatory, administrative, and clinical use

(continued)

Appendix A (continued)

Phase(s)	AADE Years	Diabetes Education Issues	AADE's Response	Results
			Instrument design and testing began Developed conceptual framework that incorporated systems theory and Donabedian concepts of structure, process, and outcomes Concurrently, AADE Diabetes Educational and Behavioral Research Summit met May 1999 in Chicago	Research summit: challenge "Is diabetes education effective and what methods are best?" Publications: • Outcomes Users Guide, Consultant Maggie Powers, PHD, RD, CDE • Executive Summary of the Diabetes Educational and Behavioral Research Summit, Chicago, IL,1999
Technology implementation Instrument development and testing	1999-2000	Task force charges were completed, but project required ongoing development and funding D-SMART instrument needed revisions with further testing Need tools for capturing diabetes outcomes continuum Need to understand membership needs and capabilities Need to understand marketing requirements Need vendor for scanning and reporting results Need outcomes reports Need validation of tools Need to understand market potential	AADE Outcomes Task Force restructured: Project Team and Clinical Advisory Group formed to continue work Tools revised based on pilot testing: D-SMART reduced to 32-item questionnaire, other tools reformatted and expanded Protocol developed: "Validity and Reliability Testing of the Diabetes Self-management Assessment Report Tool (D-SMART)" and "Field Testing of the Diabetes Educator Outcomes Guide & Educator Intervention Assessment Tool" Market research conducted at 2000 ADA meeting with 9 program managers Determine how outcomes are currently recorded and tracked Gain insight into key drivers of potential acceptance or rejection of NDEOS	Protocol implemented November 1999 to February 2000 Methods: 29 diabetes education sites (see Appendix B) were identified through a recruitment process; the data were input by patients and educators onto scannable forms and then mailed for input to a central database for analysis Results: Results were reported at the AADE annual meeting, August 2000, San Diego (for more detailed reporting of instrument development and testing, see The Development of the AADE D-SMART) User testing of the educator tool indicated that educators document the same methods and resources used in each of the 7 outcome areas Educators want a user-friendly tool that avoids redundant documentation

				Market research findings: • A more well-developed system is needed for evaluation and should expand research to managed care directors. Presentations: • Diabetes Education Outcomes American Health Plans (invited) • Drafting a Roadmap to Success-AADE Annual Meeting, Orlando, FL • NDEOS: Tools and Techniques of Diabetes Education Outcomes AADE Leadership Conference, April 2000 • National Diabetes Education Outcomes System; International Diabetes Informatics Conference, Mayo Institute, September 2000
Technology implementation Instrument development and testing	2000-2001	Current limitations of the D-SMART include literacy, vision, and language The D-ET needs to efficiently incorporate D-SMART information as well as provide documentation for process and clinical measurements Technology solutions requested by educators that addressed current work processes	The Outcomes Project Team continued system development; the Clinical Advisory Group expanded to include strategic partners Vendor request for proposal for reposing data and reporting results from the NDEOS and software vendor certification sent to vendors Protocol developed for "Prototype Testing of National Diabetes Education Outcomes System (NDEOS)"	Vendor with fax-scan technology selected through RFA process Prototype testing of tools, reports, and technology conducted from February to July 2001 at 11 diverse diabetes education sites Publications: • Tomky et al. Diabetes education outcomes: what educators are doing. Diabetes Educ. 2000;26(6):951-954. • Mulcahy, et al. National Diabetes Education Outcomes System: Application to Practice. The Diabetes Educator. 2000; 26:6 957-964.

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Appendix A (continued)

Phase(s)	AADE Years	Diabetes Education Issues	AADE's Response	Results
			Second Diabetes Educational and Behavioral Research Summit held in Baltimore, Maryland, May 10-11, 2001 Summit highlights Develop and implement the NDEOS Organize fund-raising and grant development activities to expand research activities (full report from the Second AADE Diabetes Educational and Behavioral Research Summit: Toward a Research Agenda for the American Association of Diabetes Educators. Diabetes Educ. 2001;27(6):899-907)	• Peeples et al. The conceptual framework of the National Diabetes Education Outcomes System (NDEOS). Diabetes Educ. 2001;27(4):547-562. • AADE Outcomes: Application to practice. IDF Poster Presentation, Mexico.
Technology implementation Standards development	2001-2002	Strategic direction for NDEOS development was needed to consider prototype testing results, the AADE Second Research Summit report, and alignment with association goals National trends included patient and population outcomes, data collection challenges, and integration with quality improvement activities National Standards for DSME existed, but no specificity for the collection of outcomes was included	Solicited review and recommendations from business, information technology, and industry consultants regarding strategic direction of NDEOS The AADE Outcomes Project team, the IS consultant, business consultant, and AADE staff and leadership conducted a formal process of RFA of vendors Outcomes Standards writing team convened	Consultants meeting with Outcomes Project Team and AADE Leadership and staff held in Chicago, October 2001 with recommendations: • Technology approach feasible. Develop business plan to guide decision making and fund-raising for a large technology implementation • Continue system refinement with focused testing at reference sites • Knowledge and learning regarding outcome measurement in DSME should be captured in standards

				Project implementation: For RFA, 17 vendors expressed interest, 8 submitted full proposals, and 4 were selected to present to the AADE Executive Committee and Project Team. A technology vendor was selected, a project coordinator was hired, and an AADE Outcomes Advisory group was appointed. Fundraising, to support the project, was initiated by the association in 2002. The AADE Outcome Standards were presented at the 2002 AADE annual meeting in Philadelphia, PA. The D-SMART was released as paper tool for a 1-year license as a pilot process. Publication: • Mulcahy et al. An educator's guide to the diabetes education outcomes measurement systems. Diabetes Educ. 2001;27(6): 830-848.
Technology implementation	2002-2003	Diabetes educators work in diverse clinical settings with variable technology resources and support Full system testing at experienced diabetes centers would support system refinement and scalability for a variety of applications International interest in behavioral outcomes expressed; Japan Association Diabetes Education in Nursing	Reference site implementation planned for 7 diabetes centers to complete full NDEOS system implementation and evaluation Project manager hired to provide oversight for NDEOS reference implementation Outcomes Project Team continued instrument revision, reports design, and awareness building of standards; Clinical Advisory Group expanded to include clinical and strategic partners	NDEOS technology platform development initiated; included data acquisition through browser-based format, offline paper scan, and third-party telephonic system with the ability to generate point-of-service and program reports Reference implementation training previewed at the annual meeting in Salt Lake City, 2003, and recruitment initiated

(continued)

Appendix A (continued)

Phase(s)	AADE Years	Diabetes Education Issues	AADE's Response	Results
				Publications: • Mulcahy et al. Diabetes self-management education core outcomes measure. Diabetes Educ. 2003:29(5):768-803. • Mulcahy et al. Standards for outcomes measurement of diabetes self-management education. Diabetes Educ. 2003:29(5):804-816. Presentations: • AADE Standards. American Association of Diabetes Educators National Meeting; August 2002; Philadelphia, PA. • Japan Association of Diabetes Educators; October 6, 2002; Nagoya, Japan (invited). • 61st Scientific Session American Diabetes Association; June 2001; Philadelphia, PA (invited).
Technology implementation	2003-2004	Complex information technology development and implementation became a challenge for AADE Need for products to support educators with behavior change International interest in behavioral outcomes expressed: Australian Diabetes Educators Association (ADEA)	Business consultant hired to assess project mission and scope and to support the association in determining its strategic direction AADE Board of Directors supported continuation of the project Working group developed goal-setting tool based on the AADE7 framework Program for the ADEA planned for September 2005	Consultant recommendations for project: • Focus project development and implementation at 1 site • Identify technology vendor compatible with project goals • Focus group testing with educators AADE7 Self-Care Behaviors branding policies and procedures adopted for standardized patient and professional language

				AADE7 Goal Sheet: paper version released at AADE annual meeting in 2004 in Indianapolis, IN Outcomes Project received Info World Award "Top 100 IT Visionaries of 2003" (health care) Presentation: • Behavioral outcomes in diabetes education. Presented at the ADEA meeting; September 2005; Perth, Australia (invited).
Technology implementation	2004-2005	Need implementation site that is representative of diabetes education programs and yet has the information technology support to participate in a developmental project	AADE formed an alliance with an academic diabetes program that has established, ADA-recognized programs; primary care practices; and urban and rural patient populations Fundraising with industry alliances for technology implementation AADE Outcomes Advisory Group provided input to project development	Staged implementation of full NDEOS system at academic partner sites Telephonic D-SMART tested at hospital system diabetes program First National Practice Survey administered to AADE membership Focus group conducted with educators: • Educators were primarily focused on data collection for program recognition, less so for CQI Presentations: • Diabetes education outcomes. Insulin Study Group in Japan-Kyoto, Kumamoto, and Saitama. November 2004 (invited). • 2005 AADE Annual Meeting; Indianapolis, IN.

(continued)

Appendix A (continued)

Phase(s)	AADE Years	Diabetes Education Issues	AADE's Response	Results
AADE7 system	2005-2006	Educators are practicing in increasingly diverse settings and addressing issues of chronic disease Educators are requesting an inexpensive, easy-to-use behavioral tracking tool for use in diverse settings AADE administrative responsibilities are expanding	Negotiation with diabetes organizations to include the AADE7 framework and tools in diabetes efforts The Outcomes Advisory Group recommends that a Web-based version of the AADE7 Goal Sheet be market tested with the membership The Outcomes Advisory Group was disbanded in December 2006; AADE staff has assumed the oversight aspects of the project Continued development with academic partner: Additional study goals 1. Describe patient behavior change goals 2. Determine whether patient goals affect educator response 3. Describe educator use of strategies	Continued implementation, tool revision, and evaluation of the full NDEOS system at partner sites: NDEOS evolved to AADE7 Outcomes System with plan for staged introduction to the AADE membership AADE7 IMPACT, a Web-based system for educators, was launched as a marketing test at the annual meeting in 2006 in Los Angeles; additional tools included letter-writing templates and site registration Presentations: • ADA Scientific Sessions: • Peyrot et al. Using AADE National Diabetes Education Outcomes System (NDEOS) to identify patient behavior change needs and diabetes educator responses. 2006. • Piatt G, et al. Sustainability of clinical and behavioral improvements following a multi-faceted diabetes self-management training (DSMT) interventions. 2006. • Charron-Prochownik D, et al. Patient satisfaction with a computer or telephone diabetes self-management assessment report tool (D-SMART). 2006.

				• 2006 AADE annual meeting: • AADE Outcomes System: implementation and evaluation. • Letz, Lumber. A dream come true: Voice-activated diabetes care and education system. • Standardizing behavioral measurement in diabetes self-management education. Therapeutic Patient Education Conference; April 2006; Florence, Italy. Presentations: • AADE7 IMPACT: An Internet-based Tracking Tool • CDC Diabetes Translation Conference; May 3, 2007; Atlanta, GA.
AADE7 system	2006-2007	Adoption of the tracking tool by the greater diabetes community Increased national interest in patient-centered care and measurement	Abstract submission on the AADE7 IMPACT tracking tool to various stakeholder groups Next steps are pending completion of evaluation, which is in progress	

Information was provided by internal documents of the AADE, Chicago, Illinois. Abbreviations: AADE, American Association of Diabetes Educators; ADA, American Diabetes Association; CQI, continuous quality improvement; D-ET, Diabetes Educator Tool; D-SMART, Diabetes Self-management Assessment Report Tool; DSME, diabetes self-management education; DSMT, diabetes self-management training; HCFA, Health Care Financing Administration; NDEOS, National Diabetes Education Outcomes System; RFA = request for application; SRF, Site Registration Tool.

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Appendix B

Volunteer Diabetes Education Programs/Sites Who Participated in Testing and Implementation

Year 1998-1999: Pilot Test Sites	Year 1999-2000: Beta Test Sites	Year 2000-2004: Prototype Test Sites	Year 2004-2007: Implementation Sites
1. Achieving Better Control, Wyncote, PA	1. BCBS NH	1. INOVA Diabetes Center, Fairfax, VA	1. University of Pittsburgh Diabetes Institute, Pennsylvania Sites
2. Diabetes Center, Baton Rouge, LA	2. Diabetes Center–Baton Rouge Medical Center; Baton Rouge, LA	2. Joslin Community Medical Center, Toms River, NJ	UPMC McKeesport, Janice Koshinsky and Carla DeJesus
3. Diabetes Health Center, Salt Lake City, UT	3. Fort Sanders Diabetes Center, TN	3. Joslin Diabetes Center, Clearwater, FL	UPMC St. Margaret's, Andria Pasierb and Kellie Szelc
4. Grady Memorial Hospital, Atlanta, GA	4. HealthPartners, St Paul, MN	4. Lovelace Regional Diabetes Program, Albuquerque, NM	Primary Care Sites, Sharlene Emerson
5. International Diabetes Center, Minneapolis, MN	5. Humphreys Diabetes Center, Boise, ID	5. Medford Clinic, Medford, WI	Mon Valley Hospital, Karen Pritts
6. Joslin Diabetes Center, Boston, MA	6. INOVA Diabetes Center, Fairfax, VA	6. OSCO Drug no. 522, Chicago, IL	UPMC Northwest, Amy Uhler and Deborah Dowling
7. Lahey Clinic, Westford, MA	7. International Diabetes Center, Minneapolis, MN	7. University of Connecticut Health Center, Avon, CT	Conemaugh Diabetes Center, Carl Harding
8. Longmont Clinic, Longmont, CO	8. John Hopkins Medical Institutions, Baltimore, MD	8. Uintah Basin Medical Center, Roosevelt, UT	
9. Lovelace Regional Diabetes Clinic, Albuquerque, NM	9. Joslin Diabetes Center, Clearwater, FL	9. University of Iowa Hospital and Clinics, Iowa City, IA	
10. McKenzie-Willamette Hospital, Springfield, OR	10. Kaiser Permanente Colorado, Denver, CO	10. United Auto Workers–GM Lifesteps Center, Flint, MI	
11. Multicare Associates, Fridley, MN	11. KIC Medical Center, Ketchikan, AK	11. Veterans Affairs Medical Center-Atlanta, Decatur, GA	
12. Northeast Arkansas Clinic, Jonesboro, AR	12. Lahey Clinic, Burlington, MA		
13. Norwalk Hospital, Norwalk, CT	13. Milwaukee Health Services, Milwaukee, WI		
14. Palos Community Hospital, Palos Heights, IL	14. OSCO Drug no. 522, Chicago, IL		
15. Springfield Diabetes Center, Springfield, IL	15. Ochsner Clinic, New Orleans, LA		
16. Unitah Basin Hospital, Roosevelt, UT	16. Sentara HealthCare, Norfolk, VA		
17. University of Connecticut Health Center, Avon, CT	17. Tanner Medical Center, GA		
18. VA Medical Center, Atlanta, Decatur, GA	18. Texas Diabetes Institute, San Antonio, TX		
19. Via Christa–St. Joseph Campus, Wichita, KS	19. Uintah Basin Medical Center, Roosevelt, UT VA Medical Center, Portland, OR		
20. Wilson Community Health Center, Wilson, NC	20. University of Connecticut, Farmington, CT		
21. Wyndham Community Hospital, Willimantic, CT	21. VA Black Hills Healthcare System		
	22. Veterans Administration-Atlanta, Decatur, GA		
	23. Via Christi, St. Joseph Campus, Wichita, KS		
	24. Washington Regional Medical Center		
	25. West Virginia University, Morgantown, WV		
	26. Wilson Community Health Center, Wilson, NC		

Appendix C

Acknowledgment of American Association of Diabetes Educators (AADE) Volunteers and Staff Involved in the Project Development

1997-1998

AADE President: Jan Norman

AADE Outcomes Task Force: Malinda Peeples (chair), Melinda Marynuik, Marsha Testa, Kathy Mulcahy (executive liaison), and Betty Burrier (Health Care Financing Administration)

1998-1999

AADE President: Kathy Mulcahy

AADE Outcomes Task Force: Malinda Peeples (chair), Betty Brackenridge, Ann Nettles (representing research committee), Peggy Yarborough, Melinda Marynuik, Donna Tomky, Todd Weaver; Kathy Mulcahy; Liaisons: Carole Mensing (American Diabetes Association), Deborah Young-Hyman (National Certification Board for Diabetes Educators); Facilitator: Jackie White; Consultants: Mark Peyrot (instrument design), Maggie Powers (user manual)

AADE Staff: Lois Book

1999-2000

AADE President: Kris Tobin

AADE Outcomes Project Team: Project Leader: Malinda Peeples; Board Liason and Ad Hoc Member: Kathy Mulcahy; Advisory Clinical Chair and Ad Hoc Member: Donna Tomky; Biostatistician: Todd Weaver; Information Management Advisor: Paul Upham

AADE Staff: Lois Book

2000-2001

AADE President: Ginger Kanzer-Lewis

AADE Outcomes Project Team: Project Leader: Malinda Peeples; Board Liason and Ad Hoc Member: Kathy Mulcahy; Advisory Clinical Chair and Ad Hoc Member: Donna Tomky; Biostatistician: Todd Weaver; Information Management Advisor: Paul Upham

AADE Staff: Lois Book

2001-2002

AADE President: Kathy Berkowitz

AADE Outcome Standards Writing Team: Kathy Mulcahy (chair), Melinda Marynuik, Malinda Peeples, Mark Peyrot, Donna Tomky, Todd Weaver, Peggy Yarborough

AADE Outcome Standards Reviewers: Bob Anderson, Martha Funnell, Carole' Mensing, Maggie Powers, Richard Rubin, Russ Glasgow, Lois Mauer, Linda Edwards, Gary Arsham, Linda Haas

2002-2003

AADE President: Jane Kadohiro

AADE Diabetes Outcomes Advisory Group: Kathy Mulcahy and Malinda Peeples (co-chairs), Donna Tomky, Todd Weaver

AADE Staff: Lois Book

AADE7 Goal Sheet: Virginia Valentine, Marcie Draheim, Brenda Broussard, Malinda Peeples

AADE Staff: Mary Sears

2003-2004

AADE President: Virginia Zamudio

AADE Diabetes Outcomes Advisory Group: Teresa Pearson (chair), Mary Austin, Malinda Peeples, Donna Rice, Jim Barron (consultant)

Academic Site Participant: University of Pittsburgh Diabetes Institute; Linda Siminerio, director; Janice McWilliams, project manager; Janice Koshinsky and Carla DeJesus, site implementation; Brad Ummer, development

AADE Staff: Todd Weaver, project manager

2004-2005

AADE President: Mary M. Austin

AADE Diabetes Outcomes Advisory Group: Mary Austin, chair; Malinda Peeples, Patti Geil, Tommy Johnson, Katie Weinger, Donna Rice; Consultant: Jim Barron

Academic Site Participant: University of Pittsburgh Diabetes Institute; Linda Siminerio, director; Janice McWilliams, project manager; William Noullet, data manager; Janice Koshinsky and Carla DeJesus, site implementation; Brad Ummer, development; Denise Charron-Prowchonik, Janice Zgibor, and Mark Peyrot, researchers

2005-2006

AADE President: Malinda M. Peeples

AADE Diabetes Outcomes Advisory Group: Mary Austin, chair; Deb Fillman, Patti Geil, Amparo Gonzales, Tommy Johnson, Malinda Peeples, Donna Rice, Katie Weinger; Consultant: Jim Barron

Academic Site Participant: University of Pittsburgh Diabetes Institute; Linda Siminerio, director; Janice McWilliams, project manager; Janice Koshinsky and Carla DeJesus, site implementation; Brad Ummer, development; Denise Charron-Prowchonik, Janice Zgibor, and Mark Peyrot, researchers

AADE Staff: Kelly Beumer

2006-2007

AADE President: Donna Rice

Academic Site Participant: University of Pittsburgh Diabetes Institute; Linda Siminerio, director; Janice McWilliams, project manager; Janice Koshinsky and Carla DeJesus, site implementation; Brad Ummer, development; Denise Charron-Prowchonik, Janice Zgibor, researchers

AADE Staff: Kelly Beumer

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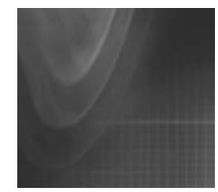
Using the American Association of Diabetes Educators Outcomes System to Identify Patient Behavior Change Goals and Diabetes Educator Responses



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Purpose

The purpose of this article is to ascertain patients' self-identified and mutually identified or agreed on (working with diabetes educators) behavior change goals and examine the diabetes educators' response to these goals during the provision of diabetes self-management education.

Methods

The American Association of Diabetes Educators Outcome System was integrated into Web-based, touch-screen, and telephonic systems within 8 sites within the Pittsburgh Regional Initiative for Diabetes Education network. Data from patients and their diabetes educators were obtained from the Diabetes Self-Management Assessment Report Tool (D-SMART®) and Diabetes Educator Tool (D-ET).

Results

Nine hundred fifty-four individuals with diabetes (type 1 and type 2) using the D-SMART self-identified healthy eating (74%) and being active (54%) as the most common behavior change goals. From that sample, 527 patients identified goals that were mutually identified or agreed on with their diabetes educator: healthy eating (94%), being active (59%), monitoring blood glucose (49%), taking medications (26%), risk reduction activities (19%), problem solving (18%), and healthy coping (18%).

Conclusion

The most common behavior change goals identified by patients (self-identified or mutually identified with their diabetes educator) were healthy eating and being active. The behavior change goal least addressed by patients and educators alike was healthy coping. Mutually identified goals among educators and patients may improve targeted appropriate educational strategies to support patients in meeting their goals.

A critical outcome of diabetes education is patient behavior change,[1] and it is the primary focus of diabetes self-management education (DSME).[2] The American Association of Diabetes Educators (AADE) Outcome System was developed to facilitate the delivery, documentation, and evaluation of patient behavior change in the provision of DSME.[3] The Outcome System is organized around the AADE 7 Self-care Behaviors, which have been identified as the key outcomes of DSME. The AADE 7 Self-care Behaviors are healthy eating, being active, monitoring blood glucose, taking medication, problem solving, risk reduction activities, and healthy coping.[3]

The Diabetes Self-management Assessment Report Tool (D-SMART®) and the Diabetes Educator Tool (D-ET) are tools of the Outcome System that track patient diabetes self-management behavior and guide the educator in patient behavior change.[3] The patients' self-reported responses from the D-SMART guide educational strategies by focusing on the behavior change goals that patients identify as most important to them. By administering the D-SMART before and after a diabetes educational session during routine visits, changes in behavior can be evaluated as outcomes of diabetes education. The D-ET provides a mechanism for the diabetes educator to document the patients' assessment, patient-identified goals agreed on by the diabetes educator, interventional strategies, delivery of services, and impact on the patients' behavioral and clinical outcomes.[3] The purpose of this article is to ascertain patients' self-identified and mutually identified or agreed on (working with diabetes educators) behavior change goals and to examine the diabetes educators' response to these goals during the provision of DSME.

Methods

The AADE Outcome System was integrated into Internet, touch-screen, and telephonic systems within 8 sites in the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) network. PRIDE is a regional health care collaboration established by the University of Pittsburgh Diabetes Institute to improve diabetes education and care in western Pennsylvania.

Program evaluation was conducted at the sites for patients with both types 1 and 2 diabetes using the system. Nine-hundred fifty-four patients completed the D-SMART, while 527 patients had at least 1 complete D-ET. Prior to a routine diabetes care visit, routine scheduled DSME session, or program, patients were asked to complete a baseline D-SMART. The proportion of educator-patient mutually agreed on goals and the proportion of goals addressed by the educator were evaluated. Patient self-identified behavioral change goals were taken from the D-SMART, and mutually identified diabetes educator responses were taken from the D-ET. Descriptive analyses were used to determine the frequency of responses and demographic characteristics of the population.

Results

Demographic characteristics of the 954 patients in the study are presented in Table 1. Fifty-six percent were female, and most patients were Caucasian (85%). More than half (56%) had a high school education or less. Eighty-seven percent had type 2 diabetes.

Patients were asked to respond to the question, "Having diabetes means you may need to make changes. What changes, if any, would you like to make now?" The most common self-identified behavior change goal was healthy eating, in which 74% of patients wanted to make changes. The second most commonly self-identified goal was being active, in which 54% of patients wished to make this behavioral change. Healthy eating and being active goals were followed by risk reduction activities (44%), healthy coping (32%), monitoring blood glucose (22%), problem solving (18%), and taking medication (17%) as self-identified behavior change goals, highest to lowest, respectively.

From that sample, 527 patients met with their educator to mutually identify agreed on behavior change goals. Mutually identified patient behavior goals and the educators' response are listed in Table 2. Once again,

Table 1

Demographic Characteristics of the Pilot Population Using the American Association of Diabetes Educators Outcomes System

Variable	n	%
Gender		
Male	419	44
Female	532	56
Race		
Caucasian	82	85
African American	804	9
Other	61	6
Level of education		
High school or less	531	56
Beyond high school	413	44

Table 2

Mutually Identified Patient Behavior Change Goals by Domain and Educator Responses to Goal Using the American Association of Diabetes Educators Outcomes System

Domain	Mutually Identified Patient Goals[a]	Educator Response to Goal[a]
Healthy eating	94	98
Activity	59	90
Risk reduction	19	80
Coping	18	48
Monitoring	49	94
Problem solving	18	72
Medication	26	75

[a]The proportion (%) of patients identifying the goal. Patients could identify more than 1 goal.

healthy eating was the most commonly identified goal (94%). Similar priorities were observed in the proportion of patients and their choice of goals; however, upon meeting with the educator, the proportion of patients identifying a particular goal increased compared with the self-identified goals, with the exception of risk reduction activities and healthy coping. Problem solving did not change. Once behavior change goals were mutually agreed on, educators responded by addressing specific goals in the following order: healthy eating 98% of the time, followed by monitoring blood glucose (94%), being active (90%), risk reduction activities (80%), taking medication (75%), problem solving (72%), and healthy coping (48%).

Conclusion

This article attempts to ascertain patients' self-identified and educator and patients' mutually identified behavior change goals and to examine the diabetes educators' response to these goals during the provision of DSME using the tools of the AADE Outcome System. The data indicated that patients engaged in self-identification of behavior change goals to a great extent. The most common behavior change goals identified by patients (self-identified or mutually identified) were healthy eating and being active. Diabetes educators likewise addressed both of these behaviors most of the time. The behavior change goal least addressed by patients and educators alike was healthy coping.

Mutually identified goals among educators and patients may assist in targeting appropriate educational strategies for patients. Education strategies depend on and are specifically targeted to address behavioral domains. Strategies identified in the D-ET are knowledge education, skill training, goal setting, behavioral contracting, confidence building, barrier resolution, and situational problem solving.

Findings suggest that increased attention should be paid to those identifying psychosocial (healthy coping) behavior change goals. Although patients identified healthy eating and being active as goals, addressing themes such as coping and problem solving in the educational process is necessary to help the patient move toward successful accomplishment of these goals.

Systems that provide ease along with opportunities for tracking and reporting educator processes have become critical in supporting DSME services. In an era that requires documentation of outcomes to substantiate and sustain the provision of health care services, technological monitoring systems are critical. Previous work has demonstrated that educators who are able to provide reliable data through a validated clinical information system

are more likely to gain administrative support for services.[4] To date, there are few systems available to support the tracking of behavior change and educator processes and outcomes. The Outcome System fills this gap as the system tracks clinical and behavioral processes and outcomes.

There were limitations to conducting the program evaluation. The patient population was largely Caucasian, representing 1 DSME network in a large health system in western Pennsylvania. Therefore, generalizability is limited; however, future expansion to other populations is planned. The evaluation was not designed as an experiment; thus, data collection could not be rigorously controlled. This evaluation is a true reflection of the clinical relevance and feasibility of implementing the AADE Outcomes System into a large DSME network. Furthermore, patients and educators may not identify and report all the behavior change goals from all domains. Thus, through discussion with the educator, initial patient goals may be modified to better reflect patient needs, facilitating more targeted interventions to bring about behavior change.

Implications/Relevance to Diabetes Educators

Although DSME is widely accepted as an important part of diabetes management,[5,6] the numbers of people who receive education are disappointedly small.[7,8] Also, it is now recognized that improvement in knowledge alone is not enough. There is an increasing appreciation that mechanisms that support behavior change in the provision of DSME are critical.[1] Organizing efforts and developing strategies to support the facilitation of DSME must be considered to successfully meet the goals set for Healthy People 2010 to increase the number of people who receive education from 40% (1998) to 60% (2010).[9] A recent survey of US nurses and physicians[10] identified 5 key goals that need to be accomplished to improve diabetes outcomes. They are as follows: reduce the barriers to effective therapy, promote effective self-management, improve psychological care for people with diabetes, enhance communication between people with diabetes and health care providers, and promote improved communication and coordination between health care providers. The AADE Outcome System helps to accomplish these goals by affording the diabetes educator an opportunity to prepare an individualized educational plan based on a comprehensive patient-centered assessment and to identify psychosocial barriers and supports, move patients toward accomplishment of their goals through identified behavior strategies, and increase communication with the team. On a system level, the Outcome System has the potential for providers and policy makers to collect data, establish benchmarks, and determine best practices in the provision of DSME in a time-saving, cost-effective way.

In summary, the AADE Outcomes System provides a comprehensive tracking system for both clinical and behavioral aspects of diabetes care. Future efforts include dissemination of the Outcome System to diverse populations, development of national and international registries that could help establish benchmarks and form public policy, and conducting research to identify best practice.

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The Diabetes Self-management Assessment Report Tool (D-SMART®): Process Evaluation and Patient Satisfaction

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The Diabetes Self-management Assessment Report Tool (D-SMART®)

Process Evaluation and Patient Satisfaction

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Purpose

The purpose of this article is to present the results of the process evaluation and patient experience in completing the Diabetes Self-management Assessment Report Tool (D-SMART®), an instrument within the AADE Outcome System to assist diabetes educators to assess, facilitate, and track behavior change in the provision of diabetes self-management education (DSME).

Methods

The D-SMART was integrated into computer and telephonic systems at 5 sites within the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) network. Data were obtained from 290 patients with diabetes using the system at these programs via paper-and-pencil questionnaires following baseline D-SMART assessments and electronic system measurement of system performance. Process evaluation included time of completion, understanding content, usability of technology, and satisfaction with the system. Patients were 58% female and 85% Caucasian and had a mean age of 58 years. Fifty-six percent of patients had no more than a high school education, and 78% had Internet access at home.

Results

Most patients reported completing the D-SMART at home (78%), in 1 attempt (86%) via the Internet (55%), and in less than 30 minutes. Seventy-six percent believed the questions were easy to understand, and 80% did not

need assistance. Age was negatively associated with ease of use. Moreover, 76% of patients believed the D-SMART helped them think about their diabetes, with 67% indicating that it gave the diabetes educator good information about themselves and their diabetes. Most (94%) were satisfied with the D-SMART. Level of satisfaction was independent of the system being used.

Conclusions

The D-SMART was easily completed at home in 1 attempt, content was understandable, and patients were generally satisfied with the wording of questions and selection of answers. The D-SMART is easy to use and enhanced communication between the patient and clinician; however, elderly patients may need more assistance. Computer-based and telephonic D-SMARTs appear to be feasible and useful assessment methods for diabetes educators.

Diabetes self-management education (DSME) is considered to be an important part of diabetes management.[1] The purposes of DSME are to promote knowledge, facilitate skill training and problem solving, and help individuals identify barriers in support of effective self-care behavior. The position of the American Association of Diabetes Educators (AADE) is that in the provision of DSME, educators should assess, promote, and measure self-care behaviors.[2] To afford the educator the tools that are necessary to collect data, support patient behavior change, and measure effectiveness, AADE developed the AADE Education Outcome System.[3]

The Diabetes Self-management Assessment Report Tool (D-SMART®) is the cornerstone of the AADE Education Outcome System and is a data collection tool that guides the educator in facilitating patient behavior change. The D-SMART is a patient self-report instrument that captures assessment information on diabetes health status, knowledge, skill confidence, barriers, and current self-management behaviors and is organized around the AADE7™ Self-care Behaviors (healthy eating, being active, monitoring, taking medication, problem solving, healthy coping, and reducing risks).[3]

The D-SMART reflects a combination of behavioral models, including the transtheoretical model,[4-6] theory of reasoned action,[7] health belief model,[8,9] self-efficacy model,[10,11] and empowerment model,[12] as well as the model formulated by one of the D-SMART developers.[13] Constructs from these models, such as stages of change, intention, barriers, self-efficacy, social support, and distress, are embedded within the tool.

The patient's self-reported responses on the D-SMART guide the education intervention by focusing on what patients feel and state are most important to them. The D-SMART captures pertinent patient information, including self-management behaviors that are then measured and quantified as outcomes of education.

The AADE Outcomes System consists of several components that can be used to validate the value of the system by demonstrating its ability to track patient self-care behavior over time (with the D-SMART) and track the diabetes educator's delivery of services and impact of diabetes interventions over time (with another instrument, the Diabetes Educator Tool [D-ET®]), such as clinical parameters (eg, levels of glycemia, cholesterol, blood pressure, and weight).

The D-SMART was integrated into computer and telephonic systems at 5 sites within the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) network to explore the feasibility of applying the D-SMART through technology and in a clinical setting. Process evaluation was conducted to explore the feasibility of integrating the AADE Outcomes System among patients with diabetes in an actual clinical setting. Process evaluation has as its criteria of success the quantity and/or quality of activity that takes place to deliver the program (the input), which is the D-SMART.[14,15] Process evaluation can include time to complete the D-SMART, understanding the content, ease of use or usability of the technology, and satisfaction with the delivery system.[14,15,16]

Methods

The D-SMART was integrated into 2 computer systems (Internet access and touch-screen access) and a telephonic system (using voice-recognition software) at 5 sites in the PRIDE network. PRIDE is a regional health care collaboration established by the University of Pittsburgh Diabetes Institute to improve diabetes education and care in western Pennsylvania. A total of 290 patients with type 1 and type 2 diabetes completed the D-SMART.

Aspects of process evaluation included actual time of administration and self-reported understanding of content, usability of technology, and overall satisfaction

with the system. Time of administration was an objective measure generated by the system, obtained by totaling the time it took to complete the D-SMART via the telephonic, Internet, and/or touch-screen systems. If patients completed the tool in multiple sessions, the total time for each session was used. Understanding of content, usability of technology, and overall satisfaction with the system were obtained using a paper-and-pencil questionnaire (described below) following baseline D-SMART assessments, completed at the time of the diabetes education clinic visit.

Patient Satisfaction Survey

The patient satisfaction survey questionnaire was developed by the team of AADE Outcomes System researchers based on several standardized measures.[16,17] This brief self-report satisfaction survey measures the patient's perception of his or her level of difficulty in both reading and understanding the content of D-SMART, the handling or use of technology associated with the computer/telephonic program, and satisfaction with the system and content. Items were examined separately or added together to create composite scores. Response options for rating items ranged from 5 = *strongly agree* to 1 = *strongly disagree*. Higher scores indicate higher approval and greater satisfaction.

Analyses

Descriptive analyses were used to determine the frequency of responses. Means, standard deviations, and ranges were used to describe continuous variables. χ^2 Analysis and Student *t* test were used to compare outcome variables between the 2 groups. Pearson product–moment correlations, Spearman rank-order correlations, and Kendall τ correlations were used to examine the association between variables.

Results

Of the 290 patients completing the D-SMART, most were Caucasian (85%) and female (58%). The patients' age ranged from 17 to 90 years (mean = 58), with 31% of the patients greater than or equal to 65 years old. Fifty-six percent had no more than a high school education. Patients had access to a computer either at home (78%) or at another location (Table 1).

On average, patients completed the assessment in 25 minutes using a touch screen, 29 minutes on the Internet, and 42 minutes on the telephonic system. Completion of the D-SMART by the touch-screen system was the fastest, while the telephonic system took the longest. Seventy-eight percent reported completing the D-SMART at home in 1 attempt (86%) via the Internet (55%). Seventy-three percent reported feeling comfortable using a computer (Table 2).

Table 1

Demographic Characteristics of Patients Completing a Satisfaction Survey for the Diabetes Self-management Assessment Report Tool (D-SMART®)

Variable	n	%
Gender		
Male	118	42
Female	164	58
Race		
African American	35	12
Caucasian	241	85
Asian	3	1
Other	5	2
Highest education level completed		
<High school degree	22	8
High school degree	136	48
Some college	68	24
College degree	56	20

Patients rated the content of the D-SMART system. Some reported that the D-SMART had too many questions (43%) or took too long to complete (40%). Only 47% felt that the responses they wanted to make were always available to choose from. Seventy-six percent felt the questions were easy to understand, and 76% felt that the D-SMART helped them to think about their diabetes.

With regard to usability of the computer system, ratings were generally positive (Table 3). Three-quarters (75%) agreed that the computer system was easy to use, with only 12% needing some assistance. With regard to usability of the telephonic system, most (93%) agreed that the voice on the telephonic system was easy to understand. However, ratings of the system's ability to capture patient responses were not as positive. Almost

Table 2

Patient Location and Access to the Internet for Completing the Diabetes Self-management Assessment Report Tool (D-SMART®)

Variable	n	%
Where did you respond to D-SMART?[a]		
Home	217	77.5
Education site	30	10.7
Somewhere else	34	12.1
Did you complete the D-SMART in 1 attempt?		
One attempt	238	86.0
Left and returned	38	14.0
Which system did you use to respond?[a]		
Internet	154	55.2
Touch screen	3	1.1
Telephone	125	44.8
Internet access[a]		
Home	157	77.7
Work	34	16.8
Public location	11	5.4
School	3	1.5
Other	20	9.9

[a]Multiple-response question, percentage may total greater than 100%.

Table 3

Patient Report of Usability of the Computer and Telephonic Diabetes Self-management Assessment Report Tool Systems

	Agree	
Variable	n	%
Computer		
It was easy to use the system.	115	75
It was easy to get on the system.	120	80
I did not need help to use the system.	119	79
The system was not confusing to me.	120	80
Telephonic		
The voice was easy to understand.	112	93
The system did not always recognize my words.	65	28
I had to repeat myself frequently.	59	49
Sometimes the system got my answers wrong.	65	54

one-fourth (28%) of the patients believed that the system did not always recognize their words, and 54% stated that the system sometimes got their answers wrong. These responses helped the researchers to understand why completion of the D-SMART took longer on the telephonic system.

Moreover, 67% said that the D-SMART gave the diabetes educator good information about themselves and their diabetes. Sixty-seven percent felt that discussing their answers on the D-SMART with their diabetes educator was helpful. Overall, 94% of patients reported being satisfied with the D-SMART. There were no group differences noted in mean satisfaction with the system between those patients using the telephonic versus the computer (combined Internet and touch screen) systems.

Finally, patient responses were examined to see if the processing outcomes were associated with patient age or education level. For the purpose of simplicity, the mean of scores for each section of the questionnaire (timing based on 1 attempt, content, system usability [computer and telephonic], overall value of satisfaction) were taken and correlated with age and education. It was found that only age with system usability was significantly correlated ($r = –0.196$, $P = .003$), whereby those who were older were less likely to be satisfied.

Conclusions/Relevance for Diabetes Educators

Results of the study indicated that the D-SMART was relatively easy to use and generally could be completed at home, online, and in 1 attempt of less than 30 minutes. Content appeared to be understandable and the information helpful. Patients were generally satisfied with the wording of the questions and selection of answers. The electronic D-SMART appears to be a feasible assessment method for diabetes educators, and it enhanced communication between the patient and clinician.

In the earlier development and testing stages of the D-SMART, patients completed a paper-and-pencil version of the questionnaire that was mailed or faxed to the

educator. This method was found to be cumbersome and required the educator to scan or manually enter patient assessment information for documentation. The Web-based program was offered to those who had access and chose the Internet, while the telephonic and touch-screen applications afforded patients who may not have sophisticated computer skills the opportunity to participate. Systems that provide ease along with opportunities for tracking and reporting educator processes have become critical in supporting DSME services,[18] providing documentation for accountability and recognition. With diabetes educators using more electronic medical records, AADE membership's growing interest in using computer technology, and the widespread availability of technology, such as Internet services, it is important to integrate D-SMART into information technology systems.

Although there has been some skepticism regarding patient use of technological applications, several diabetes computer- and telephone-based interventions have already been shown to be effective.[19-23] The researchers were pleased to learn that most patients completing the D-SMART did so at home in 1 attempt. This was particularly interesting since the study population was primarily senior with no college education. Overall user satisfaction was not associated with the type of system, patient's age, or level of education. However, older patients did report less ease of use with the systems.

To some, the D-SMART appeared to be too long. However, despite the longer version, patients still responded favorably to it. This was one of the earliest versions in the development of an electronic D-SMART, and as its implementation continues to be evaluated, the need to shorten the questionnaire has been recognized. Toward that end, a shortened version has been developed to be used for follow-up administrations. The shortened version focuses on information about specific self-care behaviors so that a change in these outcomes can be assessed over time. Attempts also are currently under way to produce a shortened version of the baseline D-SMART. It is expected that patients and clinicians alike will find it to be more user friendly.

Results also attest that there was less satisfaction with the telephonic version compared with the computer version. This was due in large part to the problems with the voice-recognition software. Subsequent versions of the telephonic system have produced improvements in voice recognition, and objective indicators of system performance are improved. Future research should be conducted to determine whether patient assessment of system performance has also improved.

Increasing patient participation is a critical element in successful chronic disease management,[24,25] and systems that support the development of both informed and activated patients have demonstrated positive outcomes.[24] Therefore, the researchers regard the fact that the D-SMART helped patients think about their diabetes and helped to improve their communication with their diabetes educator as the most important outcome identified in this study.

There were limitations to conducting the process evaluation. The evaluation was not designed as an experiment, and thus, the data collection could not be rigorously controlled. The evaluation is a true reflection of the clinical relevance and feasibility of implementing the AADE Outcomes System into a large DSME network. The AADE Outcomes System serves as an actual patient assessment and tracking system.

The patient population is another limitation. It was largely Caucasian, and the need to implement and test D-SMART in a variety of populations is recognized. Most of this study population also had at least a high school degree. The researchers also appreciate the need to test D-SMART in patients with lower education levels and expect that the tool will need to be adapted to meet the needs of those with low health and reading literacy. Finally, the D-SMART was tested in the English language. The researchers understand the need to translate the tool into other languages. An effort is currently under way to test a Hispanic version of the D-SMART.[26]

As the rates of diabetes continue to increase in epidemic proportions,[25,27,28] it becomes critical to explore innovative methods that support the delivery of DSME. If we are to meet the goals set for Healthy People 2010, to increase those reached with diabetes education from 40% (1998) to 60% (2010),[29] it is important to explore time-saving methods that help the diabetes educator meet the needs of more patients. Having the patient provide assessment information to the educator prior to the education visit allows the educator to review the patient's needs and begin the development of an educational plan. If more patients are to receive self-management training, innovative methods need to be explored and tested to support and/or enhance the traditional methods. Preliminary process evaluation of the D-SMART indicates that it is a useful tool when delivered through computer and telephonic applications.

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Development of the American Association of Diabetes Educators' Diabetes Self-management Assessment Report Tool

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Development of the American Association of Diabetes Educators' Diabetes Self-management Assessment Report Tool

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Purpose

The purpose of this article is to describe the development and testing of a new tool for collecting patient information for diabetes self-management education (DSME): the Diabetes Self-management Assessment Report Tool (D-SMART®). The D-SMART was designed through expert panel consensus based on a hybrid conceptual framework and is intended to serve multiple functions at the level of the patient, the program, and the field.

Methods

The D-SMART has completed 3 rounds of pilot testing and is currently undergoing a fourth round, with each round resulting in revisions to the original instrument.

Results

Findings from the pilot testing indicate that the instrument has acceptable reliability, validity, and sensitivity (or responsiveness) to change. A full-scale field test is currently under way, in which data from the D-SMART will be used to guide the delivery of services and to evaluate and enhance program functioning with a goal of improving education and care. Additional data from the field test are reported elsewhere, and further analyses are planned.

Conclusions

The D-SMART provides educators with a tool that measures patients' behaviors and identifies those priorities for, and barriers to, change.

In 1997, the Health Care Finance Administration, now the Centers for Medicaid and Medicare Services, challenged the American Association of Diabetes Educators (AADE) to define outcomes unique to diabetes self-management education (DSME). The AADE responded by appointing a committee to respond to this charge. Based on expert opinion, the panel selected behavior change and maintenance as the major outcome primarily achieved by DSME and/or affected by diabetes educators. In the following year, AADE appointed an Outcomes Task Force to review the diabetes education literature, summarize the evidence for DSME with a focus on patient behavior change and lifestyle management, and map the current literature back to the National Standards of Diabetes Self-management Education Programs.[1]

In performing this task, the Outcomes Task Force categorized the evidence base and 10 national standards into Donabedian's 3 elements of health care quality: structure, process, and outcomes.[2] Donabedian based his premise of quality on the supposition that good structure increases the probability of good process, and good process increases the probability of good outcomes. What was immediately realized in reviewing the national standards of DSME was the focus on structure and process with a paucity of information regarding the measurement of the intended result, specifically the measurement and monitoring of standardized outcomes for DSME.

Thus, the challenge to the Outcomes Task Force was to develop an instrument that could be a valid measure of the relevant behaviors, would have broad applicability to a variety of settings, and would be practical and easy to use. It was clear that no single instrument was available to measure the multidimensional diabetes self-management behaviors or the factors that affected them. The Outcomes Task Force accepted the challenge of developing a new tool to measure diabetes self-care behaviors, later named the Diabetes Self-management Assessment Report Tool (D-SMART®). This article describes the conceptual and empirical development and testing of the D-SMART, with attention to the issues of reliability, validity, and sensitivity to change.

Conceptual Development

The Outcomes Task Force brought together several resources that guided the development of the D-SMART. The first step was to review a set of existing DSME measurement tools:

- the diabetes education evaluation tools developed at Inova Hospital by a team led by Kathy Mulcahy and Malinda Peeples, the then-current president of AADE and the chair of the Outcomes Task Force, respectively;
- a set of tools that had been developed by Mark Peyrot, a member of the Outcomes Task Force, and his colleagues (Richard Rubin and Tom Conant) for guiding and assessing diabetes behavior change interventions. In 1999, Dr. Peyrot was hired by AADE as the Task Force's consultant for behavioral research in diabetes education; and
- an extensive set of validated instruments in the diabetes literature.

The second resource was a set of publications regarding the evaluation of diabetes education programs, including a description of a comprehensive DSME evaluation system,[3] reviews of studies of DSME,[4-6] and a number of studies of specific programs that illustrated key components of an evaluation system.[7-9] Also included were publications identifying the range of outcomes that should be evaluated, how the outcomes were related to one another, and a variety of measurement and analyses issues.[10,11]

The third resource was a set of theoretical models, the most prominent of which was a model identifying the key factors targeted by the intervention for behavior change.[12,13] This model, later termed the HOBBIT model, identified the linkages among the key components of the health and behavior change process: health outcomes, behaviors, barriers (to behavior change), intentions (to change behavior), and triggers (for behavior change, including DSME). This model incorporates insights from many other behavioral models, including the health belief model, the transtheoretical model, the theory of planned behavior, the social-cognitive model, and self-regulation theory.[14-19]

One of the major decisions was what general categories of measures should be included in the tool. This task required specification of the functions to be served

by the tool. Two broad functions were identified: (1) patient profiling and (2) behavioral assessment. The patient-profiling function was deemed important because the Outcomes Task Force's goal was to develop a system that could be adopted as a comprehensive documentation system for any DSME program. Therefore, it had to include all the data elements that would be required for an educational record, including various demographic characteristics and health conditions as well as the patient's self-care regimen. Many of these measures could be used to guide the design of an individualized educational program. The plan was also to collect data that could be used in applying for program certification/recognition (eg, American Diabetes Association program recognition).[20]

The behavioral assessment function incorporated both needs assessment and outcome measurement. Administration of the D-SMART at program entry would assess the patient's level of self-management, which would guide the development of an individualized education plan. Moreover, these data would serve as the baseline for comparison to postprogram self-management, providing a measure of patient and program outcomes.[3]

In the following, the authors focus on the development of the behavioral assessment component of the D-SMART. However, a great deal of time and effort has been devoted to the patient-profiling component, and it constitutes a significant amount of the tool's content.

It should be noted that the D-SMART was designed in conjunction with a companion tool, the Diabetes Educator Tool (D-ET®), which provided assessment of the objective health outcomes from the HOBBIT model (eg, A1C level, blood pressure, cholesterol [the ABCs], and weight). The D-ET, which is completed by the diabetes educator, also was designed to capture all of the educational interventions provided to patients. The outcome tool kit also includes a third form, the Site Report Form (SRF®), which captures site-specific information but is not discussed in this article. These 3 tools became the core components of the National Diabetes Education Outcomes System (NDEOS).

Content Development

One of the first decisions regarded the philosophy behind the tools: were they to be constructed according to the criteria for research instruments (ie, psychometric properties, especially reliability)? This would require a substantial increase in the number of items because reliability is a function of the number of items that comprise a measure. Because the tools were designed to be used in service organizations and the intent was to make them usable in settings that did not have resources to devote to comprehensive research, the Outcomes Task Force decided not to use a research-oriented strategy of creating multi-item scales.

A second major decision regarded the place of knowledge in the assessment tool. While the traditional approach to diabetes education placed a major emphasis on knowledge acquisition, the Outcomes Task Force had identified behavior as the key outcome of DSME. Therefore, the Outcomes Task Force decided not to incorporate a diabetes knowledge assessment into the D-SMART. Knowledge was incorporated into the NDEOS through the D-ET as an educator-assessed measurement. Specifically, educators were expected to conduct their own assessment of knowledge, provide the necessary education to the patient, and document the knowledge assessment and education process on the D-ET. This documentation focused on the knowledge required to achieve the desired behavior change. Thus, the acquisition of knowledge was to be driven by behavior change goals, not by a fixed curriculum.

The third decision was to identify which behavior change mediators to examine, for example, which factors diabetes educators should prioritize or seek to influence to facilitate behavior change. The single most important factor was behavior change goals or intentions. The Outcomes Task Force adopted the empowerment or patient-centered approach in which behavior change goals should arise from the patient.[21-23] In addition to assessing desire to change, patients were asked what their goals were using the same response categories as the current behavior questions (eg, frequency and duration of exercise). Behavior change intentions were also categorized in terms of readiness to change (eg, immediately, in the next 3 months, in the next year, longer).

The next factor to be selected for assessment was barriers to implementation of behavior change. In addition to specific barriers, the Outcomes Task Force identified self-efficacy, or confidence in making behavior changes, as an overarching barrier to change.

The Outcomes Task Force originally decided that each behavior should drive the assessment of intentions and barriers (as well as triggers, although the latter would be assessed in the D-ET). Thus, the format of the initial draft of the D-SMART was to assess a behavior, then the

patient's desire to change that behavior, then (if there was a desire to change) the difficulty in making that change, and (if the difficulty was high) the barriers that made behavior change difficult. The assessment strategy was designed to minimize the number of questions that a patient had to answer. Although this limited the ability to perform standard psychometric analyses (since some items were not applicable and therefore missing for patients), the Outcomes Task Force placed a higher priority on making the instrument practical to use in the day-to-day operation of DSME programs.

With the format and general content determined, the Outcomes Task Force set about identifying the specific behaviors that would be the basis for other content. Review of the materials from Inova Hospital and Peyrot and colleagues suggested that the 15 curriculum content areas of the national standards for DSME could be collapsed into 7 unique behavior domains. These diabetes self-care behavior domains included being active, healthy eating, taking medication, monitoring blood glucose, problem solving (for high, low, and sick day blood glucoses), risk reduction activities, and healthy coping.[24] As Table 1 indicates, these behaviors have become known as the AADE7™ Self-care Behaviors, with the nomenclature reflecting patient-friendly and action-oriented terminology.

Initial Pilot Test Study

After multiple drafts of the D-SMART, it was administered to several individuals with diabetes and diabetes educators to obtain feedback regarding readability and feasibility. Small revisions were made, and the initial pilot testing (or alpha testing) began in 21 diabetes education programs across the United States. Each program administered the D-SMART to adult diabetes patients (N = 579) who consented to participate in the study. Forms were forwarded to AADE and then to Mark Peyrot, who was responsible for data analysis and archiving.

Several changes were made to the D-SMART based on the initial pilot study. One major change was based on feedback from educators who recruited patients for the study; they indicated that the instrument was too long. As a result, the Outcomes Task Force made several changes to shorten the questionnaire by

- eliminating the separate list of situational barriers for each of the 7 behavioral domains in favor of a single set of general barriers,
- replacing the difficulty-of-change items with confidence in making changes,
- eliminating the readiness-to-change items for each domain, and
- eliminating the questions quantifying behavior change goals.

Other changes included simplifying response options by reducing the number of choices, clarifying instructions, and modifying question wording.

The revised D-SMART received face validity testing using an expert multidisciplinary panel that defined the components of assessment, intervention, and outcomes. Content validity was high, with more than 90% of the panel agreeing to each of the items.[25]

Second Pilot Test Study

For the second pilot study (beta testing), sites were recruited and selected based on information obtained on an application form at the 1999 AADE annual meeting. Representatives of 124 DSME programs completed the form and expressed interest in participating in the study protocol. The Task Force selected 42 representative sites based on educational setting (hospital-based, freestanding education center, health system, home health, pharmacy, etc); age, race, and ethnicity of patients; and instructional format (group, individual, both). Thirteen sites were unable to participate in the subsequent training in November 1999 because of the inability either to receive Institutional Review Board approval within the time allotted, to provide staff and resources for the study without additional funding, or to participate during the required study timeline. Subsequently, 29 sites completed training and participated in the study.

Study subjects were recruited continuously over a 6-week period between December 1999 and January 2000. Inclusion criteria included adult patients with type 1 or type 2 diabetes scheduled for DSME, and participants needed to understand English at the eighth-grade reading level. The study sites administered and collected the D-SMART 1 to 3 times from each patient over the course of 3 months. Phase 1 of the study consisted of distribution and collection of questionnaires for reliability. This phase consisted of sending a D-SMART and informed consent form in the mail with instructions to complete the D-SMART 4 to 7 days prior to coming to the DSME visit. Ideally, the patient mailed the D-SMART back to the site; otherwise, it was collected onsite. Next, the patient completed a second D-SMART immediately

Table 1

Mapping the 1995 National Standards of Diabetes Self-Management Education Programs to the AADE7™ and Specific Behaviors Measures

Content Area	AADE7	Behavioral Outcomes Measured
Exercise/activity	Being active	• Frequency/duration; d/wk
Nutrition	Healthy eating	• Frequency of overeating • Frequency of missed or skipped meals • Frequency of eating later than planned • Frequency of eating high-fat foods
Medication (oral and/or insulin)	Taking medication	• Frequency of skipping a dose of diabetes medication • Frequency of taking diabetes medication later than planned
Monitoring	Monitoring	• Frequency of testing (times/d) • Frequency of skipping testing • Frequency of testing later than planned
Prevention, detection, and treatment of acute complications	Problem solving	• Number of hypoglycemic events • Number of emergency admissions for hypoglycemia • Frequency of appropriate treatment
Appropriate monitoring and use of results		• Number of hyperglycemic events • Number of emergency admissions for hyperglycemia • Frequency of appropriate treatment
Benefits, risk, and management options for improving glucose control		• Number of diabetic ketoacidosis episodes or emergency department visits for hypoglycemic events • Number of missed days from school or work • Number of infections
Prevention, detection, and treatment of chronic complications	Reducing risks	• Frequency of obtaining service: eye examination, foot examination, flu vaccine • A1C, lipid profile, blood pressure, urine protein, weight, smoking
Foot, skin, dental care		• Foot, dental, and physical examinations
Preconception care		• Pregnancy counseling
Use of health care systems and community resources		• Receipt of all services above in this category
Risk factor reduction		• All indicators above in this category
Stress and psychosocial adjustment Family involvement and social support	Healthy coping	• Coping • Obtaining support from family or friends • Obtaining support from medical team

before the diabetes educator performed an intervention, and this second D-SMART was collected.

Phase 2 of this study consisted of the distribution and collection of surveys for validity and responsiveness testing. During this phase, a third D-SMART was mailed approximately 2 weeks after the patient was seen at a site. The patients then completed the D-SMART and returned it in a self-addressed envelope. All the D-SMART forms were

forwarded to AADE and then to Todd Weaver, who was responsible for data analysis and archiving.

Findings

Sites submitted 1403 D-SMART forms: 33% from the initial time point, 38% from the second time point, and 26% from the third time point. Approximately half were from patients receiving individual education, and the study population was also diverse in terms of gender, race/ethnicity, age, type and duration of diabetes, and treatment regimen. Statistical analyses revealed the following findings. Test-retest reliability was measured by evaluating differences in response percentages between the first and second administration of the D-SMART (patients completed the tool twice prior to an intervention). High test-retest reliability was demonstrated, with 97% of the responses not significantly different between administrations of the instrument. This finding indicates that responses remained stable in the absence of interventions to produce changes. Inter-item consistency was measured by Cronbach α for questions within the living with diabetes domain; reliability was modest (0.6 to 0.8 depending on the number of items included). However, it should be noted that most of the behavioral outcomes are single-item measures; therefore, it is not possible to examine reliability in terms of agreement of multiple items. Traditional measures of reliability assume that multiple items measure the same construct, whereas different behaviors, even within the same AADE7 domain, are conceptually independent (eg, eating fats and eating fruits/vegetables are different behaviors, not different measures of the same behavior). Indeed, studies of self-care suggest that regimen behaviors do not cluster tightly[26]; persons may perform some behaviors meticulously while ignoring others. Similarly, one's confidence about taking medication may not be similar to one's confidence about exercising. Thus, measures of inter-item consistency were not appropriate for many of the items.

Responsiveness of the D-SMART was measured by evaluating response percentages on the second (prior to intervention) and third administration (at least 2 weeks after the intervention) and analyzed in the aggregate and in subpopulations desiring a specific change. The analysis indicated that the questions and response categories in the D-SMART were sensitive enough to detect behavior changes for each outcome area.

Qualitative data from educators indicated they desired more education on outcomes management and help with integrating data collection into existing documentation and work processes and that they are looking for less time-intensive and easier methods to capture data. Additional information was obtained regarding a number of educator beliefs, including (1) behavior change is accepted as an outcome of education, (2) the D-SMART can sharply reduce variation of patient assessment and outcome measurement between educators, (3) the D-SMART provides valuable assessment information to guide educator interventions, and (4) limitations of the D-SMART include literacy, vision, and language requirements.

Third Pilot Test Study

The third study was a first attempt to assess the NDEOS implementation in a real-world setting. The purpose of the study was several-fold:

- to assess the feasibility, accuracy, and reliability of data collection and reporting using a computerized NDEOS prototype;
- to assess the feasibility and usability of a fax-based technology for data collection and reporting;
- to assess the impact of the NDEOS electronic prototype on workflow; and
- to assess the value of NDEOS system reports.

The system design included a fax- and scan-based technology data acquisition approach with database development and a reporting system. For the prototype testing, the revised tools (D-SMART, D-ET, and SRF) were produced as scannable forms, and a fax-based technology populated data from these tools into a database repository. Once the database was populated, a patient-level outcome report (point-of-service report), organized around the AADE7 behavioral areas, was generated within a few minutes of faxing the forms to a central server. The report guided the educator through an intervention and supported documentation and reporting of the visit. Program-level aggregate reports, based on the framework of structure, process, and outcomes, were produced for sites and benchmarking.

The testing was implemented with 11 diabetes education programs that had previous experience with NDEOS or were representative of a diversity of patient population, geography, or practice setting. Included in the testing were hospital-based diabetes education centers, an employee works site, managed care, university-affiliated clinics, a rural solo practitioner, and a Veterans Affairs hospital. Study participants included 279 patients with

type 1 and type 2 diabetes, 23 educators (13 registered nurses, 9 registered dieticians, 1 pharmacist), and 7 support staff members. Educators were expected to schedule the patient for an initial and follow-up visit during the time frame of the study and to have a fax machine available. The subjects completed a D-SMART prior to the intervention, and the educator completed the baseline assessments on the D-ET. After a minimum of 2 weeks after the intervention, a second D-SMART was completed by the patient and returned to the educator during the scheduled follow-up visit. At that time, the educator completed the follow-up assessments on the D-ET.

Findings

Educators had mixed reactions to the fax-based technology because they had to fax the completed D-SMART and D-ET forms to a centralized number where the data were recorded and then had to wait to receive a summary report back by fax. The approach was too slow for many educators or frustrating when multiple pages had to be placed in a fax machine and subsequently jammed or stuck together. Efficient, cost-effective methods of data entry provide the greatest challenge to making the NDEOS accessible to all educators. Other technologies recommended for consideration were computerized touch-screen and Internet-based data entry. A survey of participating educators revealed that one-third of educators thought their institution would likely support a combination of technologies; this was identified as the major goal for the next phase of the project.

Educators overall were supportive of the NDEOS, as is indicated in the following comment from a site coordinator:

> In all, participation in NDEOS gave the educators a new perspective on how to think about their education and effectiveness and added ideas to improve diabetes care as the authors continue planning their diabetes clinic in the primary care setting. Through the use of the tools, the educators identified gaps in education and are currently problem-solving how to resolve such gaps.

The tools of the NDEOS captured the critical elements for reporting program-level data for regulatory, quality, and administrative reporting. The patient-level reporting (Point-of-Service Report) has implications for use in practice when the technology can support rapid return to the educator. Integrating the NDEOS into practice will benefit educators and patients, but implementation training and ongoing support are critical. Minor suggestions were made for modification of the D-SMART, primarily focusing on improving instructions for completing the tool. Suggestions for improving the D-ET were primarily related to redundancy of data entry, which computerization may resolve.

Field Implementation Study

The current in-progress field implementation study incorporated the D-SMART and D-ET into the regular operation of a number of education programs at the University of Pittsburgh Medical Center (UPMC). The D-ET was revised based on the results of earlier studies, primarily by developing an inventory of behavior change strategies for educators to describe their activities.[13] Then, both the D-ET and D-SMART were modified for computerized administration via keyboard or touch screen. A telephonic version of the D-SMART was also tested. A set of video displays was developed to provide educators with access to D-SMART and D-ET data collected for each patient. All patients receiving diabetes education in the clinics using the system completed the full D-SMART prior to their education, and all educators filled out a D-ET recording their educational interventions. A number of participants were asked to complete a follow-up administration of the D-SMART 3 to 6 months after completion of the initial D-SMART. The UPMC has the primary responsibility for data analysis and archiving.

This study is designed to provide an evaluation of the validity of the D-SMART and D-ET within an operational context. Validity is demonstrated to the degree that the D-SMART captures behavior change. The validity of the D-ET is demonstrated to the degree that it shows the strategies employed by educators. The joint validity of the D-SMART and D-ET is determined by demonstrating that the activities of educators directed to changing a particular behavior are associated with change over time in that behavior. Another article in this special issue uses some of the data from this study to address these issues.

The study also provided data regarding the reliability (Cronbach α of inter-item consistency) of selected multi-item measures from the D-SMART, specifically those for barriers, distress, and social support (recall that most D-SMART outcomes are single-item measures of specific behaviors for which inter-item consistency is not relevant; confidence in making desired behavior changes represents another potential multi-item measure, but each

patient answers these questions only for the specific behaviors she or he wants to change, resulting in a data structure inappropriate for an overall assessment of Cronbach α). All 3 sets of items used a 4-point Likert-type set of response options ranging from *a lot* (4) to *not at all* (1). The construct barriers were measured by 13 items, an example of which is, "I don't know what to do or how to do it." These items represent general barriers that are potentially relevant to all self-care behaviors. The barriers scale had a Cronbach α of .82. The "Living With Diabetes" section of the D-SMART has 2 subscales: distress and support. The construct distress was measured by 7 items, an example of which is, "How much does diabetes interfere with your job, school, or daily activity?" The distress scale had a Cronbach α of .84. The construct support was measured by 7 items, an example of which is, "How much do you feel your family/friends support your efforts for diabetes control?" The support scale had a Cronbach α of .60. Acceptable levels of reliability for early scale development were obtained for barriers and distress, while support had a marginally acceptable level of internal consistency.[27]

The study also collected systematic user acceptance data from patients regarding the D-SMART and its different methods of administration. A small number of educators provided user acceptance data regarding use of the D-ET. Some of the user acceptance data are discussed in another article in this special issue.

In addition to the specific empirical findings that have emerged and will continue to emerge from this study, there was 1 major discovery regarding the D-SMART design. Earlier pilot studies had used the full version of the D-SMART, which included a large number of items, many of which are not outcomes (eg, patient-profiling questions). Those pilot studies were primarily research studies that relied on the willingness of patients and educators to volunteer as participants, whereas the current study had to meet the criterion of what is feasible in routine program operation. Therefore, the project work group developed a mini D-SMART that eliminated the patient-profiling questions and focused on the 20 to 30 questions regarding self-care behavior that were to be used in the analysis of behavioral outcomes. The purpose of this instrument was to decrease patient burden and, it is hoped, increase patient participation in follow-up (especially for patients who do not return to the education program for ongoing support), thus enabling consistent D-SMART administration to be more feasible for educators. An alternative use of the mini D-SMART is that it can be used in place of the full D-SMART for those who need only a standardized behavior assessment form that can then be benchmarked relative to other programs.

Another major accomplishment of this project was the development of a set of electronic (and printable) point-of-service reports for providing feedback to patients and educators regarding patients' progress in achieving behavior change goals.

Future Studies

One major validation study remains to be implemented: a classic validation study.[28] This study would employ gold standard research measurement instruments along with the D-SMART in a design similar to that of the second pilot study (2 administrations of the instruments within a 2-week period prior to an educational intervention, followed by a third administration 1 to 3 months after the educational intervention). Validity could be assessed in 2 ways not already assessed: concordance (correlation among measures) and conceptual validity (whether the D-SMART and the research instruments show the same pattern of results). It now appears that the D-SMART has reached the point at which such a study would be appropriate and worth the necessary investment of resources.

Conclusions

The National Standards for Diabetes Self-management Education were developed by several diabetes organizations to ensure consistency in the structure and process of the delivery of DSME. These standards state that patients with diabetes require both knowledge and skills to manage their disease, which results in changes in behavior. An extension of this continuum is that appropriate self-management behavior, in turn, improves clinical indicators and health status. Based on this position, the AADE Outcomes Task Force developed the D-SMART based on 7 behavioral outcome domains, now referred to as the AADE7 Self-care Behaviors. The AADE7 Self-care Behaviors were selected as the foundation for outcomes measurement in DSME based on the scientific evidence as well as their inherent attributes of being relatively specific and measurable and perceived as relatively achievable and compatible for the individual with diabetes. It is the intent of the AADE that the continuous measurement, monitoring, and management of these behavioral outcomes will guide diabetes educators in their method of delivery of promoting behavior change, leading

to improved clinical indicators and health status, rather than the traditional approach of documenting learning outcomes.[29]

The purpose of the D-SMART is to directly measure patients' behavior and identify their priorities for, and barriers to, change. The patients' responses guide educational interventions by focusing on what patients report are most important to them. Changes in behaviors are measured by administering the D-SMART before and after an educational intervention. These changes in behavior represent outcomes of DSME, and the user-friendly tool provides a consistent measurement of diabetes self-care behavioral outcomes. By identifying outcomes of diabetes education and providing tools to efficiently measure these outcomes, the value of the diabetes educator as an integral part of best practice can be consistently documented and quantified.

Although the D-SMART has undergone extensive development and testing, it is not set in stone. It does not assess all possible diabetes self-care behaviors nor all factors potentially relevant to precipitating behavior change. Future versions of the D-SMART may add new items, and it may become necessary to modify other items. However, the D-SMART provides educators with a tool ready for immediate use and can serve as an important foundation for future work in the field.

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Deploying the Chronic Care Model to Implement and Sustain Diabetes Self-management Training Programs

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Purpose

The purpose of this project was to evaluate the utility of using the 6 elements of the chronic care model (CCM; health system, community, decision support, self-management support, clinical information systems, and delivery system design) to implement and financially sustain an effective diabetes self-management training (DSMT) program.

Methods

The University of Pittsburgh Medical Center (UPMC) uses all elements of the CCM. Partnerships were formed between UPMC and western Pennsylvanian community hospitals and practices; the American Diabetes Association DSMT recognition program provided decision support. A clinical data repository and reorganization of primary care practices aided in supporting DSMT. The following process and patient outcomes were measured: number of recognized programs, reimbursement, patient hemoglobin A1C levels, and the proportion of patients who received DSMT in primary care practices versus hospital-based programs.

Results

Using elements of the CCM, the researchers were able to gain administrative support; expand the number of recognized programs from 3 to 21; cover costs through increased reimbursement; reduce hemoglobin A1C lev-

els ($P < .0001$), and increase the proportion of patients receiving DSMT through delivery in primary care (26.4% suburban; 19.8% urban) versus hospital-based practices (8.3%; $P < .0001$).

Conclusions

The CCM serves as an effective model for implementing and sustaining DSMT programs.

Diabetes self-management training (DSMT) is widely considered to be an important part of diabetes management.[1,2] One of the goals of the US Health and Human Services' *Healthy People 2010* is to increase the number of people who receive diabetes education from 40% (1998) to 60% (2010).[3]

The national standards for DSMT[4] administered through the American Diabetes Association (ADA) recognition program[5] provide a framework for delivery and quality. Medicare and other third-party payers reimburse for programs when they meet ADA requirements. Reimbursement is linked to codes, and charges are typically based on Medicare rates.[6] Reimbursement is critical in generating revenue to support nurse and dietician educators who provide DSMT. Educators can be the target of cost-cutting initiatives when financial stability cannot be demonstrated.[7]

The numbers of patients who receive diabetes education are disappointingly small.[8,9] Access to education has been proposed as a barrier, particularly in communities in which the closest DSMT program may be miles away.[10] Another potential problem may be the traditional way in which education is prescribed and delivered. Currently, physicians are expected to refer diabetes patients to a hospital-based DSMT program. This process is consistent with the current system of health care delivery as it applies to acute care where services are provided at a hospital. Although more than 90% of patients with diabetes are cared for by primary care physicians (PCPs),[11] education is rarely available in the primary care office.[12,13]

Patients and physicians at University of Pittsburgh Medical Center (UPMC) identified education as a barrier to the promotion of quality diabetes care.[10] In an effort to provide education for physician practices and outlying hospitals, the UPMC Endocrine Division supported a certified diabetes educator (CDE). This provided an immediate solution, but a long-term strategy was needed for the UPMC system.

In contrast to traditional methods, the chronic care model (CCM) provides a framework for a systematic approach and has been shown to improve processes and outcomes.[14-16] The CCM is based on the premise that effective chronic disease programs are delivered in partnership with health systems and communities.[14-16] Although the CCM has been used in diabetes improvement projects, it has never been tested in facilitating DSMT programs.[10,17,19] The CCM identifies key elements that are critical to success: (1) health system, to serve as the foundation by providing structure and goals; (2) community, to link with community resources; (3) decision support, to ensure that providers have access to evidence-based guidelines; (4) self-management support, to help patients acquire skills and confidence to self-manage; (5) clinical information systems, to provide timely access to data about patients and patient populations using clinical information systems; and (6) delivery system design, to restructure medical practices to facilitate team care.

It was the objective of this study to evaluate the benefits of using all of the elements of the CCM to expand and support DSMT. The researchers hypothesized that introducing the components of the CCM would lead to increased administrative support along with improved reimbursement for services and A1C levels. By increasing the number of programs and providing DSMT in primary care, it was hoped that some of the barriers to DSMT could be curtailed, including access.

Methods

Setting

UPMC is an integrated health system that includes 19 hospitals and a physician division with 166 primary care and 1400 academic physicians providing services for approximately 90 000 people with diabetes in western Pennsylvania. Implementation of the CCM involved a stepped approach and changes at multiple levels from 2000 to 2004. This project was referred by the

Table 1

Implementation of the Chronic Care Model (CCM)

CCM Component	Activity
Community and health system	UPMC provided educators access to resources in Finance
	Information systems
	Physician practices
	Administration in community hospitals and practices
Self-management support	Nurses and dietitians educators agreed to
	Use consistent forms, educational materials, and a curriculum
	Meet the qualifications for recognition
	Facilitate DSMT to meet the ADA recognition requirements
	Monitor and report CQI processes
Decision support	UPMC supported
	The implementation of national standards for DSMT
	Fee for ADA recognition application
	A central coordinating center to support the educators
	Seminars for training and certification
	A central advisory committee with representation from physician practices, communities, and hospital sites
Clinical information systems	MARS was used to track
	Reimbursement
	Rates of DSMT services
	A1C levels by race
Delivery system design	DSMT delivered in primary care offices was facilitated by
	A CDE who worked with office staff to schedule DSMT
	A CDE who served as a clinical resource available by telephone to physicians, office staff. and patients
	Office staff who reorganized the practices to host “diabetes days”
	Physicians who made direct referrals to the CDE

UPMC = University of Pittsburgh Medical Center; DSMT = diabetes self-management training; ADA = American Diabetes Association; CQI = continuous quality improvement; MARS = Medical Archival Retrieval System; CDE = certified diabetes educator.

University of Pittsburgh Institutional Review Board to the UPMC Quality Council, where it was approved as a quality improvement project.

The CCM implemented at UMPC is outlined in Table 1. The CCM differs from traditional approaches in that it emphasizes self-management support and training.[14,15] The ADA recognition program provided the framework to implement the evidence-based DSMT standards[5] and served as the decision support. In compliance with ADA requirements, an Advisory Committee was established and became responsible for developing an annual plan, assessing the target population, and determining methods for continuous quality improvement (CQI). The Advisory Committee realized a dual purpose could be served if reports on reimbursement, access to DSMT, and A1C levels were available. These reports would serve as important CQI measures and would give UPMC

administration the feedback necessary to gain continued support.

Elements of the CCM

In 2000, the UPMC health system designated diabetes as its quality initiative and agreed to administratively support implementation of the CCM in its network of community hospitals and practices.[17]

The Medical Archival Retrieval System (MARS), a repository of information forwarded from the UPMC electronic clinical, administrative, and financial databases, was used to provide data to the educators and served as the clinical information system. MARS has been refined and validated so that diabetes patients are accurately identified by a combination of diabetes criteria, A1C levels, glucose >200 mg/dL (11 mmol/L), medications, and International Classification of Diseases, ninth revision, codes. At the time of the initiative, only 8 of 21 hospital programs had complete data that were accessible in MARS. This report includes information from those 8 hospitals and 2 primary care practices programs.

When reports of limited access were brought to the attention of the Advisory Committee, UPMC addressed delivery system design and began to implement DSMT in primary care offices in August 2003. A CDE provided DSMT at 1 suburban and 1 urban practice identified as having large populations of diabetes patients. A CDE was available on "diabetes days," when office staff scheduled DSMT appointments. Because of space constraints in the office, DSMT was delivered on an individual basis at the start of the initiative. Group visits were facilitated later on in the project when space was available.

Population

During the tracking period between January 2, 2003, and June 30, 2004, a total of 31 150 people were identified in MARS to have diabetes in the 8 hospitals with DSMT programs (Figure 1). During this time frame 4190 people were identified as having received DSMT at those hospital programs documented by a charge for service generated in MARS. To be eligible for the A1C component of this study, a person had to have their initial education session during this time frame and have at least 2 A1C levels (1 before and 1 after the initial session). Of the 4190 people receiving DSMT, 382 (9%) were eligible for tracking A1C levels. In the suburban and urban practices, 1306 patients were identified as having diabetes using the MARS criteria.

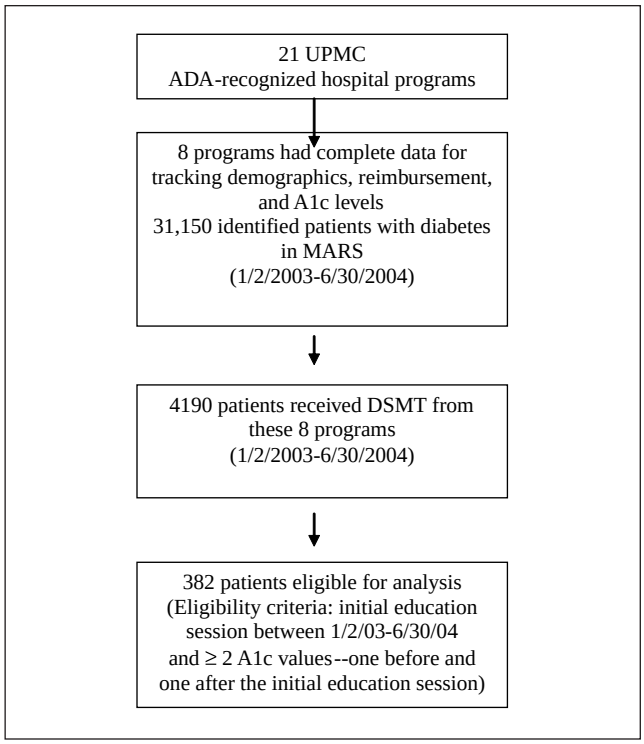

Figure 1. Monitored program populations. UPMC = University of Pittsburgh Medical Center; ADA = American Diabetes Association; MARS = Medical Archival Retrieval System; DSMT = diabetes self-management training.

Program Outcomes

Number of sites. At the start of the initiative, only 3 UPMC hospital programs had ADA recognition. Applications for additional sites were submitted throughout the initiative.

CQI Measures

Reimbursement and patient A1C levels. The tracking of reimbursement was initiated when a program received ADA recognition and bills for service could be generated. A subset of the reimbursement population was used to analyze the effect DSMT had on A1C level trends. At the time of the tracking period, the PCP offices had not

received ADA recognition and therefore could not bill for services.

Patient reach. The proportion of patients who received DSMT at 1 urban and 1 suburban primary care practice was compared to the proportion who received DSMT at the 8 hospital-based programs where DSMT services were available during the same time period (July 2003-December 2004).

Analyses. The statistical analyses incorporated both descriptive and inferential techniques. Measures of central tendency (e.g., proportions, means, standard deviations, medians, etc) were used for all descriptive analyses. In univariate analyses, Student *t* tests for continuous data and Pearson's χ^2 tests for categorical data were used to determine differences in means and proportions. In addition, for each outcome of interest, analysis of variance was used to test for differences in means between more than 2 groups, and χ^2 tests for trends were used to test for differences in proportions between more than 2 groups. To analyze the effect that education had on A1C values, a multilevel model for change was used. This type of analysis allows one to measure change over time while allowing the individuals to be their own controls. All models considered were adjusted for age.[18]

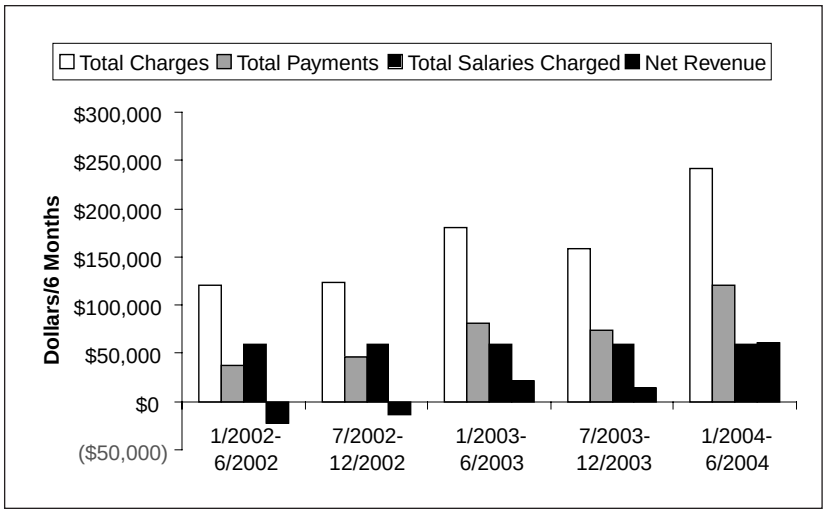

Figure 2. DSMT reimbursement and educator salary at 8 University of Pittsburgh Medical Center American Diabetes Association–recognized programs (January 2002-June 2004).

Results

Decision Support

Between 2000 and 2004, the number of ADA-recognized programs grew from 3 to 21 including pediatric, rural, academic, and 2 primary care practices.

Clinical Information Systems

MARS afforded the opportunity to track reimbursement and A1C levels. As shown in Figure 2, at the 8 DSMT hospital programs where revenue was captured, total charges in 6-month intervals increased from the beginning of the tracking period in January 2002 from $120 846.00 to $241 472.00 in June 2004. Total payment per 6 months increased from $37 192.00 to $120 572.00 over the same period. Interestingly, efficiency of collection increased from approximately 25% to 50%. Most important, diabetes educator effort was covered by the third 6-month period. Thus, at the initiation of this project, DSMT services were a loss leader. In contrast, by the conclusion, educators were more than self-supporting their efforts devoted to DSMT.

When examining patient data from the hospital programs, the mean age was 57.2 years. Patients who received DSMT at the point of service in a suburban office were significantly older than those at the urban PCP office (age: suburban = 66.2 years vs urban = 54.7 years, $P < .0001$). Patients entered the hospital DSMT programs with higher mean A1C values did those in the primary care practices (8.28% vs 7.83%). Figure 3 shows the analysis of the A1C values through 1 year after the initial education session. A mean age-adjusted decrease in A1C values in those in hospital programs (0.95%) versus primary care (0.48%) was achieved ($P = .0001$). A longer follow-up period would be necessary to determine the effects of DSMT over time.

Delivery System Design

In tracking numbers of patients who received DSMT from July 2003 through December 2004, it was found that a 2- to 3-fold greater proportion of patients were reached when DSMT was made available in PCP offices

(26.4% suburban; 19.8% urban) as compared to 8.3% of the population who were referred to hospital-based programs. Of 31 000 patients identified as having diabetes in MARS, only 13% (4190) received DSMT at hospital-based programs during the time period. Of 1306 identified diabetes patients in both the suburban and urban practices combined, 24.7% received DSMT in their PCP's office.

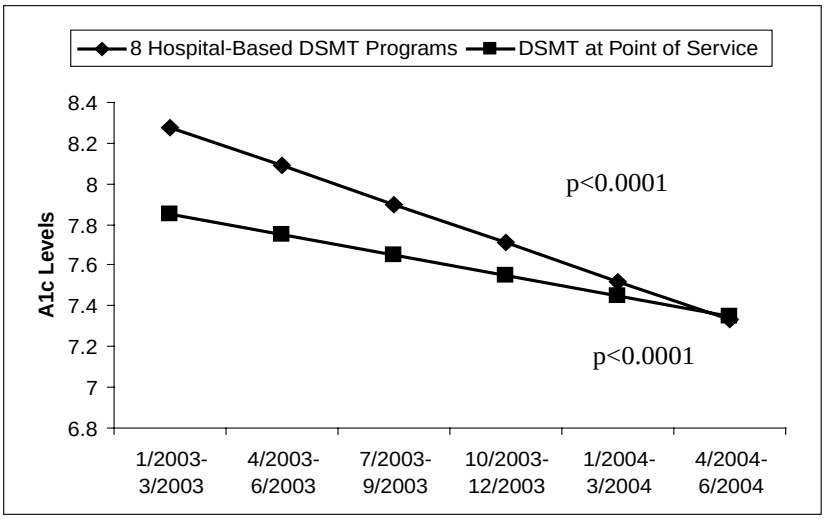

Figure 3. Age-adjusted trends in glycemic control after initial education session. DSMT = diabetes self-management training.

Discussion

In this report, it is demonstrated that the CCM is an effective framework to support DSMT, results in improved program and patient outcomes, and is fiscally self-supporting. With reliable clinical information systems, educators were able to demonstrate the benefits of DSMT delivered in different settings on A1C levels. In a fiscal environment in which hospital administrators are skeptical of services that do not generate revenue, tracking reimbursement in justifying positions was also important.

While the ADA recognition process is widely accepted, there is a paucity of literature on the delivery process, reimbursement practices, and, most important, hard outcomes. Educators in both the ADA and the American Association of Diabetes Educators (AADE) report program closings and express frustration with the implementation of Medicare benefits and receiving appropriate reimbursement.[7] The AADE and ADA collaborated to conduct a survey of DSMT programs. Their findings in 122 sites confirmed the findings of other studies that indicate that diabetes education is an underutilized service.[7-10] Nearly half of the sites reported an average visit volume of fewer than 50 visits per month, and 19% reported only 51 to 100 visits per month. More disappointing were the reimbursement practices. Of the sites that bill Medicare, only 57% were collecting the mandated collection fees, while 37% of the respondents did not even know how often they were collecting these fees.[7] Despite attempts to remedy this problem, only 57% reported having a fiscal reporting system. The ADA and AADE concluded that processes for monitoring billing and establishing a reporting system specific to DSMT were critically important.[7]

The authors took this message seriously and created a system to explore and satisfy these recommendations. Through the repository, educators had the opportunity to monitor reimbursement. UPMC education and billing staff members collaborated and reviewed monthly reports to determine payment practices. Although Pennsylvania mandates coverage for education, compensation for services was not always provided. As reported by others,[7] in addition to external reimbursement difficulties, numerous internal problems were identified throughout the system that precluded reimbursement. Education charges based on Health Care Common Procedure Coding System codes were inaccurately entered, recognition certificates were missing, and charge-entry staff neglected to enter charges. Once these problems were identified, internal efforts to correct the problems and capture reimbursement were implemented.

The authors were also eager to increase their DSMT services and realized that they needed to improve access. An important innovation was that they went beyond traditional models of DSMT delivery as a result of their system redesign; by integrating educators directly into offices, access to DSMT increased. It was demonstrated that DSMT delivered in the office has a positive effect on A1C levels along with PCPs and educators reporting other advantages that included increased communication

on management plans and CDE involvement in medication initiation and adjustments. Patients reported greater comfort with location and easy access to the educator for questions and problem solving. The intent is not to suggest that hospital-based programs be replaced or eliminated but that opportunities to support education and follow up in other settings are investigated.

To the best of the authors' knowledge, this project is the first to systematically develop a DSMT network using all of the elements of the model and report on ADA recognition and reimbursement practices. The CCM has been tested and shown to improve outcomes.[14,15] However, much of the research has focused on specific components of the CCM model, and evaluations of an overall plan are less frequent. More recently, Wagner et al[20] performed a survey and site visits of 72 chronic disease management programs that were considered to be innovative and effective. Only 1 program had instituted all 6 components of the model.

The limitations of the project are recognized. The UPMC diabetes initiative is in its infancy. As the project evolves, each of the components of the CCM continues to be developed and refined. For example, not all of the DSMT programs were linked to the data repository during the initiative.

Another weakness is that the researchers were unable to effectively track all hemoglobin A1C levels throughout the project. Patients may have had laboratory tests done elsewhere. It is recognized that factors other than DSMT may have influenced improvements in glycemic control and that A1C levels are not the only indicator for quality.[21] Other medical interventions and outcomes must be controlled for and captured in future studies.

It is recognized that reimbursement needs to increase to fully support an educator's salary. Now that billing practices have been remedied and new avenues for access have been identified, UPMC will move more educators into primary care practices, increase group visits, and begin an aggressive DSMT promotional campaign in its communities.

Although this study was performed in a large health system with access to many resources, it serves as a model for others to explore creative solutions. It provides a template for educators to explore collaboration with heretofore unlikely partners in administration, finance, and information systems and to create opportunities outside of traditional roles, such as the development of business models for sustainability. Smaller and independent facilities may seek opportunities to share data systems or form consortia to organize systemwide recognition applications. Hospital-based educators could partner with primary care practices to provide follow-up education in an office and seek creative methods for billing for services. Innovative technological methods, virtual teams, and community-based education afford other exciting opportunities that need to be tested. First and foremost, educators and physicians need to be open-minded to consider areas for change.

Developing systems that promote accessible, sustainable DSMT programs that affect metabolic outcomes have large- scale public health implications. Organizing efforts to support the facilitation of DSMT is critical in meeting the *Healthy People 2010* education objectives.

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CERTIFICATE OF RECOGNITION

The American Diabetes Association
recognizes the education service of

Diabetes Self-Management Education Program
Wilford Hall Medical Center
Lackland AFC, Texas

AS MEETING THE NATIONAL STANDARDS FOR DIABETES SELF-MANAGEMENT EDUCATION

AWARDED FOR THE PERIOD OF
May 24, 2007 - May 24, 2010

ID# 005480

Ann Albright

Ann Albright, PhD, RD
President, Health Care & Education

Diane M. Reader R.D. CDE

Diane M. Reader, RD, CDE
Chair, Committee on Recognition

American Diabetes Association®
Cure • Care • Commitment®

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
LACKLAND AFB, TX 78236-9908
MEMORANDUM FOR 759 MDOS/MMIE, ADA

10 August 2006

FROM: MMIE

SUBJECT: Diabetes Self-Management Education (DSME) Advisory Group Meeting Minutes

1. A Diabetes Self-Management Education (DSME) Advisory Group Meeting was held on **10 August 2006** at 1500 hours in the room 3A11.

A. Members Present:

Lois Wingate	Civ/Program Coordinator
Lt Col Tom Sauerwein	MC
Lt Col Nina Watson	NC/Instructional Staff
Maj Mark True	MC
Tanya Crail	CON/Instructional Team
Cates, Majorie	Patient/Community Representative

B. Members Absent:

Lt Bullard, Catherine	BSC	Duty
Lt Col Neal-Walden, Tracy	BSC	Duty
Maj Eliason, Jonathan	MC	Duty

C. Guest(s):

2. NEW BUSINESS:

A. Purpose of Advisory Group: Department is pursuing American Diabetes Association recognition. This group will annually review DSME operations and services providing input and oversight of program. Requested participation from Endocrinology, Nutritional Medicine, Lifeskills/Behavioral Medicine, Vascular Surgery and a representative from the community.

B. Program Review: Current program has been in place 18 years with updates as needed. The present version is based on Type 2 Diabetes: A Series of Teaching Outlines by the Michigan Diabetes Research and Training Center, American Diabetes Association, 2002.

1.Goal Achievement of DSME operations: Group identified 3 goals for the DSME program.

a. Provide quality education for people with diabetes in accordance with established standards and guidelines.

b. Assess patient education needs and how those needs were met by the program from a sampling of patients.

c. Annual review of the program to include: personnel needs, budget, equipment, teaching materials, space, processes, attendance, data collected, and adherence of curriculum to current national standards.

2. Data analysis of DSME operations
   a. Ms. Wingate reported results from 2005. 407 attended Class #1, 124 completed all 6 classes. Group would like to see an increase of 10% completion rate, from 30-40% in 2006.
   b. Pre-education patient needs assessment was completed in 2005. Results were reported by Lt Col Watson. See attachment 1. Those items to be least understood by patients are: A1C control values, symptoms of diabetes, and diet. Discussion included proposals for changes in curriculum to emphasize control values and common symptoms. Nutritional Medicine will review current slides and adopt a more interactive approach for discussion of diet strategies.
   c. Post education assessment period Nov 05-Apr06 (assessment completed May-Jul 06) See attachment 2.
3. Mission Statement: The following mission statement was agreed upon by the group.
   a. To provide quality comprehensive diabetes self-management education. We believe that education is the key to empowering the person with diabetes to better manage his or her diabetes and avoid the complications and achieve an optimum health status.
4. Organizational structure of DSME: Organizational Chart was reviewed (attachment 3). Currently have command support for program. Updated support letter routed.
5. Population served by DSME: Program is available to all eligible beneficiaries. Current enrollee population=60,804. 3,518 have a diagnosis of diabetes. Age breakdown: 18-40 years=106, 41-64=1710, 65+=1702. Education is available via physician referral.
6. Resources of DSME: DSME is delegated to the Endocrinology department
   a. Personnel: Endocrinology department UMD provides for 2 CDEs, Nutritional Medicine provides 1 dietitian, UPMC provides 1 dietitian and 1 CDE (slot open). Endocrionology, Behavioral Medicine and Vascular provide instructional staff. Also have a cadre of volunteers to assist with sign-in and administrative duties.
   b. Budget: provided in Endocrinology annual budget.
   c. Equipment: all A-V equipment, computers are maintained by the Endocrinology equipement custodian.
7. Curriculum review: Group concurred that current curriculum is appropriate and meets requirements for recognition. Handouts are current and appropriate.
8. Community concerns:
   a. Camp Independence: Dr Sauerwein and Ms Wingate continue to sit on board.
   b. Both CDEs hold AADE membership in local chapter.
   c. Planned community involvement: Hispanic Month presentation at Security Hill, Retiree Recognition Day in October, blood glucose screenings in November.
9. Outcome data measurements of DSME participants and operations: Group identified following for data collection over the next year.
   a. Behavior change objectives: physical activity and risk reduction
   b. Program outcome measures: eye exam and self foot exam
   c. CQI:

C. Roundtable discussion.

a. Ms. Wingate raised how often to meet. Group agreed for annual meeting. Since applying for recognition, will have ad hoc group (Wingate, Watson, and Crail) meet in May to analyze data and complete recognition application.

5. ADJOURNMENT: There being no further business, meeting was adjourned at 1650 hours. The next meeting is scheduled for 9 August 2007 at 1400 hrs in conference room 3A11.

LOIS E. WINGATE, RN, BSN, CDE
DSME Program Coordinator

MEMORANDUM FOR DIABETES SELF-MANAGEMENT EDUCATION (DSME) ADVISORY GROUP

FROM: Lois Wingate, RN, BSN, CDE/MMIE

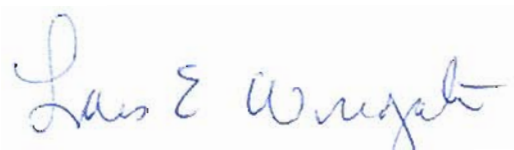
SUBJECT: Agenda for Annual Program Review and Plan 10 August 2006

1. Purpose of Advisory Group

2. Program Review

    a. Goal achievement of DSME operations
    b. Data analysis of DSME operations
    c. Mission statement of DSME
    d. Organizational structure of DSME
    e. Population served by DSME
    f. Resources of DSME
    g. Curriculum review
    h. Community concerns
    i. Outcome data measurements of DSME participants and operations
        a. Review needs survey
        b. Identify program outcome measure
        c. Identify QI project

3. Roundtable discussion



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   b. Budget: provided in Endocrinology annual budget.
   c. Equipment: all A-V equipment, computers are maintained by the Endocrinology equipement custodian.
7. Curriculum review: Group concurred that current curriculum is appropriate and meets requirements for recognition. Handouts are current and appropriate.
8. Community concerns:
   a. Camp Independence: Dr Sauerwein and Ms Wingate continue to sit on board.
   b. Both CDEs hold AADE membership in local chapter.
   c. Planned community involvement: Hispanic Month presentation at Security Hill, Retiree Recognition Day in October, blood glucose screenings in November.
9. Outcome data measurements of DSME participants and operations: Group identified following for data collection over the next year.
   a. Behavior change objectives: physical activity and risk reduction
   b. Program outcome measures: eye exam and self foot exam
   c. CQI:

C. Roundtable discussion.

a. Ms. Wingate raised how often to meet. Group agreed for annual meeting. Since applying for recognition, will have ad hoc group (Wingate, Watson, and Crail) meet in May to analyze data and complete recognition application.

5. ADJOURNMENT: There being no further business, meeting was adjourned at 1650 hours. The next meeting is scheduled for 9 August 2007 at 1400 hrs in conference room 3A11.

LOIS E. WINGAE, RN, BSN, CDE
DSME Program Coordinator

Appendix O

Deliverable #209: Final Report Design, Implement and Evaluate an Educational Program on the Importance of Screening for Diabetic Eye Disease to the Diabetic Patient Population and Physicians in Rural Communities

Appendix O

Retinal Imaging and An Educational Program on the Importance of Diabetic Eye Disease

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Final Report – Goal 1:

Design, implement and evaluate an educational program on the importance of screening for diabetic eye disease to the diabetic patient population and physicians in rural communities.

Summary

- We developed an educational video (sent as hard copy DVD) on diabetic eye disease and piloted it at a rural Community County Fair and a large community health awareness event called Healthy 4 Life.
- 63 participants with diabetes successfully viewed an educational video on eye care.
- 31.8% of the participants reported that their last eye exam was "More than 12 months ago" or "Never."
- When seeking information on diabetes, participants responded that they would ask their generalist or PCP most frequently.
- Our data showed that a diabetes eye education video could significantly improve patient knowledge on diabetic retinopathy.

Introduction

Diabetes now affects 23.6 million children and adults in the United States.[1] This is 8% of our current population and the numbers are increasing. There are 12,000 to 24,000 new cases of blindness caused by complications of diabetes each year.[1] Among 20-74 year-old patients, it is the leading cause of blindness.[1] Although laser therapy can help prevent blindness caused by diabetic retinopathy, early detection is necessary. The American Diabetes Association recommends annual eye exams for patients with diabetes.[2]

Many diabetic patients do not access regular eye care leading to poor visual outcomes.[3-7]

We hypothesized that a diabetes eye education program would improve people's knowledge of diabetes eye disease and in turn have the potential to improve the rate of eye exams and reducing risk of blindness. It has been shown that, only 50-70% of individuals with diabetes are adherent with the recommended level of eye care. We proposed to introduce an educational video to the retinal eye screening events which have been ongoing.

Background

Eye screenings were hosted at University of Pittsburgh Medical Center (UPMC) clinics and at health fairs throughout the greater Pittsburgh area. Sites included both rural and urban communities.

In our ongoing Diabetic Retinopathy Screening project, which now includes a sample of 923 patients, we have found that when asked "When was your Last Eye Exam" more than 49% of the subjects responded "Greater Than 12 Months" or "Never". When asked a question related to glycemic control as an important predictor of diabetes eye disease, only 461 (50%) of the patients were aware of their hemoglobin A1c levels, 332 (36%) were not aware of their hemoglobin A1c levels and 130 (14%) never heard of the term A1c. Of those participating in the screenings mean hemoglobin A1c was 7.3%. We suspected that people were not aware of diabetes management goals and risk prevention strategies.

Our objective in this sub-study was to develop a didactic educational video module to be shown and integrated into the current workflow of Diabetic Retinopathy Screening.

Methods

Design
This sub-study was designed to incorporate educational material on eye care, the importance of good glycemic control and sources of diabetes information into a video to be viewed as part of an eye screening program. A 10 minute video was created and presented at eye screening events. Along with the video, we also developed and administered a series of questionnaires. (Appendix A) The pre-viewing assessment questionnaire (Diabetes Eye Education Demographics) included questions on demographics and a question designed to determine where people receive their diabetes information, a 7-item assessment questionnaire identifying barriers in obtaining quality eye care (The Diabetes Eye Education Barrier Assessment) and 10 questions adapted from a standardized questionnaire available from the National Eye Institute (Diabetes Eye Education Eye-Q Assessment). Following the viewing of the educational video the Eye-Q Assessment was re-administered.

We selected two sites to pilot the study. The first was located in Fayette County, a rural community approximately one hour east of Pittsburgh. The event was billed as the *Great American Cookout* (GAC) which was a health information event sponsored by the University of Pittsburgh Diabetes Institute. It was held at the Fayette County Fair Grounds and was well attended. The second event was *The Healthy 4 Life and the American Diabetes Association Expo* (H4L). This is an annual event held in the David Lawrence Convention Center within the city of Pittsburgh. The event has a draw of both rural and urban communities and was well attended.

Screening site: Great American Cookout (GAC)
The eye screening area was inside a large pavilion which was part of the Fayette County fair grounds. Space was generous, allowing up to three subjects to participate at the same time. Traffic albeit steady did not have a large number of people with diabetes.

Often the noise level was too great to hear so a headset was procured to allow the video to be heard. The final sample was 15 subjects.

Screening site: Healthy 4 Life (H4L)
Ophthalmology and retinal imaging screening was given a prominent location on the outside end of the exhibit area at the H4L. This was a high traffic area with throughways to the main convention center and also to those entering the exhibit area. Signs were moved to better identify the area and the greeting table. The video was first set up to be shown on a television with up to four viewing at the same time. Again because of the noise level the layout was changed to allow viewing on the television and a laptop with the use of headsets. Forty-eight subjects completed the pre-viewing assessment questionnaire. Forty-two subjects completed the Eye-Q Assessment both before and after viewing.

Analysis
Data entry and data analyses were created using SPSS version 15.0. We used a paired t-test to compare the difference of questions between pre- and post-viewing. We gave „a correct answer' a value of 1 and „an incorrect answer', „Not Sure', and „Missing data' a value of 0 for each subject. Scores ranged from 0 through 10 with 10 being a perfect score.

We applied for and received permission form the University of Pittsburgh Institutional Review Board (IRB) for an exempt study.

Results

Demographics (Table 1)
The combined total number of patients from both screening sites provided a sample of 63 subjects with diabetes. Six percent had Type 1 diabetes and eighty-four percent had Type 2 diabetes. Sixty percent were female. Age ranged from 31 to 80 years and the mean age was 57.5 years old. The mean duration of diabetes diagnosis was 8 years.

Only 29 (46%) of the subjects were aware of their hemoglobin A1c levels, 26 (41%) of the subjects were not aware of their A1c levels, 2 (3%) subjects never heard of the term hemoglobin A1c and 6 (10%) had missing answers to the question. The mean self-reported hemoglobin A1c percentage was 7.1.

Where do people receive their diabetes information? (Figure 1)
This question is a cumulative multiple choice question and subjects had 1-6 choices. The question was posed to gain an understanding of where patients sought information on diabetes. When seeking information on diabetes, subjects would ask or use generalist/PCP, specialist, and nurse educator/certified diabetes educator more frequently compared to the other resources. Patients by and large relied on their generalist or primary care physician for diabetes information. Patients rarely relied on family/friends or the internet as a diabetes resource.

Barrier Assessment (refer to Table 2 for specific site details)
Combined site result summary

- Q 1 *Its too hard*

- The majority (58.7%) agreed that it was „Not At All' hard to get quality eye care.

- Q 2 *I don't have time*
  - 57% of the patients did not find that having enough time was a barrier to getting an exam
- Q3 *There is no place available*
  - 77.8% reported that having a place to get an exam was not a problem.
- Q 4 *My family/friends don't support me*
  - 78% reported that family and friends do not support them
- Q5 *I'm afraid to know results*
  - Both groups reported (67%) that they were afraid to know the results
- Q 6 *I can't afford it*
  - Both groups (60%) reported that they could not afford it
- Q 7 *I feel it is my fault*
  - Interestingly, 70% reported that they do not feel that getting eye disease is their fault
  -

Eye-Q Assessment (Table 3)
The correct response for each question was TRUE with the exception of Q2 which was FALSE.

- Q 1 *People with diabetes are more likely to develop certain eye diseases*
  - People pre and post recognized that people with diabetes are more prone to getting eye disease
- Q 2 *Diabetic eye disease usually has early warning signs*
  - People recognized that diabetic eye disease does not have early warning signs. There was a trend for a better understabnding of this concept in the H4Life group (urban) after viewing video.
- Q 3 *People with diabetes should have yearly eye exams*
  - Almost all responded correctly both pre- and post-viewing to Q 3, for combined 96.8% and 92.1%.
- Q 4 *Diabetic retinopathy is caused by changes in blood vessels in eye*
  - We saw the percentage of correct answers increase and uncertainty decrease in Q 4, diabetic retinopathy is caused by changes in blood vessels;
- Q 5 *Diabetes nurse educators are excellent sources for education and guidance*
  - Recognition of the educator as a resource improved from baseline to post assessment
- Q 6 *Laser surgery can be used to halt the progression of retinopathy*
  - Understanding of laser surgery improved with scores rising dramatically from 38.1% to 82.5%.
- Q 7 *People with diabetes should have regular eye exams*
  - People reported pre and post that regular eye exams are important
- Q 8 *Cataracts are common among people with diabetes*
  - Scores improved from 50 to 80% in people's understanding that cataracts are more common inn people with diabetes
- Q 9 *People who have good control of their diabetes have a much lower risk for eye disease*
  - At baseline people reported that good control is associated with lower risk and scores improved post test.
- Q 10 *The risk of blindness from diabetes can be reduced*

- The majority of people also reported that risk can be reduced

Paired t-test
Overall, results were significantly improved after watching the video. Prior to watching the video, participants, on average, respondents got 7.6% responses correct. After watching the video, participants got 9.2% responses correct. Significant with $p<0.0001$.

Physician education

Throughout our study, presentations both formal and informal were made to the physician community. *Causes of Blindness in Diabetes Lecture* (Appendix B mailed as hard copy CD) was presented at the following:

- Update in Internal Medicine, *"Causes of Blindness in Diabetes Mellitus",* Pittsburgh, PA, November 3, 2005

- Annual Diabetes Update, *"Tackling the Diabetes Epidemic Through a Community Approach" – Promoting Health. "Blindness from Diabetes?"* UPMC McKeesport, November 8, 2006

- Endocrine/Pathology Workshop *"Pathology of Diabetic Complications"* University. of Pittsburgh, School of Medicine, Second –year medical students. January 23, 2007

- The Pittsburgh Ophthalmology Society Spring Meeting. *"Causes of Blindness from Diabetes"* March 9, 2007.

Conclusions

For our sample we have found that most patients agreed that it was not difficult to get quality eye care and to find a facility. Having enough time to get a visit did not seem to be a barrier. Support from family/friends may be slightly lacking and patients in both community sites reported that they are afraid to get results. Although the patients reported cost as a barrier, diabetes retinal eye exams are a mandated covered service in all health plans and carriers.

Interestingly, the majority of patients recognized that good glycemia prevents complications and that diabetic eye disease can be prevented. However, these patients also reported that getting eye disease was not their fault, >25% had not had an eye exam in the past year and almost half of them did not know their A1C level.

According to pre- and post-eye education survey, our diabetes eye educational program contributed to the improvement in participant's understanding of the concepts of diabetic retinopathy, the importance of glucose control, and overall self-management of diabetes among people with diabetes. Our results demonstrated that the video improved an understanding of the cause of retinopathy, the value of diabetic nurse educators, and the use of laser surgery to halt the progression of diabetic retinopathy. Most people knew that having better control of their diabetes lowered the risk of eye disease and that the risk from blindness could be reduced.

Appendix O

Our research is not without limitations. Our sample size is small and may violate the power of this study. Our sample size in the rural community was particularly small and it is difficult to extrapolate finding with a sample of 15 subjects. Also of note is that some of the subjects were impatient with the program (many distractions at the health fairs) and did not complete the post-viewing questionnaire.

This study suggested that eye education video can be a useful tool in an effort to improve patient understanding of eye diseases caused by diabetes. Physician education remains paramount in that we found that people with diabetes gain most of their information/education from their physicians. Patients also learned that diabetes educators can serve as an important resource. Thus, education efforts should also be directed to educators.

Future efforts and studies may include:

- a shortened version of the video
- attention to environmental issues when presenting the video (head sets)
- adapting the video to emphasize themes like the importance of laser therapy and attention to related eye problems like cataracts
- evaluation of the entire program in diverse populations.

Table 1. Demographics. Combined data is the total number of GAC and H4L.

Demographics	GAC n=15 (%)	H4L n=48 (%)	COMBINED n=63 (%)
Gender			
• Male	4 (26.7)	21 (43.8)	25 (39.7)
• Female	11 (73.3)	27 (56.3)	38 (60.3)
Mean Age (Years)	58.6	57.2	57.5
Race			
• Caucasian	12 (80.0)	30 (62.5)	42 (66.7)
• Black	3 (20.0)	14 (29.2)	17 (27.0)
• Asian	0	1 (.21)	1 (1.6)
• Hispanic	0	2 (4.2)	2 (3.2)
• Multi-racial	0	0	0
• Native American	0	0	0
• Other	0	1 (2.1)	1 (1.6)
Diabetes			
• Type 1	0	4 (8.3)	4 (6.3)
• Type 2	15 (100)	38 (79.2)	53 (84.1)
• Missing	0	6 (12.5)	6 (9.5)
Mean Duration of Diabetes (Years)	8.1	8.2	8.1
Hemoglobin A1c status			
• Known	3 (20.0)	26 (54.2)	29 (46.0)
• Unknown	10 (66.7)	16 (33.3)	26 (41.3)
• Never heard of it	1 (6.7)	1 (2.1)	2 (3.2)
• Missing	1 (6.7)	5 (10.4)	6 (9.5)
Mean A1c Percentage	8.25	7.00	7.11

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Last Eye Exam			
• **Less than 1 month ago**	**0**	**3 (6.3)**	**3 (4.8)**
• **1 to 3 months ago**	**2 (13.3)**	**6 (12.5)**	**8 (12.7)**
• **3 to 6 months ago**	**3 (20.0)**	**7 (14.6)**	**10 (15.9)**
• **6 to 12 months ago**	**5 (33.3)**	**14 (29.2)**	**19 (30.2)**
• **More than 12 months ago**	**4 (26.7)**	**15 (31.3)**	**19 (30.2)**
• **Never**	**0**	**1 (2.1)**	**1 (1.6)**
• **Unknown**	**1 (6.7)**	**0**	**1 (1.6)**
• **Missing**	**0**	**2 (4.2)**	**2 (3.2)**

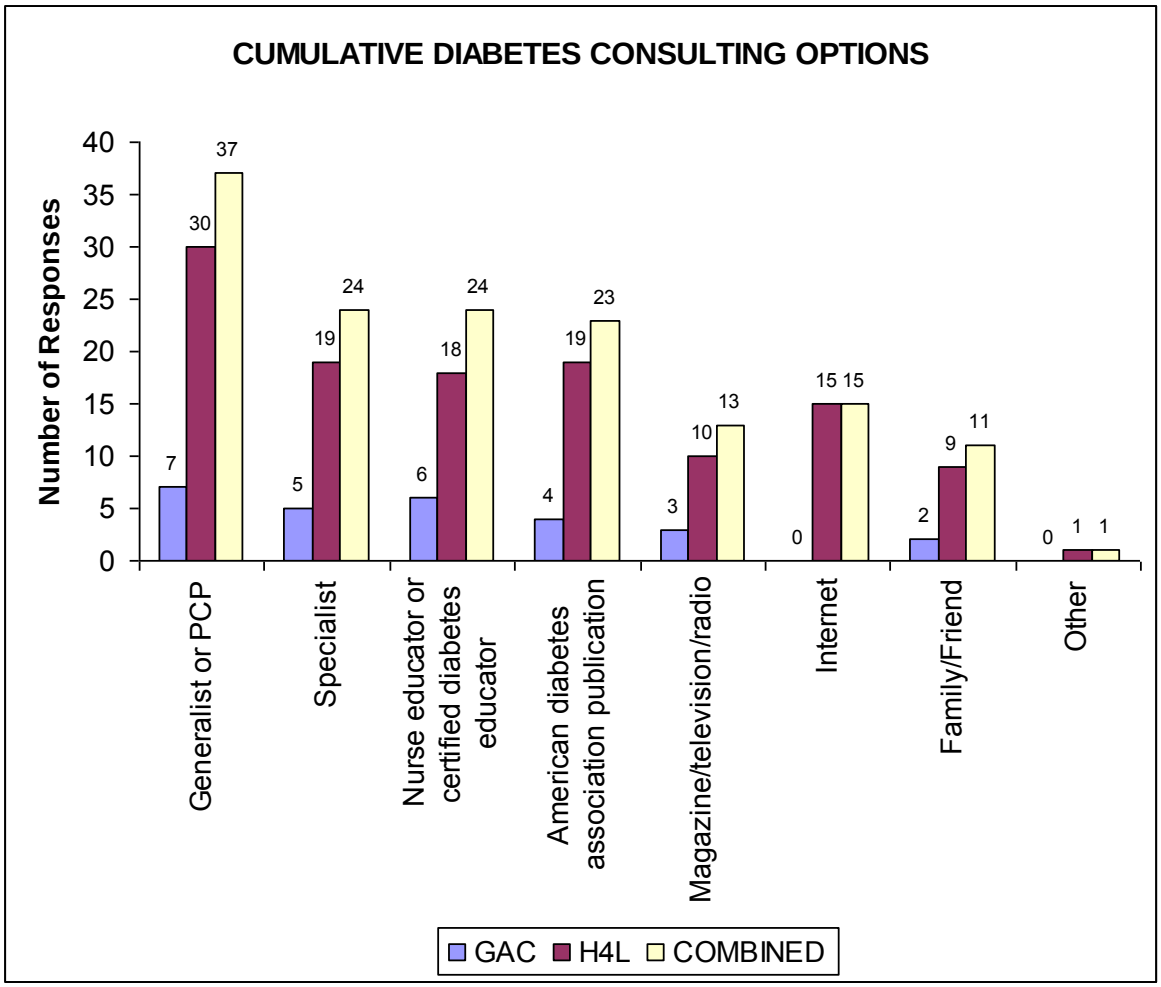

Figure 1. Cumulative diabetes consulting options. When seeking information on diabetes, subjects would use different resources. Combined data is the total number of GAC and H4L.

Appendix O

Table 2. Barrier Assessment Combined data is the total number of GAC and H4L.

	A Lot N (%)	**A Little** N (%)	**Some** N (%)	**Not At All** N (%)	**TOTAL Number** (%)
Q1. It's too hard.	GAC 2 (13.3)	GAC 1 (6.7)	GAC 5 (33.3)	GAC 7 (46.7)	GAC 15 (100)
	H4L 2 (4.2)	H4L 8 (16.7)	H4L 8 (16.7)	H4L 30 (62.5)	H4L 48 (100)
	COMBINED 4 (6.3)	COMBINED 9 (14.3)	COMBINED 13 (20.6)	COMBINED 37 (58.7)	COMBINED 63 (100)
Q2. I don't have time.	GAC 4 (26.7)	GAC 1 (6.7)	GAC 3 (20.0)	GAC 7 (46.7)	GAC 15 (100)
	H4L 6 (12.5)	H4L 7 (14.6)	H4L 5 (10.4)	H4L 29 (60.4)	H4L 47 (97.9)
	COMBINED 10 (15.9)	COMBINED 8 (12.7)	COMBINED 8 (12.7)	COMBINED 36 (57.1)	COMBINED 62 (98.4)
Q3. There is no place available.	GAC 0	GAC 1 (6.7)	GAC 1 (6.7)	GAC 13 (86.7)	GAC 15 (100)
	H4L 2 (4.2)	H4L 3 (6.3)	H4L 5 (10.4)	H4L 36 (75)	H4L 46 (95.8)
	COMBINED 2 (3.2)	COMBINED 4 (6.3)	COMBINED 6 (9.5)	COMBINED 49 (77.8)	COMBINED 61 (96.8)
Q4. My family/friends don't support me.	GAC 3 (20.0)	GAC 2 (13.3)	GAC 1 (6.7)	GAC 9 (60.0)	GAC 15 (100)
	H4L 5 (10.4)	H4L 3 (6.3)	H4L 3 (6.3)	H4L 35 (72.9)	H4L 46 (95.8)
	COMBINED 8 (12.7)	COMBINED 5 (7.9)	COMBINED 4 (6.3)	COMBINED 44 (69.8)	COMBINED 61 (96.8)
Q5. I'm afraid to know the results.	GAC 0	GAC 2 (13.3)	GAC 3 (20.0)	GAC 9 (60.0)	GAC 14 (93.3)
	H4L 2 (4.2)	H4L 8 (16.7)	H4L 5 (10.4)	H4L 33 (68.8)	H4L 46 (95.8)
	COMBINED 2 (3.2)	COMBINED 10 (15.9)	COMBINED 8 (12.7)	COMBINED 42 (66.7)	COMBINED 62 (98.4)
Q6. I cannot afford it.	GAC 4 (26.7)	GAC 1 (6.7)	GAC 1 (6.7)	GAC 9 (60.0)	GAC 15 (100)
	H4L 5 (10.4)	H4L 5 (10.4)	H4L 9 (18.8)	H4L 29 (60.4)	H4L 43 (89.6)
	COMBINED 9 (14.3)	COMBINED 6 (9.5)	COMBINED 10 (15.9)	COMBINED 38 (60.3)	COMBINED 63 (100)
Q7. I feel like it is my fault.	GAC 3 (20.0)	GAC 1 (6.7)	GAC 1 (6.7)	GAC 10 (66.7)	GAC 15 (100)
	H4L 3 (6.3)	H4L 6 (12.5)	H4L 5 (10.4)	H4L 34 (70.8)	H4L 45 (93.7)
	COMBINED 6 (9.5)	COMBINED 7 (11.1)	COMBINED 6 (9.5)	COMBINED 44 (69.8)	COMBINED 63 (100)

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Table 3. Eye-Q Assessment. Combined data is the total number of GAC and H4L.

	Pre-Viewing			Post-Viewing		
	True N (%)	**False** N (%)	**Not Sure** N (%)	**True** N (%)	**False** N (%)	**Not Sure** N (%)
Q1. People with diabetes are more likely than people without diabetes to develop certain eye diseases.	GAC 14 (93.3)	GAC 0	GAC 1 (6.7)	GAC 13 (86.7)	GAC 1 (6.7)	GAC 1 (6.7)
	H4L 47 97.9)	H4L 0	H4L 0	H4L 43 (89.6)	H4L 0	H4L 0
	COMBINED 61 (96.8)	COMBINED 0	COMBINED 1 (1.6)	COMBINED 56 (88.9)	COMBINED 1 (1.6)	COMBINED 1 (1.6)
Q2. Diabetic eye disease usually has early warning signs.	GAC 1 (6.7)	GAC 11 (73.3)	GAC 3 (20.0)	GAC 3 (20.0)	GAC 11 (73.3)	GAC 1 (6.7)
	H4L 19 (39.6)	H4L 20 (41.7)	H4L 7 (14.6)	H4L 12 (25.0)	H4L 30 (62.5)	H4L 1 (2.1)
	COMBINED 20 (31.7)	COMBINED 31 (49.2)	COMBINED 10 (15.9)	COMBINED 15 (23.8)	COMBINED 41 (85.1)	COMBINED 2 (3.2)
Q3. People with diabetes should have yearly eye examinations.	GAC 15 (100.0)	GAC 0	GAC 0	GAC 15 (100)	GAC 0	GAC 0
	H4L 46 (95.8)	H4L 0	H4L 1 (2.1)	H4L 43 (89.6)	H4L 0	H4L 0
	COMBINED 61 (96.8)	COMBINED 0	COMBINED 1 (1.6)	COMBINED 58 (92.1)	COMBINED 0	COMBINED 0
Q4. Diabetic retinopathy is caused by changes in the blood vessels in the eye.	GAC 12 (80.0)	GAC 0	GAC 2 (13.3)	GAC 14 (93.3)	GAC 0	GAC 1 (6.7)
	H4L 36 (75.0)	H4L 0	H4L 10 (20.8)	H4L 39 (81.3)	H4L 1 (2.1)	H4L 1 (2.1)
	COMBINED 48 (76.2)	COMBINED 0	COMBINED 13 (20.6)	COMBINED 53 (84.1)	COMBINED 1 (1.6)	COMBINED 2 (3.2)
Q5. Diabetic nurse educators are excellent sources of education and guidance.	GAC 12 (80.0)	GAC 0	GAC 2 (13.3)	GAC 15 (100)	GAC 0	GAC 0
	H4L 40 (83.3)	H4L 1 (2.1)	H4L 6 (12.5)	H4L 41 (85.4)	H4L 0	H4L 1 (2.1)
	COMBINED 52 (82.5)	COMBINED 1 (1.6)	COMBINED 8 (12.7)	COMBINED 56 (88.9)	COMBINED 0	Combined 1 (1.6)
Q6. Laser surgery can be used to halt the progression of diabetic retinopathy.	GAC 5 (33.3)	GAC 4 (26.7)	GAC 6 (40.0)	GAC 13 (86.7)	GAC 0	GAC 2 (13.3)
	H4L 19 (39.6)	H4L 6 (12.5)	H4L 21 (43.8)	H4L 39 (81.3)	H4L 1 (2.1)	H4L 3 (6.3)
	COMBINED 24 (38.1)	COMBINED 10 (15.9)	COMBINED 27 (42.9)	COMBINED 52 (82.5)	COMBINED 1 (1.6)	COMBINED 5 (7.9)
Q7. People with diabetes should have regular eye	GAC 15 (100)	GAC 0	GAC 0	GAC 14 (93.3)	GAC 0	GAC 0
	H4L 46 (95.8)	H4L 1 (2.1)	H4L 0	H4L 42 (87.5)	H4L 1 (2.1)	H4L 0

examinations.	COMBINED 61 (96.8)	COMBINED 1 (1.6)	COMBINED 0	COMBINED 56 (88.9)	COMBINED 1 (1.6)	COMBINED 0
Q8. Cataracts are common among people with diabetes.	GAC 10 (66.7)	GAC 2 (13.3)	GAC 3 (20.0)	GAC 13 (86.7)	GAC 0	GAC 2 (13.3)
	H4L 22 (45.8)	H4L 4 (8.3)	H4L 20 (41.7)	H4L 38 (79.2)	H4L 0	H4L 5 (10.4)
	COMBINED 32 (50.8)	COMBINED 6 (9.5)	COMBINED 23 (36.5)	COMBINED 51 (81.0)	COMBINED 0	COMBINED 7 (11.1)
Q9. People who have good control of their diabetes have a much lower risk for diabetic eye disease.	GAC 13 (86.7)	GAC 0	GAC 2 (13.3)	GAC 15 (100)	GAC 0	GAC 0
	H4L 40 (83.3)	H4L 2 (4.2)	H4L 5 (10.4)	H4L 43 (89.6)	H4L 0	H4L 0
	COMBINED 53 (84.1)	COMBINED 2 (3.2)	COMBINED 7 (11.1)	COMBINED 58 (92.1)	COMBINED 0	COMBINED 0
Q10. The risk of blindness from diabetes eye disease can be reduced.	GAC 12 (80.0)	GAC 2 (13.3)	GAC 1 (6.7)	GAC 14 (93.3)	GAC 0	GAC 1 (6.7)
	H4L 42 (87.5)	H4L 1 (2.1)	H4L 4 (8.3)	H4L 42 (87.5)	H4L 0	H4L 1 (2.1)
	COMBINED 54 (85.7)	COMBINED 3 (4.8)	COMBINED 5 (7.9)	COMBINED 56 (88.9)	COMBINED 0	COMBINED 2 (3.2)

Figure 3. The subjects were watching the diabetes eye education video by television and laptop.

Figure 4. Signs of eye screening in H4L.

Appendix O

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Appendix P

Deliverable #210: Final Report Develop a Solution for the Photography, Storing, and Tracking of Eye Images for Diabetes Patients in Outlying Communities

Appendix P

Title: Diabetes Prevention and Treatment Programs for Western PA

Contract No. W81XWH-04-2-0030

Sub-project Title: Diabetes Retinopathy

Goal: Develop a solution for the photography, storing and tracking of eye images for diabetes patients in outlying communities.

Deliverable: Copy of Evaluation process
Final Report

Submission Date: October 31, 2008

Deliverable No: 210

Retinal Imaging and an Educational Program on the Importance of Diabetic Eye Disease

Principal Investigator:
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Linda M. Siminerio, RN, PhD
Laura Bettencourt, MPH

Final Report – Goal 2:
Develop a Solution for the Photography, storing, and tracking of Eye Images for Diabetic Patients in Outlying Communities.

Abstract

Diabetic retinopathy is the most common cause of blindness in Americans under the age of 65 years.[1] It has been estimated, in several multicenter clinical trials, that blindness from diabetic retinopathy is preventable in at least 65% of cases, if laser therapy would have been applied in a timely manner.[2-5] Data from the BRFSS showed that the rate of eye exams in Pennsylvania ranged from 55.7% to 75.5% depending on the age group, from 1996 to 2000.[6] The American Academy of Ophthalmology (AAO) has published recommended guidelines for the screening of patients with diabetes mellitus.[7] Furthermore, in the early 1990's, the AAO launched an initiative to dramatically reduce the incidence of blindness from diabetic retinopathy in this country. The goal of this ambitious project, called Diabetes 2000 was threefold: 1) Enhance awareness of the importance of screening eye examinations among the diabetic patient population, 2) Reinforce the importance of screening eye exams among physicians caring for patients with diabetes, and 3) Provide continuing education for ophthalmologists in the evaluation and treatment of diabetic retinopathy. In spite of this Diabetes 2000, the screening rates for diabetic retinopathy remain low, and patients continue to experience irreversible blindness. The primary goal of our Tele-ophthalmology project was to develop and deploy a remote system to detect vision threatening diabetic retinopathy, and make recommendations for referral to an ophthalmologist for treatment.

Introduction

Diabetes Mellitus is the fifth-deadliest disease in the United States, and in terms of dollars, one of the costliest. According to the American Diabetes Association, the total annual economic cost of diabetes in 2007 was estimated to be $ 174 billion dollars, or one out of every 10 health care dollars spent in this country.[8] Diabetic Retinopathy is extremely common, as it is seen in virtually all type 1 diabetics after 20 years, and it is noted in up to 21% of type 2 diabetics at the time of diagnosis. In the United States, diabetes is responsible for 8% of legal blindness, affecting between 12,000 to 24,000 Americans every year.[9,10] It is difficult to accurately determine the actual dollar costs from blindness. In addition to the cost of Social Security Disability Income, and Medicare, there are the societal costs of loosing a valued employee from the workplace, and the costs to families that face the extra burden of caring for a person with blindness.[11]

Since the introduction of sight saving retinal laser procedures, it has been estimated that severe visual loss from diabetic retinopathy is preventable in at least 90% or more of cases with timely diagnosis and treatment.[12] Even though these laser treatments have been available for more than 20 years, Diabetic Retinopathy remains the most common cause of blindness in Americans under the age of 65 years. This statement begs the question, why are some many people going blind, when treatment is available? The poorly controlled diabetic can feel reasonably good while this insidious disease silently "eats" away at their body. Similarly, a diabetic may maintain excellent 20/20 vision, while the retina experiences increasing damage. By the time the vision is affected, and the patient becomes symptomatic, it is often very late in the course of the retinopathy. Laser treatments can be quite effective at stabilizing vision, and preventing further loss, but in general, they are not very successful in restoring lost vision. Therefore, it is critical to evaluate and treat diabetic retinopathy before vision loss is detected. This points to the importance of Screening for Diabetic Retinopathy.

The Behavioral Risk Factor Surveillance System (BRFSS) 1996-2000 showed that the rate of eye exams in Pennsylvania was age-group dependant and ranged from 55.7% to 75.5%. In spite of published guidelines from the AAO for the screening of patients with diabetes mellitus, we, as health care providers have failed. In Pennsylvania, 24.5 % to 44.3% of eligible diabetic individuals are not receiving appropriate eye care.

The hypothesis established for this study was that "a comprehensive educational outreach program to both patients and primary care physicians can result in a near 100% screening rate for diabetic retinopathy in our target population." Therefore, through education, we can enhance awareness of the importance of screening eye examinations among the diabetic patient population. Furthermore, employing digital fundus photography in convenient locations, in conjunction with Tele-Medicine, should make diabetic retinopathy screening easily available to diabetic individuals. Finally, "Laser treatment will be recommended to those individuals with threshold disease, and we will be able to markedly reduce the rate of blindness secondary to the complications of diabetic retinopathy."

Materials and Methods

The study protocol for this project was developed for the screening of patients with a diagnosis of Diabetes Mellitus, for diabetic retinopathy using the Topcon Non-Mydriatic Fundus Camera. The protocol was approved by the IRB's of the University of Pittsburgh, and the US Air Force Office of Biomedical Research and Compliance.

The clinical study was performed in three different settings. There were two locations within the complex of the University of Pittsburgh Medical Center. One study site was placed in the General Internal Medicine (GIM) Clinic, located within Montefiore Hospital, and the second was placed in the Center for Diabetes and Endocrinology (CDE), located in Falk Clinic. The third setting for the photo-screening of diabetic retinopathy was held in a number of "health fairs" that were performed in various community locations (Community Health Fairs or CHF). These community events took place in a variety of locations including hospitals, picnics, churches, and a synagogue.

In the GIM Clinic, patients were given a Tablet PC so they could enter information regarding their Personal Medical History. If they answered "yes" to having diabetes, the computer was programmed to offer them the opportunity to participate in this study. In the CDE, a "Best

Practice Alert" was programmed into the electronic medical record. When the diagnosis of diabetes was entered, a practice alert automatically appeared, suggesting participation in the study.

The study coordinators, who also served as the ophthalmic imagers, reviewed the Informed Consent with the patients, and witnessed their signatures. Registration data was then entered into the computer attached to the Topcon camera, by the coordinator. This data included demographic, medical, and ophthalmic information. Appendix A. The patient was then seated at the camera, and a maximum of three, 45-degree images were acquired for each eye. Fewer images where acquired if the image(s) were felt to be of acceptable quality. At the completion of each patient, the images were uploaded to a server for archival purposes. The software developed for this purpose was based on a Stentor-like PACS (picture archiving and communication system).

In the community screening events, the camera and computer were transported to the site with a van. In general, these events were very well advertised, and there was excellent community participation. After each community event, the images were transferred from a notebook computer into the image database (PACS) for storage, and review.

After the images were archived in the PACS, they were available for interpretation and grading over the internet, via a secure web-site. Basic historical information was supplied to the reader along with the images. This included self-reported date of diagnosis of diabetes, Hemoglobin A1c level (if known), and date of last eye exam. The images were evaluated systematically. The general quality of the images were ascertained, and graded as excellent, adequate, poor but barely gradable, and poor unable to grade. Image enhancement software such as Photoshop© was typically used to improve quality in those considered poor but barely gradable. Initially, the optic nerve was evaluated for cupping or swelling. Then the retinal vessels were studied, followed by the macular and extramacular retina. The presence or absence of maculopathy was noted, and all diabetic retinopathy related lesions were recorded as present or absent. Finally, non-diabetic lesions were listed.

A key element of this study was the method used to grade the images, which directly related to reporting the recommendation to the patient. Ophthalmologists generally employ a standardized method for the grading of diabetic retinopathy. This method requires pupillary dilation and the use of 7-field stereoscopic color photographs (14 photographs per eye), and applying a modification of the Airlie House Classification of diabetic retinopathy. Although this classification is very useful for clinical research, and patient management, it is very cumbersome and superfluous for a diabetic retinopathy screening program. In our study, we utilized a single, 45-degree photograph from each eye, and we recorded those retinal findings consistent with diabetic retinopathy. We determined that it was not necessary to report a specific Airlie House grade. Based on the constellation of findings seen in a single image, we were able to roughly approximate the Airlie House classification, while avoiding the potential error of attempting to apply a strict classification to one image. Instead, in consideration of the absence or extent of retinopathy, a recommendation was generated for a formal, dilated retinal examination by an ophthalmologist. These recommendations ranged from within six weeks for an individual who appeared to have vision threatening disease, to one year for a patient with mild or no retinopathy. In the case of images that could not be graded due to poor quality, the recommendation was for a formal eye exam within 6 weeks, in order to eliminate the possibility of missing vision threatening disease. Each patient received an opportunity for education and a recommendation regarding appropriate timing for follow-up with an ophthalmologist. Compliance with the follow-up plan was then assessed by telephone, at their recommended

time interval (6 weeks, 3 months, 6 months, and one year) to stress the importance of a complete follow-up eye exam.

Refer to Appendix B.

Results

In the course of this study, 923 participants with diagnosed diabetes mellitus (types 1 and 2) were studied. 441 subjects were screened in the setting of CHF. The remaining 482 subjects were screened in two different out-patient sites within the UPMC Presbyterian complex. 360 individuals were screened in the General Internal Medicine Clinic (GIM), and 122 patients were screened in the specialized, Center for Diabetes and Endocrinology of the Falk Clinic (CDE).

The gender was identical for both UPMC sites with 49% male, and 51% female. The mean age was 51 years in CDE while it was 56 at GIM. There was more female participation in the CHF events at 62%, and the mean age was a bit higher at 61 years. The racial breakdown for the CDE was 73% Caucasian and 28% African American, while in the GIM it was 52% and 42% respectively. In the CHF screenings, Caucasians represented 79% and African Americans was 19%. There was a much higher percentage of Type 1 diabetics in CDE at 36%, and it was only 8% and 6% for GIM and the CHF screenings respectively. This is probably due to the fact that Type 1 individuals having been diagnosed while in the pediatric age-group are more likely to have their care continued by an endocrinologist. This statistic probably has bearing on the glycosylated hemoglobin question as well. At the CDE 67% of patients were aware of their A1c value compared to 49% at GIM. In CDE, 6% never heard of the A1c test, while this number rose to 12% in GIM. At the CHF events, these results were similar to the GIM, as Hemoglobin A1c status was known by only 46% of participants and 18% had never heard of this important test. On the other hand, when queried about the “Last Eye Exam,” the rates were similar for all three groups. For CDE patients, the last eye exam was greater than12 months for 42% subjects, and it was 46% in the GIM and CHF groups. Interestingly, the recommendations were remarkably similar for the three groups. The recommendation for follow-up in one year was 77% for CDE, 74% for GIM, and 78% for CHF.

Discussion

A program to study diabetic retinopathy screening utilizing a non-mydriatic fundus camera, transmission of the images over the internet, using a Stentor-like PACS system for image archival, and a novel protocol for interpreting the images was implemented in two different out-patient, hospital-based practices, the General Internal Medicine Clinic and in the Center for Diabetes and Endocrinology, UPMC- Presbyterian Hospital. In addition, community diabetic retinopathy photo-screening events were held at a variety of health fairs in this region, using a mobile unit. This program showed that 83 to 91% of the images were of adequate quality to grade. Furthermore, 1-2% of the individuals in this study were found to have a level of disease that was considered potentially vision threatening, and were advised to seek eye care within a period of 6 weeks. As noted above, the “Recommendations” for follow-up eye care can be correlated to the level or stage of diabetic retinopathy. One might hypothesize that more advanced disease would be identified in the subspecialty CDE clinic where patients with complex management issues are treated. On the other hand, perhaps there may be less

retinopathy in patients with improved diabetic control as provided by the subspecialists. Results also suggest that people with diabetes are not receiving annual eye exams despite the recommendation. It is generally accepted that that approximately 50% of diabetics receive routine, yearly screening eye exams for diabetes, and these numbers are basically confirmatory.

The major limitation of this type of screening project is the inability to adequately image all subjects due to the current state of the technology. These cameras are termed “Non-Mydriatic” meaning diagnostic pharmacologic therapy (eyedrops) are not required for imaging of the ocular fundus. However, unless the pupil is at least 4 mm in size, it is difficult to obtain an image that can be adequately interpreted. As a people age, they tend to have smaller pupils. This problem can be compounded with the development of cataracts in aging patients as well. Finally, it can be more difficult to image the darker fundi of African-American patients due to the need for increased illumination. In the CDE, 9% of subjects had images that were of insufficient quality to permit grading, whereas this number increased to 17% in the GIM. This discrepancy may be explained by the relatively older population, and greater number of African-Americans screened in the GIM. In the CHF event group, 12% of the images were un-gradable.

Study subjects were contacted by telephone to assess their “Compliance” with recommendations based on the interpretations of their retinal images. The compliance rate was 26% for the GIM group and 34% for the CHF group. It was slightly better at 41% for the CDE group. In both instances, based on these low numbers, there appears to be a need for further education, in order to stress the importance of ongoing diabetic eye care.

References

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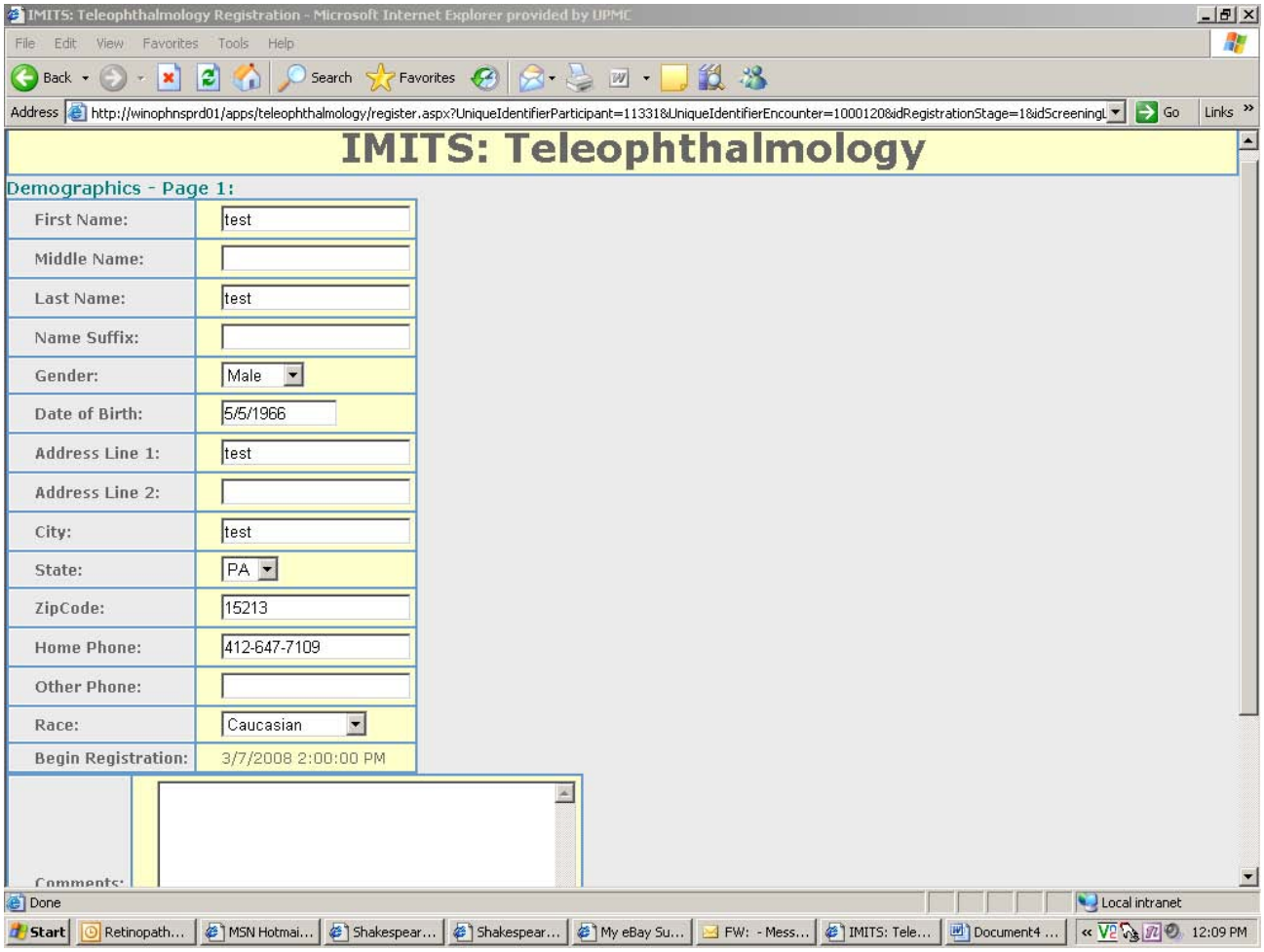
Appendix A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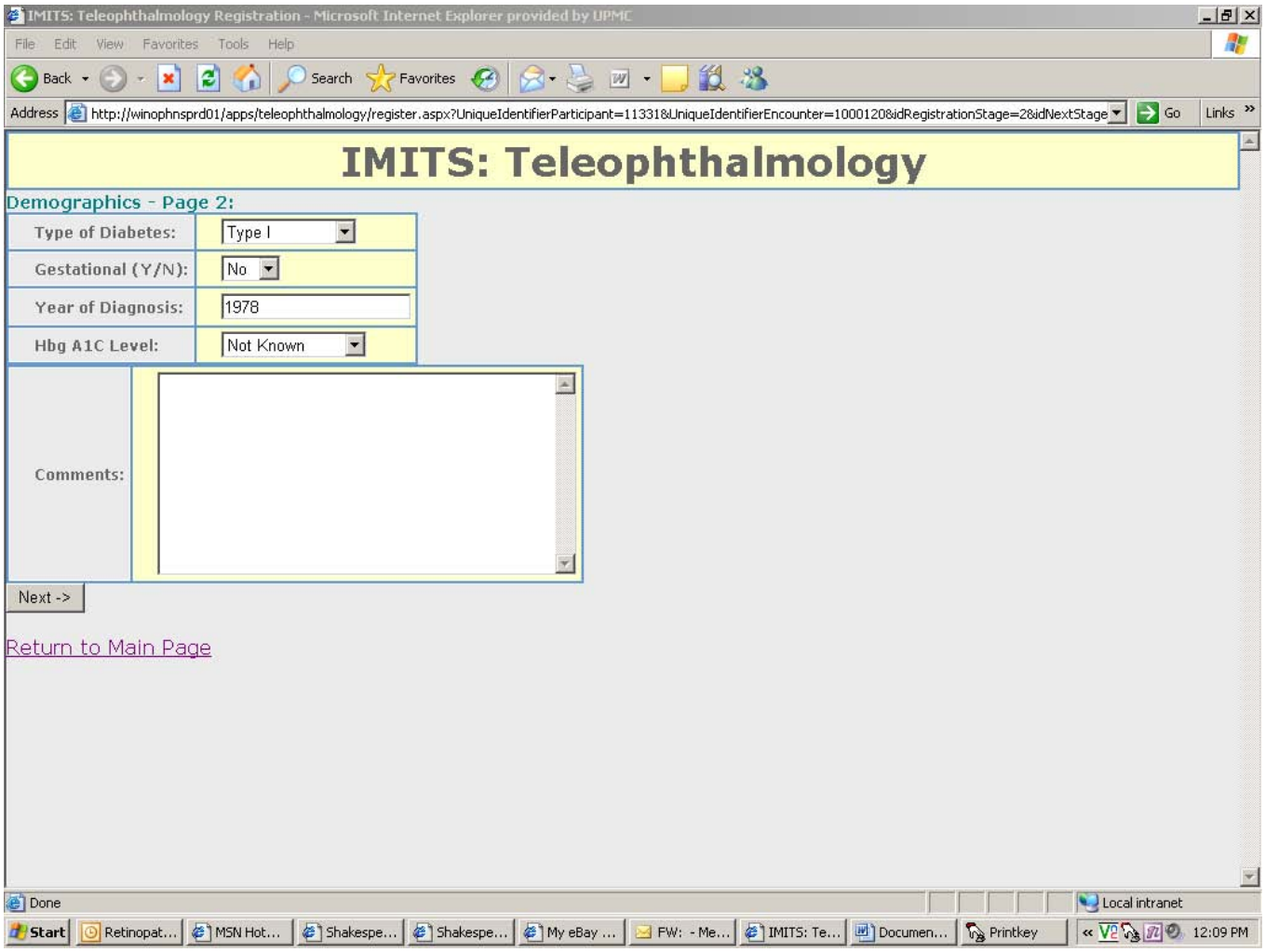
Appendix P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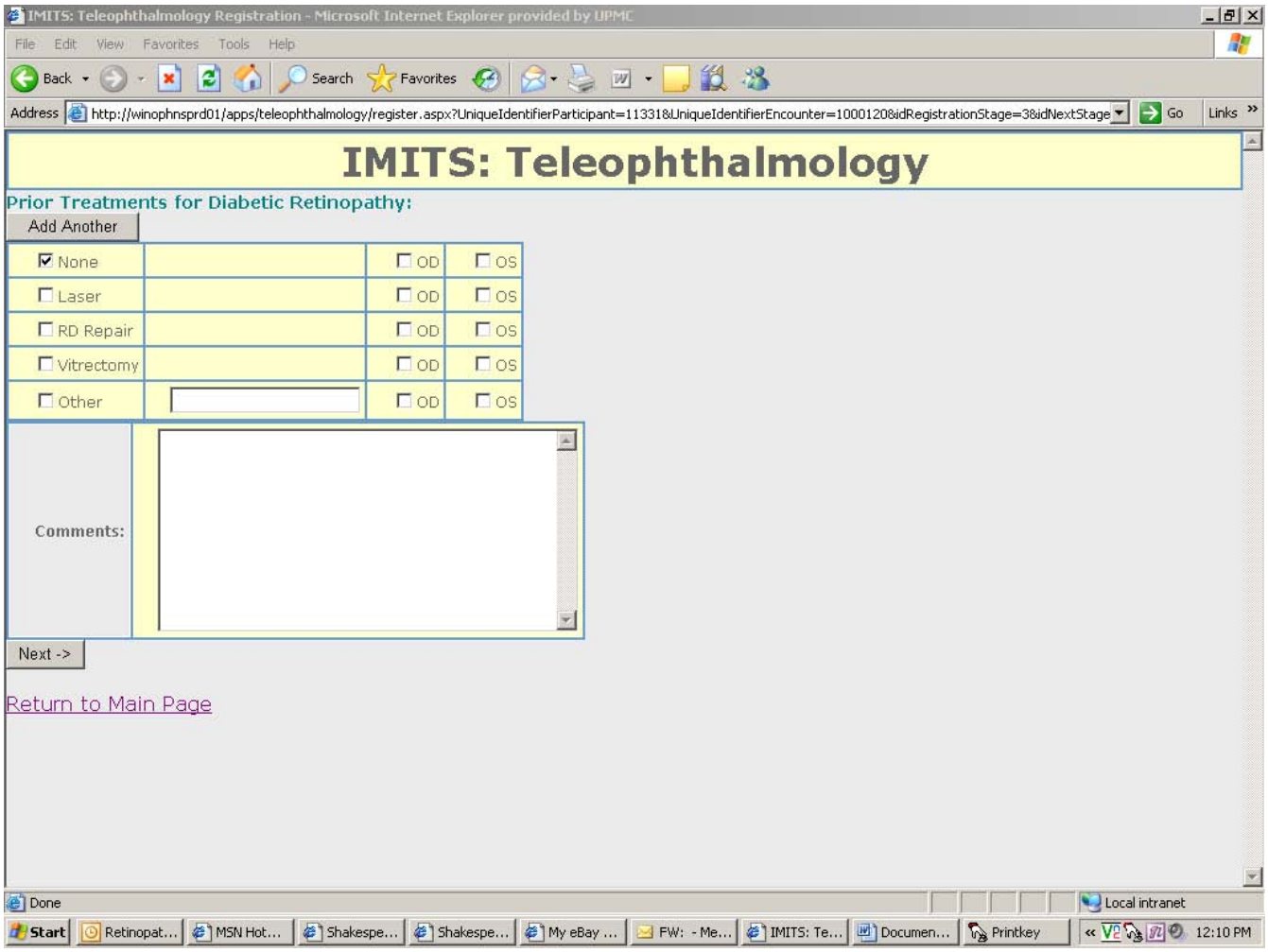
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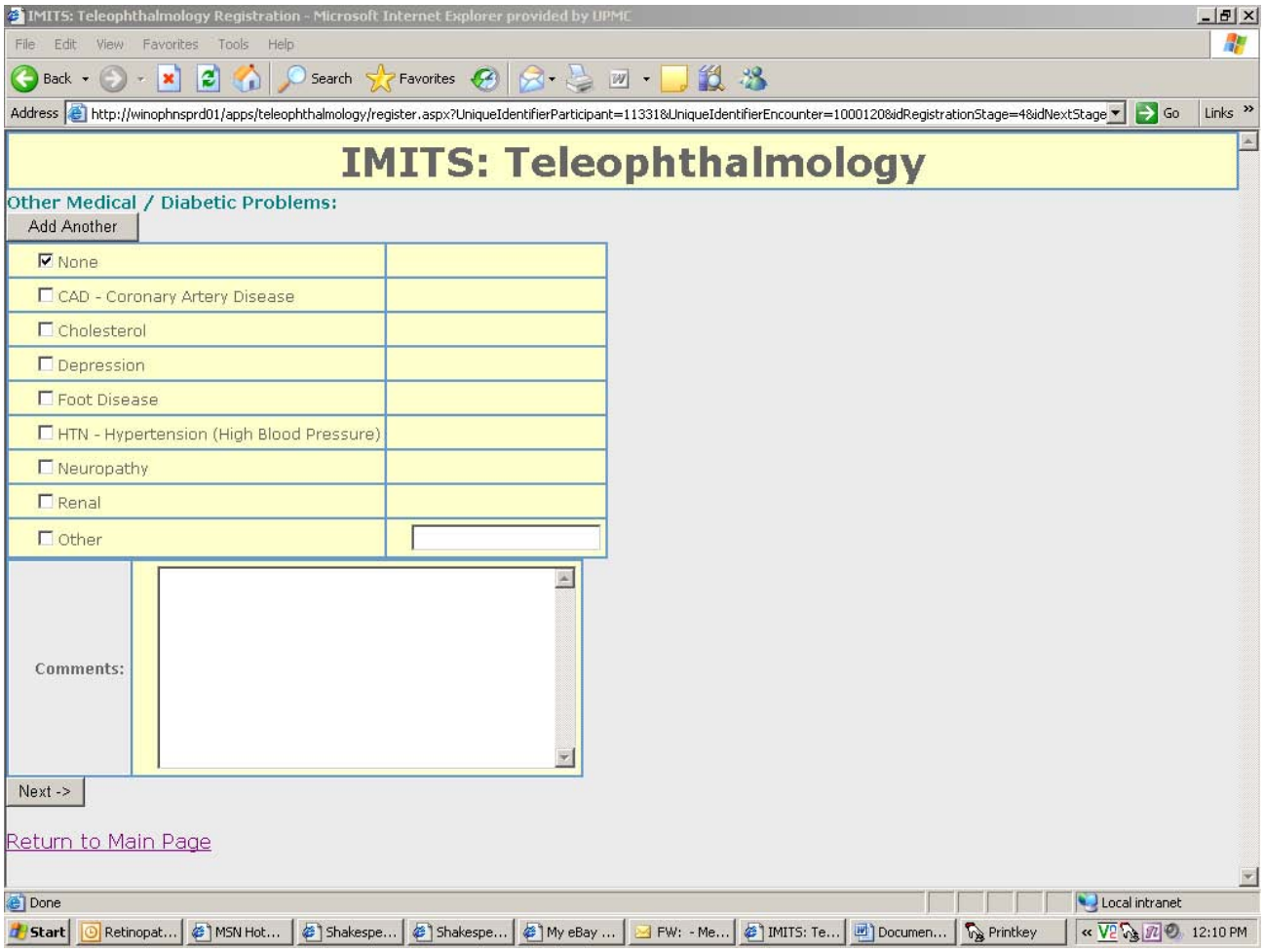
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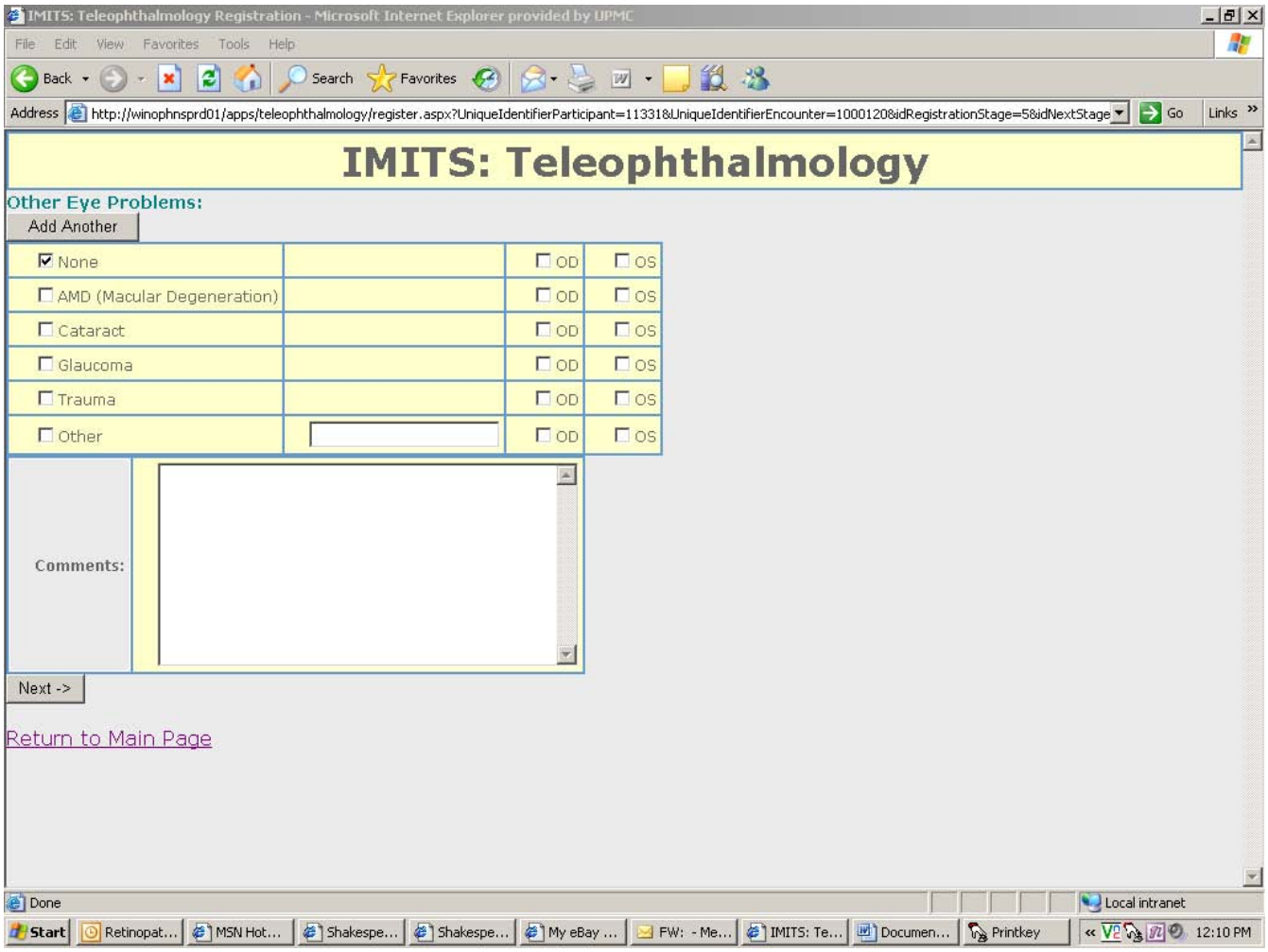
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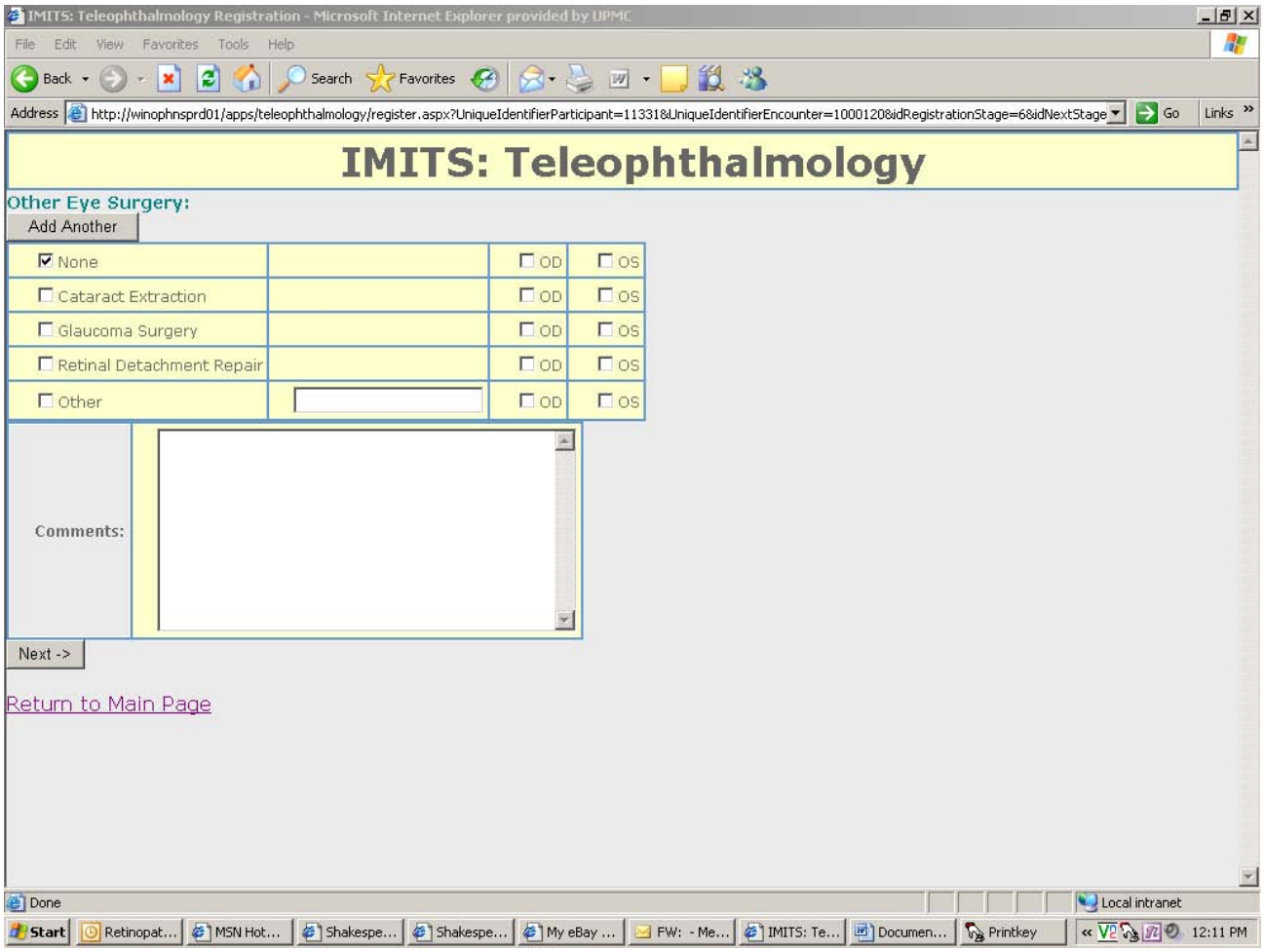
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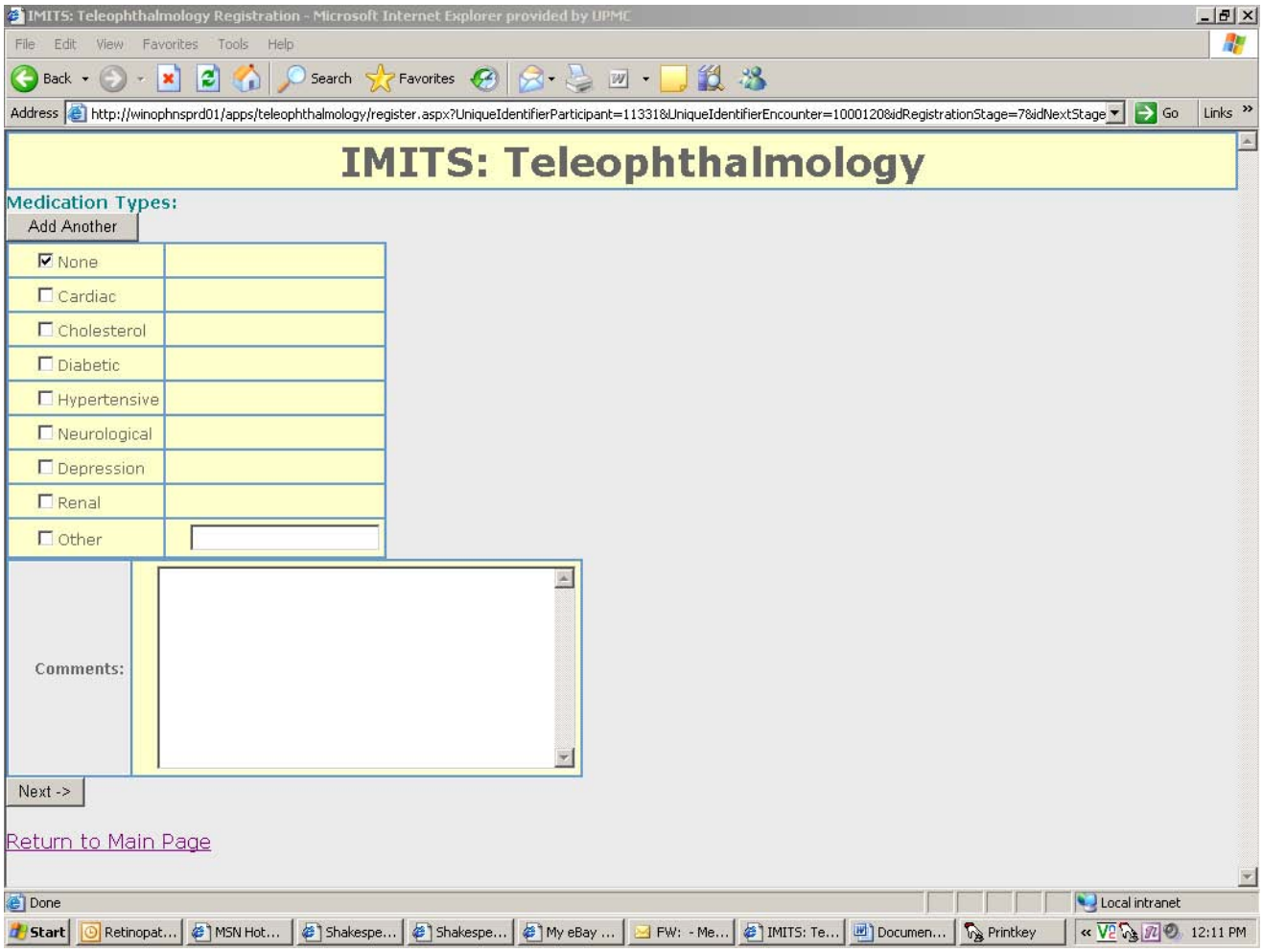
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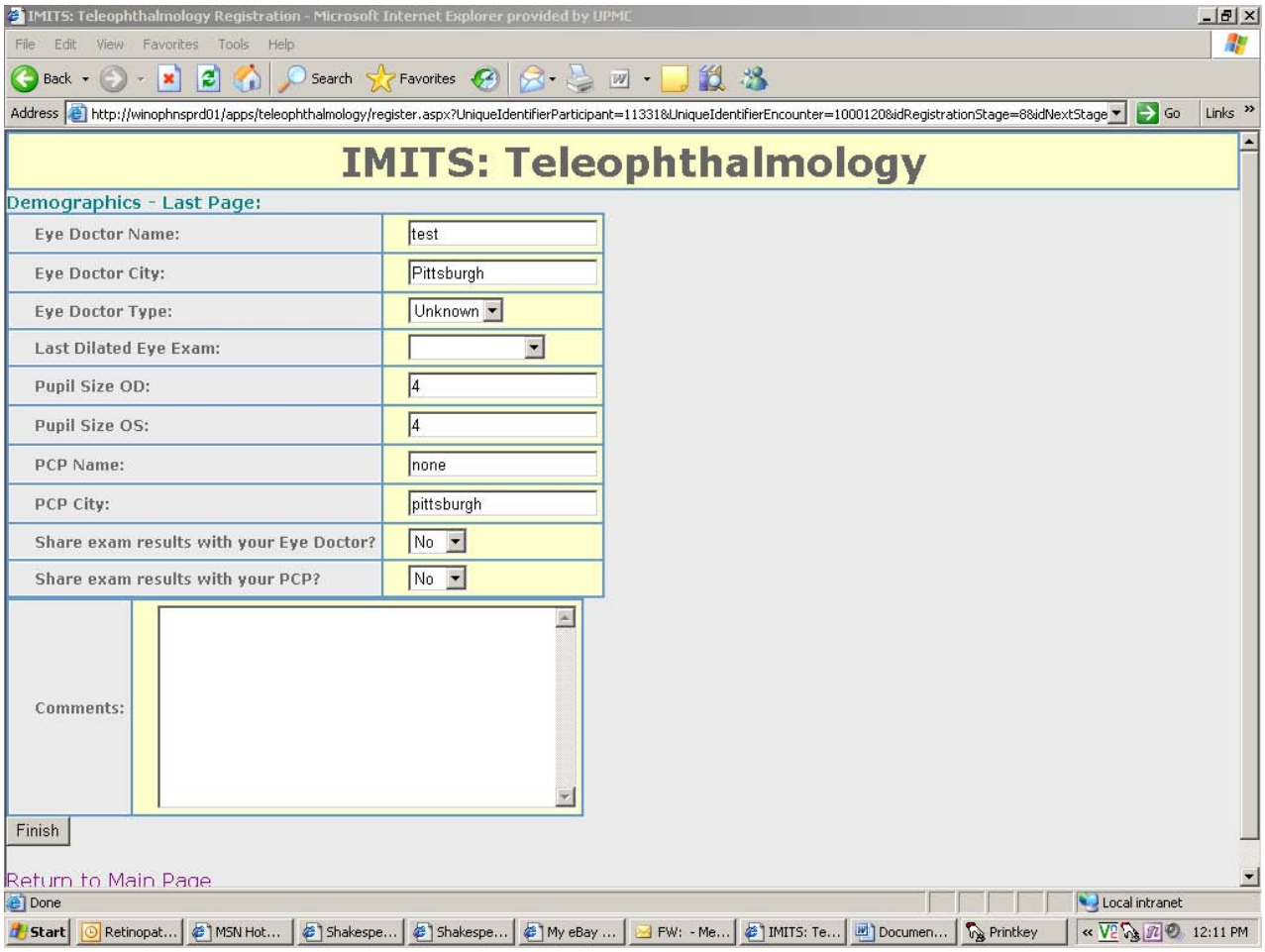
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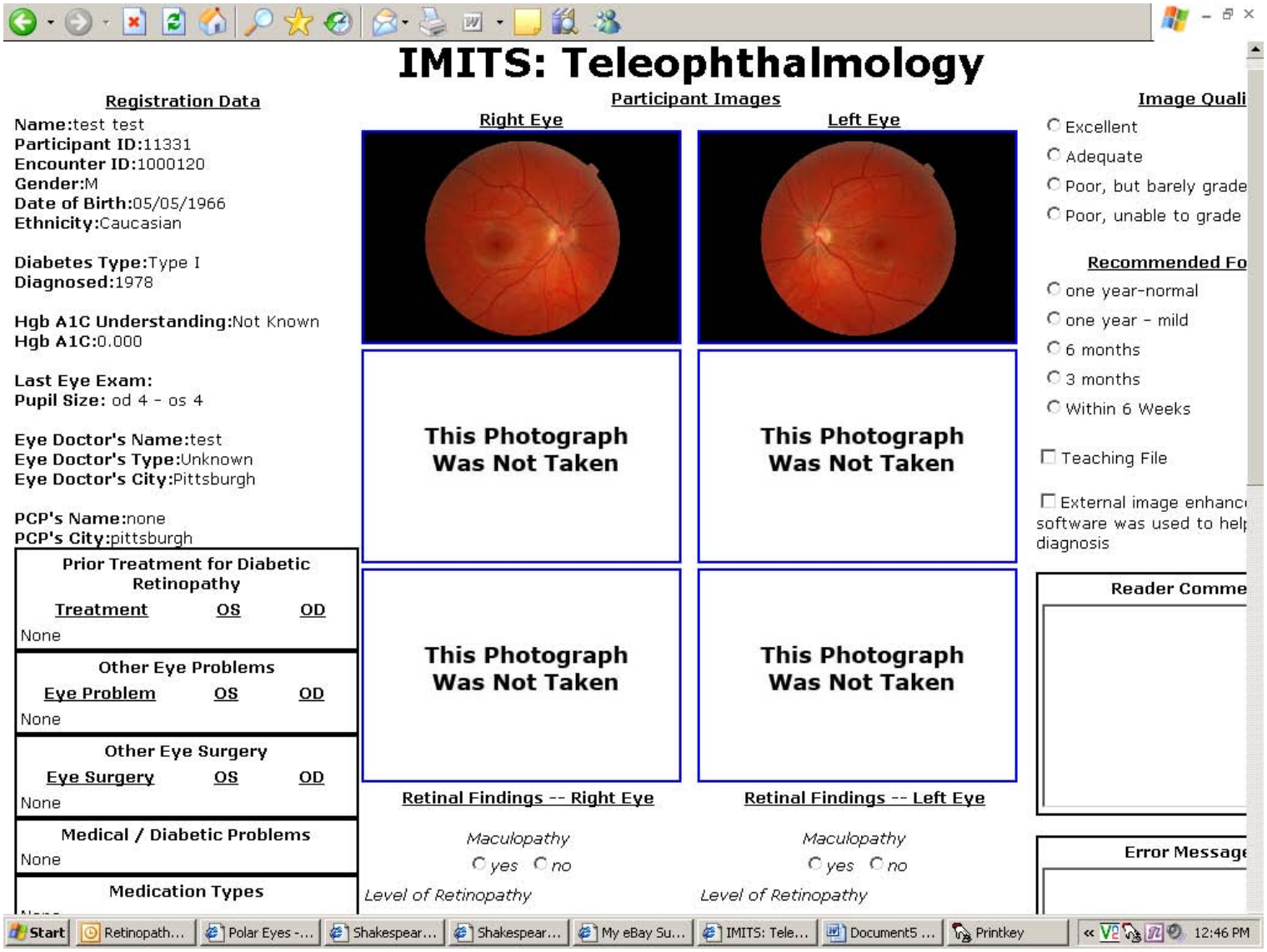
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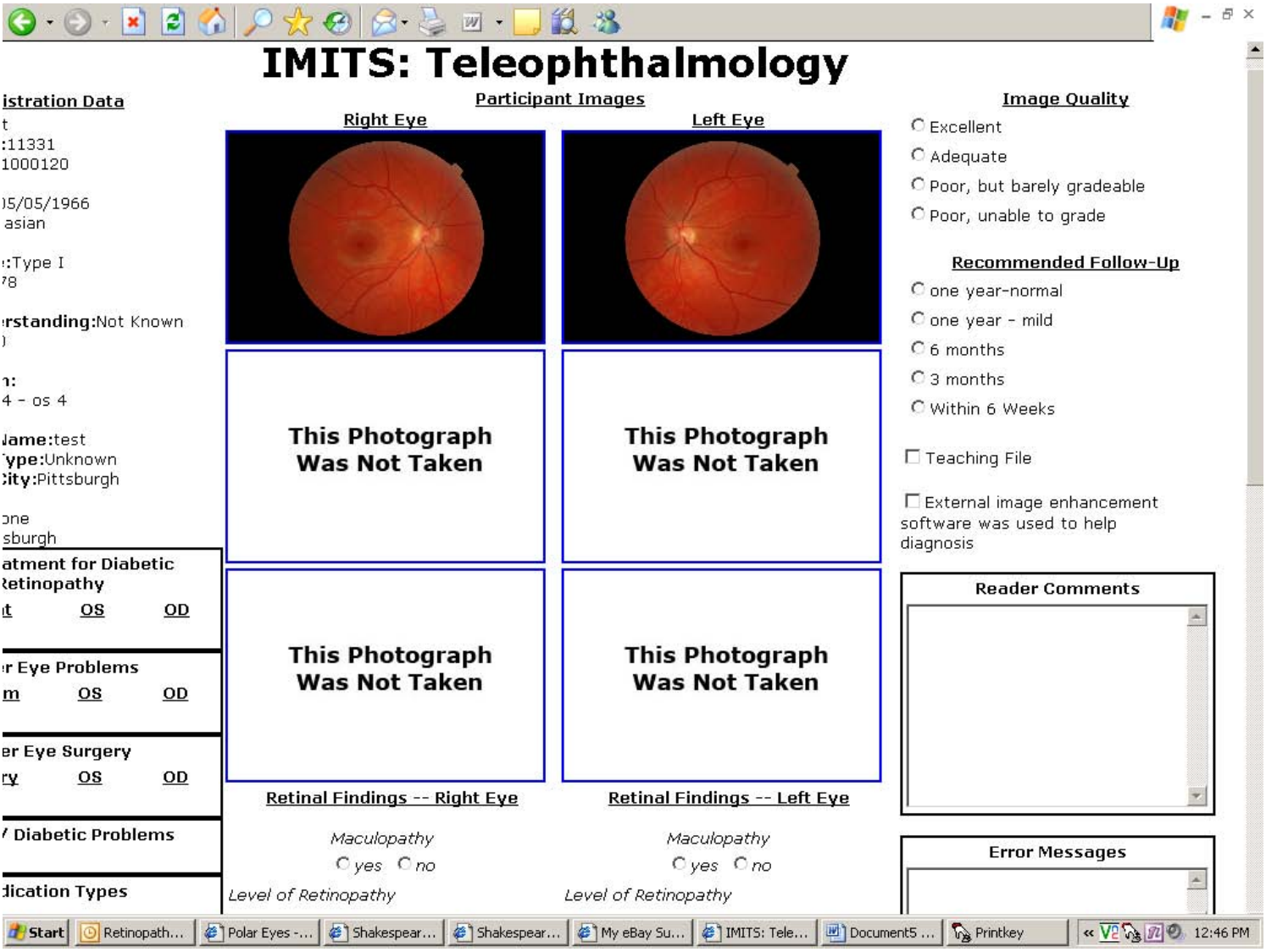
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Level of Retinopathy
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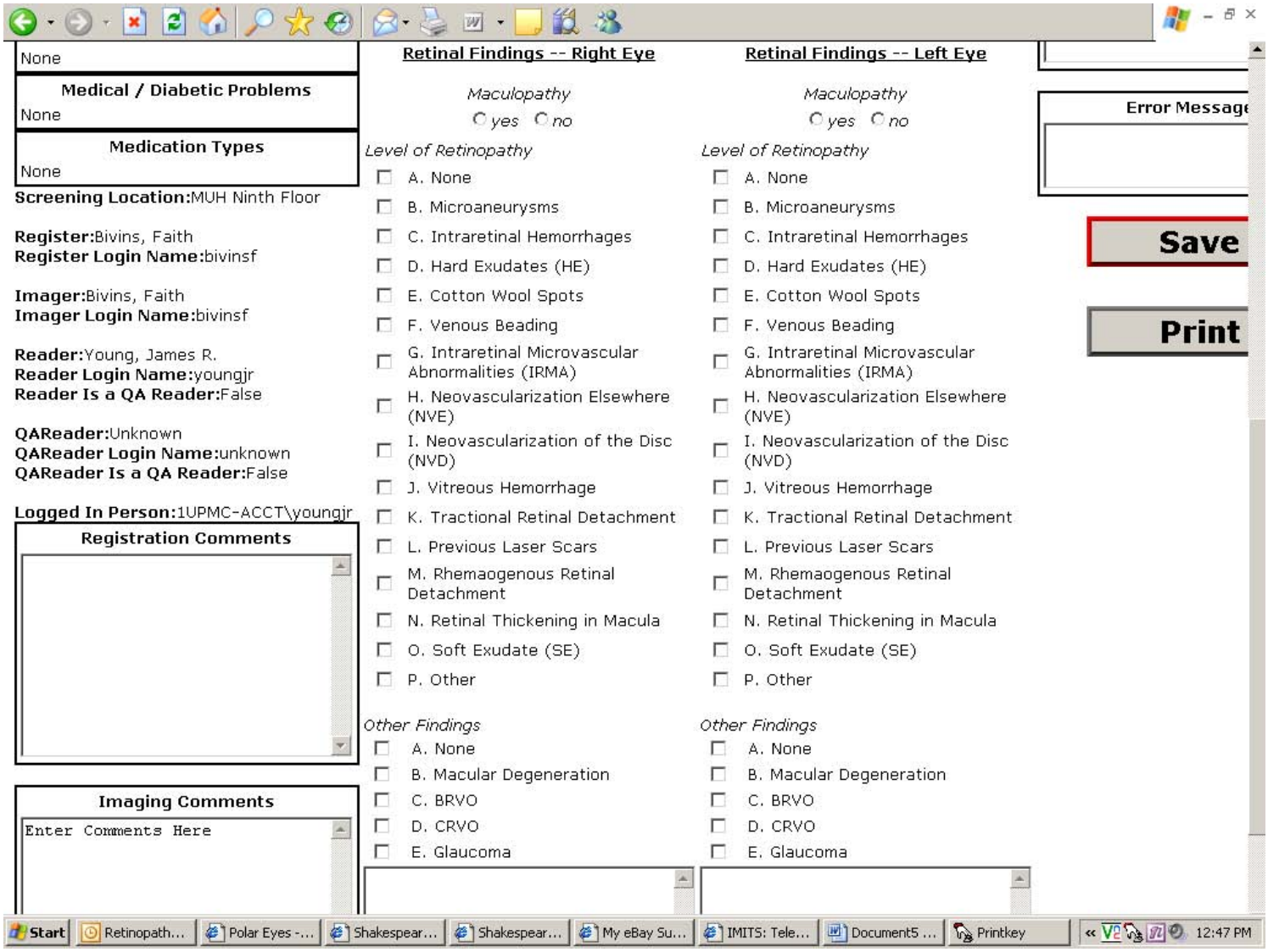
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Reader Login Name:youngjr
Reader Is a QA Reader:False
QAReader:Unknown
QAReader Login Name:unknown
QAReader Is a QA Reader:False
Logged In Person:1UPMC-ACCT\youngjr
Registration Comments
Imaging Comments
Enter Comments Here
Retinal Findings -- Right Eye
Retinal Findings -- Left Eye
Maculopathy
yes no
Level of Retinopathy
A. None
B. Microaneurysms
C. Intraretinal Hemorrhages
D. Hard Exudates (HE)
E. Cotton Wool Spots
F. Venous Beading
G. Intraretinal Microvascular Abnormalities (IRMA)
H. Neovascularization Elsewhere (NVE)
I. Neovascularization of the Disc (NVD)
J. Vitreous Hemorrhage
K. Tractional Retinal Detachment
L. Previous Laser Scars
M. Rhemaogenous Retinal Detachment
N. Retinal Thickening in Macula
O. Soft Exudate (SE)
P. Other
Other Findings
A. None
B. Macular Degeneration
C. BRVO
D. CRVO
E. Glaucoma
Error Messag
Save
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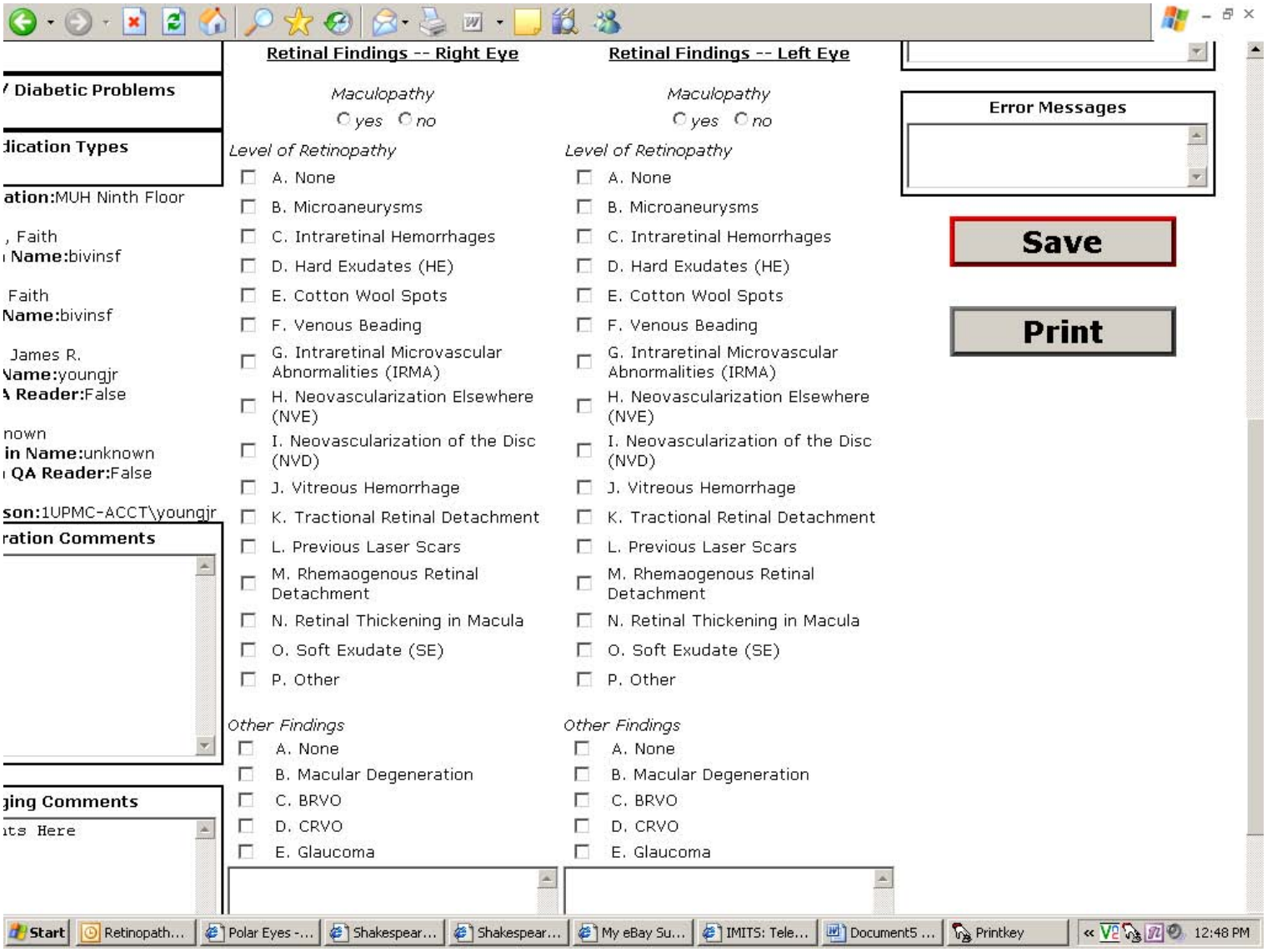
Retinopath...
Polar Eyes -...
Shakespear...
Shakespear...
My eBay Su...
IMITS: Tele...
Document5 ...
Printkey
12:47 PM


Diabetic Problems
dication Types
ation:MUH Ninth Floor
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Name:bivinsf
Faith
Name:bivinsf
James R.
Name:youngjr
Reader:False
nown
in Name:unknown
QA Reader:False
son:1UPMC-ACCT\youngjr
ration Comments
ging Comments
Retinal Findings -- Right Eye
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Level of Retinopathy
A. None
B. Microaneurysms
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yes no
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N. Retinal Thickening in Macula
O. Soft Exudate (SE)
P. Other
Other Findings
A. None
B. Macular Degeneration
C. BRVO
D. CRVO
E. Glaucoma
Error Messages
Save
Print
Start
Retinopath...
Polar Eyes -...
Shakespear...
Shakespear...
My eBay Su...
IMITS: Tele...
Document5 ...
Printkey
12:48 PM

Appendix C

Demographics	Falk Clinic (n=122)	General Internal Medicine (n=360)	Community (n=441)
Gender			
• male	60 (49%)	178 (49%)	169 (38%)
• female	62 (51%)	182 (51%)	272 (62%)
Mean Age In Years	51.1	56.1	61.6
Race			
• Caucasian	89 (73%)	186 (51.7%)	347 (78.7%)
• African American	28 (23%)	151 (41.9%)	83 (18.8%)
• Asian	1 (1%)	3 (0.8%)	4 (0.9%)
• Hispanic	3 (2%)	2 (0.6%)	3 (0.7%)
• Multi-Racial	1 (1%)	2 (0.6%)	1 (0.2%)
• Native American	0	2 (0.6%)	1 (0.2%)
• Other	0	14 (3.8%)	2 (0.5%)
Diabetes			
• Type 1	44 (36%)	29 (8%)	25 (6%)
• Type 2	78 (64%)	327 (91%)	371 (84%)
• Unknown Type	0	4 (1%)	45 (10%)
A1c Status			
• Known	82 (67%)	178 (49%)	201 (46%)
• Not Known	33 (27%)	139 (39%)	160 (36%)
• Never Heard Of	7 (6%)	43 (12%)	80 (18%)
Mean A1c Percentage	7.4	7.3	7.1
Last Eye Exam			
• Less Than 1 Month	3 (2%)	8 (2%)	23 (5%)
• 1 – 3 Months	5 (4%)	37 (10%)	40 (9%)
• 3 – 6 Months	19 (16%)	39 (11%)	46 (10%)
• 6 – 12 Months	41 (34%)	93 (26%)	96 (22%)
• Greater Than 12 Months	51 (42%)	165 (46%)	203 (46%)
• Never	3 (2%)	12 (3%)	22 (5%)
• Unknown	0	3 (1%)	3 (1%)
• Missing Data	0	3 (1%)	8 (2%)

Patient Recommendation and Compliance:

	Falk (n=122)	GIM (n=360)	Community (n=441)
Recommendation			
• Within 6 Weeks	2 (2%)	5 (1%)	6 (1%)
• Within 3 Months	10 (8%)	9 (3%)	15 (3%)
• Within 6 Months	5 (4%)	15 (4%)	15 (3%)
• One Year	94 (77%)	265 (74%)	343 (78%)
• Cannot Be Graded	11 (9%)	61 (17%)	51 (12%)
• Missing Data	0	5 (1%)	11 (3%)

	Falk (n=111)*	GIM (n=297)*	Community (n=379)*
Compliance			
• No	27 (24%)	52 (17.5%)	63 (16.6%)
• Yes	45 (41%)	77 (25.9%)	127 (33.5%)
• Scheduled	0	0	3 (0.8%)
• No Recommendation	0	2 (0.7%)	4 (1.1%)
• Unknown	19 (17%)	55 (18.5%)	63 (16.6%)
• Pending	0	82 (27.6%)	66 (17.4%)
• Missing Data	20 (18%)	29 (9.8%)	53 (14%)

* Patients who had Missing Recommendation data or images that could not be graded were excluded

Appendix Q

Appendix Q, Deliverable 126 Final Report Design, Implement, and Evaluate a Telemedicine Pilot Project Using a Mobile Screening for Detection and Treatment of Diabetic Eye Disease

Teleophthalmology
Evaluation Summary for Community and Clinical Sites (8/27/2005 - 12/31/2006)

Summary

- 653 subjects with diabetes were successfully consented, registered, imaged and had their eye photos graded. 337 were from community sites and 316 from clinical sites.
- Mean time for subjects to be registered, imaged and have eye photos graded was 00:13:13.
- 52% of the subjects reported that their last eye exam was “Greater than 12 Months” or “Never”
- 89% of our sample were instructed to follow-up with their eye doctor in one year (had no retinopathy or mycroanuisms). Only six (1.08 %) were asked to see their eye doctor within 6 weeks (proliferative retinopathy).

Community Sites

History

Diabetic retinal screening began August 27, 2005 at the David L. Lawrence Convention Center in conjunction with the *Healthy 4 Life and American Diabetes Association Expo.* Teleophthalmology software, equipment and staff were used to consent, register, image and subsequently grade eye photos. This was the first of many visits to community sites. Both urban and rural locations within Pittsburgh and surrounding areas were selected. Depending on availability of an Evaluation Team member the site would be visited to observe and make improvement suggestions. Sites that were visited included:

Temple Emanuel, March 5, 2006 (first use of the dedicated van)
Diabetes Symposium – Quality Inn, Bedford PA, March 16, 2006
McKeesport Palisades, July 18, 2006 and July 19, 2006
Fairchance Health Clinic, August 3, 2006
Yablonski Health Clinic, August 9, 2006
Uniontown Hospital Diabetes Clinic, August 22, 2006
Carmichaels Site, August 23, 2006
Indiana Regional Medical Center, August 25, 2006
Lincoln-Lemington Family Health Care Clinic, November 2, 2006

Demographics

	Community (n=337)
Gender	
• **Male**	**132 (39.2)**
• **Female**	**205 (60.8)**
Mean Age (Years)	**61**
Race	
• **Caucasian**	**265 (78.6)**
• **African American**	**64 (19.0)**
• **Asian**	**3 (0.9)**
• **Hispanic**	**3 (0.9)**
• **Multi-Racial**	**0**
• **Other/Unknown**	**2 (0.6)**
Diabetes	

Teleophthalmology
Evaluation Summary for Community and Clinical Sites (8/27/2005 - 12/31/2006)

	Community (n=337)
• Type 1 • Type 2	21 (6.2) 316 (93.8)
Mean Duration of Diabetes (Years)	7.9
Mean A1C Percentage	7.2
Last Eye Exam • Less than 1 Month • 1 – 3 Months • 3 – 6 Months • 6 – 12 Months • Greater than 12 Months • Never • Unknown	 15 (4.5) 25 (7.4) 32 (9.5) 71 (21.1) 173 (51.3) 18 (5.3) 3 (0.9)

Table 1

Observations

Each health fair/seminar/symposium seemed to have some sort of challenge. Once overcome, these challenges built for a more efficient and effective program at the next event. Some included;

- Location of camera, was it dark enough, was wiring possible etc…
- Little or no prior advertising
- Need for better and more professional signage
- Moving and storing equipment
- Software/technical problems

Focus Groups

Within a week of the first community event at the *Healthy 4 Life and American Diabetes Association Expo* two focus groups were conducted. Topics included layout, staffing needs, technical issues, images/imaging and subject's needs. Basically, the discussions set the course on how the community health fairs/seminars/symposiums would continue.

Surveys

In a concern for subject satisfaction we developed a very short, four question to be given out and collected anonymously. A total of 86 were collected and tabulated from six different sites. See Figure 1.

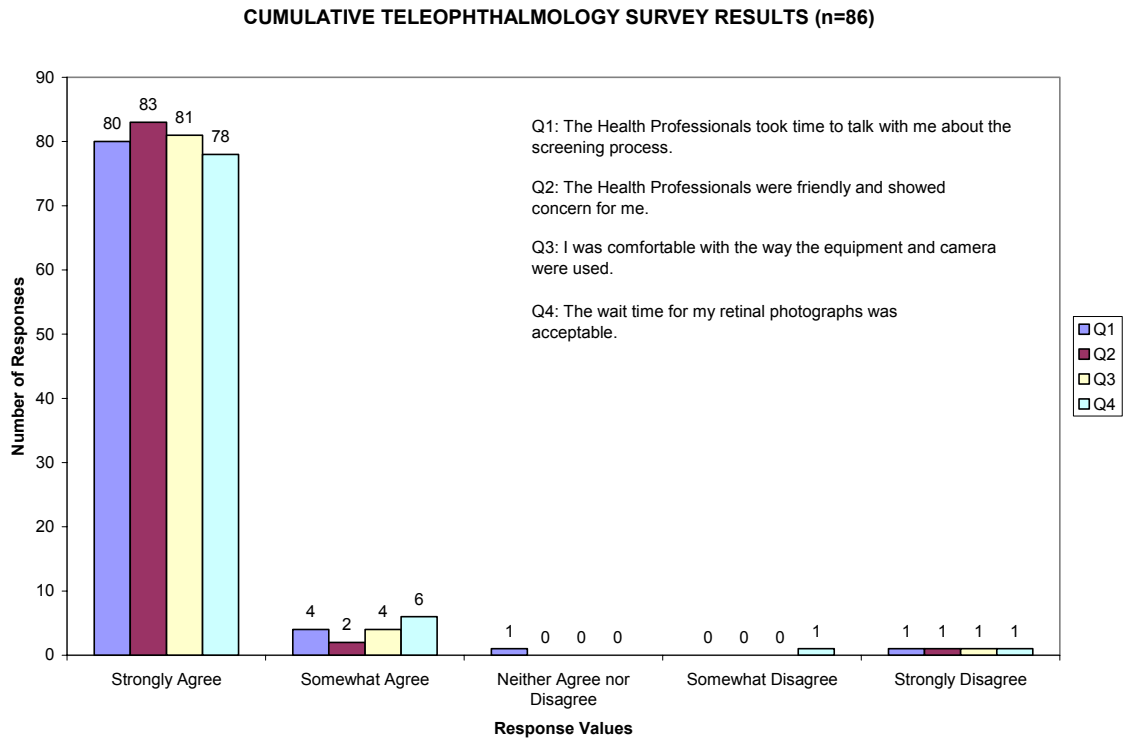

Figure 1

Suggestions

During the course of attending these events the evaluation team members were able to suggest numerous improvements to the screening process. Perhaps the most important was the production of the "TopCon Camera and LAN Network Assembly Manual". This was then used by staff to more efficiently ready the equipment before screening.

Recruitment Results

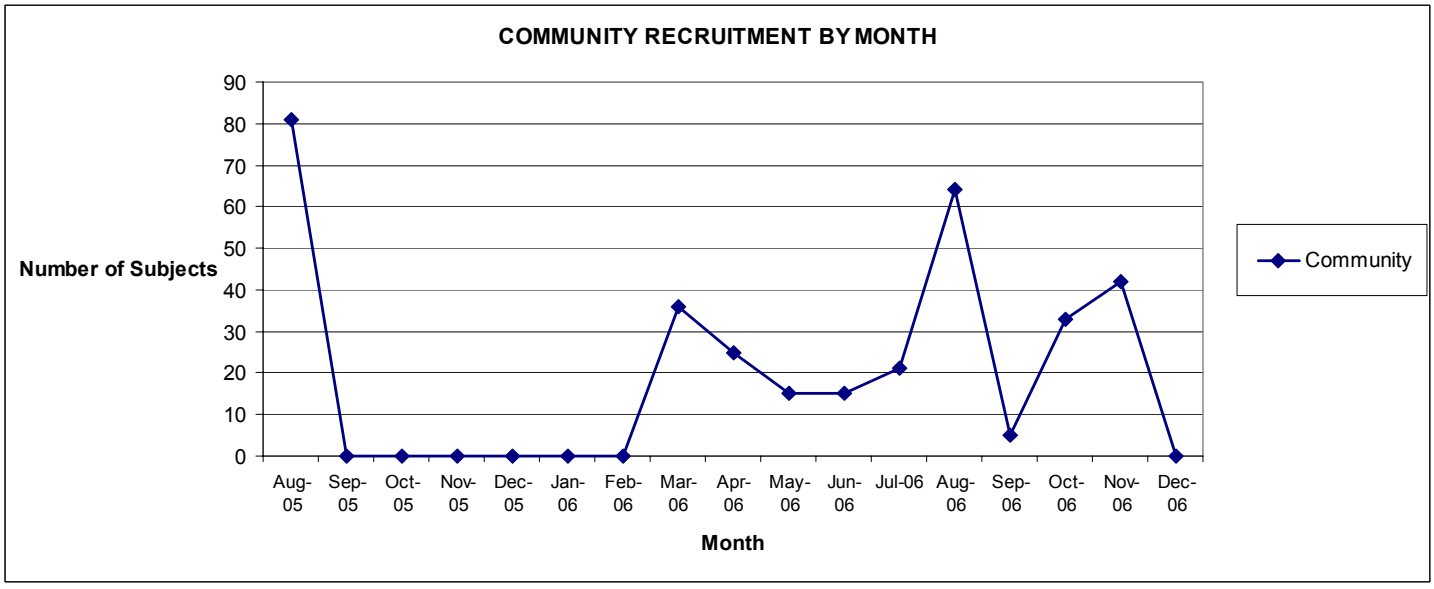

Figure 2

Follow-up and Timing Results

	Community (n=337)
Follow-up Recommendation • Within 6 Weeks • 3 Months • 6 Months • One Year • Cannot Be Graded* • Process Not Completed	 2 (0.6) 10 (3.0) 11 (3.3) 261 (77.4) 37 (11.0) 16 (4.7)
Average Process Time (min): (Registration, Imaging, Grading)	11.99

*Subjects who had a "Cannot Be Graded" rating will be contacted in order to schedule another imaging session.

Table 2

Clinical Sites

History

The first clinical site was General Internal Medicine Clinic at UPMC Montefiore Hospital. Imaging began there on November 16, 2005. This was the first site where a dedicated camera was located within the clinic. The second site was the Center for Diabetes and Endocrinology, Falk Clinic at UPMC Presbyterian Hospital and imaging began there February 28, 2006. A camera was also located within the clinic.

Demographics

	Falk Clinic (n=122)	General Internal Medicine (n=194)
Gender • Male • Female	 60 (49.2) 62 (50.8)	 91 (46.9) 103 (53.1)
Mean Age (Years)	51	57
Race • Caucasian • African American • Asian • Hispanic • Multi-Racial • Other/Unknown	 89 (73.0) 28 (23.0) 1 (0.8) 3 (2.4) 1 (0.8) 0	 99 (51.0) 86 (44.3) 1 (0.6) 0 0 8 (4.1)
Diabetes • Type 1 • Type 2	 44 (36.1) 78 (63.9)	 14 (7.2) 180 (92.8)
Mean Duration of Diabetes (Years)	12.6 9.9	
Mean A1C Percentage	7.4	7.4

	Falk Clinic (n=122)	General Internal Medicine (n=194)
Last Eye Exam		
• Less than 1 Month	3 (2.5)	2 (1.0)
• 1 – 3 Months	5 (4.1)	18 (9.3)
• 3 – 6 Months	19 (15.6)	24 (12.4)
• 6 – 12 Months	41 (33.6)	58 (29.9)
• Greater than 12 Months	51 (41.8)	89 (45.9)
• Never	3 (2.5)	2 (1.0)
• Unknown	0	1 (0.5)

Table 3

Observations

Once the location of the cameras was established, both in rooms where privacy and darkness was assured, no imaging problems were observed. Occasionally, software/programming errors similar to those in the community setting occurred. The challenge was with recruitment.

Breakfast Meetings

Retinal screening was introduced to the clinical staff at breakfast meetings. General Internal medicine was held on February 3, 2005 and at Falk Clinic on March 3, 2006. Both breakfasts were well attended by nurses and medical assistants. Many questions were asked about procedure and retinopathy. Staff was given the opportunity to visit the camera room and have their image taken.

Interviews

Interviews were conducted with the imagers in both clinics. The pager system in General Internal Medicine seems to be working fine. Sometimes the imager has to wait for patient to have blood work completed. The camera room still needs some equipment e.g. lamp. At Falk Clinic the patients are not remembering to stop at the camera room. The staff also needs to remember to phone the imager to come to escort the patient to the camera room.

Focus Group Consensus

- Increase signage.
- Question if physician needs to write order?
- Patients often in hurry.
- Staff/physicians forget to offer to patients.
- Question staff handling consent forms?
- Staff willing to help with study.
- Physicians need more information.

Suggestions

During the observation period four interventions occurred. The first were the breakfast meetings held in February, 2006. In May of 2006 the clinics began to display a poster advertising fast, easy and no eye drops required eye screening for patients with diabetes. The most dramatic improvements occurred in September, 2006 when focus groups were held at each clinic and the addition of a question asking if they were interested. In General Internal Medicine it was a

question added to their electronic tablet that a patient is asked to complete on each visit. At Falk Clinic that same question was added to the hard copy of the medical history form that the patient is asked to complete. Their impact on recruitment is displayed in Figure 3.

Recruitment Results

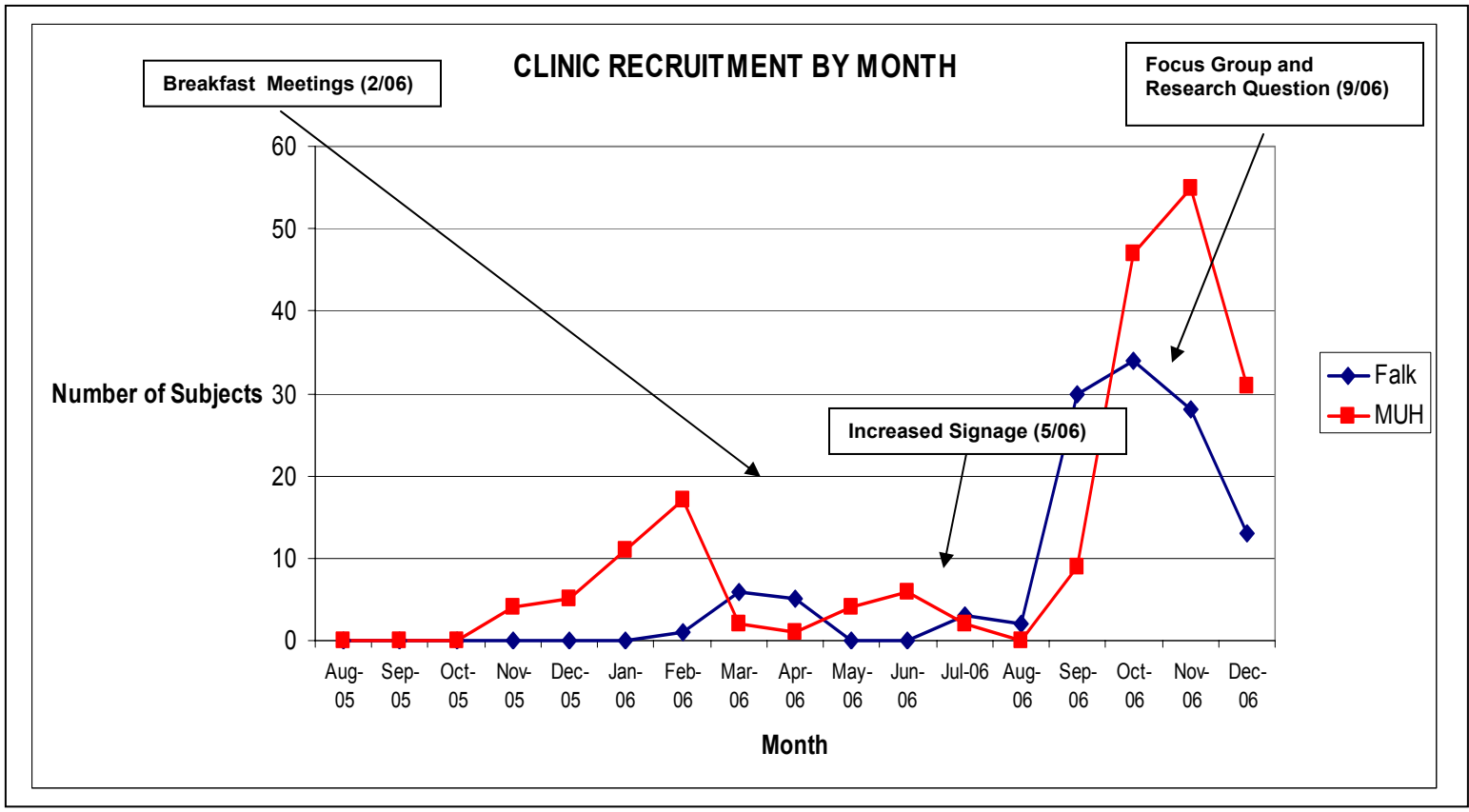

Figure 3

Follow-up and Timing Results

	Falk Clinic (n=122)	General Internal Medicine (n=200)
Follow-up Recommendation • **Within 6 Weeks** • **3 Months** • **6 Months** • **One Year** • **Cannot Be Graded***	 **2** **10** **5** **94** **11**	 **2** **5** **8** **140** **41**
Average Process Time (min): (Registration, Imaging, Grading)	**18.10 11.84**	

*Subjects who had a "Cannot Be Graded" rating will be contacted in order to schedule another imaging session.

Table 4

Appendix R

Appendix R, Deliverable 231 Copy of image collection process

UPMC

University of Pittsburgh Diabetes Institute

Contract #:	W81XWH-04-2-0030
Deliverable #:	1.5, Goal 1 [231]
Funding Year:	2005
Goal/Initiative:	Goal 1
Submitted By:	Megan G. Marks, PhD
Submission Date:	05/21/2009; Resubmission 05/28/2009
Description:	Copy of Image Collection Process

Table of Contents

Introduction

Diabetic retinopathy is the leading cause of new cases of blindness in people age 20 to 74 years in this country. (1-5) A patient with diabetic retinopathy may not become symptomatic until late in their course of retinopathy. Retinal laser treatment may stabilize visual acuity, but is less successful at improving or restoring vision that has been lost. (4) Timely laser treatment could prevent vision loss in up to 65% of diabetic patients who have retinopathy. It has also been estimated that only 77% of the 59 MDW enrolled diabetic population receives the annual recommended eye screening examinations. The screening rate for the entire Air Force Medical Service, 66%, is even lower. (7) It is tragic when someone loses vision due to lack of early detection of a treatable disorder. It is essential to educate patients and the health care providers who are caring for diabetics about the importance of annual eye exams for diabetic retinopathy. (8)

With the evolution of telemedicine, digital fundus images can be acquired in locations that are easily accessible for diabetic patients. (9-15) Key components for improved diabetic eye care are ease of access to care and enhanced prevention strategies of vision loss.

A comprehensive retinal screening program includes the continuation of retinal screening utilizing non-mydriatic digital fundus cameras, and further development of an image reading center and educational activities. A component of such is the establishment of a workable image collection process that enables timely and accurate reading of retinal images by a medically trained ophthalmologist.

Objective

Develop an image collection process that enables the accurate reading of retinal images by a medically trained ophthalmologist.

Methods

Wilford Hall Medical Center's (WHMC) ophthalmologist, Stephen Waller MD, worked with the University of Pittsburgh to translate a pre-defined image collection process into a workable collection process for clinic(s) located in the San Antonio area and participating in the retinal imaging study.

Results

The processes used to transmit and store images to the WHMC reading center to date have been dictated by connectivity limitations. Specifically, images are taken via the Topcon camera, stored on a dedicated CPU directly supporting the Topcon camera, and subsequently copied to a portable medium (e.g. CD, key drive, etc.).

The images stored on the portable medium are then transferred to another computer networked at WHMC for reading and permanent storage. Upon transfer to the networked computer, the portable medium is securely stored.

Similarly, images collected at Kelly Clinic are immediately stored to the local CPU supporting the Topcon camera, transferred to a CD and hand carried by the ophthalmology technician at the close of each work day.

Each set of images is reviewed by the Dr. Waller that yields the respective follow-up for each patient. Potential follow-up includes:

(1) Patient follow-up communicating no additional need to visit specialist and request for follow-on appointment and retinal image within one year
(2) Patient follow-up communicating request to visit specialist whereby visits are prioritized per retinal image findings.

Discussion

The image collection process is clearly cumbersome and can be improved and further automated via improved connectivity. The expected solution for transmitting retinal images from remote clinic locations is to use the Joslin Vision Network/Comprehensive Diabetes Management Program. The technical requirements for this implementation at WHMC and 37th Wing systems groups are presently being reviewed and facilitated by Mr. James Mason of AF SGR. Upon completion of all IT requirements, JVN will be implemented fully permitting images to be transferred electronically via a network rather than a portable medium. Additionally, the goal is to have all retinal images stored electronically on the WHMC PACS system. This will allow the images to become part of the electronic patient record and be accessed readily by any provider that requires baseline images for review.

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Appendix S

Appendix S, Deliverable 232 Develop Educational Activities

UPMC

University of Pittsburgh Diabetes Institute

Contract #:	W81XWH-04-2-0030
Deliverable #:	1.5, Goal 3 [232]
Funding Year:	2005
Goal/Initiative:	Goal 3
Submitted By:	Megan G. Marks, PhD
Submission Date:	05/21/2009; Resubmission 05/28/2009
Description:	Final Comprehensive Report of Educational Activities

Table of Contents

Introduction

Diabetic retinopathy is the leading cause of new cases of blindness in people age 20 to 74 years in this country. (1-5) A patient with diabetic retinopathy may not become symptomatic until late in their course of retinopathy. Retinal laser treatment may stabilize visual acuity, but is less successful at improving or restoring vision that has been lost. (4) Timely laser treatment could prevent vision loss in up to 65% of diabetic patients who have retinopathy. It has also been estimated that only 77% of the 59 MDW enrolled diabetic population receives the annual recommended eye screening examinations. The screening rate for the entire Air Force Medical Service, 66%, is even lower. (7) It is tragic when someone loses vision due to lack of early detection of a treatable disorder. It is essential to educate patients and the health care providers who are caring for diabetics about the importance of annual eye exams for diabetic retinopathy. (8)

With the evolution of telemedicine, digital fundus images can be acquired in locations that are easily accessible for diabetic patients. (9-15) Key components for improved diabetic eye care are ease of access to care and enhanced prevention strategies of vision loss.

A comprehensive retinal screening program includes the continuation of retinal screening utilizing non-mydriatic digital fundus cameras, and further development of an image reading center and educational activities. A component of such is the establishment of a comprehensive educational program for both the patient and provider(s) that assures an informed community with respect to the importance of monitoring patients having the potential for diabetic retinopathy.

Objective

Apply a two-tiered approach to have a more informed community with respect to the importance of monitoring patients at risk for diabetic retinopathy. Educate providers, patients and the patients' families as to the clinical relevance of diabetic screenings using multi-faceted medias.

Methods

Wilford Hall Medical Center's (WHMC) ophthalmologist, Stephen Waller MD, worked with the UPMC and University of Pittsburgh, and participated with Joslin Diabetes Center to establish a comprehensive knowledge base and resource dissemination at WHMC Reading Center. He coordinated via providing an infrastructure for provider education, as well as, patient education.

Provider educational efforts were concentrated in spring and summer 2006 and continue locally via Dr. Waller serving as the lead educator. Provider education focuses on information dissemination, as presented in Attachment A, *Digital Retinal Imaging for Diabetics at WHMC,* and participation in clinical domain specific summits, as presented in Attachment B, *Proto-Final Agenda for CDMP Summer Summit.* Processes are in place to maintain record of all supplemental materials presented at

various summits and newly published literature as deemed pertinent by Dr. Waller. These materials can be found within a binder entitled, "Supplementary Materials" located within the WHMC Reading Center.

Patient educational activities involve communicating with the patient at the time of their initial visit, as well as, providing ready access to informational hand-outs. Specifically, the providers, both ophthalmologist and ophthalmic technician, educate the patient and their respective families on the importance of screening, as well as the following salient points:

- Diabetes is the #1 cause of blindness in American adults of working age
- Diabetic retinopathy is directly related to blood glucose
- Hemoglobin A1c having a value of 7 or less is safe for the eyes and is the KEY to maintaining one's site for a person at risk
- Nearly every patient has the ability to maintain their A1c at a level of 7 or lower with the appropriate actions:
    - Being compliant with medicinal and pharmaceutical prescriptions
    - Losing weight as deemed necessary
    - Exercising 30 minutes daily, five times a week

Additionally, each patient and his/her family can actively consult with the ophthalmologist to gain a better understanding of the retinal screening process, frequency, and diagnostic capacity. Individuals can also use these discussion to learn more of other eye disease states, such as, glaucoma, macular degeneration,

-

Results

The educational efforts, both provider and patient, have been successful in patient's actively engaged and willing to participate in the retinal screening program at WHMC. This improved access and screening has enabled the ophthalmologist to focus on patients with disease and defer a large majority of patients presenting with normal readings to the annual retinal screening program, thereby increasing efficiency for specialist physician in the military, as well as, permit for a larger through put that may ultimately screen patients otherwise not interested and potentially at an unknown risk of clinical eye disease.

Discussion

The educational activities are clearly in place at WHMC for both the provider(s) and patients and their respective families. This has resulted in a well-informed community and improved access for patients at risk for eye disease. Efforts will continue to facilitate the maintenance of such a training program

and assure continuity within WHMC in consideration of its fluid and dynamic environment and often ever-changing personnel due to normal business operations of the military.

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59th Medical Wing

UPMC
University of Pittsburgh Medical Center

Digital Retinal Imaging for Diabetics at Wilford Hall (WHMC) in 2006

Stephen G. Waller, OD, MD, FACS

Clinical Director, Diabetes Outreach Clinic and Univ of Pittsburgh Medical Center

18 April 2006

Integrity - Service - Excellence


WILFORD HALL
MEDICAL CENTER


HELFORD HALL
USAF
MEDICAL CENTER


TOPCON
TRC·NW6S
NON-MYDRIATIC RETINAL CAMERA

Wilford Hall Medical Center

Develop America's Airmen Today ... for Tomorrow

- Located on Lackland Air Force Base in San Antonio
- Lackland is home of all USAF Basic Training for entering enlisted personnel - nearly 40,000 per year
- Hospital sees nearly 1M outpatients per year
- Formerly 1000 beds, now substantially less in same physical plant
- Ophthalmology Department
  - 5 residents graduate per year- largest DoD ophth residency
  - Center of USAF refractive surgery
- Approximately 10,000 diabetics access Wilford Hall as primary health care facility (4000 enrolled)

Diabetes Outreach Clinic (DOC)

Develop America's Airmen Today ... for Tomorrow

- Begun late 2005 with Congressional funding and partnership with Univ of Pittsburgh Med Center
- Mandate: “build a model diabetes program”
- Endocrinologist, Nurse Practitioner, Dietitian, Nurse Educators, technicians
- Ophthalmologist, two eye technicians
- Provides primary care and “one-stop shopping” for diabetics, ages 18-65
- Patients with poor diabetes control enrolled
  - Goal of demonstrating success in improved disease management and return on investment
- Currently 800+ ‘enrolled’ in DOC; goal is 3000

Current Retinal Photo Equipment

Develop America's Airmen Today ... for Tomorrow

- **Diabetes Outreach Clinic** –
  - Topcon TRC-NW6S system with Nikon D100 digital camera
  - Photo policy – initial and annual visit all patients
- **Ophthalmology Department** –
  - Topcon TRC-NW50EX with both JVC KY-F70B for color and Megaplus Model 1.4i/ 10 bit camera for B+W
  - Topcon TRC-50EX with less digital camera for B+W disc photos
  - Two dedicated professional photographers
  - Photo policy – only by exception

Current DOC Photo Protocol

Develop America's Airmen Today ... for Tomorrow

- Recently completed double-masked trial of single undilated photo reading vs. complete dilated exam vs. computer reading (latter at Texas A&M)
- 200 subjects, all from DOC population
- Naïve imager, “young” population ages 18-63
- Approximately 15% of photos “not readable”
- All other photos read ‘disease’ / ‘no disease’
- Low rate of retinopathy – less than 5%
- Subjects with proliferative or ‘clinically significant’ disease rescheduled per urgency into WHMC Retina Clinic
- Am. Telemedicine Association poster next month

Objectives

- Future of digital retinal photography at WHMC?
  - continue validated single-photo system
  - implement JVN system
  - compare the two for relative value
- DOC photo policy – increase access and improve HEDIS numbers for our enrolled population and entire hospital
- Ophthalmology Dept – focus on patients with disease while deferring large majority of normals to photo screening

Objectives

Develop America's Airmen Today ... for Tomorrow

- Partnership of JVN, Wilford Hall, and UPMC?
  - Add imaging at 3 or more other bases - WHMC as central reading center
  - Uniform training and QA for imagers and reader(s)
    - quality assurance relationship / data-sharing issues
  - Cost/benefit report / “sustainability” data for USAF leadership

Future studies

- Other studies:
  - Costs of full exam vs photo screening for diabetics in ophthalmology and optometry clinics in USAF facility
  - How efficient can an “abbreviated full exam” be?
    - Automated eye lane with elecronic record: best corrected VA, freq doubling perimetry for at risk patients, risk assessment for associated disease: glaucoma, CVD, cataracts

Questions?

Develop America's Airmen Today ... for Tomorrow

Diabetes Outreach Clinic

Develop America's Airmen Today ... for Tomorrow

Questions and Comments

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Proto-Final Agenda for CDMP Summer Summit, July 11-12, Joslin Diabetes Center

Day one – Tuesday, July 11

8:45-9:00 Breakfast and Networking
9:15-9:30 Introductions all around

9:30-10:00 Welcoming new members from Wilford Hall and asking them to talk about their practices and medical center and how they plan to use JVN/CDMP
10:00-10:15 Bio Moment

10:15-11:15 Demo of new JVN/CDMP application
11:15-Noon CADS – Decision support for insulin dosing

Lunch Break

1:00-4:30 Research Group Breakout
1:00-1:30 CDMP Demos – Q and A
1:30-4:30 Working Groups:

1:30-2:00 Medications: Presentation, DM or DM and other meds? Examples from organizations and recommendations for CDMP
2:00-2:30 Mental Health – Framing the issues
2:30-4:30 Nutrition: Speaker, Dr. Susan Oliverio - Interactive Nutrition and nutrition for self-management
- Nutrition decision support tools
- Obesity
- Discussion

4:30-5:00 Recap, announcements, break for the day, plans for group dinner this evening

Day two – Wednesday, July 12

9:00-10:30 Reports:
9:00-9:30 VA - using CDMP and DME in the real world
9:30-10:00 Digital camera and food study – Stephanie Fonda, Judy Phillips
10:00-10:30 Pilot use of iMetrikus' MetrikLink with patients
10:45-11:30 Dale Vincent and mobile phone DM management

Lunch Break

1:00-1:30 AIR CDMP usability report
1:30-2:30 Garry Welch – BayState Medical Center – Hispanic initiative and CHCs
2:30-2:45 Bio moment
2:45-4:30 Demo and discussion of the use of ultrasound to heal wounds – Celleration joins us to talk about this innovation
4:30-4:45 CDMP - The next six months – Winter Summit, January 8-9th, Boston
Adjourn

Appendix T

Appendix T, Deliverables #77 and #84 Final Report on Program

The Diabetes Telemonitoring (DiaTel) Study: Three-Month Results

Stone RA, Macpherson DS, Rao RH, Sevick MA, Cheng C, Hough LJ, Obrosky DS, Franko CM, Anglin RA, DeRubertis FR

October 13, 2006

Objectives: The purpose of this study is to compare home telemonitoring-based case management (HT) to a less intense care-coordination (CC) intervention for veterans with diabetes and suboptimal glycemic control.

Methods: The DiaTel Study is a randomized controlled trial of veterans receiving primary care at the VA Pittsburgh Healthcare System (VAPHS) between June 2004 and December 2005. Veterans prescribed at least one oral hypoglycemic agent or insulin during the previous 12 months were identified by electronic medical record review. Consenting eligible veterans with a hemoglobin A1c (HbA1c) >= 7.5% were randomized to either HT (n=65) or CC (n=73). Both groups received baseline diabetes self-management education and monthly telephone calls regarding self-monitoring. Participants assigned to HT used the Viterion 100 TeleHealth Monitor to relay home blood glucose, blood pressure and weight measurements to a nurse practitioner at the VAPHS. The nurse practitioner assessed self-management, provided education, and used the real-time data in consultation with the study endocrinologist to titrate medications for optimal disease management. CC patients were telephoned monthly by a study nurse, who provided education but made referrals to the primary care provider for treatment. Effectiveness of the interventions was assessed at the three-month clinic visit in terms of changes in HbA1c, blood pressure, weight, cholesterol, and triglycerides.

Results: Mean HbA1c, blood pressure, weight, cholesterol, and triglyceride measurements were similar in both study arms at baseline ($p>0.42$ for each). Among the 134 veterans who have been followed for at least three months, significantly larger decreases in HbA1c (1.70% vs. 0.73%; $p<0.001$) and total cholesterol (27.85 vs. 14.14 mg/dl; $p=0.01$) were observed in the HT arm relative to CC. Non-significant changes in blood pressure, weight, LDL-cholesterol, and triglycerides favored the HT arm.

Implications: The HT intervention was associated with significantly greater reductions in HbA1c and total cholesterol at three months.

Impacts: A home telemonitoring device, in conjunction with nurse practitioner case management, is feasible and improves short-term measures of diabetes care. Further study is required to ascertain the sustainability of the observed improvement.

Multiple Imputation of Right-Truncated Laboratory Data

Cheng C, Stone RA, Obrosky DS, DeRubertis FR

October 13, 2006

Objectives: To impute baseline hemoglobin A1c (HbA1c) levels in a longitudinal study where some laboratory values are reported only as exceeding a cut-point.

Methods: The Diabetes Telemonitoring Study compares home telemonitoring-based (HT) care management with less intense care coordination (CC) to help veterans with diabetes better manage their disease. The primary outcome, HbA1c, was measured for each of the 138 enrolled subjects at baseline and 3 months. At baseline, finger-stick HbA1c was performed to ascertain study eligibility ($\geq$7.5%); a separate laboratory HbA1c by venipuncture also was assessed. These finger-stick values are complete while lab values are missing for 10 veterans, including three CC veterans. Seven HbA1c laboratory values were right-truncated at 11.5%, 11.8% or 12.3%. Multiple imputation based on finger-stick values was done using the Imputation by Chained Equations algorithm in Stata. From a large number of imputations generated, we used the first 10 sets for which the imputed values for all seven truncated observations satisfied the corresponding range restrictions. We compared the multiple imputation approach, complete case analysis and simple replacement methods (substituting truncation cut-points or finger-stick values) with respect to (i) the estimated slope of lab vs. finger-stick HbA1c values and (ii) the estimated mean HbA1c in the two treatment groups.

Results: The regression coefficient for the finger-stick is 1.00 (s.e. 0.030), based on 10 imputations. The corresponding coefficients are (0.99, 0.031) for complete case analysis; (0.91, 0.028) substituting truncation points; and (0.97, 0.025) substituting finger-stick values. The estimated HbA1c means for the HT and CC groups were 9.60 (s.e. 0.20) and 9.44 (s.e. 0.16) based on 10 imputations; 9.35 (s.e. 0.15) and 9.31 (s.e. 0.17) for complete cases; 9.43 (s.e. 0.16) and 9.51 (s.e. 0.18) substituting the truncation points and 9.43 (s.e. 0.16) and 9.56 (s.e. 0.19) substituting the finger-stick values.

Conclusions: Complete case analysis and simple substitutions produced downwardly- biased estimators. Restricting multiple imputations to satisfy the truncation constraints yields unbiased estimates with variances that appropriately reflect uncertainty.

Impact Statements: A standard imputation algorithm can be readily modified to accommodate truncated reporting of laboratory data.

Appendix U

Deliverable #172 Final Report on data analysis

In-Home Diabetes Care Management/Coordination Program for Veterans: The Diabetes Telemonitoring (DiaTel) Study, Phase I

Final Report (FY04)
February 12, 2008

Frederick R. DeRubertis, MD; Principal Investigator

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Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Table of Contents

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

ABSTRACT

Objective. The purpose of this randomized clinical trial was to compare Active Care Management (ACM) and home telemonitoring (HT) to a less-intensive Care Coordination (CC) intervention for veterans with type 2 diabetes and sub-optimal glycemic control.

Research Design and Methods. The Diabetes Telemonitoring (DiaTel) Study was a randomized controlled trial of veterans receiving primary care at the VA Pittsburgh Healthcare System (VAPHS) between June 2004 and December 2005. Veterans prescribed at least one oral hypoglycemic agent or insulin during the previous 12 months were identified by electronic medical record review. Consenting eligible veterans with a hemoglobin A1c (HbA1c) $\geq$7.5% were randomized to either ACM+HT (n=73) or CC (n=77). Both groups received baseline diabetes self-management education and monthly telephone calls regarding self-monitoring. Participants assigned to ACM+HT used the Viterion 100 TeleHealth Monitor to relay home blood glucose, blood pressure and weight measurements to a nurse practitioner at the VAPHS. The nurse practitioner assessed self-management, provided education, and used the real-time data in consultation with the study endocrinologist to titrate medications for optimal disease management. CC participants were telephoned monthly by a study nurse, who provided education but made referrals to the primary care provider for treatment. Effectiveness of the intervention was assessed at the 3 and 6 month clinic visits in terms of mean difference at 3 and 6 months and differential change over time for HbA1c, blood pressure, lipids, and weight. Secondary outcomes included satisfaction with care, indices of resource utilization, quality of life, and factors associated with adherence to the diabetes regimen. In the ACM+HT arm we also examined process-oriented factors associated with the telemonitoring-based intervention, including frequency of capillary glucose self-monitoring by participants and frequencies of low and high capillary glucose readings.

Results. Mean HbA1c, blood pressure, cholesterol, triglyceride, and weight measurements were similar in both study arms at baseline ($p>0.45$ for each). Significantly larger decreases in HbA1c were observed in the ACM+HT arm relative to CC at 3 months (1.65% vs. 0.75%) and 6 months (1.72% vs. 0.81%; $p<0.001$ for each). Non-significant changes in blood pressure, LDL-cholesterol, and triglycerides favored the ACM+HT arm. Participants in the ACM+HT arm expressed significantly higher satisfaction with their diabetes care at 3 and 6 months relative to participants in the CC arm ($p<0.01$ for each). Significant improvements in physical health-related quality of life were experienced in the ACM+HT arm relative to CC at 3 months ($p<0.05$) but this difference was not sustained at 6 months. No significant differences were observed in perceptions related to social support, reinforcing behaviors related to self-care, self-efficacy, outcome expectancies, and mental health-related quality of life.

Conclusions. Compared to CC, the ACM+HT intervention was associated with a significant reduction in HbA1c at 3 and 6 months, with most of the benefit achieved by 3 months. The improved glycemic control appears to be due to the active medication management by a study-specific provider, facilitated by the timely data transmission by the home telemonitoring device. This approach has the potential to improve short-term management of high-risk patients with poorly controlled diabetes, such as those with active infection or at increased risk for the latter.

INTRODUCTION

Within the Veterans Health Administration (VHA), diabetes ranks among the leading causes of morbidity and mortality. Between 500,000 and 730,000 veterans receive care for diabetes within the VHA each year, and diabetes accounts for about 25% of all pharmacy costs.[1] [2] [3] According to local performance measures at the initiation of this study, 35% of veterans in the VA Pittsburgh Healthcare System (VAPHS) had HbA1c levels in excess of 8%, above the targets recommended by either the American Diabetes Association (ADA; 7.0%) or the VHA (8.0%) for adequate glycemic control. About 50% of local veterans with diabetes had blood pressure (BP) readings above the ADA target of 130/80; 22% had BP greater than 140/90. Participant factors, such as non-adherence to an optimal regimen, and system factors, such as limited frequency and duration of contact with primary care providers (PCPs) and limited access to specialty care are recognized barriers to optimal glycemic, BP, and lipid control. Inadequate control, in turn, is associated with increased morbidity and mortality due to micro- and macrovascular disease.[1] [2] [4] [5] [6]

Home-based telemedicine is emerging as a tool for chronic disease management, because it enables access to specialty care from distant locations, provides automated education and feedback, and facilitates patient communication with providers. Independent of our study, such a system has been adopted in the VA Healthcare System nationally to improve management of prevalent chronic diseases, including diabetes, for defined high-cost users of the system.

Home telehealth approaches that involve education, counseling, and/or transmission of clinical data uploaded from peripheral measurement devices (e.g. glucose meters, sphygmomanometers, and weight scales) may reduce barriers to self-management and improve outcomes in adults with type 2 diabetes. A number of studies have evaluated the effectiveness of telehealth interventions, including three clinical investigations involving veterans with type 2 diabetes.[7] [8] [9] [10]One used telemonitoring for messaging and collection of participant data regarding symptoms and self-management,[7] and a second involved bi-weekly automated calls that provided counseling, self-management guidance, and optional education messages; [8] [9] neither involved peripheral uploads of clinical data. A third reported two telemonitoring initiatives in two different diabetic veteran subpopulations, one in which veterans requiring aggressive wound management were instructed to send weekly photographs of their wounds to a care manager (who referred for further evaluation as needed), and the other in which telemonitoring was used for daily telemessaging, symptom monitoring, and weekly uploads of glucose results and vital signs (with referral as needed).[10] These interventions resulted in reduced utilization;[7] [10] less depression and bed days due to illness; greater self-efficacy, satisfaction with care, and self-management effort; and better HbA1c levels.[8] [9] None of these studies targeted veterans with poor glycemic control and none involved real-time nurse practitioner adjustment of the veterans' medication regimens.

The DiaTel Study was a two–phase, randomized clinical trial to evaluate telemonitoring paired with real-time medication management for veterans with poor glycemic control. The goal of Phase I was to evaluate the short-term effectiveness of the intervention. The goal of Phase II was to examine the nature of contact required to sustain effectiveness of the intervention over time. We report Phase I here; Phase II will be reported separately.

In Phase I, we evaluated a 6-month Active Care Management intervention for veterans with poor glycemic control that included home telemonitoring (ACM+HT) combined with intensive medication management by a Certified Registered Nurse Practitioner (CRNP). The intervention was compared to a lower intensity Care Coordination (CC) intervention, which

consisted of monthly telephone contact with a study registered nurse. We examined the following hypothesis:

Compared to CC, ACM+HT participants will experience greater improvements in HbA1c, BP, lipids (total cholesterol, HDL, LDL, and triglycerides) and weight. We defined improvement in terms of mean differences at 3 and 6 months as well as differential change over time. In addition, we examined change over time within each treatment arm separately.

We conducted secondary analyses to examine differences between ACM+HT and CC with regard to satisfaction with care, quality of life, and behavioral factors associated with adherence to the diabetes self-management regimen. We described changes in medication management in both treatment arms over the course of the intervention. For participants randomized to the ACM+HT intervention, we described process-oriented factors such as the frequency of capillary glucose self-monitoring using home glucose meters and the frequencies of unacceptably low and high capillary glucose readings as defined by the Viterion device.

RESEARCH DESIGN AND METHODS

Design. The DiaTel Study was a randomized clinical trial of veterans with type 2 diabetes who were enrolled to receive primary care at VAPHS. The Primary Care Division of VAPHS is based at three main VA campuses, within the city limits of Pittsburgh, Pennsylvania, and at five community-based outpatient clinics located in suburban or rural areas. The study was reviewed and approved by the Institutional Review Board of the VAPHS. All participants provided signed informed consent.

Sample. The sampling frame was developed under a separate VA-approved protocol, and the process is summarized in Figure 1. Using the VA electronic medical and pharmacy records, the sampling frame was assembled using the following criteria: veterans who (1) had at least one outpatient visit in a primary care clinic between June 1, 2004 and December 31, 2005, (2) received ongoing pharmacologic treatment for diabetes for 12 or more months prior to the index visit, and (3) had a most recent HbA1c of $\geq$ 8.0%. Veterans were excluded if they had been referred to the VAPHS Diabetes Clinic, had a life expectancy of less than 5 months, were 80 years of age or older, were participating in another study, resided in an institutional setting (e.g. a nursing home, personal care home, or prison), or had home telephone equipment that was incompatible with the Viterion device, which required a land-based, analog telephone line. A total of 1104 potentially eligible veterans were identified.

PCP's screened 1098 potentially eligible veterans for appropriateness for this study, of whom 1055 were sent a letter inviting them to participate in the trial (Figure 2). Veterans who did not respond to this letter were contacted by clinic staff to solicit their participation and obtain informed consent. Eligibility was verified by a point-of-care capillary HbA1c using the DCA 2000. Participants were randomized to either ACM+HT or CC. Randomization was stratified by quartile of capillary HbA1c within each site, and blocked on time to insure balance over time.

Interventions

Active Care Management with Home Telemonitoring (ACM+HT). Participants randomized to ACM+HT received a 6-month diabetes management support intervention using the Viterion 100 Monitor home telemonitoring device. The Viterion is a home-based technology that permits (1) continuous home messaging, with participant reminders and education; (2) ongoing monitoring at home of blood glucose, BP, and weight; and (3) daily transmission of these data via a secure network to the study providers.[11] Participants were instructed to upload

glucose, BP, and weight readings from Viterion-compatible peripheral devices and transmit readings to the study CRNP on a daily basis. Participants were provided enough glucose strips to perform 3 capillary glucose tests each day during the intervention period. The CRNP reviewed glucose, BP, and weight, as well risk stratification reports generated by the Viterion. The CRNP provided telephone follow-up within 24 hours for participants generating "high risk" reports Monday through Friday, and telephone follow-up within 72 hours for participants generating "high risk" reports on a Friday afternoon through Monday morning. A "high risk" report was defined as one or more of the following: (1) blood glucose value consistently greater than 300 mg/dl for 72 hours; (2) blood glucose value of less than 50 mg/dl [note: participants were instructed at enrollment to seek emergency medical attention following single episodes of severe symptomatic hypoglycemia, repeated episodes of symptomatic hypoglycemia in a 24 hour period, and/or the need for third-party assistance to manage the hypoglycemic episode]; (3) blood pressure greater than 180 mmHg systolic and/or 100 mmHg diastolic for 72 hours; (4) blood pressure less than 90 mmHg systolic and 60 mmHg diastolic within a 24 – 48 hour period [note: participants were instructed at enrollment in the study to seek emergency medical attention for episodes of potential severe postural hypotension as reflected by postural syncope or dizziness upon rising.]. Medication adjustments were made using a standardized algorithm, under the supervision of the study Endocrinologist.

The CRNP also made monthly calls to each participant in the ACM+HT group to provide direct self-management counseling tailored to specific issues for individual participants.. In addition to the glucose and BP data provided to the CRNP, participant responses to Viterion educational messages informed the CRNP about the adequacy of the participant's self-management knowledge; this information provided the basis for educational support delivered with monthly telephone contacts.

Care Coordination (CC). Participants randomized to CC received 6 months of monthly monitoring contacts from a certified diabetes educator study nurse who inquired about general health conditions, status of diabetes, BP, weight control, and compliance with the prescribed diabetic regimen. Participants reporting any issues regarding their general health or diabetes were directed to contact their PCP. The PCP was also notified of the problem electronically by the study nurse via the VA Computerized Patients Record System (CPRS). CC participants also were provided enough glucose strips to perform 3 capillary glucose tests each day during the intervention period. The study nurse answered general questions about diabetes, diet, exercise, and medications during the monthly telephone call. Participants also were permitted to initiate contact with the study nurse to discuss any questions or concerns they had related to their diabetes management. CC represents more frequent patient contact than the current standard of usual primary care at VAPHS, and controlled for the alternative explanation that improvements experienced by the ACM+HT group were due solely to the extra attention they received.

Measures. Measurement visits were made at baseline, 3 and 6 months. Participants presented to the VAPHS for measurement of weight, BP, HbA1c and a fasting lipid panel, after which breakfast was provided. After completion of the measurement visit, participants were provided cafeteria coupons for breakfast. After breakfast, the additional measures were obtained including veterans' perceptions of health-related quality of life, satisfaction with care, and factors influencing adherence to the diabetes regimen.

Veterans' perceptions: Health-related quality of life was assessed using two measures. The Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12) measures a variety of domains, including physical functioning, physical role functioning, bodily pain, general health,

vitality, social functioning, emotional role functioning, and mental health. The SF-12 yields a physical component score (PCS) subscale score and a mental component score (MCS) subscale score, with a higher scores indicative of better health-related quality of life.[12] [13] The Problem Areas in Diabetes (PAID) questionnaire contains 20 questions that measure a range of emotional states reported by individuals with diabetes. PAID scores range from 0 to 100, with higher scores indicating greater emotional distress.[14] [15]

Participant satisfaction with care. Participant satisfaction with care was assessed with the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the change version of the DTSC (DTSQc). Both are 8-item instruments developed specifically to address the satisfaction of patients with their care, including satisfaction with treatment, blood glucose control, convenience of care, flexibility, personal understanding of the regimen, recommendation of treatment to others, and likelihood of continuing with current care. The DTSQ is a status questionnaire administered at baseline and 3 months. DTSQc was administered at 6 months.[16] [17] [18]

Factors influencing adherence to the diabetes regimen. The Multidimensional Diabetes Questionnaire (MDQ), which is theoretically linked to a social learning perspective of diabetes, was designed to provide a comprehensive assessment of diabetes-related cognitive and social factors that influence adherence to the diabetes regimen and other self-care behaviors. The MDQ includes 41 items grouped into 3 sections: (1) perceptions related to diabetes and related social support, (2) positive and misguided reinforcing behaviors related to self-care activities, and (3) self-efficacy and outcome expectancies.[19]

Other data. General health and sociodemographic information including race, gender, education, and selected comorbidities were obtained from participant interview and abstracted from the VA local clinical database (VistA) using the graphical interface CPRS. The VistA database, including physician notes and pharmacy records, was abstracted to ascertain the baseline medication regimen (dose), and changes in the regimen (dose and date) for oral hypoglycemic agents, insulin, antihypertensive medications, and lipid-lowering medications. Blood glucose, BP, lipids, and weight were transmitted approximately daily to the CRNP by participants in the ACM+HT arm of the study. Indices of health resource utilization at the VAPHS (outpatient visits emergency room visits, and hospitalizations) were obtained from the VistA database. Self-reported utilization at non-VA facilities was ascertained via participant interviews at 3 and 6 months.

Blood glucose measurements transmitted using the Viterion device. In ACM+HT participants only, the capillary glucose, BP and cholesterol data transmitted to the CRNP via the telemonitoring device were obtained from Viterion. We summarized the frequencies of transmitted results as well as results that did not meet specified target levels that were set by the Viterion system to trigger alerts to providers.

STATISTICAL METHODS

General approach. We used an intent-to-treat approach to analyze the data from this clinical trial. All participants were included to the extent possible. One feature of the data that mandated special methods was the reporting of a small number of HbA1c values as being greater than an arbitrary cutpoint (i.e., >11.5%, >11.8% or >12.3%). Because deleting these right-truncated values or substituting the cutpoints would introduce bias, we used a modified multiple imputation approach in this analysis. Multiple imputation also allowed us to include participants with a small amount of missing data for other variables, and provided appropriate variance estimates and valid tests.

This study was designed to detect a 1% difference in HbA1c with 80% power using a 0.05-level 2-sided test. The primary outcomes were specified a priori, and no adjustments were made for multiple comparisons. P-values < 0.05 were considered to be statistically significant throughout.

Multiple imputation. To account for right-truncated or missing HbA1c values at baseline, 3- and 6 months, we used multiple imputation with a chained equations algorithm[20] as implemented in Stata SE 9.2.[21] The algorithm cycles through a set of predictive equations for a vector of variables $X = (X_1, X_2,\ldots, X_k)$. For the t-+1st imputation of missing X_1: draw X_1^{t+1} from $P(X_1 \mid X_2^t, X_3^t,\ldots, X_k^t)$, and repeat the comparable step for the remaining missing variables. These steps are repeated until convergence. The MICE algorithm assumes that data are missing at random (MAR), i.e. the probability that an observation is missing does not depend on the true value. Based on the complete cases, an imputed value for a missing baseline HbA1c was obtained by adding noise to the predicted value from a simple linear regression model with the capillary HbA1c as the predictor. Missing HbA1c values at 3 and 6 months were imputed from the other HbA1c values and treatment arm. This approach was modified to impute the right-truncated HbA1c values: 100 imputations were generated assuming MAR, and only imputed data sets that satisfied all of the right-truncation constraints (e.g. that the imputed value >12.3% when the observed was reported as >12.3%) were retained.

Once the M imputed datasets were obtained, each was analyzed separately using the appropriate statistical methods (i.e. linear regression). The M estimated regression coefficients were averaged to obtain an overall estimate of each parameter in the model, and the corresponding variances from these separate analyses were combined using Rubin's rules (1987), i.e. the total variance = W + B * (1 + 1/M), where W is the average within-imputation variance and B is the between-imputation variance. All statistical tests involving outcome variables with missing data are based on the multiply imputed data.

Baseline comparisons. Descriptive statistics are presented using the mean of the M imputations for each missing data point. Chi-squared statistics were used to compare ACM+HT and CC participants at baseline.

Between treatment arm comparisons at each timepoint. Mean HbA1c values were compared for the ACM+HT and CC arms at the baseline, 3 and 6 month timepoints. Linear regression was used to obtain the multiple-imputation version of a t-test by regressing the outcome on a dummy variable for treatment arm. The same approach was taken for other continuous variables, with t-tests used when multiple imputation was not required. Data values were also shown in dotplots, with mean values connected over time. The proportions of participants in each treatment arm who reached identified target values at each timepoint were compared using Chi-squared tests.

Between treatment arm changes over time (differential changes from baseline). For each continuous outcome, difference scores were computed between each pair of time points (baseline - 3 months, baseline - 6 months, and 3 months – 6 months). The corresponding difference scores were compared for the ACM+HT and CC arms ($diff_{ACM}$-$diff_{CC}$), again using linear regression if necessary to accommodate multiple imputation (regressing the difference score on a dummy variable for treatment arm) or a t-test.

Within treatment arm changes over time. Each difference score (baseline – 3 months, baseline - 6 months, and 3 months – 6 months) within each treatment group was compared to zero using linear regression including only an intercept, or a t-test, as appropriate.

Analysis of indices of resource utilization. We summarized the number of outpatient visits, emergency room visits, and hospitalizations at VAPHS by intervention arm. Non-VA utilization summarized as well. Treatment arms were compared using Chi-squared tests.

Analysis of medication data. We summarized the proportions of participants who started or stopped taking insulin over the study period. For participants on insulin, we calculated the total daily units of insulin from all sources at baseline and 6 months, compared the two treatment arms at baseline and 6 months, and evaluated change between baseline and 6 months using t-tests. We also modeled the association between baseline and 6 month daily insulin doses using linear regression.

Antihypertensive and lipid-lowering medications were summarized by treatment arm in terms of the number of medication changes over the 6-month study period (i.e. new medications or dose changes for existing medications); treatment arms were compared using Chi-squared tests. The mean number of medication changes in each treatment arm by 6 months was compared using a t-test.

Analysis of blood glucose measurements transmitted by the Viterion device. Based on incomplete preliminary data for 64 participants in the ACM+HT arm, we summarized the number who transmitted data at all and the average number of glucose checks registered on their glucose meters per day. We summarized the numbers of participants with glucose measurements < 50 mg/dL and >170 mg/dL during the first and last 30 days on study, and compared proportions using Chi-squared tests. We also modeled the HbA1c at 6 months as a function of the baseline HbA1c and the average frequency capillary glucose checks per day, using linear regression.

RESULTS

Recruitment and follow-up. Of the 1098 veterans in the initial sampling frame, 1,055 were deemed appropriate for the study and were sent letters inviting their participation (Table 1); up to three mailings were sent to non-responders. Of the 658 (62.4%) who responded, 381 (57.9%) agreed to be contacted to discuss the study. Of those 367 who completed a telephone screen, 226 (61.6%) thought that they would meet remaining eligibility criteria that could not be ascertained prior to signing informed consent, and agreed to participate. Of these, 211 (93.4%) presented to the VAPHS for signed informed consent, additional screening, and baseline measurement. The 150 consenting veterans who had a capillary HbA1c $\geq$ 7.5% at the baseline assessment were enrolled in the study and randomized, with 73 veterans allocated to ACM+HT and 77 allocated to CC. Of the 150 randomized participants, 3ACM+HT and 2 CC participants were excluded subsequently because they were found to have exclusion criteria at baseline, and 2 CC participants withdrew prior to attending the education session. Another 6 ACM+HT participants withdrew after the initial education session.

The number of participants completing the interviews at baseline, 3 months, and 6 months is summarized by treatment arm in Table 2. All participants completed the baseline assessment, 4 CC and 6 ACM+HT participants missed the 3-month assessment and 7 CC and 8 ACM+HT participants (including 1 death) missed the 6-month assessment. The numbers of truncated or missing HbA1c values also are summarized in Table 2. A total of 8 HbA1c values in the ACM+HT arm and 9 HbA1c values in the CC arm were missing without concomitant point-of-care capillary values.

Baseline characteristics. The baseline characteristics for the remaining 73 CC participants and 64 ACM+HT participants are summarized in Table 3. About one-third of the participants in both treatment arms were aged 65 or older; the vast majority was male and non-Hispanic white. The predominant comorbidities were coronary artery disease and congestive heart failure. There were no significant differences by treatment arm for any of the characteristics shown in Table 3.

The types of medications at baseline, 3 and 6 months are summarized in Table 4. The vast majority of participants in both arms was taking oral hypoglycemic agents, antihypertensive medications, and lipid lowering medications at all three time points, and more than 50% of participants were taking insulin. There were no significant differences by treatment arm in the proportion of participants taking each of these types of medications at any timepoint ($p>0.14$ for each).

Impact of the intervention on the primary outcomes. Mean comparisons at each timepoint are summarized for the CC and ACM+HT treatment arms in Table 5. The p-values test the differences between treatment arms at each timepoint. None of these variables differed by treatment arm at baseline ($p>0.45$ for each). Compared to CC, HbA1c was significantly lower in the ACM+HT arm at both 3 and 6 months (0.75% and 0.74% lower, respectively; $p<0.001$ for each). The 11 mg/dL difference in cholesterol at 3 and 6 months was not statistically significant overall; this result was sensitive to the presence of an extremely high value (about 400 mg/dl) in the ACM+HT arm and did achieve statistical significance when this point was dropped. None of the other primary outcomes in Table 5 differed significantly by treatment arm at either 3 or 6 months; except for HDL cholesterol and weight, these change scores favored the intervention arm.

The distributions of these primary outcomes are shown graphically in Figure 3, with HbA1c shown in the first panel. Although mean HbA1c is similar for both arms at baseline, the mean HbA1c for the ACM+HT arm (solid line) is about 0.75% lower than the corresponding value for the CC arm (dotted line) at both 3 and 6 months. The figure also shows the distribution of HbA1c values at or below 7%. At 3 months, 4 participants in the CC arm (5.5%) and 11 participants in the ACM+HT arm (17.2%) achieved a HbA1c of 7% or less (p=0.03). At 6 months, 4 participants in the CC arm (5.5%) and 15 participants in the ACM+HT arm (23.4%) achieved a HbA1c of 7% or less (p<0.01).

The second panel of Figure 3 shows the distributions of systolic BP over time. At baseline, 26.0% of CC and 28.1% of ACM+-HT participants had systolic BP readings $\leq$130 mmHg. These proportions increased to 39.7% and 45.3%, respectively, at 3 months and 46.6% and 46.9%, respectively, at 6 months (p>0.50 at each time point). A majority of participants in both treatment arms met the diastolic BP target of $\leq$80mmHg at baseline (57.5% of CC participants and 60.9% of ACM+HT participants (Figure 3, third panel). These proportions increased to 63.0% and 67.2%, respectively, at 3 months and 72.6% and 78.1%, respectively, at 6 months (p>0.64 at each time point).

The lower left panel of Figure 3 shows the LDL cholesterol distribution over time. A majority of participants in both treatment arms met the LDL cholesterol target of $\leq$100 mg/dl at baseline (52.2% of CC participants and 52.5% of ACM+HT participants (p=0.97). These proportions increased to 63.8% and 72.9%, respectively, at 3 months (p=0.27). At 6 months, significantly more ACM+HT participants (79.7%) than CC participants (59.4%) met the LDL cholesterol target (p=0.014).

The last panel in Figure 3 shows the triglyceride distributions over time. At baseline, 58.9% of CC participants and 51.6% of ACM+HT participants met the triglyceride target of $\leq$150mg/dl. Triglyceride levels improved over time in the HT arm but not in the CC arm: at 3 months, 53.4% of CC participants and 65.6% of ACM+HT participants met this target; the corresponding proportions at 6 months were 57.5% and 62.5%. However, none of these differences was statistically significant (p>0.14 for each).

Between treatment arm changes in primary outcomes over time (differential changes over time). Significantly greater decreases in HbA1c were observed in the ACM+HT arm relative to CC at 3 months (1.65% vs. 0.75%) and 6 months (1.72% vs. 0.81%), corresponding to differential drops of 0.91% at both time points (p<0.001 for each; Table 6). The differential drop in total cholesterol of 12.7 mg/dL between baseline and 3 months was of borderline statistical significance (p=0.07); however, the drop became 10.6 mg/dL when the outlier was excluded (p=0.12). None of the other change scores in Table 6 differed by treatment arm between baseline and 3 months or baseline and 6 months. This study provides no evidence of differential change in any of these outcomes between 3 and 6 months (p>0.25 for each).

Within treatment arm changes in primary outcomes over time. HbA1c, BP, cholesterol, and LDL-cholesterol all improved significantly within both treatment arms at 3 months and 6 months, relative to baseline (Table 7). Triglycerides declined significantly only in the ACM+HT arm. HDL also declined significantly in both treatment arms at the 3 and 6 month time points relative to baseline. Participants in the ACM+HT arm gained an average of 4 pounds between 3 and 6 months (p=0.01). None of the other within group changes between these time points was statistically significant.

Impact of the intervention on the secondary outcomes. The distributions of the secondary outcomes are summarized for the CC and ACM+HT treatment arms at baseline, 3 and 6 months in Table 8. The only statistically significant differences were that the PCS subscale of the SF-12 favored the CC arm at baseline and 6 months (p=0.02 for each); satisfaction with care (DTSQ) was 3.0 points higher in the ACM+HT arm at 3 months and 3.3 points higher at 6 months (p<=0.01 for each). Borderline significant differences in the MDQ outcome expectancies subscale score at baseline and 6 months suggested that ACM+HT participants had somewhat greater belief that adherence to the diabetes regimen would be of benefit to them. None of the other secondary outcomes in Table 8 differed significantly by treatment arm at any time point.

Between treatment arm changes in secondary outcomes over time (differential changes from baseline) are summarized in Table 9. Significantly larger improvements in treatment satisfaction (DTSQ) were observed in the ACM+HT arm relative to CC at 3 months (6.66 vs. 3.27) and 6 months (7.61 vs. 3.98; p=0.01 for each). ACM+HT participants also experienced greater improvements in the PCS subscale of the SF-12 relative to CC at 3 months (1.68 vs. -1.63; p=0.03), but this difference was not sustained at 6 months. None of the other change scores in Table 9 differed by treatment arm.

Within treatment arm changes in secondary outcomes over time. Within each treatment arm, participants improved significantly at both 3 and 6 months relative to baseline on the PAID, DTSQ, and MDQ self-efficacy score (Table 10). Significant improvements also were observed in both treatment arms on the MDQ interference score at 3 months and the MDQ severity score at 6 months, and within the ACM+HT arm for the MDQ severity score at 3 months. Except for improvement in the PCS subscale of the SF-12 in the CC arm, none of the within group changes between 3 and 6 months was statistically significant.

Indices of resource use. (To be completed and submitted as an addendum to the report)

Insulin dosage adjustment. At baseline, 40 of the CC participants and 39 of the ACM+HT participants were on insulin (Figure 5). Six months later, 1 of the CC participants stopped taking insulin while 3 started on insulin, and 1 of the ACM+HT participants stopped taking insulin while 5 started on insulin. The distribution of average daily insulin dose at baseline, 3 and 6 months is shown in Figure 6 for all participants who were taking insulin during the study period. Although mean dose is similar for both arms at baseline, the mean daily dose for the ACM+HT arm (solid line) is about 17.8 IUs higher than the corresponding value for the CC arm (dotted line) at both 3 and 6 months (p=0.02 and p=0.048, respectively; Table 11). For all participants ever on insulin, the baseline dose is plotted versus the dose at 6 months in Figure 7. The largest dose increases occurred in the ACM+HT arm, as denoted by the data points in the upper left corner of this graph.

Other medications. By 6 months, ACM+HT participants had an average of 1.81 medication changes (either medication or dose) involving oral hypoglycemic agents while CC participants had 1.77 (p=0.91, Table 12). By 6 months, ACM+HT participants had an average of 3.14 changes of antihypertensive medications while CC participants had significantly fewer (1.94 on averge, p=0.02); ACM+HT participants had an average of 1.38 changes of lipid-lowering medications, compared to 1.14 in the CC arm (p=0.29). Although the average number of medication changes for oral hypoglycemic and lipid-lowering medications did not differ significantly by treatment arm, relatively more ACM+HT than CC participants had at least one medication change for each of these classes of medications.

Compliance with Viterion. Based on preliminary data with incomplete follow-up on some ACM+HT participants, five ACM+HT participants never transmitted any data after the initial training class. Another 8 participants transmitted less than once per day, on average.

Capillary blood glucose checks using the glucose meter. About 80% of ACM+HT participants performed capillary glucose measurements between once and four times per day, on average. A non-significant inverse association was observed between HbA1c at 6 months and average daily frequency of capillary glucose checks using the glucose meter (r=-0.18, p=0.16), i.e. participants who monitored their blood glucose more frequently showed some tendency to have better glucose control.

Frequencies of low and high capillary glucose measurements in the ACM+HT arm: We compared the average percentages of blood glucose measurements <50 mg/dl (and >170 mg/dl) across participants during the first 30 days and the last 30 days of the study. Hypoglycemia was rare: on average 0.7% of a participant's transmitted glucose measurements were <50 mg/dl during the first 30 days and 1.2% were <50 mg/dl during the last 30 days (p=0.26 based on a paired t-test). These low measurements were concentrated in 23 participants (39%); within this subgroup, the average percentage of low measurements was 1.8% in the first 30 days and 3.0% in the last 30 days (p=0.27). Hyperglycemia was more common, particularly in the first 30 days, with an average of 50.7% of transmitted glucose measurements being >170 mg/dl compared to 36.7% in the last 30 days (p<0.001). All 59 ACM+HT participants who transmitted glucose data had at least one transmitted glucose measurement >170 mg/dl during this time period.

DISCUSSION

This study was designed to detect a 1% difference in HbA1c, a decline that has been associated with corresponding significant reduction in micro- and macrovascular complications in those with type 2 diabetes.[22] [23] We observed a **s**ignificantly greater reduction from baseline of 0.9% in HbA1c at 3 and 6 months in the ACM+HT arm compared to the CC arm. This improvement was accompanied by a slightly higher percentage of participants who started insulin during the study period in the ACM+HT arm, and a significantly higher average increase in the daily insulin dose of 17.8 IU in the ACM+HT arm compared to the CC arm. Most of improvement attributable to the intervention had occurred by 3 months, with very little change between 3 and 6 months.

The weight gain observed in ACM+HT participants is consistent with the results from several studies which have found that intensification of hypoglycemic medication management, and in particular higher doses of insulin, to be accompanied by a significant weight gain in those with type 1 and type 2 diabetes.[24] [25] [26] [27] [28] [29] [30] Weight gain may place patients at increased risk of macrovascular complications. However, Larger suggests that most of the weight gain experienced after insulin initiation is a "catch-up" weight regain, and that there is no evidence that weight gain is associated with deterioration in the lipid profile, arterial hypertension, or an excess risk of cardiovascular events.[31] Indeed, in DiaTel we observed non-significant changes in blood pressure, LDL-cholesterol, and triglycerides favoring the ACM+HT arm.

Patient satisfaction is widely considered to be an indicator of quality of care, [32] [33] and has been shown to be associated with better adherence to the diabetes self-management regimen.[34] Telemedicine has been advocated as a mode of health care delivery because of its potential to minimize inequalities and improve access to care. While most telemedicine interventions appear to be acceptable to patients, evaluation of patient satisfaction tends to focus on the technological aspects of the intervention.[35] With DiaTel we evaluated the extent to which a telemedicine-based intervention improves overall satisfaction with their diabetes care, and found that participants in the ACM+HT arm expressed greater satisfaction at both 3 and 6 months.

Participants randomized to ACM+HT reported greater physical health-related quality life at 3 months than CC participants, but this difference was not sustained at 6 months. Additionally, the ACM+HT intervention did not influence mental health-related quality of life, emotional distress related to diabetes, or behavioral factors shown to influence self-management. Such findings should not be surprising given that the ACM+HT intervention focused on medication management, rather than more general lifestyle management that would involve attention to behavioral predictors and consequences of diabetes self-management.

Indices of resource use. (To be completed and submitted as an addendum to the report)

Implications for practice. The ACM+HT intervention offers a number of benefits over the usual clinical care provided to patients with type 2 diabetes. ACM+HT permits the clinician to address glycemic problems as they occur. In usual practice, many diabetic patients are scheduled for routine evaluation every 1 to 6 months, at which time clinicians titrate medications to address glycemia during the prior interval. The clinician must assume that factors influencing previous glycemia are static, and must rely on the patient to contact them if additional changes are required before their next scheduled visit. Such an approach requires the patient to perform,

correctly interpret, and communicate capillary glucose results to their clinician, a process that presumes a degree of knowledge, ability, and motivation that does not pertain to all patients.

The clinician also often must base medication titration on incomplete information. When patients are unwilling to perform daily capillary glucose checks and/or maintain a glucose log, clinicians must rely on self-reported periodic glycemia fluctuations or HbA1c results to titrate medications. HbA1c values provide a weighted average of serum glucose readings over a 2-3 month period of time but reveal little about within-day variation. While we identified no studies evaluating bias regarding self-reported glycemia, there are clearly patients who over-estimate adherence to other self-management behaviors (i.e. patients may over-state the frequency with which they perform glucose checks and/or may minimize glycemic problems).[36] [37] [38] Telemonitoring enables the clinician to titrate medications in response to capillary glucose results uploaded directly from the glucometer, and to monitor these levels closely.

Finally, when adjustments are made in medications, clinicians assume that patients will adhere to the new regimen. However, a recent meta-analysis found that only 36-61% of patients adhere to their oral diabetes medications and only 63-73% adhere to insulin as prescribed.[39] Frequent change in the medication regimen is a factor in lack of adherence.[40] [41] [42] Telemonitoring facilitates a timely evaluation of the response of patients to a change in their medication regimen, and quickly documents a suboptimal response.

About 80% of ACM+HT participants performed capillary glucose measurements between once and four times per day, on average, during the study period. While comparable data from the CC participants are not available, National Health and Nutrition Examination Survey data revealed that 29% of those taking insulin, 65% of those on oral diabetes medications, and 80% of those managing their diabetes with diet alone never monitored their blood sugar or monitored it less than once per month.[43] The high rates of self-monitoring in the DiaTel Study ACM+HT group may have resulted from the fact that the Viterion device enabled timely information exchange between the patient and the provider and rapid provider responses to reported changes which, in turn, reinforced self-monitoring behavior. Others have found patient discontinuation of self-monitoring to be related to perceived lack of interest in meter readings on the part of health care providers.[44] Use of the Viterion may have reinforced the patients' perceptions that self-monitoring was relevant to their management regimen. Recent meta-analyses support the notion that capillary glucose monitoring, when effectively translated into therapeutic actions, improves glycemic control.[45] [46]

Strengths of the study. This randomized clinical trial is the first systematic evaluation of active care management supported by a home telemessaging device in a veteran patient population with diabetes, even though these devices have been adopted widely for high users of resources within the VA healthcare system. This study has demonstrated that veterans can and will use such a device to transmit data to a provider, and also suggests that increased frequency of home capillary glucose monitoring is associated with decreased HbA1c. A second strength is that multiple imputation of truncated HbA1c values provided a valid statistical approach to include the data for participants with extremely high HbA1c values while avoiding the bias and variance underestimation inherent in simpler approaches, such as complete-case analysis or simple substitution of point-of-care capillary HbA1c values.

Limitations. Home telemonitoring technology is improving at a rapid pace. We used the Viterion 100 monitoring device, which is tied to a telephone land line. More portable technologies, such as cell phones, may be more convenient for patients. Because these devices work by transmitting timely information to a provider who can manage medications, we believe

that our results would likely generalize to other such devices. The fact that the study is limited to veterans restricts generalizability to non-veterans and females. However, the veteran population is of interest in and of itself due to its unique characteristics and separate health care system as well as the high prevalence of diabetes and other comorbidities. Another potential limitation is that our CC arm provided a higher level of contact than occurs in the usual primary care setting, so that our results may underestimate the true effect of the ACM+HT intervention compared to usual care.

Conclusion. In conclusion, active care management supported by a home telemonitoring device is feasible in the VA and rapidly improves glucose control in veterans with poorly controlled diabetes treated in the outpatient setting. The major benefits appear to be achieved by 3 months, thus, this approach has potential application for improvement of short-term outpatient management of high-risk patients with poorly controlled diabetes, such as those with active infections or risk factors for infections.

TABLES

Table 1. Missing assessments by treatment arm

Missing Assessment			
Treatment arm	**Baseline**	**3-months**	**6-months**
CC (N=73)	0	4	7
ACM+HT (N=64)	0	6	8 (including 1 death)
Total	0	12	15

Table 2. Missing or truncated HbA1c values by treatment arm

Missing HbA1c				
Treatment arm		**Baseline**	**3-months**	**6-months**
CC (N=73)	Right-truncation	2	1	1
	Missing, have capillary HbA1c to impute	1	1	2
	Missing, no capillary HbA1c	0	3	5
ACM+HT (N=64)	Right-truncation	5	0	1
	Missing, have capillary HbA1c to impute	2	2	0
	Missing, no capillary HbA1c	0	4	5
	Dead	0	0	1
Total		10	11	15

Table 3. Baseline characteristics of participants in the Care Coordination (CC) and Active Care Management (ACM+HT) treatment arms.

	CC (N=73)		ACM+HT (N=64)		
Characteristics	**n**	**%**	**n**	**%**	***p-value***
Age group					*0.98*
<45 years	4	5.48	3	4.69	
45-65 years	43	58.9	38	59.38	
>=65 years	26	35.62	23	35.94	
Division/CBOC					
UD	35	47.95	30	46.20	
HD	9	12.33	10	15.63	
AP	14	19.18	14	21.88	
AQ	2	2.74	2	3.13	
GB	3	4.11	2	3.13	
UN	3	4.11	0	0.00	
WA	2	2.74	1	1.56	
SC	5	6.85	5	7.81	
Gender					*0.18*
Male	71	97.26	64	100.00	
Female	2	2.74	0	0.00	
Race					*0.24*
White, not of Hispanic origin	59	80.82	46	71.88	
African-American or black, not of Hispanic origin	12	16.44	18	28.13	
Asian or Pacific Islander	1	1.37	0	0.00	
American Indian or Alaskan Native	1	1.37	0	0.00	
Employment status					*0.09*
Employed full-timed (>=35 hours/week)	18	24.66	5	7.81	
Employed part-timed (<35 hours/week)	8	10.96	8	12.50	
Homemaker, not working outside the home	1	1.37	2	3.13	
Retired	38	52.05	37	57.81	
Unemployed	8	10.96	12	18.75	
Marital status					*0.48*
Single, never married	12	16.44	7	10.94	
Married, or living as married	40	54.79	32	50.00	
Widowed	4	5.48	7	10.94	
Separated or divorced	17	23.29	18	28.13	
Living arrangement					*0.21*
Private residence (house or apartment), living alone	19	26.03	23	35.94	
Private residence, living with others	54	73.97	41	64.06	
Education					*0.59*
Grade school (year 1 through 8) or less	2	2.74	2	3.13	
Some high school	6	8.22	5	7.81	
Completed high school or GED	30	41.10	23	35.94	
Some college or association school	12	16.44	19	29.69	
Completed technical or vocational school	13	17.81	8	12.50	
Completed college or more	10	13.70	7	10.94	
Comorbidities					
CAD	24	32.88	25	39.06	*0.45*
CHF	9	12.33	13	20.31	*0.20*
COPD	6	8.22	4	6.25	*0.66*

Table 4. Number of participants on each type of medication at baseline, 3 and 6 months, by treatment arm.

	CC N=73		**ACM+HT N=64**		
	n	**%**	**n**	**%**	***p-value***
Baseline					
Oral hypoglycemic agent	57	78.08	47	73.44	*0.53*
Insulin	40	54.79	39	60.94	*0.47*
Antihypertensive medication	66	90.41	56	87.50	*0.59*
Lipid lowering medication	62	84.93	48	75.00	*0.15*
3-months					
Oral hypoglycemic agent	56	76.71	45	70.31	*0.40*
Insulin	40	54.79	39	60.94	*0.47*
Antihypertensive medication	67	91.78	58	90.63	*0.81*
Lipid lowering medication	63	86.30	52	81.25	*0.42*
6-months					
Oral hypoglycemic agent	56	76.71	44	68.75	*0.37*
Insulin	42	57.53	43	67.19	*0.25*
Antihypertensive medication	68	93.15	58	90.63	*0.59*
Lipid lowering medication	63	86.30	50	78.13	*0.38*

Table 5. Time-specific means and standard deviations of primary outcomes by treatment arm.

Primary outcome	Time	CC (N=73)		ACM+HT (N=64)		$Diff_{CC-ACM}$		*P-value*
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SE**	
HbA1c (%)	Base	9.44	1.40	9.60	1.61	-0.16	0.26	*0.53*
	3m	8.70	1.25	7.95	1.18	0.75	0.21	*<0.001*
	6m	8.63	1.32	7.89	1.23	0.74	0.22	*<0.001*
BPSYS (mmHg)	Base	142.26	18.95	144.84	21.72	-2.58	3.47	*0.46*
	3m	137.13	21.38	135.89	23.31	1.24	3.75	*0.74*
	6m	132.98	18.98	132.00	24.27	0.99	3.65	*0.79*
BPDIAS (mmHg)	Base	80.51	10.12	79.94	13.26	0.57	2.00	*0.78*
	3m	76.64	12.88	75.37	12.04	1.27	2.10	*0.55*
	6m	75.92	13.17	72.37	14.65	3.55	2.34	*0.13*
Weight (lbs)	Base	223.54	47.91	226.65	45.39	-3.11	8.01	*0.70*
	3m	222.02	49.57	225.51	44.50	-3.49	8.08	*0.67*
	6m	223.88	48.58	229.54	47.64	-5.65	8.23	*0.49*
CHO (mg/dl)	Base	175.59	43.51	177.30	54.20	-1.71	8.36	*0.84*
	3m	160.75	37.48	149.78	37.17	10.97	6.40	*0.09*
	6m	159.12	37.22	148.15	40.21	10.96	6.57	*0.10*
CHO Without outlier	3m	160.75	37.48	147.55	32.88	13.20	6.10	*0.03*
	6m	159.12	37.22	146.04	36.80	13.07	6.32	*0.04*
HDL (mg/dl)	Base	38.37	13.05	38.39	13.49	-0.02	2.27	*0.99*
	3m	36.24	11.03	34.99	10.70	1.26	1.87	*0.50*
	6m	36.37	13.58	35.10	11.31	1.27	2.15	*0.55*
LDL* (mg/dl)	Base	101.78	32.04	98.77	36.26	3.01	6.04	*0.62*
	3m	92.31	32.17	86.31	27.65	5.99	5.36	*0.27*
	6m	91.16	30.62	82.28	27.93	8.88	5.28	*0.10*
TRI (mg/dl)	Base	194.07	160.36	191.35	133.33	2.72	25.41	*0.92*
	3m	169.97	133.60	149.91	114.13	20.06	21.44	*0.35*
	6m	170.73	115.88	152.45	99.70	18.29	18.35	*0.32*

* CC: N=69; ACM+HT: N=59

Note: The p-value tests the difference between the treatment arm means (CC-ACM) at each timepoint. A positive difference (CC-ACM) indicates that the mean for that outcome at that timepoint is lower in the ACM+HT arm than in the CC arm.

Table 6. Between-group changes over time in primary outcomes by treatment arm.

Primary outcome	Timepoints	CC (N=73)		ACM+HT (N=64)		$Diff_{ACM}$-$Diff_{CC}$		
		$Diff_{CC}$	SD	$Diff_{ACM}$	SD	Mean	SE	*P-value*
HbA1c (%)	Base-3m	0.75	1.27	1.65	1.42	0.91	0.23	*<0.001*
	Base-6m	0.81	1.42	1.72	1.51	0.91	0.25	*<0.001*
	3m-6m	0.07	0.86	0.06	0.87	-0.003	0.15	*0.98*
BPSYS (mmHg)	Base-3m	5.13	20.13	8.95	20.77	3.82	3.42	*0.27*
	Base-6m	9.28	19.92	12.85	26.20	3.57	3.90	*0.36*
	3m-6m	4.15	21.31	3.90	27.22	-0.25	4.16	*0.95*
BPDIAS (mmHg)	Base-3m	3.87	11.43	4.57	12.47	0.70	2.00	*0.73*
	Base-6m	4.59	12.52	7.57	13.84	2.98	2.21	*0.18*
	3m-6m	0.72	11.97	2.99	14.12	2.28	2.24	*0.30*
Weight (lbs)	Base-3m	1.52	14.22	1.14	10.78	-0.38	2.13	*0.86*
	Base-6m	-0.34	10.98	-2.89	14.71	-2.54	2.15	*0.24*
	3m-6m	-1.87	10.15	-4.03	12.35	-2.16	1.91	*0.26*
CHO (mg/dl)	Base-3m	14.84	39.56	27.52	42.42	12.68	7.02	*0.07*
	Base-6m	16.47	43.90	29.14	44.39	12.67	7.52	*0.09*
	3m-6m	1.63	27.94	1.62	28.51	-0.01	4.98	*1.00*
CHO Without outlier	Base-3m	14.84	39.56	25.40	39.19	10.56	6.78	*0.12*
	Base-6m	16.47	43.90	26.91	40.95	10.44	7.28	*0.15*
	3m-6m	1.63	27.94	1.51	28.72	-0.13	5.02	*0.98*
HDL (mg/dl)	Base-3m	2.13	6.71	3.41	12.39	1.28	1.68	*0.45*
	Base-6m	2.00	6.47	3.29	9.92	1.29	1.40	*0.36*
	3m-6m	-0.13	5.93	-0.11	8.18	0.02	1.25	*0.99*
LDL* (mg/dl)	Base-3m	9.48	29.92	12.46	33.43	2.98	5.60	*0.60*
	Base-6m	10.62	31.98	16.49	34.84	5.87	5.97	*0.33*
	3m-6m	1.14	27.77	4.03	22.62	2.89	4.48	*0.52*
TRI (mg/dl)	Base-3m	24.09	126.76	41.43	114.50	17.34	20.88	*0.41*
	Base-6m	23.34	111.67	38.90	113.58	15.56	18.99	*0.41*
	3m-6m	-0.76	80.17	-2.54	87.46	-1.78	14.45	*0.90*

* CC: N=69; ACM+HT: N=59

Note: The p-value tests the difference in the change scores between treatment arms ($Diff_{ACM}$- $Diff_{CC}$) at each pair of timepoints. A positive $Diff_{ACM}$- $Diff_{CC}$ indicates that the decrease over time is larger in the ACM+HT arm than in the CC arm.

Table 7. Summary p-values testing changes over time in the primary outcomes within each treatment arm.

Secondary outcome	Time points	CC (N=73)	ACM+HT (N=64)
HbA1c (%)	Base-3m	<0.001	<0.001
	Base-6m	<0.001	<0.001
	3m-6m	0.51	0.56
BPSYS (mmHg)	Base-3m	0.005	0.005
	Base-6m	0.003	<0.001
	3m-6m	0.61	0.10
BPDIAS (mmHg)	Base-3m	0.007	0.002
	Base-6m	<0.001	<0.001
	3m-6m	0.27	0.14
Weight (lbs)	Base-3m	0.36	0.40
	Base-6m	0.79	0.12
	3m-6m	0.12	0.01
CHO (mg/dl)	Base-3m	0.002	<0.001
	Base-6m	0.002	<0.001
	3m-6m	0.62	0.65
CHO Without outlier	Base-3m	0.002	<0.001
	Base-6m	0.002	<0.001
	3m-6m	0.62	0.68
HDL (mg/dl)	Base-3m	0.01	0.03
	Base-6m	0.01	0.01
	3m-6m	0.85	0.91
LDL* (mg/dl)	Base-3m	0.011	0.006
	Base-6m	0.007	0.001
	3m-6m	0.73	0.18
TRI (mg/dl)	Base-3m	0.11	0.005
	Base-6m	0.08	0.008
	3m-6m	0.94	0.82

* CC: N=69; ACM+HT: N=59

Note: Each p-value tests the mean difference between pairs of time points within a treatment arm.

Table 8. Time-specific means and standard deviations of secondary outcomes by treatment arm.

Secondary outcome	Time	CC (N=73)		ACM+HT (N=64)		$Diff_{CC-ACM}$		
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SE**	***P-value***
SF-12 PCS	Base	43.46	10.15	39.04	11.14	4.42	1.82	*0.02*
	3m	41.83	10.85	40.72	11.41	1.11	1.88	*0.56*
	6m	44.04	10.18	39.65	11.12	4.39	1.82	*0.02*
SF-12 MCS	Base	44.06	10.35	43.33	11.82	0.73	1.89	*0.70*
	3m	44.31	10.50	41.63	12.68	2.68	2.01	*0.19*
	6m	42.77	12.55	42.81	12.68	-0.04	2.16	*0.99*
PAID	Base	33.11	23.54	33.84	18.61	-0.72	3.66	*0.84*
	3m	28.36	22.26	25.50	18.17	2.86	3.49	*0.41*
	6m	27.27	21.15	24.57	20.44	2.70	3.54	*0.45*
DTSQ Satisfaction	Base	23.92	7.68	23.55	7.01	0.37	1.26	*0.77*
	3m	27.19	7.18	30.21	5.49	-3.02	1.09	*0.01*
	6m	27.89	6.36	31.16	6.49	-3.26	1.10	*<0.01*
MDQ sec I: Interference	Base	2.32	1.63	2.54	1.45	-0.22	0.27	*0.41*
	3m	2.00	1.49	2.25	1.60	-0.25	0.26	*0.34*
	6m	2.10	1.60	2.31	1.67	-0.21	028	*0.46*
MDQ sec I: Severity	Base	3.45	1.60	3.76	1.53	-0.31	0.27	*0.26*
	3m	3.19	1.73	3.39	1.71	-0.20	0.29	*0.49*
	6m	2.92	1.62	3.15	1.63	-0.22	0.27	*0.42*
MDQ sec III: Self-efficacy	Base	58.62	22.39	56.39	21.82	2.22	3.79	*0.56*
	3m	63.50	20.85	64.15	21.04	-0.66	3.54	*0.85*
	6m	64.06	21.07	64.38	21.10	-0.32	3.63	*0.93*
MDQ sec III: Outcome expectancies	Base	86.30	17.08	91.03	11.19	-4.73	2.51	*0.06*
	3m	89.32	13.57	92.12	11.78	-2.80	2.20	*0.21*
	6m	87.86	15.32	92.22	12.06	-4.35	3.37	*0.07*

Note: The p-value tests the difference between the treatment arm means (CC-ACM) at each time point. A positive difference (CC-ACM) indicates that the mean for that outcome at that time point is lower in the ACM+HT arm than in the CC arm.

Table 9. Between-group changes over time in secondary outcomes by treatment arm.

Secondary outcome	Time points	CC (N=73)		ACM+HT (N=64)		$Diff_{ACM}$-$Diff_{CC}$		
		$Diff_{CC}$	SD	$Diff_{ACM}$	SD	Mean	SE	*P-value*
SF-12 PCS	Base-3m	1.63	9.03	-1.68	8.18	-3.31	1.48	*0.03*
	Base-6m	-0.58	7.92	-0.61	9.43	-0.03	1.49	*0.99*
	3m-6m	-2.21	8.84	1.07	8.56	3.28	1.51	*0.03*
SF-12 MCS	Base-3m	-0.25	9.35	1.70	10.54	1.95	1.73	*0.26*
	Base-6m	1.29	11.01	0.52	9.09	-0.77	1.73	*0.66*
	3m-6m	1.54	12.50	-1.18	11.69	-2.72	2.08	*0.19*
PAID	Base-3m	4.76	12.97	8.34	15.97	3.58	2.46	*0.15*
	Base-6m	5.84	16.84	9.26	18.55	3.42	2.98	*0.25*
	3m-6m	1.08	15.96	0.93	16.07	-0.15	2.71	*0.96*
DTSQ Satisfaction	Base-3m	-3.27	7.65	-6.66	7.09	-3.39	1.26	*0.01*
	Base-6m	-3.98	7.04	-7.61	8.23	-3.63	1.32	*0.01*
	3m-6m	-0.71	6.27	-0.95	6.51	-0.24	1.07	*0.82*
MDQ sec I: Interference	Base-3m	0.32	1.15	0.29	1.05	-0.03	0.19	*0.86*
	Base-6m	0.22	1.27	0.23	1.31	0.01	0.23	*0.98*
	3m-6m	-0.10	1.14	-0.06	1.21	0.04	0.20	*0.85*
MDQ sec I: Severity	Base-3m	0.27	1.24	0.37	1.37	0.10	0.22	*0.64*
	Base-6m	0.53	1.26	0.61	1.51	0.08	0.23	*0.73*
	3m-6m	0.26	1.31	0.24	1.64	-0.02	0.25	*0.94*
MDQ sec III: Self-efficacy	Base-3m	-4.88	16.29	-7.76	18.23	-2.88	2.91	*0.32*
	Base-6m	-5.44	17.53	-7.99	20.26	-2.55	3.24	*0.43*
	3m-6m	-0.56	13.67	-0.23	13.94	0.34	2.42	*0.89*
MDQ sec III: Outcome expectancies	Base-3m	-3.02	15.38	-1.09	12.02	1.93	2.40	*0.42*
	Base-6m	-1.56	16.74	-1.18	12.15	0.38	2.50	*0.88*
	3m-6m	1.46	14.48	-0.10	12.17	-1.55	2.29	*0.50*

Note: The p-value tests the difference in the change scores between treatment arms ($Diff_{ACM}$- $Diff_{CC}$) at each pair of time points. A negative $Diff_{ACM}$- $Diff_{CC}$ indicates that the increase over time is larger in the ACM+HT arm than in the CC arm.

Table 10. Summary p-values testing changes over time in the secondary outcomes within each treatment arm.

Secondary outcome	Time points	CC (N=73)	ACM+HT (N=64)
SF-12 PCS	Base-3m	0.13	0.11
	Base-6m	0.53	0.61
	3m-6m	0.04	0.32
SF-12 MCS	Base-3m	0.82	0.20
	Base-6m	0.32	0.65
	3m-6m	0.30	0.42
PAID	Base-3m	0.003	<0.001
	Base-6m	0.004	<0.001
	3m-6m	0.56	0.65
DTSQ Satisfaction	Base-3m	<0.001	<0.001
	Base-6m	<0.001	<0.001
	3m-6m	0.34	0.25
MDQ sec I: Interference	Base-3m	0.02	0.03
	Base-6m	0.14	0.17
	3m-6m	0.47	0.70
MDQ sec I: Severity	Base-3m	0.07	0.04
	Base-6m	0.001	0.002
	3m-6m	0.09	0.24
MDQ sec III: Self-efficacy	Base-3m	0.01	0.001
	Base-6m	0.01	0.002
	3m-6m	0.73	0.90
MDQ sec III: Outcome Expectancies	Base-3m	0.10	0.47
	Base-6m	0.43	0.44
	3m-6m	0.39	0.95

Note: Each p-value tests the mean difference between pairs of time points within a treatment arm.

Table 11. Mean insulin dosage and mean changes in insulin dosage over time for all participants on insulin during the study period, by treatment arm.

	CC (N=43)		**ACM+HT (N=44)**		**$Diff_{CC-ACM}$**		
Insulin dosage	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SE**	***P-value***
Baseline	65.28	43.27	72.70	58.29	-7.43	11.03	*0.50*
3m	62.81	42.78	88.00	77.42	-25.19	13.45	*0.06*
6m	75	47.70	100.27	77.76	-25.27	13.87	*0.07*
	CC (N=43)		**ACM+HT (N=44)**		**$Diff_{CC-ACM}$**		
Change	**$Diff_{CC}$**	**SD**	**$Diff_{ACM}$**	**SD**	**Mean**	**SE**	***P-value***
Base-3m	2.47	31.31	-15.30	36.27	17.76	7.27	*0.02*
Base-6m	-9.72	25.93	-27.57	52.42	17.85	42.22	*0.048*
3m-6m	-12.19	32.56	-12.27	52.98	0.09	9.45	*0.99*

Note: Each p-value tests the difference between the treatment arm means (CC-ACM) at each timepoint. A negative $Diff_{CC-ACM}$ indicates that the mean insulin dosage at that timepoint is higher in the ACM+HT arm than in the CC arm. A positive $Diff_{CC}$-$Diff_{ACM}$ indicates that the mean increase in insulin dosage over time is larger in the ACM+HT arm than in the CC arm.

Table 12. Mean number of medication changes (medication or dosage) at 6 months by treatment arm.

	CC			**ACM+HT**			**$Diff_{CC-ACM}$**		
Type of medication	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**Mean**	**SE**	***P-value***
Oral hypoglycemic	31	1.77	1.06	31	1.81	1.17	-0.03	0.28	*0.91*
Antihypertensive	31	1.94	1.81	42	3.14	2.45	-1.21	0.52	*0.02*
Lipid-lowering	21	1.14	0.48	32	1.38	0.91	-0.23	0.22	*0.29*

Note: The p-value tests the difference between the treatment arm means (CC-ACM) at 6 months. A negative $Diff_{CC-ACM}$ indicates that more medication changes were made in the ACM+HT arm than in the CC arm.

FIGURES

Figure 1. DiaTel Study design (Phase I and Phase II)

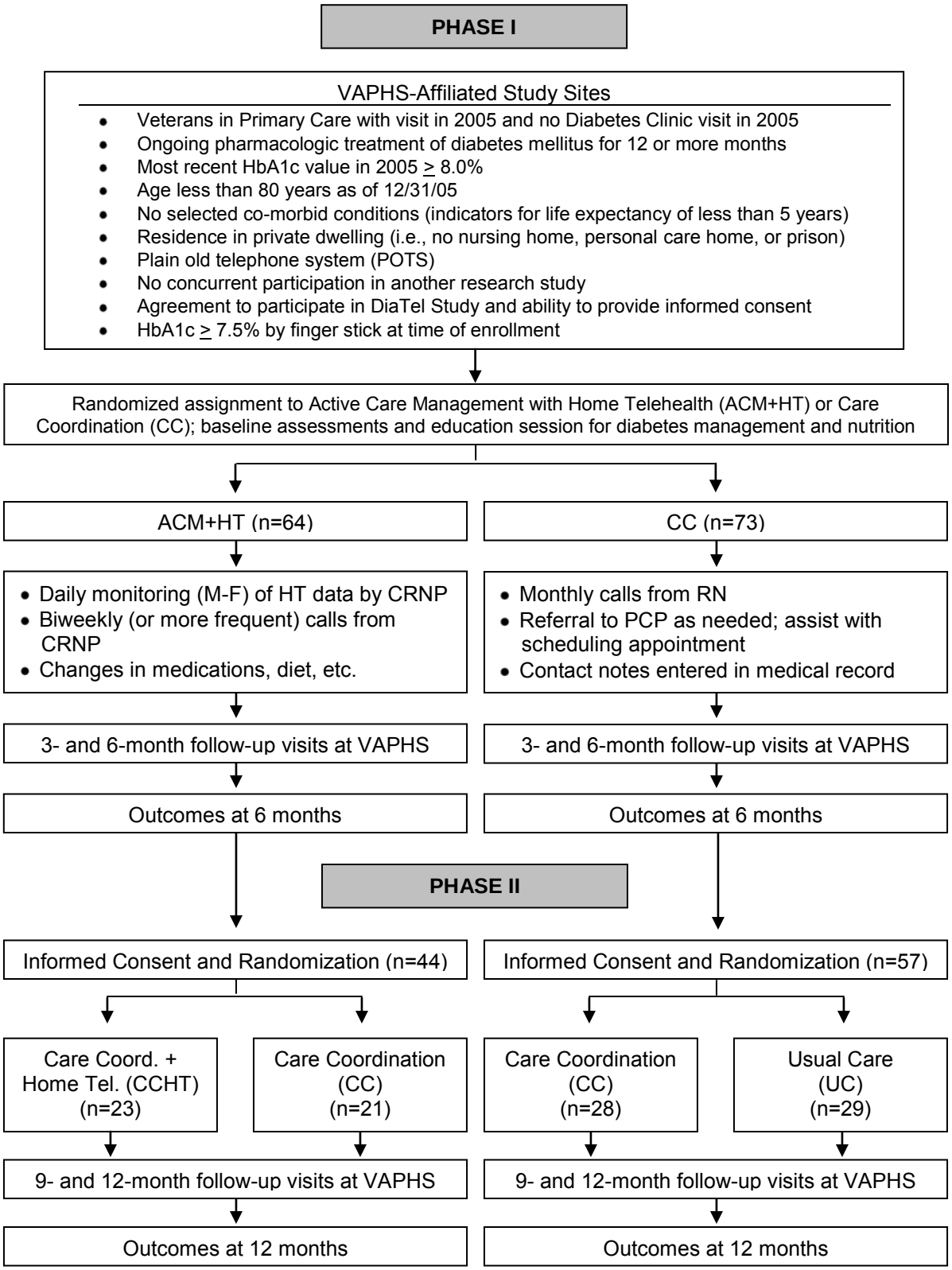


Figure 2. Development of the DiaTel Study sampling frame

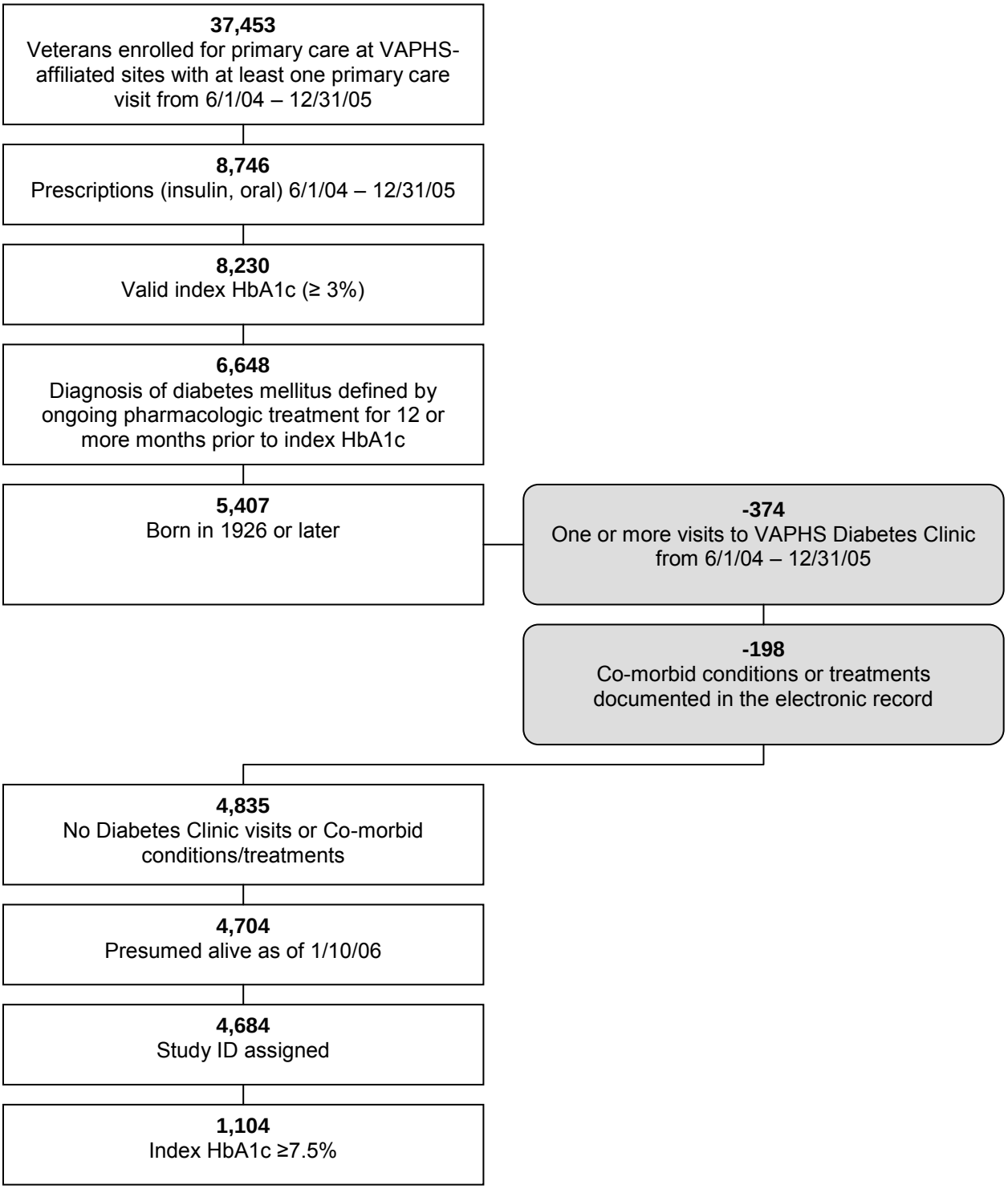


Figure 3. Screening and Phase I Enrollment

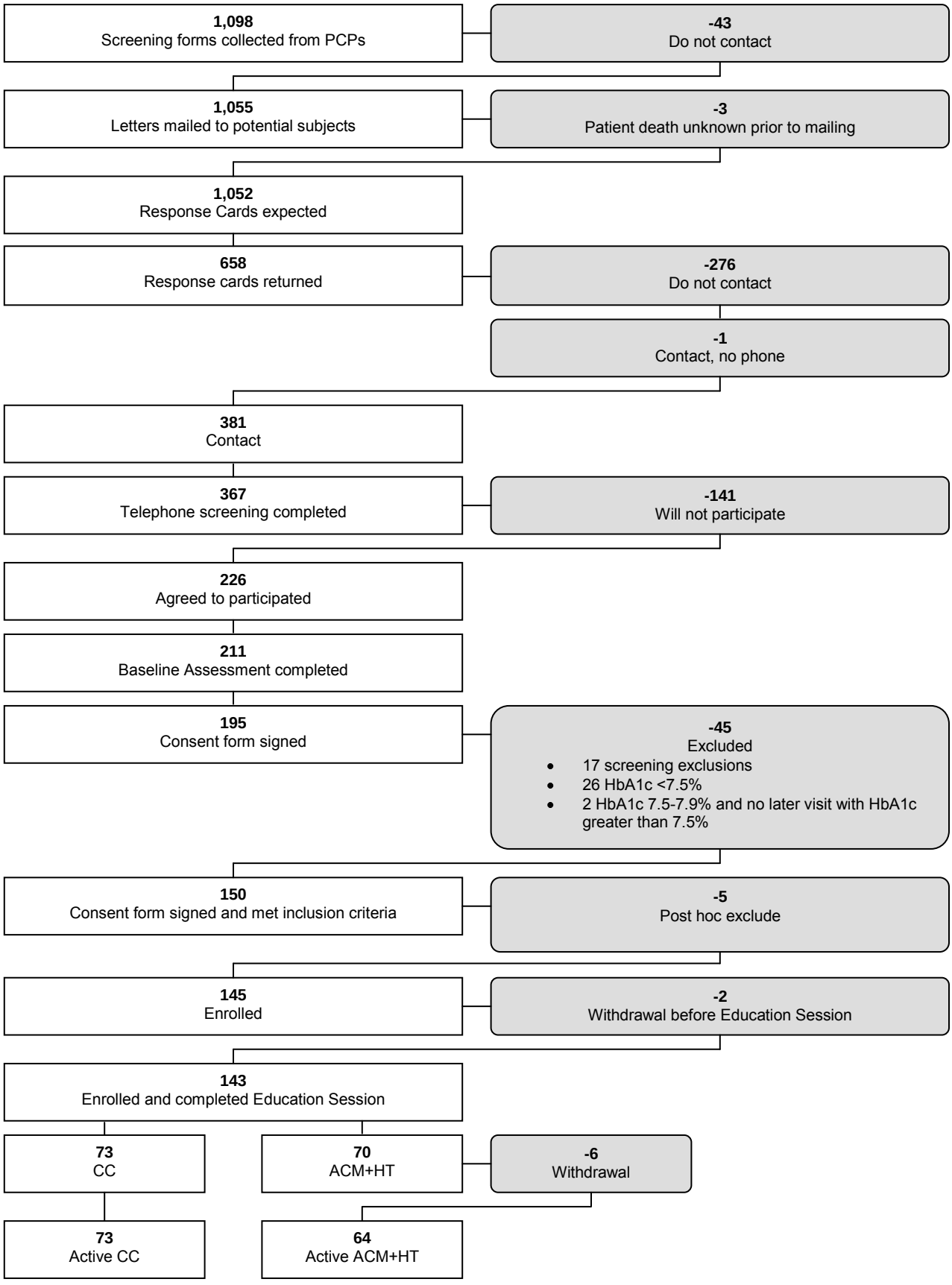


Figure 4a. Scatter diagrams of the distributions of primary outcome measures at baseline, 3 and 6 months by treatment arm.

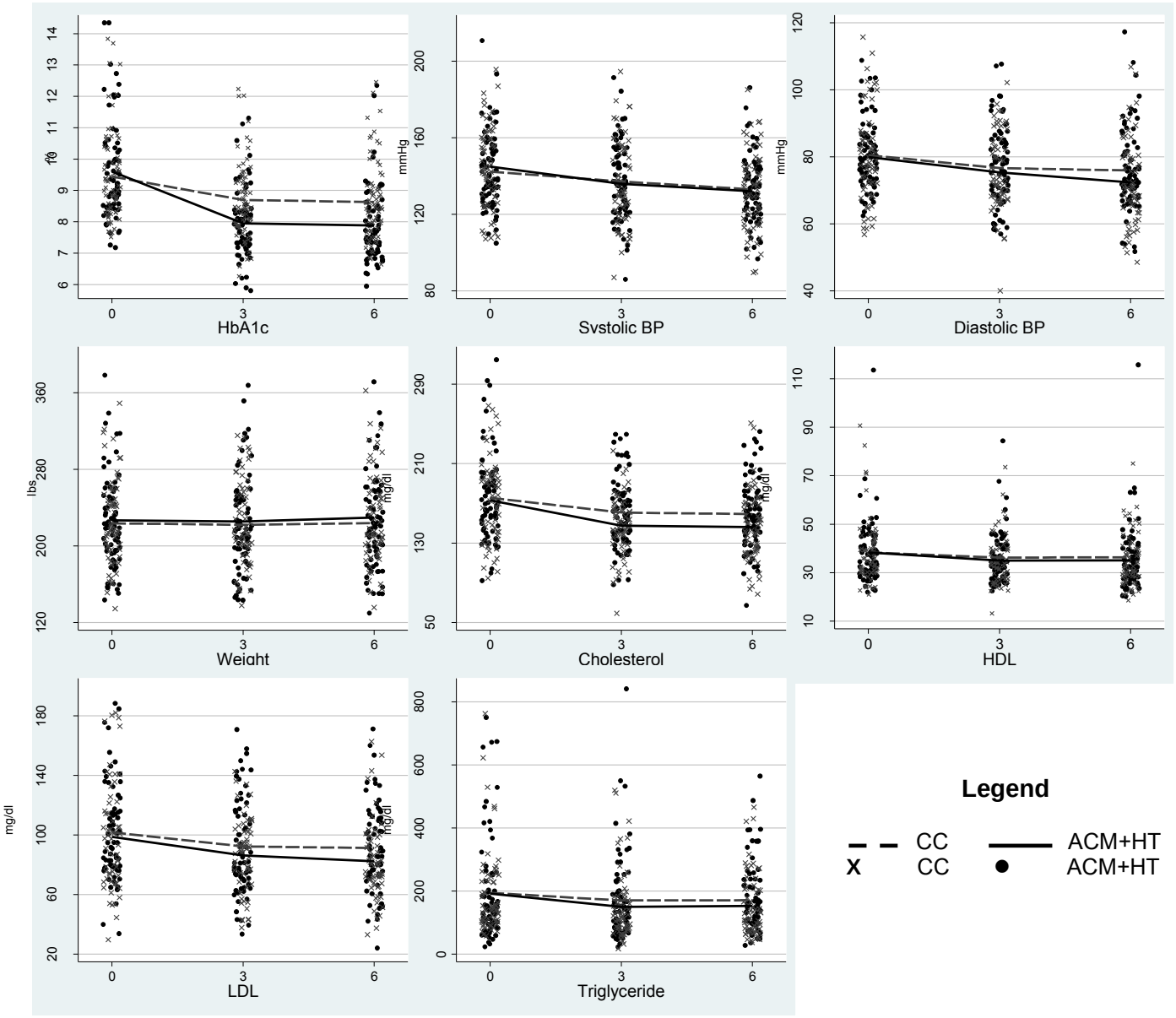


Figure 4b. Bar graphs of the distributions of primary outcome measures at baseline, 3 and 6 months by treatment arm.

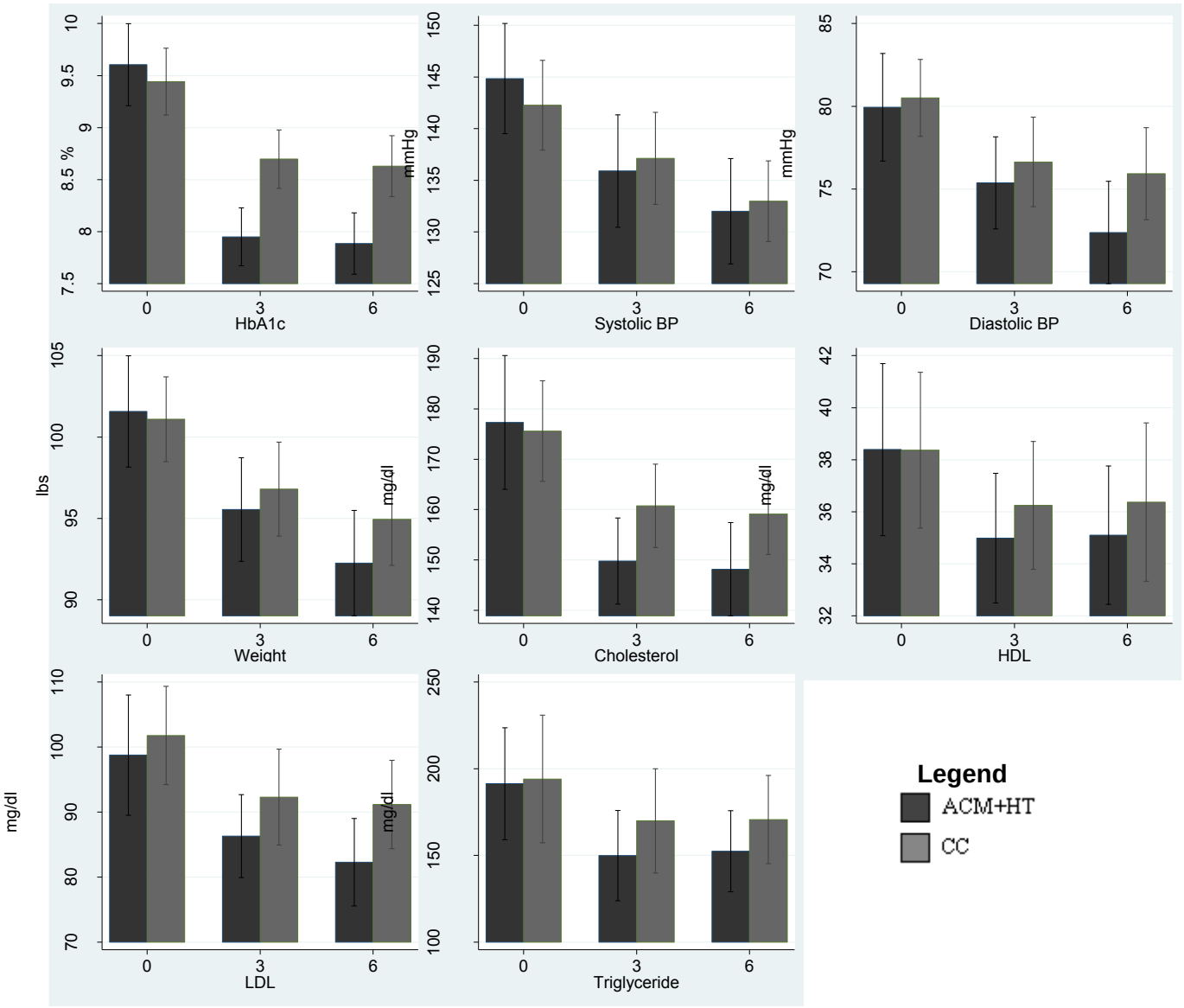


Figure 5a. Scatter diagrams of the distributions of secondary outcome measures at baseline, 3 and 6 months by treatment arm.

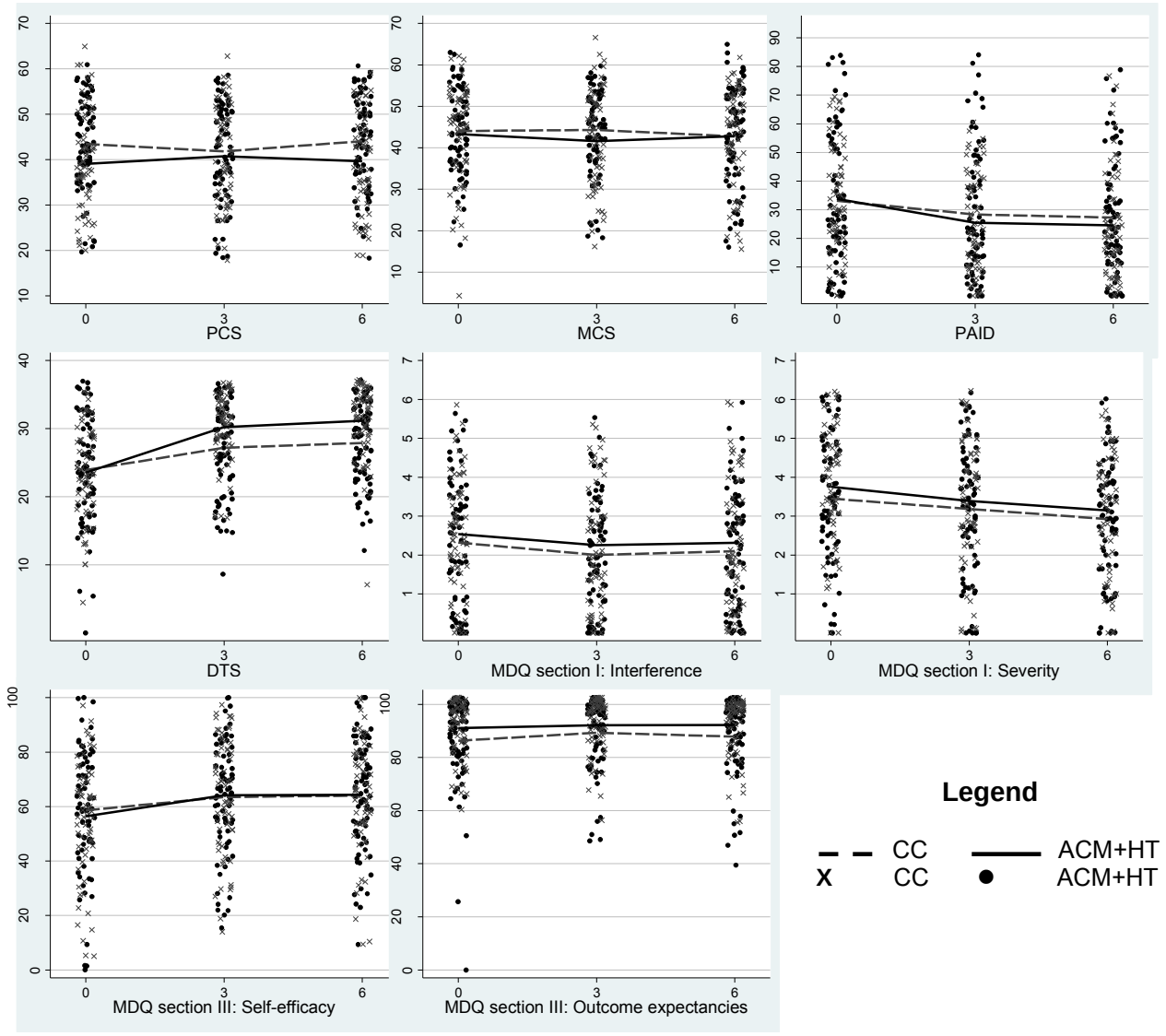


Figure 5b. Bar graphs of the distributions of secondary outcome measures at baseline, 3 and 6 months by treatment arm.

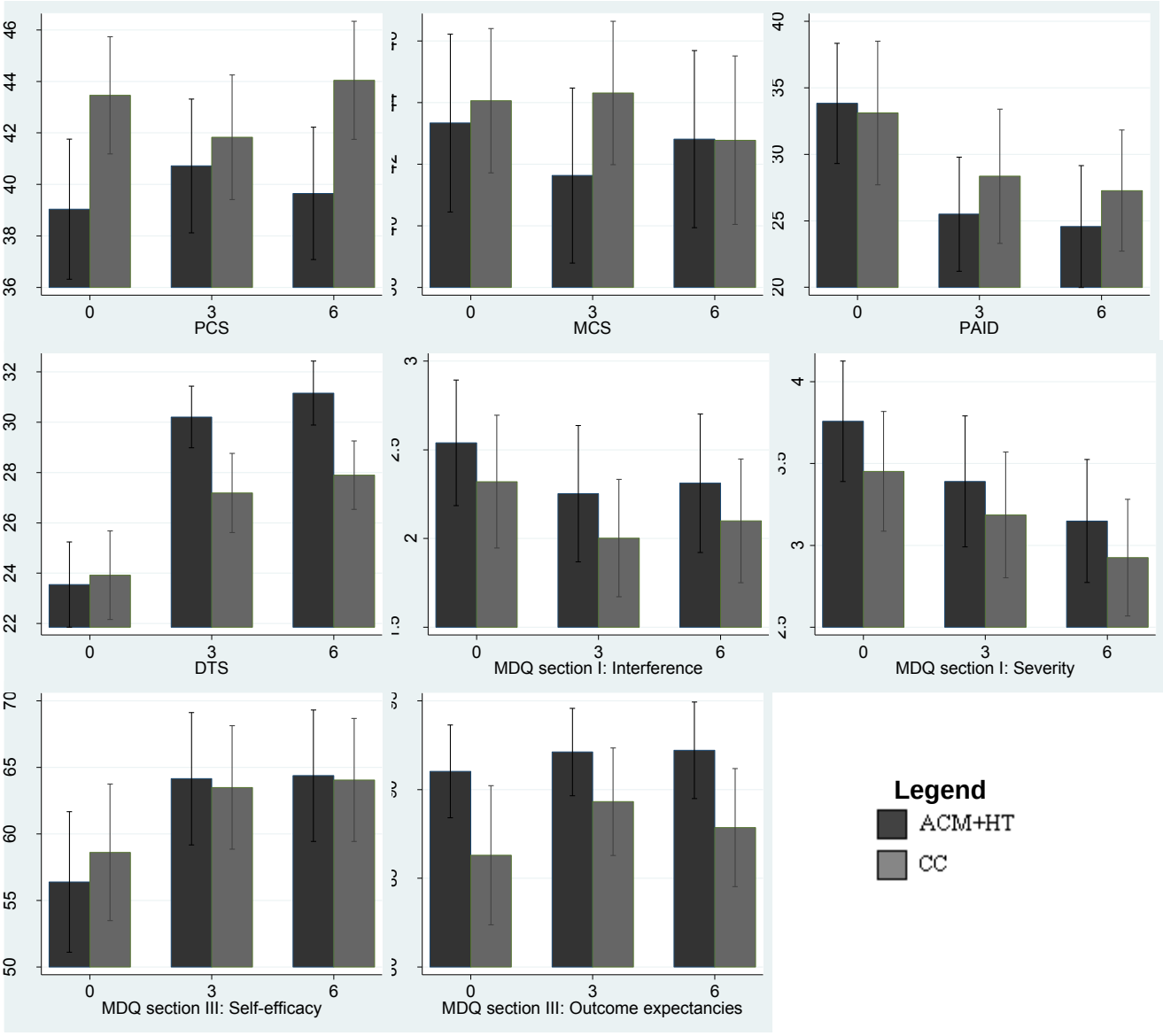


Figure 6. Insulin status at baseline and 6-months by treatment arm.

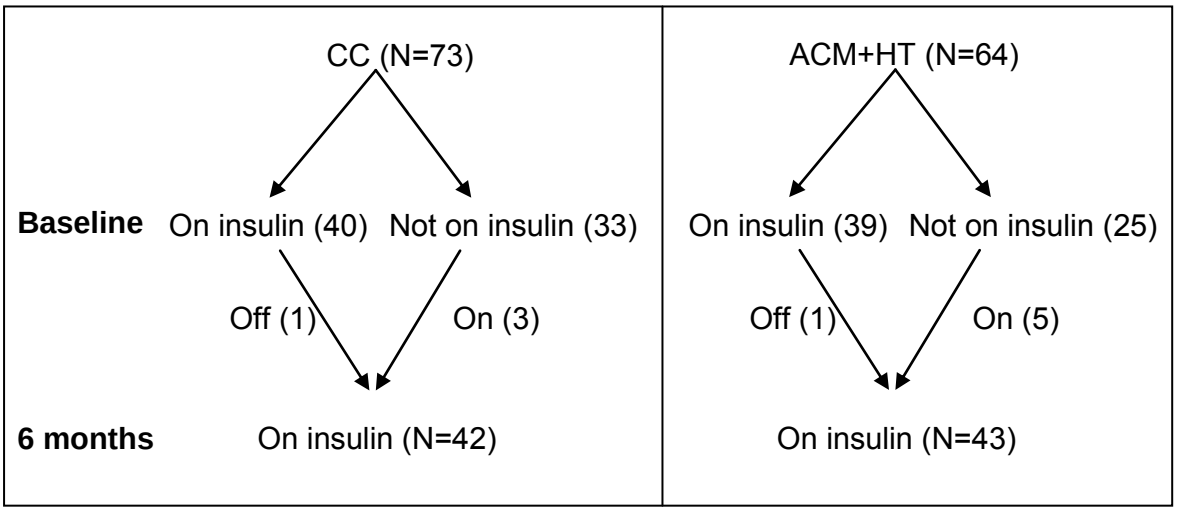


Figure 7. Daily insulin dose as baseline, 3 and 6 months by treatment arm for all participants ever on insulin during the study period.

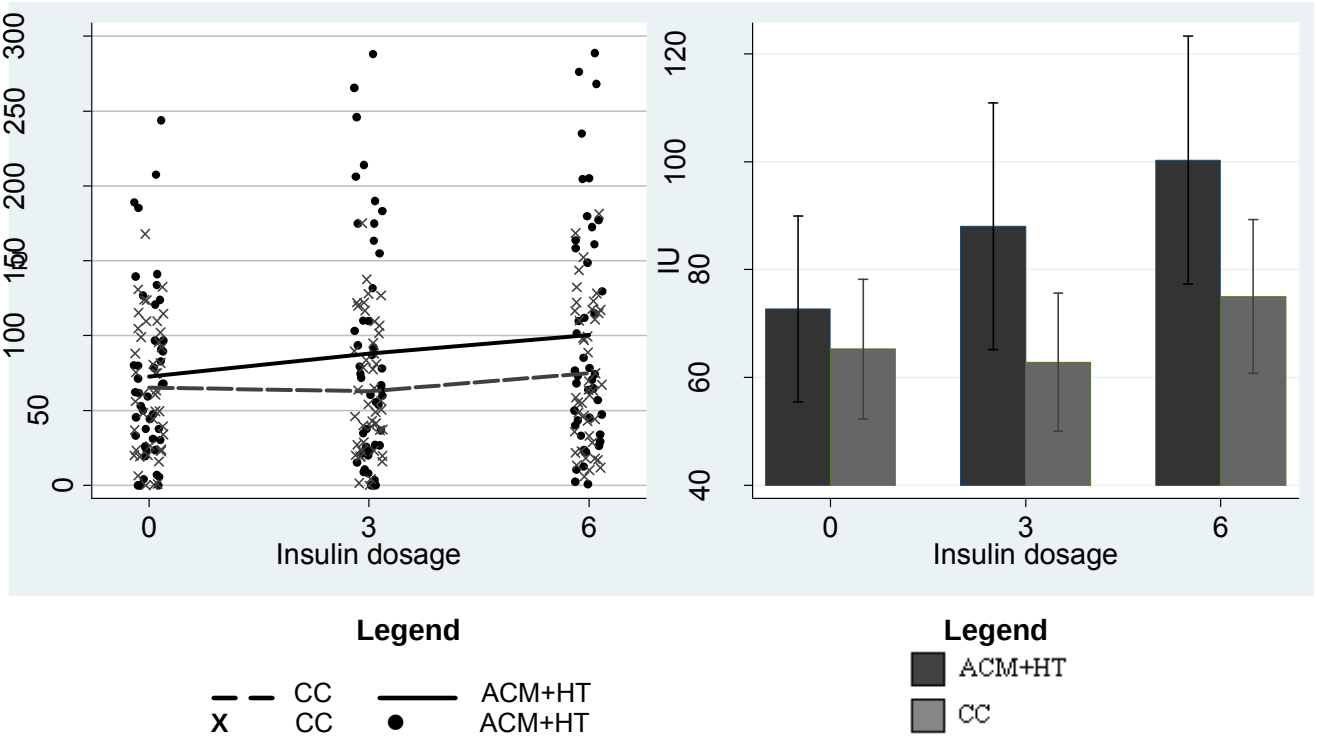
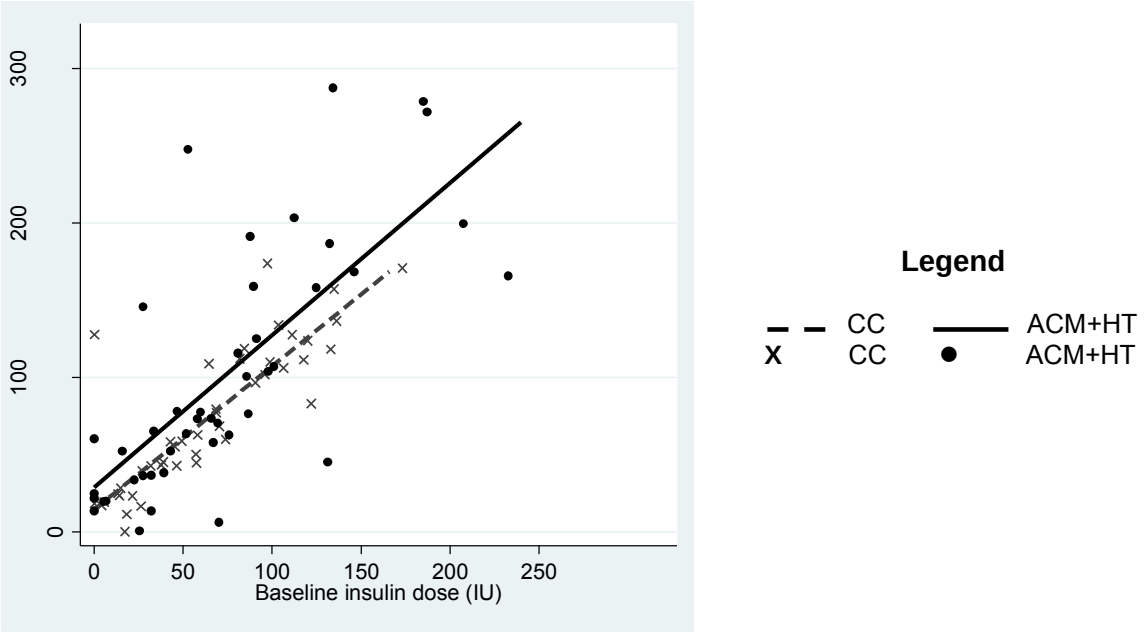


Figure 8. Daily insulin dose at baseline and 6 months by treatment arm for all participants ever on insulin during the study period.



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In-Home Diabetes Care Management/Coordination Program for Veterans: The Diabetes Telemonitoring (DiaTel) Study, Phase I

Final Report (FY04)
February 12, 2008

Frederick R. DeRubertis, MD; Principal Investigator

Appendices

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APPENDIX A. List of Investigators and Research Staff

In-Home Diabetes Care Management/Coordination Program for Veterans:
The Diabetes Telemonitoring (DiaTel) Study, Phase I

Principal Investigator

- Frederick R. DeRubertis, MD; Vice President of the Medical Specialty Service Line, VA Pittsburgh Healthcare System (VAPHS); Professor and Vice Chairman of Medicine, University of Pittsburgh School of Medicine

Co-Investigators

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- R. Harsha Rao, MD; Chief of Endocrinology, VAPHS; Professor of Medicine, University of Pittsburgh School of Medicine
- Mary Ann Sevick, ScD, RN; Core Investigator, Center for Health Equity Research and Promotion (CHERP, VA Center of Excellence); Associate Professor of Medicine, University of Pittsburgh School of Medicine
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Endocrine Consultants

- Wei Hao, MD
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Research Staff

- Rebecca Anglin, RN, CDE; Care Coordination Manager
- Nichole Bayliss, MA; Research Associate
- Chunrong Cheng, MS; Statistician
- Carol Franco, MSN, CRNP; Active Care Management Manager
- Julie Heinzl, MS, RD,CDE; Nutritionist and Educator
- Linda Hough, MPH; Coordinator
- D. Scott Obrosky, MS; Statistician and Programmer

Acknowledgment: Primary Care Service Line, VA Pittsburgh Healthcare System

APPENDIX B. Algorithms for Diabetes Care

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In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
Required Procedures for the Active Care Management Group

I. Glucose Monitoring

The Bayer Ascensia Contour Blood Glucose Meter is an attached peripheral to the Viterion 100 Monitor system. Data from the glucose meter is downloaded via the Viterion TeleHealthcare Network to a PC in the project office and reviewed daily by the project nurse practitioner.

Subjects are asked to monitor their blood glucose level at least twice daily throughout the study. In general, morning fasting levels and one other (pre-meal or bedtime) are to be assessed. During periods of treatment adjustment, more frequent measurements may be requested. Postprandial (PP) glucose measurements (two hours after a meal) are recommended for subjects with acceptable fasting glucoses but with HbA1c levels above normal. PP glucose measurements may also be valuable at other stages and are suggested as intermittent evaluations in all subjects. Subjects on pre-meal rapid-acting insulin should check PP levels four times daily.

II. Hypoglycemia

Hypoglycemia is a major fear of many patients, and a potential barrier to tight control. Increased hypoglycemia is an inevitable consequence of intensive therapy in essentially all studies to date. Patient education can help alleviate fears of this complication, and allow rapid recognition and correction of the problem. Subjects in this study will be taught to recognize causes and symptoms of hypoglycemia.

Treatment of hypoglycemia is standardized based on the following guidelines:

1) For blood glucose levels between 50 and 70 mg/dl, 10-15g of carbohydrate should be ingested. Sources of this amount of carbohydrate include 2-4 glucose tablets, 8-10 hard candies, 4-6 ounces of either non-diet soft drinks or fruit juice.

2) For blood glucose levels less than 50mg/dl, 20-30g of carbohydrate should be used. Whenever possible, glucose levels should be tested prior to treatment, and then again 15-20 minutes after initiating treatment. A repeat treatment may be necessary, if the glucose remains low.

3) If it is more than 1-2 hours before the next meal, the intake of some food with a longer duration of action is appropriate, such as cheese and crackers, peanut butter, or low fat milk to provide protein to prevent recurrent hypoglycemia. Because fat delays carbohydrate absorption, foods containing fat may not act fast enough to treat hypoglycemia.

Subjects are to be advised to always carry fast-acting carbohydrates (glucose tablets, juice, candies, etc.). **Note:** All suspected or proven hypoglycemic episodes must be carefully documented with glucose levels, symptoms, and contributing factors, and reported by phone call to the CRNP. Severe hypoglycemia requiring the assistance of another person should be reported by a phone call as soon as possible with all available information recorded.

III. Insulin Injections

It is expected that most subjects will require exogenous insulin in their treatment. The insulin preparations to be used in this study include short acting (i.e., “regular insulin”); intermediate acting, NPH or lente insulin; the rapid synthetic insulins Lispro and Aspart; and the long acting

synthetic glargine insulin. Modifications of insulin doses are to be based on daily blood glucose values from home glucose monitoring. These modifications may occur on a daily basis in some subjects.

IV. Precautions for Glycemic Control

Metformin Treatment Monitoring:

Subjects who have serum creatinine levels >1.4 mg/dl, ALT > three times normal, or CHF requiring treatment with digitalis or diuretics should NOT be given or maintained on metformin. If a subject develops any contraindication to metformin after being prescribed metformin as part of the study regimen, metformin should be discontinued and treatment advanced as per instructions for the next sequential step.

Subjects who have a contraindication for metformin at entry should substitute 8 mg Amaryl® in place of metformin.

Rosigliatazone (Avandia) Treatment Monitoring.

Subjects with elevations of ALT > 2.5 times normal, or known liver disease should NOT receive rosiglitazone. Liver function testing (LFT) (ALT, bilirubin, alkaline phosphatase) should be performed every 1.5 months during the first year of treatment with rosiglitazone and quarterly thereafter.

If while taking rosiglitazone, subjects develop jaundice, have elevations of ALT > 2.5 times normal, or other signs of liver dysfunction occur and persist for >1 week, rosiglitazone should be discontinued and treatment advanced as per instructions for the next sequential step.

Subjects with a history of congestive heart failure (CHF) prior to entry, or subjects presenting with a new confirmed diagnosis of CHF during the study should NOT receive, or should discontinue, rosiglitazone. Treatment should be advanced as per instructions for the next sequential step.

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In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
ALGORITHM FOR GLYCEMIC CONTROL

- **Goals of Active Care Management** are HbA1c ≤ 7.0% and avoidance of hypoglycemic signs or symptoms.
- A **step transition** is effected after maximal dose in a step is given and Fasting Plasma Glucose (FPG) levels consistently (1 week) exceed 140 mg/dl while last HbA1c is >7.0%. Otherwise, a step transition is effected when HbA1c levels are >7.0% after 6 weeks of unchanged treatment.
- **Note:** For subjects on insulin (either alone or in combination with oral agents) at time of enrollment, proceed directly to Step 2 (oral agents + insulin)

Step 1: Assessment of oral agents.
For subjects on oral agents, only, assess types and doses of current hypoglycemic agents and modify by increasing dose and/or type. Classes of oral agents to be used include the following from the VA formulary: sulfonylureas, glinides, glitazones, metformin, and acarbose, among others. In general, doses of a single agent will be maximized before adding a second oral agent, except for glitazones. Doses of oral agents or addition of another oral agent will be made on a weekly basis. For glitazones, 12-16 weeks are needed for assessment of maximum benefit. For subjects already on metformin, added effect of a glitazones is generally a 1% decline in HbA1c. Accordingly, subjects already on a sulfonylurea (or glinide) plus metformin, will be advanced to insulin at bedtime rather than a glitazone.

Step 2: Daily insulin injection.
A. Educate subject in injection techniques, care of insulin, needles, pens, etc.

B. Add intermediate or long-acting insulin at bedtime (h.s.) targeted to normal FPG. (NPH, Novolin N® or Glargine®). Once evening insulin is begun, measure FBG. If FBG averages over 140 mg/dl over 3 days without hypoglycemia, increase insulin dose by 5 units at least every 2-10 days until normal FBG is attained or further increases cause hypoglycemia not corrected by changing meal times or insulin type (e.g., switching to glargine).

   For subjects not on insulin at entry and with HbA1c >8%:
   - Lean subjects – start with 10 units injected at h.s.
   - Obese subjects – start with 20 units injected at h.s.
   - Then increase these as above.

C. Anticipate late actions of rosiglitazone. Adjust insulin dose accordingly.

Step 3: Additional daily insulin injection.
A. For subjects on NPH h.s. convert to evening Glargine®, or 70/30 insulin b.i.d. Continue targeting FBG as a priority, as well as other pre-meal or h.s. blood glucose, as appropriate.

B. In this and subsequent steps, alpha glycosidase inhibitors (acarbose, miglitol) may be added as tolerated before meals to reduce postprandial levels.

   The initial daily dose for acarbose and miglitol is 50 mg t.i.d. 3 times per day, i.e., to be taken with the first bite of each of 3 main meals. This dose can be increased up to 100 mg t.i.d. 3 times per day at the discretion of the study physician. Subjects taking acarbose or miglitol for the first time should initially be prescribed 50 mg, taken only once per day with dinner to accommodate the side effect of flatulence.

Step 4: Multiple dialing injections.

A. Substitute or continue Lantus® insulin (glargine) at h.s. in dose equivalent to highest dose in Step 3.

B. Continue oral agents.

C. Add short-acting insulin injections before each meal, at doses adjusted to control without causing hypoglycemic events. REGULAR OR ASPART INSULIN (Novolog®) SHOULD NOT BE MIXED IN THE SAME SYRINGE WITH GLARGINE (Lantus®). Continue targeting FBG as a priority, as well as other pre-meal or h.s. blood glucose, as appropriate. Subjects should learn carbohydrate counting for maximal benefit.

D. Alpha glycosidase inhibitors (acarbose, miglitol) may be added/continued as tolerated before meals to reduce postprandial levels. An alternative is to use nateglinide (Starlix®) before meals. In that case, Amaryl® or other secretagogue should not be used.

Step 5: Pump or other regimens.

Consider insulin pump for subjects who reach Step 5. Continue targeting FBG as a priority, as well as other pre-meal or HS blood glucose, as appropriate.

Therapy should be directed at abnormalities. Add or adjust therapy to correct fasting or PP hyperglycemia or recurrent hypoglycemia. Use available agents as clinically indicated. If nateglinide (Starlix®) is indicated, it may be given before meals in the appropriate dose, but in that case the patient should not receive another secretagogue (i.e., Amaryl®). Most subjects will be on more than one oral agent.

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
ALGORITHM FOR LIPID CONTROL

For hypercholesterolemia, pure or predominant mixed; first line treatment is a 3-hydroxy-3-methyglutaryl-coenzyme A (HMG CoA) reductase inhibitor. The dosages suggested are based on expected responses from published trials. Individual patient responses may require increased (up to the maximum recommended dose) or decreased amounts. The optimal level of LDL cholesterol is still not known but levels substantially below 100 mg/dl may be desirable in subjects with CAD.

Subjects with pure or predominant hypertriglyceridemia must be treated first with medical nutrition therapy and glycemic control. If treatment goals are not achieved, first line therapy is administration of a fibrate (gemfibrozil or fenofibrate). Subjects with triglyceride levels over 400 mg/dl should be treated immediately with pharmacological agents. In individual cases attempts to withdraw fibrate therapy may be appropriate with careful monitoring after glucose goals are met. In all cases, other causes for increased triglycerides, e.g. alcohol, should be addressed.

Therapeutic approaches to HDL deficiency are limited. Increased exercise and triglyceride reduction are the mainstays.

In summary, subjects with increased LDL levels or with LDL predominant mixed hyperlipidemia should be treated with HMG CoA reductase inhibitor therapy. Multiple studies have established expected responses to HMG CoA reductase inhibitors.

I. Precautions

Niaspan® should be used with caution. Subject compliance may be compromised by side effects. In many subjects, the detrimental effects of Niaspan® on glucose control can be easily overcome, but in a few subjects this agent can have serious effects on glucose control. All subjects in whom this therapy is initiated should be closely monitored for side effects, and the agent discontinued if the effects impair ability to achieve the primary glucose goals of the study. The major side effect of lipid therapy and especially of the combination of HBG CoA reductase and fibrate therapy is rhabdomyolysis (or muscle breakdown). Clinically, this complication is manifested by muscle pain and, if accompanied by laboratory evidence of elevated serum creatine kinase (CPK) three times normal, immediate cessation of therapy is indicated. Reinstitution of therapy should be done only after review by the study PI and the Safety Monitoring Board.

II. Initiation of Treatment

Initial LDL

- If LDL > 100 mg/dl, initiate Medical Nutrition Therapy (MNT), including optimization of glycemic goals for treatment arm
- If after 3-6 months, LDL still > 100 mg/dl, begin Drug Therapy
- If LDL > 130 mg/dl, proceed to MNT and Drug Therapy

Initial Triglycerides

- If TG > 150 mg/dl, initial MNT and glycemic goals
- If TG > 400 mg/dl, proceed to MNT and Drug Therapy
- If after 3-6 months of MNT, TG still > 150 mg/dl, start or increase fibrate (gemfibrozil, fenofibrate)

ADA Goals of Treatment

- LDL <100 mg/dl
- TG <150 mg/dl

American Diabetes Association. Standards of medical care in diabetes. Diabetes Care 2004; 27(Suppl 1): S15-S35.

III. Treatment Algorithm by Lipid Category

A. Hypercholesterolemia

1. Pure hypercholesterolemia, and mixed dyslipidemia with hypercholesterolemia predominant over hypertriglyceridemia – LDL >100 mg/dl after MNT, or LDL > 130 mg/dl.
    - First line Rx is HMG CoA reductase inhibitor montotherapy.
      Initial treatment and dose:
      Atorvastatin (dose range 10-80 mg) with evening meal
      -or-
      Simvastatin (dose range 5-80 mg) with evening meal

    (Study physician may choose to start with low doses and titrate up if necessary. Attempts to decrease higher doses if goals are reached may also be necessary.)

    High atorvastatin or simvastatin dose (80 mg) may be needed, especially as sole treatment for mixed hyperlipidemia *(Diabetes Care, 2000(1):23, S-60)*. Myopathy is dose-related, and risk increases with combination with Niaspan or fibrates. In such subjects, initial dose of statins should not exceed 10 mg.

2. Combination TG/LDL-C lowering (if LDL-C still >100mg/dl after above up-titration).
    - If TG ≥ 200 mg/dl and/or if HDL is abnormal:
      Add fenofibrate 201 mg q.p.m. or gemfibrozil 600 b.i.d., 30 minutes before meals.
    - If, after above step, TG still ≥ 200 mg/dl and/or if HDL is still abnormal, and/or if LDL-C is still >100 mg/dl:
      Consider adding or switching to Niaspan; start at 500 mg p.h.s; increase 500 mg monthly until goals are obtained. Maximal dose is 2 g. q.h.s.
    - If TG < 200 mg/dl and if HDL is abnormal: add colestipol tablets 4 g t.i.d.
    - If, after above step, LDL-C remains > 100 mg/dl:
      Up-titrate colestipol tablets to 4 g t.i.d.
    - If, after above step, LDL-C remains > 100 mg/dl:

Consider adding or switching to Niaspan (start at 500 mg q.h.s. and increase by 500 mg monthly). The use of Niaspan may worsen glucose control and should not be done without close monitoring of glucose levels and prompt adjustment of glucose therapy. In general, this agent should not be used until the subject is in the appropriate range for glucose for his/her treatment group and should be discontinued if that level cannot be restored by treatment change.

B. Hypertriglyceridemia/HDL deficiency

1. Pure hypertriglyceridemia, pure HDL deficiency, and mixed dyslipidemia with hypertriglyceridemia remaining after Rx of hypercholesterolemia
   - First line Rx is fenofibrate monotherapy 201 mg, q.p.m.
   - If fenofibrate is unavailable, substitute genfibrozil at 600 mg 30 minutes before a.m. and p.m. meals

2. Combination TG lowering/HDL raising
   - If TG remains >200 mg/dl and/or HDL-C <35 mg/dl for males (<45 mg/dl for females), add or switch to Niaspan by 500 mg, q.h.s. up to 2 g, q.h.s.

3. Combination LDL/TG lowering.
   - If after fenofibrate and/or Niaspan for hypertriglyceridemia/low LDL, LDL-C remains >100 mg/dl, add or switch to atorvastatin or simvastatin 10 mg with evening meal.
   - If LDL-C still remains >100 mg/dl after above addition, up-titrate atorvastatin or simvastatin to 20,40, and 80 mg, h.s., as needed.

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
ALGORITHM FOR MANAGEMENT OF HYPERTENSION

I. Definition

Hypertension is defined as:

a. sitting blood pressure (BP) at or greater than 140 mm Hg systolic or at or greater than 90 mm Hg diastolic, without treatment; and

b. ongoing hypertension drug treatment with BP levels prior to treatment at or higher than 140 mm Hg systolic or 90 mm Hg diastolic.

II. Measurement of Blood Pressure

Home Measurement of BP

Subjects are to monitor BP at home at least twice daily (AM and PM) using A&D-VA-767 BP monitor, a peripheral device to the Viterion 100 Monitor system. Value will be transmitted via the Viterion TeleHealthcare Network to a PC.

Subjects should be seated with their arm bared, supported, and positioned at heart level. They should not have smoked or ingested caffeine within 30 minutes prior to measurement. Measurement should begin after 5 minutes of quiet rest.

Office Measurement of BP

BP measurements are to be made at each study clinic visit using both the patient's home BP device and a mercury manometer. Both measurements are to be recorded, but the latter value is to be used as the reading of record and employed to assess the accuracy of the home device. Measurement should begin after 5 minutes of quiet rest. Data will be reviewed for systematic discrepancies between readings obtained from each device.

III. Treatment Goal

Target blood pressure is $\leq$ 130/80 obtained with the mercury manometer at the clinic visit. Any treatment modality that fails to keep BP less than or equal to 130/80 demands an additional step using readings from either the home BP values and/or the clinic readings.

IV. Treatment

Lifestyle modifications, with or without drug therapy.

For subjects with BP <140/90 and not on anti-hypertensive treatment, this modality alone may be tried first for at least 1 month. If BP >130/80, or BP does not remain at less than 130/80, life style modifications will be accompanied by drug treatment as well.

BP can improve with:

- Weight reduction (if obese)
- Moderation of dietary sodium (no salt added, no salty or processed foods)
- Consumption of fresh fruits and vegetables
- Limitation of alcohol to not more than one drink-equivalent per day
- Increased physical activity (if sedentary)
- Smoking cessation
- Stress management

Step scheme for drug treatment of hypertension.

1) Angiotensin Converting Enzyme (ACE) Inhibitor; e.g,. lisinopriol. If not tolerated (cough), Angiotensin Receptor Blocker (ARB); e.g., losartan.

2) Add hydrochlorothiazide (HCTZ) 12.5 mg. Titrate to a maximum of 25 mg if necessary. If creatinine >2 mg/dl, substitute a loop diuretic to be given twice daily. For subjects with hypokalemia, spironolactone (12.5 – 50 mg) or triamterene (25-20 mg) may be substituted for HCTZ, with appropriate monitoring of serum potassium.

3) Add a calcium channel blocker, in long acting form; e.g., verapamil, diltiazem, or a long-acting dihydropyridine. Dihydropyridine in short-acting form should not be used to treat hypertension.

4) Add selective beta-blocker at low dose (e.g. titrate to maximal dose of atenolol, 50 mg/day).

5) Add an alpha-blocker; e.g., prazosin, doxazosin or terazosin. Initial doses should be given at bedtime to avoid syncope.

6) Add Clonidine. If the patch is used to replace oral clonidine, effects may not be seen until 2-3 days after switching from oral. The oral treatment should be tapered over 2 or 3 days while the patch is administered.

V. General considerations:

A new drug may be added after maximal effective dose of current treatment has failed to attain goals (unless a separate indication for the new drug exists). Treatment is to be individualized based on a subject's characteristics (race, fluid retention, serum potassium, other conditions-post MI, CHF, etc). A minimum of two weeks of observation of the effects of a dose or doses of current hypertensive agents should be conducted, before another new antihypertensive agent is prescribed or the dose or agent is advanced.

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

APPENDIX C. Data Collection Instruments

Screening and Enrollment

- Subject Screening Form (Primary Care Provider)
- Letter from Primary Care Provider
- Response Card
- Telephone Log
- Subject Screening Form (Subject)
- Informed Consent Form
- Baseline Intake Form

Questionnaires and Chart Reviews

- Baseline Assessment
- Monthly Follow-Up (ACM+HT)
- Monthly Follow-Up (Care Coordination)
- Three-Month Intake Form
- Three-Month Assessment
- Six-Month Intake Form
- Six-Month Assessment
- Medical Record Review

Other

- Daily Log
- Telephone Contacts

Subject Screening Form (PCP)

DIATEL STUDY	Form 01	Date Form Completed (mm/dd/yyyy)	Initials of Reviewer	Subject ID Number
	SCRNPCP	__ __ / __ __ / 2 0 0 __	__ __ __	__ __ - __ __ __ __

Patient Name: _____ SS#: _____

Date of Birth: _____ VA PCP: _____

The above-referenced patient has been identified through an IRB-approved medical record review as potentially eligible for a research study, ***"The Diabetes Telemonitoring (DiaTel) Study,"*** being conducted at the VAPHS by Dr. Frederick DeRubertis and colleagues. We will be examining different telephone-based interventions to help veterans with diabetes attain and maintain better glycemic control.

You have been identified as this person's primary care provider at the VA. If you are not the PCP for the above-named patient, please check here [ ] and return this form to Dr. DeRubertis (111-U).

We are asking for your assistance in identifying potential subjects who would be ineligible for the study. The three criteria listed below are not readily accessible from the coding structure in VistA or by interviews with subjects.

Does this person have any of the following:
Please check "no," "yes," or "don't know (DK)" for each.

		NO	YES	DK
1.	End-stage liver disease (Child-Pugh classification B or C)?	☐ 0	☐ 1	☐ 8
2.	Any physical impairment (and no live-in caregiver) that would preclude participation in a study that involves the use of a telemessaging unit and telephone counseling?	☐ 0	☐ 1*	☐ 8
	*If YES, please specify:_____			
3.	Any cognitive impairment that would preclude participation (i.e., ability to provide informed consent)?	☐ 0	☐ 1*	☐ 8
	*If YES, please specify:_____			

Assessment for participation:
Please check only one box.

This person should be invited to participate in the study: ☐ 1

This person should NOT be invited to participate in the study: ☐ 0→ Please specify reason(s):

_____

_____

Thank you.

Office use:
Letter mailed to potential subject with PCP approval: Yes ☐ 1 No ☐ 0 Not Applicable ☐ 8

Date(s): M-1 _____ M-2 _____ M-3 _____

DIATEL STUDY SCRN_PCP.10.22.05

VA Pittsburgh Healthcare System
Heinz ★ Highland Drive ★ University Drive

The Diabetes Telemonitoring (DiaTel) Study

<September 30, 2005>

<Subject Name>
<Address>
<Address>

<Dear Mr. LastName>:

Living with diabetes is hard. It means that you have to make changes, every day, in the way that you live. The Diabetes Telemonitoring (DiaTel) Study is enrolling veterans in a new research study to help people with diabetes stay healthy. The study will focus on making sure you have regular contact with a health professional who will check on how well you have been able to control your blood sugar, blood pressure, blood lipids, and weight to prevent heart disease and other complications of diabetes. The study involves regular telephone contact to help you manage your health, with occasional visits (about every 3 months for 6 months) to the VA.

If you are interested in learning more about the study, please return the response card in the envelope provided. If you check "YES," a study nurse will call you to ask a few questions about your health and to schedule an appointment to the VAPHS University Drive Division in Oakland. All of the details about the study will be explained to you at this visit, which should take about an hour.

If you come to the VA for the study's baseline visit, you will be given a $20 gift card to a Giant Eagle supermarket in appreciation for your time. If you enroll in the study, you will be given $20 gift cards for the 3-month and 6-month follow-up visits as well.

You have no obligation to participate in this study. If you decide you do not want to learn anything more about it, please check "NO" on the response card, and you will not be contacted by anyone from the study. This decision will have no effect on your usual care.

You may also call the project office at 412-688-6998, if you would like to enroll in this study or you have any questions.

Sincerely,

<Primary Care Provider>
<Subject Study ID #>

Primary Care Service Line

DiaTel Study Response Card
VA Pittsburgh Healthcare System

Your Signature: _____

YES, I would like to be called by someone from the study (please check box): [ ] 1

Telephone number to use: _____

NO, I do not want to be called by someone from the study (please check box): [ ] 0

Thank you for your response. Please return this card in the enclosed envelope.

UD #: Date Mailed: (1) (2) (3) Date Received:

Note: Response card was 3.5" x 8.5" yellow card stock

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

TELEPHONE LOG2

DiaTel Study	Form 12.1					Primary Care Telephone Calls						
	TLOG2					U	D	—				

Patient Name:	SSN (final four):	Name of PCP:	Patient's home phone:	Patient's work/cell phone:

Date	Time	Outcome (circle response)								Initials
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____
_______	________	Completed*	Busy	No Answer	Disconnected	Wrong #	Call Back	Hang-up	Left Message	_____

Notes:

*OK for DiaTel Personnel to Call?	Yes	No	Died	Out of Area	No Response

TLog2.doc 01/19/06

Subject Screening Form (Subject)

DIATEL STUDY	Form 02	Date of Screening (mm/dd/yyyy)	Initials of Screener	Subject ID Number
	SCRNSUB	__ __ / __ __ / 2 0 0 __	__ __ __	__ __ — __ __ __ __

Patient Name: _____ VA PCP: _____

Telephone Introduction:
May I speak with Mr./Ms. _____? My name is _____ and I am calling about the VA Diabetes Study. You recently completed a response card giving me permission to contact you. We are delighted that you are interested in the study.

In-Person and Telephone Screen:
May I take a few minutes of your time to tell you a little more about the study?

[ ] Yes → Proceed as below [ ] No→ May I schedule another time to call you?

Date/times_____

Do not contact [ ]

Presentation of Study:
The purpose of this research study is to compare two different methods of telephone follow-up for veterans with diabetes to help them better manage their disease. The goal is to help veterans get better control of their blood sugar, blood pressure, cholesterol levels, and weight.

You would be eligible for this study if

1. *You agree to have your diabetes managed at the VA for the six months of the study;*
2. *You were born in 1926 or later; and*
3. *You have a plain old telephone system (i.e., not digital)*

You would NOT be eligible for this study if

4. *You are currently participating in any other research study;*
5. *You are living in a nursing home or personal care home;*
6. *You use oxygen therapy at home to help you breathe;*
7. *You have dialysis treatments for kidney failure; or*
8. *You have had a heart, lung, kidney, or liver transplant.*

Participation in the study is completely voluntary. If you decide you do not want to participate, your medical care at the VA will not be affected in any way.

We are asking everyone who agrees to participate to schedule an appointment with us for fasting lab work and completing a questionnaire. The first thing we would do at that visit is to ask you to sign a consent form after we describe the study and answer any questions you might have. If you qualify for the study based on your HbA1c level from a finger-stick blood sample, this visit should take about an hour.

The second part of the baseline visit is scheduled for about a week later, and will include a one-hour education session about diabetes. After the education session you will be given a glucometer, testing supplies, a blood pressure monitor, and digital scale to take home with you. We will teach you how to use the equipment. Depending on your group assignment, you may also receive a small machine to hook up to your home telephone so that daily readings can be sent to a nurse practitioner at the VA hospital. This education visit should take less than two hours.

All participants will be asked to return for a brief follow-up visit for lab work and completing a questionnaire at three and six months. You will be given a $20 gift card from Giant Eagle for each visit, except the education session.

SCRN_SUB2.12.28.05

Subject Screening Form (Subject) page 2

DIATEL STUDY	Form 02		Initials of Screener	Subject ID Number
	SCRNSUB			—

Do you have any questions?

If you think you meet the conditions for this study and would like to participate, may I schedule your first appointment?

Yes ☐1 → record below

No ☐0 → exclude (does not want to participate in study)
Not everyone we talk with is interested in participating. However, you may be interested in attending diabetes education sessions held every Tuesday at the University Drive Division. I can mail a pamphlet to you. There is no charge for attending these sessions and they are designed to help veterans learn more about controlling their diabetes. Thank you very much for taking the time to talk with me today.

Call back ☐2 → date and time_____

Baseline Visit I:

Day: Monday Tuesday Wednesday Thursday Friday

Date ___ ___/___ ___/___ ___ ___ ___

Time ___ ___:___ ___ am pm

Please go to the 10 East waiting room (room 10E-147) on the day of your appointment.

Remember for this appointment you need to be fasting; nothing to eat after midnight. On the morning of your visit, you can take all medications EXCEPT your diabetes medications. Please bring those with you to take while you are here. We also ask that you bring all of your pill bottles with you or a list of the medications and doses you are taking.

We will call you a day or two before your appointment to remind you of these instructions.

Thank you for being part of the DiaTel Study. We look forward to meeting you.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Subject Name: _____ Last 4 SSN:_____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

LAY TITLE: DiaTel Study

STUDY CONTACT INFORMATION:
If you have a general question about this research study you may call Lin Hough at 412-688-6998, Carol Franko at 412-688-6175, or any of the investigators listed below.

If you experience a medical problem that you feel may be related to this study, please call Dr. Frederick DeRubertis, Chief of Medicine, at 412-688-6146. In the case of a medical emergency, contact your local emergency medical service or go to your local emergency room.

Principal Investigator:	Frederick R. DeRubertis, MD VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6146
Co-Investigator:	R. Harsha Rao, MD VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6000, ext. 814394
Co-Investigator:	David S. Macpherson, MD, MPH VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6113
Co-Investigator:	Wei Hao, MD VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6146

VA FORM 10-1086 JUNE 1990 (revised 07/2005) Subject's Initials_____

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 2 of 10)

Subject Name: _____ Last 4 SSN:_____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

STUDY CONTACT INFORMATION (continued)

Co-Investigator:	Mary Ann Sevick, ScD, RN Center for Health Equity Research and Promotion; VAPHS University Drive C (151-C) Pittsburgh, PA 15240 (412) 688-6000, ext. 815824
Co-Investigator:	Roslyn A. Stone, PhD Center for Health Equity Research and Promotion; VAPHS University Drive C (151-C) Pittsburgh, PA 15240 (412) 688-6000, ext. 814857
Coordinator:	Lin Hough, MPH VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6998
Study Nurse Practitioner:	Carol Franko, CRNP VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6175
Research Nurse:	Rebecca Anglin, RN, CDE VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 (412) 688-6223
Certified Diabetes Educator:	Julie Heinzl, RD, LDN, CDE VA Pittsburgh Healthcare System University Drive C (111-U) Pittsburgh, PA 15240 412-688-6223

STUDY SPONSOR: Department of Defense; United States Air Force

VA FORM 10-1086 JUNE 1990 (revised 07/2005) Subject's Initials_____

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 3 of 10)

Subject Name: _____ Last 4 SSN:_____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

PURPOSE OF THE RESEARCH STUDY:

Why is this research being done?

Many people with diabetes have a difficult time doing all of the things that are required of them to successfully manage their disease. The purpose of this research study is to compare two different methods of telephone follow-up for veterans with diabetes to help them better manage their disease.

Who is being asked to take part in this research study?

Veterans who are having difficulty controlling their blood sugar are being invited to participate in this study. We hope to enroll a total of 200 veterans with diabetes who use the primary care outpatient clinics at the VA Pittsburgh Healthcare System (VAPHS) or a related VAPHS community-based outpatient clinic (CBOC). You have been invited to participate in this research study because you have been diagnosed with diabetes, your HbA1c (a measurement of blood sugar) was 8.0% or higher at least once in the past 18 months, and you have had a primary care clinic visit at the VAPHS or a related VAPHS clinic.

DESCRIPTION OF THE RESEARCH STUDY:

What procedures will be performed for research purposes?

If you decide to take part in this research study, you will undergo screening and measurement procedures, described below, that are not part of your standard medical care. You also will be asked to go to the VAPHS for the treatment of your diabetes during the study period, and agree to participate in the intervention group to which you are assigned (described below).

Screening Procedures:

Study personnel will contact veterans who have been mailed a letter from their VAPHS primary care provider. The purpose of the study will be explained at that time and a few general health questions will be asked to determine whether or not the study is appropriate for the veteran.

If you agree to a study visit after this initial contact with study personnel, an appointment will be made for you at a VAPHS location. You will be asked to "fast" (in other words, do not eat or drink anything other than water) for at least 8 hours before your visit, and not take your diabetes medications that morning. You will be asked to bring your diabetes medications with you to take after the baseline visit.

Study personnel will review this consent form with you to answer any questions you may have and to make sure you understand everything that will be asked of you if you decide to participate. If you sign

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 4 of 10)

Subject Name: _____ Last 4 SSN:_____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

this consent form, the study nurse will take a small sample of blood from your finger to estimate your average blood sugar over the past 2-3 months. This test is called a glycosylated hemoglobin (HbA1c) test and gives a good estimate of how well your diabetes is being managed over time. While waiting for the results of this blood test (approximately 6 minutes), you will have your blood pressure and weight measured by study personnel.

If your HbA1c is less than 7.5% on the day of your baseline visit, then you are doing well in controlling your blood sugar and are not eligible to participate in the study. If this is true for you, you will be given a meal voucher for the cafeteria and you will resume taking your diabetes medications as usual. In appreciation for your time for this initial visit, you will be given a $20 gift card for a Giant Eagle supermarket.

Initial Measurement Procedures:

If your finger stick HbA1c is 7.5% or higher on the day of your visit, you are eligible to participate in the study and you will be asked to stay for additional lab work. Approximately two tablespoons of blood will be taken from your arm by placing a small needle in your vein (this is called "venipuncture"). The blood will be used for the following tests:

- HbA1c (this is different from the finger stick test and may be a more accurate measurement of your average blood sugar over the past 2-3 months);
- cholesterol and triglycerides (also known as fats or lipids) to evaluate your risks for heart disease;
- serum creatinine to evaluate your kidney function;
- serum electrolytes to evaluate normal minerals in your blood; and
- liver function tests to evaluate your liver.

In addition to the blood samples, you will be asked for a urine specimen for a test of the amount of protein in your urine, another test that will let us know how healthy your kidneys are.

Study personnel will review the baseline assessment questionnaire with you to make sure it is complete and to answer any questions you may have. The questionnaire has questions about your health-related quality of life, satisfaction with care, and attitudes about diabetes.

This initial visit will take less than two hours of your time. At the end of this visit, you will be given a meal voucher for the cafeteria and a $20 gift card for a Giant Eagle supermarket in appreciation for your time.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 5 of 10)

Subject Name: _____ Last 4 SSN:_____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

Experimental Procedures:

After this first screening and measurement visit has been completed, researchers will randomly assign those who have agreed to participate in the study to one of two groups: Intervention Group 1 or Intervention Group 2. This random assignment is similar to the flip of a coin. Neither you nor the researchers will know beforehand who will be assigned to which group. It is important that you remain in the study regardless of the group to which you are assigned. This is necessary so that the researchers can compare the two groups and determine if there are any benefits for participants in either Intervention Group 1 or Intervention Group 2.

You will be asked to return to the VAPHS within one to two weeks of your first study (baseline) appointment for a 2-3 hour group education and orientation session. Up to ten other participants may be joining you at this session. A Certified Diabetes Educator will talk to the group about the best approaches for managing your diabetes, and will answer questions you may have. You also will be told whether you have been assigned to Intervention Group 1 or Intervention Group 2. Study personnel will describe what this means for you.

If you are assigned to Intervention Group 1, you can expect the following:

1. During the education/orientation session, you will be taught how to conduct and record measurements of your blood sugar, blood pressure, and weight. You will be given the equipment and supplies needed to do this at no charge to you. The equipment will be yours to keep after the study is completed.
2. The study nurse will contact you monthly by telephone and provide educational assistance with self-management. The study nurse will suggest you contact your VA primary care provider (physician, nurse practitioner, or physician assistant) if you need adjustments in your medication or if you experience other health problems. You may also call the study nurse before the scheduled monthly calls if you have any questions about your diabetes.

If you are assigned to Intervention Group 2, you can expect the following:

1. During the education/orientation session, you will be taught how to conduct and record measurements of your blood sugar, blood pressure, and weight. You will be given the equipment and supplies needed to do this at no charge to you. The equipment will be yours to keep after the study is completed.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 6 of 10)

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

2. You will be taught how to use a small machine (about the size of a radio) that connects to your telephone. This machine will send daily readings of your blood pressure, blood glucose, and weight to the study nurse. This will not increase your phone bill. You will be given the machine, at no charge, to take home with you and use while the study is being conducted. This machine must be returned after the study is completed.
3. You will receive diabetes management through the study's nurse practitioner who will contact you on a regular basis to discuss your treatment. The nurse practitioner will adjust your medications as needed, and will inform your primary care provider about any changes made.

By agreeing to participate in this study, veterans in both groups will have regular telephone contact with a study nurse to help them monitor and manage their blood sugar, blood pressure, cholesterol levels, and weight. The study nurse will work with you and the study doctor to make sure you have the information you need to manage your diabetes. The study nurse will put notes in your medical record for your primary care provider to make sure that he or she knows how you are doing. Your participation in this research study will last for six months. At the end of this study, you may be invited to continue to participate if additional grant funding is available.

Additional measurements:

In addition to the regular telephone contact with the study nurses to help you manage your diabetes, you also will be asked to return to the VA for follow-up appointments at three months and six months after the education and orientation session. Study staff will schedule a specific appointment time for you. These visits will be very similar to the initial (baseline) visit for blood tests and answering questions about your health-related quality of life, satisfaction with care, attitudes about diabetes, and any doctor or hospital visits you may have had.

We will ask you to bring your glucometer and blood pressure monitor with you so we can check their accuracy, and we will ask you to bring your medications so we can be sure we have the correct information in our files. As with the initial (baseline) visit, we will ask you to fast for 8 hours (not eat or drink anything but water) before the visit. The follow-up visits are expected to take less than an hour of your time. After each measurement visit, you will be given a $20 gift card to Giant Eagle in appreciation for your time.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 7 of 10)

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

Study personnel also will review your medical record for the 12 months before your enrollment in the study in addition to the six months you are enrolled in the study. They will collect data about your blood pressure, blood sugar, cholesterol levels, weight, and other indicators of your health, including visits to emergency rooms, hospital admissions, and medications you were prescribed. This information will be used to compare your health while participating in the study with your health before participating. This review of your medical record will require no effort on your part.

RISKS AND BENEFITS:
The risks associated with this study are minimal. You will receive standard treatments for diabetes guided by the study doctor and nurse, in collaboration with your primary care provider. However, because the study may improve the care of diabetes, there may be an increased risk of hypoglycemic (low blood sugar) and hypotensive (low blood pressure) episodes and other side effects from your usual diabetes and blood pressure medications. The study nurse will provide you with detailed information about the nature and management of hypoglycemia, the risks of hypotension, and other potential drug side effects. If you should experience a side effect from your diabetes treatment, you may be evaluated by a study physician or referred for evaluation to your primary care provider or to a local emergency room when appropriate. Your primary care provider will be informed of any side effects you experience.

Drawing blood is a standard procedure but it may cause some discomfort, bruising, light-headedness, dizziness, fainting, and, rarely, infection.

You may directly benefit from participating in this study that is designed to improve the quality of care for veterans with diabetes. Your participation may help medical research determine whether the regular contact with the study nurse along with home-health monitoring tested in this study do or do not improve the quality of care for veterans with diabetes.

ALTERNATIVES TO PARTICIPATION:
You may choose not to participate in this research study. If you decide not to participate in this study, you will continue to receive usual care at the VAPHS for the treatment of your diabetes.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 8 of 10)

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

INVESTIGATOR INITIATED WITHDRAWAL: The investigators may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you withdraw, you may be asked to return for a final study visit in order to assure your safety. You must withdraw in writing in order to withdraw your permission for us to continue to use the protected health information we have already collected about you. Even if you withdraw your permission for us to use the information about you, we are required by regulatory agencies to record any information that relates to the safety of any study- related intervention.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law.

COST AND PAYMENTS: There will be no cost to you for your participation in this study, however if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You will be given a $20 gift card for a Giant Eagle supermarket the same day you complete each assessment (baseline, 3 months, and 6 months). Transportation costs will be paid for by the study, if requested.

VA FORM 10-1086 JUNE 1990 (revised 07/2005) Subject's Initials_____

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 9 of 10)

Subject Name: _____ Last 4 SSN:_____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

PRIVACY AND CONFIDENTIALITY:

- Information that will be used: During the course of this study, we will collect private information such as your name, date of birth, Social Security Number, laboratory values including blood sugar levels, cholesterol (lipids) levels, kidney and liver function tests, physical examination findings such as blood pressure and weight, and other medical information. We will also collect information about Emergency Room and hospital visits you may have during the 6-month study period. Your name and Social Security Number will be used only as necessary within the VA Pittsburgh Healthcare System, but other private information may be disclosed to the study sponsor, Department of Defense; United States Air Force, after removal of information that identifies you specifically.
- If you have an adverse experience during the course of the study, your entire medical record may be used and disclosed as clinically necessary as well as pursuant to federal and state laws and regulations.
- The People/Organizations Who May Use or Disclose the Information: Your information will be used only as specified above and under the direction of Dr. Frederick DeRubertis and his research team. Your private information may also be used by employees of the VA Pittsburgh Healthcare System Research and Development Office, as necessary, to perform their duties regarding research quality assurance.
- The People/Organizations Who Will Receive the Information: You understand that every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. If your private information is released to outside entities as specified above, further disclosure will be limited by federal and state privacy laws and regulations. Your information may also be disclosed to the Education and Compliance Officer of the VA Pittsburgh Healthcare System in order to perform audit and compliance duties. You understand that your private health information may also be reviewed by the institutional review board, which is a group at this hospital that oversees all research. You understand that research records, just like hospital medical records, may be released or disclosed pursuant to applicable federal and state law as well as to federal and state agencies that are responsible for oversight of medical research. You also understand that medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under federal laws and regulations. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.
- Expiration Date: The personal health information collected about you for this study will be used by the study team until the study has ended and all the information has been collected and analyzed.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Page 10 of 10)

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: Diabetes Telemonitoring (DiaTel) Study

Principal Investigator: Frederick R. DeRubertis, MD VAMC: Pittsburgh (646)

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. Frederick DeRubertis or his authorized representative has explained the study to you and answered all of your questions. You have been fully informed of the risks, discomforts, and possible benefits of this research study. You have been fully informed of other treatment choices available to you.

You understand your rights as a research subject, and you voluntarily consent to participate in this research study. You understand what the study is about and how and why it is being done. You will receive a copy of this signed consent form.

If you have any questions about the research or your rights as a participant in this study, you can call Dr. Steven H. Graham, Associate Chief Of Staff /R&D, VA Subcommittee on Human Studies (SHS) at (412) 365-4274.

As long as the study is renewed as required by the SHS, your signature on this document is valid for the duration of the entire research study and you understand that you will be notified of any changes in the study that will affect you.

By signing this form, you agree to participate in this research study.

_____	_____	
Subject's Signature	Date	
_____	_____	_____
Signature of Witness	Witness (Print)	Date
_____	_____	_____
Investigator/Person Obtaining Consent	Researcher (Print)	Date

Protocol #02324 (version 2.2); December 12, 2005

VA FORM 10-1086 JUNE 1990 (revised 07/2005) **Subject's Initials**_____

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Baseline Intake

DiaTel Study	Form 04	Data Collector ID #	Data Collector Initials	Subject ID Number
	BASEIN			

Subject (Last Name): _____ First Name: _____

Date of Baseline Intake (MM/DD/YYYY): ___ ___ / ___ ___ / 2 0 0 ___

1. Signed Informed Consent form — Yes — No → do not enroll: END

Screening Questions:

1.1	Where do you usually go for your diabetes care? VA	Other → **Non-VA PCP:*** _____	
1.1.a	Are you willing to have your diabetes managed at the VA for the 6 months of the study?	Yes	No → exclude
1.2	What is your date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___	≥ 1926	≤1925 → exclude
1.3	Are you currently participating in any other clinical or medical research studies?	No	Yes → exclude
1.4	Are you currently living in a nursing home or a personal care home?	No	Yes → exclude
1.5	Is your telephone service through the Internet (digital)?	No	Yes → exclude
1.6	Do you have any trouble reading a newspaper, or have other difficulties with your vision?	No	Yes → *script
1.7	Do you have trouble using the telephone because of any hearing or voice problems?	No	Yes → *script
	Script: To participate in this study, you need to be able to read numbers and messages from the equipment being used. You also need to be able to talk with a nurse or dietician on the telephone. Is there someone at home would be able to help you with these things?	Yes	No → exclude
1.8	Do you use oxygen therapy at home to help you breathe?	No	Yes → exclude
1.9	Do you have dialysis treatments for kidney failure?	No	Yes → exclude
1.10	Have you ever had a heart, lung, kidney, or liver transplant?	No	Yes → exclude

2. HbA1c (finger stick) ___ . ___ %
3. Eligible for DiaTel Study (HbA1c ≥ 7.5% and screen) — Yes — No → skip to Q14
4. Blood pressure ___ / ___ mm/Hg
5. Height ___ . ___ inches
6. Weight ___ . ___ pounds
7. Lab work ordered (blood and urine) — Yes — No
8. Baseline Assessment form completed — Yes — No
9. Intervention assignment — Group 1 (CC) — Group 2 (Viterion)
10. Follow-up education session scheduled — Yes — No → call to schedule

Date: ___ ___ / ___ ___ / ___ ___ ___ ___ Time: _____

***Non-VA PCP contact information:**

11. History of coronary artery disease (CAD) — Yes — No
12. History of congestive heart failure (CHF) — Yes — No
13. History of chronic obstructive pulmonary disease (COPD) — Yes — No
14. Grocery store gift card given — Yes — No

Veterans not enrolled because of ineligibility are to be given a voucher for the cafeteria and a grocery store gift card; skip lab work, Baseline Assessment, intervention assignment, education session, and co-morbid conditions.

DiaTel Study BASEIN 01.06.06

ID #: | | | — | | | | |

The Diabetes Telemonitoring (DiaTel) Study

Baseline Assessment

Baseline Assessment

DiaTel Study	Form 05	Data Reviewer ID #	Data Reviewer Initials	Subject ID Number
	BASE			

Date of Completion (MM/DD/YYYY): ___/___/2000

A. Contact Information

Please provide the following information so we can make sure our records are accurate:

Last name: _____ First name: _____ M.I.: ___

Address: _____

_____

City: _____ State: ___ Zip: _____

Home telephone: ___ -- ___ -- ____

Other telephone: ___ -- ___ -- ____

In case we cannot contact you for follow-up using the telephone numbers listed above, please give us the following information for a relative or friend who does not live with you but would be able to help us reach you.

Contact's last name: _____ First name: _____

Address: _____

City: _____ State: ___ Zip: _____

Home telephone: ___ -- ___ -- ____

Other telephone: ___ -- ___ -- ____

Relationship to you (please check only one box):

- ☐ 1 Spouse or significant other
- ☐ 2 Parent
- ☐ 3 Child
- ☐ 4 Brother or sister
- ☐ 5 Other family member
- ☐ 6 Friend
- ☐ 7 Other *

*please specify other: _____

B. Background Information

This series of questions is a standard collection of background information. Please check only one box for each question. As with everything else in the study, all of the information is confidential.

1. What is your current employment status?

Employed full-time (35 hours or more per week)*	☐ 1
Employed part-time (less than 35 hours per week)*	☐ 2
Homemaker, not working outside the home	☐ 3
Retired	☐ 4
Unemployed	☐ 5
**If employed (full-time or part-time), number of hours worked per week:*	☐☐

2. Which best describes your marital status?

Single, never married	☐ 1
Married, or living as married	☐ 2
Widowed	☐ 3
Separated or divorced	☐ 4

3. Which best describes your living arrangements?

Private residence (house or apartment), living alone	☐ 1
Private residence (house or apartment), living with others	☐ 2
Other (please specify on the line below):	☐ 3

_____

4. What is the highest level of formal education you have completed?

Grade school (years 1 through 8) or less	☐ 1
Some high school	☐ 2
Completed high school or GED	☐ 3
Some college or associate degree	☐ 4
Completed technical or vocational school	☐ 5
Completed college or more	☐ 6

5. Which of the following best describes your race.

White, not of Hispanic origin	☐ 1
African-American or Black, not of Hispanic origin	☐ 2
Hispanic	☐ 3
Asian or Pacific Islander	☐ 4
American Indian or Alaskan Native	☐ 5
Other (please specify on the line below):	☐ 6

_____

C. Your Health and Well-Being

These are some basic questions about your habits and behavior.

1. Have you ever smoked cigarettes?

No.....	☐ 0 →	Skip to question 2.
Yes, in the past	☐ 1 →	What year did you quit? ☐☐☐☐
Yes, current smoker	☐ 2	

→ a. Total number of years you smoked/ or have been smoking cigarettes? ☐☐ years

→ b. Average number of cigarettes smoked per day when smoking? ☐☐☐ cigarettes

2. How often do you have a drink containing alcohol?

Never.....	☐ 0 →	Skip to question 3.
Monthly or less	☐ 1	
2 – 4 times a month	☐ 2	
2 – 3 times a week	☐ 3	
4 or more times a week	☐ 4	

→ a. How many drinks containing alcohol do you have on a typical day when you are drinking?

1 or 2	3 or 4	5 or 6	7 to 9	10 or more
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

→ b. How often do you have six or more drinks on one occasion?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

3. How often do you have at least 30 minutes of daily physical activity (include work around the house, gardening, walking, exercise programs, sports)?

Never	Less than 1 day each week	1 – 2 days each week	3 – 4 days each week	5 or more days each week
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

4. Are you able to identify foods that contain carbohydrates?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. Which meals do you eat daily, or almost every day (please check all that apply)?

Breakfast	Mid-morning snack	Lunch	Mid-afternoon snack	Dinner	Evening snack
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

C. Your Health and Well-Being (continued)

These next questions ask for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer every question by marking the answer as indicated. If you are unsure how to answer a question, please give the best answer you can.

(Circle one number on each line)

6. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
1	2	3	4	5

7. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
b. Climbing **several** flights of stairs	1	2	3

8. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
a. **Accomplished less** than you would like	1	2	3	4	5
b. Were limited in the **kind** of work or other activities	1	2	3	4	5

9. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
a. **Accomplished less** than you would like	1	2	3	4	5
b. Didn't do work or other activities as **carefully** as usual	1	2	3	4	5

C. Your Health and Well-Being (continued)

10. During the past 4 weeks, how much did **pain** interfere with your normal work (include both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	3	4	5

11. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	1	2	3	4	5	6
b. Did you have a lot of energy?	1	2	3	4	5	6
c. Have you felt downhearted and blue?	1	2	3	4	5	6

12. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

D. Problem Areas in Diabetes

Which of the following diabetes issues are currently problems for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Some-what serious problem	Serious problem
1. Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
2. Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
3. Feeling scared when you think about living with diabetes?	0	1	2	3	4
4. Uncomfortable social situation related to your diabetes care? (e.g., people telling you what to eat?)	0	1	2	3	4
5. Feelings of deprivation regarding food and meals?	0	1	2	3	4
6. Feeling depressed when you think about living with diabetes?	0	1	2	3	4
7. Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
8. Feeling overwhelmed by your diabetes?	0	1	2	3	4
9. Worrying about low blood sugar reactions?	0	1	2	3	4
10. Feeling angry when you think about living with diabetes?	0	1	2	3	4
11. Feeling constantly concerned about food and eating?	0	1	2	3	4
12. Worrying about the future and the possibility of serious complications?	0	1	2	3	4
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
14. Not "accepting" your diabetes?	0	1	2	3	4
15. Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
17. Feeling alone with your diabetes?	0	1	2	3	4
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4
19. Coping with complications of diabetes?	0	1	2	3	4
20. Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4

E. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer the following by circling one number for each question.

1. How satisfied are you with your current treatment?

6	5	4	3	2	1	0
Very satisfied						Very dissatisfied

2. How often have you felt that your blood sugars have been unacceptably high recently?

6	5	4	3	2	1	0
Most of the time						None of the time

3. How often have you felt that your blood sugars have been unacceptably low recently?

6	5	4	3	2	1	0
Most of the time						None of the time

4. How convenient have you been finding your treatment to be recently?

6	5	4	3	2	1	0
Very convenient						Very inconvenient

5. How flexible have you been finding your treatment to be recently?

6	5	4	3	2	1	0
Very flexible						Very inflexible

6. How satisfied are you with your understanding of your diabetes?

6	5	4	3	2	1	0
Very satisfied						Very dissatisfied

7. Would you recommend this form of treatment to someone else with your kind of diabetes?

6	5	4	3	2	1	0
Yes, I would definitely recommend the treatment						No, I would definitely not recommend the treatment

8. How satisfied would you be to continue with your present form of treatment?

6	5	4	3	2	1	0
Very satisfied						Very dissatisfied

F. Multidimensional Diabetes Questionnaire: Section I

We are interested to learn more about your diabetes and the way it affects your life. For each question, circle the number that corresponds best to your situation.

1. To what extent does your diabetes interfere with your daily activities?

   0 1 2 3 4 5 6

   Not at all Extremely

2. To what extent does your spouse (or significant other, companion, or a person who lives with you) support you with your diabetes?

   (_____Check here if you live alone, then skip to question 3.)

   0 1 2 3 4 5 6

   Not at all Extremely

3. To what extent do you consider your diabetes to be a severe health problem?

   0 1 2 3 4 5 6

   Not at all Extremely

4. To what extent does your diabetes decrease your satisfaction or pleasure from social or recreational activities?

   0 1 2 3 4 5 6

   Not at all Extremely

5. To what extent do your family and friends support you or help you with your diabetes?

   0 1 2 3 4 5 6

   Not at all Extremely

6. To what extent do you worry about long-term complications of diabetes?

   0 1 2 3 4 5 6

   Not at all Extremely

7. To what extent does your diabetes interfere with your effectiveness at work?

   (_____Check here if you do not work, then skip to question 8.)

   0 1 2 3 4 5 6

   Not at all Extremely

8. To what extent does your diabetes interfere with your relationship with your spouse (or significant other, companion, or a person who lives with you)?

   (_____Check here if you live alone, then skip to question 9.)

   0 1 2 3 4 5 6

   Not at all Extremely

F. Multidimensional Diabetes Questionnaire (Section I continued)

9. To what extent do you worry about your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

10. To what extent does your spouse (or significant other, companion, or a person who lives with you) pay attention to you because of your diabetes?

(_____Check here if you live alone, then skip to question 11.)

0	1	2	3	4	5	6
Not at all						Extremely

11. To what extent does your diabetes prevent you from traveling as much as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

12. To what extent does your doctor or health care team support you or help you with your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

13. To what extent does your diabetes interfere with your ability to participate in social or recreational activities?

0	1	2	3	4	5	6
Not at all						Extremely

14. To what extent does you diabetes interfere with your ability to plan your activities?

0	1	2	3	4	5	6
Not at all						Extremely

15. To what extent does your diabetes prevent you from being as active as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

16. To what extent does your diabetes prevent you from having a schedule that you like (for example, to sleep late)?

0	1	2	3	4	5	6
Not at all						Extremely

If you **live alone,** please check this box ☐, then skip to **Section III, page 11.**

If you **do not live alone,** please check this box ☐, then continue with **Section II on the next page.**

F. Multidimensional Diabetes Questionnaire: Section II

We are interested to learn about the way your spouse (or significant other, companion, or another person who lives with you) responds to you concerning your self-care program. On the scale listed below each question, circle the number that best indicates how often he or she responds to you in that particular way.

My spouse (or significant other, companion, or another person who lives with me):

1. Congratulates me when I follow my diet.

   0 1 2 3 4 5 6

   Never Very often

2. Hassles me about my diabetes medication (pills, insulin).

   0 1 2 3 4 5 6

   Never Very often

3. Congratulates me for regularly measuring my blood glucose level.

   (_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)

   0 1 2 3 4 5 6

   Never Very often

4. Hassles me about exercise.

   (_____Check here if you have been advised **not** to exercise.)

   0 1 2 3 4 5 6

   Never Very often

5. Reminds me to take care of my feet.

   (_____Check here if foot care has **not** been recommended.)

   0 1 2 3 4 5 6

   Never Very often

6. Congratulates me when I follow my meal schedule (meals and snacks).

   0 1 2 3 4 5 6

   Never Very often

7. Reminds me to take my diabetes medication (pills, insulin).

   0 1 2 3 4 5 6

   Never Very often

8. Helps me to adjust my food intake when I exercise.

   (_____Check here if you have been advised **not** to exercise.)

   0 1 2 3 4 5 6

   Never Very often

F. Multidimensional Diabetes Questionnaire (Section II continued)

My spouse (or significant other, companion, or another person who lives with me):

9. Hassles me about my diet.

0	1	2	3	4	5	6
Never						Very often

10. Plans family activities in a way that allows me to take my medication at the right time.

0	1	2	3	4	5	6
Never						Very often

11. Hassles me about measuring my blood sugar.

(_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)

0	1	2	3	4	5	6
Never						Very often

12. Encourages me to exercise.

(_____Check here if you have been advised **not** to exercise.)

0	1	2	3	4	5	6
Never						Very often

Multidimensional Diabetes Questionnaire: Section III

Treatment of diabetes involves several self-care activities (for example, diet, exercise, etc). People sometimes find it difficult, or do not see the importance of following one or more of these self-care activities. We would like to know how this applies to you. Read each question carefully and circle the number that corresponds best to your situation.

1. How confident are you in your ability to follow your diet?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

2. How confident are you in your ability to test your blood sugar at the recommended frequency?

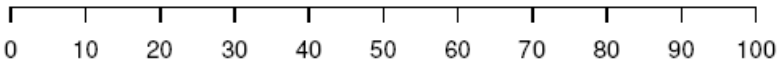
(_____Check here if measuring of blood sugar levels has **not** been recommended.)

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

F. Multidimensional Diabetes Questionnaire (Section III continued)

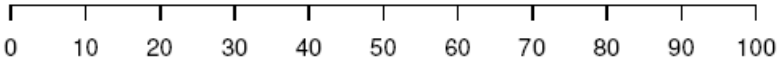
3. How confident are you in your ability to exercise regularly?

   (_____Check here if you have been advised **not** to exercise.)



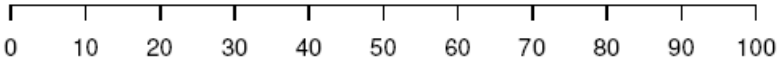
Not at all confident — Very confident

4. How confident are you in your ability to keep your weight under control?



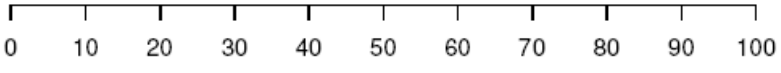
Not at all confident — Very confident

5. How confident are you in your ability to keep your blood sugar level under control?



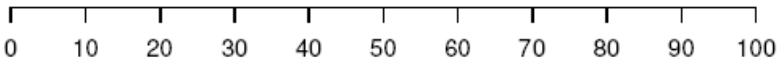
Not at all confident — Very confident

6. How confident are you in your ability to resist food temptations?



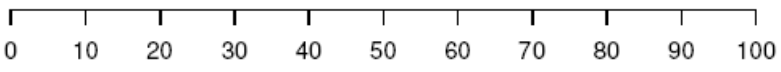
Not at all confident — Very confident

7. How confident are you in your ability to follow your diabetes treatment (diet, medication, blood sugar testing, physical activities?)



Not at all confident — Very confident

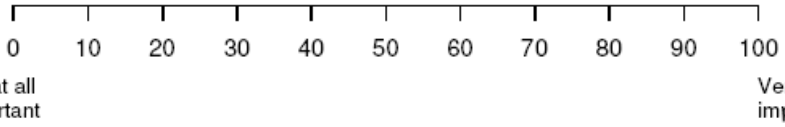
8. To what extent do you think that following your diet is important for controlling your diabetes?



Not at all important — Very important

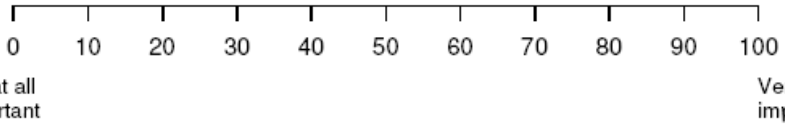
F. Multidimensional Diabetes Questionnaire (Section III continued)

9. To what extent do you think that taking your medication as recommended (pills, insulin) is important for controlling your diabetes?



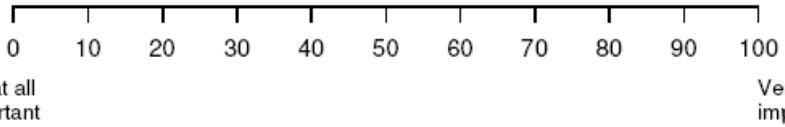
10. To what extent do you think that exercise is important for controlling your diabetes?

(_____Check here if you have been advised **not** to exercise.)

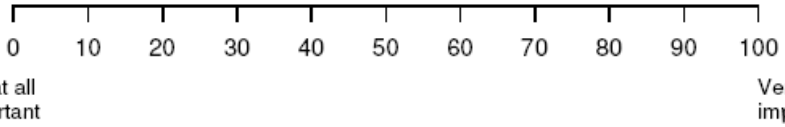


11. To what extent do you think that measuring your blood sugar is important for controlling your diabetes?

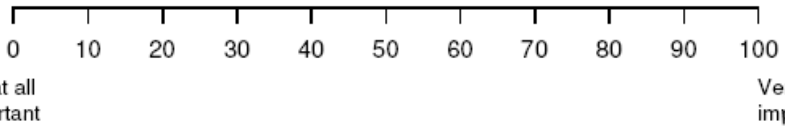
(_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)



12. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for controlling your diabetes?



13. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for delaying and/or preventing long-term diabetes complications (problems related to eyes, kidneys, heart, or feet)?



Thank you for completing the Baseline Assessment.

Monthly Follow-Up (Viterion)

DiaTel Study	Form 06	Data Collector ID #	Data Collector Initials	Subject ID Number
	MO-VI			—

Subject (Last Name): _____ First Name: _____

Date of Monthly Follow-Up (MM/DD/YYYY): __ __ / __ __ / 2 0 0 __

START TIME: ___ ___ ___ ___

Periodically, I will be calling to review a summary of your data for the previous month or so. The purpose of this is to identify trends or recurring problems and should only take a few minutes. Do you have time for this now?

If no, schedule time for next call: _____

It might be helpful to have the binder with your daily log to refer to during this call.

1.a. The Viterion reports during the past month indicate you [have been / have not been] sending your **blood glucose** data as prescribed. Please [continue to / remember to] check your glucose as instructed. [Underline: Twice daily, three times a day, four times a day] Reinforcement statement

Blood glucose data via Viterion:

0 Not checking

1 Less than once each day →

2 Once each day →

3 Two or more times each day

4 Other (specify: _____)

1.b. Are you recording the results on the daily log that was given to you at the education session?

0 No → reinforce importance of daily records (part of study)

1 Sometimes → reinforce importance of daily records (part of study)

2 Yes (or usually) → provide positive reinforcement

2. During the past month, your blood glucose results were more than 250 mg/dl...

0 Never

1 Once a week or less

2 More than once a week but less than once a day →

3 Once a day or more often →

8 Don't know (not checking or seldom checking blood glucose levels)

DiaTel Study MO-VI 1.04.06

3. During the past month, your blood glucose results were less than 70 mg/dl...

   0 Never

   1 Once a week or less

   2 More than once a week but less than once a day

   3 Once a day or more often →

   Referral to PCP: Yes No N/A

   8 Don't know (not checking or seldom checking blood glucose levels)

Please remember to read the daily tips that are sent through the Viterion...

- *A normal blood glucose is between 80 and 120.*
- *If your blood glucose is 50 to 70, drink ½ cup of juice or regular soft drink, 1 glass of skim milk, or 5-6 hard candies. Check your blood glucose again in 15 minutes; if it is not above 70, repeat treatment. Eat a light snack if it will be more than one hour until your next meal.*
- *If your blood glucose is less than 50, drink 1 cup of juice or regular soft drink and check it again in 15 minutes. If it is still below 50, repeat juice or soft drink. If not above 70 after second attempt, call your PCP or have someone take you to the nearest emergency room.*
- *If your blood glucose is ever above 400, call your PCP.*

4.a. The Viterion reports for the past month indicate you [have been / have not been] sending your **blood pressure** data as prescribed. Please [continue to / remember to] check your glucose as instructed. [Underline: Twice daily, three times a day, four times a day] Reinforcement statement

Blood pressure data via Viterion:

   0 Not checking → reinforce importance of checking and recording in daily log (ask if there are any problems with using the monitor); Skip to Q6

   1 Less than once a week → _____

   2 Once or twice a week → _____

   3 Several times a week

   4 Daily

4.b. Are you recording the results on the daily log in the binder we gave to you?

   0 No → reinforce importance of daily records (part of study)

   1 Sometimes → reinforce importance of daily records (part of study)

   2 Yes (or usually) → provide positive reinforcement

5. Skip to Q6 (three most recent BP measurements not applicable for Viterion subjects)

DiaTel Study MO-VI 1.04.06

6. Do you have any questions about meal planning or specific food choices?

0 no

1 yes → discuss; refer to nutritionist if needed

Referral to nutritionist: Yes No

Remember it is important to follow a regular routine for your diet. It is best to eat three meals each day and a snack at bedtime.

7.a. The Viterion reports for the past month indicate you [have been / have not been] sending your **weight** data as prescribed. Please [continue to / remember to] check your weight as instructed. [Underline: Twice daily, three times a day, four times a day] Reinforcement statement

0 Not checking → reinforce importance of checking and recording in log (ask if there are any problems with using the digital scale); Skip to Q8

1 less than once a week

2 once or twice a week

3 several times a week

4 daily

7. b. Are you recording the results on the daily log?

0 No → reinforce importance of weekly/daily records (part of study)

1 Sometimes → reinforce importance of weekly/daily records (part of study)

2 Yes (or usually) → provide positive reinforcement

8. Have you made any changes in your diabetes management during the past month? (circle all that apply)

0 No

1 Medications (specify): _____

2 Diet (specify): _____

3 Activities (specify): _____

9.a. Are you having any problems or do you have any questions about managing your diabetes?

0 No (Skip to Q10)

1 Yes (list) → _____

_____

_____

_____

_____

DiaTel Study MO-VI 1.04.06

9.b. Action taken for problems/ questions

0 None

1 Counseling

2 Referral to nutritionist

3 Referral to PCP

4 Other (specify): _____

10. In the past month, have you had any medical care outside of the VA system?

0 No

1 Yes

If YES, how many times...

10.a. ...did you go to a non-VA emergency room? 0 1 2 Other: _____

10.b. ...were you admitted overnight to a non-VA hospital? 0 1 2 Other: _____

Non-VA Hospital admission 1: Number of days ___ ___

Non-VA Hospital admission 2: Number of days ___ ___

Non-VA Hospital admission 3: Number of days ___ ___

10.c. ...did you visit to a non-VA doctor's office or clinic? 0 1 2 Other: _____

Co-morbid Conditions – Daily Tip;
It appears you [have been / have not been] reading the daily tip that is sent through the Viterion. I recommend that you [continue to] check the daily tip to get reminders and helpful information about managing your diabetes.
Reinforcement statement

END TIME: ___ ___ ___ ___

Those are all of the questions I have for you....

Will make another summary call next month (unless 3- or 6-month visit is scheduled)

Monthly Follow-Up (CC)

DiaTel Study	Form 07	Data Collector ID #	Data Collector Initials	Subject ID Number
	MO-CC			—

Subject (Last Name): _____ First Name: _____

Date of Monthly Follow-Up (MM/DD/YYYY): __ __ / __ __ / 2 0 0 __

START TIME: ___ ___ ___ ___

You may recall that your participation in the study includes a monthly telephone call from us. We are interested in knowing how things have been going for you during the past month, particularly with the management of your diabetes. I need to ask you some questions but this should only take a few minutes. Do you have time for this now?

If no, schedule time for next call: _____

It might be helpful to have the binder with your daily log to refer to during this call.

1.a. On a typical day during the past month, how often did you check your **blood glucose**? (circle one number)

0 Not checking → reinforce importance of checking and recording on daily log (ask if there are any problems with glucometer or supplies); Skip to Q4a

1 Less than once each day → ask about PCP's instructions: _____

2 Once each day → ask about PCP's instructions: _____

3 Two or more times each day

4 Other (specify: _____)

1.b. Are you recording the results on the daily log that was given to you at the education session?

0 No → reinforce importance of daily records (part of study)

1 Sometimes → reinforce importance of daily records (part of study)

2 Yes (or usually) → provide positive reinforcement

2. Please refer to your log or think about your blood glucose results over the past month. How often were they more than 250 mg/dl?

0 Never

1 Once a week or less

2 More than once a week but less than once a day → ask if s/he knows why

3 Once a day or more often → have participant read log for past three days; if more than one in four (25%) are greater than 250, refer to PCP

Referral to PCP: Yes No N/A

8 Don't know (not checking or seldom checking blood glucose levels)

3. Again, during the past month, how often was your blood glucose less than 70 mg/dl?

   0 Never

   1 Once a week or less

   2 More than once a week but less than once a day

   3 Once a day or more often → have participant read log for past three days; if more than one in four (25%) are less than 70, refer to PCP

   Referral to PCP: Yes No N/A

   8 Don't know (not checking or seldom checking blood glucose levels)

Please remember that...

- *A normal blood glucose is between 80 and 120.*
- *If your blood glucose is 50 to 70, drink ½ cup of juice or regular soft drink, 1 glass of skim milk, or 5-6 hard candies. Check your blood glucose again in 15 minutes; if it is not above 70, repeat treatment. Eat a light snack if it will be more than one hour until your next meal.*
- *If your blood glucose is less than 50, drink 1 cup of juice or regular soft drink and check it again in 15 minutes. If it is still below 50, repeat juice or soft drink. If not above 70 after second attempt, call your PCP or have someone take you to the nearest emergency room.*
- *If your blood glucose is ever above 400, call your PCP.*

4.a. During the past month, how often did you usually check your **blood pressure**? (circle one number)

   0 Not checking → reinforce importance of checking and recording in daily log (ask if there are any problems with using the monitor); Skip to Q6

   1 Less than once a week → ask about PCP's instructions: _____

   2 Once or twice a week → ask about PCP's instructions: _____

   3 Several times a week

   4 Daily

4.b. Are you recording the results on the daily log in the binder we gave to you?

   0 No → reinforce importance of daily records (part of study)

   1 Sometimes → reinforce importance of daily records (part of study)

   2 Yes (or usually) → provide positive reinforcement

5. What were your three most recent blood pressure readings, starting with the most recent? (Note: if all are over 140/90, refer to PCP for treatment).

		Was this before or after taking your BP medication?		
a.	_____ / _____	before	after	N/A (no BP meds Rx)
b.	_____ / _____	before	after	N/A (no BP meds Rx)
c.	_____ / _____	before	after	N/A (no BP meds Rx)

Referral to PCP: Yes No N/A

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6. Do you have any questions about meal planning or specific food choices?

   0 no

   1 yes → discuss; refer to nutritionist if needed

   Referral to nutritionist: Yes No

   Remember it is important to follow a regular routine for your diet. It is best to eat three meals each day and a snack at bedtime.

7.a. How often do you usually check your weight?

   0 Not checking → reinforce importance of checking and recording in log (ask if there are any problems with using the digital scale); Skip to Q8

   1 less than once a week

   2 once or twice a week

   3 several times a week

   4 daily

7.b. Are you recording the results on the daily log?

   0 No → reinforce importance of weekly/daily records (part of study)

   1 Sometimes → reinforce importance of weekly/daily records (part of study)

   2 Yes (or usually) → provide positive reinforcement

8. Have you made any changes in your diabetes management during the past month? (circle all that apply)

   0 No

   1 Medications (specify): _____

   2 Diet (specify): _____

   3 Activities (specify): _____

9.a. Are you having any problems or do you have any questions about managing your diabetes?

   0 No (Skip to Q10)

   1 Yes (list) → _____

   _____

   _____

   _____

   _____

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9.b. Action taken for problems/ questions

0 None

1 Counseling

2 Referral to nutritionist

3 Referral to PCP

4 Other (specify): _____

10. In the past month, have you had any medical care outside of the VA system?

0 No

1 Yes

If YES, how many times...

10.a. ...did you go to a non-VA emergency room? 0 1 2 Other: _____

10.b. ...were you admitted overnight to a non-VA hospital? 0 1 2 Other: _____

Non-VA Hospital admission 1: Number of days ___ ___

Non-VA Hospital admission 2: Number of days ___ ___

Non-VA Hospital admission 3: Number of days ___ ___

10.c. ...did you visit to a non-VA doctor's office or clinic? 0 1 2 Other: _____

Co-morbid Conditions

CAD 0 No 1 Yes→ continue (Q11)

CHF 0 No 1 Yes→ continue (Q12-14)

COPD 0 No 1 Yes→ continue (Q15-17)

If none, stop.

END TIME: ___ ___ ___ ___

Those are all of the questions I have for you....

Will call again next month (unless 3- or 6-month visit is scheduled)

Comorbid Conditions

CAD:

11. CAD: Have you experienced any new or increasing chest pain or discomfort recently?

0 No 1 Yes* 8 DK

CHF:

12. CHF: Have you had an increase of more than three pounds overnight any time in the past week?

0 No 1 Yes* 8 DK

13. CHF: Are you having more ankle swelling than usual?

0 No 1 Yes* 8 DK

14. CHF: Are you more short of breath than usual?

0 No 1 Yes* 8 DK

COPD:

15. COPD (Ask only if Q14 has not already been asked): Are you more short of breath than usual?

0 No 1 Yes* 8 DK

16. COPD: Are you coughing up increasing amounts of yellow or green phlegm?

0 No 1 Yes* 8 DK

17. Do you have any fever or chills?

0 No 1 Yes* 8 DK

*If "Yes" to any --> please call your PCP or case manager to discuss this further.

END TIME: ___ ___ ___ ___

Those are all of the questions I have for you....

Will call again next month (unless 3- or 6-month visit is scheduled)

DiaTel Study MO-CC 1.03.06

Three-Month Follow-Up Visit

DiaTel Study	Form 10	Data Collector ID #	Data Collector Initials	Subject ID Number
	VISIT3MO			—

Subject (Last Name): _____ First Name: _____

Date of Three-Month Follow-Up Visit (MM/DD/YYYY): ___ / ___ / 2 0 ___

1.	Blood pressure	___ / ___	mm/Hg
2.	Weight	___ . ___	pounds
3.	Glucometer checked for accuracy	Yes	No → Reason:
4.	Blood pressure monitor checked for accuracy	Yes	No → Reason:
5.	Lab work (blood and urine) ordered and completed	Yes	No → Reason:
6.	Monthly Follow-Up form completed	Yes	No → Reason:
7.	Daily log reviewed	Yes	No → Reason:
8.	Three-Month Assessment form completed	Yes	No → Reason:
9.	Gift card given ($20)	Yes	No → Reason:

Notes:

DiaTel Study THREEIN 03.28.06

ID #: | | | — | | | | |

The Diabetes Telemonitoring (DiaTel) Study

Three-Month Assessment

Three-Month Assessment

DiaTel Study	Form 08	Data Collector ID #	Data Collector Initials	Subject ID Number
	THREE			—

Last name: First name: M.I.:

Date of Completion (MM/DD/YYYY): / / 2 0 0

At your Baseline Assessment, you gave us your home address, telephone number(s), and the name of a person to contact if we could not reach you. Has any of that information changed since that time?

No ☐

Yes ☐ → Please provide new information:

Address:

City: State: Zip:

Home telephone: -- --

Other telephone: -- --

A. Your Health and Well-Being

These questions ask for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. For each of the following questions, please check one box that best describes your answer for each question.

1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	☐ 1	☐ 2	☐ 3
Climbing several flights of stairs.....	☐ 1	☐ 2	☐ 3

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Were limited in the kind of work or other activities.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Were limited in the kind of work or other activities.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (include both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

A. Your Health and Well-Being (continued)

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Did you have a lot of energy?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Have you felt downhearted and depressed?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the past 4 weeks,

8. How often have you had at least 30 minutes of daily physical activity (include work around the house, gardening, walking, exercise programs, sports)?

Never	Less than 1 day each week	1 – 2 days each week	3 – 4 days each week	5 or more days each week
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

9. How often have you been able to identify foods that contain carbohydrates?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. Which meals have you eaten daily, or almost every day (please check all that apply)?

Breakfast	Mid-morning snack	Lunch	Mid-afternoon snack	Dinner	Evening snack
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

B. Problem Areas in Diabetes

Which of the following diabetes issues are currently problems for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

		Not a problem	Minor problem	Moderate problem	Some-what serious problem	Serious problem
1.	Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
2.	Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
3.	Feeling scared when you think about living with diabetes?	0	1	2	3	4
4.	Uncomfortable social situation related to your diabetes care? (e.g., people telling you what to eat?)	0	1	2	3	4
5.	Feelings of deprivation regarding food and meals?	0	1	2	3	4
6.	Feeling depressed when you think about living with diabetes?	0	1	2	3	4
7.	Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
8.	Feeling overwhelmed by your diabetes?	0	1	2	3	4
9.	Worrying about low blood sugar reactions?	0	1	2	3	4
10.	Feeling angry when you think about living with diabetes?	0	1	2	3	4
11.	Feeling constantly concerned about food and eating?	0	1	2	3	4
12.	Worrying about the future and the possibility of serious complications?	0	1	2	3	4
13.	Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
14.	Not "accepting" your diabetes?	0	1	2	3	4
15.	Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
16.	Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
17.	Feeling alone with your diabetes?	0	1	2	3	4
18.	Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4
19.	Coping with complications of diabetes?	0	1	2	3	4
20.	Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4

C. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer the following by circling one number for each question.

1. How satisfied are you with your current treatment?

6	5	4	3	2	1	0
Very satisfied						Very dissatisfied

2. How often have you felt that your blood sugars have been unacceptably high recently?

6	5	4	3	2	1	0
Most of the time						None of the time

3. How often have you felt that your blood sugars have been unacceptably low recently?

6	5	4	3	2	1	0
Most of the time						None of the time

4. How convenient have you been finding your treatment to be recently?

6	5	4	3	2	1	0
Very convenient						Very inconvenient

5. How flexible have you been finding your treatment to be recently?

6	5	4	3	2	1	0
Very flexible						Very inflexible

6. How satisfied are you with your understanding of your diabetes?

6	5	4	3	2	1	0
Very satisfied						Very dissatisfied

7. Would you recommend this form of treatment to someone else with your kind of diabetes?

6	5	4	3	2	1	0
Yes, I would definitely recommend the treatment						No, I would definitely not recommend the treatment

8. How satisfied would you be to continue with your present form of treatment?

6	5	4	3	2	1	0
Very satisfied						Very dissatisfied

D. Multidimensional Diabetes Questionnaire: Section I

We are interested to learn more about your diabetes and the way it affects your life. For each question, circle the number that corresponds best to your situation.

1. To what extent does your diabetes interfere with your daily activities?

   0 1 2 3 4 5 6

   Not at all Extremely

2. To what extent does your spouse (or significant other, companion, or a person who lives with you) support you with your diabetes?

   (_____Check here if you live alone, then skip to question 3.)

   0 1 2 3 4 5 6

   Not at all Extremely

3. To what extent do you consider you diabetes to be a severe health problem?

   0 1 2 3 4 5 6

   Not at all Extremely

4. To what extent does your diabetes decrease your satisfaction or pleasure from social or recreational activities?

   0 1 2 3 4 5 6

   Not at all Extremely

5. To what extent do your family and friends support you or help you with your diabetes?

   0 1 2 3 4 5 6

   Not at all Extremely

6. To what extent do you worry about long-term complications of diabetes?

   0 1 2 3 4 5 6

   Not at all Extremely

7. To what extent does your diabetes interfere with your effectiveness at work?

   (_____Check here if you do not work, then skip to question 8.)

   0 1 2 3 4 5 6

   Not at all Extremely

8. To what extent does your diabetes interfere with your relationship with your spouse (or significant other, companion, or a person who lives with you)?

   (_____Check here if you live alone, then skip to question 9.)

   0 1 2 3 4 5 6

   Not at all Extremely

D. Multidimensional Diabetes Questionnaire (Section I continued)

9. To what extent do you worry about your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

10. To what extent does your spouse (or significant other, companion, or a person who lives with you) pay attention to you because of your diabetes?

(_____Check here if you live alone, then skip to question 11.)

0	1	2	3	4	5	6
Not at all						Extremely

11. To what extent does your diabetes prevent you from traveling as much as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

12. To what extent does your doctor or health care team support you or help you with your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

13. To what extent does your diabetes interfere with your ability to participate in social or recreational activities?

0	1	2	3	4	5	6
Not at all						Extremely

14. To what extent does you diabetes interfere with your ability to plan your activities?

0	1	2	3	4	5	6
Not at all						Extremely

15. To what extent does your diabetes prevent you from being as active as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

16. To what extent does your diabetes prevent you from having a schedule that you like (for example, to sleep late)?

0	1	2	3	4	5	6
Not at all						Extremely

If you **live alone**, please check this box ☐, then skip to **Section III, page 9.**

If you **do not live alone**, please check this box ☐, then continue with **Section II on the next page.**

D. Multidimensional Diabetes Questionnaire: Section II

We are interested to learn about the way your spouse (or significant other, companion, or another person who lives with you) responds to you concerning your self-care program. On the scale listed below each question, circle the number that best indicates how often he or she responds to you in that particular way.

My spouse (or significant other, companion, or another person who lives with me):

1. Congratulates me when I follow my diet.

   0 1 2 3 4 5 6
   Never Very often

2. Hassles me about my diabetes medication (pills, insulin).

   0 1 2 3 4 5 6
   Never Very often

3. Congratulates me for regularly measuring my blood glucose level.

   (_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)

   0 1 2 3 4 5 6
   Never Very often

4. Hassles me about exercise.

   (_____Check here if you have been advised **not** to exercise.)

   0 1 2 3 4 5 6
   Never Very often

5. Reminds me to take care of my feet.

   (_____Check here if foot care has **not** been recommended.)

   0 1 2 3 4 5 6
   Never Very often

6. Congratulates me when I follow my meal schedule (meals and snacks).

   0 1 2 3 4 5 6
   Never Very often

7. Reminds me to take my diabetes medication (pills, insulin).

   0 1 2 3 4 5 6
   Never Very often

8. Helps me to adjust my food intake when I exercise.

   (_____Check here if you have been advised **not** to exercise.)

   0 1 2 3 4 5 6
   Never Very often

D. Multidimensional Diabetes Questionnaire (Section II continued)

My spouse (or significant other, companion, or another person who lives with me):

9. Hassles me about my diet.

0	1	2	3	4	5	6
Never						Very often

10. Plans family activities in a way that allows me to take my medication at the right time.

0	1	2	3	4	5	6
Never						Very often

11. Hassles me about measuring my blood sugar.

(_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)

0	1	2	3	4	5	6
Never						Very often

12. Encourages me to exercise.

(_____Check here if you have been advised **not** to exercise.)

0	1	2	3	4	5	6
Never						Very often

Multidimensional Diabetes Questionnaire: Section III

Treatment of diabetes involves several self-care activities (for example, diet, exercise, etc). People sometimes find it difficult, or do not see the importance of following one or more of these self-care activities. We would like to know how this applies to you. Read each question carefully and circle the number that corresponds best to your situation.

1. How confident are you in your ability to follow your diet?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

2. How confident are you in your ability to test your blood sugar at the recommended frequency?

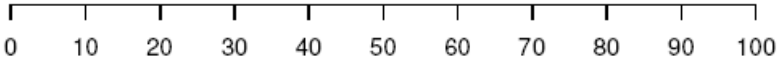
(_____Check here if measuring of blood sugar levels has **not** been recommended.)

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

D. Multidimensional Diabetes Questionnaire (Section III continued)

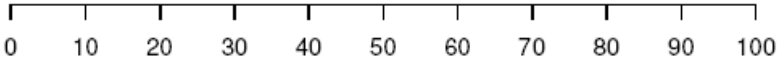
3. How confident are you in your ability to exercise regularly?

   (_____Check here if you have been advised **not** to exercise.)



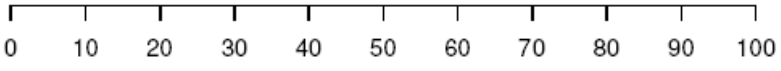
Not at all confident — Very confident

4. How confident are you in your ability to keep your weight under control?



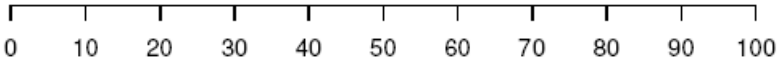
Not at all confident — Very confident

5. How confident are you in your ability to keep your blood sugar level under control?



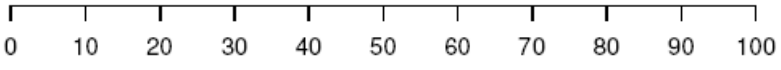
Not at all confident — Very confident

6. How confident are you in your ability to resist food temptations?



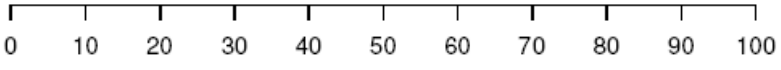
Not at all confident — Very confident

7. How confident are you in your ability to follow your diabetes treatment (diet, medication, blood sugar testing, physical activities?)



Not at all confident — Very confident

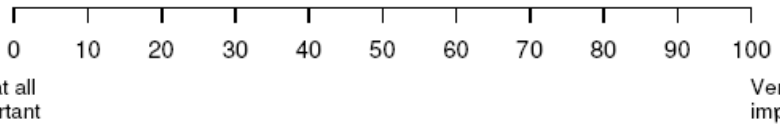
8. To what extent do you think that following your diet is important for controlling your diabetes?



Not at all important — Very important

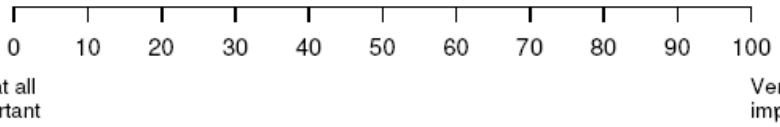
D. Multidimensional Diabetes Questionnaire (Section III continued)

9. To what extent do you think that taking your medication as recommended (pills, insulin) is important for controlling your diabetes?



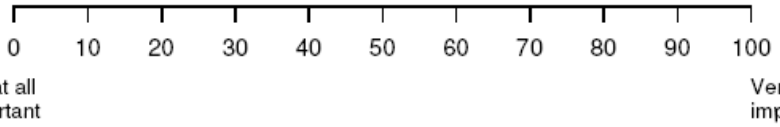
10. To what extent do you think that exercise is important for controlling your diabetes?

(_____Check here if you have been advised **not** to exercise.)

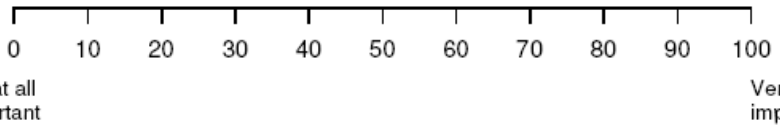


11. To what extent do you think that measuring your blood sugar is important for controlling your diabetes?

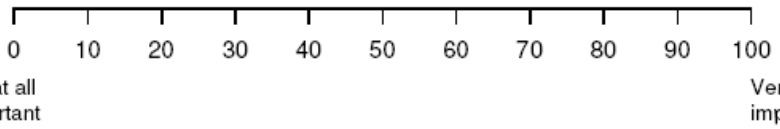
(_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)



12. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for controlling your diabetes?



13. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for delaying and/or preventing long-term diabetes complications (problems related to eyes, kidneys, heart, or feet)?



Thank you for completing the Three-Month Assessment.

Six-Month Follow-Up Visit

DiaTel Study	Form 11	Data Collector ID #	Data Collector Initials	Subject ID Number
	SIXIN			—

Subject (Last Name): _____ First Name: _____

Date of Six-Month Follow-Up Visit (MM/DD/YYYY): ___/___/2 0 0 ___

1.	Blood pressure	___ / ___	mm/Hg
2.	Weight	___ . ___	pounds
3.	Glucometer checked for accuracy	Yes	No → Reason:
4.	Blood pressure monitor checked for accuracy	Yes	No → Reason:
5.	Lab work (blood and urine) ordered and completed	Yes	No → Reason:
6.	Monthly Follow-Up form completed	Yes	No → Reason:
7.	Daily log reviewed	Yes	No → Reason:
8.	Six-Month Assessment form completed	Yes	No → Reason:
9.	Gift card given ($20)	Yes	No → Reason:
10.	Phase Two Consent Form signed	No	
		Yes →	Randomized to:
			CCHT
			CC
			UC*

* # of strips/ 90 days in UC =

Notes:

DiaTel Study SIXIN 05.11.06

ID #: | | | — | | | | |

The Diabetes Telemonitoring (DiaTel) Study

Six-Month Assessment

Six-Month Assessment

DiaTel Study	Form 09	Data Collector ID #	Data Collector Initials	Subject ID Number
	SIX			—

Last name: First name: M.I.:

Date of Completion (MM/DD/YYYY): / / 2 0 0

Has your home address or telephone number changed since the last time you were here (for either the baseline or three-month assessment)?

No ☐

Yes ☐ → Please provide new information:

Address:

City: State: Zip:

Home telephone: -- --

Other telephone: -- --

A. Your Health and Well-Being

These questions ask for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. For each of the following questions, please check one box that best describes your answer for each question.

1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	☐ 1	☐ 2	☐ 3
Climbing several flights of stairs.....	☐ 1	☐ 2	☐ 3

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Were limited in the kind of work or other activities.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Were limited in the kind of work or other activities.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (include both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

A. Your Health and Well-Being (continued)

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Did you have a lot of energy?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Have you felt downhearted and depressed?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the past 4 weeks,

8. How often have you had at least 30 minutes of daily physical activity (include work around the house, gardening, walking, exercise programs, sports)?

Never	Less than 1 day each week	1 – 2 days each week	3 – 4 days each week	5 or more days each week
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

9. How often have you been able to identify foods that contain carbohydrates?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. Which meals have you eaten daily, or almost every day (please check all that apply)?

Breakfast	Mid-morning snack	Lunch	Mid-afternoon snack	Dinner	Evening snack
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

B. Problem Areas in Diabetes

Which of the following diabetes issues are currently problems for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

		Not a problem	Minor problem	Moderate problem	Some-what serious problem	Serious problem
1.	Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
2.	Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
3.	Feeling scared when you think about living with diabetes?	0	1	2	3	4
4.	Uncomfortable social situation related to your diabetes care? (e.g., people telling you what to eat?)	0	1	2	3	4
5.	Feelings of deprivation regarding food and meals?	0	1	2	3	4
6.	Feeling depressed when you think about living with diabetes?	0	1	2	3	4
7.	Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
8.	Feeling overwhelmed by your diabetes?	0	1	2	3	4
9.	Worrying about low blood sugar reactions?	0	1	2	3	4
10.	Feeling angry when you think about living with diabetes?	0	1	2	3	4
11.	Feeling constantly concerned about food and eating?	0	1	2	3	4
12.	Worrying about the future and the possibility of serious complications?	0	1	2	3	4
13.	Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
14.	Not "accepting" your diabetes?	0	1	2	3	4
15.	Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
16.	Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
17.	Feeling alone with your diabetes?	0	1	2	3	4
18.	Feeling that your friends and family are not supportive of your diabetes management efforts?	0	1	2	3	4
19.	Coping with complications of diabetes?	0	1	2	3	4
20.	Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4

C. Diabetes Treatment Satisfaction

For the past several months, you have been taking part in a diabetes treatment study. At the start of the study, you may have had a change of treatment. Today, we would like to know how your experience of your current treatment (including medication and diet) has changed from your experience of treatment before the study began. Please answer each question by circling a number to indicate the extent to which you have experienced changes. If you have experienced no change, please circle "0."

1. How satisfied are you with your current treatment?

3	2	1	0	-1	-2	-3
Much more satisfied now						Much less satisfied now

2. How often have you felt that your blood sugars have been unacceptably high recently?

3	2	1	0	-1	-2	-3
Much more of the time now						Much less of the time now

3. How often have you felt that your blood sugars have been unacceptably low recently?

3	2	1	0	-1	-2	-3
Much more of the time now						Much less of the time now

4. How convenient have you been finding your treatment to be recently?

3	2	1	0	-1	-2	-3
Much more convenient now						Much less convenient now

5. How flexible have you been finding your treatment to be recently?

3	2	1	0	-1	-2	-3
Much more flexible now						Much less flexible now

6. How satisfied are you with your understanding of your diabetes?

3	2	1	0	-1	-2	-3
Much more satisfied now						Much less satisfied now

C. Diabetes Treatment Satisfaction (continued)

7. How likely would you be to recommend your present treatment to someone else with your kind of diabetes?

3	2	1	0	-1	-2	-3
Much more likely to recommend the treatment now						Much less likely to recommend the treatment now

8. How satisfied would you be to continue with your present form of treatment?

3	2	1	0	-1	-2	-3
Much more satisfied now						Much less satisfied now

D. Multidimensional Diabetes Questionnaire: Section I

We are interested to learn more about your diabetes and the way it affects your life. For each question, circle the number that corresponds best to your situation.

1. To what extent does your diabetes interfere with your daily activities?

0	1	2	3	4	5	6
Not at all						Extremely

2. To what extent does your spouse (or significant other, companion, or a person who lives with you) support you with your diabetes?

(_____Check here if you live alone, then skip to question 3.)

0	1	2	3	4	5	6
Not at all						Extremely

3. To what extent do you consider you diabetes to be a severe health problem?

0	1	2	3	4	5	6
Not at all						Extremely

4. To what extent does your diabetes decrease your satisfaction or pleasure from social or recreational activities?

0	1	2	3	4	5	6
Not at all						Extremely

5. To what extent do your family and friends support you or help you with your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

D. Multidimensional Diabetes Questionnaire (Section I continued)

6. To what extent do you worry about long-term complications of diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

7. To what extent does your diabetes interfere with your effectiveness at work?

(_____Check here if you do not work, then skip to question 8.)

0	1	2	3	4	5	6
Not at all						Extremely

8. To what extent does your diabetes interfere with your relationship with your spouse (or significant other, companion, or a person who lives with you)?

(_____Check here if you live alone, then skip to question 9.)

0	1	2	3	4	5	6
Not at all						Extremely

9. To what extent do you worry about your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

10. To what extent does your spouse (or significant other, companion, or a person who lives with you) pay attention to you because of your diabetes?

(_____Check here if you live alone, then skip to question 11.)

0	1	2	3	4	5	6
Not at all						Extremely

11. To what extent does your diabetes prevent you from traveling as much as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

12. To what extent does your doctor or health care team support you or help you with your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

13. To what extent does your diabetes interfere with your ability to participate in social or recreational activities?

0	1	2	3	4	5	6
Not at all						Extremely

D. Multidimensional Diabetes Questionnaire (Section I continued)

14. To what extent does you diabetes interfere with your ability to plan your activities?

0	1	2	3	4	5	6
Not at all						Extremely

15. To what extent does your diabetes prevent you from being as active as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

16. To what extent does your diabetes prevent you from having a schedule that you like (for example, to sleep late)?

0	1	2	3	4	5	6
Not at all						Extremely

If you **live alone,** please check this box ☐, then skip to **Section III, page 10.**

If you **do not live alone,** please check this box ☐, then continue with **Section II on the next page.**

D. Multidimensional Diabetes Questionnaire: Section II

We are interested to learn about the way your spouse (or significant other, companion, or another person who lives with you) responds to you concerning your self-care program. On the scale listed below each question, circle the number that best indicates how often he or she responds to you in that particular way.

My spouse (or significant other, companion, or another person who lives with me):

1. Congratulates me when I follow my diet.

   0 1 2 3 4 5 6

   Never Very often

2. Hassles me about my diabetes medication (pills, insulin).

   0 1 2 3 4 5 6

   Never Very often

3. Congratulates me for regularly measuring my blood glucose level.

   (_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)

   0 1 2 3 4 5 6

   Never Very often

4. Hassles me about exercise.

   (_____Check here if you have been advised **not** to exercise.)

   0 1 2 3 4 5 6

   Never Very often

5. Reminds me to take care of my feet.

   (_____Check here if foot care has **not** been recommended.)

   0 1 2 3 4 5 6

   Never Very often

6. Congratulates me when I follow my meal schedule (meals and snacks).

   0 1 2 3 4 5 6

   Never Very often

7. Reminds me to take my diabetes medication (pills, insulin).

   0 1 2 3 4 5 6

   Never Very often

8. Helps me to adjust my food intake when I exercise.

   (_____Check here if you have been advised **not** to exercise.)

   0 1 2 3 4 5 6

   Never Very often

D. Multidimensional Diabetes Questionnaire (Section II continued)

My spouse (or significant other, companion, or another person who lives with me):

9. Hassles me about my diet.

0	1	2	3	4	5	6
Never						Very often

10. Plans family activities in a way that allows me to take my medication at the right time.

0	1	2	3	4	5	6
Never						Very often

11. Hassles me about measuring my blood sugar.

(_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)

0	1	2	3	4	5	6
Never						Very often

12. Encourages me to exercise.

(_____Check here if you have been advised **not** to exercise.)

0	1	2	3	4	5	6
Never						Very often

Multidimensional Diabetes Questionnaire: Section III

Treatment of diabetes involves several self-care activities (for example, diet, exercise, etc). People sometimes find it difficult, or do not see the importance of following one or more of these self-care activities. We would like to know how this applies to you. Read each question carefully and circle the number that corresponds best to your situation.

1. How confident are you in your ability to follow your diet?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

2. How confident are you in your ability to test your blood sugar at the recommended frequency?

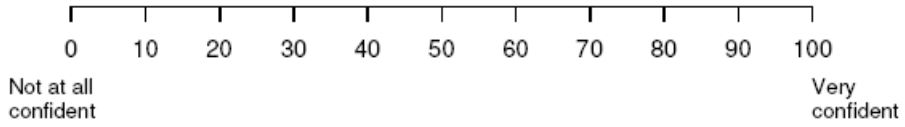
(_____Check here if measuring of blood sugar levels has **not** been recommended.)

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

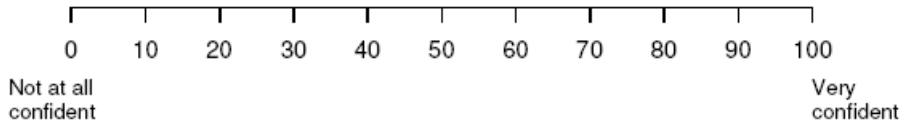
D. Multidimensional Diabetes Questionnaire (Section III continued)

3. How confident are you in your ability to exercise regularly?

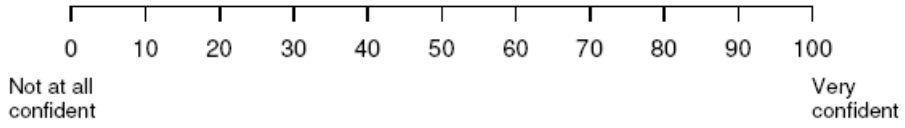
   (_____Check here if you have been advised **not** to exercise.)



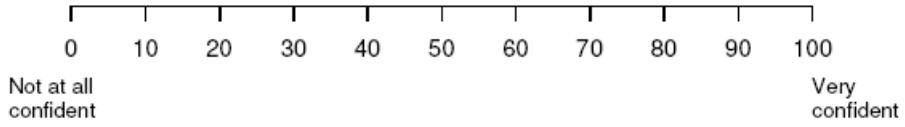
4. How confident are you in your ability to keep your weight under control?



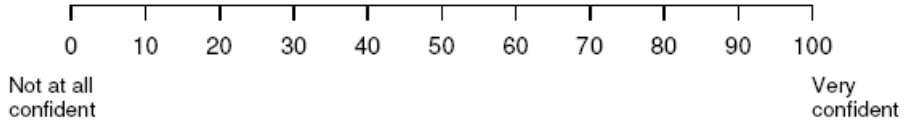
5. How confident are you in your ability to keep your blood sugar level under control?



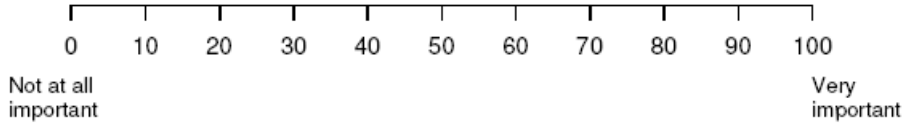
6. How confident are you in your ability to resist food temptations?



7. How confident are you in your ability to follow your diabetes treatment (diet, medication, blood sugar testing, physical activities?)

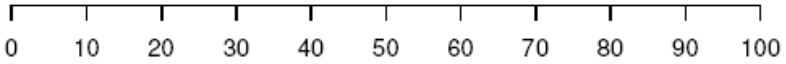


8. To what extent do you think that following your diet is important for controlling your diabetes?



D. Multidimensional Diabetes Questionnaire (Section III continued)

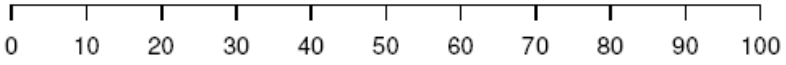
9. To what extent do you think that taking your medication as recommended (pills, insulin) is important for controlling your diabetes?



Not at all important — Very important

10. To what extent do you think that exercise is important for controlling your diabetes?

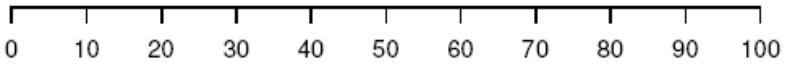
(_____Check here if you have been advised **not** to exercise.)



Not at all important — Very important

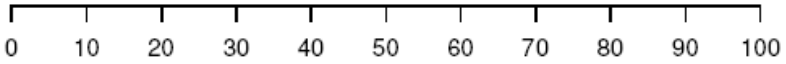
11. To what extent do you think that measuring your blood sugar is important for controlling your diabetes?

(_____Check here if self-monitoring of blood sugar levels has **not** been recommended.)



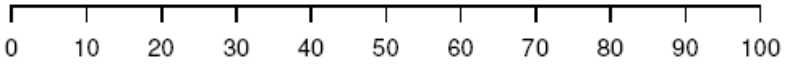
Not at all important — Very important

12. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for controlling your diabetes?



Not at all important — Very important

13. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for delaying and/or preventing long-term diabetes complications (problems related to eyes, kidneys, heart, or feet)?



Not at all important — Very important

Thank you for completing the Six-Month Assessment.

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Medication Review

DiaTel Study	Form	Data Collector ID #	Data Collector Initials	Subject ID Number
	MEDS			___ ___ — ___ ___ ___ ___

Subject (Last Name): ____________ First Name: ____________

Date Form Completed (MM/DD/YY): __ __ / __ __ / 2 0 0 __

Date of Baseline Visit (MM/DD/YYYY): __ __ / __ __ / 2 0 0 __

Date of 6-month Follow-up (MM/DD/YY):* __ __ / __ __ / 2 0 0 __

* if 6-mo follow-up was not completed, enter 7.5-month date

Was the list of medications reviewed with subject…

At Baseline Visit?	Yes ☐	No ☐	
At 3-Month Visit?	Yes ☐	No ☐	N/A ☐ (no visit)
At 6-Month Visit?	Yes ☐	No ☐	N/A ☐ (no visit)

Name of Medication	Code	Dosage	Units	Cycle	Route	Source (check all that apply): Note in CPRS	Med Orders or Pharm Data	Interview (Patient-Report)	Study Chart Notes
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___	STOP DATE: ___ ___/___ ___/___ ___	CHANGE MADE BY:	Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐			
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___	STOP DATE: ___ ___/___ ___/___ ___	CHANGE MADE BY:	Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐			
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___	STOP DATE: ___ ___/___ ___/___ ___	CHANGE MADE BY:	Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐			
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___	STOP DATE: ___ ___/___ ___/___ ___	CHANGE MADE BY:	Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐			

DiaTel Study 03.01.07 Page ____ of ____

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Medication Review

Subject ID # ___ ___ - ___ ___ ___ ___

Source (check all that apply)

Name of Medication	Code	Dosage	Units	Cycle	Route	Note in CPRS	Med Orders or Pharm Data	Interview (Patient-Report)	Study Chart Notes
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐
•	___ ___ ___	___ ___ ___ ___ • ___	___	___ ___	___	☐	☐	☐	☐
START DATE: ___ ___/___ ___/___ ___		STOP DATE: ___ ___/___ ___/___ ___		CHANGE MADE BY:		Study Personnel ☐	Other (VA) ☐	Other (non-VA) ☐	Subject ☐

DiaTel Study 03.01.07 Page ____ of ____

DIATEL DAILY LOG

Name: _____

Date	Glucose Monitoring (as instructed)						
	Before Breakfast	Before Lunch	After Lunch	Before Dinner	After Dinner	Bedtime	2 - 5 am
/01/							
/02/							
/03/							
/04/							
/05/							
/06/							
/07/							
/08/							
/09/							
/10/							
/11/							
/12/							
/13/							
/14/							
/15/							
/16/							
/17/							
/18/							
/19/							
/20/							
/21/							
/22/							
/23/							
/24/							
/25/							
/26/							
/27/							
/28/							
/29/							
/30/							
/31/							

DiaTel Study DAILY LOG 09/20/05

DIATEL DAILY LOG

ID#: _____

Day of Month	Weight	Blood Pressure (as instructed)			
		BP1	BP2	BP3	BP4
01					
02					
03					
04					
05					
06					
07					
08					
09					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

DiaTel Study DAILY LOG 09/20/05

TELEPHONE CONTACTS

DiaTel Study	Form 13	Data Collector ID #	Data Collector Initials	Subject ID Number
	PHONE			—

Date of Telephone Contact (MM/DD/YYYY): ___/___/2 0 0 ___

Start Time: ____ End Time: ____

Type of Contact:

Initiated by Project Office ☐ *(include calls in response to messages left for subject)*
- Scheduled Monthly Follow-Up ☐
- Viterion Data ☐
- Other ☐ (specify): _____

Initiated by Subject ☐

Topics Discussed:

Medications	Glucose	Hypertension	Lipids
Reason for meds	☐	☐	☐
Timing	☐	☐	☐
Side effects	☐	☐	☐
Contraindications	☐	☐	☐
Adjustments	☐	☐	☐
Other	☐	☐	☐

Glucose Monitoring..... ☐
- Frequency ☐
- Timing ☐
- High levels: action to take ☐
- Low levels: action to take ☐
- Maintaining paper record ☐
- Other (specify): ☐ _____ __

Physical Activity/ Exercise..... ☐
- Importance of exercise ☐
- Seeking MD advice ☐
- When not to exercise ☐
- Walking (footwear, malls) ☐
- Other (specify): ☐ _____ __

Nutrition/ Diet..... ☐
- Identifying carbohydrates ☐
- Counting carbohydrates ☐
- Meal planning ☐
- Portion control ☐
- Snacking guidelines ☐
- Alcohol guidelines ☐
- Other (specify): ☐ _____ __

Co-Morbid Conditions..... ☐
- CAD ☐
- CHF ☐
- COPD ☐
- Other (specify): ☐ _____ __

Other (specify):..... ☐ _____ __ _____ __ _____ __

Actions:

Referral to: PCP ☐ Nutritionist/CDE ☐ Ophthalmology ☐ Podiatry ☐

Other ☐_____ __ __

Change in medication ☐

Other ☐_____ __ __

13.PHONE. 01.12.06 ***Record time for end of telephone call, above.***

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

APPENDIX D. Statistical Analyses: Details and Location of Data

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
In-Home Diabetes Care Management/Coordination Program for Veterans:
The Diabetes Telemonitoring (DiaTel) Study, Phase I

HbA1c:

Pulling data: N:\Diatel\final phase I\HbA1c\ pulling phase 1 hba1c.sas
Original data: N:\Diatel\final phase I\HbA1c\hba1c.dta
Data management: includes add and drop some obs, show missing and imputation
Program:N:\Diatel\final phase I\HbA1c\hba1c phase 1 data management and imputation.do
Data after finger imputation: N:\Diatel\final phase I\HbA1c\fingerimputed10.dta
Data after imputation for #924 and #657: N:\Diatel\final phase I\hba1c\imputed1step1
Data after imputation for #22: N:\Diatel\final phase I\hba1c\imputed1step2
One eligible set after above two imputations: N:\Diatel\final phase I\HbA1c\set1.dta
Put 10 sets together: N:\Diatel\final phase I\HbA1c\final10sets.dta
Mean of above 10 sets: N:\Diatel\final phase I\HbA1c\finalhba1c.dta

HbA1c	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE)(CC-HT)		P-value
Baseline	9.52	1.50	9.44	1.40	9.60	1.61	*-0.16*	*0.26*	*0.53*
3m	8.35	1.28	8.70	1.25	7.95	1.18	*0.75*	*0.21*	*<0.001*
6m	8.28	1.33	8.63	1.32	7.89	1.23	*0.74*	*0.22*	*<0.001*
Drop							HT-CC		
Base-3m	1.17	142	0.75	1.27	1.65	1.42	**0.91**	**0.23**	**<0.001**
Base-6m	1.24	1.53	0.81	1.42	1.72	1.51	**0.91**	**0.25**	**<0.001**
3m-6m	0.07	0.87	0.07	0.86	0.06	0.87	**-0.003**	**0.15**	**0.984**

micombine reg lab_value3
micombine reg lab_value3 if group==1
micombine reg lab_value3 if group==2

Blue part (italics): micombine regress lab_value1 group

Red part (bold): micombine reg diff3 group, other option for the red part as following
micombine regress lab_value2 lab_value1 group
micombine regress lab_value3 lab_value1 group
micombine regress lab_value3 lab_value2 group

Here is the difference

HbA1c	Diff(SE)(CC-HT)		P-value
Drop	HT-CC		
Base-3m	**0.82**	**0.18**	**<0.001**
Base-6m	**0.81**	**0.20**	**<0.001**
3m-6m	**-0.13**	0.15	0.40

Example:

```
. micombine reg diff1 group

Multiple imputation parameter estimates (10 imputations)
------------------------------------------------------------------------------
      diff1 |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
------------+-----------------------------------------------------------------
      group |   .9094424   .2299669     3.95   0.000     .4546387    1.364246
      _cons |  -.1641753   .3550572    -0.46   0.645    -.8663692    .5380186
------------------------------------------------------------------------------
137 observations.

. micombine regress lab_value2 lab_value1 group

Multiple imputation parameter estimates (10 imputations)
------------------------------------------------------------------------------
 lab_value2 |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
------------+-----------------------------------------------------------------
 lab_value1 |   .4272907   .0608645     7.02   0.000     .3069113    .5476701
      group |  -.8164466   .1767226    -4.62   0.000    -1.165973   -.4669201
      _cons |   5.478849   .6265941     8.74   0.000     4.239555    6.718143
------------------------------------------------------------------------------
137 observations.
```

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	<0.001	<0.001
Base-6m	<0.001	<0.001	<0.001
3m-6m	0.377	0.505	0.556

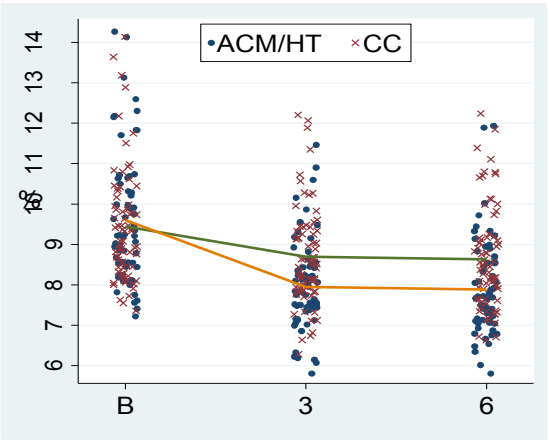
```
micombine reg diff3
micombine reg diff3 if group==1
micombine reg diff3 if group==2
```

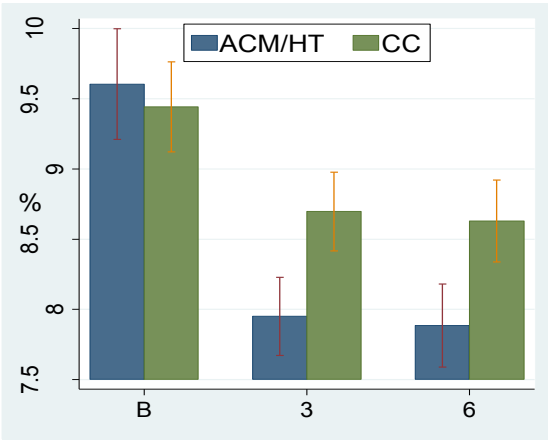
	Number of meeting target for HbA1c (<=7%)					
Time	Total (n=137)		CC (n=73)		HT(n=64)	
Baseline	0	0 %	0	0 %	0	0 %
3 month	15	10.95 %	4	5.48 %	11	17.19 %
6 month	19	13.87 %	4	5.48 %	15	23.44 %

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

```
. tab group target if n==2,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        69          4 |        73
           |     94.52       5.48 |    100.00
-----------+----------------------+----------
        HT |        53         11 |        64
           |     82.81      17.19 |    100.00
-----------+----------------------+----------
     Total |       122         15 |       137
           |     89.05      10.95 |    100.00

          Pearson chi2(1) =   4.7945   Pr = 0.029


. tab group target if n==3,row chi2
           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        69          4 |        73
           |     94.52       5.48 |    100.00
-----------+----------------------+----------
        HT |        49         15 |        64
           |     76.56      23.44 |    100.00
-----------+----------------------+----------
     Total |       118         19 |       137
           |     86.13      13.87 |    100.00

          Pearson chi2(1) =   9.2067   Pr = 0.002

. logit target group n if n!=2

note: n != 3 predicts failure perfectly
      n dropped and 137 obs not used

Logistic regression                             Number of obs   =        137
                                                LR chi2(1)      =       9.60
                                                Prob > chi2     =     0.0019
Log likelihood = -50.353583                     Pseudo R2       =     0.0870

------------------------------------------------------------------------------
      target |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       group |   1.664042   .5929313     2.81   0.005      .501918    2.826166
       _cons |  -2.847812   .5142885    -5.54   0.000    -3.855799   -1.839825
------------------------------------------------------------------------------
```





BPSYS

Pulling data: N:\Diatel\final phase I\BpWeight\pulling phase 1 bpweight.sas

Original data: N:\Diatel\final phase I\BpWeight\bpweight.dta

Program: N:\Diatel\final phase I\BpWeight\ bpweight phase 1.do

After imputation: N:\Diatel\final phase I\BpWeight\bpsys10sets

Final data: N:\Diatel\final phase I\BpWeight\finalbpsys.dta

BPSYS	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	143.47	20.26	142.26	18.95	144.84	21.72	-2.58	3.47	0.46
3m	136.55	22.57	137.13	21.38	135.89	23.31	1.24	3.75	0.74
6m	132.52	21.96	132.98	18.98	132.00	24.27	0.99	3.65	0.79
Change							HT-CC		
Base-3m	6.91	20.82	5.13	20.13	8.95	20.77	3.82	3.42	0.27
Base-6m	10.94	23.44	9.28	19.92	12.85	26.20	3.57	3.90	0.36
3m-6m	4.03	24.19	4.15	21.31	3.90	27.22	-0.25	4.16	0.95

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.033	0.001
Base-6m	<0.001	<0.001	<0.001
3m-6m	0.053	0.101	0.256

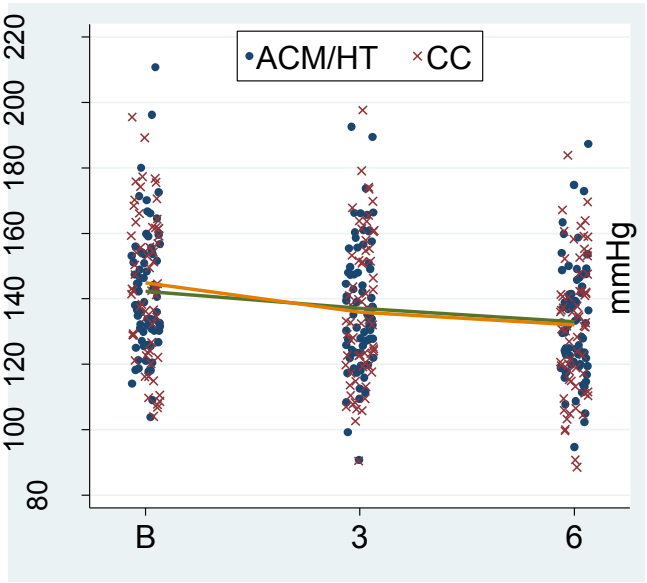
	Number of meeting target for Systolic BP (<=130mmHg)					
Time	Total (n=137)		CC (n=73)		HT(n=64)	
Baseline	37	27.01 %	19	26.03 %	18	28.13 %
3 month	58	42.34 %	29	39.73 %	29	45.31 %
6 month	64	46.72 %	34	46.58%	30	46.88 %

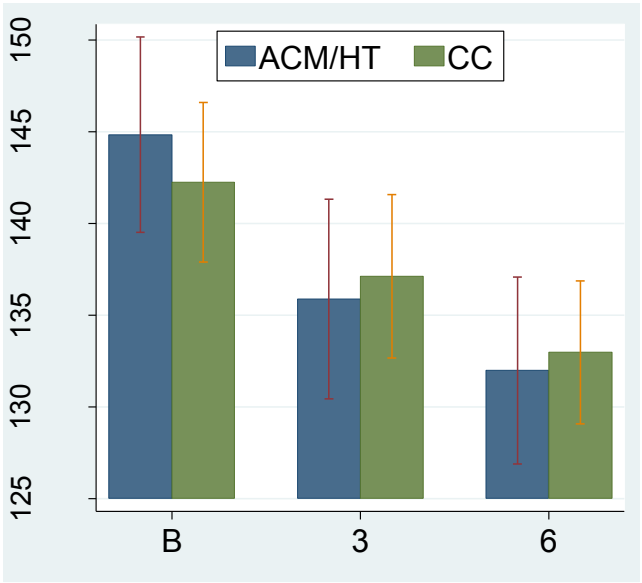
```
. tab group target if n==1,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        54         19 |        73
           |     73.97      26.03 |    100.00
-----------+----------------------+----------
        HT |        46         18 |        64
           |     71.88      28.13 |    100.00
-----------+----------------------+----------
     Total |       100         37 |       137
           |     72.99      27.01 |    100.00

          Pearson chi2(1) =   0.0761   Pr = 0.783
```

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

```
. tab group target if n==2,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        44         29 |        73
           |     60.27      39.73 |    100.00
-----------+----------------------+----------
        HT |        35         29 |        64
           |     54.69      45.31 |    100.00
-----------+----------------------+----------
     Total |        79         58 |       137
           |     57.66      42.34 |    100.00

          Pearson chi2(1) =   0.4360   Pr = 0.509

. tab group target if n==3,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        39         34 |        73
           |     53.42      46.58 |    100.00
-----------+----------------------+----------
        HT |        34         30 |        64
           |     53.13      46.88 |    100.00
-----------+----------------------+----------
     Total |        73         64 |       137
           |     53.28      46.72 |    100.00

          Pearson chi2(1) =   0.0012   Pr = 0.972
```





Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

BPDIAS (file location same as BPSYS)

BPDIAS	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	80.24	11.65	80.51	10.12	79.94	13.26	0.57	2.00	0.78
3m	76.04	12.67	76.64	12.88	75.37	12.04	1.27	2.10	0.55
6m	74.26	14.24	75.92	13.17	72.37	14.65	3.55	2.34	0.13
Change									
Base-3m	4.20	12.11	3.87	11.43	4.57	12.47	0.70	2.00	0.73
Base-6m	5.98	13.51	4.59	12.52	7.57	13.84	2.98	2.21	0.18
3m-6m	1.78	13.03	0.72	11.97	2.99	14.12	2.28	2.24	0.31

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.005	0.005
Base-6m	<0.001	0.003	<0.001
3m-6m	0.112	0.610	0.095

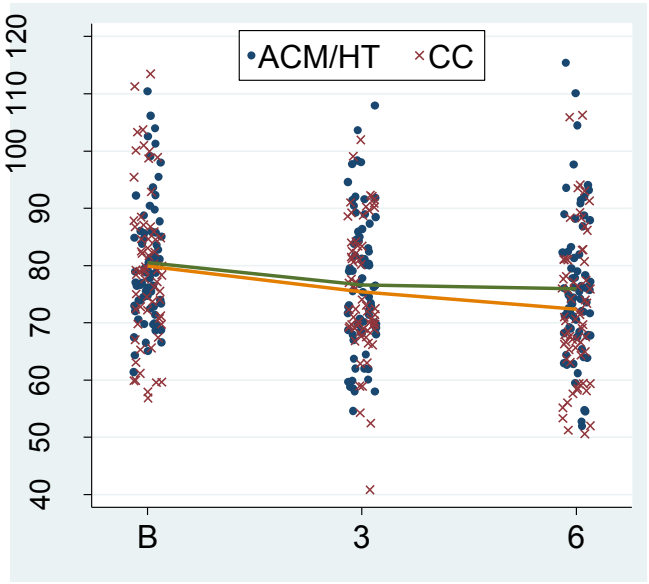
	Number of meeting target for Diastolic BP (<=80mmHg)					
Time	Total (n=137)		CC (n=73)		HT(n=64)	
Baseline	81	59.12 %	42	57.53 %	39	60.94 %
3 month	89	64.96 %	46	63.01 %	43	67.19 %
6 month	103	75.18 %	53	72.60%	50	78.13 %

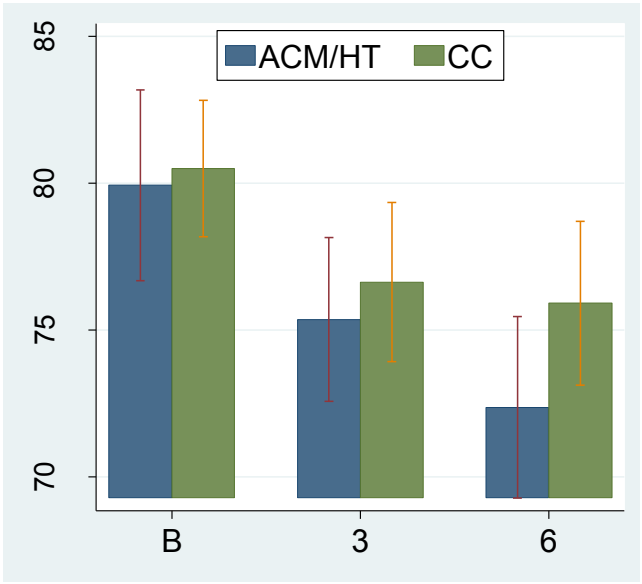
```
. tab group target if n==1,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        35         38 |        73
           |     47.95      52.05 |    100.00
-----------+----------------------+----------
        HT |        33         31 |        64
           |     51.56      48.44 |    100.00
-----------+----------------------+----------
     Total |        68         69 |       137
           |     49.64      50.36 |    100.00

          Pearson chi2(1) =   0.1785   Pr = 0.673
```

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

```
. tab group target if n==2,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        29         44 |        73
           |     39.73      60.27 |    100.00
-----------+----------------------+----------
        HT |        23         41 |        64
           |     35.94      64.06 |    100.00
-----------+----------------------+----------
     Total |        52         85 |       137
           |     37.96      62.04 |    100.00

          Pearson chi2(1) =   0.2078   Pr = 0.648

. tab group target if n==3,row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        21         52 |        73
           |     28.77      71.23 |    100.00
-----------+----------------------+----------
        HT |        17         47 |        64
           |     26.56      73.44 |    100.00
-----------+----------------------+----------
     Total |        38         99 |       137
           |     27.74      72.26 |    100.00

          Pearson chi2(1) =   0.0827   Pr = 0.774
```





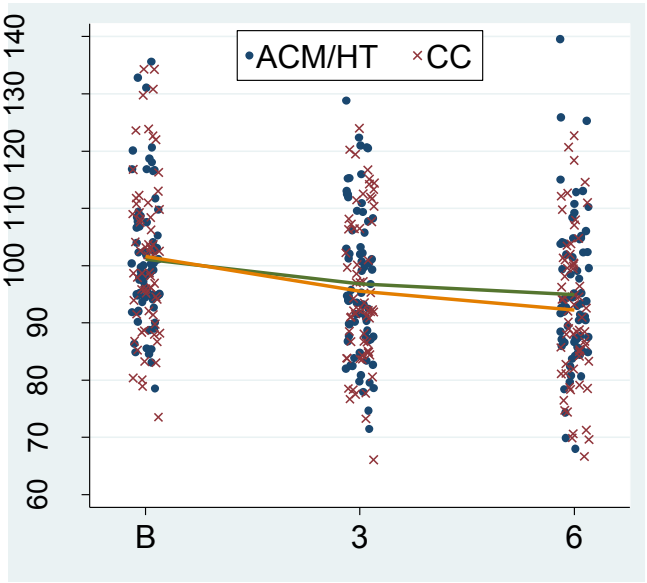
Appendix U

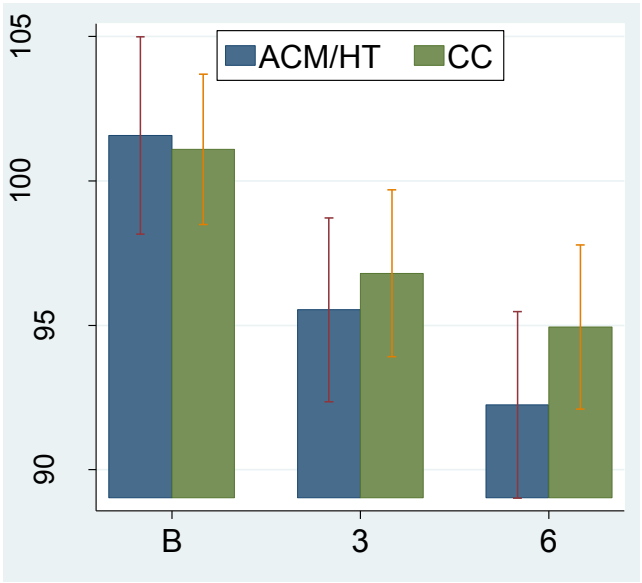
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

MAP(file location same as BPSYS)

MAP	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	101.32	12.59	101.09	10.42	101.57	10.45	-0.48	2.16	0.824
3m	96.21	15.54	96.80	14.12	95.54	12.96	1.26	2.35	0.592
6m	93.68	20.42	94.94	14.87	92.25	16.04	2.69	2.50	0.284
Change									
Base-3m	5.10	14.10	4.29	13.17	6.03	14.57	1.74	2.31	0.453
Base-6m	7.63	15.90	6.15	14.31	9.33	16.79	3.18	2.61	0.226
3m-6m	2.53	15.92	1.86	14.22	3.30	17.75	1.43	2.75	0.602

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.007	0.002
Base-6m	<0.001	<0.001	<0.001
3m-6m	0.05	0.267	0.142

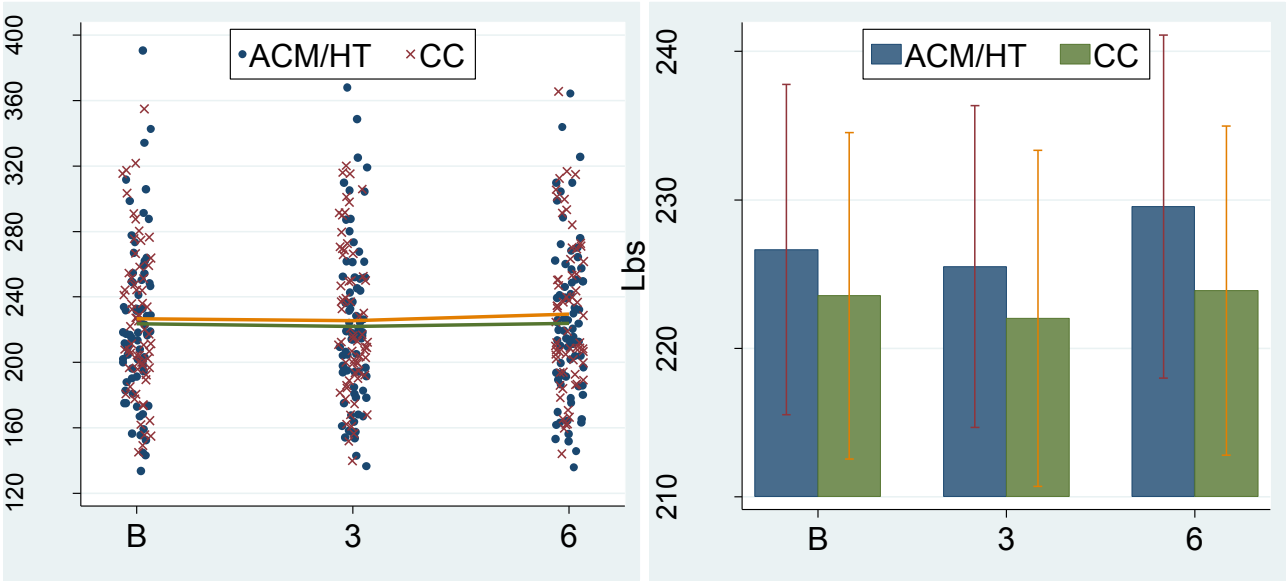




Weight (file location same as BPSYS)

Weight	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	224.99	46.61	223.54	47.91	226.65	45.39	-3.11	8.01	0.699
3m	223.65	47.21	222.02	49.57	225.51	44.50	-3.49	8.08	0.666
6m	226.52	48.15	223.88	48.58	229.54	47.64	-5.65	8.23	0.493
Change									
Base-3m	1.34	12.99	1.52	14.22	1.14	10.78	-0.38	2.13	0.857
Base-6m	-1.53	13.25	-0.34	10.98	-2.89	14.71	-2.54	2.15	0.238
3m-6m	-2.87	11.40	-1.87	10.15	-4.03	12.35	-2.16	1.91	0.261

	P-value		
Change	Combined	CC	HT
Base-3m	0.228	0.363	0.401
Base-6m	0.179	0.791	0.122
3m-6m	0.004	0.121	0.011



Cholesterol

Pulling data: N:\Diatel\final phase I\all other lab\lab data all.sas

Original data: N:\Diatel\final phase I\all other lab\cho.dta

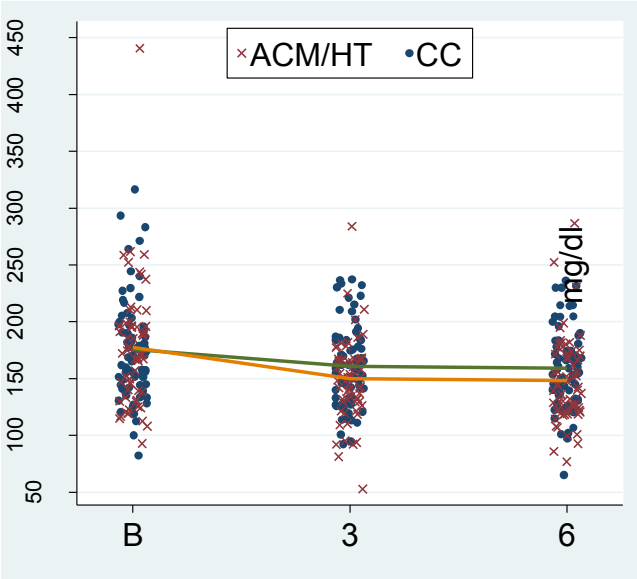
Program: N:\Diatel\final phase I\all other lab\cho.do

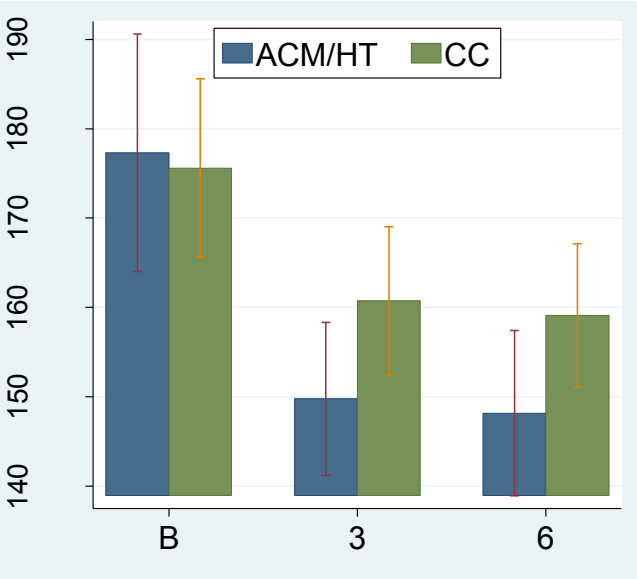
After imputation: N:\Diatel\final phase I\all other lab\cho10sets.dta

Final data: N:\Diatel\final phase I\all other lab\finalcho.dta

CHO	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	176.39	48.62	175.59	43.51	177.30	54.20	-1.71	8.36	0.838
3m	155.62	37.61	160.75	37.48	149.78	37.17	10.97	6.40	0.089
6m	154.00	39.20	159.12	37.22	148.15	40.21	10.96	6.57	0.098
Change									
Base-3m	20.76	41.27	14.84	39.56	27.52	42.42	12.68	7.02	0.073
Base-6m	22.39	44.69	16.47	43.90	29.14	44.39	12.67	7.52	0.094
3m-6m	1.63	27.31	1.63	27.94	1.62	28.51	-0.01	4.98	0.998

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.002	<0.001
Base-6m	<0.001	0.002	<0.001
3m-6m	0.486	0.619	0.650





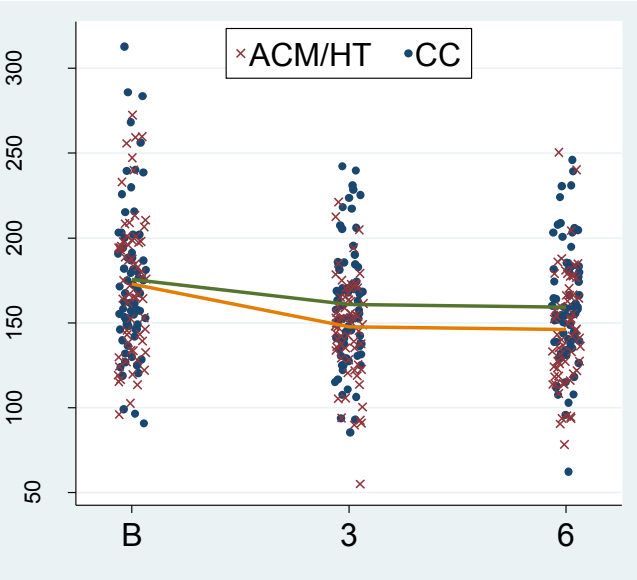
Appendix U

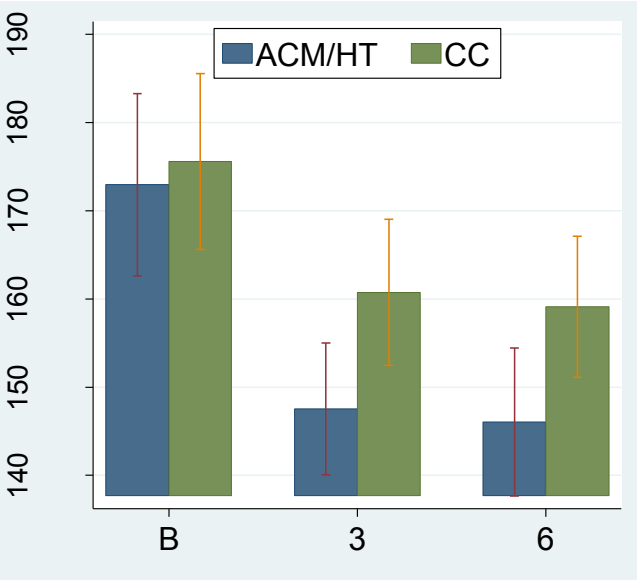
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Without the outlier

CHO	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	174.37	42.65	175.59	43.51	172.95	41.93	-2.63	7.36	0.721
3m	154.64	35.92	160.75	37.48	147.55	32.88	13.20	6.10	0.032
6m	153.06	37.79	159.12	37.22	146.04	36.80	13.07	6.32	0.041
Change									
Base-3m	19.73	39.76	14.84	39.56	25.40	39.19	10.56	6.78	0.122
Base-6m	21.31	43.17	16.47	43.90	26.91	40.95	10.44	7.28	0.154
3m-6m	1.57	27.50	1.63	27.94	1.51	28.72	-0.13	5.02	0.980

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.002	<0.001
Base-6m	<0.001	0.002	<0.001
3m-6m	0.504	0.619	0.679





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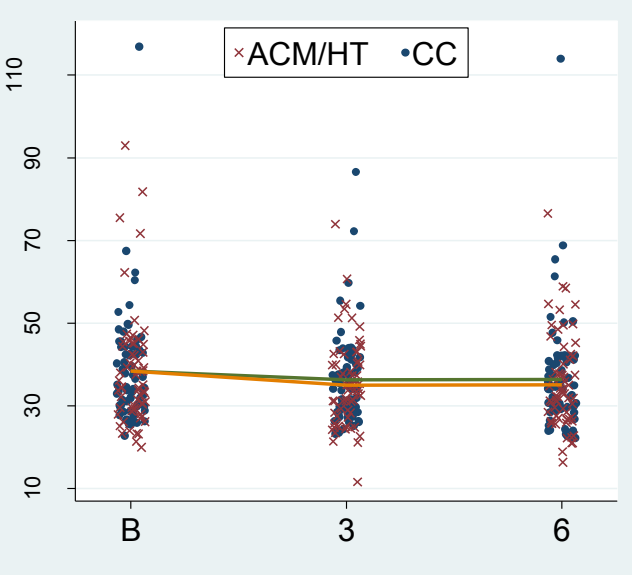
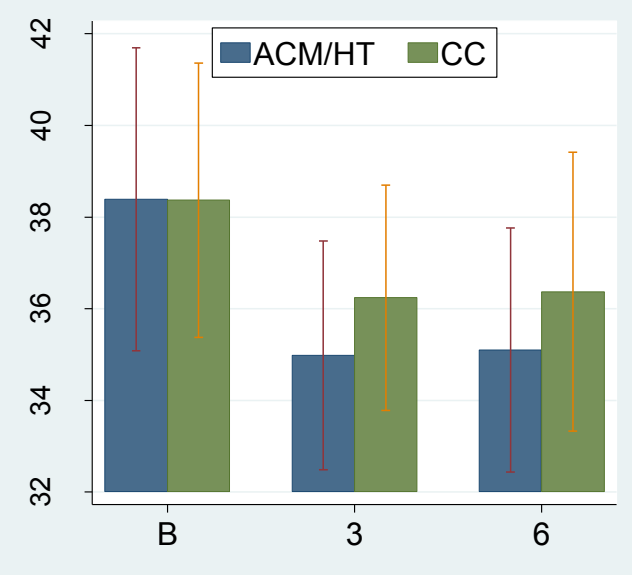
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

HDL(file location same as CHO)

HDL	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	38.38	13.21	38.37	13.05	38.39	13.49	-0.02	2.27	0.993
3m	35.65	10.84	36.24	11.03	34.99	10.70	1.26	1.87	0.502
6m	35.78	12.59	36.37	13.58	35.10	11.31	1.27	2.15	0.554
Change									
Base-3m	2.73	9.75	2.13	6.71	3.41	12.39	1.28	1.68	0.449
Base-6m	2.60	8.33	2.00	6.47	3.29	9.92	1.29	1.40	0.359
3m-6m	-0.12	6.86	-0.13	5.93	-0.11	8.18	0.02	1.25	0.990

	P-value		
Change	Combined	CC	HT
Base-3m	0.001	0.008	0.032
Base-6m	<0.001	0.010	0.010
3m-6m	0.834	0.851	0.911





Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

LDL(file location same as CHO)

LDL	Combined (128)(SD)		CC (69)(SD)		HT(59)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	100.40	33.94	101.78	32.04	98.77	36.26	3.01	6.04	0.619
3m	89.54	30.29	92.31	32.17	86.31	27.65	5.99	5.36	0.265
6m	87.07	29.26	91.16	30.62	82.28	27.93	8.88	5.28	0.095
Change									
Base-3m	10.85	31.58	9.48	29.92	12.46	33.43	2.98	5.60	0.596
Base-6m	13.33	32.99	10.62	31.98	16.49	34.84	5.87	5.97	0.327
3m-6m	2.48	25.83	1.14	27.77	4.03	22.62	2.89	4.48	0.520

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.011	0.006
Base-6m	<0.001	0.007	0.001
3m-6m	0.280	0.733	0.176

	Number of meeting target for LDL (<=100mg/dl)					
Time	Total (n=128)		CC (n=69)		HT(n=59)	
Baseline	67	52.34 %	36	52.17 %	31	52.54 %
3 month	87	67.97 %	44	63.77 %	43	72.88 %
6 month	88	68.75 %	41	59.42%	47	79.66 %

```
. tab group target if n==1, row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        33         36 |        69
           |     47.83      52.17 |    100.00
-----------+----------------------+----------
        HT |        28         31 |        59
           |     47.46      52.54 |    100.00
-----------+----------------------+----------
     Total |        61         67 |       128
           |     47.66      52.34 |    100.00

          Pearson chi2(1) =   0.0017   Pr = 0.967
```

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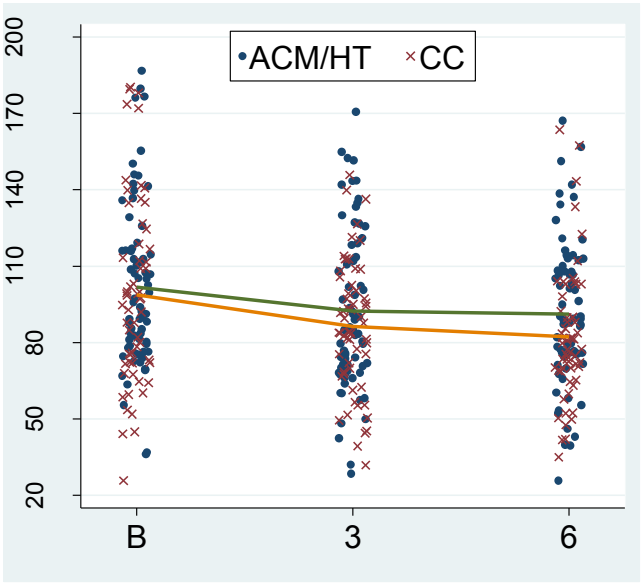
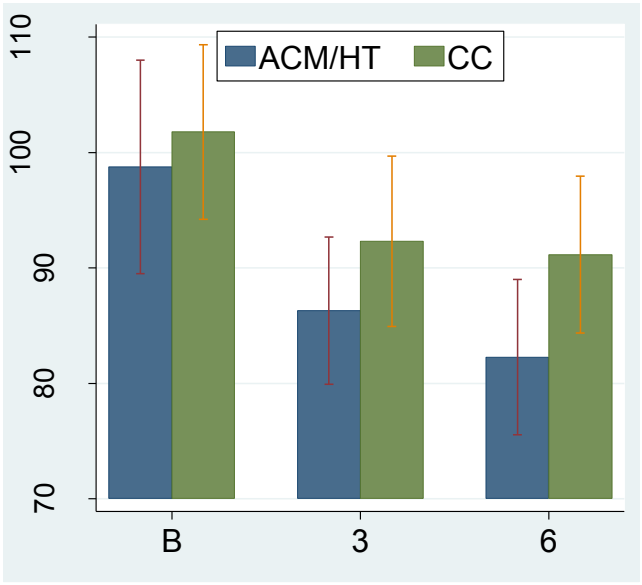
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

```
. tab group target if n==2, row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        25         44 |        69
           |     36.23      63.77 |    100.00
-----------+----------------------+----------
        HT |        16         43 |        59
           |     27.12      72.88 |    100.00
-----------+----------------------+----------
     Total |        41         87 |       128
           |     32.03      67.97 |    100.00

          Pearson chi2(1) =   1.2133   Pr = 0.271

. tab group target if n==3, row chi2
           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        28         41 |        69
           |     40.58      59.42 |    100.00
-----------+----------------------+----------
        HT |        12         47 |        59
           |     20.34      79.66 |    100.00
-----------+----------------------+----------
     Total |        40         88 |       128
           |     31.25      68.75 |    100.00

          Pearson chi2(1) =   6.0649   Pr = 0.014
```





LDL (mg/dl)

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Triglyceride (file location same as CHO)

TRI	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	192.80	147.82	194.07	160.36	191.35	133.33	2.72	25.41	0.915
3m	160.60	124.83	169.97	133.60	149.91	114.13	20.06	21.44	0.351
6m	162.19	110.04	170.73	115.88	152.45	99.70	18.29	18.35	0.321
Change									
Base-3m	32.19	120.86	24.09	126.76	41.43	114.50	17.34	20.88	0.408
Base-6m	30.61	114.25	23.34	111.67	38.90	113.58	15.56	18.99	0.414
3m-6m	-1.59	82.73	-0.76	80.17	-2.54	87.46	-1.78	14.45	0.902

	P-value		
Change	Combined	CC	HT
Base-3m	0.002	0.109	0.005
Base-6m	0.002	0.078	0.008
3m-6m	0.823	0.936	0.817

	Number of meeting target for Triglyceride (<=150mg/dl)					
Time	Total (n=137)		CC (n=73)		HT(n=64)	
Baseline	76	55.47 %	43	58.90 %	33	51.56 %
3 month	81	59.12 %	39	53.42 %	42	65.63 %
6 month	82	59.85 %	42	57.53%	40	62.50 %

```
. tab group target if n==1, row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        30         43 |        73
           |     41.10      58.90 |    100.00
-----------+----------------------+----------
        HT |        31         33 |        64
           |     48.44      51.56 |    100.00
-----------+----------------------+----------
     Total |        61         76 |       137
           |     44.53      55.47 |    100.00

          Pearson chi2(1) =   0.7442   Pr = 0.388
```

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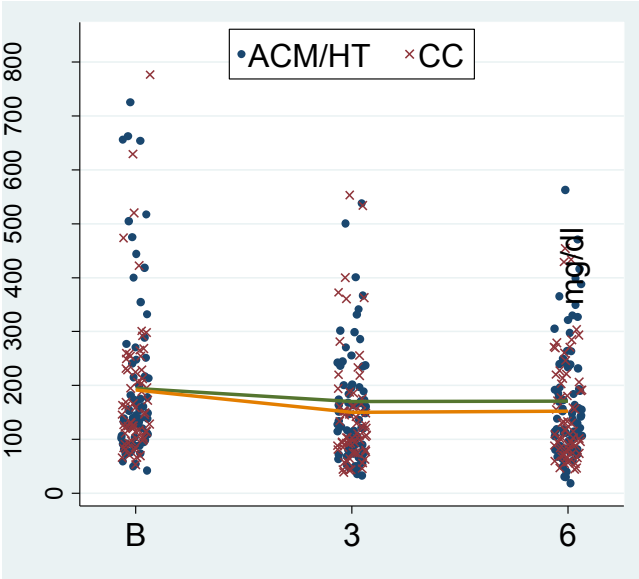
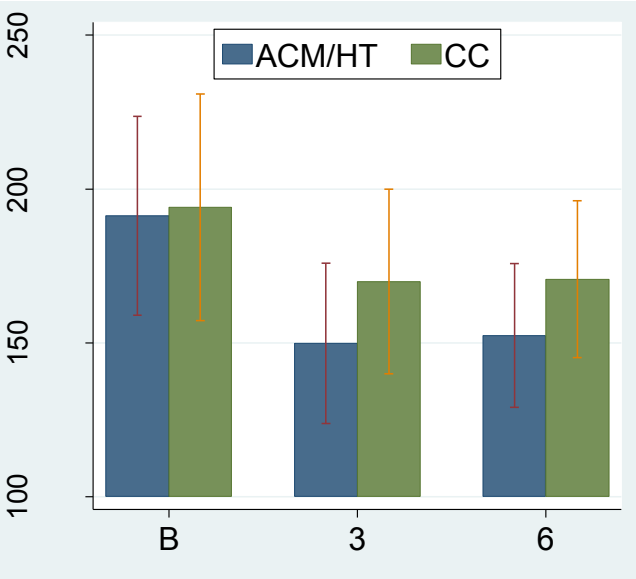
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

```
. tab group target if n==2, row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        34         39 |        73
           |     46.58      53.42 |    100.00
-----------+----------------------+----------
        HT |        22         42 |        64
           |     34.38      65.63 |    100.00
-----------+----------------------+----------
     Total |        56         81 |       137
           |     40.88      59.12 |    100.00

          Pearson chi2(1) =   2.1004   Pr = 0.147

. tab group target if n==3, row chi2

           |        target
     group |         0          1 |     Total
-----------+----------------------+----------
        CC |        31         42 |        73
           |     42.47      57.53 |    100.00
-----------+----------------------+----------
        HT |        24         40 |        64
           |     37.50      62.50 |    100.00
-----------+----------------------+----------
     Total |        55         82 |       137
           |     40.15      59.85 |    100.00

          Pearson chi2(1) =   0.3500   Pr = 0.554
```





Questionnaires

PAID (Problem Areas in Diabetes, range: 0-100)

It ranges from 0 to 100, where a higher score indicates greater emotional distress. For subjects who did the PAID assessment, they almost answered all the questions. Those small amounts of missing were replaced by mean. For those subjects who missed the assessment, their missing values were multiply imputed.

Pulling data: N:\Diatel\final phase I\questionnaire analysis\PAID\program to pull paid.sas

Original data: N:\Diatel\final phase I\questionnaire analysis\PAID \paid.dta

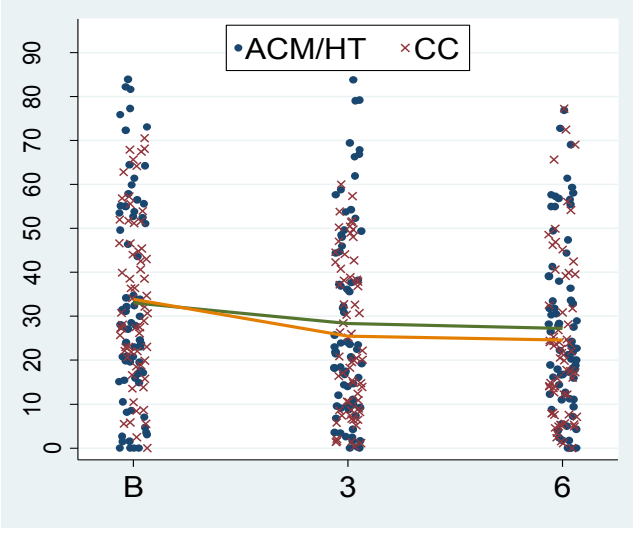
Program: N:\Diatel\final phase I\questionnaire analysis\PAID \paid analysis.do

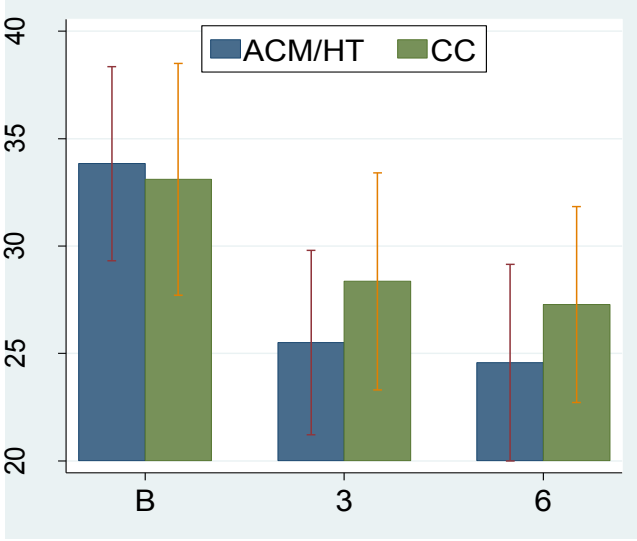
After imputation: N:\Diatel\final phase I\questionnaire analysis\PAID \paid10sets.dta

Final data: N:\Diatel\final phase I\questionnaire analysis\PAID \finalpaid.dta

PAID	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	33.45	21.30	33.11	23.54	33.84	18.61	-0.72	3.66	0.844
3m	27.02	20.52	28.36	22.26	25.50	18.17	2.86	3.49	0.414
6m	26.01	20.95	27.27	21.15	24.57	20.44	2.70	3.54	0.447
Change									
Base-3m	6.43	14.63	4.76	12.97	8.34	15.97	3.58	2.46	0.148
Base-6m	7.44	17.98	5.84	16.84	9.26	18.55	3.42	2.98	0.253
3m-6m	1.10	16.20	1.08	15.96	0.93	16.07	-0.15	2.71	0.955

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.003	<0.001
Base-6m	<0.001	0.004	<0.001
3m-6m	0.467	0.564	0.645





Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

MDQ (Multidimensional Diabetes Questionnaire, range: section (1,2): 0-6 section(3): 0-100) (file location under questionnaire analysis\MDQ)

MDQ has 3 sections.
Section 1: general perceptions of diabetes and related social support. It also has 3 parts: perceived interference, perceived severity and perceived social support. The first part includes one question not applicable to subjects living alone. It is treated as missing and replaced with mean. The 3rd part only has 4 questions and 2 of them are not applicable for subjects living alone. The other 2 questions are designed for support from family, friends or doctors. How do deal with this kind of missing?

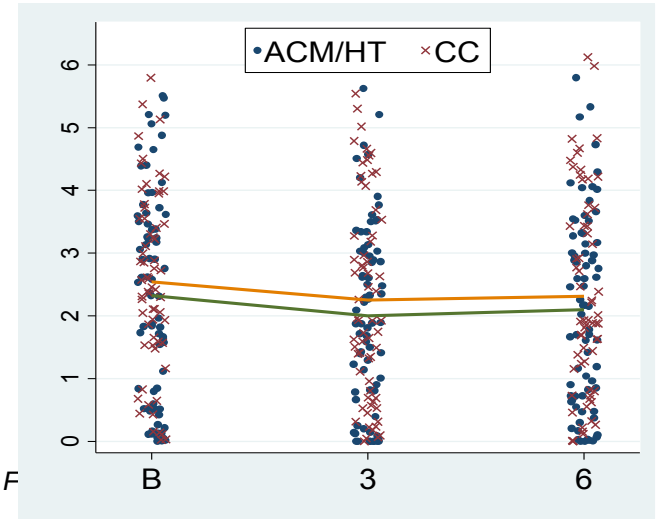
Section 2 is about social support and not applicable at all to subjects living alone. They would skip the whole section. There is dilemma like this: subjects lived alone at baseline, but not 3 month, etc. How to deal with these situations?

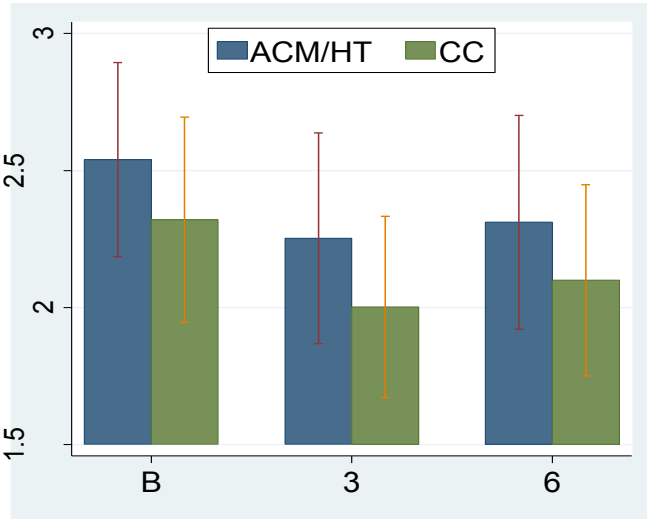
Section 1: general perceptions of diabetes and related social support

- **Interference** : items (1+4+7+8+11+13+14+15+16)/9, the smaller, the better

Interference	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	2.42	1.55	2.32	1.63	2.54	1.45	-0.22	0.27	0.411
3m	2.12	1.55	2.00	1.49	2.25	1.60	-0.25	0.26	0.341
6m	2.20	1.61	2.10	1.60	2.31	1.67	-0.21	028	0.455
Change									
Base-3m	0.30	1.12	0.32	1.15	0.29	1.05	-0.03	0.19	0.864
Base-6m	0.22	1.25	0.22	1.27	0.23	1.31	0.01	0.23	0.976
3m-6m	-0.08	1.17	-0.10	1.14	-0.06	1.21	0.04	0.20	0.848

	P-value		
Change	Combined	CC	HT
Base-3m	0.002	0.021	0.033
Base-6m	0.038	0.140	0.169
3m-6m	0.429	0.469	0.701





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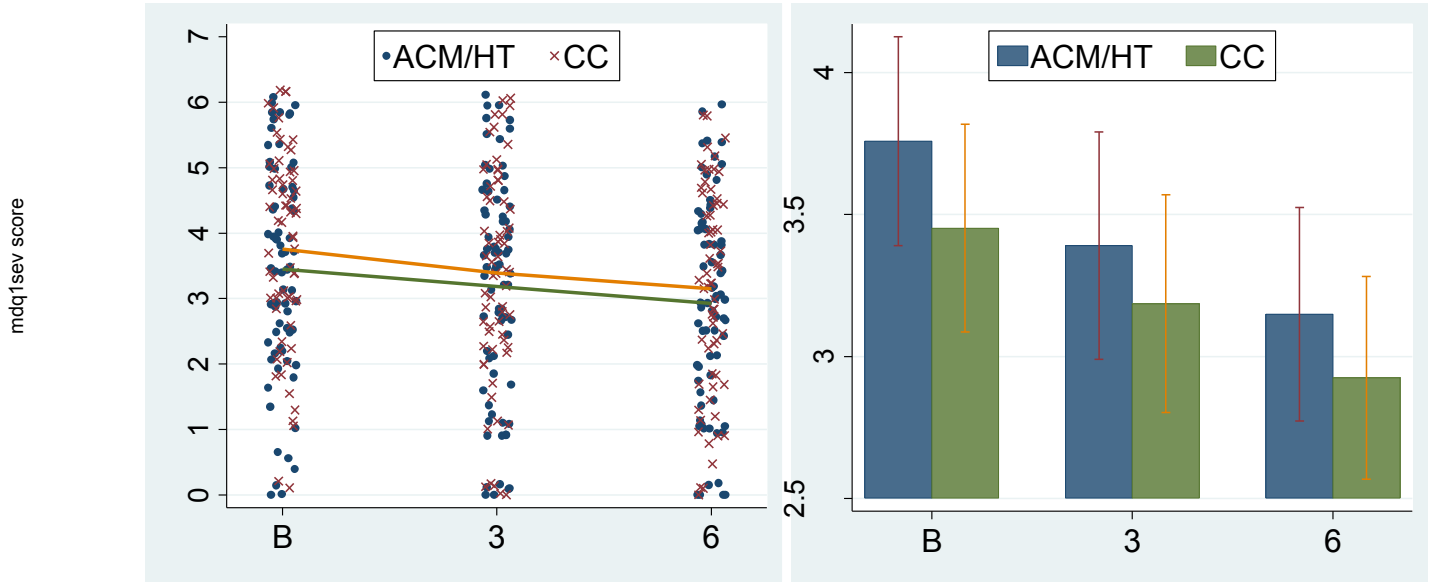
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

- **Severity**: items(3+6+9)/3, the smaller, the better

Severity	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	3.59	1.57	3.45	1.60	3.76	1.53	-0.31	0.27	0.257
3m	3.28	1.73	3.19	1.73	3.39	1.71	-0.20	0.29	0.486
6m	3.03	1.64	2.92	1.62	3.15	1.63	-0.22	0.27	0.416
Change									
Base-3m	0.31	1.33	0.27	1.24	0.37	1.37	0.10	0.22	0.643
Base-6m	0.57	1.39	0.53	1.26	0.61	1.51	0.08	0.23	0.728
3m-6m	0.25	1.50	0.26	1.31	0.24	1.64	-0.02	0.25	0.937

	P-value		
Change	Combined	CC	HT
Base-3m	0.006	0.070	0.037
Base-6m	<0.001	0.001	0.002
3m-6m	0.051	0.092	0.244



- **Social support** : items(2+5+10+12)/4, the larger, the better

#2. To what extent does your spouse (or significant other, companion, or a person who lives with you) support you with diabetes? (skip if live alone)

#10. To what extent does your spouse (or significant other, companion, or a person who lives with you) pay attention to you because of your diabetes? (skip if live alone)

#5. To what extent do your family and friends support you or help you with your diabetes?

Baseline	CC	VI	Total
0	3	0	3
	5.45	0.00	3.03
1	2	1	3
	3.64	2.27	3.03
2	5	4	9
	9.09	9.09	9.09
3	7	5	12
	12.73	11.36	12.12
4	12	8	20
	21.82	18.18	20.20
5	9	9	18
	16.36	20.45	18.18
6	17	17	34
	30.91	38.64	34.34
Total	55	44	99
	100.00	100.00	100.00

3-month	CC	VI	Total
0	4	1	5
	7.84	2.13	5.10
1	1	2	3
	1.96	4.26	3.06
2	2	1	3
	3.92	2.13	3.06
3	8	3	11
	15.69	6.38	11.22
4	8	4	12
	15.69	8.51	12.24
5	12	11	23
	23.53	23.40	23.47
6	16	25	41
	31.37	53.19	41.84
Total	51	47	98
	100.00	100.00	100.00

6-month	CC	VI	Total
0	6	1	7
	12.00	2.63	7.95
2	4	2	6
	8.00	5.26	6.82
3	7	6	13
	14.00	15.79	14.77
4	7	2	9
	14.00	5.26	10.23
5	12	7	19
	24.00	18.42	21.59
6	14	20	34
	28.00	52.63	38.64
Total	50	38	88
	100.00	100.00	100.00

#12. To what extent does your doctor or health care team support you or help you with your diabetes?

Baseline	CC	VI	Total
0	4	1	5
	5.56	1.59	3.70
1	4	3	7
	5.56	4.76	5.19
2	6	2	8
	8.33	3.17	5.93
3	11	12	23
	15.28	19.05	17.04
4	13	10	23
	18.06	15.87	17.04
5	19	11	30
	26.39	17.46	22.22
6	15	24	39
	20.83	38.10	28.89
Total	72	63	135
	100.00	100.00	100.00

3-month	CC	VI	Total
0	2	0	2
	2.94	0.00	1.59
1	1	0	1
	1.47	0.00	0.79

```
          2 |          4          1 |          5
            |       5.88       1.72 |       3.97
------------+----------------------+-----------
          3 |          8          5 |         13
            |      11.76       8.62 |      10.32
------------+----------------------+-----------
          4 |         12          3 |         15
            |      17.65       5.17 |      11.90
------------+----------------------+-----------
          5 |         15         18 |         33
            |      22.06      31.03 |      26.19
------------+----------------------+-----------
          6 |         26         31 |         57
            |      38.24      53.45 |      45.24
------------+----------------------+-----------
      Total |         68         58 |        126
            |     100.00     100.00 |     100.00


   6-month |         CC          VI |      Total
-----------+----------------------+-----------
          0 |          2          0 |          2
            |       2.99       0.00 |       1.63
-----------+----------------------+-----------
          2 |          3          1 |          4
            |       4.48       1.79 |       3.25
-----------+----------------------+-----------
          3 |         13          5 |         18
            |      19.40       8.93 |      14.63
-----------+----------------------+-----------
          4 |          8          3 |         11
            |      11.94       5.36 |       8.94
-----------+----------------------+-----------
          5 |         14         16 |         30
            |      20.90      28.57 |      24.39
-----------+----------------------+-----------
          6 |         27         31 |         58
            |      40.30      55.36 |      47.15
-----------+----------------------+-----------
      Total |         67         56 |        123
            |     100.00     100.00 |     100.00
```

Section II: social incentives related to self-care activities

- **Positive reinforcing behaviors**: items (1+3+4+6+7+8+10+12)/8, the larger, the better
- **Misguided reinforcing behaviors**: item .(2+4+9+11)/4, the smaller, the better

. xttrans alone

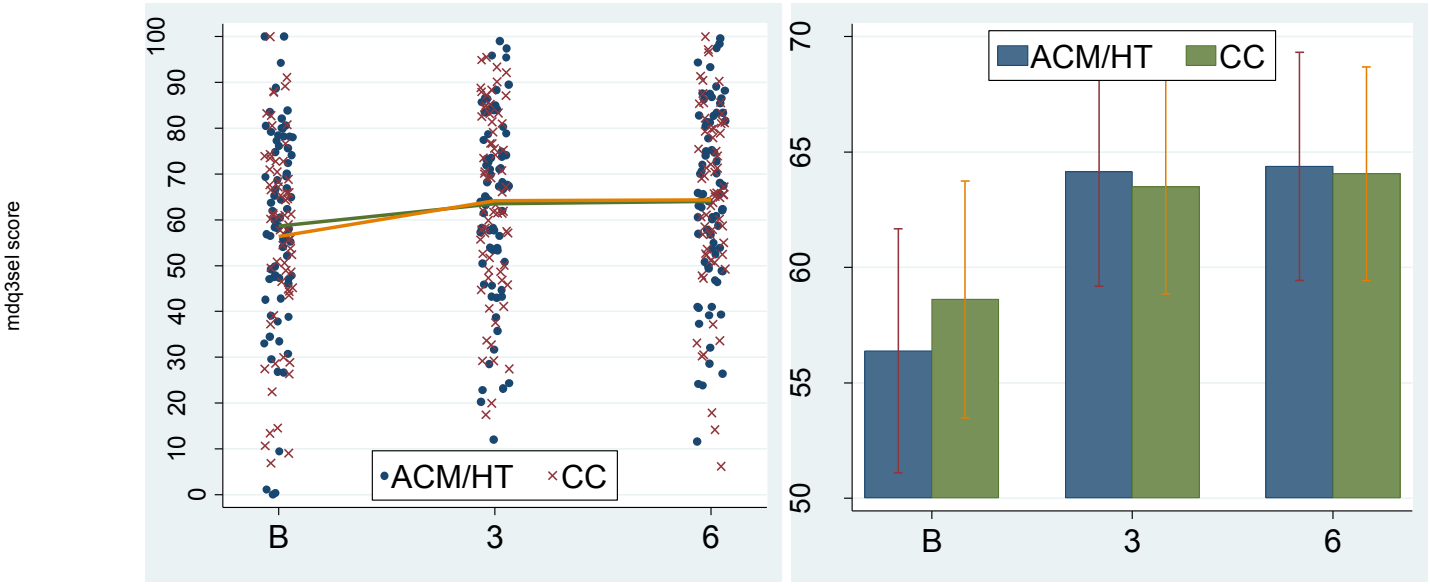
```
           |       alone
     alone |         0          1 |     Total
-----------+----------------------+----------
         0 |     94.27       5.73 |    100.00
         1 |     32.20      67.80 |    100.00
-----------+----------------------+----------
     Total |     79.68      20.32 |    100.00
```

Section III: self-efficacy and outcomes expectancies

- **Self-efficacy**: items (1+2+3+4+5+6+7)/7, the larger, the better

Self-efficacy	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	57.58	22.07	58.62	22.39	56.39	21.82	2.22	3.79	0.558
3m	63.80	21.11	63.50	20.85	64.15	21.04	-0.66	3.54	0.853
6m	64.21	20.91	64.06	21.07	64.38	21.10	-0.32	3.63	0.929
Change									
Base-3m	-6.23	17.47	-4.88	16.29	-7.76	18.23	-2.88	2.91	0.323
Base-6m	-6.63	18.79	-5.44	17.53	-7.99	20.26	-2.55	3.24	0.433
3m-6m	-0.41	13.44	-0.56	13.67	-0.23	13.94	0.34	2.42	0.890

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	0.013	0.001
Base-6m	<0.001	0.010	0.002
3m-6m	0.724	0.726	0.897

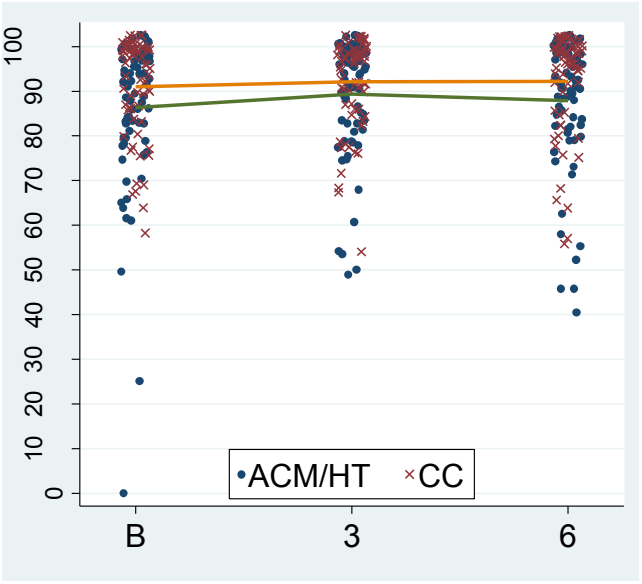


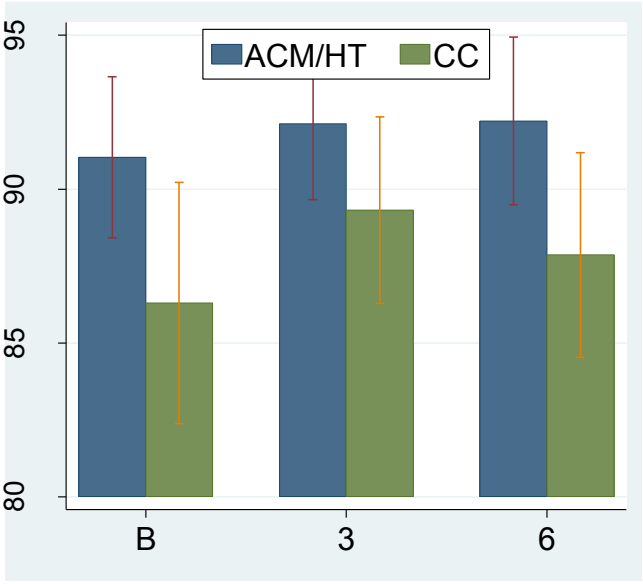
Appendix U

- **Outcome expectancies**: items (8+9+10+11+12+13)/6, the larger, the better

Outcome	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	88.51	14.77	86.30	17.08	91.03	11.19	-4.73	2.51	0.061
3m	90.63	12.78	89.32	13.57	92.12	11.78	-2.80	2.20	0.205
6m	89.90	14.08	87.86	15.32	92.22	12.06	-4.35	3.37	0.068
Change									
Base-3m	-2.12	13.86	-3.02	15.38	-1.09	12.02	1.93	2.40	0.422
Base-6m	-1.39	14.90	-1.56	16.74	-1.18	12.15	0.38	2.50	0.880
3m-6m	0.73	13.53	1.46	14.48	-0.10	12.17	-1.55	2.29	0.499

	P-value		
Change	Combined	CC	HT
Base-3m	0.076	0.098	0.472
Base-6m	0.278	0.428	0.439
3m-6m	0.528	0.393	0.950





Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
Item by item

1 How confident are you in your ability to follow your diet?

		Rank sum	Rank expected	P-value
Baseline	CC	4887	4860	0.9032
	ATM	4158	4185	
3m	CC	4381.5	4416	0.8662
	ATM	3746.5	3712	
6m	CC	3956.5	4059	0.5944
	ATM	3546.5	3444	

2 How confident are you in your ability to test your blood sugar at the recommended frequency?

		Rank sum	Rank expected	P-value
Baseline	CC	4723.5	4655	0.317
	ATM	4054.5	4123	
3m	CC	4482	4416	0.7432
	ATM	3646	3712	
6m	CC	3967.5	4059	0.6296
	ATM	3535.5	3444	

3 How confident are you in your ability to exercise regularly?

		Rank sum	Rank expected	P-value
Baseline	CC	4917.5	4757	0.4663
	ATM	3993.5	4154	
3m	CC	4114	4286	0.3964
	ATM	3761	3591	
6m	CC	4210	4026	0.3354
	ATM	3171	3355	

4 How confident are you in your ability to keep your weight under control?

		Rank sum	Rank expected	P-value
Baseline	CC	5162.5	4964	0.378
	ATM	4017.5	4216	
3m	CC	4820.5	4416	0.0486
	ATM	3307.5	3712	
6m	CC	4380	4059	0.0963
	ATM	3123	3444	

5 How confident are you in your ability to keep your blood sugar levels under control?

		Rank sum	Rank expected	P-value
Baseline	CC	5030.5	4964	0.7672
	ATM	4149.5	4216	

3m	CC	4037	4416	0.0636
	ATM	4091	3712	
6m	CC	3805.5	4059	0.1891
	ATM	397.5	3444	

6 How confident are you in your ability to resist food temptations?

		Rank sum	Rank expected	P-value
Baseline	CC	5123	4964	0.4793
	ATM	4057	4216	
				0.9186
3m	CC	4437	4416	
	ATM	3691	3712	
6m	CC	4006.5	4059	0.7859
	ATM	3496.5	3444	

7 How confident are you in your ability to follow your diabetes treatment? (diet, medications, blood sugar testing, exercise)?

		Rank sum	Rank expected	P-value
Baseline	CC	5054	4927.5	0.5682
	ATM	3991	4117.5	
3m	CC	4182.5	4416	0.2529
	ATM	3945.5	3712	
6m	CC	4070	4059	0.9545
	ATM	3433	3444	

8 To what extent do you think that following your diet is important for controlling your diabetes? (diet, medications, blood sugar testing, exercise)?

		Rank sum	Rank expected	P-value
Baseline	CC	4465.5	4964	
	ATM	4714.5	4216	0.0173
3m	CC	4354	4416	0.7448
	ATM	3774	3712	
6m	CC	3674	4059	0.0312
	ATM	3829	3444	

9 To what extent do you think that taking your medication as recommended is important for controlling your diabetes?

		Rank sum	Rank expected	P-value
Baseline	CC	4937.5	4964	0.8902
	ATM	4242.5	4216	
3m	CC	4384.5	4381.5	0.9857
	ATM	3616.5	3619.5	

6m	CC	3952	4154	0.205
	ATM	3674	3472	

10 To what extent do you think that exercise is important for controlling your diabetes?

		Rank sum	Rank expected	P-value
Baseline	CC	4691	4860	0.4274
	ATM	4354	4185	
3m	CC	4099	4284	0.3171
	ATM	3776	3591	
6m	CC	3821	4120.5	0.0995
	ATM	3682	3382.5	

11 To what extent do you think that measuring your blood sugar is important for controlling your diabetes?

		Rank sum	Rank expected	P-value
Baseline	CC	4552	4860	0.1432
	ATM	4493	4185	
3m	CC	4205	4381.5	0.3206
	ATM	3796	3619.5	
6m	CC	3904	4154	0.1453
	ATM	3722	3472	

12 To what extent do you think that following your diabetes treatment is important for controlling your diabetes?

		Rank sum	Rank expected	P-value
Baseline	CC	4602.5	4964	0.0717
	ATM	4577.5	4216	
3m	CC	4265.6	4284	0.9122
	ATM	3609.5	3591	
6m	CC	3978.5	4154	0.287
	ATM	3647.5	3472	

13 To what extent do you think that following your diabetes treatment is important for delaying and/or preventing long-term diabetes complications?

		Rank sum	Rank expected	P-value
Baseline	CC	4722.5	4964	0.2219
	ATM	4457.5	4216	
3m	CC	4357	4381.5	0.881
	ATM	3644	3619.5	
6m	CC	4038.5	4154	0.4649
	ATM	3587.5	3472	

Appendix U

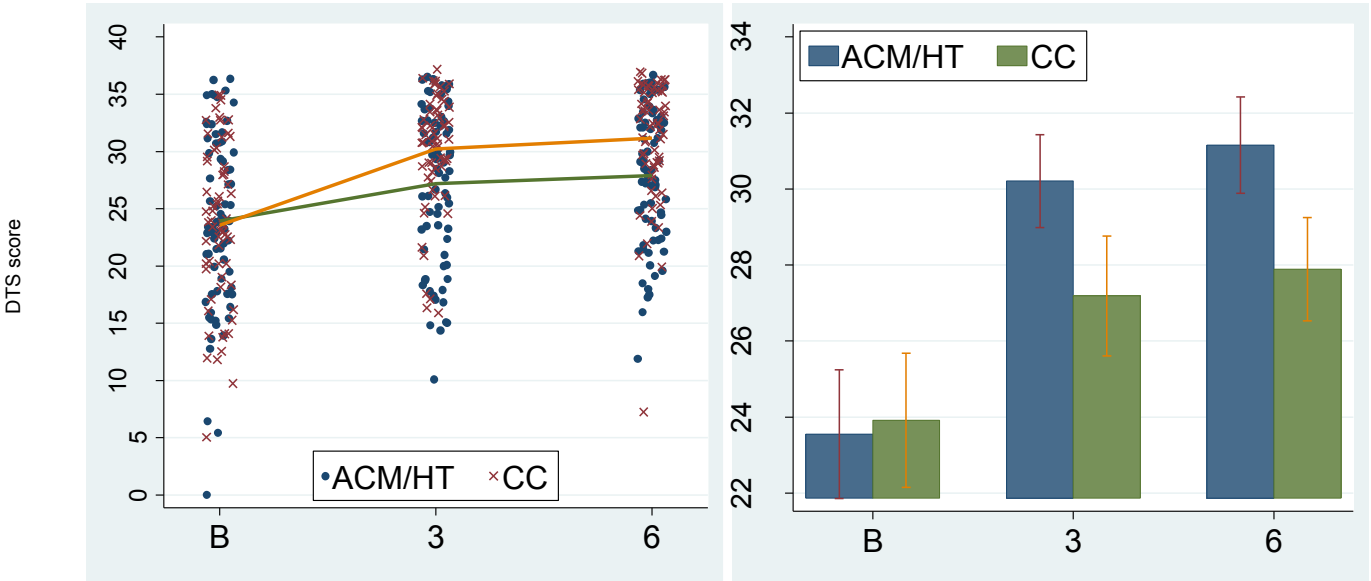
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

DTS Diabetes Treatment Satisfaction (range: 0-36)

- **Treatment satisfaction**: items (1+4+5+6+7+8), the larger, the better

Outcome	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	23.75	7.35	23.92	7.68	23.55	7.01	0.37	1.26	0.771
3m	28.60	6.69	27.19	7.18	30.21	5.49	-3.02	1.09	0.006
6m	29.42	6.64	27.89	6.36	31.16	6.49	-3.26	1.10	0.004
Change									
Base-3m	-4.85	7.62	-3.27	7.65	-6.66	7.09	-3.39	1.26	0.008
Base-6m	-5.67	7.78	-3.98	7.04	-7.61	8.23	-3.63	1.32	0.007
3m-6m	-0.82	6.56	-0.71	6.27	-0.95	6.51	-0.24	1.07	0.821

	P-value		
Change	Combined	CC	HT
Base-3m	<0.001	<0.001	<0.001
Base-6m	<0.001	<0.001	<0.001
3m-6m	0.146	0.339	0.248



Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

- **How often have felt blood sugars unacceptably high recently?**

CC

tsbluhgh	Baseline	3-month	6-month	Total
None of the time	2	5	5	12
1	5	8	5	18
2	5	14	8	27
3	18	9	11	38
4	13	15	11	39
5	12	11	18	41
Most of the time	18	6	7	31
Total	73	68	65	206

Pearson chi2(12) = 21.1284 Pr = 0.049

ACM

tsbluhgh	Baseline	3-month	6-month	Total
None of the time	0	3	10	13
1	2	7	8	17
2	4	9	5	18
3	11	11	6	28
4	18	20	13	51
5	12	7	8	27
Most of the time	15	2	5	22
Total	62	59	55	176

Pearson chi2(12) = 35.0421 Pr = 0.000

- **How often have felt blood sugars unacceptably low recently?**

CC

tsblulow	Baseline	3-month	6-month	Total
None of the time	33	24	9	66
1	12	15	5	32
2	11	9	8	28
3	5	8	27	40
4	8	6	11	25
5	2	5	4	11
Most of the time	2	1	1	4
Total	73	68	65	206

Pearson chi2(12) = 43.7552 Pr = 0.000

ACM

tsblulow	Baseline	3-month	6-month	Total
None of the time	26	12	7	45
1	18	12	3	33
2	8	13	5	26
3	6	5	7	18
4	2	8	25	35
5	2	8	4	14
Most of the time	0	1	4	5
Total	62	59	55	176

Pearson chi2(12) = 61.2842 Pr = 0.000

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

How often have felt blood sugars unacceptably high recently?

		Rank sum	Rank expected	P-value
Baseline	CC	4744	4964	0.3208
	ATM	4436	4216	
3m	CC	4365.5	4352	0.947
	ATM	3762.5	3776	
6m	CC	4276	3932.5	0.0667
	ATM	2984	3327.5	

How often have felt blood sugars unacceptably low recently?

		Rank sum	Rank expected	P-value
Baseline	CC	5071	4964	0.6188
	ATM	4109	4216	
3m	CC	3955	4352	0.05
	ATM	4173	3776	
6m	CC	3447	3932.5	0.0086
	ATM	3813	3327.5	

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

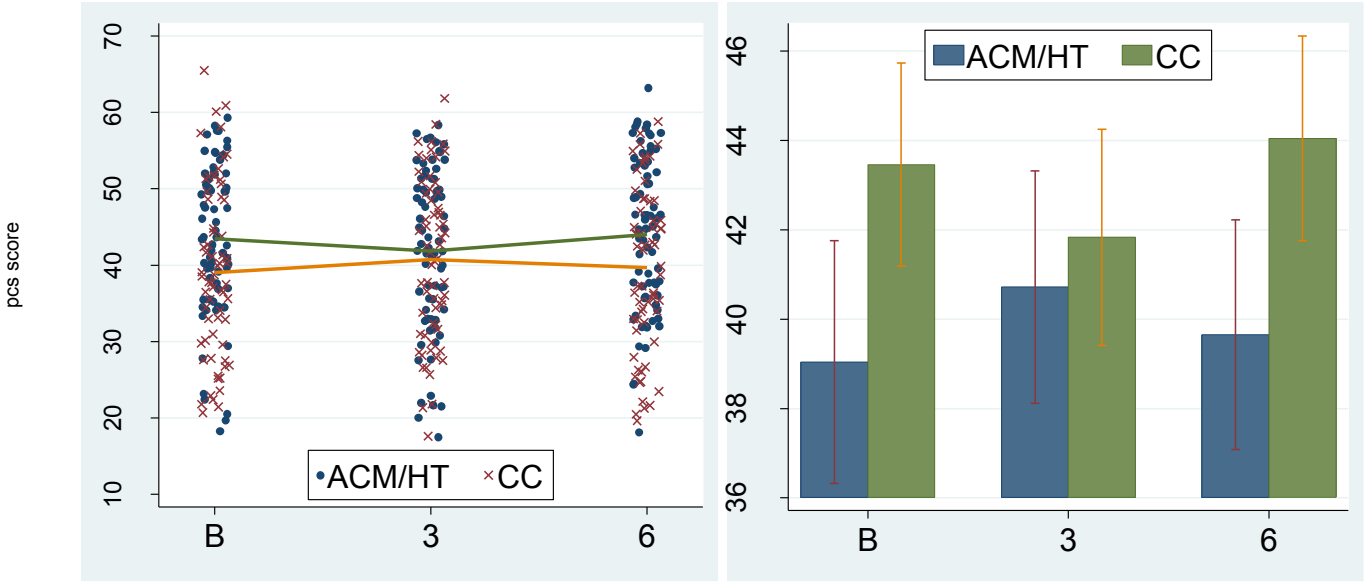
SF12 (range: 0-100)

The SF12 generates two scores; a mental component score and a physical component score. In a general population the mean score on each component is around 50, with scores of 40-49 indicating mild disability, scores of 30-39 indicating moderate disability and scores below 30 indicating severe disability.

- **PCS:** the larger, the better

PCS	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	41.39	10.81	43.46	10.15	39.04	11.14	4.42	1.82	0.016
3m	41.31	11.22	41.83	10.85	40.72	11.41	1.11	1.88	0.556
6m	41.99	10.81	44.04	10.18	39.65	11.12	4.39	1.82	0.017
Change									
Base-3m	0.08	8.81	1.63	9.03	-1.68	8.18	-3.31	1.48	0.027
Base-6m	-0.60	8.57	-0.58	7.92	-0.61	9.43	-0.03	1.49	0.986
3m-6m	-0.68	8.80	-2.21	8.84	1.07	8.56	3.28	1.51	0.031

	P-value		
Change	Combined	CC	HT
Base-3m	0.911	0.128	0.106
Base-6m	0.417	0.531	0.606
3m-6m	0.367	0.036	0.323



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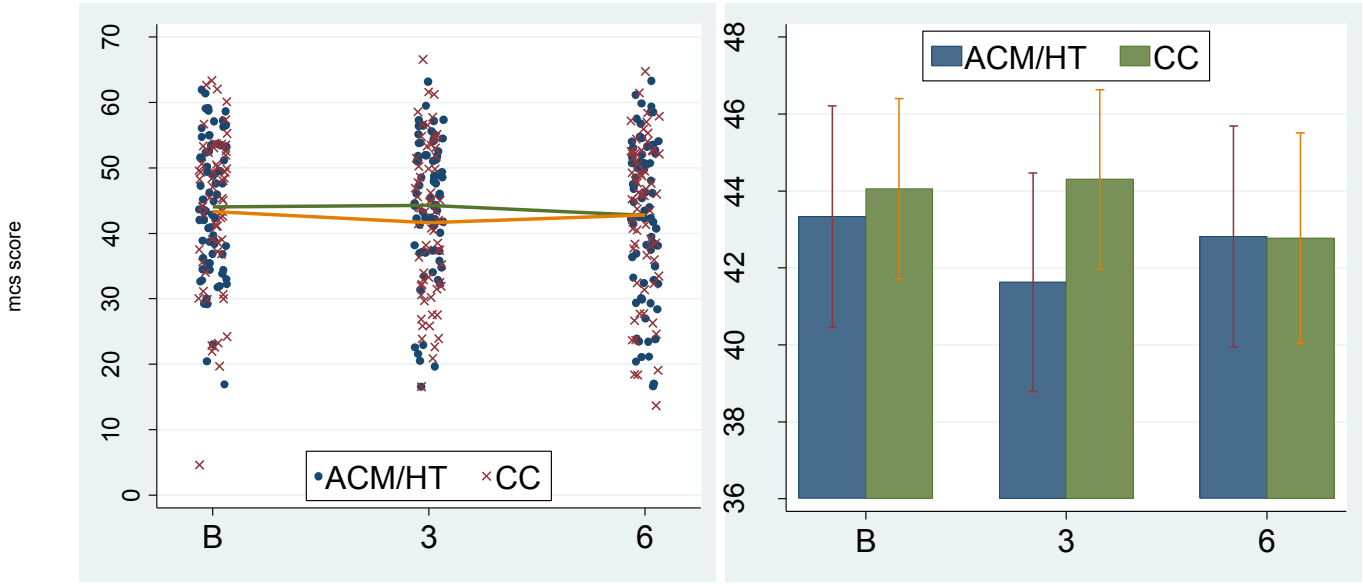
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

- **MCS:** the larger, the better

MCS	Combined (137)(SD)		CC (73)(SD)		HT(64)(SD)		Diff(SE) (CC-HT)		P-value
Baseline	43.72	11.06	44.06	10.35	43.33	11.82	0.73	1.89	0.700
3m	43.06	11.46	44.31	10.50	41.63	12.68	2.68	2.01	0.185
6m	42.79	12.56	42.77	12.55	42.81	12.68	-0.04	2.16	0.986
Change									
Base-3m	0.66	9.80	-0.25	9.35	1.70	10.54	1.95	1.73	0.262
Base-6m	0.93	10.16	1.29	11.01	0.52	9.09	-0.77	1.73	0.660
3m-6m	0.27	12.19	1.54	12.50	-1.18	11.69	-2.72	2.08	0.193

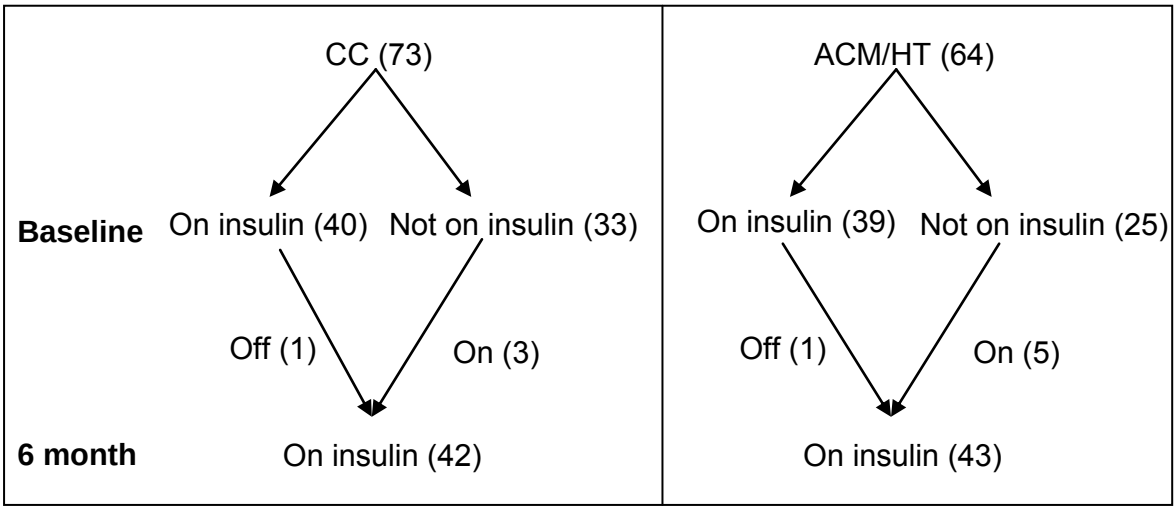
	P-value		
Change	Combined	CC	HT
Base-3m	0.430	0.821	0.201
Base-6m	0.287	0.321	0.648
3m-6m	0.799	0.297	0.422



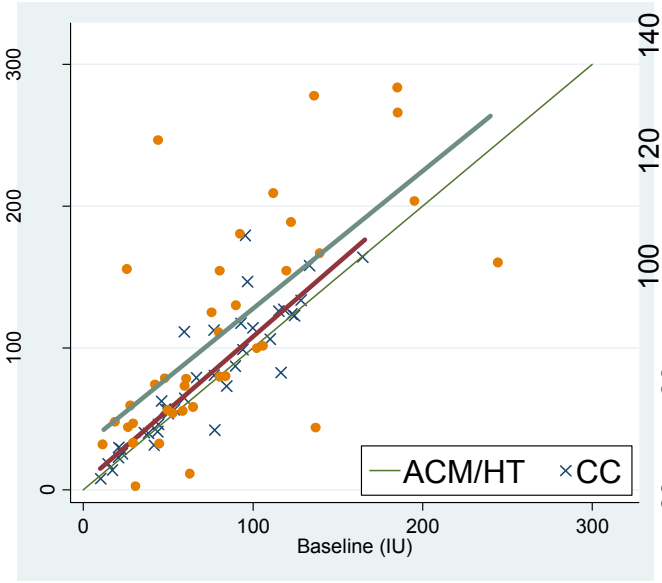
Appendix U

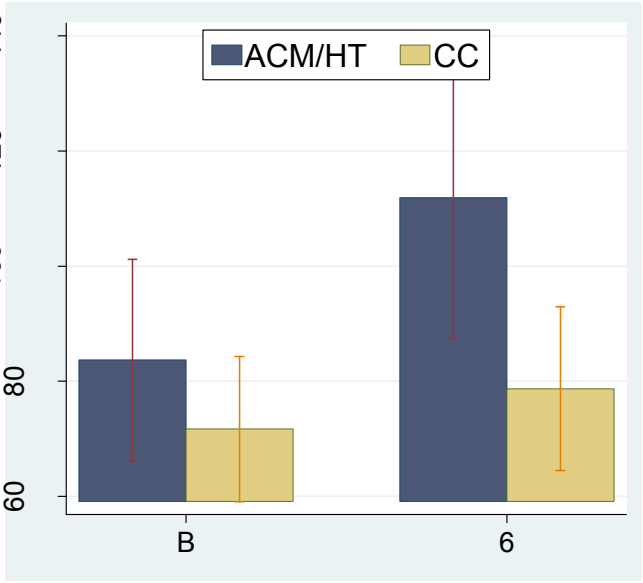
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

Phase I medicine data




```
Included all subjects ever on insulin during phase I

. reg totalend totalinitial group

      Source |       SS       df       MS              Number of obs =      87
-------------+------------------------------           F(  2,    84) =   64.20
       Model |  223332.689     2  111666.345           Prob > F      =  0.0000
    Residual |  146114.161    84   1739.4543           R-squared     =  0.6045
-------------+------------------------------           Adj R-squared =  0.5951
       Total |  369446.851    86  4295.89361           Root MSE      =  41.707

------------------------------------------------------------------------------
    totalend |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
totalinitial |   .9653842    .087978    10.97   0.000     .7904303    1.140338
       group |   18.10429   8.967288     2.02   0.047     .2718549    35.93673
       _cons |  -6.123675   15.07479    -0.41   0.686    -36.10155     23.8542
------------------------------------------------------------------------------
```





stnum	group	totalstart	totalend	diff
242	VI	190	282	92
322	VI	28	155	127
532	VI	48	240	192
890	VI	140	280	140
913	VI	114	210	96
2061	VI	140	45	-95
2068	VI	90	186	96
2382	CC	0	132	132

```
. ttest totalinitial, by(group)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      43    65.27907    6.599131     43.2734    51.96148    78.59666
      VI |      44    72.70455    8.786977    58.28621    54.98392    90.42517
---------+--------------------------------------------------------------------
combined |      87    69.03448    5.495143    51.25528     58.1105    79.95846
---------+--------------------------------------------------------------------
    diff |           -7.425476     11.0261               -29.34831    14.49736
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -0.6734
Ho: diff = 0                     degrees of freedom =       85

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.2512         Pr(|T| > |t|) = 0.5025          Pr(T > t) = 0.7488


. ttest totalend, by(group)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      43          75    7.274784    47.70395    60.31889    89.68111
      VI |      44    100.2727    11.72218    77.75614     76.6327    123.9128
---------+--------------------------------------------------------------------
combined |      87    87.78161    7.026954    65.54307    73.81249    101.7507
---------+--------------------------------------------------------------------
    diff |           -25.27273    13.86896               -52.84794     2.30249
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -1.8223
Ho: diff = 0                     degrees of freedom =       85

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0360         Pr(|T| > |t|) = 0.0719          Pr(T > t) = 0.9640


. gen diff=totalend-totalinitial
```

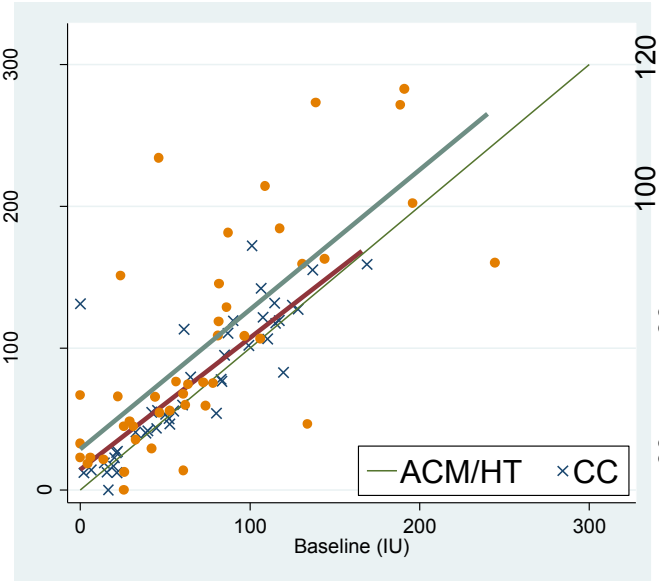
Appendix U

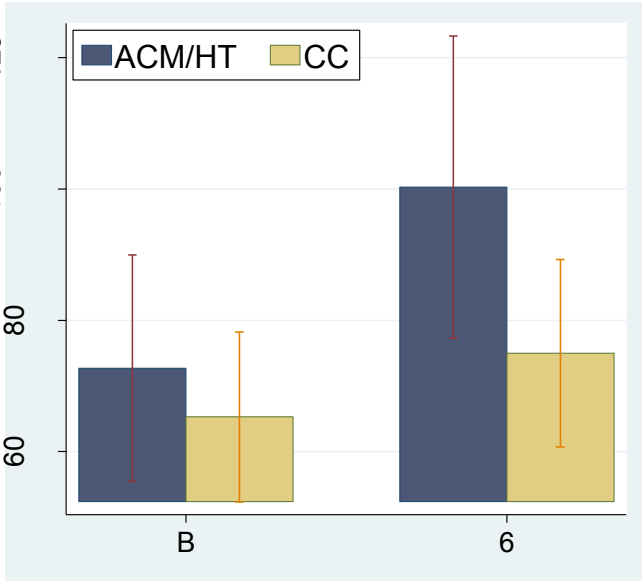
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

```
. ttest diff, by(group)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      43     9.72093    3.954241    25.92969    1.740949    17.70091
      VI |      44    27.56818    7.902177    52.41711    11.63192    43.50444
---------+--------------------------------------------------------------------
combined |      87    18.74713    4.526651    42.22179    9.748442    27.74581
---------+--------------------------------------------------------------------
    diff |           -17.84725    8.898885               -35.54062   -.1538846
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -2.0056
Ho: diff = 0                     degrees of freedom =       85

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0240         Pr(|T| > |t|) = 0.0481          Pr(T > t) = 0.9760
```

Only restricted subjects always on insulin during phase I.

```
. reg totalend totalinitial group

      Source |       SS       df       MS              Number of obs =      77
-------------+------------------------------           F(  2,    74) =   56.31
       Model |  192657.429     2  96328.7143           Prob > F      =  0.0000
    Residual |  126592.104    74  1710.70411           R-squared     =  0.6035
-------------+------------------------------           Adj R-squared =  0.5928
       Total |  319249.532    76  4200.65174           Root MSE      =  41.361

------------------------------------------------------------------------------
    totalend |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
totalinitial |   .9933262   .0992256    10.01   0.000     .7956149    1.191037
       group |   21.29123    9.50255     2.24   0.028     2.356985    40.22547
       _cons |   -13.7873   15.98554    -0.86   0.391    -45.63918    18.06459
------------------------------------------------------------------------------
```





```
. ttest totalinitial, by(group)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      39    71.66667     6.43847    40.20823    58.63267    84.70067
      VI |      38    83.65789    8.937771    55.09612    65.54825    101.7675
---------+--------------------------------------------------------------------
combined |      77    77.58442     5.49216    48.19351    66.64583      88.523
---------+--------------------------------------------------------------------
    diff |           -11.99123    10.97121                -33.847    9.864545
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -1.0930
Ho: diff = 0                                     degrees of freedom =       75

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.1390         Pr(|T| > |t|) = 0.2779          Pr(T > t) = 0.8610

. ttest totalend, by(group)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      39    78.69231    7.265651    45.37397    63.98377    93.40085
      VI |      38    111.8947    12.50313    77.07448    86.56099    137.2285
---------+--------------------------------------------------------------------
combined |      77    95.07792    7.386062    64.81244     80.3673    109.7885
---------+--------------------------------------------------------------------
    diff |           -33.20243    14.36885               -61.82665   -4.578213
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -2.3107
Ho: diff = 0                                     degrees of freedom =       75

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0118         Pr(|T| > |t|) = 0.0236          Pr(T > t) = 0.9882

. gen diff=totalend-totalinitial

. ttest diff, by(group)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      39    7.025641    2.906665    18.15212    1.141406    12.90988
      VI |      38    28.23684    9.007618    55.52668    9.985675    46.48801
---------+--------------------------------------------------------------------
combined |      77    17.49351    4.807633    42.18681    7.918275    27.06874
---------+--------------------------------------------------------------------
    diff |           -21.2112    9.364988               -39.86721   -2.555189
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -2.2649
Ho: diff = 0                                     degrees of freedom =       75

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0132         Pr(|T| > |t|) = 0.0264          Pr(T > t) = 0.9868

gen bigdiff=2 if diff>40
replace bigdiff=1 if diff<-40
replace bigdiff=0 if bigdiff==.
```

```
           |            bigdiff
   intvass |         0        <-40       >40 |     Total
-----------+---------------------------------+----------
        CC |        40           0          3 |        43
        VI |        29           3         12 |        44
-----------+---------------------------------+----------
     Total |        69           3         15 |        87

. xi:reg lab3 lab1 group i.bigdiff

i.bigdiff         _Ibigdiff_0-2       (naturally coded; _Ibigdiff_0 omitted)

      Source |       SS       df       MS              Number of obs =      87
-------------+------------------------------           F(  4,    82) =    9.24
       Model |  47.7487422     4  11.9371855           Prob > F      =  0.0000
    Residual |   105.98635    82  1.29251647           R-squared     =  0.3106
-------------+------------------------------           Adj R-squared =  0.2770
       Total |  153.735092    86  1.78761735           Root MSE      =  1.1369

------------------------------------------------------------------------------
        lab3 |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
        lab1 |   .4599742   .0835414     5.51   0.000     .2937838    .6261646
       group |   -.516744   .2594746    -1.99   0.050    -1.032922   -.0005663
 _Ibigdiff_1 |  -.8631399   .7116299    -1.21   0.229    -2.278798    .5525186
 _Ibigdiff_2 |  -.7793267   .3518987    -2.21   0.030    -1.479365   -.0792881
       _cons |   4.969597   .8820975     5.63   0.000     3.214824     6.72437
------------------------------------------------------------------------------
```

Blood pressure (# of changes in phase 1)

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      31    1.935484    .3244035    1.806202    1.272964    2.598004
      VI |      42    3.142857    .3773054    2.445219    2.380873    3.904841
---------+--------------------------------------------------------------------
combined |      73    2.630137    .2649681    2.263888    2.101933    3.158341
---------+--------------------------------------------------------------------
    diff |           -1.207373    .5204543               -2.24513   -.1696169
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -2.3198
Ho: diff = 0                                     degrees of freedom =       71

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.0116         Pr(|T| > |t|) = 0.0232          Pr(T > t) = 0.9884


------------------------------
> group = CC

     change |      Freq.     Percent        Cum.
------------+-----------------------------------
    otherva |         12       20.00       20.00
    subject |          2        3.33       23.33
          9 |         46       76.67      100.00
------------+-----------------------------------
      Total |         60      100.00

------------------------------
```

Appendix U

```
-> group = VI

     change |      Freq.     Percent        Cum.
------------+-----------------------------------
studyperson |         35       26.52       26.52
    otherva |         13        9.85       36.36
      nonva |          1        0.76       37.12
    subject |          1        0.76       37.88
          9 |         82       62.12      100.00
------------+-----------------------------------
      Total |        132      100.00
```

CHO(# of changes in phase 1)

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      21    1.142857    .1043281    .4780914    .9252325    1.360482
      VI |      32       1.375    .1603298    .9069623    1.048005    1.701995
---------+--------------------------------------------------------------------
combined |      53    1.283019     .105637    .7690493    1.071043    1.494995
---------+--------------------------------------------------------------------
    diff |           -.2321429    .2156479               -.6650741    .2007884
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -1.0765
Ho: diff = 0                                     degrees of freedom =       51

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.1434         Pr(|T| > |t|) = 0.2868          Pr(T > t) = 0.8566


------------------------------
-> group = CC

     change |      Freq.     Percent        Cum.
------------+-----------------------------------
    otherva |          2        8.33        8.33
          9 |         22       91.67      100.00
------------+-----------------------------------
      Total |         24      100.00

------------------------------
-> group = VI

     change |      Freq.     Percent        Cum.
------------+-----------------------------------
studyperson |          9       20.45       20.45
    otherva |          3        6.82       27.27
    subject |          3        6.82       34.09
          9 |         29       65.91      100.00
------------+-----------------------------------
      Total |         44      100.00
```

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

CHO(# of changes in phase 1)

```
Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
      CC |      31    1.774194    .1895647    1.055452    1.387051    2.161336
      VI |      31    1.806452    .2095533    1.166743    1.378487    2.234417
---------+--------------------------------------------------------------------
combined |      62    1.790323    .1401387    1.103454    1.510098    2.070547
---------+--------------------------------------------------------------------
    diff |           -.0322581    .2825728               -.5974878    .5329717
------------------------------------------------------------------------------
    diff = mean(CC) - mean(VI)                                    t =  -0.1142
Ho: diff = 0                                     degrees of freedom =       60

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.4547         Pr(|T| > |t|) = 0.9095          Pr(T > t) = 0.5453

------------------------------
-> group = CC

     change |      Freq.     Percent        Cum.
------------+-----------------------------------
    otherva |         34       21.38       21.38
      nonva |          3        1.89       23.27
    subject |          5        3.14       26.42
          9 |        117       73.58      100.00
------------+-----------------------------------
      Total |        159      100.00

------------------------------
-> group = VI

     change |      Freq.     Percent        Cum.
------------+-----------------------------------
studyperson |         47       33.10       33.10
    otherva |          6        4.23       37.32
      nonva |          2        1.41       38.73
          9 |         87       61.27      100.00
------------+-----------------------------------
      Total |        142      100.00
```

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I
Summary for Viterion data in phase 1 (most finished phase I)

Viterion blood glucose data

1. The first data transmitted in the class are excluded.

There are totally 64 subjects in the ACM group. Among them, 5 subjects never transmitted any data after the class. (275,408,2109,2161,2294(maxn=2))

2. The following frequency measures how many blood glucose values checked per day from the first checking date to the last checking date in phase 1.

```
       freq |      Freq.     Percent        Cum.
------------+-----------------------------------
      never |          5        7.81        7.81
       <1/d |          8       12.50       20.31
  [1-1.5)/d |         21       32.81       53.13
  [1.5-2)/d |         10       15.63       68.75
    [2-3)/d |         16       25.00       93.75
    [3-4)/d |          4        6.25      100.00
------------+-----------------------------------
      Total |         64      100.00
```

Treat it as continuous variable

```
. xi: reg lab3 lab1 averagen

      Source |       SS       df       MS              Number of obs =      64
-------------+------------------------------           F(  2,    61) =   11.04
       Model |  24.3960355     2  12.1980177           Prob > F      =  0.0001
    Residual |  67.4151583    61  1.10516653           R-squared     =  0.2657
-------------+------------------------------           Adj R-squared =  0.2416
       Total |  91.8111938    63  1.45732054           Root MSE      =  1.0513

------------------------------------------------------------------------------
        lab3 |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
        lab1 |   .3641503   .0825292     4.41   0.000      .199123    .5291775
    averagen |  -.2996145   .1615131    -1.86   0.068      -.62258     .023351
       _cons |   4.854891   .8288533     5.86   0.000     3.197497    6.512286
------------------------------------------------------------------------------
```

Treat it as categorical variable

```
. xi: reg lab3 lab1 i.freq

      Source |       SS       df       MS              Number of obs =      64
-------------+------------------------------           F(  6,    57) =    3.28
       Model |  23.6192947     6  3.93654911           Prob > F      =  0.0077
    Residual |   68.367569    57  1.19943104           R-squared     =  0.2568
-------------+------------------------------           Adj R-squared =  0.1785
       Total |  91.9868637    63  1.46010895           Root MSE      =  1.0952

------------------------------------------------------------------------------
        lab3 |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
        lab1 |   .3533563   .0866566     4.08   0.000     .1798294    .5268831
    _Ifreq_1 |  -.1173524   .6246566    -0.19   0.852    -1.368206    1.133501
    _Ifreq_2 |  -.4582069   .5454791    -0.84   0.404     -1.55051    .6340961
    _Ifreq_3 |   -.660016     .59986    -1.10   0.276    -1.861215     .541183
    _Ifreq_4 |  -.6397197   .5620702    -1.14   0.260    -1.765246    .4858066
    _Ifreq_5 |  -.9392288   .7347528    -1.28   0.206    -2.410546    .5320882
       _cons |    4.99851   .9504684     5.26   0.000      3.09523     6.90179
------------------------------------------------------------------------------
```

Appendix U

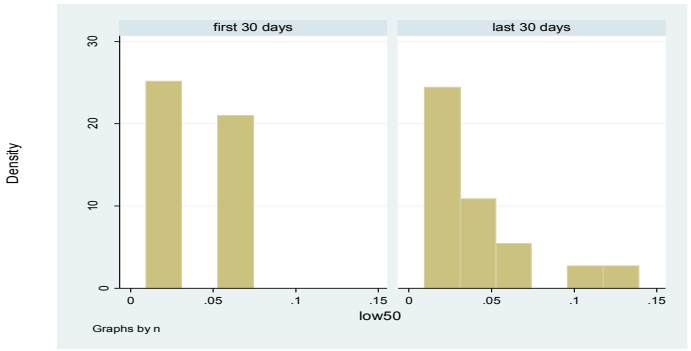
In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I

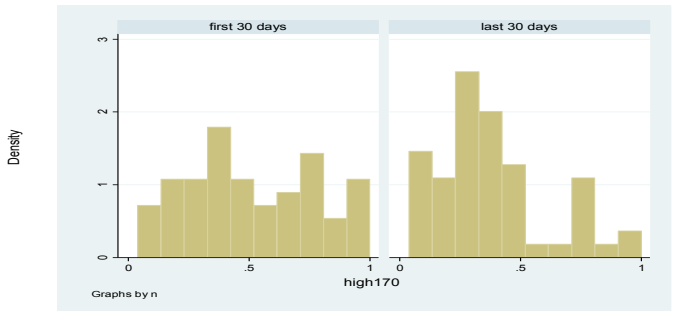
Paired t-test

```
. ttest low50first=low50last if low50first>0 | low50last>0

Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
low50f~t |      23     .018438    .0053274    .0255493    .0073897    .0294864
low50l~t |      23    .0297127    .0068222     .032718    .0155643     .043861
---------+--------------------------------------------------------------------
    diff |      23   -.0112746    .0098906    .0474336   -.0317864    .0092372
------------------------------------------------------------------------------
     mean(diff) = mean(low50first - low50last)                     t =  -1.1399
 Ho: mean(diff) = 0                              degrees of freedom =       22

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.1333         Pr(|T| > |t|) = 0.2666          Pr(T > t) = 0.8667

. ttest high170first=high170last if high170first>0 | high170last>0

Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
high~rst |      59    .5069016    .0356424    .2737745    .4355556    .5782477
high~ast |      59    .3668386    .0312512    .2400454    .3042824    .4293947
---------+--------------------------------------------------------------------
    diff |      59    .1400631    .0348952    .2680355    .0702126    .2099135
------------------------------------------------------------------------------
     mean(diff) = mean(high170first - high170last)                 t =   4.0138
 Ho: mean(diff) = 0                              degrees of freedom =       58

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.9999         Pr(|T| > |t|) = 0.0002          Pr(T > t) = 0.0001
```

Appendix U

In-Home Diabetes Care Management/Coordination Program for Veterans: DiaTel Study, Phase I





Appendix V

Deliverable #173: In-home Diabetes Care Management/Coordination Program for Veterans

Contract #:	W81XWH-04-2-0030
Funding Year:	2005
Initiative:	In-home Diabetes Care Management/Coordination Program for Veterans
Goal:	Goal 1 b/c
Date Sent:	03/15/2008
Description:	Final Report

In-Home Diabetes Care Management/Coordination Program for Veterans: The Diabetes Telemonitoring (DiaTel) Study, Phase II

Final Report (FY05)
February 18, 2008

Frederick R. DeRubertis, MD; Principal Investigator

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ABSTRACT

Objective. The objective of Phase II of the DiaTel Study was to ascertain the intensity of subsequent management required to sustain improvements in glycemic, blood pressure (BP), and lipid control among consenting participants from Phase I of the DiaTel Study (separate report).

Research Design and Methods. Phase I of the DiaTel Study was a randomized controlled trial of 137 veterans with diabetes and poor glucose control who received primary care at the VA Pittsburgh Healthcare System (VAPHS) between June 2004 and December 2005. Consenting eligible veterans were randomized to either Active Care Management plus Home Telemonitoring (ACMHT) or Care Coordination (CC). In ACMHT, the Viterion 100 TeleHealth Monitor was used to relay home blood glucose, BP and weight measurements to a nurse practitioner (CRNP) at the VAPHS who actively managed medications. In CC, standard primary care was enhanced via monthly telephone calls from a study nurse who made referrals to a primary care provider (PCP) as needed. After 6 months of follow-up, the ACM+HT participants showed a significantly greater reduction in the primary outcome, HbA1c, than did CC participants. Upon completion of Phase I, participants were asked for their consent to be re-randomized and followed for an additional 6 months. Consenting Phase I ACMHT participants were randomized to either CC plus home telemessaging (CCHT), which was ACMHT without the active medication management by the nurse practitioner, or CC (as in Phase I). Consenting Phase I CC participants were randomized to either continued CC or back to standard care by their PCP, referred to as usual care (UC). Effectiveness of the intervention was assessed at the 9- and 12-month clinic visits in terms of mean difference at 9 and 12 months and differential change over time for HbA1c, BP, lipids, and weight. Secondary outcomes included quality of life, satisfaction with care, and resource utilization. We also described use of oral hypoglycemic, antihypertensive, and lipid-lowering medications as well as insulin. Analyses focused on pairwise comparisons of the ACMHT-to-CCHT and ACMHT-to-CC arms in order to assess the continued use of the Viterion telehealth messaging and monitoring in the absence of active drug management by a CRNP, and the ACMHT-to-CC in order to assess the carry-over effect of the initial experience with the Viterion telehealth monitoring. The CC-to-CC and CC-to-UC arms were designed to assess the effects of frequent nurse contact and/or "attention control" factors.

Results. The mean HbA1c levels at 12 months were inversely related to the intensity of the intervention, i.e., lowest (8.03%) for ACMHT-CCHT, 8.16% for ACMHT-CC, 8.71% for CC-CC, and highest (8.84%) for CC-UC. However, these differences were not statistically significant. There were significant decreases in cholesterol from 6 to 12 months in the CC-CC arm relative to both the ACMHT-CC ($p=0.01$) and CC-UC ($p=0.04$) arms. Other differences among the treatment arms were generally small and not significant.

Conclusions. The data demonstrate that marked improvements in glycemic control achieved in the ACMHT participants during DiaTel Phase I can be sustained for at least six months after active medication management by a CRNP is discontinued. Moreover, there were no apparent benefits to glycemic control from continued transmission of glucose data via a home telemedicine device. The smaller improvements in glycemic control achieved in the CC participants during DiaTel Phase I were also sustained for at least six months even upon return to UC.

INTRODUCTION

More than 650,000 veterans receive care for diabetes within the Veterans Health Administration (VHA) each year.[1] According to local performance measures at the initiation of this study, 25% of veterans in the VA Pittsburgh Healthcare System (VAPHS) had HbA1c levels $\geq$ 8%, indicating suboptimal glycemic control.[2] Suboptimal glycemic control is associated with increased morbidity and mortality due to micro- and macrovascular disease.[3-5]

It is often difficult to achieve diabetic treatment targets under conditions of usual primary medical care, typically a 20-minute patient encounter every three or four months with a primary care practitioner (PCP). Our Diabetes Telemonitoring (DiaTel) Study, Phase I, in the VAPHS assessed two strategies to improve glycemic, blood pressure (BP), and lipid control in diabetics with suboptimal glycemic control.[6] We compared Active Care Management plus Home Telemonitoring (ACMHT) with Care Coordination (CC). ACMHT used a home telemonitoring support system (Viterion 100) which enabled daily transmission to and review of blood glucose and BP values by a certified registered nurse practitioner (CRNP) who made frequent adjustments of therapy. CC was enhanced usual care (UC) that involved a monthly telephone call from a project nurse, certified in diabetes education, and referral to a PCP as needed. In Phase I of the DiaTel study, 137 participants randomized to the two study arms were followed for 6 months. This study demonstrated that compared to CC, the ACMHT intervention was associated with a significantly greater reduction in HbA1c of 0.9% at 3 and 6 months, with most of the benefit achieved by 3 months.[6] However, glycemic control improved significantly in both groups compared to baseline.

The objective of Phase II of the DiaTel study was to assess the intensity of subsequent intervention required for sustaining improvements in glycemic, BP, and lipid control in participants from Phase I. Consenting subjects from the Phase I ACMHT arm were randomized to either CCHT or CC, alone, while consenting subjects from the Phase I CC arm were randomized to either CC or UC. CCHT involved monthly telephone calls but no active management by the CRNP; CCHT participants continued to transmit home blood glucose, BP, and weight daily to the project office, but abnormal values were referred to their PCP for possible therapeutic intervention. CC was defined as in Phase I; UC was referral back to the PCP for routine care. The primary aim of Phase II was to assess whether glycemic, BP, and lipid control at the end of an additional 6 months of follow-up differed for participants randomized to the four groups specified above (i.e., ACMHT-to-CCHT, ACMHT-to-CC, CC-to-CC, and CC-to-UC). We hypothesized that better control would be achieved by the more intensive intervention approaches. Specifically, we hypothesized that:

1. better control would be sustained by participants in ACMHT-to-CCHT relative to participants in ACMHT-to-CC (i.e., the continued use of the Viterion telehealth messaging and monitoring would be effective in the absence of active drug management by a CRNP);
2. better control would be sustained by participants in the ACMHT-to-CC arm relative to participants in the CC-to-CC arm (i.e. the initial experience with the Viterion telehealth monitoring would have a carry-over effect); and

3. better control would be sustained by participants in the CC-to-CC arm relative to participants in the CC-to-UC arm (i.e. more frequent nurse contact and/or "attention control" would be beneficial to participants).

In addition, we conducted secondary analyses to assess differences in the treatment arms with respect to satisfaction with care, health-related quality of life, and resource use. We also described changes in the medication regimens over the course of the study.

RESEARCH DESIGN AND METHODS

Design. Phase II was a continuation of the DiaTel Study Phase I trial, a randomized clinical trial of veterans with type 2 diabetes who received care for from the Primary Care Division in the VAPHS (3 divisions and 5 community-based outpatient clinics). Participants who completed the 6 month visit of DiaTel Phase I were invited to participate in this Phase II study. Participants who consented were re-randomized to subsequent management at the same or lower intensity as in Phase I, and followed for an additional 6 months (Figure 1). The study was reviewed and approved by the VAPHS Institutional Review Board. All participants provided signed informed consent.

Sample. Participants were veterans who met all of the DiaTel entry criteria at the time of their enrollment in the Phase I trial and completed their 6-month visit. The entry criteria were: (1) had at least one outpatient visit in a primary care clinic at VAPHS between June 1, 2004 and December 31, 2005, (2) received ongoing pharmacologic treatment for diabetes for 12 or more months prior to the index visit, and (3) had a most recent HbA1c of at least 8.0%. Veterans were excluded if they had been referred to the VAPHS Diabetes Clinic, had a life expectancy of less than 5 years, were 80 years of age or older, were participating in another study, resided in an institutional setting (e.g. a nursing home, personal care home, or prison), or had home telephone equipment that was incompatible with the Viterion device.

Interventions

Care Coordination with Home Telemonitoring (CCHT). CCHT participants continued to use the Viterion 100 Monitoring system, including: (1) continuous home messaging, with participant reminders and education; (2) ongoing monitoring at home of blood glucose, BP, and weight; and (3) daily transmission, to the extent possible, of the home monitoring data via a secure network to the study CRNP. The Viterion home monitor was connected to the subject's telephone landline. Text messages and reminders for measurements were sent from the project office to the subject's home. Subjects were asked to use peripheral devices connected to the Viterion monitor to measure and transmit their blood glucose, BP, and weight. However, active management of glycemia, BP, and lipids by the CRNP was discontinued; the study CRNP reviewed these data daily (Monday through Friday) and informed the study physician and PCP of any critical values. CCHT participants continued to receive monthly telephone calls consistent with CC as described below. This study arm was similar to the national VHA effort in CCHT.

Care Coordination (CC). CC involved monthly monitoring of participants via telephone by a study RN who inquired about general health conditions, status of diabetes, BP, weight control, and compliance with diet, exercise, smoking cessation, and prescribed medication. The

study nurse was a certified diabetes educator and answered general questions about diabetes, diet, exercise, and medications during the monthly telephone call or more frequently when participants initiated unscheduled contact. If participants reported any issues regarding their health or diabetes, they were directed to contact their PCP. Progress notes were entered in the VA Computerized Patient Record System (CPRS) and forwarded to the PCP.

For the CCHT and CC participants, the PCPs were informed of the following circumstances that might indicate that the participant should be evaluated for a possible change in medication regimen: (1) BP exceeding 190/110 for those subjects doing home BP monitoring, or possible symptomatic hypotension as reflected by postural dizziness or postural syncope, (2) a sustained increase or decrease of 20 mmHg in systolic and/or diastolic readings for five consecutive days, (3) a single blood glucose < 50 or multiple glucoses in excess of 300 for 72 hours, and (4) blood glucose trends over 14 days representing an increase in HbA1c of 1%.

Usual Care (UC). Participants randomized to UC were managed according to standard care practices operative within the Primary Care Clinics of VAPHS. Their only contact with study personnel were at the 9 and 12 month follow-up assessments. For all treatment arms, the subject's PCP was responsible for any interventions using FDA-approved drugs in the VAPHS formulary for the treatment of diabetes, hypertension, and hyperlipidemia.

Measures. Phase I final assessments at 6 months served as the baseline for Phase II. Additional measurement visits were made at 9 and 12 months. As in Phase I, participants presented to the VAPHS for measurement of BP, HbA1c, and fasting lipid panel. Secondary outcome measures were (1) the proportion of subjects in each treatment arm with HbA1c $\leq$ 7%, BP $\leq$ 130/80, LDL-cholesterol $\leq$100 mg/dl, and triglycerides $\leq$150 mg/dl at 9 and 12 months.

Other outcome measures and data collection instruments were a subset of those for Phase I: health-related quality of life was assessed using both the Medical Outcomes Study 12-Item Short Form Health Survey (SF-12) and the Problem Areas in Diabetes (PAID) questionnaire, and satisfaction with care was assessed using the Diabetes Treatment Satisfaction Questionnaire (DTSQ). Resource use data within the VAPHS (number of outpatient clinic visits, emergency room visits, and hospitalizations) were collected by electronic medical record review in VistA. Non-VA resource use was ascertained by subject interview at the 9 and 12 month follow-up visits. Changes in the medication regimen (medications and/or dosage) were tracked using the VA CPRS data from this clinical trial. Each outcome was considered separately, and all participants were included to the extent possible. We used a modified multiple imputation algorithm as in Phase I to account for truncated HbA1c values. We also used multiple imputation to include participants with missing data for other variables; however, due to the very small number of missing values, the average of the imputed values was used in the analysis.

The primary analysis focused on HbA1c, BP, and lipid levels at 9 and 12 months and differential changes over time. These hypotheses were tested using pair-wise comparisons of the following pairs of treatment arms:

(1) ACMHT-to-CCHT and ACMHT-to-CC
(2) ACMHT-to-CC and CC-to-CC
(3) CC-to-CC and CC-to-UC

These pairwise comparisons were based on two-sample t-tests made at the 0.05 level, with no adjustment for multiple comparisons. Changes over time within a treatment arm were assessed using paired t-tests. Other continuous outcomes were analyzed using similar methods. Presented below are profile plots of the continuous outcomes by intervention arm at each timepoint, with the mean levels connected by lines. The proportions of subjects who achieve (or maintain) adequate control of HbA1c, BP, LDL-cholesterol, and triglycerides at 9 and 12 months according to recommended target values are also described. These proportions were compared using chi-squared statistics.

RESULTS

Enrollment and randomization. Of the 137 participants who completed Phase I, 101 (44/64 (68.8%) from the ACMHT arm and 57/73 (78.1%) from the CC arm) consented to participate in Phase II**.** Baseline characteristics of patients who did and did not consent to participate in Phase II are summarized by Phase I treatment arm in Table 1. There were no statistically significant differences between Phase II participants and non-participants in either Phase I treatment arm, although there is some indication that relatively more African Americans in the ACMHT arm continued on in Phase II (p=0.06).

Among consenting Phase I ACMHT participants, 23 (52.2%) were randomized to CCHT and 21 (47.7%) were randomized to CC. Among consenting Phase I CC participants, 28 (49.1%) were randomized to CC and 29 (50.9%) were randomized to UC (Figure 1).

Follow-up: Follow-up at 9 and 12 months is summarized in Table 2. The 7 missing assessments (3 at 9 months and 4 at 12 months) all occurred among participants in the CC-UC arm. There were 2 right-truncated HbA1c values, and very little missing HbA1c data.

Medication use. CC-CC participants were somewhat less likely to be taking insulin at all three timepoints than participants in the other treatment arms (Table 3). The vast majority of participants in all four treatment arms were taking antihypertensive and lipid lowering medications at 6, 9 and 12 months. None of the pairwise comparisons in Table 3 was statistically significant (p>0.14 for each).

Impact of the interventions on primary outcomes.

HbA1c. The mean HbA1c over time is shown by treatment arm in the first panel of Figure 2. The baseline, 3 and 6 month measurements reflect Phase I of the study for those participants who continued on to Phase II; participants in Phase II were randomized after their 6 month follow-up, so the 6-month measurement serves as the reference point for Phase II. HbA1c was significantly lower for the ACMHT-CCHT participants at 6 months than for participants in either of the CC arms in Phase I (p=0.02 for each pairwise comparison). At 6 months, there were no significant differences between ACMHT-CCHT and ACMHT-CC, ACMHT-CC and CC-CC, or CC-CC and CC-UC (p>0.10 for each, Table 4). The mean HbA1c values at 12 months are inversely associated with the intensity of the treatment arm, i.e. lowest for ACMHT-CCHT (8.03%), then ACMHT-CC (8.16%), then CC-CC (8,71%), and highest for CC-UC (8.84%); however, ACMHT-CCHT was not significantly lower than ACMHT-CC (p=0.67), ACMHT-CC

was not significantly lower than CC-CC (p=0.11), and CC-CC was not significantly lower than CC-UC (p=0.72).

Although trajectories generally increased over time after 6 months, there was little evidence of differential change over time between the ACMHT-CCHT and ACMHT-CC, ACMHT-CC and CC-CC, or CC-CC and CC-UC arms (p>0.50 for each comparison, except for the slope between 6 and 9 months comparing CC-CC and CC-UC; Table 5). The only within-treatment arm change that approached statistical significance was an increase in mean HbA1c of 0.35% in the CC-UC arm between 6 and 9 months (p=0.06; Table 6).

The HbA1c distributions across time are shown by treatment arm in Figure 3(a). About 14% of the participants in each treatment arm met the ADA target value of HbA1c≤7% at 12 months (p>0.90 for each of the three pairwise treatment comparisons).

Systolic BP. There were no significant differences in systolic BP by treatment arm at 6 months (p>0.14 for each pairwise comparison; second panel, Figure 2). At 9 and 12 months, no significant differences were observed between mean systolic BP between the ACMHT-CCHT and ACMHT-CC arms, the ACMHT-CC and CC-CC arms, or the CC-CC and CC-UC arms (p>0.34 for each, Table 4). There was no evidence of differential drop over time between any of these pairs of treatment arms (p>0.32 for each; Table 5). The only significant within-arm change over time was a mean decrease in systolic BP of 5.93 mmHg in the CC-CC arm between 9 and 12 months (p>0.05; Table 6); the mean decrease of 6.07 mmHg in the CC-UC arm between 6 and 12 months did not reach statistical significance (p=0.08).

The systolic BP distributions across time are shown by treatment arm in Figure 3(b). At 12 months, the target value of systolic BP ≤ 130 mmHg was met by 47.8% of participants in the ACMHT-CCHT arm, 61.9% in the ACMHT-CC arm, 60.7% in the CC-CC arm, and 53.9% in the CC-UC arm (p>0.34 for the three pairwise comparisons).

Diastolic BP. There is some evidence that mean diastolic BP was lower for participants in the ACMHT-CC arm than the CC-UC arm at 6 months (p=0.057; third panel, Figure 2). At 9 and 12 months, no significant differences were observed in mean diastolic BP between the ACMHT-CCHT and ACMHT-CC arms, the ACMHT-CC and CC-CC arms, or the CC-CC and CC-UC arms (p>0.41 for each, Table 4). Between 6 and 12 months, mean diastolic BP decreased by 2.96 mmHg in the CC-CC arm and increased by 2.90 mmHg in the ACMHT-CC arm (p=0.04 for the differential drop over time; Table 5). The only significant within-arm change was a decrease in mean diastolic BP of 6.18 mmHg in the CC-UC arm between 6 and 12 months (p=0.01; Table 6).

The diastolic BP distributions across time are shown by treatment arm in Figure 3(c). At 12 months, the target value of diastolic BP ≤ 80 mmHg was met by 91.3% of participants in the ACMHT-CCHT arm, 85.7% in the ACMHT-CC arm, 71.4% in the CC-CC arm, and 84.6% in the CC-UC arm (p>0.22 for the three pairwise comparisons).

Weight. At 6 months, participants in the CC-CC arm were on average about 30 pounds lighter than participants in the ACMHT-CCHT and CC-UC arms (p=0.01 and 0.02, respectively;

fourth panel, Figure 2). These differences persisted over time (p=0.03 for CC-CC vs. CC-UC at 12 months; Table 4), with little evidence of differential change over time (p>0.18 for the three pairwise comparisons; Table 5). Participants in the CC-CC arm gained an average of 2.46 pounds between 6 and 12 months (p=0.04; Table 6). The weight distributions across time are shown by treatment arm in Figure 3(d).

Cholesterol. At 6 months, mean cholesterol was higher for participants in the CC-CC arm than in the ACMHT-CC arm (p=0.035; fifth panel, Figure 2). However, mean cholesterol levels continued to decrease in the CC-CC arm at 9 and 12 months while they generally increased in the other three arms. None of the three pairwise treatment comparisons was significantly different from zero at either 9 or 12 months (p>0.26 for each; Table 4). Compared to CC-UC participants, CC-CC participants showed differential drops in mean cholesterol of 20.3 mg/dl at 9 months and 18.8 mg/dl at 12 months (p=0.02 and 0.04, respectively; Table 5). CC-CC participants also had a differential drop of 24.4 mg/dl at 12 months, compared to ACMHT-CC participants (p=0.01). Increases in cholesterol between 6 and 12 months were similar in the ACMHT-CCHT and ACMHT-CC arms (p>0.23 for each). The only significant within-arm changes over time were a decrease of 14.07 mg/dl in the CC-CC arm between 6 and 12 months (p=0.04; Table 6) and increases of 15.35 mg/dl in the ACMHT-CCHT arm between 9 and 12 months (p=0.02) and 8.94 mg/dl in the CC-UC arm between 6 and 9 months (p=0.05). The increase of 10.33 mg/dl between 6 and 12 months in the ACMHT-CC arm approached statistical significance (p=0.07). The cholesterol distributions across time are shown by treatment arm in Figure 3(e).

HDL. At 6 months, mean HDL was about 7 mg/dl higher for participants in the CC-CC arm than in the ACMHT-CCHT arm (p=0.04; sixth panel, Figure 2). Except for participants in the CC-UC arm between 9 and 12 months, mean HDL increased in all arms after 6 months. With the possible exception of somewhat higher mean HDL in the CC-CC arm compared to the CC-UC arm at 12 months (39.89 mg.dl vs. 35.49 mg/dl, p=0.08; Table 4), the differences between ACMHT-CCHT and ACMHT-CC, ACMHT-CC and CC-CC, or CC-CC and CC-UC in either mean HDL at 9 or 12 months (p>0.14 for each; Table 4) or differential change across time (p>0.20 for each; Table 5) did not reach statistical significance. Significant within-treatment arm changes over time include increases in HDL from 6 to 12 months for the ACMHT-CCHT arm (3.61 mg/dl, p=0.03; Table 6) and the ACMHT-CC arm (2.90 mg/dl, p=0.01), and in CC-UC from 6 to 9 months (2.92 mg/dl, p=0.01). The HDL distributions across time are shown by treatment arm in Figure 3(f).

LDL. At 6 months, mean LDL was somewhat lower for ACMHT-CC participants compared to CC-CC participants (p=0.09; seventh panel, Figure 2); none of the other pairwise contrasts even approached statistical significance (p>0.15 for each). Mean profiles were similar to those for cholesterol; except for the CC-CC arm, mean LDL generally increased between 6 and 12 months. Although none of the three pairwise comparisons of mean LDL values was significantly different from zero at either 9 or 12 months (p>0.11; Table 4), the CC-CC arm showed a different trajectory than both ACMHT-CC and CC-UC between 6 and 12 months (p=0.05 for each; Table 5), and from CC-UC at 9 months as well (p=0.03).

The LDL distributions across time are shown by treatment arm in Figure 3(g). A majority of participants in each treatment arm met the triglyceride target of LDL ≤ 100 mg/dl at 12 months (60.9% of ACMHT-CCHT, 83.3% of ACMHT-CC, 76.0% of CC-CC, and 66.7% of CC-UC). None of the three pairwise comparisons was statistically significant (p>0.11 for each).

Triglycerides. Mean triglyceride levels were similar at 6 months (p>0.12 for each pairwise comparison; eighth panel, Figure 2). As for cholesterol and LDL, triglyceride levels decreased between 6 and 12 months in the CC-CC arm and generally increased in the other arms. None of the three pairwise comparisons of mean triglyceride values was significantly different from zero at either 9 or 12 months (p>0.20 for each; Table 4). The trajectories were somewhat different between 6 and 9 months for the ACMHT-CCHT and ACMHT-CC arms, with a decrease of 13.04 mg/dl in the ACMHT-CCHT arm and an increase of 21.92 mg/dl in the ACMHT-CC arm (p=0.08; Table 5). None of the within-arm changes over time was statistically significant (p>0.11 for each; Table 6).

The triglyceride distributions across time are shown by treatment arm in Figure 3(h). A majority of participants in the ACMHT-CC, CC-CC, and CC-UC treatment arms met the target triglyceride level ≤ 150 mg/dl at 12 months (47.8% in ACMHT-CCHT, 61.9% in ACMHT-CC, 60.7% in CC-CC, and 65.4% in CC-UC). None of the three pairwise comparisons was statistically significant (p>0.34 for each).

Impact of the intervention on secondary outcomes.

SF-12. Profile plots of the mean physical component scores (PCS) of the SF-12 are shown in the first panel of Figure 4. At 6 months, CC-CC participants had significantly higher PCS than ACMHT-CCHT and ACMHT-CC participants (8.11 points higher, p=0.01 [comparison not tabled] and 7.19 points higher, p=0.01 (Table 7), respectively) and non-significantly higher PCS than CC-UC participants (5.05 points, p=0.07). Mean PCS were significantly higher at both 9 and 12 months for CC-CC participants compared to ACMHT-CC participants (8.29 and 8.74 points higher, respectively, p≤0.01 for each). Mean PCS did not differ significantly between the ACMHT-CCHT and ACMHT-CC arms or between the CC-CC and CC-UC arms at either 9 or 12 months (p>0.15 for each). There was no significant differential change over time for any of the three treatment comparisons (p>0.13 for each; Table 8). The only borderline significant within-arm change was an increase of 2.76 points in mean PCS in the ACMHT-CCHT arm between 9 and 12 months (p=0.06; Table 9).

Profile plots of the mean mental component scores (MCS) of the SF-12 are shown in the second panel of Figure 4. There were no significant pair-wise differences at 6, 9, or 12 months (p>0.14 for each; Table 7). Mean MCS decreased 2.57 points between 6 and 12 months in the ACMHT-CCHT arm and increased 4.37 points in the ACMHT-CC arm (p=0.02; Table 8). The difference between the mean MCS increase of 4.71 points between 6 and 9 months in the CC-CC arm and the mean decrease of 1.52 points in the CC-UC arm approached statistical significance (p=0.07). The only significant within-arm change was the increase of 4.71 points between 6 and 9 months in the CC-CC arm (p=0.02; Table 9). The within-arm increases between 6 and 12 months in the ACMHT-CC and CC-CC arms were of borderline statistical significance (4.37 points, p=0.06 and 3.21 points, p=0.09, respectively).

PAID questionnaire. Profile plots of the mean PAID questionnaire scores are shown in the third panel of Figure 4. There were no significant differences between any of the treatment arms at 6 months ($p>0.51$ for each pairwise comparison). The ACMHT-CC arm consistently had the lowest mean scores. The 9.74 differential between the ACMHT-CC and CC-CC arms at 9 months was not statistically significant ($p=0.09$; Table 7), and neither were any of the other pairwise treatment comparisons at 9 or 12 months. The 5.57 point decrease between 6 and 9 months in the ACMHT-CC arm was not significantly different than the 0.78 point increase in the ACMHT-CCHT arm ($p=0.08$; Table 8) or the 0.36 point increase in the CC-CC arm ($p=0.09$). The difference between the 4.09 point drop in the ACMHT-CC arm and the 2.02 point increase in the CC-CC arm between 6 and 12 months was of borderline statistical significance ($p=0.07$). The only significant within-arm change over time was the 5.57 point drop in the ACMHT-CC arm between 6 and 9 months ($p=0.02$; Table 9).

DTSQ. Profile plots of the mean DTSQ scores are shown in the fourth panel of Figure 4. There were no significant differences between the Phase II participants in any of the treatment arms at 6 months ($p>0.09$ for each pairwise comparison). The largest mean DTSQ score, 31.07 points in the ACMHT-CCHT arm, was only 2.73 point larger than the smallest (CC-UC). There were no significant pair-wise differences at either 9 or 12 months ($p>0.14$ for each; Table 7), no differential changes over time ($p>0.12$ for each; Table 8), and no significant changes within any treatment arm over time ($p> 0.09$; Table 9).

Indices of resource use. (To be completed and submitted as an addendum to the report)

Insulin dosage adjustment. At 6 months, 16 (69.6%) of the ACMHT-CCHT participants, 16 (76.2%) of ACMHT-CC participants, 11 (39.3%) of CC-CC participants, and 22 (75.9%) of the CC-UC participants were on insulin (Figure 5). At 12 months, 1 of the ACMHT-CCHT participants and 1 of the CC-CC participants stopped taking insulin while 3 CC-CC participants started on insulin. The profile plot of mean insulin dosage over time is shown in Figure 6 for all Phase II participants who were taking insulin between 6 and 12 months. Although the mean insulin dose appears to be highest across time for the participants in the ACMHT-CC arm, none of the pairwise comparisons of means at 6, 9, or 12 months were statistically significantly different from zero ($p>0.21$; Table 10). There were no significant differential changes across time ($p>0.22$ for each pairwise comparison; Table 11). The only significant within-arm changes over time were an increase of 18.0 IUs in the mean insulin dosage for participants in the CC-UC arm between 6 and 12 months ($p=0.02$; Table 12) and an increase of 6.5 IUs for participants in the CC-CC arm between 9 and 12 months ($p=0.03$). The dosage distributions are shown for the three pairwise comparisons in Figure 7. Figure 8 shows a scatterplot of the insulin dosage at 6 and 12 months. With few exceptions, the data points cluster around the $y=x$ line for all four treatment arms.

DISCUSSION

None of the hypotheses regarding between group differences in HbA1c were supported by the data. However, there were a few findings pertaining to glycemic control worth noting. In particular, both ACMHT-CCHT and ACMHT-CC experienced only a slight increase in HbA1c from 6 to 12 months (0.26% and 0.19% respectively) following the cessation of active medication management by the CRNP. This finding is inconsistent with those of the Norris et al. meta-analysis, showing that intervention effects are generally lost within 2-3 months of an intervention being withdrawn.[7] The studies reviewed by Norris et al. differed from DiaTel in that they emphasized education and behavioral intervention methods. While the ACMHT intervention provided some education and behavioral counseling, the primary orientation of CRNP activities was titration of medications to real-time glucose transmissions. These findings suggest that a short-term ACMHT intervention for a period possibly as brief as 3 months, during which most improvement was observed, is an effective intervention approach for achieving and sustaining glycemic control for at least 12 months in veterans who have been unable to achieve HbA1c goals after 12 months or more of standard diabetes care.

Also notable is that the rate of increase in HbA1c from 6-12 months appeared to be consistent between the ACMHT-CCHT and ACMHT-CC groups. While long-term telemonitoring may be useful for purposes other than managing glycemia, these findings suggest that after initial improvements in glycemia are achieved with ACMHT, continued prompting and education via the home telemedicine device used in this study offered no significant advantage over a monthly phone call from a nurse coordinator. Whether improvement in glycemic control achieved in the ACMHT during the first 6 months of the study could have been sustained by a direct return to UC is not known. However, this possibility is suggested by the fact that the CC group did sustain the improvement in glycemic control which they achieved during the first 6 months of the study. That mean HbA1c values at 12 months were inversely associated with intensity of the treatment arm is consistent with the findings of Norris et al. that better glycemic control was achieved in interventions with more frequent contacts.[7]

None of the hypotheses regarding between group differences in the remaining primary outcomes of BP, weight, or lipids were supported by the data. This is not surprising given that participants were not required to have abnormal values of these variables at baseline and, thus, no improvements were observed. None of the hypotheses regarding between group differences in the secondary outcomes of quality of life, distress, or satisfaction with care were supported by the data.

Of note were the patterns observed in the CC-CC arm participants. Between 6 and 12 months, systolic BP in the CC-CC group declined nearly 6 mm/Hg. Steady reductions in total cholesterol, LDL, and triglycerides, and a steady rise in HDL after the third months of the study were observed in CC-CC. CC-CC participants also experienced an improvement between 6 and 9 months on the mental health component of the SF-12. While the reasons for these improvements are not entirely clear, these findings may be related to differences in continuity and the nature of follow-up contacts made by the study RN versus the CRNP. Participants in CC-CC received monthly calls from the same study RN for the 12-month duration of the study. Communication between the study RN and CC-CC participants was not driven by real-time glucose results and,

thus, the study RN-participant communications may have focused more generally on diabetes and lifestyle management.

Limitations. The major limitations of DiaTel Study Phase II were the relatively small size of the study groups and short duration of follow-up. The relatively small sample sizes in the four treatment arms limited our power to detect differences that could be clinically meaningful; it is uncertain whether improvements would have been sustained beyond the 6-month observation period.

Conclusion. The Phase I DiaTel Study suggests that improvements in glycemic control can be achieved in an abbreviated (3 month) telemonitoring intervention in which a CRNP titrates the medication in response to real-time transmissions of glucometer results. Phase II demonstrates that glycemic improvements are sustained for at least 6 months after active CRNP medication management is discontinued. The DiaTel Phase II data also suggest that improvement in glycemic control can be sustained without continued use of a home telemonitoring device. Moreover, the data support a sustained benefit in improvement of glycemic control when participants are returned to UC after a period of CC.

Thus, the DiaTel Study results shed light on the efficacy of different interventions for both achieving and sustaining improved glycemic control in veterans who have been unable to achieve HbA1c targets after a year or more of standard primary care.

TABLES

Table 1. Baseline characteristics of DiaTel Study Phase I patients who did and did not participate in Phase II, by Phase I treatment arm (Active Care Management plus Home Telemonitoring (ACMHT) and Care Coordination (CC)).

	ACMHT N=64				
	Not in Phase II N=18		In Phase II N=46		
Characteristics	**n***	**%**	**n***	**%**	**P-value**
Age group					0.27
<45 years	2	11.11	1	2.17	
45-65 years	9	50.00	29	63.04	
>=65 years	7	38.89	16	34.78	
Division/CBOC					0.58
UD	10	55.56	20	43.48	
HD	4	22.22	6	13.04	
AP	2	11.11	12	26.09	
AQ	0	0.00	2	4.35	
GB	0	0.00	2	4.35	
UN	0	0.00	0	0.00	
WA	0	0.00	1	2.17	
SC	2	11.11	3	6.52	
Gender					
Male	18	100.00	46	100.00	
Female	0	0.00	0	0.00	
Race					
White, not of Hispanic origin	16	88.89	30	65.22	0.06
Black, not of Hispanic origin	2	11.11	16	34.78	
Asian or Pacific Islander	0	0.00	0	0.00	
American Indian or Alaskan Native	0	0.00	0	0.00	
Employment status					0.85
Employed full-timed (>=35 hours/week)	2	11.11	3	6.52	
Employed part-timed (<35 hours/week)	2	11.11	6	13.04	
Homemaker, not working outside the home	0	0.00	2	4.35	
Retired	10	55.56	27	58.70	
Unemployed	4	22.22	8	17.39	
Marital status					
Single, never married	1	5.56	6	13.04	0.38
Married, or living as married	7	38.89	25	54.35	
Widowed	3	16.67	4	8.70	
Separated or divorced	7	38.89	11	23.91	
Living arrangement					0.76
Private residence (house or apartment), alone	7	38.89	16	34.78	
Private residence, with others	11	61.11	30	65.22	
Education					0.55
Grade school (year 1 through 8) or less	0	0.00	2	4.35	
Some high school	1	5.56	4	8.70	
Completed high school or GED	6	33.33	17	36.96	
Some college or association school	5	27.78	14	30.43	
Completed technical or vocational school	2	11.11	6	13.04	
Completed college or more	4	22.22	3	6.52	
Comorbidities					
CAD	7	38.89	18	39.13	0.89
CHF	4	22.22	9	19.57	0.81
COPD	2	11.11	2	4.35	0.31

Table 1. (continued)

	CC N=73				
	Not in Phase II N=18		In Phase II N=55		
Characteristics	**n***	**%**	**n***	**%**	**P-value**
Age group					0.11
<45 years	0	0.00	0	0.00	
45-65 years	8	44.44	36	65.45	
>=65 years	10	55.56	19	34.55	
Division/CBOC					0.20
UD	5	27.78	30	54.55	
HD	2	11.11	7	12.73	
AP	3	16.67	11	20.00	
AQ	1	5.56	1	1.82	
GB	2	11.11	1	1.82	
UN	1	5.56	2	3.64	
WA	1	5.56	1	1.82	
SC	3	16.67	2	3.64	
Gender					0.41
Male	18	100.00	53	96.36	
Female	0	0.00	2	3.64	
Race					0.33
White, not of Hispanic origin	14	77.78	45	81.82	
Black, not of Hispanic origin	3	16.67	9	16.36	
Asian or Pacific Islander	0	0.00	1	1.82	
American Indian or Alaskan Native	1	5.56	0	0.00	
Employment status					0.32
Employed full-timed (>=35 hours/week)	5	27.78	13	23.64	
Employed part-timed (<35 hours/week)	0	0.00	8	14.55	
Homemaker, not working outside the home	0	0.00	1	1.82	
Retired	12	66.67	26	47.27	
Unemployed	1	5.56	7	12.73	
Marital status					0.76
Single, never married	4	22.22	8	14.55	
Married, or living as married	8	44.44	32	58.18	
Widowed	1	5.56	3	5.45	
Separated or divorced	5	27.78	12	21.82	
Living arrangement					0.42
Private residence (house or apartment), alone	6	33.33	13	23.64	
Private residence, with others	12	66.67	42	76.36	
Education					0.76
Grade school (year 1 through 8) or less	0	0.00	7	12.73	
Some high school	2	11.11	4	7.27	
Completed high school or GED	8	44.44	22	40.00	
Some college or association school	4	22.22	8	14.55	
Completed technical or vocational school	3	16.67	10	18.18	
Completed college or more	1	5.56	9	16.36	
Comorbidities					
CAD	7	38.89	17	30.91	0.53
CHF	3	16.67	6	10.91	0.52
COPD	3	16.67	3	5.45	0.13

Table 2. Summary of missing assessments and missing or truncated HbA1c values at each Phase II follow-up visit, by treatment arm.

Missing assessments	Follow-up Visit		
Treatment arm	6-months	9-months	12-months
ACMHT-CCHT (N=23)	0	0	0
ACMHT-CC (N=21)	0	0	0
CC-CC (N=28)	0	0	0
CC-UC (N=29)	0	3	4
Total	0	3	4

	Missing or truncated HbA1c	Follow-up Visit		
Treatment arm		6-months	9-months	12-months
ACMHT-to-CCHT (N=23)	None	Complete		
ACMHT-CC (N=21)	Right-truncation	1	0	0
CC-CC (N=28)	None	Complete		
CC-UC (N=29)	Right-truncation	0	0	1
	Missing, have capillary HbA1c	0	0	1
	Missing, no capillary HbA1c	2	2	3
Total		3	2	5

Table 3. Number of Phase II participants on each type of medication at 6, 9, and 12 months, with pairwise comparisons by treatment arm

Type of medication	ACMHT-CCHT N=23			ACMHT-CC N=21		
	n	%		n	%	P-value
6-months						
Oral hypoglycemic agent	18	78.26		10	47.62	0.31
Insulin	16	69.57		16	76.19	0.85
Antihypertensive	22	95.65		18	85.71	0.80
Lipid lowering	21	91.30		16	76.19	0.69
9-months						
Oral hypoglycemic agent	18	78.26		12	57.14	0.51
Insulin	16	69.57		16	76.19	0.85
Antihypertensive	22	95.65		20	95.24	1.00
Lipid lowering	21	91.30		17	80.95	0.79
12-months						
Oral hypoglycemic agent	16	69.57		11	52.38	0.64
Insulin	14	60.87		16	76.19	0.64
Antihypertensive	22	95.65		20	95.24	0.99
Lipid lowering	21	91.30		16	76.19	0.69

Type of medication	ACMHT-CC N=21			CC-CC N=28		
	n	%		n	%	P-value
6-months						
Oral hypoglycemic agent	10	47.62		24	85.71	0.21
Insulin	16	76.19		11	39.29	0.17
Antihypertensive	18	85.71		25	89.29	0.92
Lipid lowering	16	76.19		22	78.57	0.94
9-months						
Oral hypoglycemic agent	12	57.14		24	85.71	0.37
Insulin	16	76.19		12	42.86	0.79
Antihypertensive	20	95.24		27	96.43	0.98
Lipid lowering	17	80.95		25	89.29	0.82
12-months						
Oral hypoglycemic agent	11	52.38		23	82.14	0.39
Insulin	16	76.19		13	46.43	0.29
Antihypertensive	20	95.24		27	96.43	0.98
Lipid lowering	16	76.19		25	89.29	0.71

Table 3. (continued)

Type of medication	CC-CC N=28			CC-UC N=29		
	n	%		n	%	P-value
6-months						
Oral hypoglycemic agent	24	85.71		19	65.52	0.51
Insulin	11	39.29		22	75.86	0.15
Antihypertensive	25	89.29		27	93.10	0.91
Lipid lowering	22	78.57		27	93.10	0.66
9-months						
Oral hypoglycemic agent	24	85.71		20	68.97	0.59
Insulin	12	42.86		22	75.86	0.59
Antihypertensive	27	96.43		28	96.55	1.00
Lipid lowering	25	89.29		27	93.10	0.91
12-months						
Oral hypoglycemic agent	23	82.14		19	65.52	0.58
Insulin	13	46.43		22	75.86	0.26
Antihypertensive	27	96.43		27	93.10	0.93
Lipid lowering	25	89.29		27	93.10	0.91

Table 4. Time-specific means and standard deviations for primary outcomes by Phase II treatment arm. Each p-value tests the difference between the designated treatment arm means (e.g. ACMHT-CC minus ACMHT-CCHT) at that timepoint. A positive difference $Diff_{ACMCC-ACMCCHT}$ indicates that the mean for that outcome at that timepoint is lower in the ACMHT-CCHT arm than in the ACMHT-CC arm.

HbA1c (%)	**ACMHT-CCHT(23)** Mean	SD	**ACMHT-CC (21)** Mean	SD	$Diff_{ACMCC-ACMCCHT}$ Mean	SE	P-value
6 months	7.77	0.82	7.97	1.41	0.20	0.34	0.57
9 months	7.93	0.96	8.04	1.34	0.12	0.35	0.74
12 months	8.03	1.03	8.16	1.03	0.14	0.31	0.67
BPSYS (mmHg)							
6 months	136.09	23.01	127.71	20.39	-8.37	6.58	0.21
9 months	137.04	17.34	131.14	23.94	-5.90	6.26	0.35
12 months	131.13	16.69	129.43	18.60	-1.70	5.32	0.75
BPDIAS (mmHg)							
6 months	70.91	13.62	68.81	9.62	-2.10	3.59	0.56
9 months	71.96	11.14	71.29	11.01	-0.67	3.64	0.86
12 months	69.26	9.54	71.71	12.20	2.45	3.29	0.46
Weight (lbs)							
6 months	244.66	45.72	230.33	46.22	-14.32	13.87	0.31
9 months	240.73	35.70	229.06	52.85	-11.66	13.49	0.39
12 months	246.23	39.00	321.44	52.41	-14.79	13.85	0.29
Cholesterol (mg/dl)							
6 months	149.35	42.59	140.38	35.27	-8.97	11.85	0.45
9 months	149.26	29.61	145.38	42.17	-3.88	10.91	0.72
12 months	164.61	42.35	150.71	39.17	-13.89	12.33	0.27
HDL (mg/dl)							
6 months	32.00	8.11	36.10	10.56	-4.09	2.83	0.15
9 months	34.20	8.09	37.96	10.18	3.75	2.76	0.18
12 months	35.61	7.69	39.00	9.63	3.39	2.62	0.20
LDL (mg/dl)							
6 months	85.27	34.08	75.89	24.82	-9.38	9.56	0.33
9 months	85.83	27.11	75.89	32.58	-9.94	9.32	0.29
12 months	96.12	38.13	80.33	36.65	-15.79	11.80	0.19
Triglyceride (mg/dl)							
6 months	158.57	77.38	139.29	95.96	-19.28	26.18	0.47
9 months	145.52	66.72	161.21	119.72	15.68	28.88	0.59
12 months	164.61	81.35	156.90	108.19	-7.70	28.70	0.79

Table 4. (continued)

HbA1c (%)	**ACMHT-CC (21)** Mean	SD	**CC-CC (28)** Mean	SD	$Diff_{CCCC-ACMCC}$ Mean	SE	P-value
6 months	7.97	1.41	8.56	1.14	0.59	0.36	0.11
9 months	8.04	1.34	8.53	1.22	0.49	0.37	0.19
12 months	8.16	1.03	8.71	1.25	0.55	0.34	0.11
BPSYS (mmHg)							
6 months	127.71	20.39	130.36	17.49	2.64	5.42	0.63
9 months	131.14	23.94	133.18	15.49	2.04	5.64	0.72
12 months	129.43	18.60	127.25	13.70	-2.18	4.61	0.64
BPDIAS (mmHg)							
6 months	68.81	9.62	74.75	12.73	5.94	3.32	0.08
9 months	71.29	11.01	73.79	10.13	2.50	3.30	0.45
12 months	71.71	12.20	71.79	10.69	0.07	3.28	0.98
Weight (lbs)							
6 months	230.33	46.22	210.96	48.74	-19.37	13.76	0.17
9 months	229.06	52.85	212.85	47.76	-16.21	14.43	0.27
12 months	321.44	52.41	213.43	48.51	-18.01	14.49	0.22
Cholesterol (mg/dl)							
6 months	140.38	35.27	163.64	34.17	23.26	10.00	0.02
9 months	145.38	42.17	152.32	29.81	6.95	10.28	0.50
12 months	150.71	39.17	149.57	29.53	-1.14	9.81	0.91
HDL (mg/dl)							
6 months	36.10	10.56	39.11	17.21	3.01	4.26	0.48
9 months	37.96	10.18	39.57	11.48	1.61	3.16	0.61
12 months	39.00	9.63	39.89	9.69	0.89	2.79	0.75
LDL (mg/dl)							
6 months	75.89	24.82	91.72	27.21	15.83	8.11	0.06
9 months	75.89	32.58	82.98	23.88	7.08	8.60	0.41
12 months	80.33	36.65	80.49	23.38	0.16	9.15	0.99
Triglyceride (mg/dl)							
6 months	139.29	95.96	184.79	139.61	45.50	35.49	0.21
9 months	161.21	119.72	171.07	174.65	9.87	44.37	0.83
12 months	156.90	108.19	167.96	146.56	11.06	37.99	0.77

Table 4. (continued)

HbA1c (%)	**CC-CC (28)** Mean	SD	**CC-UC (27)** Mean	SD	$Diff_{CCUC-CCCC}$ Mean	SE	P-value
6 months	8.56	1.14	8.53	1.18	-0.03	0.31	0.92
9 months	8.53	1.22	8.87	1.25	0.34	0.33	0.31
12 months	8.71	1.25	8.84	1.38	0.13	0.35	0.72
BPSYS (mmHg)							
6 months	130.36	17.49	133.99	14.83	3.64	4.43	0.42
9 months	133.18	15.49	132.54	23.27	-0.64	5.34	0.91
12 months	127.25	13.70	127.92	18.24	0.67	4.37	0.88
BPDIAS (mmHg)							
6 months	74.75	12.73	75.62	11.64	0.87	3.33	0.80
9 months	73.79	10.13	72.73	11.49	-1.05	2.94	0.72
12 months	71.79	10.69	69.44	10.57	-2.35	2.90	0.42
Weight (lbs)							
6 months	210.96	48.74	241.33	50.23	30.37	13.47	0.03
9 months	212.85	47.76	242.30	49.52	29.45	12.99	0.03
12 months	213.43	48.51	243.85	51.85	30.42	13.66	0.03
Cholesterol (mg/dl)							
6 months	163.64	34.17	154.45	38.60	-9.19	9.90	0.36
9 months	152.32	29.81	163.38	41.74	11.06	9.82	0.27
12 months	149.57	29.53	159.13	37.37	9.56	9.13	0.30
HDL (mg/dl)							
6 months	39.11	17.21	33.97	9.94	-5.14	3.86	0.19
9 months	39.57	11.48	36.88	10.16	-2.69	2.96	0.37
12 months	39.89	9.69	35.49	8.63	-4.41	2.50	0.08
LDL (mg/dl)							
6 months	91.72	27.21	88.86	31.88	-2.87	8.45	0.74
9 months	82.98	23.88	96.18	35.31	13.20	8.58	0.13
12 months	80.49	23.38	93.12	32.37	12.63	8.04	0.12
Triglyceride (mg/dl)							
6 months	184.79	139.61	165.10	89.29	-19.68	32.17	0.54
9 months	171.07	174.65	172.65	146.07	1.58	44.00	0.97
12 months	167.96	146.56	158.37	84.55	-9.59	32.90	0.77

Table 5. Between-group changes over time in primary outcomes by Phase II treatment arm. Each p-value tests the difference in the change scores between treatment arms at each pair of timepoints. A negative $Diff_{ACMCCHT}$ indicates that the measure is increasing over time. A positive $Diff_{ACMCCHT}$ -$Diff_{ACMCC}$ indicates that the difference over time in the ACMHT-CCHT arm either decreases more or increases less than in the ACMHT-CC arm.

HbA1c Change (%)	**ACMHT-CCHT (23)** $Diff_{ACMCCHT}$	SD	**ACMHT-CC (21)** $Diff_{ACMCC}$	SD	$Diff_{ACMCCHT}$ -$Diff_{ACMCC}$ Mean	SE	P-value
6m-9m	-0.15	0.86	-0.07	1.01	-0.08	0.28	0.78
6m-12m	-0.25	0.91	-0.19	0.82	-0.06	0.26	0.82
9m-12m	-0.10	0.64	-0.12	0.81	0.019	0.22	0.93
BPSYS (mmHg)							
6m-9m	-0.96	23.99	-3.43	20.09	2.47	6.71	0.71
6m-12m	4.96	30.01	-1.71	18.10	6.67	7.56	0.38
9m-12m	5.91	16.61	1.71	15.92	4.20	4.92	0.40
BPDIAS (mmHg)							
6m-9m	-1.04	8.88	-2.48	10.13	1.43	2.87	0.62
6m-12m	1.65	12.91	-2.90	9.82	4.56	3.48	0.20
9m-12m	2.70	8.98	-0.43	8.49	3.12	2.64	0.24
Weight (lbs)							
6m-9m	3.93	29.32	1.27	11.07	2.66	6.60	0.69
6m-12m	-1.57	18.29	-1.11	10.14	-0.46	4.52	0.95
9m-12m	-5.50	20.72	-2.38	7.05	-3.12	4.75	0.52
Cholesterol (mg/dl)							
6m-9m	0.09	35.91	-4.99	17.67	5.08	8.66	0.56
6m-12m	-15.26	44.31	-10.33	25.09	-4.93	11.00	0.66
9m-12m	-15.35	29.81	-5.34	25.75	-10.01	8.44	0.24
HDL (mg/dl)							
6m-9m	-2.20	5.27	-1.86	4.84	-0.34	1.53	0.82
6m-12m	-3.61	7.41	-2.90	4.52	-0.70	1.87	0.71
9m-12m	-1.40	7.14	-1.04	4.86	-0.36	1.86	0.85
LDL (mg/dl)							
6m-9m	-0.56	31.89	0.00	12.84	-0.56	7.99	0.94
6m-12m	-10.85	39.43	-4.43	23.39	-6.61	10.51	0.55
9m-12m	-10.29	25.67	-4.44	6.12	-5.85	8.12	0.48
Triglyceride (mg/dl)							
6m-9m	13.04	42.72	-21.92	81.19	34.96	19.31	0.08
6m-12m	-6.04	69.26	-17.62	80.15	11.58	22.53	0.61
9m-12m	-19.09	57.24	4.30	87.51	-23.39	22.10	0.30

Table 5. (continued)

HbA1c Change (%)	**ACMHT-CC (21)** $Diff_{ACMCC}$	SD	**CC-CC (28)** $Diff_{CCCC}$	SD	$Diff_{ACMCCHT}$-$Diff_{CCCC}$ Mean	SE	P-value
6m-9m	-0.07	1.01	0.03	0.71	-0.10	0.25	0.68
6m-12m	-0.19	0.82	-0.15	1.16	-0.04	0.30	0.90
9m-12m	-0.12	0.81	-0.18	1.01	0.06	0.27	0.81
BPSYS (mmHg)							
6m-9m	-3.43	20.09	-2.82	15.43	-0.61	5.07	0.91
6m-12m	-1.71	18.10	3.11	16.08	-.82	4.90	0.33
9m-12m	1.71	15.92	5.93	14.96	-4.21	4.44	0.35
BPDIAS (mmHg)							
6m-9m	-2.48	10.13	0.96	9.62	-3.44	2.84	0.23
6m-12m	-2.90	9.82	2.96	9.75	-5.87	2.82	0.04
9m-12m	-0.43	8.49	2.00	7.33	-2.43	2.26	0.29
Weight (lbs)							
6m-9m	1.27	11.07	-1.88	5.41	3.15	2.40	0.19
6m-12m	-1.11	10.14	-2.46	6.09	1.35	2.33	0.56
9m-12m	-2.38	7.05	-0.58	5.12	-1.80	1.74	0.31
Cholesterol (mg/dl)							
6m-9m	-4.99	17.67	11.32	36.90	-16.32	8.73	0.07
6m-12m	-10.33	25.09	14.07	34.09	-24.40	8.83	0.01
9m-12m	-5.34	25.75	2.75	27.16	-8.09	7.67	0.30
HDL (mg/dl)							
6m-9m	-1.86	4.84	-0.46	9.64	-1.40	2.30	0.55
6m-12m	-2.90	4.52	-0.79	10.63	-2.12	2.48	0.40
9m-12m	-1.04	4.86	-0.32	4.47	-0.72	1.34	0.59
LDL (mg/dl)							
6m-9m	0.00	12.84	8.75	28.57	-8.75	7.22	0.23
6m-12m	-4.43	23.39	11.24	26.33	-15.67	7.77	0.05
9m-12m	-4.44	6.12	2.49	24.09	-6.92	7.70	0.37
Triglyceride (mg/dl)							
6m-9m	-21.92	81.19	13.71	125.15	-35.64	31.36	0.26
6m-12m	-17.62	80.15	16.82	91.91	-34.44	25.15	0.18
9m-12m	4.30	87.51	3.11	89.77	1.19	25.64	0.96

Table 5. (continued)

HbA1c Change (%)	**CC-CC (28)** $Diff_{CCCC}$	SD	**CC-UC (27)** $Diff_{CCUC}$	SD	$Diff_{CCCC}$-$Diff_{CCUC}$ Mean	SE	P-value
6m-9m	0.03	0.71	-0.35	0.91	0.37	0.22	0.09
6m-12m	-0.15	1.16	-0.31	1.43	0.16	0.35	0.65
9m-12m	-0.18	1.01	0.03	1.38	-0.22	0.33	0.51
BPSYS (mmHg)							
6m-9m	-2.82	15.43	1.45	21.96	-4.28	5.14	0.41
6m-12m	3.11	16.08	6.07	17.01	-2.97	4.50	0.51
9m-12m	5.93	14.96	4.62	26.61	1.31	5.82	0.82
BPDIAS (mmHg)							
6m-9m	0.96	9.62	2.89	12.04	-1.93	2.95	0.52
6m-12m	2.96	9.75	6.18	10.33	-3.22	2.73	0.24
9m-12m	2.00	7.33	3.29	13.11	-1.29	2.86	0.65
Weight (lbs)							
6m-9m	-1.88	5.41	-0.97	9.74	-0.92	2.12	0.67
6m-12m	-2.46	6.09	-2.52	8.78	0.05	2.04	0.98
9m-12m	-0.58	5.12	-1.55	10.46	0.97	2.22	0.66
Cholesterol (mg/dl)							
6m-9m	11.32	36.90	-8.94	21.76	20.26	8.33	0.02
6m-12m	14.07	34.09	-4.68	31.41	18.75	8.94	0.04
9m-12m	2.75	27.16	4.25	24.64	-1.50	7.08	0.83
HDL (mg/dl)							
6m-9m	-0.46	9.64	-2.92	5.62	2.45	2.17	0.26
6m-12m	-0.79	10.63	-1.52	4.83	0.73	2.28	0.75
9m-12m	-0.32	4.47	1.40	5.55	-1.72	1.37	0.21
LDL (mg/dl)							
6m-9m	8.75	28.57	-7.32	20.92	16.06	7.18	0.03
6m-12m	11.24	26.33	-4.26	26.34	15.49	7.53	0.05
9m-12m	2.49	24.09	3.06	22.97	-0.57	6.73	0.93
Triglyceride (mg/dl)							
6m-9m	13.71	125.15	-7.55	114.59	21.27	32.73	0.52
6m-12m	16.82	91.91	6.73	67.53	10.09	22.09	0.65
9m-12m	3.11	89.77	14.28	90.75	-11.18	24.58	0.65

Table 6. Summary p-values testing changes over time in the primary outcomes within each treatment arm. Each p-value tests the mean difference between pairs of timepoints within a treatment arm.

Within group change		P-value			
		ACMHT-CCHT	ACMHT-CC	CC-CC	CC-UC
HbA1c	6m-9m	0.41	0.75	0.83	0.06
	6m-12m	0.20	0.30	0.49	0.27
	9m-12m	0.46	0.51	0.35	0.90
BPSYS	6m-9m	0.85	0.44	0.34	0.74
	6m-12m	0.44	0.67	0.32	0.08
	9m-12m	0.10	0.63	0.05	0.39
BPDIAS	6m-9m	0.58	0.28	0.60	0.23
	6m-12m	0.55	0.19	0.12	0.01
	9m-12m	0.16	0.82	0.16	0.21
Weight	6m-9m	0.51	0.61	0.08	0.62
	6m-12m	0.68	0.62	0.04	0.16
	9m-12m	0.22	0.14	0.55	0.46
Cholesterol	6m-9m	0.99	0.21	0.12	0.05
	6m-12m	0.11	0.07	0.04	0.45
	9m-12m	0.02	0.35	0.60	0.39
HDL	6m-9m	0.06	0.09	0.80	0.01
	6m-12m	0.03	0.01	0.70	0.12
	9m-12m	0.36	0.34	0.71	0.21
LDL	6m-9m	0.93	1.00	0.14	0.10
	6m-12m	0.20	0.43	0.04	0.44
	9m-12m	0.07	0.48	0.61	0.52
Triglyceride	6m-9m	0.16	0.23	0.57	0.74
	6m-12m	0.68	0.33	0.34	0.62
	9m-12m	0.12	0.82	0.86	0.43

Table 7. Time-specific means and standard deviations for secondary outcomes by Phase II treatment arm. Each p-value tests the difference between the designated treatment arm means (e.g. ACMHT-CC minus ACMHT-CCHT) at that timepoint. A positive difference $Diff_{ACMCC-ACMCCHT}$ indicates that the mean for that outcome at that timepoint is lower in the ACMHT-CCHT arm than in the ACMHT-CC arm.

PCS	**ACMHT-CCHT(23)** Mean	SD	**ACMHT-CC (21)** Mean	SD	$Diff_{ACMCC-ACMCCHT}$ Mean	SE	P-value
6 months	38.75	13.32	39.66	9.91	0.91	3.39	0.79
9 months	37.46	11.63	36.58	9.94	-0.88	3.28	0.79
12 months	40.22	10.73	37.52	11.83	-2.70	3.40	0.43
MCS							
6 months	44.10	11.68	40.55	13.10	-3.55	3.74	0.35
9 months	41.41	11.51	42.37	12.97	0.96	3.69	0.80
12 months	41.53	13.27	44.92	11.43	3.38	3.75	0.37
PAID							
6 months	24.24	21.08	22.90	20.61	-1.34	6.29	0.83
9 months	25.03	16.67	17.33	16.19	-0.77	4.96	0.13
12 months	25.22	19.73	18.81	16.69	-6.41	5.54	0.25
DTSQ							
6 months	31.07	4.03	30	6.99	-1.07	1.70	0.53
9 months	29.52	5.16	30.33	6.26	0.81	1.72	0.64
12 months	30.09	5.50	31.33	4.56	1.25	1.53	0.42

PCS	**ACMHT-CC (21)** Mean	SD	**CC-CC (28)** Mean	SD	$Diff_{CCCC-ACMCC}$ Mean	SE	P-value
6 months	39.66	9.91	46.86	9.58	7.19	2.81	0.01
9 months	36.58	9.94	45.41	8.29	8.23	2.61	0.00
12 months	37.52	11.83	45.25	8.74	7.74	2.94	0.01
MCS							
6 months	40.55	13.10	40.42	11.71	-0.13	3.56	0.97
9 months	42.37	12.97	45.13	10.98	2.75	3.43	0.43
12 months	44.92	11.43	43.63	10.78	-1.28	3.19	0.69
PAID							
6 months	22.90	20.61	26.71	19.51	3.81	5.77	0.51
9 months	17.33	16.19	27.07	21.75	9.74	5.65	0.09
12 months	18.81	16.69	28.73	23.75	9.91	6.07	0.11
DTSQ							
6 months	30.00	6.99	28.39	5.87	-1.66	1.74	0.34
9 months	30.33	6.26	29.84	7.25	-2.40	1.85	0.20
12 months	31.33	4.56	30.37	5.58	-2.30	1.56	0.15

Table 7. (continued)

PCS	**CC-CC (28)** Mean	SD	**CC-UC (27)** Mean	SD	$Diff_{CCUC-CCCC}$ Mean	SE	P-value
6 months	46.86	9.58	41.81	10.75	-5.05	2.77	0.07
9 months	45.41	8.29	42.43	11.71	-2.98	2.74	0.28
12 months	45.25	8.74	41.79	9.21	-3.47	2.44	0.16
MCS							
6 months	40.42	11.71	45.21	12.94	4.79	3.35	0.15
9 months	45.13	10.98	43.69	12.79	-1.44	3.24	0.66
12 months	43.63	10.78	45.58	9.63	1.94	2.79	0.49
PAID							
6 months	26.71	19.51	25.75	20.40	-0.96	5.43	0.86
9 months	27.07	21.75	27.05	20.47	-0.02	5.76	1.00
12 months	28.73	23.75	25.02	23.40	-3.71	6.42	0.57
DTSQ							
6 months	28.34	5.19	28.39	5.87	0.05	1.61	0.97
9 months	27.93	6.52	29.84	7.25	1.91	1.89	0.32
12 months	29.03	5.96	30.37	5.58	1.34	1.57	0.40

Table 8. Between-group changes over time in secondary outcomes by Phase II treatment arm. Each p-value tests the difference in the change scores between treatment arms at each pair of timepoints. A negative $Diff_{ACMCCHT}$ indicates that the measure is increasing over time. A positive $Diff_{ACMCCHT}$ -$Diff_{ACMCC}$ indicates that the difference over time in the ACMHT-CCHT arm either decreases more or increases less than in the ACMHT-CC arm.

	ACMHT-CCHT (23)		**ACMHT-CC (21)**		$Diff_{ACMCCHT}$ -$Diff_{ACMCC}$		P-value
PCS	$Diff_{ACMCCHT}$	SD	$Diff_{ACMCC}$	SD	Mean	SE	
6m-9m	1.29	8.11	3.08	9.19	-1.79	2.61	0.50
6m-12m	-1.47	7.88	2.14	8.10	-3.61	2.41	0.14
9m-12m	-2.76	6.77	-0.94	7.21	-1.82	2.11	0.39
MCS							
6m-9m	2.69	11.35	-1.82	10.82	4.51	3.35	0.19
6m-12m	2.57	8.99	-4.37	10.14	6.93	2.88	0.02
9m-12m	-0.12	10.22	-2.54	10.14	2.42	3.07	0.44
PAID							
6m-9m	-0.78	12.97	5.57	9.78	-6.35	3.49	0.08
6m-12m	-0.98	13.62	4.09	12.45	-5.07	3.94	0.21
9m-12m	-0.20	13.04	-1.48	12.31	1.28	3.83	0.74
DTSQ							
6m-9m	1.54	4.36	-0.33	1.06	1.88	1.39	0.18
6m-12m	0.98	5.51	-1.33	4.33	2.31	5.06	0.13
9m-12m	-0.57	3.15	-1.00	4.07	0.43	1.09	0.69

PCS	**ACMHT-CC (21)** $Diff_{ACMCC}$	SD	**CC-CC (28)** $Diff_{CCCC}$	SD	$Diff_{ACMCC}$-$Diff_{CCCC}$ Mean	SE	P-value
6m-9m	3.08	9.19	1.45	8.54	1.63	2.55	0.52
6m-12m	2.14	8.10	1.60	6.20	0.54	2.04	0.79
9m-12m	-0.94	7.21	0.16	6.87	-1.09	2.03	0.59
MCS							
6m-9m	-1.82	10.82	-4.71	10.41	2.88	3.06	0.35
6m-12m	-4.37	10.14	-3.21	9.51	-1.15	2.83	0.69
9m-12m	-2.54	10.14	1.49	9.66	-4.04	2.85	0.16
PAID							
6m-9m	5.57	9.78	-0.36	13.17	5.93	3.42	0.09
6m-12m	4.09	12.45	-2.02	10.17	6.11	3.23	0.07
9m-12m	-1.48	12.31	-1.65	11.00	0.18	3.34	0.96
DTSQ							
6m-9m	-0.33	1.06	-1.59	8.14	0.74	1.39	0.60
6m-12m	-1.33	4.33	-1.98	8.46	0.64	1.59	0.69
9m-12m	-1.00	4.07	-0.91	4.68	-0.10	1.37	0.94

Table 8. (continued)

PCS	**CC-CC** (28) $Diff_{CCCC}$	SD	**CC-UC** (27) $Diff_{CCUC}$	SD	$Diff_{CCCC}$-$Diff_{CCUC}$ Mean	SE	P-value
6m-9m	1.45	8.54	-0.62	11.72	2.07	2.78	0.46
6m-12m	1.60	6.20	0.03	8.92	1.58	2.08	0.45
9m-12m	0.16	6.87	0.65	7.44	-0.49	1.95	0.80
MCS							
6m-9m	-4.71	10.41	1.52	14.10	-6.22	3.36	0.07
6m-12m	-3.21	9.51	-0.37	13.08	-2.84	3.10	0.36
9m-12m	1.49	9.66	-1.89	11.31	3.38	2.86	0.24
PAID							
6m-9m	-0.36	13.17	-1.30	13.97	-0.94	3.69	0.80
6m-12m	-2.02	10.17	0.74	12.35	-2.75	3.07	0.37
9m-12m	-1.65	11.00	2.03	15.65	-3.69	3.66	0.32
DTSQ							
6m-9m	0.41	4.82	-1.59	8.14	2.00	1.81	0.27
6m-12m	-0.69	6.22	-1.98	8.46	1.29	2.01	0.52
9m-12m	-1.10	5.21	-0.91	4.68	-0.20	1.37	0.89

Table 9. Summary p-values testing changes over time in the secondary outcomes within each treatment arm. Each p-value tests the mean difference between pairs of timepoints within a treatment arm.

Within group change		P-value			
		ACMHT-CCHT	ACMHT-CC	CC-CC	CC-UC
PCS	6m-9m	0.46	0.14	0.38	0.79
	6m-12m	0.38	0.24	0.18	0.99
	9m-12m	0.06	0.56	0.90	0.66
MCS	6m-9m	0.27	0.45	0.02	0.59
	6m-12m	0.19	0.06	0.09	0.89
	9m-12m	0.96	0.26	0.42	0.40
PAID	6m-9m	0.78	0.02	0.89	0.64
	6m-12m	0.73	0.15	0.30	0.76
	9m-12m	0.94	0.59	0.43	0.51
DTSQ	6m-9m	0.10	0.76	0.66	0.34
	6m-12m	0.40	0.17	0.56	0.24
	9m-12m	0.40	0.27	0.27	0.34

Table 10. Mean insulin dosage (IU) at each timepoint for all participants on insulin during the study period, with pairwise treatment comparisons. Each p-value tests the difference between the treatment arms means (e.g. ACMHT-CC minus ACMHT-CCHT) at each timepoint. A positive $Diff_{ACMCC-ACMCCHT}$ indicates that the mean insulin dosage at that timepoint is higher in the ACMHT-CC arm than in the ACMHT-CCHT arm.

Insulin	**ACMHT-CCHT (15)** Mean	SD	**ACMHT-CC (16)** Mean	SD	$Diff_{ACMCC-ACMCCHT}$ Mean	SE	p-value
6 month	84.07	74.02	100.56	70.81	16.50	26.01	0.53
9 month	68.80	41.43	96.25	73.68	27.45	21.67	0.22
12 month	87.07	83.50	106.50	17.49	19.43	27.60	0.49
	ACMHT-CC (16) Mean	SD	**CC-CC (12)** Mean	SD	$Diff_{CCCC-ACMCC}$ Mean	SE	p-value
6 month	100.56	70.81	71.67	60.36	-28.90	25.43	0.27
9 month	96.25	73.68	72.75	63.59	-23.50	26.58	0.38
12 month	106.50	17.49	79.25	66.77	-27.25	26.20	0.31
	CC-CC (12) Mean	SD	**CC-UC (20)** Mean	SD	$Diff_{CCUC-CCCC}$ Mean	SE	p-value
6 month	71.67	60.36	63.05	50.13	-8.62	19.76	0.67
9 month	72.75	63.59	84.70	77.09	11.95	26.45	0.65
12 month	79.25	66.77	81.05	45.39	1.80	19.80	0.93

Table 11. Mean changes in insulin dosage (IU) over time for all participants on insulin during the study period, with pairwise treatment comparisons. A negative $Diff_{ACMCCHT}$ indicates that the measure is increasing over time. A positive $Diff_{ACMCCHT}$ -$Diff_{ACMCC}$ indicates that the difference over time in the ACMHT-CCHT arm either decreases more or increases less than in the ACMHT-CC arm.

Insulin	**ACMHT-CCHT (15)** $Diff_{ACMCCHT}$	SD	**ACMHT-CC (16)** $Diff_{ACMCC}$	SD	$Diff_{ACMCCHT}$ -$Diff_{ACMCC}$ Mean	SE	p-value
6m-9m	15.27	78.88	4.31	21.56	10.95	20.47	0.60
6m-12m	-3.00	75.88	-5.94	28.30	2.94	20.31	0.89
9m-12m	-18.27	66.09	-10.25	49.49	-8.02	18.03	0.66
	ACMHT-CC (16)		**CC-CC (12)** $Diff_{CCCC}$	SD	$Diff_{ACMCC}$-$Diff_{CCCC}$ Mean	SE	p-value
6m-9m	4.31	21.56	-1.08	10.88	5.40	6.81	0.44
6m-12m	-5.94	28.30	-7.58	14.76	1.65	8.99	0.86
9m-12m	-10.25	49.49	-6.50	8.70	-3.75	8.42	0.66
	CC-CC (12) $Diff_{CCCC}$	SD	**CC-UC (20)** $Diff_{CCUC}$	SD	$Diff_{CCCC}$-$Diff_{CCUC}$ Mean	SE	p-value
6m-9m	-1.08	10.88	-21.65	56.99	20.57	16.74	0.23
6m-12m	-7.58	14.76	-18.00	32.45	10.42	9.98	0.30
9m-12m	-6.50	8.70	3.65	54.26	-10.15	15.88	0.53

Table 12. Summary p-values testing changes in insulin dosage over time within each treatment arm. Each p-value tests the mean difference between pairs of timepoints within a treatment arm.

Within group change		P-value			
		ACMHT-CCHT	ACMHT-CC	CC-CC	CC-UC
Insulin dosage	6m-9m	0.47	0.44	0.74	0.11
	6m-12m	0.88	0.42	0.10	0.02
	9m-12m	0.30	0.17	0.03	0.77

FIGURES

Figure 1. Design of the Diabetes Telemonitoring (DiaTel) Study, Phase I and Phase II

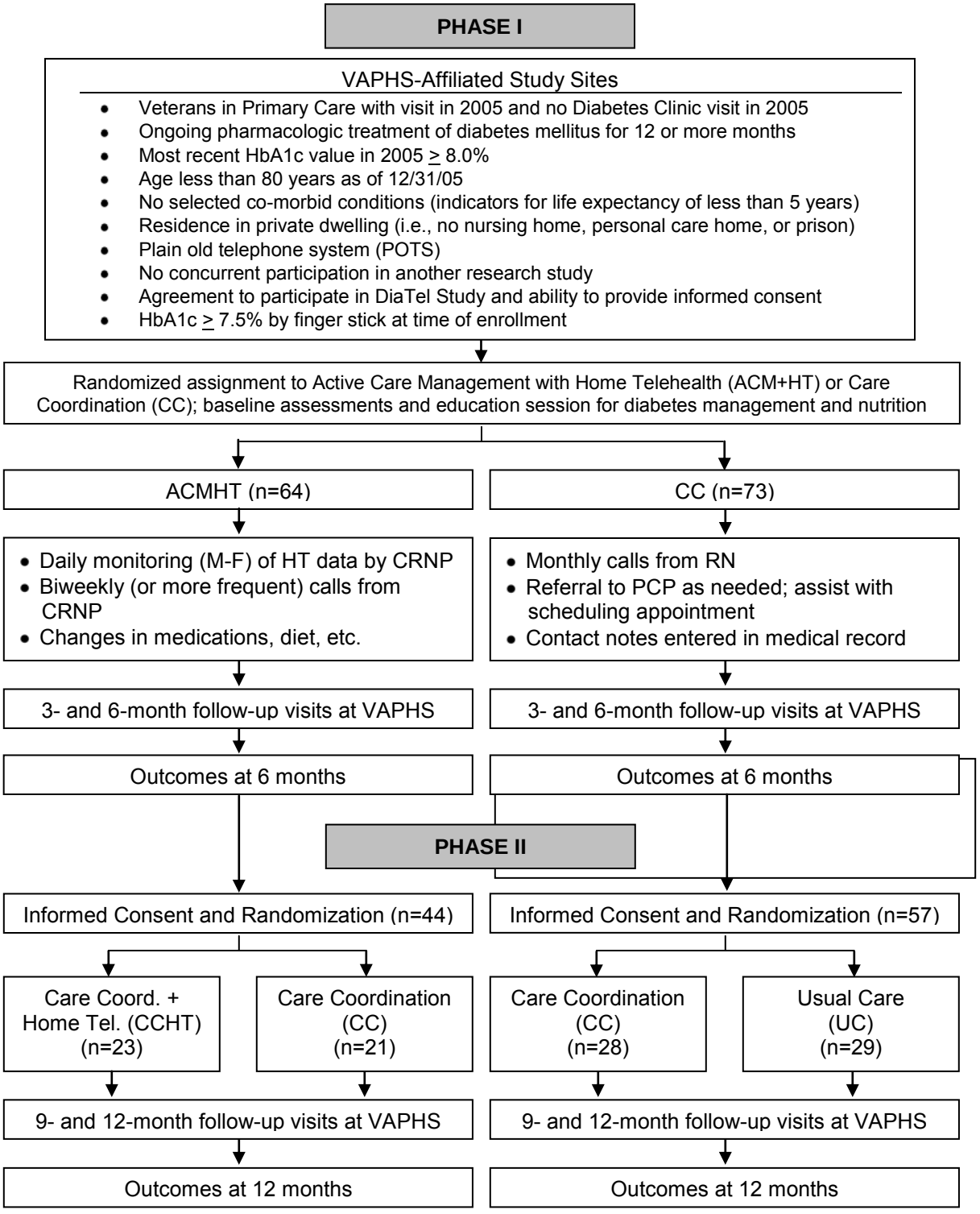


Figure 2. Profile plots of mean primary outcomes over time by Phase II treatment arm. Participants were re-randomized at 6 months, so the values at 0, 3 and 6 months reflect Phase I measurements for these Phase II participants. The treatment arms are labeled as follows: ACMHT-to-CCHT (filled-in arrows), ACMHT-to-CC (filled-in squares), CC-to-CC (open circles), CC-to-UC (open diamonds).

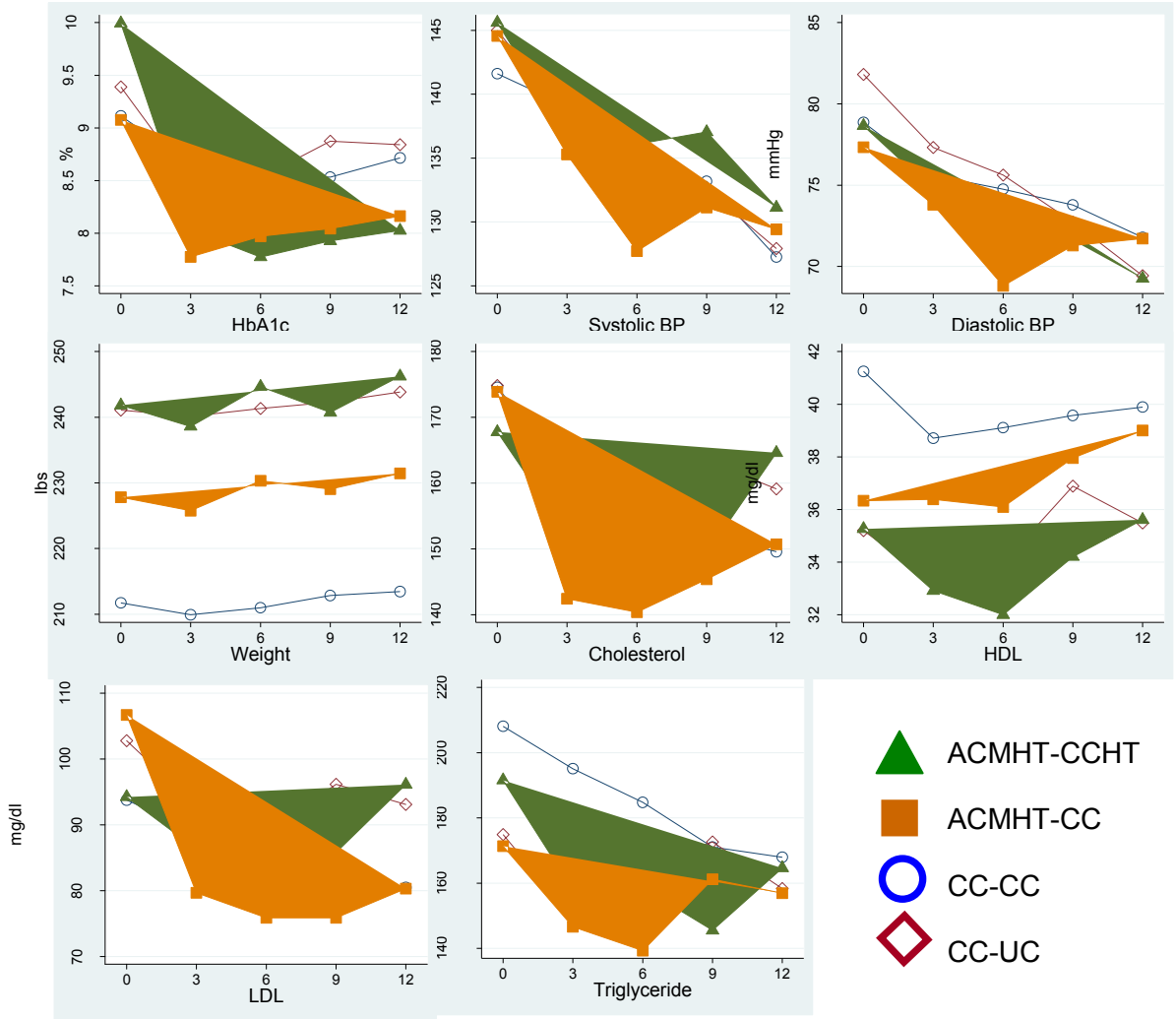
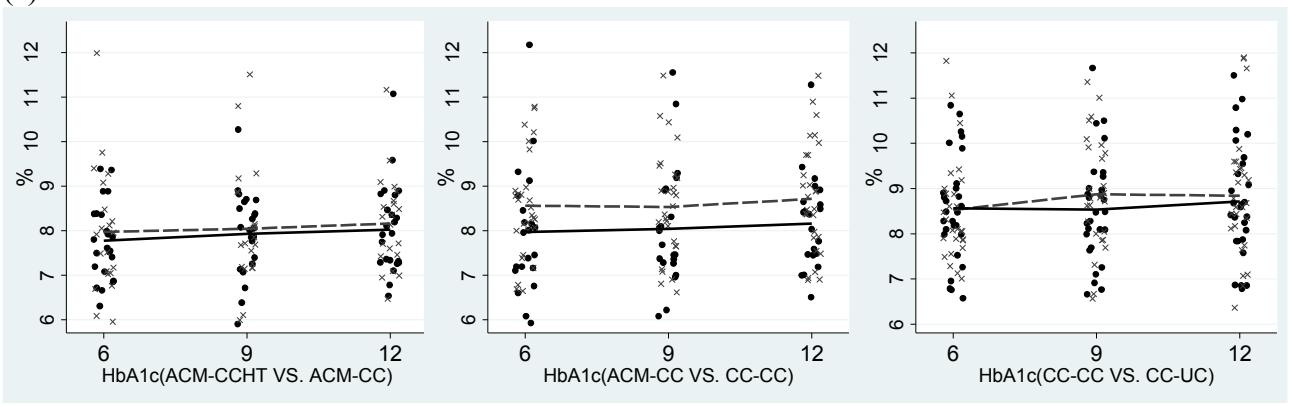
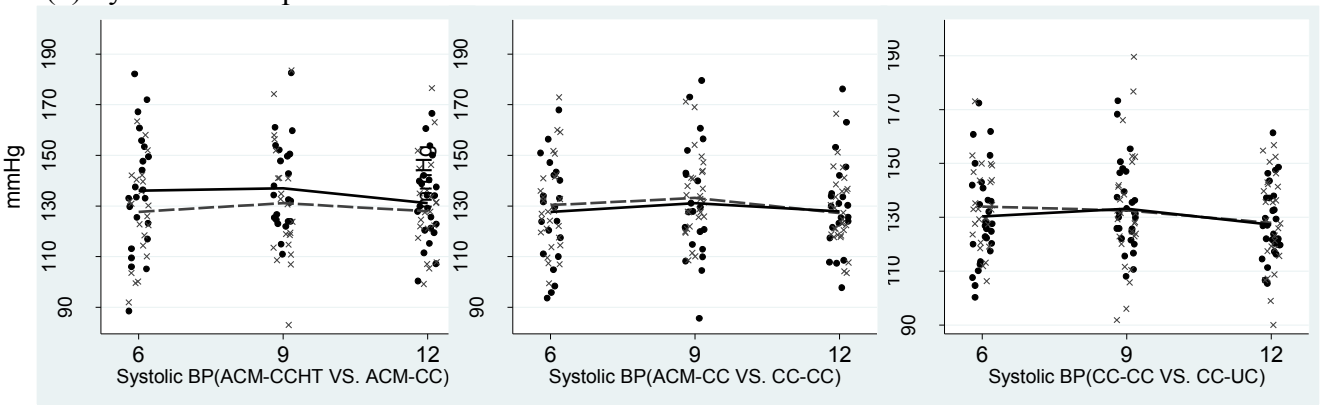


Figure 3. Pairwise comparisons of primary outcomes at 6, 9, and 12 months by treatment arm for (a) HbA1c, (b) systolic blood pressure, (c) diastolic blood pressure, (d) weight, (e) cholesterol, (f) HDL, (g) LDL, and (h) triglycerides. In each plot, an x denotes the data points and a dotted line connects the time-specific means for the less intensive intervention; a solid dot denotes the data points and a solid line connects the time-specific means for the more intensive intervention.

(a) HbA1c



(b) Systolic blood pressure



(c) Diastolic blood pressure

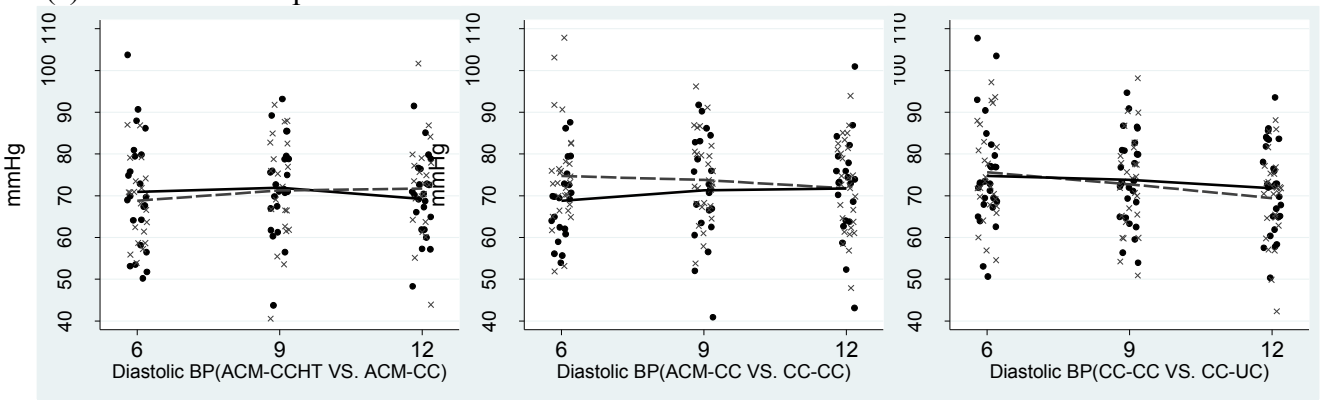
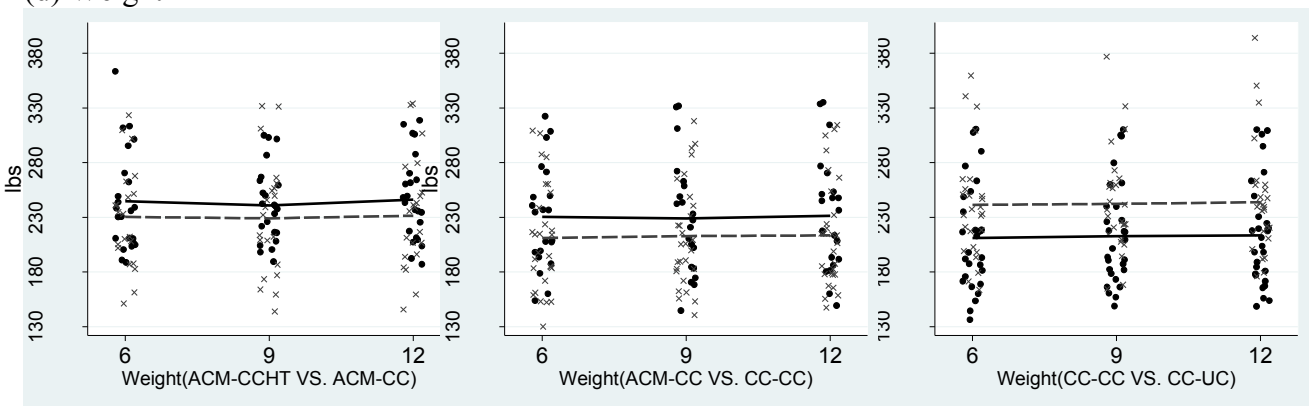
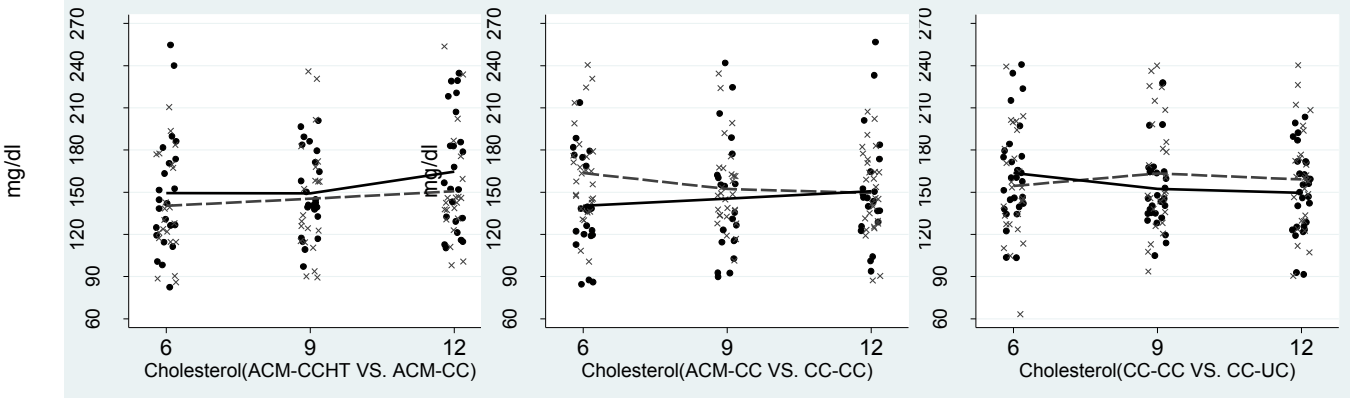


Figure 3. (continued)

(d) Weight



(e) Cholesterol



(f) HDL

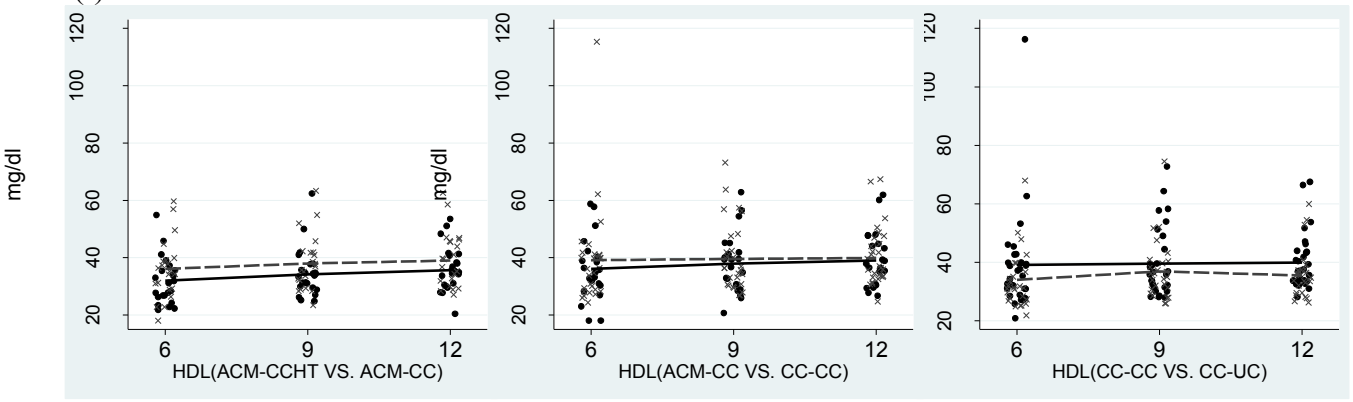
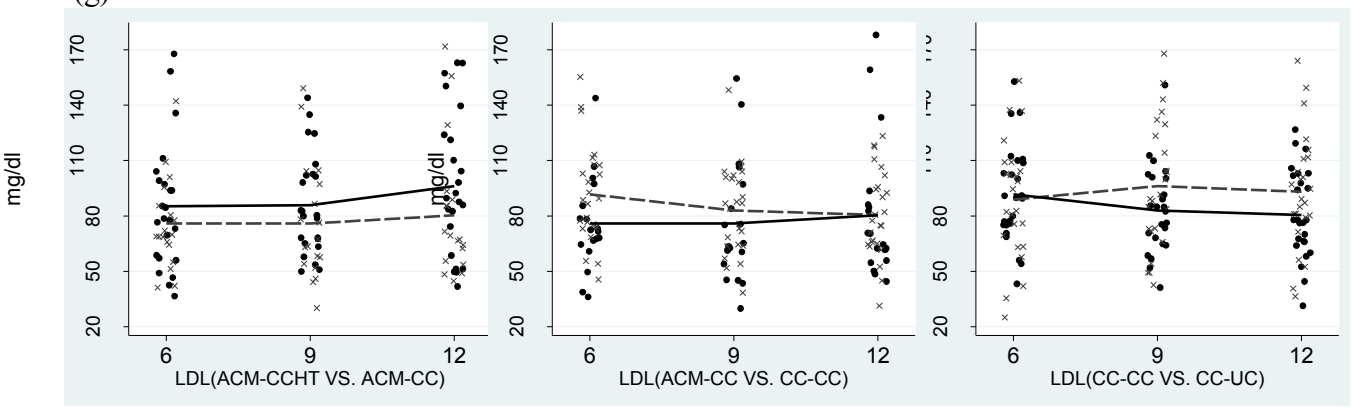


Figure 3. (continued)

(g) LDL



(h) Triglycerides

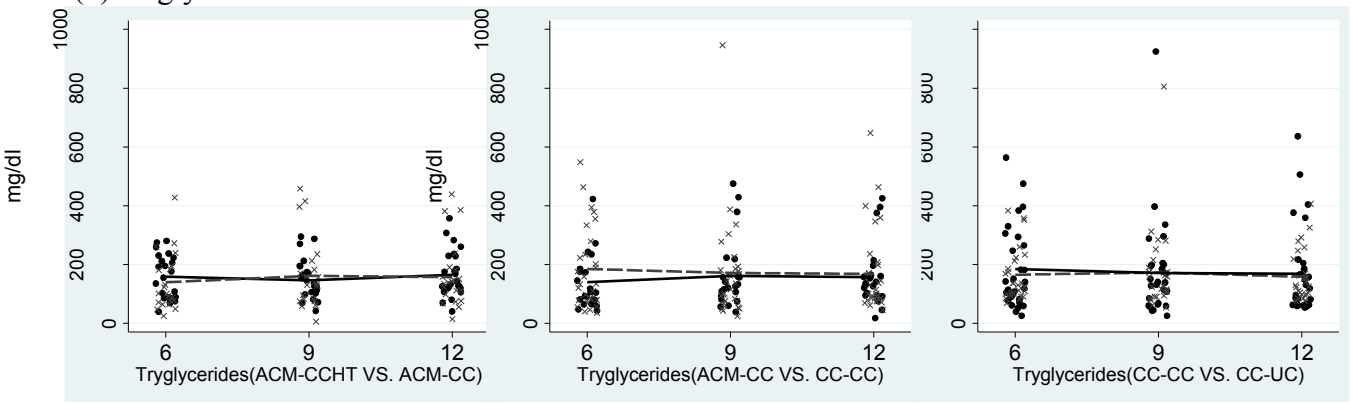


Figure 4. Profile plots of mean secondary outcomes over time by Phase II treatment arm. Participants were re-randomized at 6 months, so the values at 0, 3 and 6 months reflect Phase I measurements for these Phase II participants. The treatment arms are labeled as follows: ACMHT-to-CCHT (filled-in arrows), ACMHT-to-CC (filled-in squares), CC-to-CC (open circles), CC-to-UC (open diamonds).

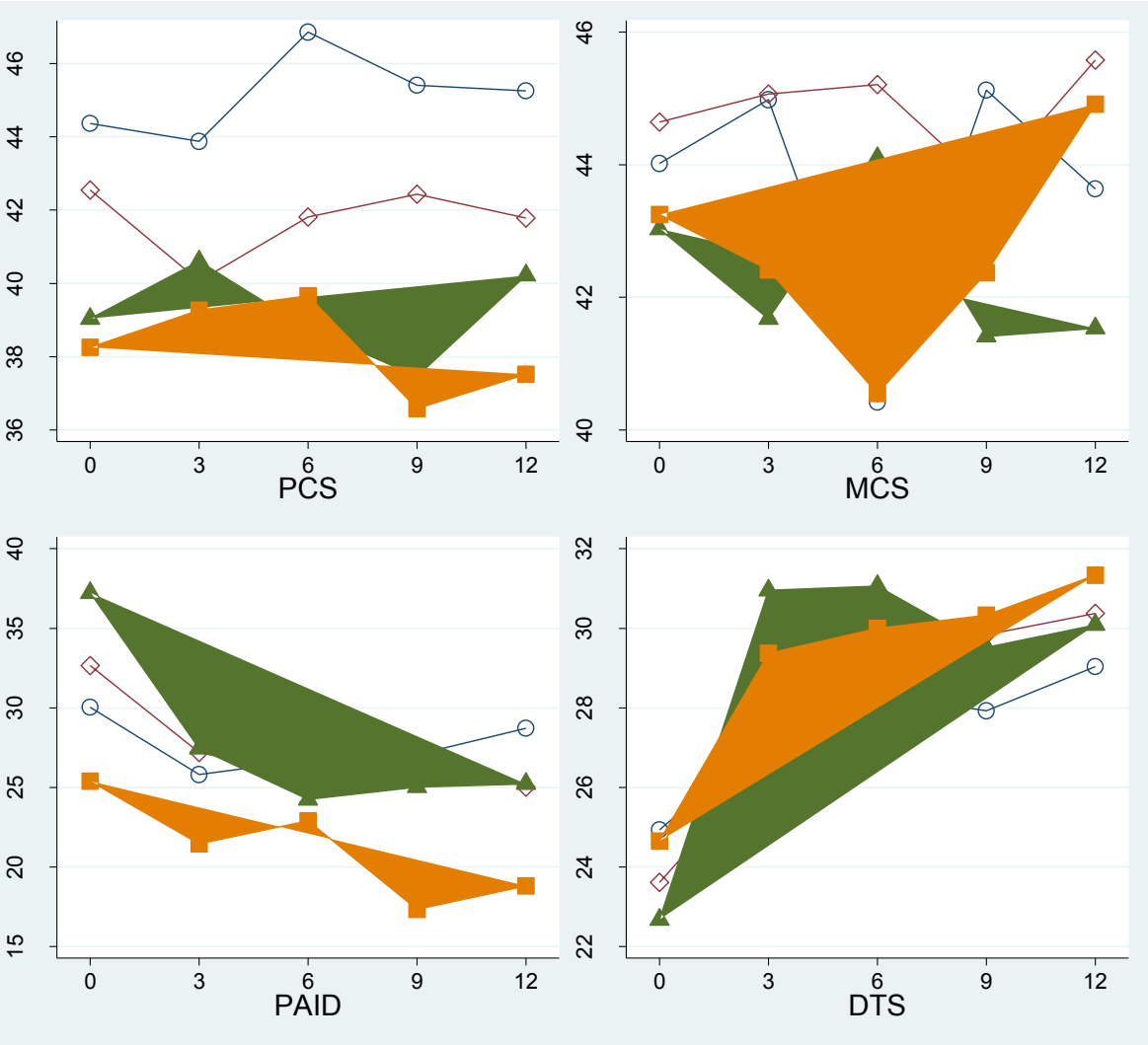


Figure 5. Insulin status at 6 and 12 months by treatment arm.

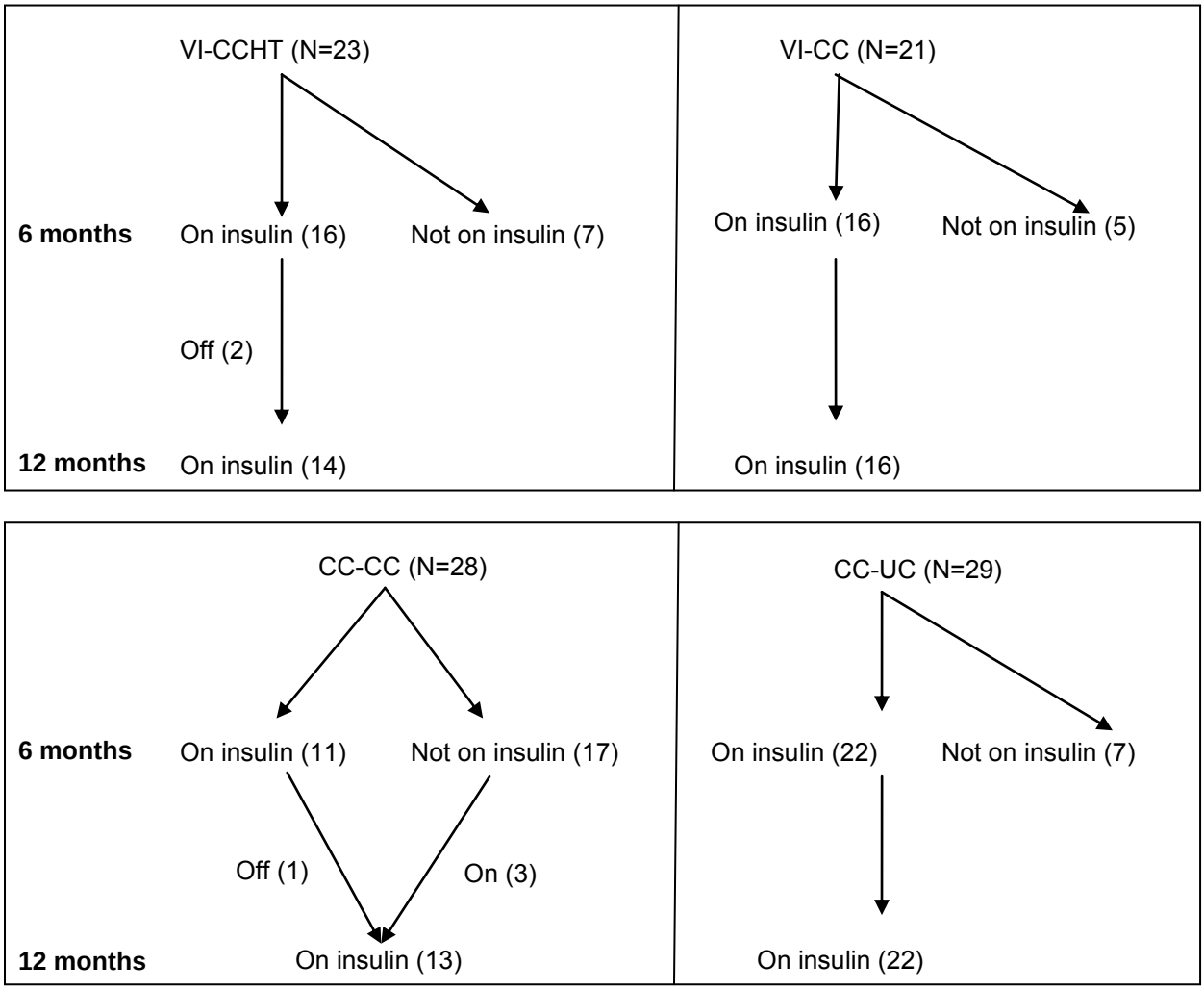


Figure 6. Profile plot of mean insulin dosage over time by Phase II treatment arm. Participants were re-randomized at 6 months, so the values at 0, 3 and 6 months reflect Phase I measurements for these Phase II participants. The treatment arms are labeled as follows: ACMHT-to-CCHT (filled-in arrows), ACMHT-to-CC (filled-in squares), CC-to-CC (open circles), CC-to-UC (open diamonds).

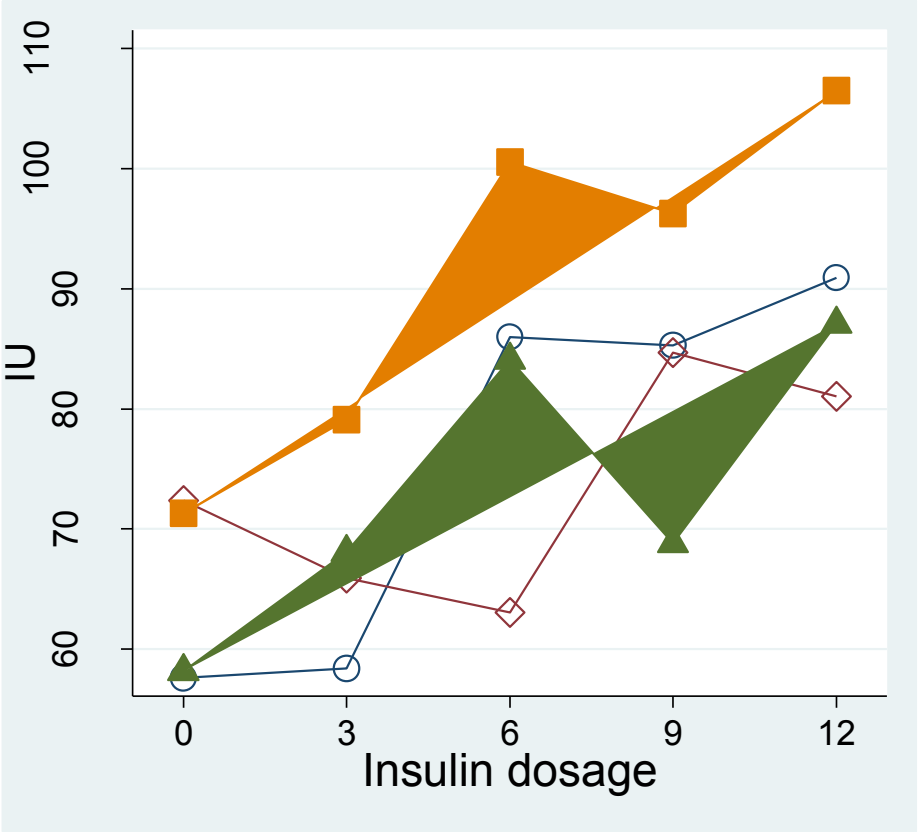


Figure 7. Pairwise comparisons of primary outcomes at 6, 9, and 12 months by treatment arm for insulin dosage. In each plot, an x denotes the data points and a dotted line connects the time-specific means for the less intensive intervention; a solid dot denotes the data points and a solid line connects the time-specific means for the more intensive intervention.

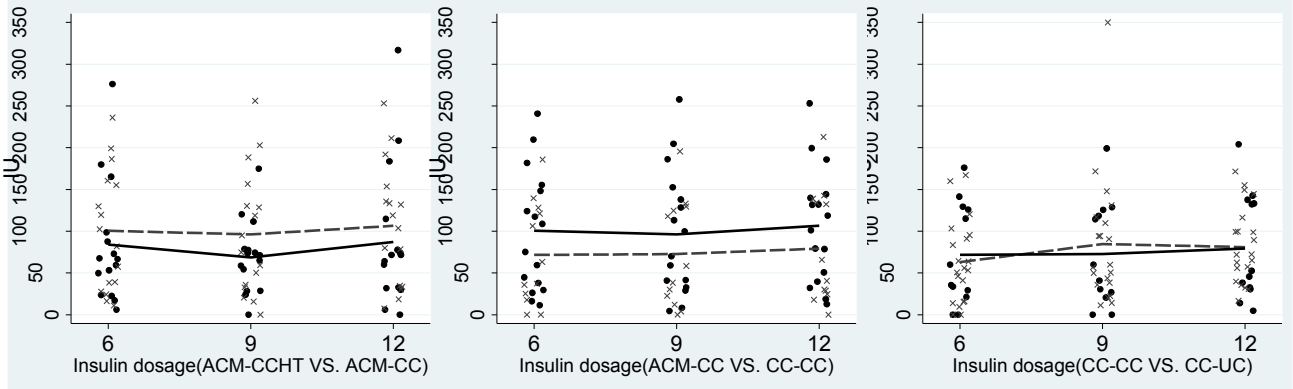
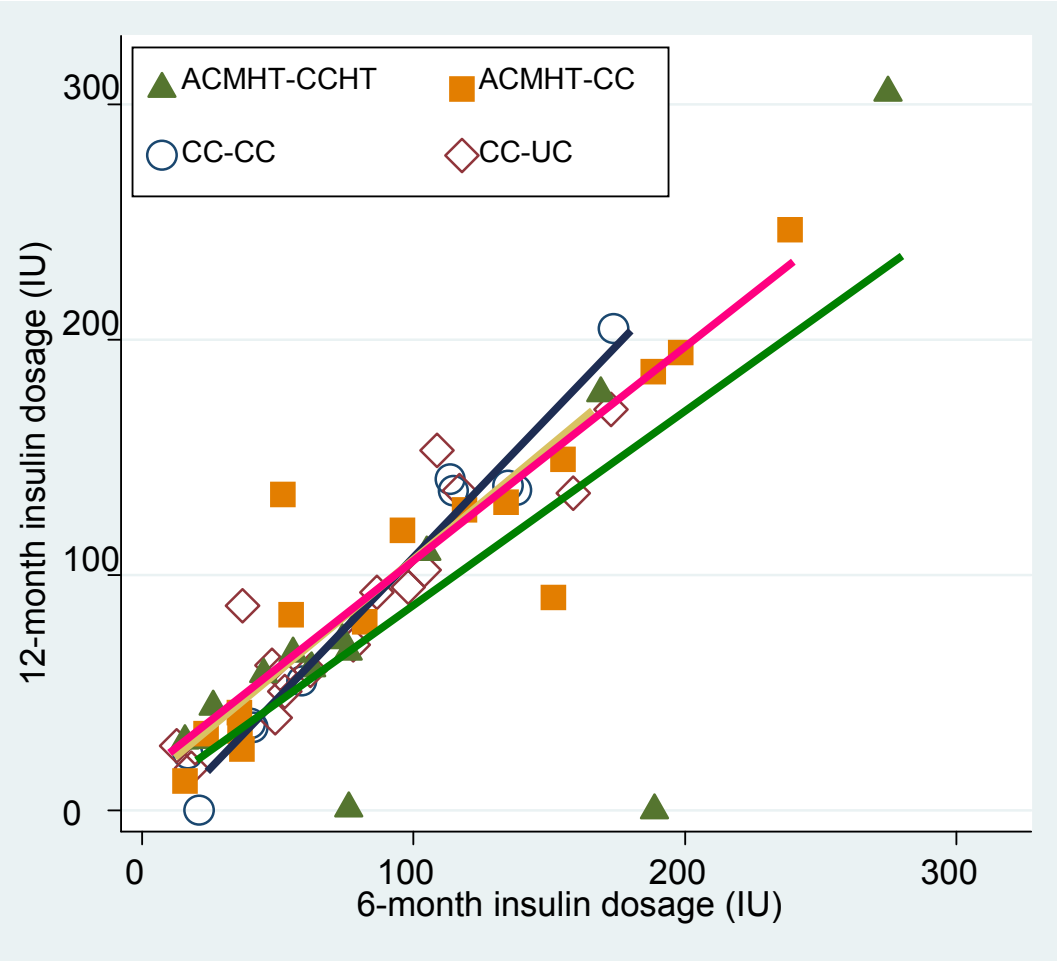


Figure 8. Scatterplot of insulin dosage at 6 and 12 months by treatment arm for participants ever on insulin in Phase II.



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Appendix W

CHHS Diabetes Support Groups

4B-A

CHHS Diabetes Support Groups

A

DATA MANAGEMENT

All forms used for the program are now linked to an ACCESS data base developed and maintained by the Primary Care Institute. Data transcription is provided by CHHS for smoking cessation programs and by PCI for Fitness and diabetes programs. Ad hoc reporting and summary assessments can now be produced promptly and accurately. Each month group facilitators review reports on missing data and needed referrals.

COLLECTION AND ASSESSMENT OF OUTCOMES DATA

My Diabetes Progress Report: We encourage members to engage in a partnership with their physicians by the utilization of "My Diabetes Progress Report" form. The physicians are asked to provide members with current, one year ago, and two years ago results of HbA1c, LDL, HDL, blood pressure and weight, and also to set desired goals with the member in each one of these categories. There is also a comment section on the form where physicians can give specific advice. The members bring their completed progress report back to us. We keep a copy and return the original to them. Displayed on outcomes analysis report (attached) as percentage of participants with progress report submitted in last six months, and number of reports received in last month.

Support Group Member Self-Assessment: Performed yearly on group members to assess member estimate of impact of program on mastery of self-management tasks. Data transcribed and analyzed by PCI. Will appear on analysis report showing average Likert score for each mastery item.

CHHS/PCI Diabetes Knowledge Assessment: A unique situational knowledge assessment tool (attached) has been field tested in groups. It should be available on-line in the next month. It will be repeated to assess knowledge acquisition in the next three months.

Attendance: Gathered at each support group session. Displayed on outcomes analysis report (attached) as average visits/participant, average number of participants per session by site and for all sites combined (month and YTD), number of new participants, sessions held by site and combined (month and YTD).

Action Steps: Results of previous action step and nature of next step are gathered at each support group session from each participant. Displayed on outcomes analysis report (attached) as percentage of participants with active action plans and percentage of active action plans whose goal were met.

Weight Control Group: Weight gathered at each support group session. Displayed on outcomes analysis report (attached) as average visits/participant, average number of participants per session by site and for all sites combined (month and YTD), number of new participants, sessions held by site and combined (month and YTD). Weight related action plan data is also displayed. Starting in August 2005 all members have height measured to allow calculation of BMI.

Community Outreach: Data gathered from diabetes nurses on a monthly basis. Displayed on outcomes analysis report (attached) as number of community outreach programs, number of contacts, number of medical office outreach programs, number of medical office contacts.

Smoking Intervention: Data gathered at each support group session from each participant. Displayed on outcomes analysis report (attached) as present smokers, smokers at entry to program, percentage of smokers who smoke now, number of referrals made (completed), and number with smoking action item. Data from community-wide recruiting of diabetics to our smoking cessation programs is collected through the IPPA forms.

Exercise Intervention: Data gathered at each support group session from each participant. Displayed on outcomes analysis report (attached) as number now active but previously sedentary, sedentary at entry to program, percentage of sedentary persons who are now active, number of sedentary persons now using step counter. Data from community-wide recruiting of diabetics to our exercise programs is collected through the IPPA forms.

A

Results of Diabetes Knowledge Testing Using Michigan Diabetes Knowledge Test and CHHS/PCI Situation Knowledge test

Michigan DKT	Correct	N		Fitzgerald1998	Murala2002	CHHS-2005	UPMC-SFPP2005
1	15	17	diab diet for all	84%		76%	88.2%
2	15	17	high carb food ID	45%	50%	32%	88.2%
3	12	17	high fat food ID	32%	32%	26%	70.6%
4	11	17	free food ID	56%	42%	55%	64.7%
5	13	17	HbA1c time frame	29%	44%	47%	76.5%
6	17	17	best blood glucose test	74%		68%	100.0%
7	13	17	effect of juice on BG	54%	65%	26%	76.5%
8	10	17	wrong rx for low BG	53%	57%	55%	58.8%
9	12	17	effect of exercise on BG	85%		76%	70.6%
10	15	17	effect of infection on BG	79%		76%	88.2%
11	16	17	proper foot care	88%		92%	94.1%
12	17	17	benefit of low fat diet on heart	85%		79%	100.0%
13	17	17	sx of nerve disease	77%	13%	63%	100.0%
14	17	17	lung not affect by DM	91%		92%	100.0%
15	11	17	sign/sx of DKA	19%		5%	64.7%
16	12	17	what to do if sick	78%		55%	70.6%
17	17	17	cause high BG	39%	42%	26%	100.0%
18	9	17	cause insulin rxn	58%	58%	26%	52.9%
19	11	16	duration of action NPH	83%			68.8%
20	12	16	effect skipped insulin dose	71%			75.0%
21	15	16	insulin rxn action	64%	70%		93.8%
22	16	16	low BG cause	70%	70%		100.0%
23	16	16	effect skipped meal in tDDM	38%	30%		100.0%
				adults	men 65yo	diab supp grp	FP res & alland

CCHS/PCI DKT	correct	answered
1	20	20
2	20	20
3	20	20
4	20	20
5	17	20
6	19	20
7	18	20
8	20	20
9	15	20
10a	16	19
10b	18	19
10c	19	19
10d	10	19
10e	16	19

Situation			Support Group Members	Faculty and Residents	CHHS Board Members
nocturnal sweating			82%	100%	70%
acute visual disturbance			92%	100%	100%
acute chest discomfort			76%	100%	80%
acute febrile illness			97%	100%	80%
new unilateral numbness			66%	86%	100%
sore foot			100%	95%	80%
stop smoking is most important first step			63%	90%	90%
best restaurant meal choices			100%	100%	90%
cut calories to lose weight quickly			50%	75%	60%
LDL goal			34%	84%	30%
HbA1c goal			50%	66%	10%
BP goal			61%	100%	70%
Veg & Fruit goal			66%	53%	10%
Exercise time goal			79%	84%	70%
			diab supp grp CHHS-2005	FP res & alland UPMC-SFPP2005	CHHS Board CHHS-BO2005

Knowledge Testing

4B-13

NEXT PHASE PLAN

Proposal Title: Diabetes Prevention and Treatment Programs for Western PA

Project Abstract

Background

Government statistics show that almost 65% of American adults, or more than 120 million people, are overweight or obese. There is a strong link between obesity and diabetes. As the rates of obesity rise, so will the epidemic of diabetes. Diabetes is the fifth leading cause of death by disease in the United States, and annual costs are $132 billion. Without proper medical care and patient education, individuals with diabetes will experience devastating, costly complications. Research shows that if patients at risk for developing diabetes make lifestyle changes, they can decrease their chance of progressing to diabetes by 58%. For those with diabetes, complications can be prevented and/or delayed with proper treatment and education.

Carefully controlled research has clarified interventions that reduce the sequelae of diabetes. Despite agreement with guidelines for diabetes management, doctors often fail to enact appropriate care. Patients are often either unaware of, or mistrust, advice about diabetes interventions; even when patients agree with care goals, they often lack the instrumental knowledge, resources, and motivation to take action steps. The UPMC-Shadyside Primary Care Institute partners with the faith-based Centers for Healthy Hearts and Souls to develop community-based exercise groups, smoking cessation programs, and diabetes support groups in order to reduce cardiovascular risk in the African-American community. The proposed project will tie together these medical practice and community efforts to improve diabetes care and outcomes. It will also expand these successful programs to new sites.

Hypothesis

Culturally-tailored, community-based programs for diabetes support will improve mastery and outcomes for diabetic patients. Modules to encourage smoking cessation, exercise initiation, and depression awareness will be integrated to enhance action steps by diabetics, their family and care takers, and at-risk individuals. Regular attendance at support group meetings, improvement of knowledge about the critical "numbers" for diabetics, sense of mastery related to tobacco avoidance, exercise, stress management, diet, and knowledge about diabetes self-care will improve. A unique scenario-based diabetes knowledge assessment will be implemented. Physician-assessed markers of diabetes, hypertension, hyperlipidemia, and obesity will also improve. Patients who participate in smoking cessation programs and fitness programs will also show improvement. Two new diabetes support groups will be developed to connect to UPMC's parallel practice–based diabetes care improvement projects throughout Allegheny County.

Objectives

To study and determine if:

1. Community-based diabetes support groups help patients increase mastery and improve markers of diabetes outcome.

2. Community-based smoking cessation programs help diabetics to quit smoking and avoid second hand smoke.
3. Community-based exercise groups engage diabetic patients and family members in activities that reduce cardiovascular risk and improve quality of life.

Methods

The UPMC-Shadyside Primary Care Institute partnership with the faith-based Centers for Healthy Hearts and Souls (CHHS) has developed community-based exercise groups, smoking cessation programs, and diabetes support groups in order to reduce cardiovascular risk in the African-American community.

CHHS Diabetes Education and Support Program

Project funding for year 2 will allow continuation at prior sites (Kingsley Center[2], Alma-Illery Health Center, Bethany Baptist, Hill House Community Center), and new sites in Braddock and the Northside. In year 2, funding will allow new site implementation on the Southside and in Wilkinsburg. Year 2 funding will permit the field testing and national dissemination of the improved diabetes knowledge assessment methodology which was developed in year 1. Year 2 funding will now support the infrastructure required to integrate programs for what will now be a comprehensive county-wide community-based diabetes program.

Support Group Concept: Each group member is being trained to take better care of his/her own diabetes, that of a significant other or his/her own risk status. We suggest that people replace the question "Why Me?" with the question "What Would God Have Me Learn from My Efforts to Live with Diabetes." Each group member has been chosen as a Diabetes Messenger and must therefore take responsibility for passing on information about achieving better health to their family and friends.

Group Structure: Each group of 15 to 30 individuals meets every two weeks at local churches or community centers. The group is led by the Diabetes Nurse and a Lay Advocate with the assistance of the group's Physician. A typical meeting includes a spiritual greeting, introduction and testimony of new members, sharing of action steps and new problems or questions, stretching and snack, topical presentation or video vignette, an educational handout and spiritual message.

Educational Tools:

1. "Message to the Messenger" is produced by Nurse Hart for each group meeting and includes topical information, resource information, and motivational messages.
2. Anderson's "Living With Diabetes" videotape vignettes of church-based support groups is used regularly in new groups to trigger discussions and create an understanding of the support group model.
3. Diabetes knowledge games, virtual tours to fast food restaurants, reservoir walks, health fair visits, and presentations by health care experts provide variety.
4. Whenever possible the experienced patients in the group are encouraged to teach other members, under the watchful supervision of the doctor and nurse.

5. A Digiwalker pedometer program helps members to understand their present exercise level, to set goals for improvement, and to measure their achievement.
6. Resource materials such as the CDC manual "Take Charge of Your Diabetes," the CHHS Diet (modified DASH diet), and a fast food menu guide provide a basis for self-improvement between group meetings.
7. Action step avowal and completion will now become a central function of the group process.

Integration of Fitness and Smoking Cessation components.

CHHS Smoking Cessation Programs

Project funding in year 1 has allowed new programming to accommodate high-risk individuals from the diabetes programs. Program facilitators have made presentations at diabetes support group meetings, and a smoking message has become part of each meeting. Referrals to the formal smoking cessation programs has received high priority in scheduling and follow-up. Six of eleven smokers in the support groups have established quit smoking action steps. As a result of project efforts, 140 persons with diabetes or high-risk for diabetes participated in the smoking cessation program outlined below.

Group Structure: The smoking cessation programs are directed by an experienced community-based registered nurse with an MPH degree. Each group of 4-8 individuals meets over a six week period at local churches or community centers. Each group is led by trained community facilitators using an American Cancer Society-approved methodology. Individuals who will not attend a group receive telephone counseling and in some case home visits for counseling. Subsidized nicotine replacement therapy is available through funding from Tobacco Free Allegheny (TFA), and is now provided through commercial and state-supported health plans.

Formal assessment includes an initial "Readiness Questionnaire" and "Smoking History"; CO monitoring; self-report; and attendance. A well-organized follow-up program utilizing phone and mail contacts aims to help each person to meet his/her smoking cessation goals. Program outcomes are reviewed quarterly as part of the TFA contract.

Outreach increased remarkably as a result of CHHS' contract with Tobacco Free Allegheny. Workshops available to diabetes groups include "The Benefits of Not Smoking During Pregnancy," "The CHHS Smoking Cessation Program: A Community Resource Available to You," "Tobacco and Diabetes: Message to the Messenger," and "Exposure to Direct and Indirect Tobacco Smoke Pollution." Two videos for use in groups have been produced: "The Soulful Truth about Quitting Smoking," and "After the Smoke Clears."

CHHS Healthy Lifestyles Fitness Programs

These community-based programs have handled over 15,000 visits in five sites involving over 2000 men and women since 1998. Project funding in year 1 allowed development of new programming to accommodate highly sedentary individuals in the diabetes programs. Facilitators from the Fitness Programs have participated with diabetes support

group members to help them learn enjoyable and practical exercise techniques. Work-out routines were reformulated to allow low capacity patients to use slower tempos and less strenuous choreography: chair exercise, line dancing, and low impact stepping form the central portion of this special program. Home exercise videos and handouts will allow support group members to replicate many facility-based activities at home.

Group Structure: Each group of 20–50 individuals meets one to three times a week at local churches or community centers. Each group is led by the trained Program Facilitators with supervision by Dr. Block and consultation by the UPMC Sports Medicine Fellowship Program. A typical session includes a spiritual greeting, introduction and testimony of new members, sharing of health information and then 45 minutes of warm-up, work out, and warm down.

Facilities for the low impact fitness program have been made available for free as a result of partnerships with such organizations as the Kingsley Center in East Liberty, the YMCA, and Hosanna House in Wilkinsburg.

Formal assessment includes an initial "Readiness Questionnaire" and a "Nutrition History"; a quarterly "ACSM Fitness Evaluation" which includes stamina, strength, flexibility, and body composition testing; and attendance. (see appendix documents H,I, J)

Outreach includes media spots, church and community demonstrations, and mailings. High-risk participants will receive phone reminders.

Exercise outcomes are the most remarkable result of the program thus far. Referrals to CHHS and other local programs have received high priority in scheduling and follow-up. Forty of forty-seven sedentary support group members have met exercise action steps. Ninety-seven members of the CHHS diabetes support groups now participate in the special low-impact CHHS exercise program at Kingsley center on Mondays and Wednesdays. Twelve members are regularly reporting pedometer readings. As a result of project efforts, 292 persons with diabetes or high-risk for diabetes participated in the exercise and fitness programs.

Critical Parameters for Assessing Program Effectiveness

Program Results since 2000:

site	visits/group meeting total	year 1	year 2	year 3	year 4	meetings	total visits
Alma Illery	4.4		3.9	3.9	7.6	37	162
Bethany Baptist	5 6	4.0	5.1	7 4	5.6	47	265
Matilda Theiss	4.6			3.5	7.3	14	64
St James A.M.E.Original	12.2	12.3	10.0			23	280
St. James A.M.E. #1	8.4		10.0	6.5	9.0	53	444
St. James A.M.E #2	11.3		11.2	10.5	16 5	50	564
Grand Total	8.3					224	1779

	total visits by individual only once	>4 visits	>9 visits	>14 visits
number of participants with given visit total	49	102	58	36
number of participants	212	212	212	212
ratio of participants with given visit total	23%	48%	27%	17%

Among forty participants with multi-year participation, HbA1c went from an average of 7.92 down to 6.99, average LDL went from 112.5 to 113, and average weight went from 216.9 to 199.5 pounds. Members rated themselves as having made moderately large changes in activity, diet, self-care, and ability to talk openly about diabetes. Small but positive changes were noted in seeking support from others and understanding their diabetes care numbers.

New evaluation techniques were developed in year 1 of the contract.. A 14 question scenario-based diabetes knowledge assessment was developed and field tested. It differs markedly from the fact-testing of previous tools; instead we collect information on the person's response to difficult situations. The situations were adapted from stories from support group members in the first three years of our project.

Action step avowal and completion became the focus of categorical and quantitative evaluation in the first contract year. Manual forms, reminder forms, and automated reports support the facilitator's efforts to lead group members towards mastery and behavior change.

Through the use of ACCESS data base technology, concurrent automated reports allow the facilitators in each group to know who is overdue for progress reports, what action steps are pending, who has a pending referral, and who has begun to have attendance problems.

Year 2 Deliverables:

The amount and continuity of support group attendance must be high to justify the outlay of time and money. At least two new on-going groups should have been developed by the end of the second contract year (ten total). Groups should average 8-15 members to assure individual participation. If groups become larger they should be divided into new groups of appropriate size. At least 50% of members should attend at least ten sessions in the year to assure a core of experienced diabetics. Regular attendees should show improvement of mastery on self-assessments and improvement in care parameters on doctor's reports. All smokers passing through the group should have documented follow-

up and an initial quit rate of 30% is a minimum goal. All sedentary individuals should have documented follow-up of activity action steps. Those who participate in CHHS programs should show an improvement in flexibility and stamina on repeat testing. The substantial ancillary data being collected should be used to shed light on the components and causes of project successes and failures. Publications detailing these experiences should be produced to assure public review and appreciation of findings and experience.

Relevance

Successful cultural tailoring of prevention and disease management programs is essential to care in the military where ethnic and racial diversity are the rule, rather than the exception. Utilization of retired community nurses and training of lay advocates provides vital culturally-competent resources in underserved communities.

Reduction of the consequences of diabetes will prevent suffering among military personnel and their families, reduce costs to the military, and allow personnel to achieve improved job performance.

Retirees living in civilian communities, but receiving care financed by the Defense Department, need culturally-competent community education and systematic ambulatory chronic care to avoid unnecessary expenditures and morbidity.

1.1 Statement of Work

Goal 1: Continue, improve, and expand diabetes support groups.

Continue diabetes education and support groups at the present sites (Kingsley Center [3], Alma-Illery Health Center, Bethany Baptist, Matilda Theiss Health Center), and the two additional sites developed with Year 1 funding (Braddock and Northside). Add two more groups (Wilkinsburg and Southside) in Year 2.

Program Director: Julia Hart, R.N. with Bruce Block, MD

Time Frame	Task
Week 1-13	1. Hire and train physicians, nurses, and lay advocates as needed 2. Continue biweekly meetings of existing support groups 3. Modify Access database and reports 4. Design marketing and recruitment plan for new sites
Week 14-26	1. Implement marketing and recruitment plan 2. Organize and initiate groups in 2 new sites
Week 27-39	1. Run groups and collect data 2. Review and analyze data 3. Outline re-funding plan for next year 4. Mid-year meeting of participants
Week 40-52	1. Run groups and collect data 2. Review accomplishments and plan next phase

Goal 2: Integrate smoking cessation programs with Diabetes Improvement Project.

Program facilitators will make presentations and lead discussions at diabetes support group meetings, and a smoking message will be part of each meeting. Referrals to the formal smoking cessation programs will receive high priority in scheduling and follow-up.

Program Director: Dereitra Neal-Ferguson, RN, MPH with Bruce Block, MD

Time Frame	Task
Week 1-12	1. Review CHHS database and develop registry of diabetic patients who smoke or have exposure at home or workplace 2. Assess needs of diabetic patients who smoke and their caretakers 3. Provide curriculum to stress disease specific risks of smoking and benefits of quitting for CV health 4. Review and select project evaluation instruments 5. Retrain facilitators as needed
Week 13-17	1. Implement marketing and recruitment plan for new programs in concert with diabetes program director 2. Evaluate and enroll diabetics from education and support groups based on group or telephone counseling preference 3. Identify site(s) for smoking cessation groups
Week 18-26	1. Continue telephone and group programs (6 weeks) 2. Analyze data, modify programs (2 weeks)
Week 27-39	1. Run remainder of groups and collect data 2. Mid-year meeting of participants
Week 40-52	1. Run remainder of groups and collect data 2. Review and analyze recent data, present and publish 3. Outline re-funding plan for next year

Goal 3: Integrate fitness programs with Diabetes Improvement Project

Program have been modified to accommodate highly sedentary individuals in the diabetes programs. Facilitators from the Fitness Programs participate with diabetes support group members to help them learn enjoyable and practical exercise techniques. Activities provided for free at Kingsley Center recreational facility in the East End community.

Program Director: Paul Pelmon with Bruce Block, MD

Time Frame	Task
Week 1-13	1. Assess fitness needs of diabetic patients 2. Design group programs attuned to these needs
Week 14-26	1. Implement marketing and recruitment plan 2. Organize and initiate one new program 3. Modify existing programs as needed

Week 27-39	1. Run groups and collect data 2. Review and analyze recent data, present and publish 3. Outline re-funding plan for next year 4. Mid-year meeting of participants
Week 40-52	1. Run groups and collect data 2. Review accomplishments and plan next phase

Centers for Healthy Hearts and Souls
Diabetes Support Group Monthly and Cumulative Report
January through July 2005

Site	Visits This Month	Visits YTD	New Participants This Month	New Participants YTD	Participants This Month	Participants YTD	Total Sessions This Month	Total Sessions YTD	Participants/ Session This Month	Participants/ Session YTD	Mtg Cancellations This Month*	Reason
Alma Illery	11	122	1	7	11	29	1	14	11.0	8.7	1	Picnic
Bethany Baptist	3	64	0	7	3	18	1	11	3.0	5.8	1	Picnic
Hill House	3	15	0	4	3	15	1	6	3.0	2.5	1	Picnic
Kingsley Group #1	9	147	1	11	9	32	1	14	9.0	10.5	1	Picnic
Kingsley Group #2	11	179	0	11	11	42	1	13	11.0	13.8	1	Picnic
Matilda Theiss		18	0	2		8	0	5		3.6		
TOTAL	37	545	2	42	37	136	5	63	7.4	8.7	5	

Site	% Participants with Active Action Plans	% of Active Action Plans Met	# lab reports received this month	% With Lab Progress Report in Last 6 mos
Alma Illery	83%	57%	0	31%
Bethany Baptist	94%	24%	0	28%
Hill House	73%	0%	0	0%
Kingsley Group #1	91%	36%	0	31%
Kingsley Group #2	74%	48%	0	31%
Matilda Theiss*				0%
	82%	44%	0	27%

*Matilda Theiss group disbanned. Participants transferrad to other locations.

Diabetes Support Group Weight Control Monthly Report

Site	Visits This Month	Visits YTD	New Participants This Month	New Participants YTD	Participants This Month	Participants YTD	Total Sessions This Month	Total Sessions YTD	Participants in Wt Program/ Session This Month	All Participants/ Session YTD	% Participants with Weight Related Action Plans-This Month	% Participants with Weight Related Action Plans-YTD	% of Weight Action Plans Met-YTD
Alma Illery	9	100	2	22	9	26	1	14	9.0	7.1	44%	31%	38%
Bethany Baptist	3	53	0	17	3	17	1	11	3.0	4.8	33%	18%	0%
Hill House	3	4	0	4	3	6	1	6	3.0	0.7	0%	33%	0%
Kingsley Group #1	9	119	1	26	9	30	1	14	9.0	8.5	78%	50%	40%
Kingsley Group #2	7	121	0	24	7	26	1	13	7.0	9.3	71%	46%	25%
Matilda Theiss	0	14		7		7		5		2.8		29%	0%
TOTAL	31	420	3	100	31	112	5	63	6.2	6.7	55%	38%	29%

	# of Community Outreach Programs	# Contacts	# of Medical Office Outreach Programs	# Contacts	
November, 2004	2	41			
December, 2004	2	40			
January, 2005	2	35	1		(Delivered Brochures)
February, 2005	5	194			
March, 2005	2	100	2	28	(Mailed Brochures)
April, 2005	8	408	2	0	(Mailed Brochures)
May, 2005	2	18	0	18	(Mailed brochures to one site)
June, 2005	6	117	0		Made public service announcement heard by 300 people at Fair
July, 2005	4	610	1		(Mailed Brochures)

DATA ANALYSIS
SHEET

43-C

Site	Present Smokers	Smokers at Entry to Program	% Smokers who Smoke Now	# of Referrals Made	Smoking Action Items
Alma Illery	7	7	100%	7	5
Bethany Baptist	1	1	100%	1	0
Hill House	0			0	0
Kingsley Group #1	0	1	0%	0	1
Kingsley Group #2	4	4	100%	4	0
Matilda Theiss	1	1	100%	1	
TOTAL	11	11	100%	11	6

Site	Now Active Previously Sedentary Participants	Sedentary at Entry to Program	% of Sedentary Who Are Now Active	Step Counts	Participants at Kingsley Center Exercise Program
Alma Illery	12	12	100%	4	
Bethany Baptist	6	10	60%	2	
Hill House	1	2	50%		
Kingsley Group #1	5	6	83%	3	
Kingsley Group #2	14	16	88%	3	
Matilda Theiss	2	2	100%		
TOTAL	40	47	85%	12	97

Self Evaluations (WI. Program)	12
Knowledge Assessments	38

PHQ-9 Depression Screen

# Completed	% Abnormal	Referred

Demographics:

Avg Age of Participants: 52 Age Range: 34-84

Females	83
Males	19

Personal Health Assessment

Excellent	3	1%
Very Good	10	11.5%
Good	42	35%
Fair	34	41.5%
Poor	7	8%
Don't know	2	3%
	98	100%

Participant Status

Diabetic	87
At Risk	10
Caretaker	1
At Risk Caretaker	2
No Answer	2
	102

Needs Assessments and Recruiting

Every person contacted in CHHS outreach programs is asked to fill out the IPPA form. The CHHS IPPA form contains screening questions about diabetes, exercise and smoking. Information was sent to each person with a positive response to any screening question. These forms identified 686 persons with diabetes of whom 129 were recruited to the diabetes support group, 292 participated in the Healthy Lifestyle Fitness programs, and 140 attended smoking cessation meetings.

Smoking Cessation

46- D

CHHS

Smoking Cessation Program

Participants

- Allegheny County African American Community
- Medically Underserved
- Those at increase risk for tobacco related morbidity and mortality
  - Pregnant women
  - Infants & children
  - Those with co-morbid conditions (diabetics)

Recruitment

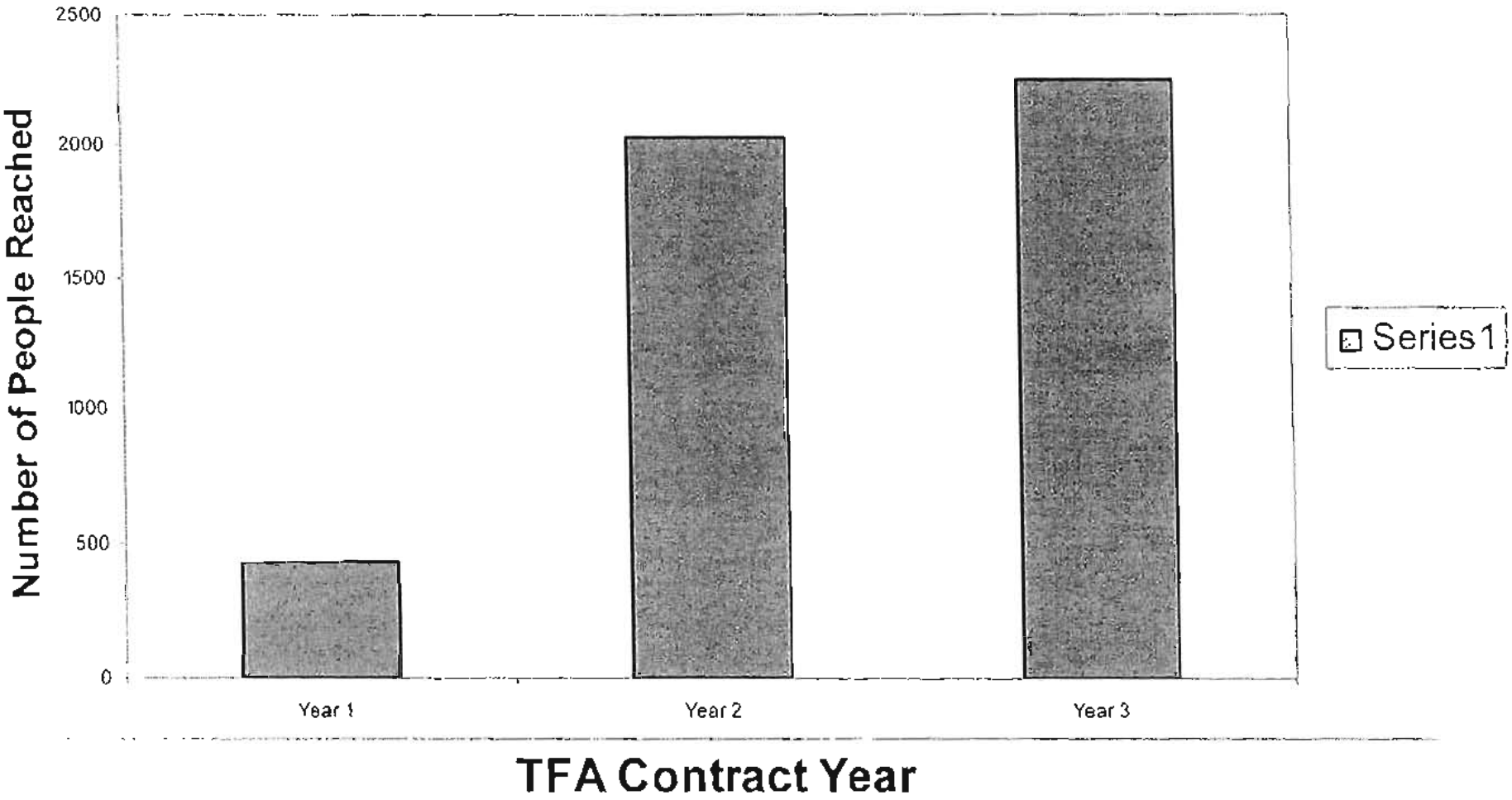
- Word of Mouth
- Health provider/agency referrals
- Community-based workshops and presentations
- Print and electronic media
- Intra-agency referral systems
  - IPPA form
  - Newsletters
  - Church bulletins
  - Local faith-based publications

Program Options

Counseling

- ☐ Group
- ☐ One-on-one & telephone follow-up
- ☐ Combination home visits & group counseling
  - support group meetings for expectant parents
- ☐ *Relapse prevention
  - Quarterly support group activities
  - Combined fitness and smoking cessation program

Outreach Event Attendance/year



Data Collection

- IPPA
- Smoking Survey
- Participant tracking
  - CO testing
  - Attendance
  - Change in cigarette consumption
  - Follow-up
    - 1 month, 3 month, 6 month, 9 month 1year

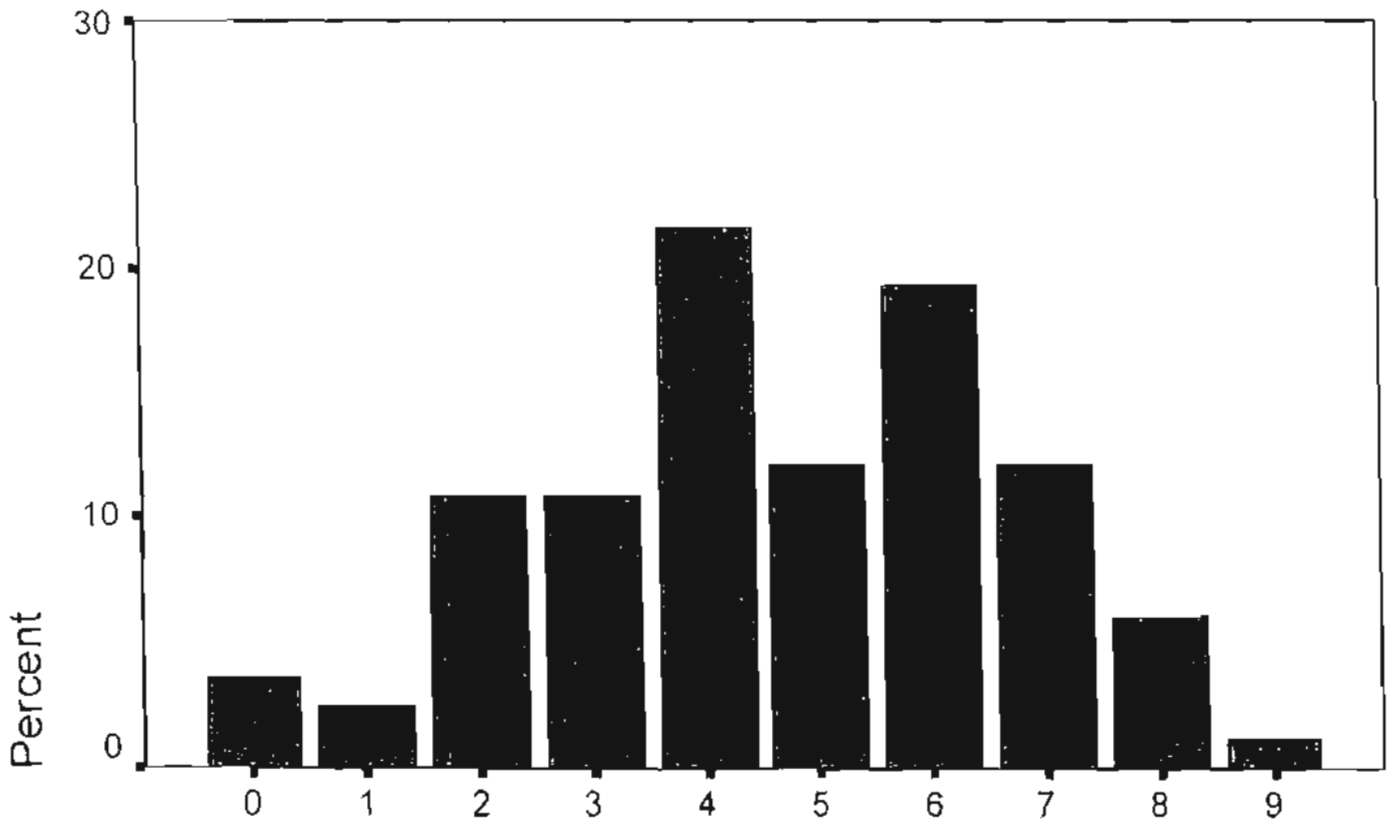
Program Evaluation/Modification

- Data Driven and outcome based

Example: Based on survey findings FTND scores were higher for program participant verse non-participants. In addition NRT therapy was associated with increased quit rates.

Fagerstrom Test For Nicotine Dependence

Current Year Contact - Participants



4B- E

Centers for Healthy Hearts and Souls
Diabetes Education and Support
Marketing and Recruitment Plan

1. Marketing Trends
   a. Brochures
   b. News Papers and other publications
   c. Radio Talk Shows
   d. Television Talk Shows (Advertisement)
   e. Church Announcements
   f. Word of Mouth

2. Market Segments (Who are our participants? What do they want and need?)
   a. Minority people with type II diabetes
   b. People at risk for type 2 diabetes
   c. Care givers of type 2 diabetics

3. Competitors & Replacements (Who are our competitors? Why are we better?)
   a. No other community based diabetes support and education programs
   b. We encourage, equip and challenge people to take control of their diabetes

4. Complements (who can help to sell and promote the program)
   a. The participants and their families
   b. Physician offices
   c. Pastors/Church Health Ministries
   d. Staff and other project participants

5. Communication (Public Statement)
   Our diabetes education and support program provides instrumental knowledge for the development and implementation of culturally-tailored, community-based programs that link clinical imperatives to consumer actions. Exercise involvement, smoking cessation and depression awareness help narrow the health disparities gap and provide essential steps to reach publicly declared 2010 health goals.

   You don't have to feel alone with your diabetes.
   We know it isn't easy to admit you have an illness. No one likes to feel they've lost control of their lives. We want you to know that you are not alone.

   We are here for each other to learn and get better together. Join Us.

Marketing and Recruitment (May 2004-August 2005)
Executed Plan for All CHHS Programs

A. Develop and distribute brochure at churches, health fairs, community organizations, physician offices, family and community gathers
B. Meet with physicians
C. Send letters and other mailings to all participants
D. Pittsburgh Courier and Rejoice, The Mount News Paper Advertisements
E. Meet with Pastors and other community leaders
F. Completion of Initial Program Participant Assessment (IPPA) form
G. Visit churches and various community groups provide presentations
H. Meet with senior residences provide healthy meals and information
I. Radio talk shows
J. WQED/PCTV talk shows
K. Diabetes Expo Presentation
L. Healthy 4 Life Partnership (channel 4 WTAE)
M. National Minority Health Summit
N. PA Diabetes Stakeholders Group
O. AARP Groups Presentation
P. Housing Authority Health Fair Presentation
Q. Sylvania Place Senior Residence Presentation
R. Lambreth Senior Residence Presentation
S. Hill House Senior Citizens Center
T. Utilize church bulletins and postings
U. Develop a diabetes educational video
V. Collaborate with American Diabetes Association, other Health Associations, and providers