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Chronic diseases affect over 90 million Americans and result in high health care costs and tremendous personal and societal burden. Diabetes is, arguably, among the most pervasive and researched chronic diseases. Research shows that much of the costs and burden of diabetes can be mitigated with appropriate education, care- and self-management. This project, called the Comprehensive Management for Chronic Disease (CMICD), focused on innovative technology approaches to improving education about and management of diabetes. The CMICD included: virtual education techniques for training nurses (VNE); an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; a video cell phone approach to providing patients with daily, personalized reminders and education; and a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD were developed and evaluated for accuracy and usability as part of this effort (CADS), other components were or were to be deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others were deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project examined both patient outcomes and providersô changes in knowledge as appropriate. Although the CMICD focused on the management of diabetes, the management approaches within the CMICD are applicable to a variety of other chronic diseases as well, including asthma, depression, and arthritis. This Final Report presents the results of this project.

**15. SUBJECT TERMS**
Telemedicine, diabetes, technology, care-management, decision support, nursing education

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**Introduction**

Diabetes mellitus (DM) affects approximately 24 million people in the United States (Centers for Disease Control, 2005) and is associated with devastating complications in both personal and financial terms. Diabetes is the leading cause of blindness, non-traumatic amputations, and renal failure in adults and reduces life expectancy by 5-10 years. The direct ($153 billion) and indirect ($65 billion) costs of DM care have dramatically increased along with the epidemic increase in the number of those with DM over the past 10 years (Centers for Disease Control and Prevention, 2008; PharmaLive.com, accessed 14January2010). The vast majority of these costs are related to hospitalizations resulting from the chronic complications of diabetes, with only about 15% of the costs attributable to professional visits and pharmaceuticals. Much of the costs and burden of diabetes can be mitigated with appropriate education, care, and self-management.

This project, a collaboration among Walter Reed National Military Medical Center (WRNMC), Mount Aloysius College, and the Henry M. Jackson Foundation, deployed and tested an innovative, technologically sophisticated program for managing and improving outcomes of diabetes. The program is called the Comprehensive Management Initiative for Chronic Disease (CMICD) and included the following: a) virtual education techniques for training nurses (VNE); b) a video cell phone approach to providing patients with daily, personalized reminders and education; c) an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; and d) a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD were developed and evaluated for accuracy and usability as part of this effort (CADS), other components were deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE), and others were deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project examined both patient outcomes and providers' changes in knowledge as appropriate. Although the CMICD focused on the management of diabetes, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis.

**Body**

a. Task/objective regarding Virtual Education Techniques -- to determine whether the use of virtual education techniques can improve diabetes knowledge for practicing registered nurses as well as student nurses

The increased incidence and prevalence of diabetes in rural areas of west-central Pennsylvania, coupled with the scarcity of certified diabetes educators in this geographic location, threatens to become a major public health concern. One response to this growing crisis would be to provide continuing, high quality diabetes education for nurses who care for patients with diabetes in a variety of in-patient and out-patient settings. Such education is often less accessible to nurses who live and practice in rural areas, where distance and time present formidable barriers to educational access. Virtual diabetes education techniques that combined best educational practices with telehealth technology offered a promising solution to this problem.

Thus, the CMICD evaluated the effectiveness of and satisfaction with virtual diabetes nursing education techniques compared to the effectiveness of and satisfaction with traditional, face-to-face, classroom-based diabetes nursing education. The study design for this evaluation was a quasi-experimental design (i.e., nonrandom assignment) with two groups -- half received the in-person training and half received a web-based version. Specifically, traditional diabetes education for nurses taught by certified diabetes educators and clinicians and offered from Walter Reed Army Medical Center (WRAMC; before it was closed) was made available in a web-based format to registered nurses in a rural area of west-central Pennsylvania (PA).

Effectiveness was measured as change (improvement) in diabetes knowledge and nursing skill as measured by pre- and post-class questionnaires. Satisfaction with the education delivery methods was measured using validated questionnaires. Statistical analyses examined whether there were within and between group differences in learning outcomes and satisfaction.

For the web-version of the education, we created and uploaded all course content to a secure web site available only to the PA students. The course content was divided into 'modules' (by lecture) and was synchronized with the "live" lectures delivered by the instructors. After each module, the web site interactively "quizzed" the students on the material presented. We also videotaped a "live" examination of a patient with diabetes by a Nurse Practitioner of the Diabetes Institute at WRAMC, and made this available on the web site. Certain lectures were also provided via video-teleconference to facilitate communication between the students in rural PA with the instructors in Washington, DC, and to integrate the PA students into the course. We held three Nurses Workshops in which we enrolled 24 nurses at the WRAMC site and 32 at the rural PA site.

The results of this quasi-experiment are as follows:

**i)** Students preferred face-to-face interaction with instructors and other students. Difference between the groups was significant: $t=2.70$, $df = 34$, $p< .01$.;

**ii)** The WRAMC group felt that they knew the instructor and other students better than did the rural PA group. Not surprisingly, the online students had little to no knowledge of or interaction with other nurses taking the online course. The difference between the groups was large and highly significant: $t=7.75$, $df=34$, $p<0001$;

**iii)** Both groups felt that material presented met their professional needs. There was no difference between the 2 groups on this measure. Means were very close and highly positive. ***This is what we would hope to see in a comparison of two approaches in which we were hoping for non-inferiority of the new approach.;***

**iv)** Both groups were highly satisfied with the content of the course and were likely to take a similar course in the future (the groups did not differ);

**v)** Both groups performed significantly better on the knowledge (pre and post-test) scores after taking the course [$F(1, 34)$ 48.24, $p < .001$]. There was no significant difference between the in-class and on-line scores and both groups increased about equally (i.e., no significant interaction).

We also conducted a focus group of the PA study participants who did the online course. The group opened discussion with favorable comments about the experience in general. They all felt that the course was very comprehensive and covered all areas of diabetes (peds, geriatric, maternity, etc). They all felt that the course brought to light how outdated their knowledge was about diabetes. Even the RNs that worked for the diabetes institute felt they learned a lot, especially about the medications. They commented that rural PA was behind in diabetes pharmaceuticals. Other positive input included an appreciation of being able to work at their own pace and have the ability to go back over material for review and/or to take notes. They all liked being able to see the speaker. They felt better connected if they saw the speaker at the beginning of each module. There were several modules that did not show the speaker at any time, which they did not like.

They were all in agreement about the last module -- the health assessment. They did not like it and felt it was very deficient. The speaker mainly talked through it while the "patient" just sat there with little or no participation looking uncomfortable. They felt this module was disappointing after going through all the

other modules which they felt were very informative and detailed. None of them felt they learned anything from this module.

They all felt that the pharmaceutical module was a lot of information to absorb. One participant described it as overwhelming. They all said it would have been nice to hear the brand names of the drugs; not just the generic names because they rarely hear or work with generic names. Many of them said they had to look up the brand names which gave them a better understanding. A couple of the participants felt the pharmaceutical module may have been too detailed.

Another drawback that they all agreed on was that the classroom participants would ask questions that were not audible to the online participants. The online participants would hear the answers or explanations that the speaker gave, but didn't hear the question which was very frustrating. They said the speaker should have repeated the question before answering it.

There was some discussion about the content of the online course and whether it covered the pre/post test questions. The group was split 4 to 3 that there were questions asked on the tests that were not explained or covered in the content.

None of the RNs in the focus group experienced any technical difficulties while taking the course. All RNs expressed a very positive experience and would definitely participate in future offerings.

Summation:

Positives:

1. Content of the course was very comprehensive.
2. The speakers/presenters did an excellent job.
3. Had plenty of time (10 weeks) to complete the course.
4. Could work at their own pace.
5. Could review any of the material as much as they liked.
6. Could apply knowledge in their work (patient population).
7. Appreciated the incentives to participate/complete the course (CE credits and Sheetz gift card to cover gas for the pre/post test).
8. Format of the course was easy to access and follow. No technical difficulties.

Negatives:

1. Missed visual of the speakers.
2. No interaction.
3. Couldn't ask questions.
4. The health assessment -- no useful knowledge gained.
5. Pharmaceuticals too detailed and used generic names.
6. Course content did not cover test questions 100%.
7. Could not hear the questions that the classroom participants were asking.

Suggestions:

1. Repeat classroom questions before giving answers/explanations.
2. Email a reminder every two weeks about how much time they have left to complete the course.

3. Show the speaker at the beginning of each module and post their picture with credentials and short bio on index page.

Motivation for participating:

1. CE credits
2. Wanted to update their diabetes knowledge
3. Reputable sources: Walter Reed Army Medical Center Diabetes Institute and Mount Aloysius College
4. Convenient
5. Gift card to cover gas

We do not expect to publish the results of this study. Rather, they are to be translated directly into our educational practices.

b. Task/objective regarding Video Cell Phone Reminders – to determine if a video cell phone reminder system will improve compliance and glycemic control in patients with diabetes mellitus

Control of blood sugar has been shown in multiple studies to reduce the incidence of diabetes complications (Diabetes Control and Complications Trial Research Group, 1993; United Kingdom Prevention of Diabetes Study, 1998). Many people with diabetes struggle to achieve and maintain good glycemic control despite numerous new medications and technologies. There are numerous challenges to accomplishing appropriate control and various approaches to doing so.

The use of self blood glucose monitoring and techniques to improve medication compliance are among the more "non-invasive" methods that have been associated with improvement in diabetes management. Self blood glucose monitoring and medication adherence are each associated with improved glycemic control and reduction in adverse outcomes in both type 1 and in type 2 diabetes. For example, each additional blood glucose measurement results in a decrease in A1c of 0.32% (Schutt et al., 2006). Also, there is a lower rate of fatal and non-fatal cardiovascular events in those who self-monitor their blood glucose (Martin et al., 2006). With respect to medication adherence, once study found that for every 10% increment in drug adherence on a continuous scale resulted in a 0.6% improvement in A1c (Schectman et al, 2002). However, another study found that 27% of patients on 1 or more meds were non-adherent with their drug regimen, resulting in higher A1c's (Krapek et al., 2004). Despite the evidence in favor of these relatively non-invasive methods for achieving diabetes control, patient adherence to self-monitoring and medications is not consistent with providers' recommendations; e.g., 23% of patients with type 1 diabetes are non-adherent (Cramer and Pugh, 2005).

To address this, we conducted a study examining the clinical efficacy of video-based, diabetes/tips reminders, delivered daily via cell phone, on A1c, medication adherence, self-monitoring of blood glucose, and various psychosocial outcomes. The study was a one-year, prospective randomized trial, with the active intervention during the first 6 months. Patients with poorly-controlled Type 1 or Type 2 diabetes (i.e., A1c $\geq$ 8.0%) were recruited from the outpatient clinics of the Diabetes Institute in the Walter Reed Health Care System.

To be eligible for the study, patients had be at least 18 years of age, had to have received care from a Nurse Practitioner (NP) of the Diabetes Institute for at least six months and still be poorly controlled, and had to be taking oral hypoglycemic medications and/or insulin. Patients who were pregnant, lactating, planning to become pregnant, without reliable contraception, or using glucocorticoids, amphetamines, anabolic, or weight-reducing agents were excluded.

Recruitment took place from November 2007 to February 2009. Study staff examined the appointment schedules of the Diabetes Institute's NPs for upcoming appointments and determined the eligibility of these scheduled patients by looking in the electronic medical record. Study staff then contacted all eligible patients by phone or in person to describe the study. All eligible and interested patients provided written informed consent.

Following enrollment, participants were randomized to receive 'usual care' or video messages daily from their own NP. The study used block randomization, which assumed the ratio of active intervention to control was balanced.

Six NPs created 540 (total, factoring in all NPs' videos) 30-60 second videos covering self-care topics outlined by the American Association of Diabetes Educators (AADE) – e.g., healthy eating, being active, monitoring, etcetera. Videos of the patients' NP were sent in random order, at the time of day determined by the participants after randomization. Each video could be viewed multiple times throughout the 24-hour period before the next video was sent.

All enrolled participants received a broadband-enabled cell phone and service for six months, paid for by the study.

Sixty-five participants enrolled in and completed the 12-month study. This sample size was sufficient to detect a decline in A1C of 1.0% (with a standard deviation of 0.90) in the treatment group of 0.50% (with a standard deviation of 0.40) in the usual care group, assuming power is 0.80 and alpha is 0.05. Note that the study had planned for smaller within-group declines in A1C and smaller between-group differences, so the sample size estimate was larger, but interim analyses of A1C change and funding constraints pointed to stopping recruitment at 65.

We analyzed the data and found that both groups experienced declines in A1c. For the video messages group, mean [standard deviation (SD)] decline in A1c from baseline was 1.2% (1.8%), 1.1% (2.3%), 1.2% (2.2%), and 1.3% (1.8%) at 3, 6, 9, and 12 months, respectively. For the usual care group, it was 0.4% (1.2%). 1.1% (1.6%), 1.1% (1.7%), 0.9% (1.6%) at 3, 6, 9, and 12 months. Post-hoc analyses of covariance (ANCOVA) indicated that the two groups' change in A1c from baseline to 3 months, with the baseline A1c included, was significantly different ($p = 0.02$).

The rates of change in A1c over 12 months were significantly different from zero for both treatment groups after controlling for A1c level at the time of enrollment, age, gender, and type of diabetes [(a) $p < 0.002$ for time*usual care and $p = 0.01$ for time*time*usual care and (b) $p = 0.002$ for time*video messages and $p = 0.004$ for time*time*video messages] (Figure 1). The 12-month, adjusted rate of change was greater at all time points for the video messages group, but the group differences were modest -- about 0.1% to 0.2% per time point, with a cumulative decline in A1c at 12 months of 1.2% for the video message group and 1.0% for the usual care group. Age was also significant; i.e., older age was related to decreasing A1c. Gender and type of diabetes were not significant.

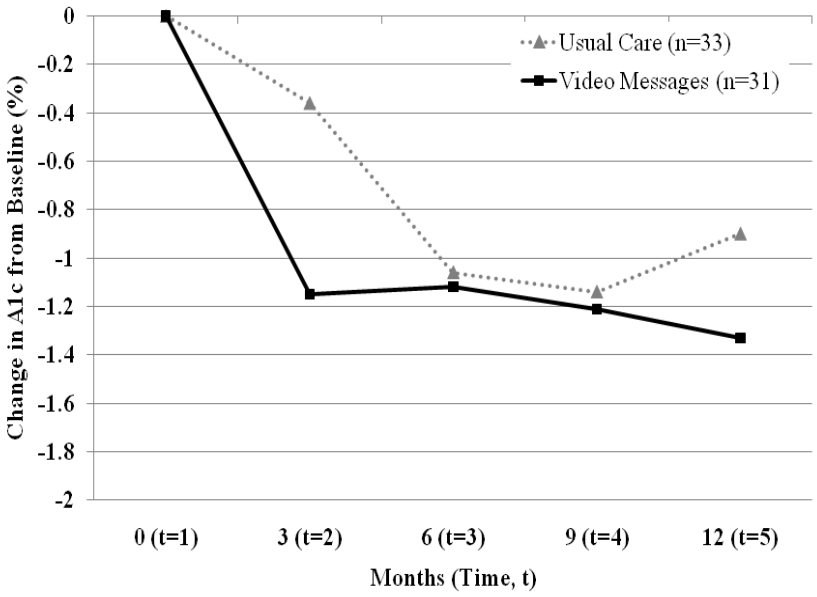


**Figure 1. Mean Change in A1c from Baseline, by Treatment Group and Over Time.**

**Notes:** Change = later A1c - baseline A1c.

Analysis of A1c by viewership found that the consistent viewers experienced the greatest improvement. Mean (SD) A1c decline between baseline and 6 months -- the period of time in which decline was greatest -- was 0.8% (2.2%) for the subjects in the early cessation group, 0.6% (1.4%) for the intermittent viewers, and 1.9% (3.1%) for the persistent viewers. As of 12 months, mean (SD) A1c decline from baseline for the subjects in the early cessation group was 1.1% (1.9%), 1.3% (1.3%) for the intermittent viewers, and 1.7% (2.4%) for the persistent viewers.

The changes suggested by the means were supported by more complicated, "adjusted" statistical models; i.e., 12-month rate of change in A1c was significant for the early cessation group ($p < 0.001$ for time*cessation group and $p = 0.004$ for time*time* cessation group) and the persistent viewers ($p < 0.001$ for time*persistent group and $p < 0.001$ for time*time*persistent group), and the cumulative, adjusted decline over 12 months was 0.6% greater for the persistent viewership group than for the early cessation group (Figure 2).

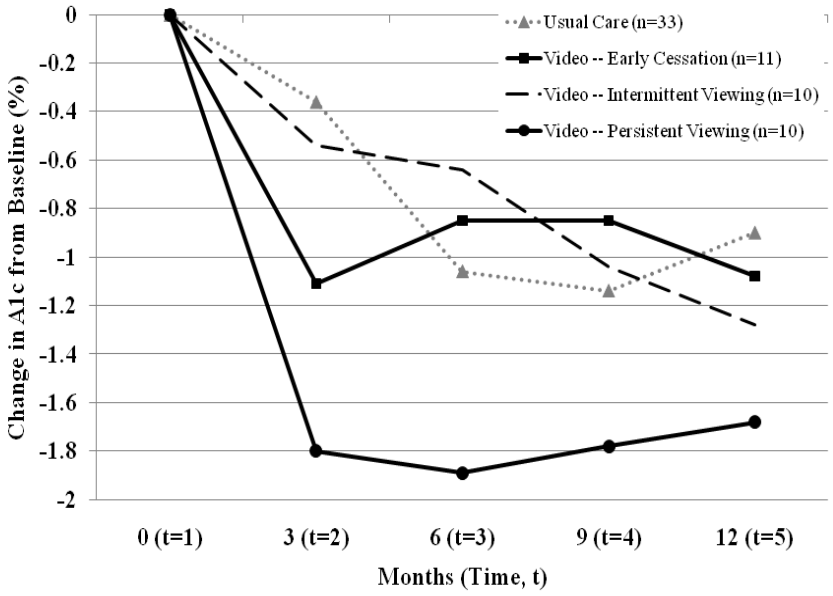


**Figure 1. Mean Change in A1c from Baseline, by Treatment Group and Over Time.**
**Notes:** Change = later A1c - baseline A1c.

The study groups did not differ in terms of whether they provided SMBG data or the amount of hyperglycemia (> 180 mg/dl or > 240 mg/dl) identified by those data. Hypoglycemia (< 70 mg/dl) was slightly more frequent for the video messages group ($p = 0.05$ for both time ranges). Further analyses of hypoglycemia indicate that the highest frequency of hypoglycemic readings was observed for the subjects in the group that did not view the videos ('early cessation group'). There were no significant within-group changes in SMBG metrics over time.

Weight and BP did not change during the study period.

We published the results. The citation is: Bell AM, Fonda SJ, Walker S, Schmidt V, Vigersky RA. Mobile phone-based video messages for diabetes self-care support. *Journal of Diabetes Science and Technology* 2012;6(2):310-319. A copy of the article is included in the Appendix.

c. Task/objective regarding the Deployment of a Telehealth Eye Care Program in rural PA – to deploy this program in clinics in the 12th Congressional District of PA with links to a central reading station at WRAMC

Diabetic eye disease is the leading cause of blindness among working-age adults, yet it is largely preventable with timely diagnosis and treatment (Diabetic Retinopathy Study Research Group, 1981; Early Treatment Diabetic Retinopathy Research Group, 1991). Diabetes-related vision loss is often caused by a combination of poor access to and compliance with periodic eye examinations that target early detection of sight-threatening eye disease. Even in settings with little or no financial barriers to health care, compliance with periodic eye examinations is suboptimal. For example, annual compliance with eye examinations among diabetic patients is 53%, 67.7%, and 52.2% in the Indian Health Service, Department of Veterans Affairs, and the Department of Defense health care systems (Indian Health Service, 2000; Department of Veterans

Affairs, 2000; Department of Defense, 2000). We suspect these rates are worse in geographical regions, such as rural PA, where access to care is more difficult.

To address this problem, we have planned to bring a telehealth eye care program to rural PA. The program was originally developed at the Beetham Eye Institute. This program and those modeled after it are well-described and validated (Aiello et al., 1998; Cavallerano AA et al., 2003; Cavallerano JD et al, 2005; Bursell et al., 2001; Chow et al., 2006). For diagnosis of diabetic retinopathy and diabetic macular edema, the telehealth eye care assessments agree substantially with mydriatic seven-standard field Early Treatment Diabetic Retinopathy Study (ETDRS) protocol photography (Bursell et al., 2001) and with dilated clinical examinations by retina specialists (Cavallerano JD et al., 2005). For diagnosis of nondiabetic eye disease among people with DM, the telehealth eye care assessments agree substantially with dilated clinical examinations by retina specialists (Chow et al., 2006). The Principal Investigator of this grant has validated the telehealth eye care program in both a single clinic and multi-clinic setting, the latter utilizing a hub-and-spoke design with cameras deployed in satellite clinics and a central reading facility at a tertiary care facility; Ahmed and colleagues have shown the telehealth eye care program to be nearly 100% sensitive and specific in the two-thirds of images that are technically capable of being graded (Ahmed et al., 2006). The telehealth diabetes eye care program has also been shown to have better diagnostic and clinical outcomes at lower costs compared to conventional clinic-based eye examinations when used to detect sight-threatening proliferative diabetic retinopathy in the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs (Whited et al., 2005). In addition to being clinically valid and cost-effective, the telehealth eye care program increased patient adherence with recommended standards of care for periodic eye examinations and follow-up treatment (Davis et al., 2003; Conlin et al., 2006; Wilson et al., 2005) and was found to be associated with decline in A1c and lipid levels over time (compared with standard care not involving the telehealth eye care program) (Fonda et al., 2007).

We have experienced many difficulties with this task/objective. We have accomplished much, but then have had insurmountable obstacles. First, we sought to enlist clinics in PA to participate in a randomized controlled trial of the program. We attended 4 meetings, one of which was with the Medical Director of the largest health care provider in the area (Conemaugh Health System). Although initially expressing interest, physicians in that area have refused to participate. They did not agree with substituting the telehealth program for an annual dilated exam (which would be a requirement of a randomized controlled trial) and they were concerned that supporting such a program would adversely affect their revenue by taking patients away. Their refusal forced us to rethink the original research plan.

Since physicians in PA were not willing to conduct a randomized controlled trial of the telehealth eye care program) we developed a new deployment and evaluation plan. We planned a pre-/post-test of the deployment as before, but the deployment involved participating in health fairs and weeklong screenings throughout that targeted geographical area, rather than integrating into a clinic. All people with diabetes who have no prior history of diabetic retinopathy would have been eligible, and we planned to screen them and provide education in the public health-oriented format of the health fair. We also planned to follow study participants over time. This approach was novel and had a public health focus. We submitted a revised Statement of Work which was approved.

We identified 2 local sites willing to participate in weeklong “fairs” or screenings, as well as a local collaborator to assist us. We also identified an Ophthalmology practice in the area where we will, if necessary, be able to refer study/screening participants who are found to have diabetic retinopathy during the screening. This was a challenge because it is still the case that most telehealth eye care programs take place in fixed locations, namely clinics. Next, we received IRB approval at the local level. But then we lost our local champion in rural PA (Dr. Grady), where the study was to b**e** conducted**.** She no longer had an affiliation at the local college where the study received local approval. As important, the federal reviewer identified several large obstacles to this approach; in particular, it would have required local approval at each site we did a fair!

To deal with this obstacle, we submitted another revision to the Statement of Work -- a plan to conduct the study in a socioeconomically disadvantaged area within Washington, DC. This change would have allowed us to submit the protocol to a local IRB, together with someone we would have worked with locally, to carry out the exact same study design as previously described in the earlier Revision to the Statement of Work. We planned to complete the eye screenings ourselves, using our existing equipment and becoming trained in the use of the equipment. The spirit of the protocol was to deploy a public health-oriented telehealth intervention that could identify and prevent diabetic retinopathy-related blindness in an at-risk, underserved population. We developed culturally-relevant eye education, which was to be given to each study participant. Lastly, we identified local champions at Washington Hospital Center, who would have submitted the protocol to their IRB.

The final obstacle, however, prevented us from carrying this work forward – namely insufficient funds to support the Washington Hospital Center staff who wanted to participate on condition that they be brought in as collaborators/consultants (by all means a reasonable expectation!).

d. Task/objective regarding the Use of the Comprehensive Diabetes Management Program (CDMP) by Primary Care Providers – to supply providers in rural PA with CDMP, an interactive, modular, web-based care- and self-management tool for physician, care managers and patients

The CDMP is an interactive, modular, web-based tool for physicians, care managers, and patients, designed to a) provide a high level of continuous care and communication between patients, care managers, and physicians, b) draw on the latest clinical guidelines and guide care managers and physicians in following them, c) focus on patients' clinical and behavioral problem areas, and d) increase the role of the diabetes patient in the care planning process and management. Among the CDMP's modules are the Behavior Assessment Tool (BAT), which is a questionnaire designed to assess patients' barriers to effective diabetes care, and two Nutrition Assessment Tools (NAT-A and NAT-B), which are intended to assess why people eat certain ways. The CDMP also has an overall risk stratification algorithm, which uses a variety of data drawn from the patient's record (such as lab values, blood pressure readings, smoking status, whether or not the patient had a particular exam, etc.) to indicate how the patient compares to established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. The CDMP was developed after the aforementioned telehealth eye care program, because it is well-known that prevention and appropriate management of diabetic retinopathy requires good care- and self-management of diabetes overall. The telehealth eye care program is integrated into the CDMP.

As with the telehealth eye care program, the original study was proposing an evaluation of the quality of diabetes care pre- and post-implementation of the CDMP. The challenges encountered for the above applied to this project as well.

e. Task/objective regarding the Use of a Computer-Assisted Decision Support (CADS) System to improve glycemic control -- to deploy CADS to primary care providers in a pilot study as a proof-of-concept study

Due to the complexity of diabetes, its co-morbidities such as hypertension and hyperlipidemia, and the seriousness of its complications, people with diabetes are usually best monitored by highly skilled health care professionals who are equipped with the latest information to help ensure early detection and appropriate treatment and to provide diabetes education to patients. But due to a dearth of endocrinologists in both military and civilian health care settings, primary care providers (PCPs) (including family practitioners, nurse generalists and physicians' assistants) provide care to the vast majority of patients with diabetes who are not

necessarily equipped with the latest information. And in a healthcare environment where a shortage of Certified Diabetes Educators exists, especially in rural areas, the burden of diabetes education often falls on staff registered nurses in hospitals, physician offices, and other healthcare facilities who may lack the expertise and/or time to provide this service. It is imperative, therefore, to give these providers the advanced technology and health information management tools to support effective care management.

To transfer this knowledge to PCPs, the Principal Investigator developed a series of rules-based algorithms to provide decision support to primary care providers for the management of their patients with diabetes. We call it a Computer-Assisted Decision Support (CADS) System. The software allows for: download of patient self-monitored blood glucose data from memory meters to a central database; display of the data in tabular and graphical form; generation of descriptive statistics; assessment of overall level of control; and evaluation of hypoglycemia and hyperglycemia. A numerical score synthesizing all of the elements of good control is computed and presented. The software identifies a series of potential problems and prioritizes them (e.g. overnight hypoglycemia, hypoglycemia at other times of day, hyperglycemia, excessive postprandial excursions, etc.). The programs then identify the most appropriate change(s) needed in therapy involving oral or injectable regimens for type 2 diabetes, alone or in various combinations. The program indicates which dose or doses of medications should be increased or decreased, when there has been 'failure' of a regimen to provide an adequate level of control consistent with goals for A1c and glycemic levels, and also provides recommendations for moving to another regimen.

After the first version of the CADS System was developed, we determined that we should integrate it with the CDMP so as to facilitate remote patient upload of their self-monitored blood glucose data and to provide the CADS System with as much background information about each patient as possible.

At the beginning of the funding period for this grant, the original software developer, Health Sentry, did not release the required software code to us as scheduled, seriously delaying the integration of CADS with the aforementioned CDMP. The need to integrate with CDMP meant we needed additional time and a Revised Statement of Work. We submitted a Revised Statement of Work and it was approved. The integration was successfully accomplished.

After logging into CDMP and selecting the patient one is working with, the user of CADS can generate and analysis that will provide care recommendations (Figure 3). The screenshot below shows the analysis setup page within CADS within CDMP. Factors considered for generation of recommendations are:

- Patient Information (diabetes type, gender, age, target A1C, range of dates for analysis)
- Glucose Data
- Laboratory Results (A1C, ALT, creatinine)
- Current and Past Medications (drugs, dose, frequency, side effects)
- Comorbid Conditions

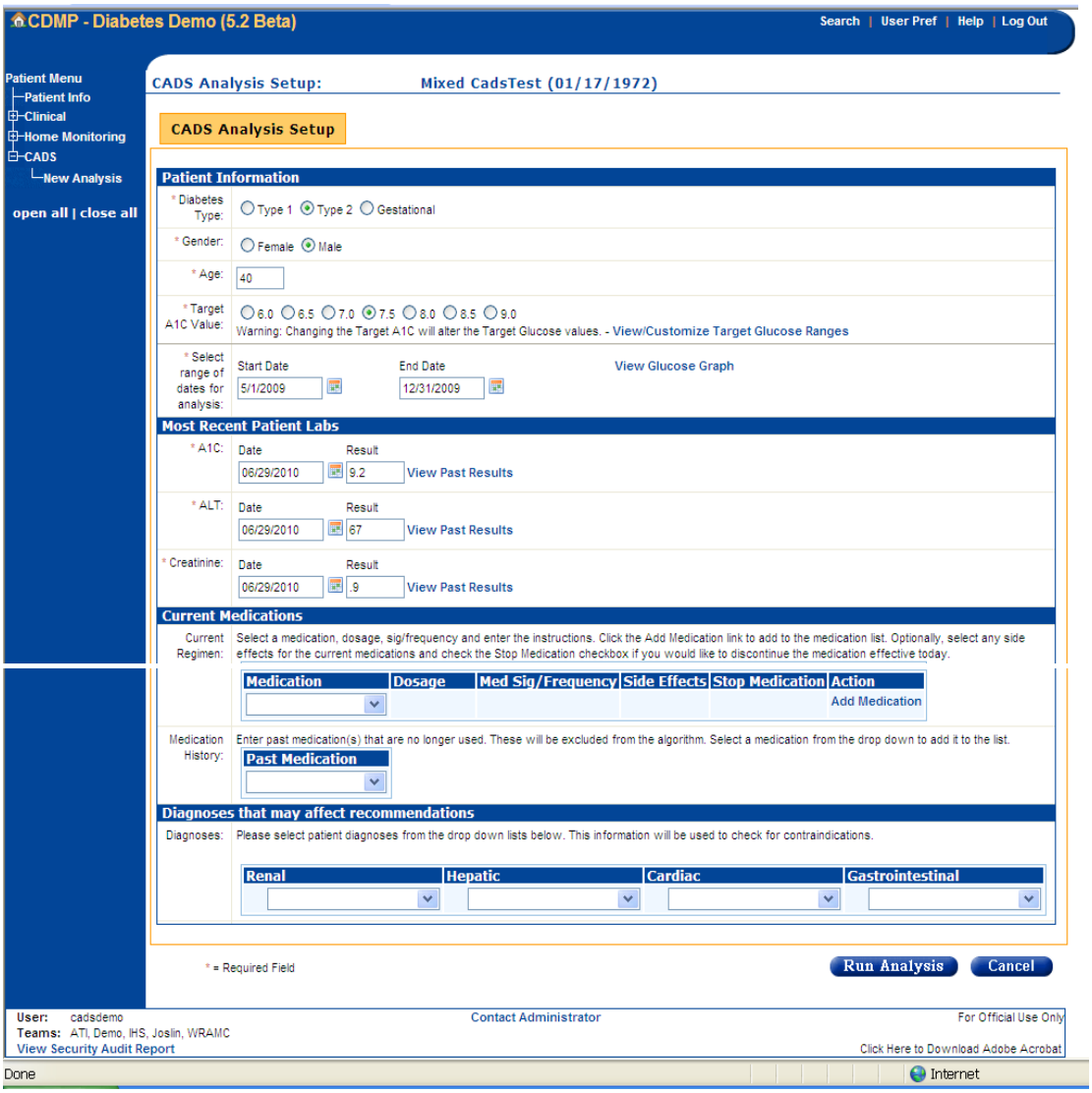


**Figure 3. Screenshot of Set-up Page within CADS**

Setting the target A1C value will automatically set the upper and lower limits of the target range for each of 8 separate times of day, and for the whole day ("AllDay") (Figure 4). If the clinician, wishes to modify any of these values, s/he simply enters a value into the text box. In general, the higher the target A1C is set, the higher the upper and lower limits of the target range will be in order to minimize risk of hypoglycemia. This functionality makes CADS extremely individualized to the needs of the patient and also translates a general target (A1c) into specific, concrete goals (blood glucose at each meal).

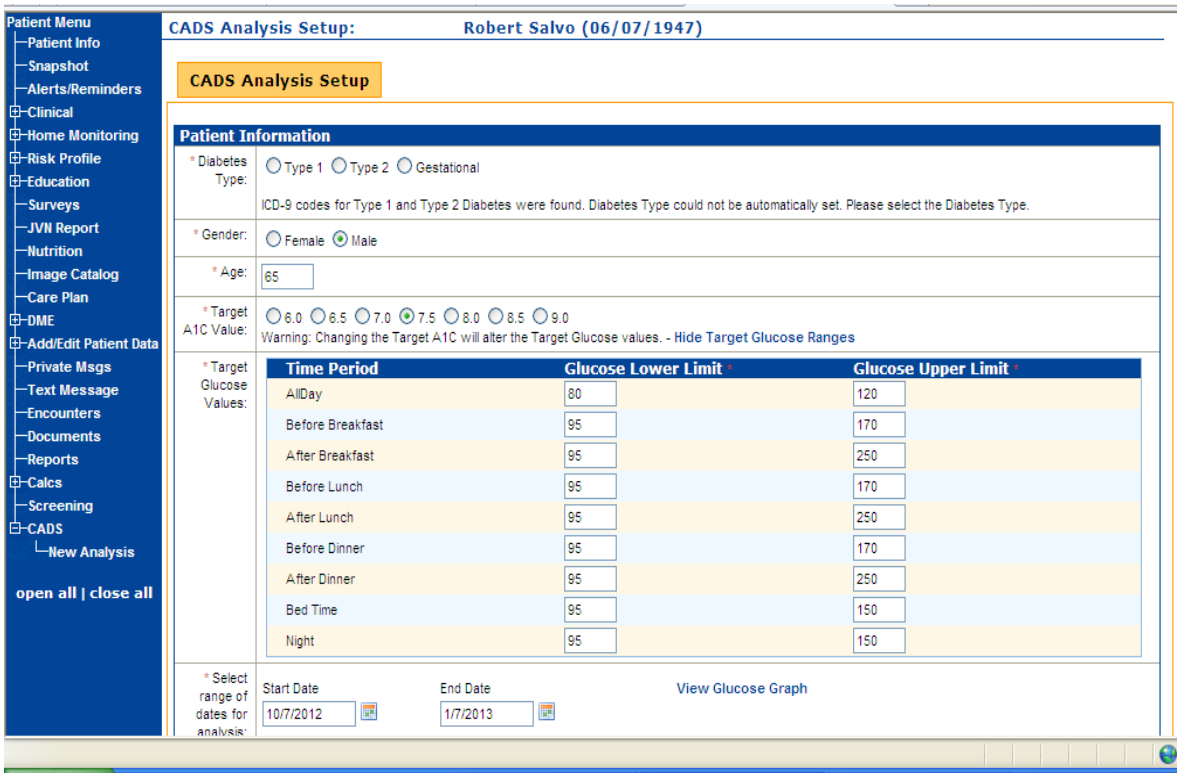


**Figure 4. Setting target A1c and glucose values within CADS**

After completing the entire set-up process, the clinician clicks “Run Analysis” at the bottom of the set-up page and CADS generates a series of recommendations based on the patient information, labs, medications, diagnoses, date range, and A1c (actual, predicted, and target). Figure 5 shows the recommendations for a patient who was taking Metformin and Acarbose. Typically, several recommendations are general and the clinician can view them by clicking “View Next” or “View Previous.” The clinician can also write his/her own recommendation.


**Figure 5. Example recommendation within CADS**

In a user evaluation of the CADS System by a Nurse Practitioner in our clinic, we found that the system was not yet ready for circulation to PCPs. In response, we developed the interface more fully, we devised an improved process for collecting the patients' self-monitored blood glucose data, and we created new, more user-friendly graphs of the self-monitored blood glucose data. Also, new medications for diabetes have been added to the market since the drafting of the original rules and algorithms for the CADS System, so we expanded the application to include those. We additionally developed new use cases, which we discovered as part of the user feedback process. The new use cases ensure that the CADS System is more accurate and complete. Lastly, we wrote a protocol for a full testing of the application (to be performed under separate funding) and developed a Technical Assessment Questionnaire to be administered to providers using the application.

Per the Revised Statement of Work, the outstanding deliverable is now a vetted (with respect to usability and accuracy) CADS System. The user guide for CADS, as it is being used in an ongoing clinical trial under separate funding, is included in the Appendix. The user guide shows much of the functionality not reported here in the interest of space.

**Key Research Accomplishments**

Virtual Education Techniques:

- Completed construction of computer and video-teleconferencing lab at Mount Aloysius
- Scheduled the workshop events
- Completed protocol draft and submitted to IRB
- Completed workshop agenda at Walter Reed
- Developed interactive web site for all of the course content and quizzes

- Conducted 3 workshops and enrolled study participants
- Completed analyses and presented results in this report
- Completed a focus group and presented results in this report

Video Cell Phone Tips/Reminders:

- Created an extensive library of videos
- Drafted protocol, submitted it to the IRB, and received approval
- Recruited 65 subjects and completed the protocol with them
- Conducted analyses of the outcomes
- Published a peer-reviewed paper of our results in the *Journal of Diabetes Science and Technology*

Telehealth Eye Care Program and Comprehensive Diabetes Management Program:

- Met with health care providers and Medical Directors to enlist clinics to participate – which led to rethinking the methodology
- Contracted to buy the equipment needed (but eventually obtained better, free equipment – see below)
- Identified local champions in PA
- Identified and enlisted local sites for a public health-type "fair" or screening
- Established the new methodology by which we will conduct the study
- Drafted a protocol
- The protocol was approved by the local IRB and now we are preparing a response to the federal IRB
- Lost our local champion and revised the plan to do the same study in a socioeconomically disadvantaged area in Washington, DC
- Identified new local champions in DC
- Obtained a few Canon systems to be used for this project (at no cost to this project!!)
- Drafted educational material on eyes and diabetes, for the screening study

Computer-Assisted Decision Support System:

- Developed the interface and how we are going to collect the data so that the application can perform its tasks
- Integrated fully with CDMP
- Through user feedback process, discovered/developed additional use cases
- Developed a Technical Assessment Questionnaire to be administered to providers observing the application
- Wrote a protocol for a full test under new funding
- Created new and improved graphs of the self-monitored blood sugar data
- Completed integration of the system with CDMP
- Wrote a User Guide

**Reportable Outcomes**

The following are presentations we have given to date and include some information from these projects:

- Vigersky R, Bell A, Fonda S, Sami S, Walker S, Schmidt V. Using cell phone reminders in diabetes mellitus. Abstract. *Telemedicine and e-Health* 2009; 15: S31.
- Fonda SJ. A cell phone intervention for improving adherence to diabetes therapy. Presented at the US Army Telemedicine Partnership Series 2010. mHealth: The use of cell phones for Healthcare Applications. Annual Meeting of the American Telemedicine Association, May 2010.
- Fonda SJ. "e-, i-, or m-health? Blurring Boundaries between Provider and Patient-Centered Management". Annual Meeting of the Diabetes Technology Society, November 13, 2010.

- Bell AM, Fonda SJ, Walker S, Schmidt V, Vigersky RA. Mobile phone-based video messages for diabetes self-care support. *Journal of Diabetes Science and Technology* 2012;6(2):310-319.

The following are projects that we have applied for funds to support. Aspects of these projects have grown out of what we have learned conducting this project. In brief, the projects will:

- Develop and study a Personal Health Record Application (PHR-A) that captures information about daily living important for diabetes & provides decision support with actionable advice for diabetes self-care
- Develop a self administered stereo non mydriatic automated retinal camera (SNARC) containing automated retinal lesion (ARL) detection using adaptive optics
- Study the use of a Computer-Assisted Decision Support (CADS) system to improve outcomes in patients with Type 2 Diabetes who are treated by Primary Care Providers.

**Conclusion**

The CMICD was a multi-project effort involving a blend of research (i.e., hypothesis-testing) and development of new telehealth/telemedicine tools. We believe that the projects herein have the potential to address and/or prevent the serious complications of diabetes, even in geographical regions or socioeconomic settings where access to diabetes education and/or care are limited. One such project can reduce or prevent complications through the use of diabetes tips and reminders sent via a relatively low-cost, ubiquitous and familiar tool, the cell phone. Another project has the potential to do so through the combination of telemedicine technologies and public health-based education to provide a quick, convenient, and low-cost evaluation for diabetic retinopathy. The evaluation for diabetic retinopathy can then lead to a care management plan based in best practices guidelines, using our medical informatics tool, the CDMP. Although the potential value of telehealth tools for diabetic retinopathy seemed obvious to us, the introduction of a screening tool that did not require a specialist to take the images was an unanticipated threat to the eye care doctors in rural PA and ultimately undermined the success of this project. Yet another project can mitigate diabetes complications with the development and distribution of diabetes expertise – as computer-assisted decision support – to providers who are generalists and/or do not have the time to stay apprised of the many and varied drug regimens for diabetes management. Finally, with the CMICD, nurses in rural areas who care for patients with diabetes but do not have access to or time-flexibility for diabetes-specific continuing education can now receive this education through the Internet, at their own pace and while continuing to work. Although the content of the tips, decision support, education, and clinical guidelines is all about diabetes, the approaches here can easily be applied to other chronic diseases.

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**Appendices**

1. Bell AM, Fonda SJ, Walker S, Schmidt V, Vigersky RA. Mobile phone-based video messages for diabetes self-care support. *Journal of Diabetes Science and Technology* 2012;6(2):310-319.
2. CADS User Manual for use of CADS in an ongoing multicenter clinical trial (sponsored separately from this project).

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ORIGINAL ARTICLE

# Mobile Phone-Based Video Messages for Diabetes Self-Care Support

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## Abstract

***Background:***

This study examined whether mobile phone-based, one-way video messages about diabetes self-care improve hemoglobin A1c (A1C) and self-monitoring of blood glucose (SMBG).

***Methods:***

This was a 1-year prospective randomized trial with two groups. The active intervention lasted 6 months. The study enrolled 65 people with A1C >8.0% who were established (>6 months) patients in the endocrinology clinics of the Walter Reed Health Care System. Participants were randomized to receive "usual care" or self-care video messages from their diabetes nurse practitioner. Video messages were sent daily to cell phones of study participants. Hemoglobin A1c and SMBG data were collected at 0, 3, 6, 9, and 12 months.

***Results:***

Participants who received the messages had a larger rate of decline in A1C than people who received usual care (0.2% difference over 12 months, adjusting for covariates; $p = .002$ and $p = .004$ for the interaction between time and group and for the quadratic effect of time by group, respectively). Hemoglobin A1c decline was greatest among participants who received video messages and viewed >10 a month (0.6% difference over 12 months, adjusting for covariates; $p < .001$ for the interaction between time and group and the quadratic effect). Self-monitoring of blood glucose metrics were not related to the intervention.

***Conclusions:***

A one-way intervention using mobile phone-based video messages about diabetes self-care can improve A1C. Engagement with the technology is an important predictor of its success. This intervention is simple to implement and sustain.

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**Abbreviations:** (A1C) hemoglobin A1c, (BP) blood pressure, (mhealth) mobile health, (NP) nurse practitioner, (SD) standard deviation, (SMBG) self-monitoring of blood glucose, (SMS) short message service

**Keywords:** diabetes education, lifestyle, mobile health, telemedicine

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## Introduction

Despite the well-documented benefits of glycemic control[1,2] and a secular trend to overall improvement in people with diabetes,[3] glycemic control is still suboptimal in many patients. According to the National Health and Nutrition Examination Survey, 43.2% of people with diabetes had hemoglobin A1c (A1C) levels greater than or equal to the generally recommended target of 7.0%.[3] Achieving target glycemic control typically requires a multifactorial approach with considerable commitment from the person with diabetes to examine and interpret random blood glucose readings correctly, take medications as prescribed, follow a balanced, whole foods-based diet, and engage in regular physical activity. For a variety of reasons, many people with diabetes do not adhere to these requirements;[4–8] failure to do so may be due to inadequate education about the purpose and outcomes of such behaviors and the absence of support and/or reminders.

Researchers have sought to determine whether mobile health (mhealth) on a cell phone can support diabetes management and self-care.[9] Such a solution is attractive because cell phones are ubiquitous, mobile (support can be available anytime and anywhere), and increasingly "smart." The "smart" features of cell phones allow patients to upload or manually type in-home monitoring data, receive provider feedback via a phone call or short message service (SMS), receive reminders and tips, and access information at a Web site through the cell phone's browser. Thus far, some but not all mhealth research suggest that mobile phone-based interventions to support diabetes care result in favorable clinical outcomes, particularly if the intervention involves two-way communication with data inputs from the patients and individualized feedback from a health care provider.[9–15]

In the present study, people with diabetes received daily, asynchronous one-way videos of diabetes-related tips and reminders delivered via cell phones. The intervention was an adjunct to usual and specialty diabetes care, aimed at providing generalized lifestyle support to people who were not meeting glycemic targets despite receiving specialty diabetes care. The primary study hypothesis was that those subjects who received daily video messages on their mobile phones about diabetes self-care over 6 months would improve their glycemic control at 6 months and that it would continue over the ensuing 6 months. In addition, we hypothesized that the intervention would be associated with greater adherence to SMBG and better glycemic metrics derived from self-monitoring data.

## Methods

### *Design Overview*

The study was a 1-year prospective randomized trial, with active intervention during the first 6 months.

### *Participants and Recruitment*

Patients with poorly controlled type 1 or type 2 diabetes (i.e., A1C ≥8.0%) were recruited from the outpatient clinics of the Diabetes Institute in the Walter Reed Health Care System, Washington, DC. The Walter Reed Health Care System treats active duty military, retirees from the military, and their dependents. All diabetes supplies, including meters and strips, are provided to patients without charge.

To be eligible for the study, patients had to be at least 18 years of age, had to have received care from a nurse practitioner (NP) of the Diabetes Institute for at least 6 months and still be poorly controlled (A1C >8%), and had to be taking oral hypoglycemic medications and/or insulin. All patients were able to demonstrate their ability to use a mobile phone and were provided with a mobile phone and subscription for 6 months. Patients who were pregnant, lactating, planning to become pregnant, without reliable contraception, or using glucocorticoids, amphetamines, anabolic, or weight-reducing agents were excluded.

Recruitment took place from November 2007 to February 2009 (**Figure 1**). Study staff examined the appointment schedules of the Diabetes Institute's NPs for upcoming appointments and determined the eligibility of these scheduled patients by looking in the electronic medical record. Study staff then contacted all eligible patients by phone or in person to describe the study. The study was approved by the Human Use Committee/ Institutional Review Board at the Walter Reed Army Medical Center. All eligible and interested patients provided written, informed consent.

The study enrolled 65 participants. The achieved power for this study is 0.93 given a medium effect of 0.25, an alpha of 0.05, a correlation of 0.40 between repeated factors, and a correction for nonsphericity in which epsilon is 0.40.

One participant had a baseline A1C that was greater than 15%, an outlying value, so the analyses exclude those data ($n$ = 64).

### *Intervention*

Following enrollment, participants were randomized to receive usual care (defined as the care that would be provided if the patient was not in the study) or video messages daily from their own NP. The study used block randomization, which assumed the ratio of active intervention to control was balanced.

Six NPs created 540 30- to 60-second videos covering self-care topics outlined by the American Association of Diabetes Educators,[7]—e.g., healthy eating, being active, monitoring.[16] Samples of the scripts for the videos are in the online **Appendix** (**Table 1**), and sample videos are available at: http://www.wramc.army.mil/Patients/healthcare/medicine/diabetes/Pages/default.aspx. Video messages of the NPs were sent to their patients in random order, at the time of day determined by the participants after randomization. Each video could be viewed multiple times throughout the 24-hour period before the next video was sent.

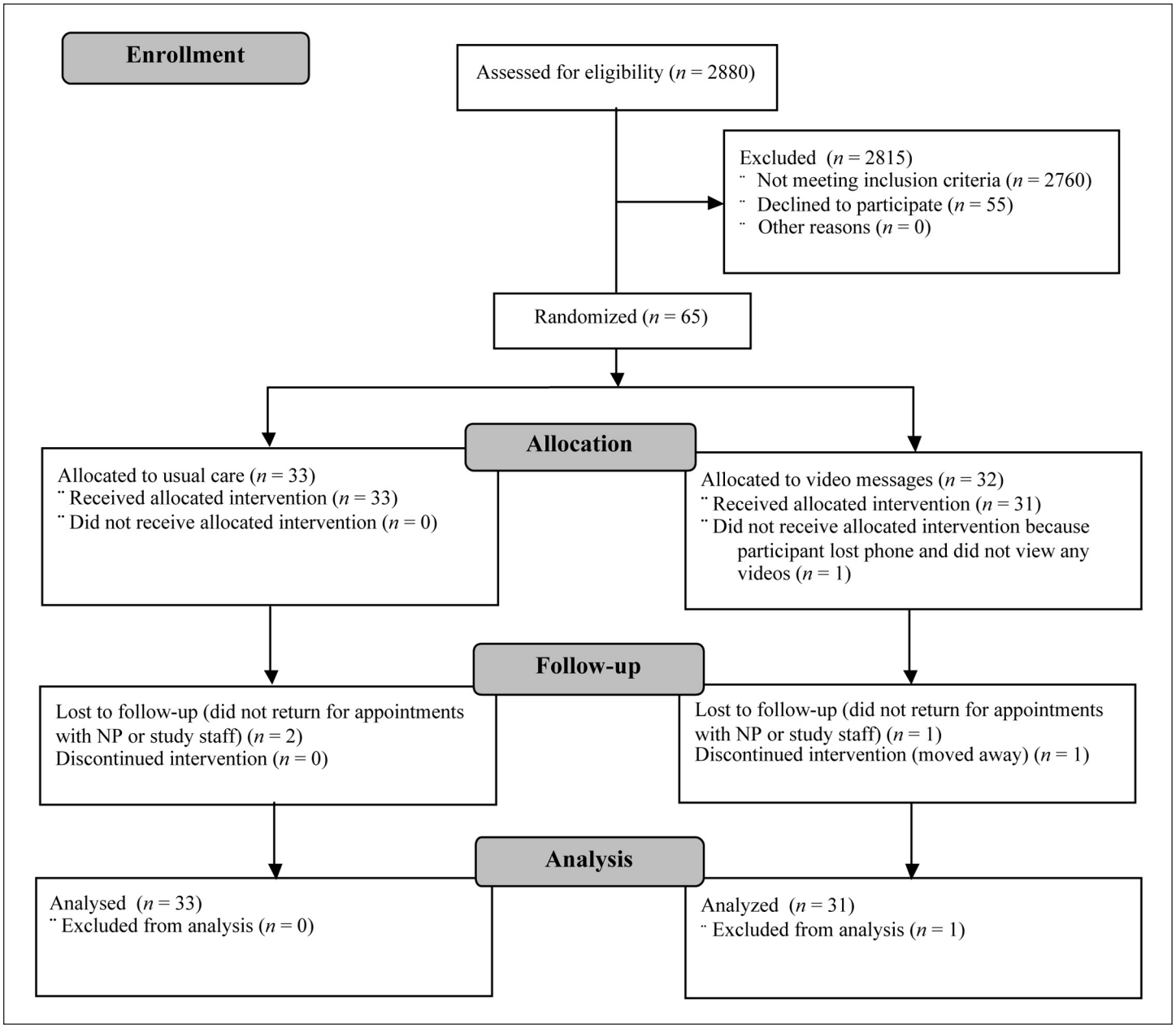


**Figure 1.** CONSORT diagram.

All enrolled participants received a broadband-enabled cell phone and service for 6 months, paid for by the study.

### *Measures*

Participants were seen by the study staff at baseline and quarterly thereafter for the collection of study metrics. The primary research outcome was glycemic control as measured by A1C. The A1C was measured using a COBAS® C 111 analyzer (Roche Diagnostics, Indianapolis, IN) with a Tina-quant® HbA1c Gen. 2 whole blood assay (Roche Diagnostics) in the Walter Reed Clinical Laboratory. The secondary research outcomes were change in weight, change in blood pressure (BP), whether the participants provided SMBG measurement data (as a proxy for whether they collected it), the proportion of SMBG measurements that were above 180 mg/dl and below 70 mg/dl, and the mean of participants' SMBG values at each quarterly visit.

We counted the number of videos each participant viewed per month and then grouped participants as follows: (1) did not view videos at all or did so briefly at the beginning of their participation and then stopped in the first 2 months (early cessation; $n = 11$); (2) viewed the videos throughout the active intervention but <10/month, sometimes missing whole weeks (intermittent viewers; $n = 10$); and (3) viewed 10+ videos/month (persistent viewers; $n = 10$).

We obtained age, gender, race/ethnicity, duration of diabetes, type of diabetes, and medications used to manage diabetes at baseline from the medical record.

### *Statistical Analysis*

The analyses examined group differences in background characteristics and changes from baseline of the outcome measures using *t*-tests and chi-square tests. Next, the analyses estimated multilevel (i.e., mixed or individual growth) models for repeated measures to characterize within- and inter-individual change in actual A1C values. These models included potentially confounding background characteristics defined as such by clinical experience (e.g., type of diabetes) or demographics (e.g., gender, age) and quadratic effects for time, which permitted analyses of the anticipated leveling of change in A1C after cessation of the intervention. The analyses then used chi-square tests or Fisher's exact test to examine group differences in the provision of SMBG data and analysis of variance to test for within- and between-group differences in the SMBG metrics. All statistical analyses used SAS® 9.2 (SAS Institute Inc., Cary, NC).

## Results

Characteristics of the study population are shown in **Table 1**. Mean age of the participants was 55 (video messages group) and 60 years (usual care group). Overall, most participants attended at least some college, were African American, had type 2 diabetes, and were obese. Mean years since diabetes diagnosis and medication usage were similar between the two groups.

Both groups experienced declines in A1C (**Figure 2A**). For the video messages group, mean [standard deviation (SD)] decline in A1C from baseline was 1.2% (1.8%), 1.1% (2.3%), 1.2% (2.2%), and 1.3% (1.8%) at 3, 6, 9, and 12 months, respectively. For the usual care group, it was 0.4% (1.2%), 1.1% (1.6%), 1.1% (1.7%), and 0.9% (1.6%) at 3, 6, 9, and 12 months. *Post hoc* analyses of covariance indicated that the change in A1C from baseline to 3 months, with the baseline A1C included, was significantly different ($p = .02$) between the two groups.

The rates of change in A1C over 12 months were significantly different from zero for both treatment groups after controlling for A1C level at the time of enrollment, age, gender, and type of diabetes [(a) $p < .002$ for time × usual care and $p = .01$ for time × time × usual care; and (b) $p = .002$ for time × video messages and $p = .004$ for time × time × video messages]. The 12-month, adjusted rate of change was greater at all time points for the video messages group, but the group differences were modest—approximately 0.1–0.2% per time point, with a cumulative decline in A1C at 12 months of 1.2% for the video message group and 1.0% for the usual care group. Age was also significant; i.e., older age was related to decreasing A1C. Gender and type of diabetes were not significant.

Analysis of A1C by viewership found that the consistent viewers experienced the greatest improvement (**Figure 2B**). Mean (SD) A1C reduction between baseline and 6 months—the period of time in which decline was greatest—was 0.8% (2.2%) for the subjects in the early cessation group, 0.6% (1.4%) for the intermittent viewers, and 1.9% (3.1%) for the persistent viewers. As of 12 months, mean (SD) A1C decline from baseline for the subjects in the early cessation group was 1.1% (1.9%), 1.3% (1.3%) for the intermittent viewers, and 1.7% (2.4%) for the persistent viewers. The changes suggested by the means were supported by the adjusted models. Specifically, for the early cessation group and the persistent viewers, the 12-month rate of change in A1C and the quadratic effect of time were statistically significant [(a) $p < .001$

**Table 1.**
**Baseline Characteristics of the Study Participants, Total and by Group[a]**

| Measure | Total sample ($n$ = 64) | Video messages group ($n$ = 31) | Usual care group ($n$ = 33) | $p$ value |
|---|---|---|---|---|
| Age (mean, SD) | 58 (11) | 55 (10) | 60 (11) | .06 |
| Male ($n$, %) | 35 (55%) | 15 (48%) | 20 (61%) | .33 |
| Education ($n$, %): | | | | |
| Less than HS grad | 4 (6%) | 1 (3%) | 3 (9%) | .23 |
| Completed HS | 8 (13%) | 4 (13%) | 4 (12%) | |
| Some college | 28 (44%) | 17 (55%) | 11 (33%) | |
| College grad or higher | 23 (36%) | 8 (26%) | 15 (45%) | |
| Ethnicity ($n$): | | | | |
| Black | 37 (58%) | 19 (61%) | 18 (55%) | .78 |
| Asian | 3 (5%) | 2 (6%) | 1 (3%) | |
| Hispanic | 4 (6%) | 2 (6%) | 2 (6%) | |
| White | 20 (31%) | 8 (26%) | 12 (36%) | |
| Type 2 (%) | 59 (92%) | 27 (87%) | 32 (97%) | .14 |
| Years since diagnosis (mean, SD) | 13 (9) | 14 (9) | 13 (9) | .64 |
| Systolic BP (mean, SD) | 136 (19) | 132 (21) | 139 (17) | .16 |
| Diastolic BP | 78 (11) | 77 (10) | 80 (12) | .20 |
| Body mass index (mean, SD) | 34 (7) | 33 (6) | 35 (8) | .29 |
| Medications—taking ($n$, %): | | | | |
| Exenatide (Byetta®) | 4 (6%) | 2 (6%) | 2 (6%) | .95 |
| Sitagliptin (Januvia®) | 1 (2%) | 1 (3%) | 0 (0%) | .30 |
| Metformin | 34 (53%) | 18 (58%) | 16 (48%) | .44 |
| Sulfonylurea | 25 (39%) | 11 (35%) | 14 (42%) | .57 |
| Thiazolidinedione | 8 (13%) | 3 (10%) | 5 (15%) | .51 |
| Basal insulin +/- other medication | 28 (44%) | 15 (48%) | 13 (39%) | .54 |
| Prandial insulin +/- basal insulin | 45 (70%) | 22 (71%) | 23 (70%) | .91 |
| A1C at baseline (mean, SD) | 9.3 (1.3) | 9.6 (1.5) | 9.0 (0.9) | .07 |

[a] One subject was excluded from analyses because s/he had an outlying A1C value at baseline. Not all columns total 64 because of missing data resulting from nonresponse. Subjects were often taking multiple medications, so the sum of the percentages exceeds 100. $P$ values are for the statistical comparisons of the two treatment groups. These comparisons required chi-square tests and $t$-tests, depending on the level of measurement.

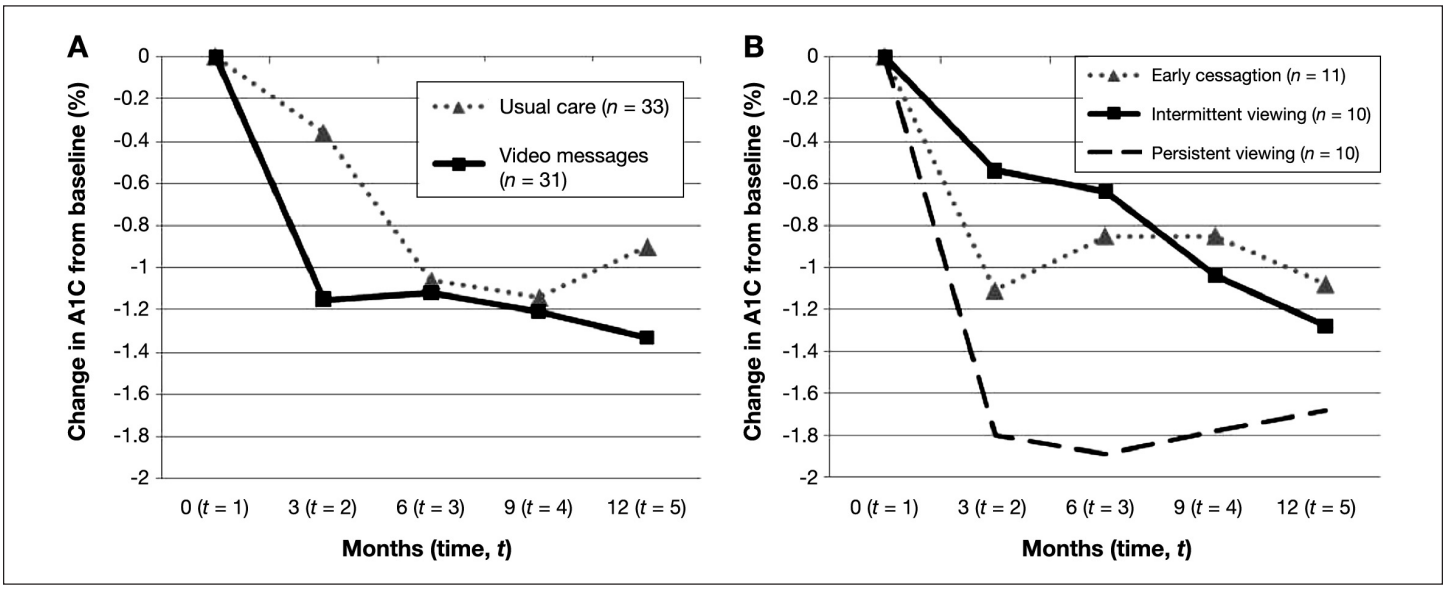


**Figure 2.** Mean change in A1C from baseline, by treatment group and over time. Change = later A1C – baseline A1C. **(A)** Two main treatment groups, video messages vs usual care. **(B)** Viewership groups within the video messages group, with the usual care group indicated as reference [note that this line is identical to the line in **(A)**]. The intervention ended at 6 months.

for time × cessation group and $p = .004$ for time × time × cessation group; and (b) $p < .001$ for time × persistent group and $p < .001$ for time × time × persistent group]. The cumulative, adjusted decline in A1C over 12 months was 0.6% greater for the persistent viewership group than for the early cessation group, which is a clinically meaningful difference.

From the multilevel models for **Figure 2A**, the equations for the two treatments are as follows:

(1) Video Group A1C Over Time = 13.2 – 1.19 (time) + .15 (time) (time) – 0.02 (age) + 0.02 (male) – 0.53 (diabetes type 1); and (2) Usual Care Group A1C Over Time = 12.7 – 0.97 (time) + 0.12 (time) (time) – 0.02 (age) + 0.02 (male) – 0.53 (diabetes type 1).

From the multilevel models for **Figure 2B**, the equations for the viewership groups are as follows:

(1) Early Cessation Group A1C Over Time = 12.8 – 0.94 (time) + 0.11 (time) (time) - 0.01 (age) + 0.23 (male) – 1.25 (diabetes type 1); (2) Intermittent Group A1C Over Time = 12.0 – 0.20 (time) – 0.02 (time) (time) – 0.01 (age) + 0.23 (male) – 1.25 (diabetes type 1); and (3) Persistent Group A1C Over Time = 15.0 – 2.70 (time) + 0.38 (time) (time) – 0.01 (age) + 0.23 (male) – 1.25 (diabetes type 1).

The study groups did not differ in terms of whether they provided SMBG data or glycemia metrics—the amount of hyperglycemia (>180 mg/dl or >240 mg/dl) identified by those data. The data are available in the online **Appendix** (**Table 2**). Hypoglycemia (<70 mg/dl) was slightly more frequent for the video messages group ($p = .05$ for both time ranges). Further analyses of hypoglycemia indicate that the highest frequency of hypoglycemic readings was observed for the subjects in the group that did not view the videos (early cessation group). There were no significant within-group changes in SMBG metrics over the first 6 months or the subsequent 6 months.

Weight and BP did not change during the study period (data not shown).

## Discussion

This study sought to determine whether mobile phone-based, one-way video messages about diabetes self-care improve A1C and SMBG. The study enrolled people with diabetes who, despite having received specialty diabetes care for at least 6 months and being on medications, were not meeting the A1C goals promulgated by all professional associations. The overall purpose of the video messages was to augment primary and specialty diabetes care. We found that participants in the video messages group experienced a greater rate of decline in A1C over time than those who received usual care, especially in the first 3 months. However, the rate of decline was greatest among people who received the videos and viewed them consistently; this difference was statistically significant and clinically meaningful (i.e., 1.1% difference in unadjusted means and 0.6% cumulative, adjusted difference between those who received messages and did not watch them at all or stopped in the first 2 months of the study). Participants' improvement continued in the 6 months following cessation of the intervention despite no longer having access to the videos, suggesting a legacy effect.

A limitation of this study is that the average A1C for the video messages group was higher at baseline than that of the usual care group ($p = .07$), and it is well known that people with higher A1Cs are more likely to experience larger improvements in A1C than people with A1Cs closer to generally recognized targets. The analyses accommodated this difference through the use of multilevel models. These models allowed us to examine all data over time to get an overall sense of group differences in rates of change, not just mean changes from baseline at each individual time point. Additionally, they included treatment group as a fixed effect and generated a result for this effect, which represented the mean difference of the outcome between the two groups at baseline; in other words, the model adjusted for possible baseline differences in the outcome between the groups. Lastly, the models specified covariance structures for repeated measurements of the participants over time; the best covariance structure in this case was autoregressive order 1, which recognized that temporally proximate observations/values have higher correlations than distant observations/values.

We designed the study to investigate the effect of a mobile intervention that would augment usual and specialty diabetes care, because mhealth has been shown to be successful in chronic disease management, including asthma, cystic fibrosis, smoking cessation, and others.[9] Application of mhealth in diabetes care has varied in focus: one study compared cell phone-based support to internet-based support and found both modes were related to improvement in glycemic control;[17] one examined email reminders for blood glucose readings versus SMS and found participants responded more to SMS;[18] another qualitative study found that study

participants adjusted their medication, food habits, and/or physical activity while using a new cell phone system for diabetes self-care.[19] Results from randomized trials comparing a cell phone intervention with usual care are mixed, with some showing no group differences in glycemic control based on intention-to-treat analyses[10] and some showing marked improvements in glycemic control,[12,13] especially when study participants received individualized support.[14,15]

Our findings for A1C were consistent with previous examinations of mobile phones for diabetes management documenting a decline in A1C, but the decline we report here is not as great. An important difference between our intervention and others is that A1C improved with one-way support, meaning there was no additional input from the health care providers as part of the intervention after the creation of the videos, and all the participants received the same videos irrespective of their particular interests or needs. As noted above, other mobile phone-based diabetes interventions that also achieved improvement in A1C had included individualized support from health care providers. Although these two-way interventions led to a greater drop in A1C than we found, the continual input needed from health care providers as part of the interventions is more costly and difficult to implement widely than our approach, especially if patients use their own phones and service. A more individualized strategy in using our approach, but one that does not require continual response from health care providers, would be to send only those videos to patients that address their specific needs or interests. This can be accomplished through querying the patients and further software development. Due to our study design, it cannot be determined whether the effectiveness of the video messages is, in part, related to the familiarity that the patients had with the NP in the video. Further studies may be able to determine whether or not a generic provider would be equally effective.

Our SMBG findings differed from other studies where mobile phone-based interventions improved self-care behavior, such as SMBG.[18–21] The reason for this might be due to limitations in study design; we did not have SMBG data for the months preceding enrollment, thereby restricting our ability to examine change, and the study design did not require the participants to monitor their blood glucose and record the values on the same days at the same time. Such a prospective and/or systematic design might have resulted in a better understanding of whether the videos increased the frequency of SMBG, how often hypo- and hyperglycemia occurred, as well as the daily glucose pattern.

None of the participants allocated to the video messages group watched the videos daily, i.e., per protocol, yet many experienced improvement in A1C. This suggests that intermittent reinforcement may be a more practical yet equally effective strategy. The rationale for intermittent reinforcement is that frequent—but not daily—contact might be most effective for providing diabetes self-care support, because it is more likely to grab the recipient's attention and keep them engaged for a longer period of time. Further research may show that patients will benefit as much (or more) from less frequent messages.

One of the strengths of our study is that the results would appear to be applicable to most patients with diabetes, because the demographics, clinical characteristics, and medication usage is typical of those patients treated in most outpatient settings.

## Conclusions

A one-way intervention using mobile phone-based video messages about diabetes self-care can modestly improve A1C. Engagement with the technology is an important predictor of its success. This intervention is simple to implement and sustain.

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# Appendix

**Table 1.**
**Example Text for Videos**

| Category | Number | Content |
|---|---|---|
| Healthy eating | 1 | Including more soluble fiber with your meals and snacks will help control your blood glucose and cholesterol levels better. Examples of foods with soluble fiber are grains, such as oat and barley, dried beans and peas, and vegetables and fruits. |
| | 2 | According to the American Diabetes Association, a healthy diet has multiple servings of fruits and vegetables, whole grains, low-fat dairy foods, fish, lean meats, poultry, and healthy fats. |
| | 3 | Cholesterol is found only in animal products. There is no cholesterol in plant foods. You can reduce your intake of cholesterol by making up your meals using mainly plant sources and including only low-fat, low-cholesterol meats, meat products, and dairy. |
| | 4 | Here is a tip on portion sizes. One ounce of meat looks like a small matchbox, and 3 ounces of meat looks like a deck of cards. A medium potato is about the size of a computer mouse. One cup of cooked rice is about the size of an adult's fist. One ounce of cheese or a tablespoon of salad dressing is about the size of an adult's thumb. |
| | 5 | The average American gains about 2 pounds of weight every year. This average weight gain can be the result of eating an extra 19 calories a day. Nineteen calories per day! |
| Being active | 1 | Regular exercise will help with control blood sugar levels, reduce risk of heart disease and stroke, control weight, and boost energy levels. Just 30 minutes a day or two 15-minute sessions can make a big difference in your well-being. |
| | 2 | Regular exercise will improve your blood sugar levels by helping your body's own insulin to move the sugar out of your blood and into your cells. The end result is lower blood sugar levels. |
| | 3 | Be sure to talk to your health care provider about what type of exercise is best for you. In general, aerobic exercises are the best because they involve using your large muscles nonstop for at least 15 minutes. Examples of aerobic exercises are brisk walking, bicycling, swimming, rowing, and jogging. |
| | 4 | Regular exercise will help you to lose weight or maintain your healthy weight by burning extra calories much faster. With every 5 pounds of body fat that you lose, your blood sugar levels will improve significantly. |
| | 5 | If you were to burn an extra 100 calories a day by increasing your physical activity, you could lose up to 10 pounds a year. Here are a few tips for increasing your physical activity: get off the subway or bus one stop earlier and walk the extra distance; go for a 15-minute walk on your lunch break; take your kids out for a bike ride after dinner; and set your alarm for 15 minutes earlier and go out for a walk. |
| Medications | 1 | Take the time to make a list of your medications, including those for your diabetes and other medications as well. For each pill, write the name, dose, when and how often you are supposed to take it, and the reason for each medication. Show the list to your pharmacist and talk with him/her about the side effects of your medications and whether or not they can be taken together. Remember to always carry the list with you, especially when you go to any of your healthcare appointments. |
| | 2 | Some diabetes oral medications can cause your blood sugar to go low. Talk with your health care provider or pharmacist about which—if any—of your medications can have this effect, and be sure to check your blood sugar before taking them. |
| | 3 | When you go to your appointments with your health care providers, bring all of the medicines you are taking. This will help him/her determine more accurately the date of prescription, dose, prescriber, pharmacy used, and other details that can help you. |
| | 4 | If you have problems using your hands and your health care provider has prescribed insulin for you, ask your provider about injection aids, such as an insulin pen device. |
| | 5 | People with diabetes have a 2- to 4-fold increased risk for cardiovascular disease. Thus, your health care provider has or will prioritize treating any risk factors for cardiovascular disease that you might have. This often means prescribing medications for treating your cholesterol levels and blood pressure. So don't be surprised if your health care provider prescribes multiple medications—some for your blood sugar and some for your cardiovascular risk factors. |
| Monitoring and reducing risks | 1 | In general, target blood sugar levels are 80–120 when you wake up in the morning, 80–120 before meals, 80–140 2 hours after meals, and 100–140 at bedtime. Those are good targets to aim for. However, depending on your individual situation, you and your provider may have set different goals, and you need to continue using those goals. |

Continued →

**Table 1. Continued**

| Category | Number | Content |
|---|---|---|
| | 2 | Check your blood sugar levels according to the plan you talked about with your provider. The more you test your blood sugar, the more you will know how you are taking care of your diabetes. Be sure to bring in your test results to your next appointment so that you and your health care provider can review them and set other goals if needed. |
| | 3 | The day-to-day blood sugar testing tells you what your blood sugar is at the time you test it and can help you fine tune things like your eating plan and your exercise plan. The A1C test gives you an idea about your average blood sugar levels over the previous 3 months. It basically tells you what your average blood sugar level has been, not what it is at this point in time. So you need both results to have a better idea of your overall diabetes control. |
| | 4 | Regularly monitoring your blood sugar, cholesterol, and blood pressure—and keeping them at or below target levels—along with regular eye and food exams and kidney function tests—help to prevent or slow diabetes complications. So be aware of your test results to help manage your diabetes better. |
| | 5 | Because high blood pressure is a silent killer, it's important to have it checked at every appointment and at least twice a year. It should be less than 130/80. If high blood pressure is left untreated, it can lead to blood vessel damage, heart disease, stroke, and kidney and eye problems. Keep an eye on your blood pressure. |
| Problem-solving and coping | 1 | Researchers have found that some people who get too little sleep or not good quality sleep end up with the worst overall blood sugar control. If you're having trouble getting a good night's sleep, talk to your doctor. Here are a few better-sleep tips: keep a regular bedtime and wake-up time—even on weekends; relax with a before-bed routine, such as reading, listening to soothing music, or taking a warm bath; and invest in a comfortable mattress. |
| | 2 | You don't have to be perfect to manage your diabetes successfully, however, you will need to make the best effort to understand how to take good care of yourself. In order to learn how to manage your diabetes and what your goals are, be prepared to make several visits to see your health care provider. Also be sure to register for and attend the diabetes classes if you haven't already done so. |
| | 3 | Did you know that your success at managing your diabetes will depend on: (1) How knowledgeable you are about management of diabetes. (2) Whether you believe that you will be successful at managing your diabetes. (3) Whether you have made a conscious decision to take control of your diabetes. |
| | 4 | Living with diabetes can cause a lot of uncomfortable and changing emotions, including denial, anger, anxiety, and fear. If these or other feelings are making it difficult for you to take care of yourself and enjoy your life, consider talking to someone you love or trust who understands diabetes or just understands you. Sharing your emotions can help you to manage them. |
| | 5 | Depression makes it harder to initiate and stick to health behaviors for your diabetes self-care. Depression is also at least twice as common among people with diabetes. This application provides a module to help you track your mood. However, if you have often felt depressed, down, or hopeless in the past month, perhaps you should talk to your provider. Depression is a health problem for which there are many effective treatments. |

**Table 2.**
**Metrics from Self-Monitoring of Blood Glucose Logs, By Treatment Group and Viewership Group**

| | Usual care group | | Video messages group | | Early cessation group | | Intermittent viewer group | | Persistent viewer group | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 0–6 months | 0–12 months | 0–6 months | 0–12 months | 0–6 months | 0–12 months | 0–6 months | 0–12 months | 0–6 months | 0–12 months |
| # of subjects with data/total (%) | 23/33 (70) | 23/33 (70) | 17/31 (55) | 17/31 (55) | 4/11 (36) | 4/11 (36) | 7/10 (70) | 7/10 (70) | 6/10 (60) | 6/10 (60) |
| Mean (SD) glucose mg/dl | 193 (63) | 192 (64) | 194 (48) | 190 (37) | 195 (32) | 195 (32) | 208 (65) | 201 (44) | 177 (33) | 175 (31) |
| Mean (SD) % readings <70 mg/dl | 2 (2)[a] | 3 (3)[a] | 5 (6)[a] | 5 (6)[a] | 9 (9) | 9 (9) | 4 (4) | 4 (4) | 4 (5) | 4 (5) |
| Mean (SD) % readings >180 mg/dl | 47 (25) | 45 25) | 48 (21) | 47 (20) | 51 (24) | 51 (24) | 53 (22) | 52 (20) | 41 (21) | 39 (20) |
| Mean (SD) % readings >240 mg/dl | 22 (25) | 22 (25) | 26 (19) | 24 (16) | 28 (14) | 28 (14) | 30 (26) | 28 (20) | 19 (13) | 19 (13) |

[a] Group differences for 0–6 months data were statistically significant ($p$ = .05). No other comparisons found significant differences, so the notation is not shown.

# COMPUTER ASSISTED DECISION SUPPORT

For Management of Patients with Type 2 Diabetes

# CADS

Quick Reference User Guide

June 13, 2012

Version 1

## NOTE:

This software is being introduced as part of a research study that has been approved at the Walter Reed National Military Medical Center (WRNMMC), Wilford Hall Ambulatory Surgery Center (WHASC), and the University of Hawaii (UH).

In order to main the integrity of the study, only physicians and other providers who have been enrolled in the study, consented, and randomized to CADS (the intervention arm) are authorized to use this program.

Table of Contents

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## INTRODUCTION TO CADS

**Primary Purpose of CADS:**

- To enhance primary care providers' (PCPs) ability to help their patients on basal insulin, oral hypoglycemic agents, non-insulin injections, or diet and exercise to achieve and maintain glycemic control.

**Reasons for failure to achieve glycemic goals:**

- Patients
    - Insufficient education and/or inability to use self monitoring of blood glucose (SMBG) effectively
    - Inability or lack of resources to download glucose data at home or in clinics
- Providers
    - Inadequate amount of time allowed for PCP to identify patterns and discuss with patients
    - Overwhelming number of single and combination agents available to treat hyperglycemia
    - Clinical inertia

**Difficulties in maintaining glycemic goals:**

- Patients
    - Patients do not understand how to use SMBG to make lifestyle changes, e.g. diet and physical activity
    - Infrequent use of SMBG
    - Inefficient use of SMBG efficiently (i.e., pre and post prandial, aka structured or paired testing)
    - Inability or unwillingness to download SMBG data
- Providers
    - Not feasible to download SMBG data in Clinic
      No time available to analyze SMBG data
    - Therapy not adjusted frequently enough
      Numerous medications and combinations are available, but most physicians use only a subset
    - Cannot access literature, guidelines, algorithms

***CADS is the result of the development of a comprehensive set of algorithms by two endocrinologists with combined experience of more than 50 years as diabetologists. CADS makes recommendations, but the provider determines treatment!***

## CADS: Key Elements

- Patients will
  - Perform SMBG 2-4X/day, 4X/day once a week, and 8X/day once a month.
  - Upload glucometer every 2 weeks using a device called *i*Metrikus and a landline telephone (WR & WH) or using a cell phone and a glucometer called MyGlucoHealth (UH).
- Research Coordinator (RC) at WRNMMC & WHASC[1] will
  - Upload into CADS the necessary information for CADS to work, e.g. current medications, current laboratory values, current A1C level, and after discussion with the PCP, target A1C level for each patient.
  - Send provider's patient's BG data to coincide with patient's quarterly visits &/or t-cons.
  - Send providers the recommendations made by CADS for that set of data.
- CADS will
  - Provide statistics and graphs that identify glucose values and patterns
  - Make recommendations for therapy
    - Note: If 10% or more of the patient's BG levels are < 60 mg/dL, CADS will provide recommendations that address the hypoglycemia.
    - **Addressing hypoglycemia is always CADS first consideration!**
  - Identify major types of clinical problems &/or co-morbid conditions that would be contraindications to certain medications

**Benefits of CADS**

- Data available for you – the clinician – at the time of clinic visits and telephone consultations
- Quick, easy
- Automated access to SMBG data
- Automated access to laboratory data
  - A1C, Liver function tests, Renal function tests, Lipid panels
- Automated access to diagnoses
  - Possible contraindications to various medications identified
- Record of previous medications
  - Record of previous adverse events and side effects
- Ability to export or print a file for inclusion in the patient's medical record

Features which may be added at a later date

- Automated generation of a clinic note
- Automated generation of an electronic prescription
- Ability for patient to view SMBG data, graphs and statistics

**IMPORTANT THINGS TO REMEMBER**

- Only applicable for *Type 2 Diabetes* patients who are using diet and exercise, oral meds, non-insulin injectables, and basal insulin
- Not for Type 1 Diabetes
- Not for acute therapy, e.g. DKA, hyperosmolarity, or hospitalized patients
- Not for use in children, adolescents, for diabetes during pregnancy or for gestational diabetes

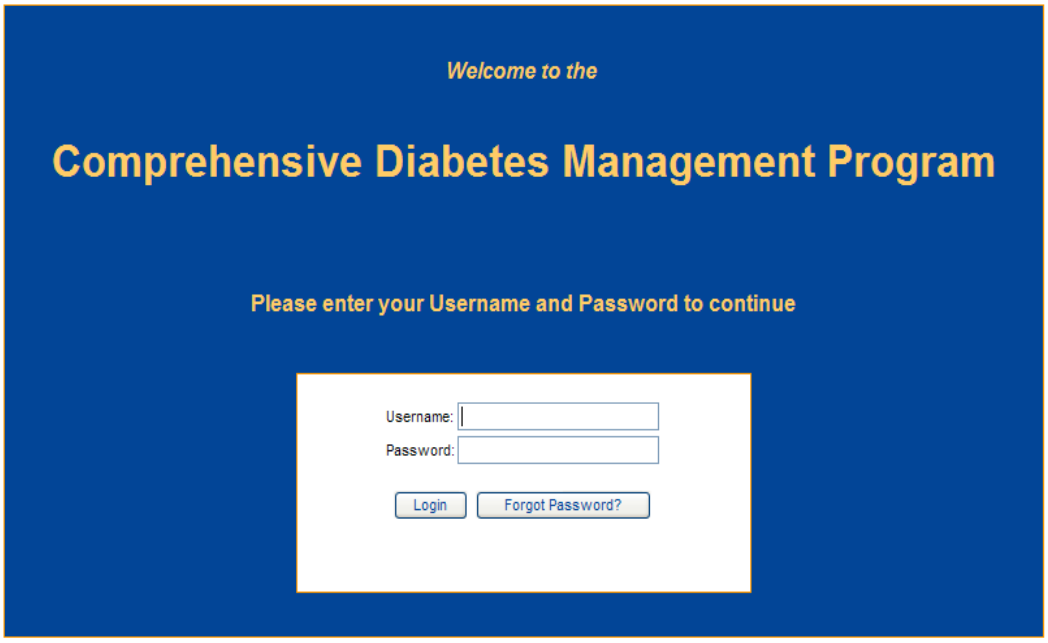
**Each physician/clinician must exercise their clinical judgment in view of the total clinical situation**.

**If in doubt, seek additional information and consult a colleague or a specialist!**

## USING CADS TO GET TREATMENT RECOMMENDATIONS

1. Login
2. Select Patient
3. Enter the CADS System
4. Run Analysis
5. Enter the target A1C
6. View Recommendations for Therapy
    - View multiple alternatives
    - Select preferred recommendation
    - Modify as desired
    - Record your comments re your decision
    - "Sign off" on recommendations
7. View other resources
    - Literature, Guidelines, Prescribing Information, Formulary, Costs of Medications

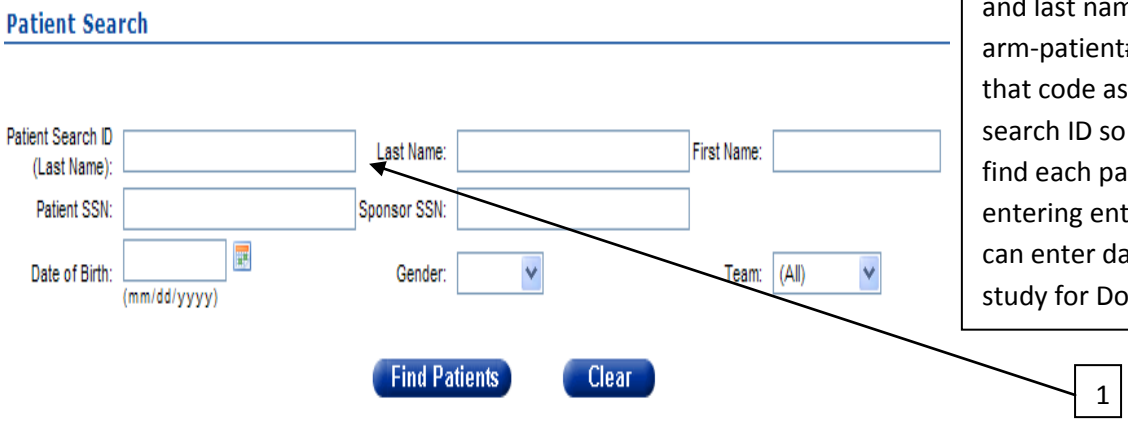
STEP 1: LOGIN



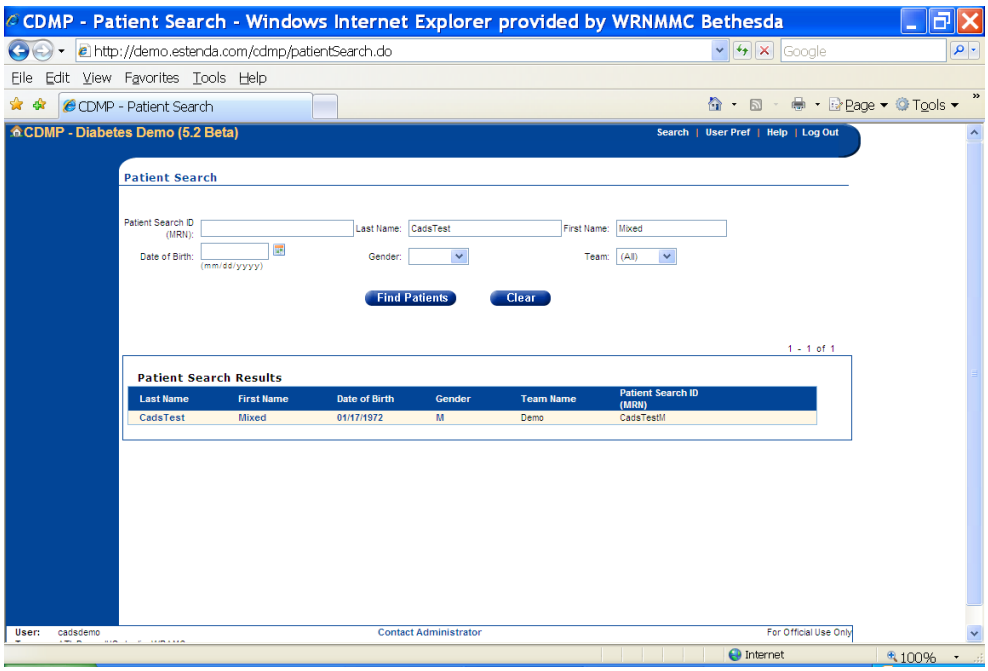

Each user will receive a Username and Password to log in to the system.

STEP 2: SELECT PATIENT

Split the patient's alphanumeric study ID code between the first (site-clinic) and last names (provider-arm-patient#). Use part of that code as the patient search ID so you can quickly find each patient without entering entire code. You can enter date of entry into study for DoB.




Select the patient by entering the Last Name or First Name (Arrow #1). Then select the [Find Patients] button.

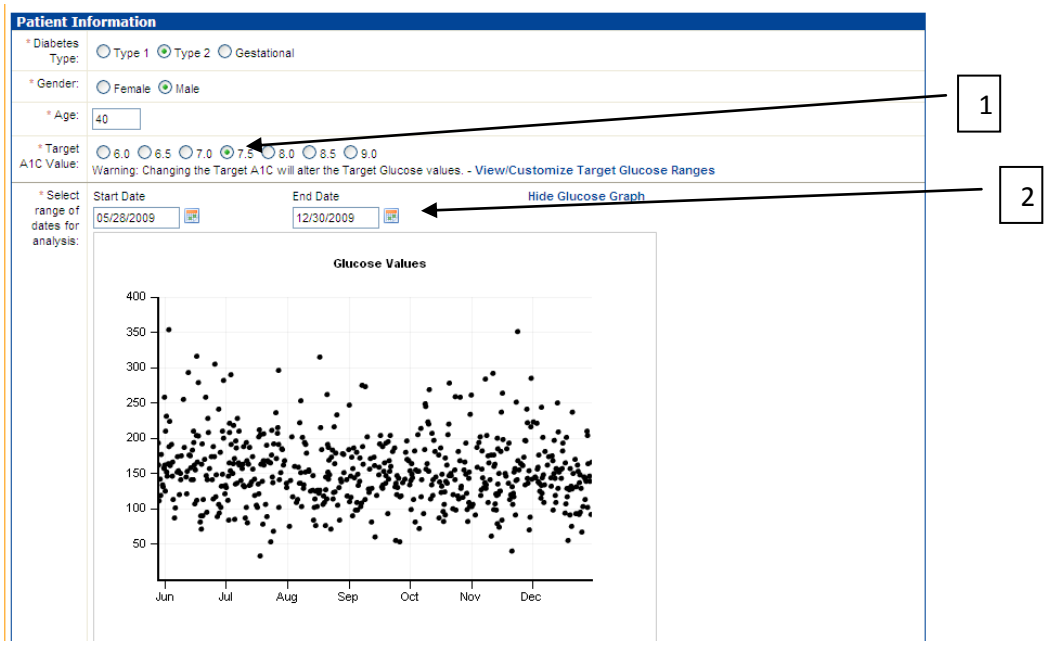



To select a specific patient, simply click on that patient's Last Name (CadsTest) or First Name (Mixed). For this example, the patient's name is Mixed CadsTest, for data entry purposes the patients name will be First name (site-clinic) and last name (provider-arm-patient#).

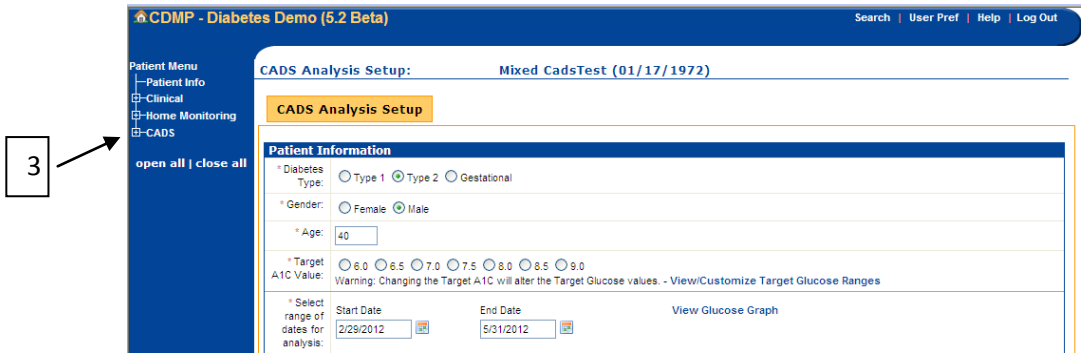
STEP 3: ENTER THE CADS SYSTEM

After selecting the Patient, you will be ready to enter the **CADS** System**.**

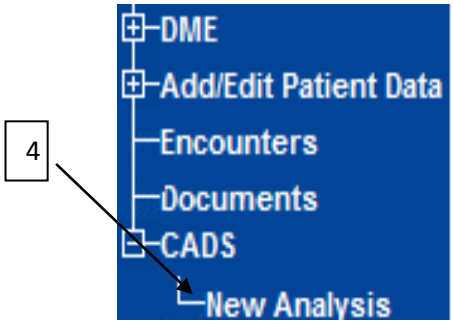
At this point, you will need to select the Target A1c value for this patient. Remember, this needs to be done every time you run a new CADS analysis (Arrow #1). You will also enter the Start Date and End Date for the range of glucose data that you are using for this CADS analysis (Arrow #2).



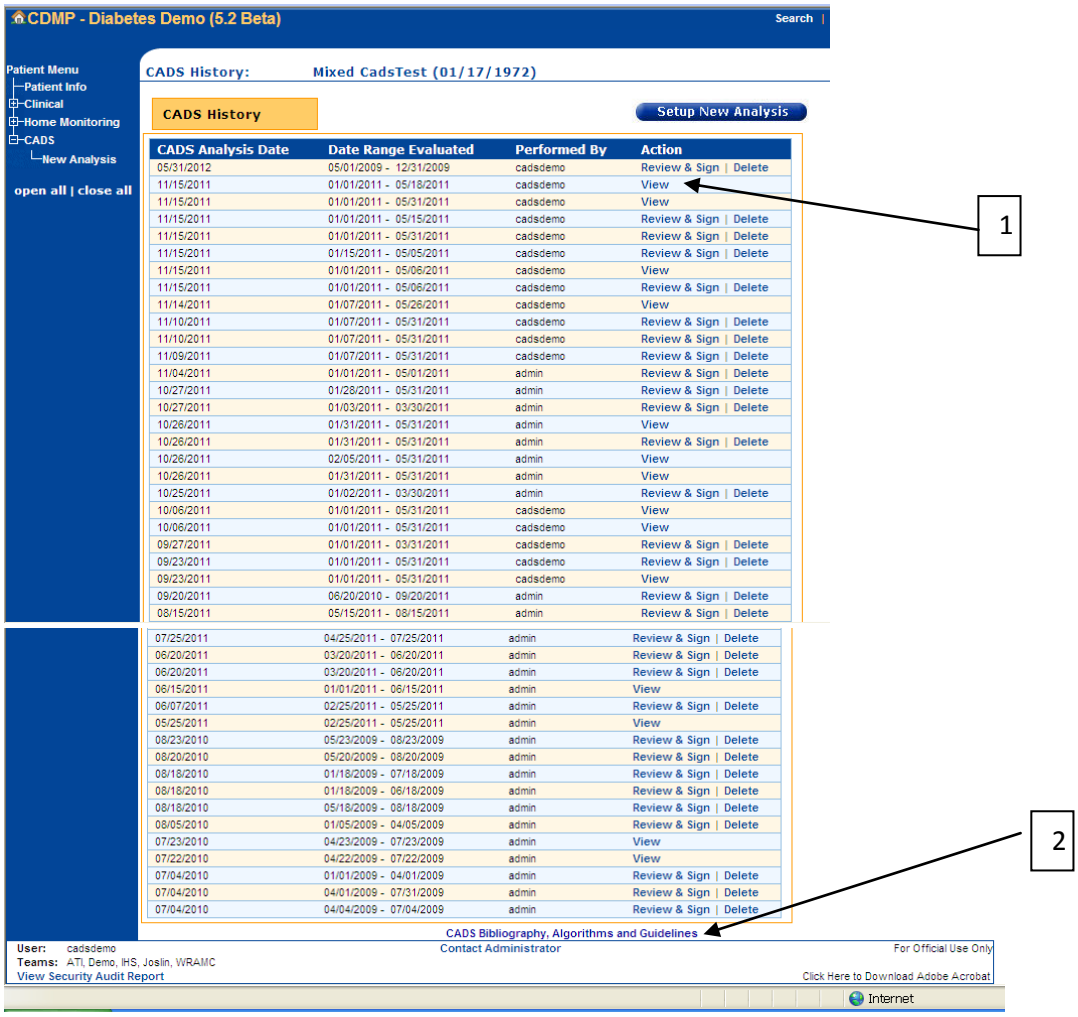
STEP 4: RUN ANALYSIS




Select **CADS** (Arrow #3) from the menu on the bottom of the navigation panel at the left of the screen.

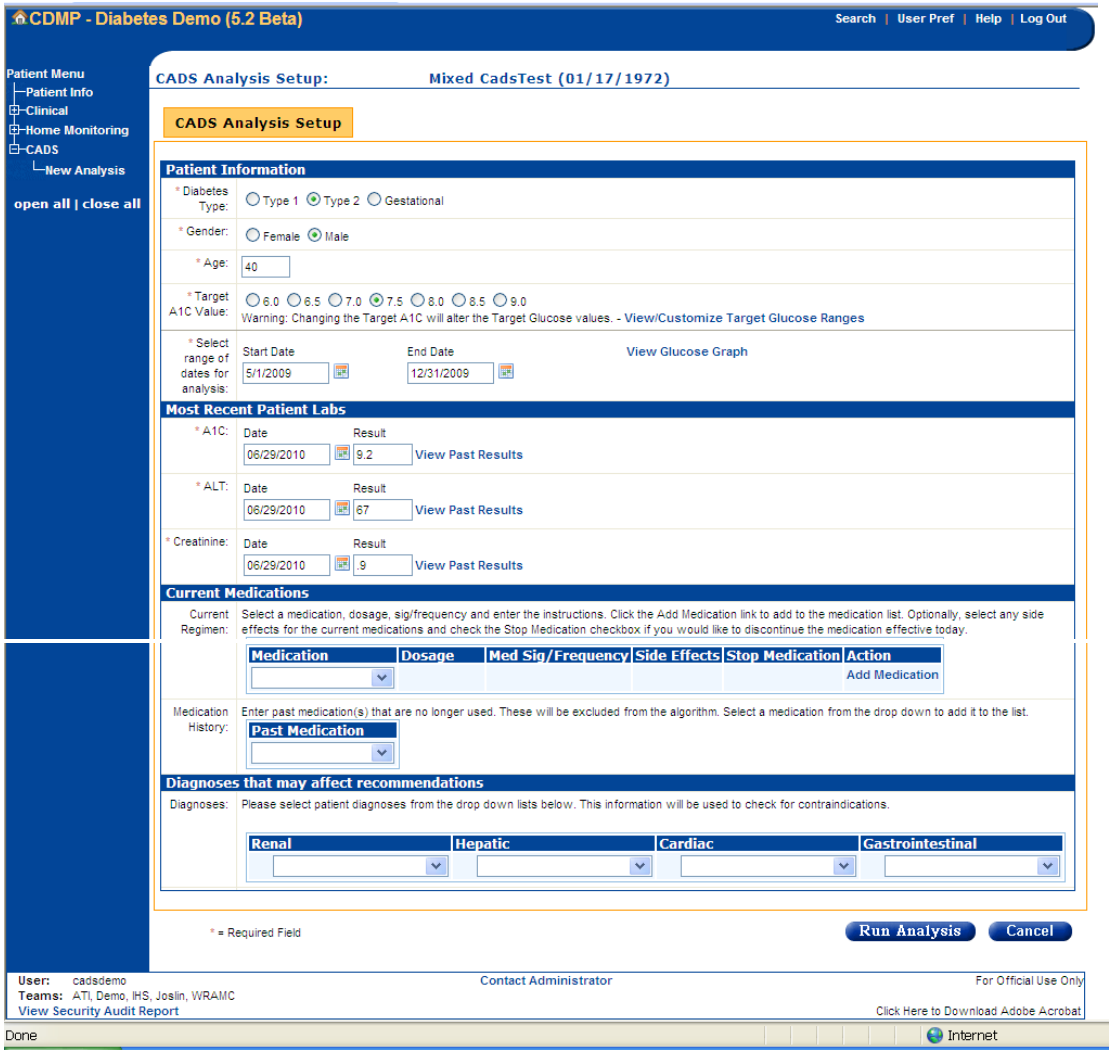



- After selecting CADS, the New Analysis choice will open. To perform a New Analysis of the available data, select New Analysis (Arrow # 4)
- You can also select run analysis at the bottom of the page.




To view a previously performed analysis, select **<u>View</u>** under **Action (**Arrow #1). You can also select background reading material is available (Arrow #2)

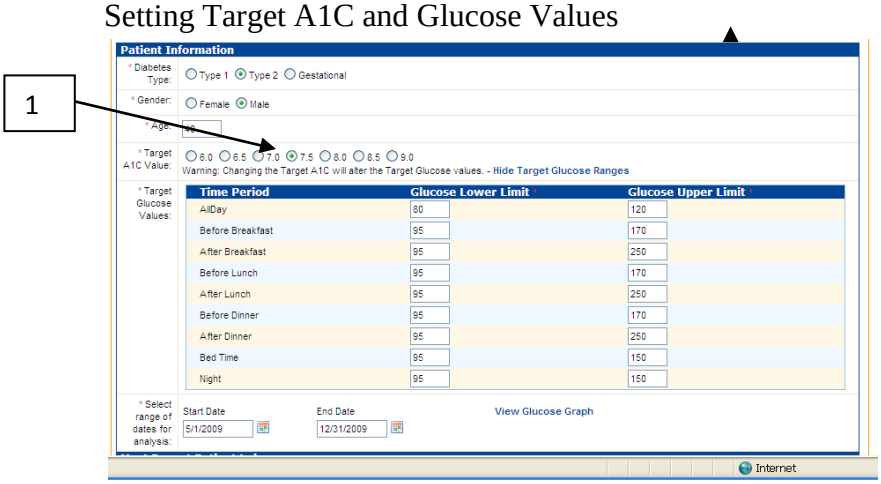
STEP 5: ENTER THE TARGET A1C




Factors considered for generation of recommendations:

- **Patient Information** (diabetes type, gender, age, target A1C, range of dates for analysis)
- **Glucose Data**
- **Laboratory Results** (A1C, ALT, creatinine)
- **Current and Past Medications** (drugs, dose, frequency, side effects)
- **Comorbid Conditions**

Setting Target A1C and Glucose Values

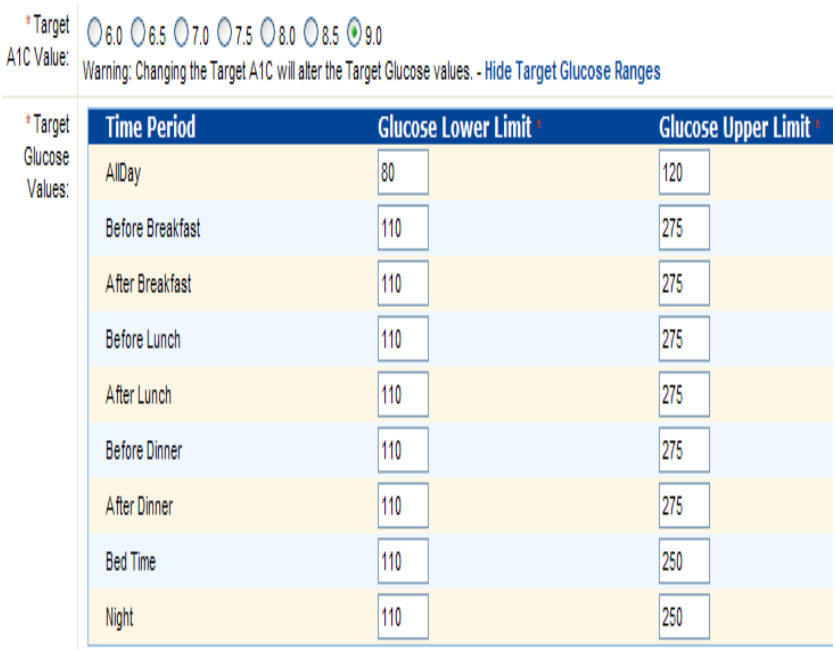



Setting the target A1C value (Arrow # 1) will automatically set the upper and lower limits of the target range for each of 8 separate times of day, and for the whole day ("AllDay").

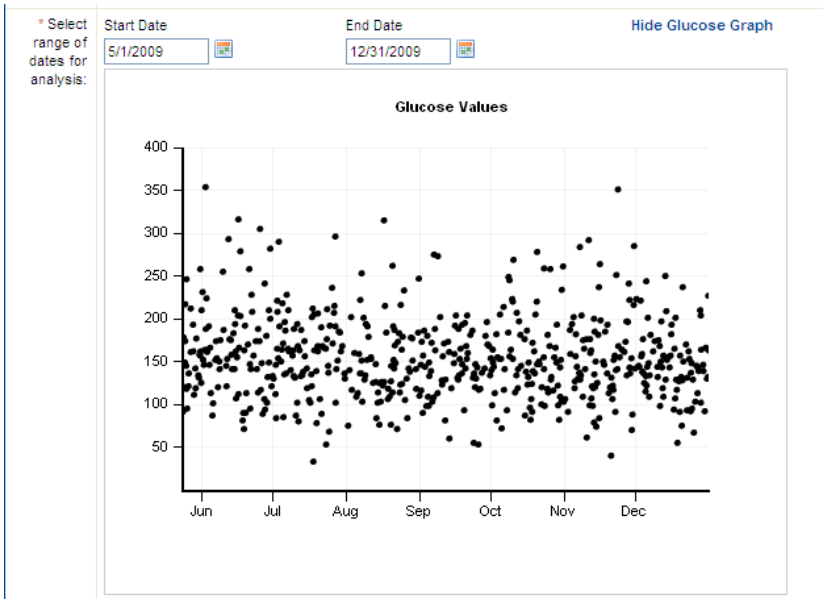
If you, the clinician, wish to modify any of these values, simply enter a value into the text box.

In general, the higher the target A1C is set, the higher the upper and lower limits of the target range will be in order to minimize risk of hypoglycemia.

For example, notice how the Glucose Lower Limit and Glucose Upper Limit change now that the Target A1c is set at 9.0 instead of 7.5.

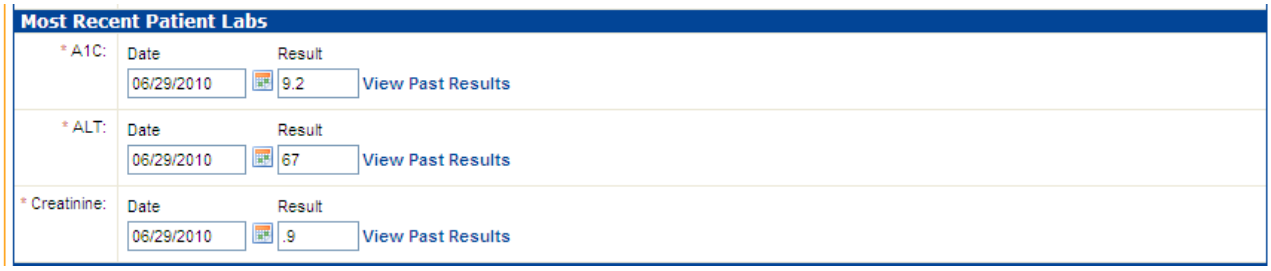


Select Date Range for Analysis

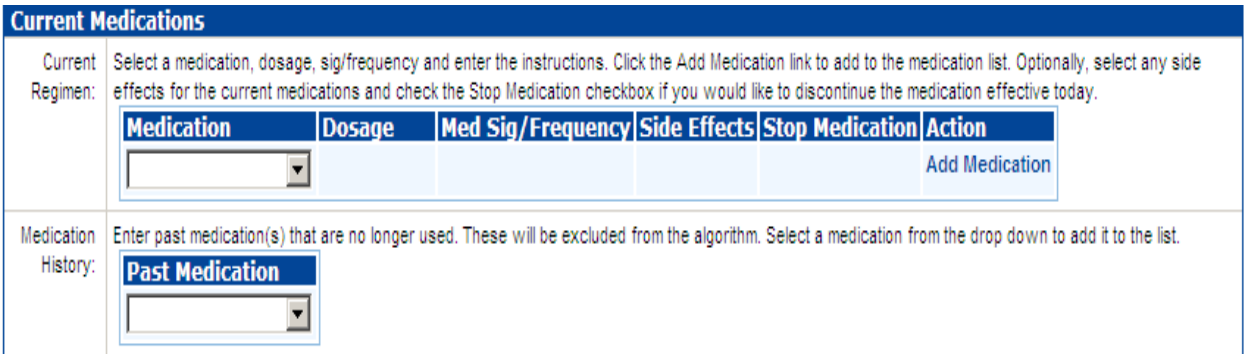



This Graph Glucose over time will be displayed automatically when you select a date range for glucose data analysis.

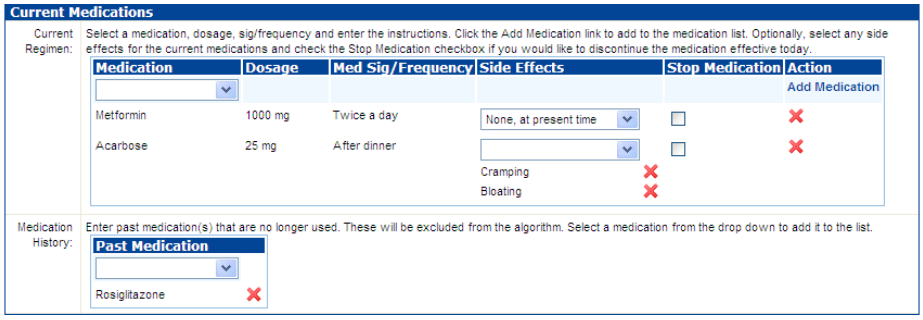
Enter/View Laboratory Results



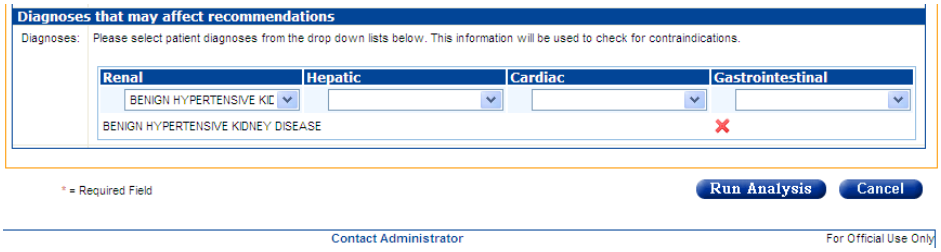

Enter/View Current Medications



This patient is taking two oral diabetes medications, Metformin and Acarbose. These were added by selecting the Medication in the dropdown menu, selecting the dosage, selecting the frequency and then clicking on the Add Medication button. If a mistake is made, you can remove the medication by clicking on the **X** next to the listing. The analysis also takes into account that this patient was previously on Rosiglitazone and will not include that medication in the recommendations.



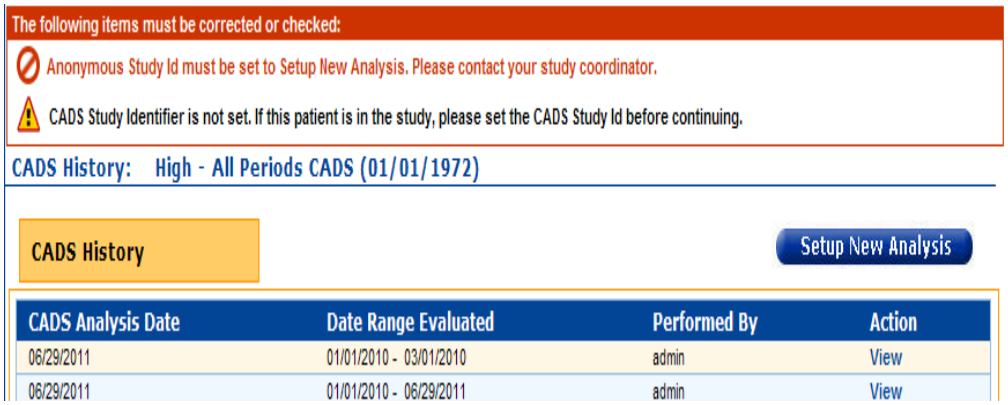

Diagnoses that May Affect Recommendations




For each drop menu (Renal, Hepatic, Cardiac, Gastrointestinal) select any pertinent diagnoses that this patient currently has to be factored into the CADS analysis.

After you have confirmed that the information is accurate, select Run Analysis.

POTENTIAL ISSUES




Two messages may be displayed at the top of the **CADS History** page. If the **Anonymous Study ID** has not been set, the message in red will be displayed. You will not be able to continue until it has been entered.

- If you see the **CADS Study Identifier** warning and the patient is part of the study, do not continue! Contact Sara Salkind or Susan Walker to make sure the patient's study identifier is properly configured

STEP 6: VIEW RECOMMENATIONS FOR THERAPY


Analysis of patient information, labs, medications, diagnoses, date range, and A1C (actual, predicted, and target) generates a ***Recommendation***. You can ***Accept Recommendation*** and ***Sign*** or select ***View Next (Recommendation)***.

The links below the recommendation (Formulary | Prescribing Information | Patient Information or Add Comments) provide more information for you or your patient and allow you to write comments.

**Items shown on the right hand side of the Recommendations screen identify the**

- Range of dates for SMBG data used in analysis
- Current A1C Lab value and date
- Predicted A1C based on SMBG Values
- Selected Target Value for A1C as specified by the clinician and entered into CADS Setup

**Date Range Analyzed**
05/01/2009 - 12/31/2009

**A1C Data**

| Type | Value | |
|---|---|---|
| Lab | 9.2 | 06/29/2010 |
| Predicted | 7.1 | |
| Target | 7.5 | |

**Problems**

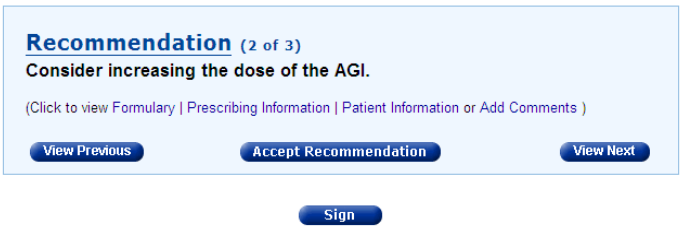
| Period | Problem |
|---|---|
| Before Breakfast | High |
| After Breakfast | |
| Before Lunch | Low |
| After Lunch | Low |
| Before Dinner * | |
| After Dinner | Low |
| Bed Time | High |
| Night | High |

* less than 20 results in period

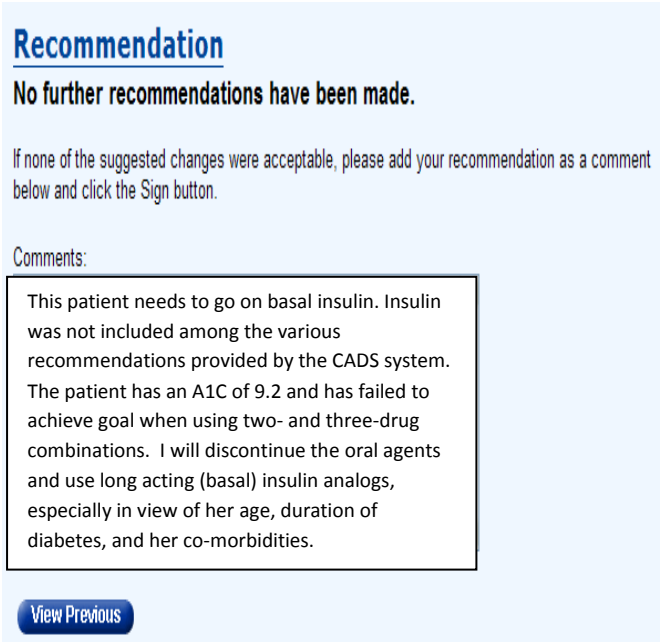
Problems shows a list of Problems identified at each of 8 time periods per day

- NOTE: If a time period has less than 20 values – this is flagged with an asterisk (*) because there are insufficient results to make a conclusive recommendation. A recommendation will still be made but with significantly less confidence.

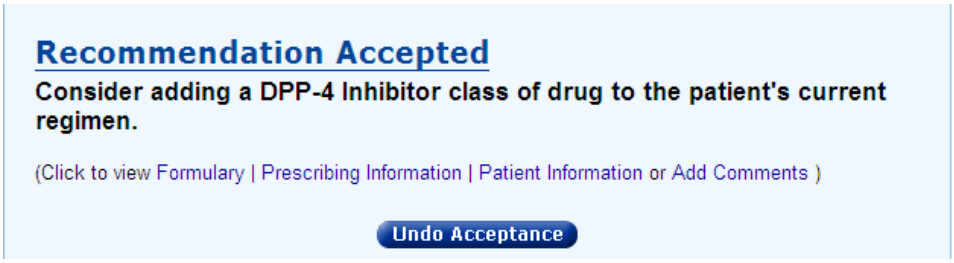
Second recommendation (2 of the 3 that CADS will provide)




The “View Previous” button means “View Recommendation # 1” (the prior recommendation)
The “View Next” button means “View Recommendation # 3” (the next recommendation)
After viewing all of the potential recommendations you will see this screen. The provider can enter their own recommendation at this point and click the “Sign” button.




ACCEPT AND SIGN

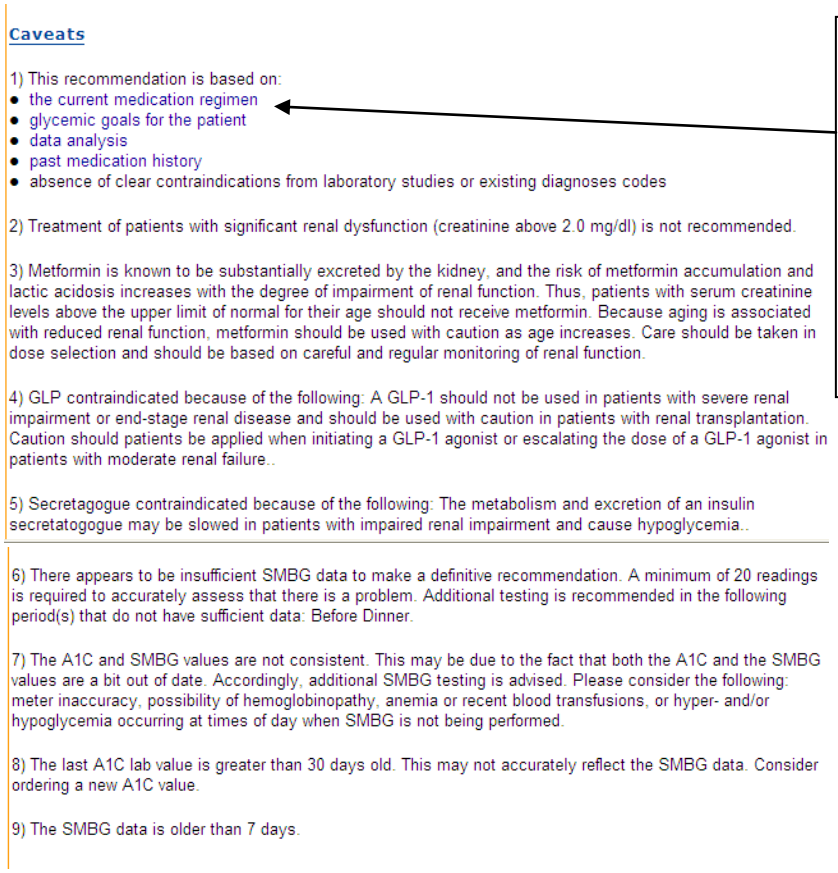



**Reviewing Signed CADS Analysis**

Once signed, a CADS Analysis **cannot be changed** – when viewing you can see the recommendation that has been accepted.

## STEP 7: CADS RESULTS: CAVEATS

Caveats include the rationale for the recommendation, as well as any contraindications or caution that needs to be addressed.



**Caveats**

1) This recommendation is based on:
- the current medication regimen
- glycemic goals for the patient
- data analysis
- past medication history
- absence of clear contraindications from laboratory studies or existing diagnoses codes

2) Treatment of patients with significant renal dysfunction (creatinine above 2.0 mg/dl) is not recommended.

3) Metformin is known to be substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive metformin. Because aging is associated with reduced renal function, metformin should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.

4) GLP contraindicated because of the following: A GLP-1 should not be used in patients with severe renal impairment or end-stage renal disease and should be used with caution in patients with renal transplantation. Caution should patients be applied when initiating a GLP-1 agonist or escalating the dose of a GLP-1 agonist in patients with moderate renal failure..

5) Secretagogue contraindicated because of the following: The metabolism and excretion of an insulin secretatogogue may be slowed in patients with impaired renal impairment and cause hypoglycemia..

6) There appears to be insufficient SMBG data to make a definitive recommendation. A minimum of 20 readings is required to accurately assess that there is a problem. Additional testing is recommended in the following period(s) that do not have sufficient data: Before Dinner.

7) The A1C and SMBG values are not consistent. This may be due to the fact that both the A1C and the SMBG values are a bit out of date. Accordingly, additional SMBG testing is advised. Please consider the following: meter inaccuracy, possibility of hemoglobinopathy, anemia or recent blood transfusions, or hyper- and/or hypoglycemia occurring at times of day when SMBG is not being performed.

8) The last A1C lab value is greater than 30 days old. This may not accurately reflect the SMBG data. Consider ordering a new A1C value.

9) The SMBG data is older than 7 days.

The blue type indicates that these are sections of the caveats that link to additional information within CADS. Click on the blue section to get more information about any of the caveats that are highlighted in blue.

STEP 8: PROBLEM SECTION

The problems section repeats the areas that were previously identified by showing the patterns and periods of hypoglycemia, hyperglycemia, and/or target glucose values.

**A1C Data**

| Type | Value | |
|---|---|---|
| Lab | 9.2 | 06/29/2010 |
| Predicted | 7.1 | |
| Target | 7.5 | |

**Problems**

| Period | Problem |
|---|---|
| Before Breakfast | High |
| After Breakfast | |
| Before Lunch | Low |
| After Lunch | Low |
| Before Dinner * | |
| After Dinner | Low |
| Bed Time | High |
| Night | High |

* less than 20 results in period

## STEP 8: VIEW GRAPHS AND INFORMATION PROVIDED BY THE GLUCOSE DATA

## CADS DISPLAYS

- Glucose log book
- Statistics: Mean, % Low, % High, by time of day
- Graphs:
  - Glucose by Date
  - Glucose by Time of Day
  - Glucose in Relationship to Meals
  - Glucose by Day of the Week
  - Pie Charts: % High, % Low, % in Target range
  - "Stacked bar charts": a more compact way to display data from Pie-charts
  - Two dimensional display vs. date and time of day

## SMBG DATA

- Glucose Summary
- Graphs
  - By Date
  - By Time of Day
  - By Day of the Week
  - Pie Charts
  - Stacked bar charts

Glucose Log Book

CADS Results for 05/31/2012: Mixed CadsTest (DOB 01/17/1972)

Recommendations | Glucose Summary | Glucose Log Book | Glucose Graphs | Input Data

| Date | Daily Average | Before Breakfast | After Breakfast | Before Lunch | After Lunch | Before Dinner | After Dinner | Bedtime | Night | Total Daily Readings |
|---|---|---|---|---|---|---|---|---|---|---|
| Time Period | | 07:00 AM - 09:00 AM | 09:00 AM - 11:30 AM | 11:30 AM - 12:30 PM | 12:30 PM - 03:00 PM | 03:00 PM - 06:00 PM | 06:00 PM - 09:00 PM | 09:00 PM - 11:00 PM | 11:00 PM - 07:00 AM | |
| Range | | 95 - 170 | 95 - 250 | 95 - 170 | 95 - 250 | 95 - 170 | 95 - 250 | 95 - 150 | 95 - 150 | |
| 05/24/2009 | 142 | 178 | | | 120 | | 149 | | 91 174 | 5 |
| 05/25/2009 | 164 | 145 | | | 118 246 | | 95 | | 217 | 5 |
| 05/26/2009 | 128 | | 121 | | 136 | | | | | 2 |
| 05/27/2009 | 186 | 161 212 | | | | | | | | 2 |
| 05/28/2009 | 155 | 193 | | 162 | | | 111 | | | 3 |
| 05/29/2009 | 146 | | | 119 | | | 177 | | 142 | 3 |
| 05/30/2009 | 132 | | | | 134 | | 131 | | | 2 |
| 05/31/2009 | 178 | 157 | 258 | | 162 | | 125 | | 158 210 | 6 |
| 06/01/2009 | 176 | 231 | | | 152 | | 146 | | | 3 |
| 06/02/2009 | 235 | | 164 | | 354 | | 188 | | | 3 |
| 06/03/2009 | 192 | | | | | | | | 224 161 191 | 3 |
| 06/04/2009 | 141 | 146 | | 166 | | | 113 | | | 3 |
| 06/05/2009 | 94 | | 87 | | | | 101 | | | 2 |
| 06/06/2009 | 163 | | | | | | 152 | | 174 | 2 |
| 06/07/2009 | 137 | 154 | | | | | 120 | | | 2 |
| 06/08/2009 | 155 | 150 | | | 141 | | 175 | | | 3 |
| 06/09/2009 | 255 | | | | | | | 255 | | 1 |
| 06/10/2009 | 187 | | | | | | | | 187 | 1 |
| 06/11/2009 | 139 | 145 | | 121 | | | 153 | | | 3 |
| 12/06/2009 | 150 | 201 | | | 148 | | 109 | | 144 | 4 |
| 12/07/2009 | 157 | 181 | | | | | | | 134 | 2 |
| 12/08/2009 | 162 | | | | 162 | | | | | 1 |
| 12/09/2009 | 174 | | | | | | | | 174 | 1 |
| 12/10/2009 | 150 | 144 | | 132 | | | 175 | | | 3 |
| 12/11/2009 | 153 | | 98 | | | 150 | | | 168 197 | 4 |
| 12/12/2009 | 132 | | | 119 | | | 109 157 | | 143 | 4 |
| 12/13/2009 | 178 | | | | 250 | | 129 | | 155 | 3 |
| 12/14/2009 | 180 | 152 | | | | | | | 209 | 2 |
| 12/15/2009 | 152 | | 143 | | 156 | | 157 | | | 3 |
| 12/16/2009 | 187 | 193 | | | | | | | 182 | 2 |
| 12/17/2009 | 141 | 94 | | 165 | | | 107 | | 201 | 4 |
| 12/18/2009 | 100 | | | 117 | | | 55 | | 129 | 3 |
| 12/19/2009 | 125 | | | | 127 | | 91 | 157 | | 3 |
| 12/20/2009 | 111 | 132 | | | 75 | | 128 | | | 3 |
| 12/21/2009 | 193 | 150 | | | | | | | 237 | 2 |
| 12/22/2009 | 131 | | 170 | | | | 93 131 | | | 3 |
| 12/23/2009 | 157 | | | | 162 | | 153 | | | 2 |
| 12/24/2009 | 118 | 92 | | 137 | | | 148 | 95 | | 4 |
| 12/25/2009 | 98 | | | | | | 67 | | 129 | 2 |
| 12/26/2009 | 124 | 103 | | | | | 145 | | | 2 |
| 12/27/2009 | 131 | 113 | | | 142 | | 139 | | | 3 |
| 12/28/2009 | 170 | 210 | | | 102 204 | | 164 | | | 4 |
| 12/29/2009 | 142 | | | | 146 | | 139 | | | 2 |
| 12/30/2009 | 129 | | | | | 166 | | | 92 | 2 |
| 12/31/2009 | 163 | 130 | | 132 | | | 227 | 163 | | 4 |
| # Readings | 2 | 117 | 37 | 53 | 80 | 7 | 156 | 26 | 119 | 595 |
| Average | 154 | 161 | 168 | 130 | 162 | 150 | 135 | 180 | 166 | 2 |

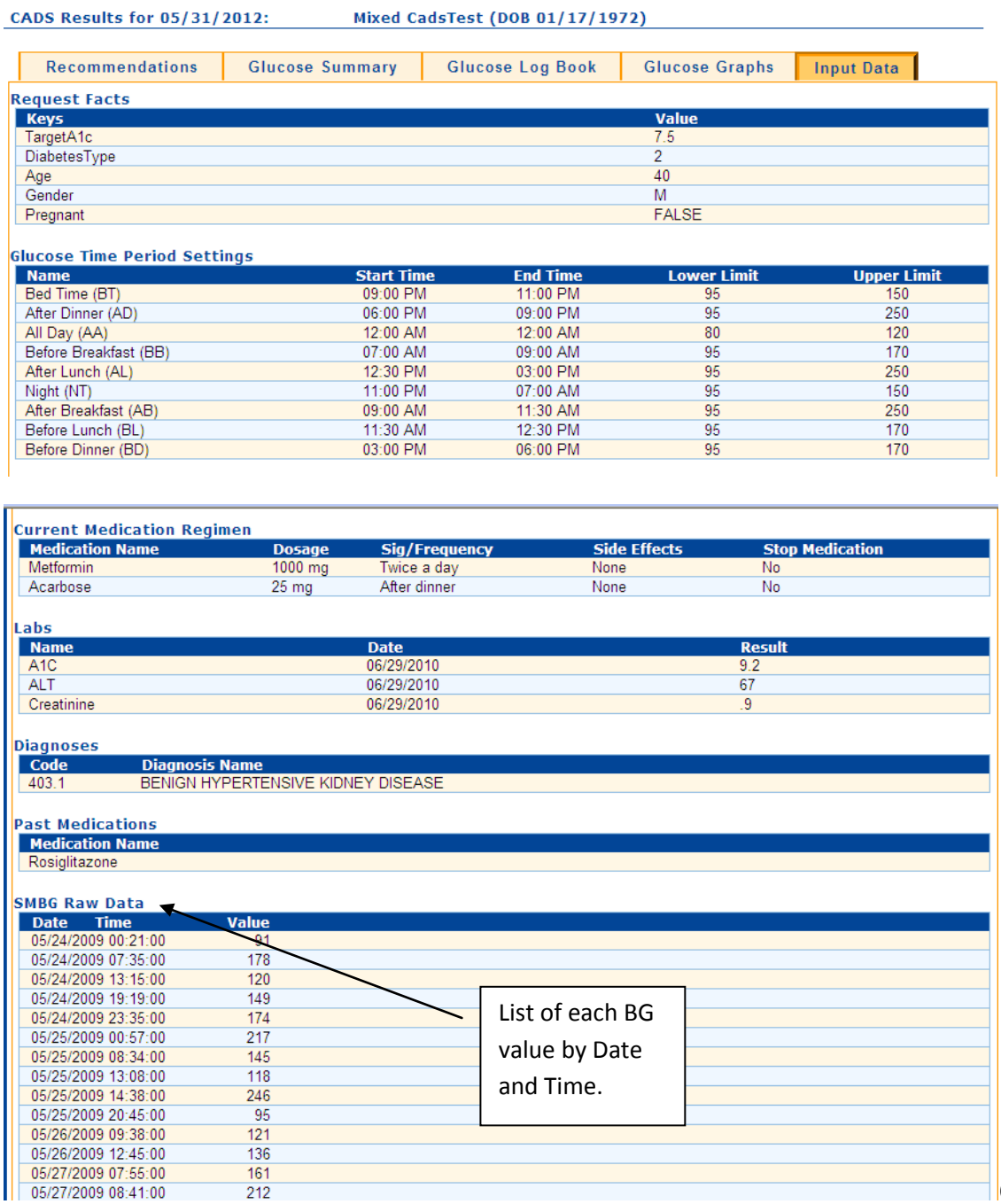
**# of Readings/time period** and **Average Reading** are the bottom values in Glucose Log Book

Red = High  Blue = Low  Black = In Target

VIEW GLUCOSE GRAPHS AND DATA FROM GLUCOMETER

This page provides a summary of

- Target A1C
- Target glucose range by time of day and in relationship to meals
- Demographic variables (i.e., type of diabetes, age, gender, pregnant)



CADS Results for 05/31/2012: Mixed CadsTest (DOB 01/17/1972)

Recommendations | Glucose Summary | Glucose Log Book | Glucose Graphs | Input Data

**Request Facts**

| Keys | Value |
|---|---|
| TargetA1c | 7.5 |
| DiabetesType | 2 |
| Age | 40 |
| Gender | M |
| Pregnant | FALSE |

**Glucose Time Period Settings**

| Name | Start Time | End Time | Lower Limit | Upper Limit |
|---|---|---|---|---|
| Bed Time (BT) | 09:00 PM | 11:00 PM | 95 | 150 |
| After Dinner (AD) | 06:00 PM | 09:00 PM | 95 | 250 |
| All Day (AA) | 12:00 AM | 12:00 AM | 80 | 120 |
| Before Breakfast (BB) | 07:00 AM | 09:00 AM | 95 | 170 |
| After Lunch (AL) | 12:30 PM | 03:00 PM | 95 | 250 |
| Night (NT) | 11:00 PM | 07:00 AM | 95 | 150 |
| After Breakfast (AB) | 09:00 AM | 11:30 AM | 95 | 250 |
| Before Lunch (BL) | 11:30 AM | 12:30 PM | 95 | 170 |
| Before Dinner (BD) | 03:00 PM | 06:00 PM | 95 | 170 |

**Current Medication Regimen**

| Medication Name | Dosage | Sig/Frequency | Side Effects | Stop Medication |
|---|---|---|---|---|
| Metformin | 1000 mg | Twice a day | None | No |
| Acarbose | 25 mg | After dinner | None | No |

**Labs**

| Name | Date | Result |
|---|---|---|
| A1C | 06/29/2010 | 9.2 |
| ALT | 06/29/2010 | 67 |
| Creatinine | 06/29/2010 | .9 |

**Diagnoses**

| Code | Diagnosis Name |
|---|---|
| 403.1 | BENIGN HYPERTENSIVE KIDNEY DISEASE |

**Past Medications**

| Medication Name |
|---|
| Rosiglitazone |

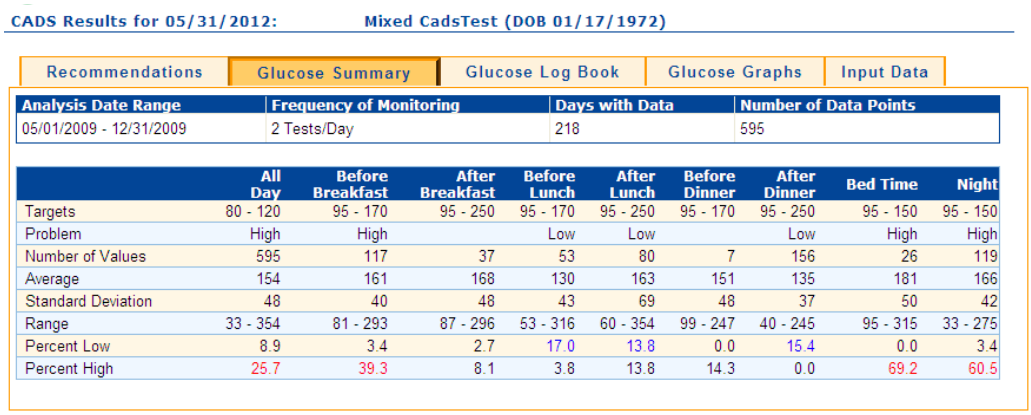
**SMBG Raw Data**

| Date Time | Value |
|---|---|
| 05/24/2009 00:21:00 | 91 |
| 05/24/2009 07:35:00 | 178 |
| 05/24/2009 13:15:00 | 120 |
| 05/24/2009 19:19:00 | 149 |
| 05/24/2009 23:35:00 | 174 |
| 05/25/2009 00:57:00 | 217 |
| 05/25/2009 08:34:00 | 145 |
| 05/25/2009 13:08:00 | 118 |
| 05/25/2009 14:38:00 | 246 |
| 05/25/2009 20:45:00 | 95 |
| 05/26/2009 09:38:00 | 121 |
| 05/26/2009 12:45:00 | 136 |
| 05/27/2009 07:55:00 | 161 |
| 05/27/2009 08:41:00 | 212 |



Glucose

Summary Tab



CADS Results for 05/31/2012: Mixed CadsTest (DOB 01/17/1972)

Recommendations | Glucose Summary | Glucose Log Book | Glucose Graphs | Input Data

| Analysis Date Range | Frequency of Monitoring | Days with Data | Number of Data Points |
|---|---|---|---|
| 05/01/2009 - 12/31/2009 | 2 Tests/Day | 218 | 595 |

| | All Day | Before Breakfast | After Breakfast | Before Lunch | After Lunch | Before Dinner | After Dinner | Bed Time | Night |
|---|---|---|---|---|---|---|---|---|---|
| Targets | 80 - 120 | 95 - 170 | 95 - 250 | 95 - 170 | 95 - 250 | 95 - 170 | 95 - 250 | 95 - 150 | 95 - 150 |
| Problem | High | High | | Low | Low | | Low | High | High |
| Number of Values | 595 | 117 | 37 | 53 | 80 | 7 | 156 | 26 | 119 |
| Average | 154 | 161 | 168 | 130 | 163 | 151 | 135 | 181 | 166 |
| Standard Deviation | 48 | 40 | 48 | 43 | 69 | 48 | 37 | 50 | 42 |
| Range | 33 - 354 | 81 - 293 | 87 - 296 | 53 - 316 | 60 - 354 | 99 - 247 | 40 - 245 | 95 - 315 | 33 - 275 |
| Percent Low | 8.9 | 3.4 | 2.7 | 17.0 | 13.8 | 0.0 | 15.4 | 0.0 | 3.4 |
| Percent High | 25.7 | 39.3 | 8.1 | 3.8 | 13.8 | 14.3 | 0.0 | 69.2 | 60.5 |

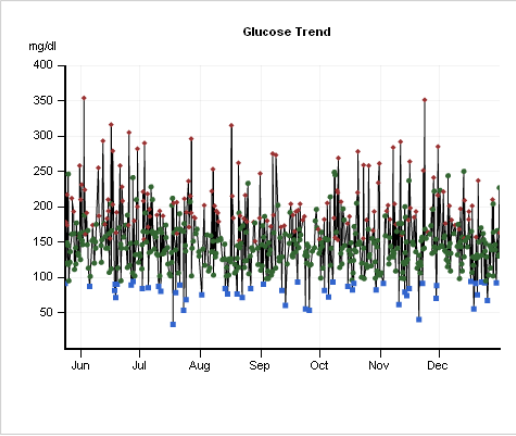
Glucose Summary identifies

- Analysis Date Range
- Frequency of Monitoring
- Days with Data
- Number of Data Points
- Target BG range for each time range
- Percentage of low BG values by time of day
- Percentage of target BG values by time of day
- Percentage of high BG values

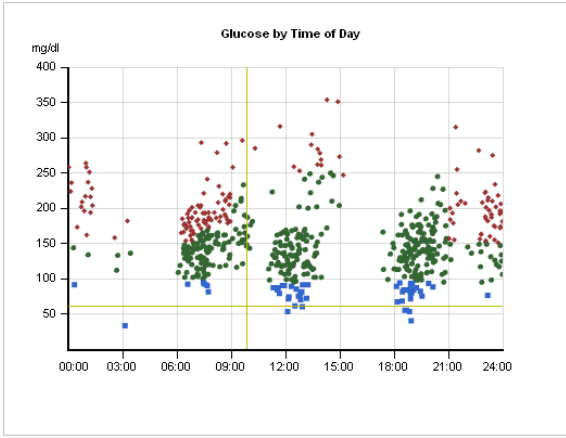
Problem areas are noted in “Percent low” and “Percent high” by the color change (red or blue). For example, this person has a high percentage of low BG readings before and after lunch, while bedtime and night readings run high.

Glucose Graphs

- To see the glucose graphs – click the "glucose graphs" tab on the screen above (between Glucose Log Book and Input Data)




Trends over Time

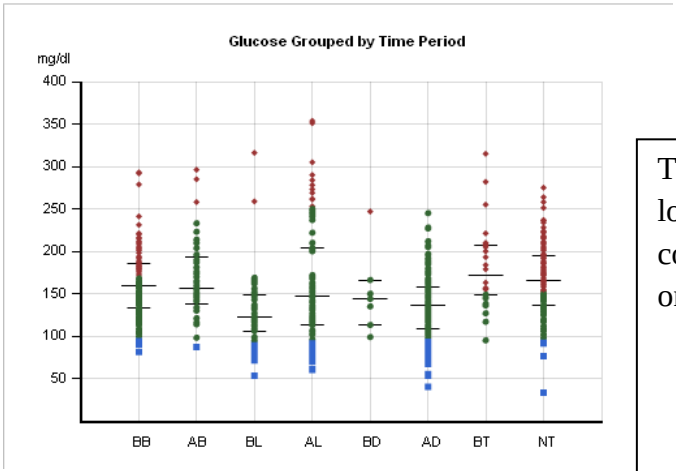


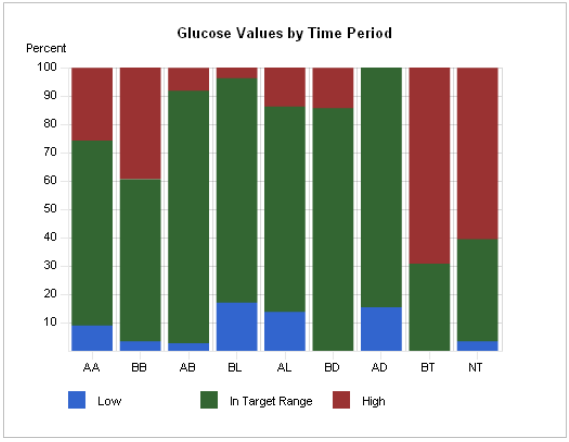

Trends by Time of Day

Remember: the colors mean the same things on these graphs that they did previously:

red = high
blue = low
green = target range

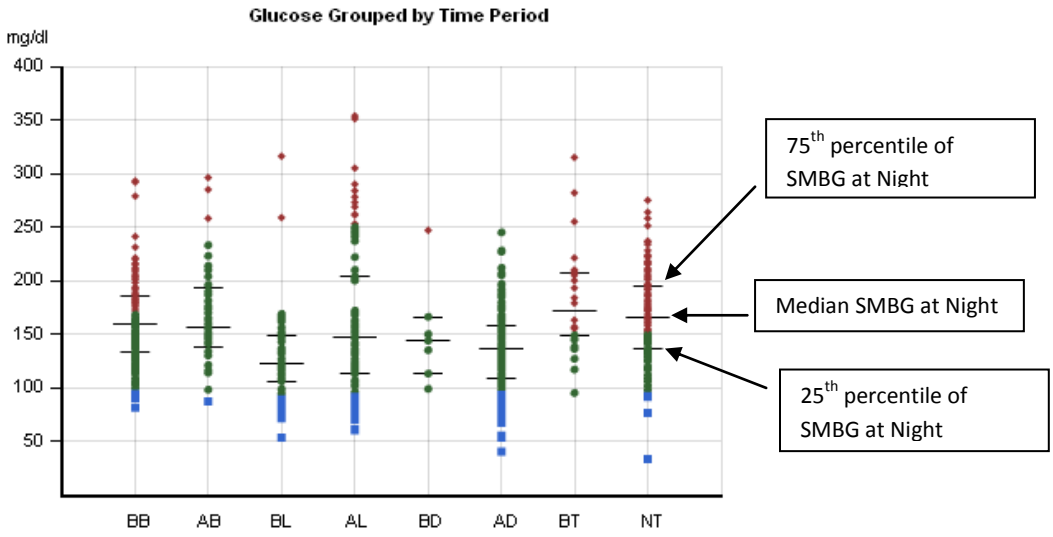
There are a lot of options for types of graphs that CADS can produce. Here are a few more examples:




The abbreviations on the lower axis of the graphs correpond to the time chunks on previous screens:

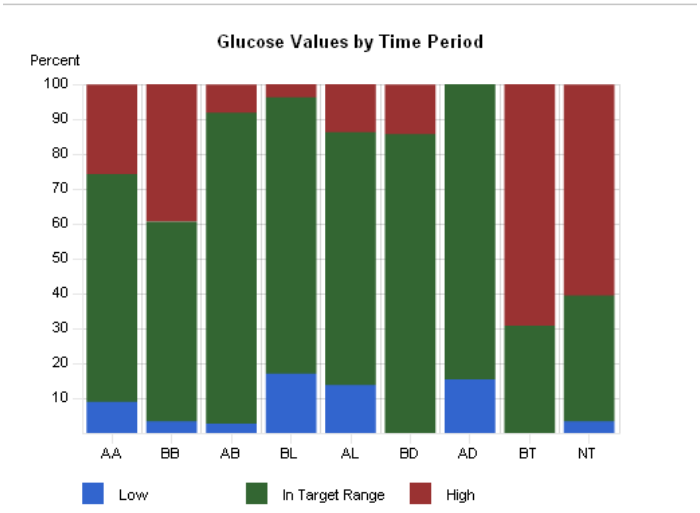
AA: All Day
BB: before breakfast
AB: after breakfast
BL: before lunch
AL: after lunch
BD: before dinner
AD: after dinner
BT: Bedtime
NT: Nighttime



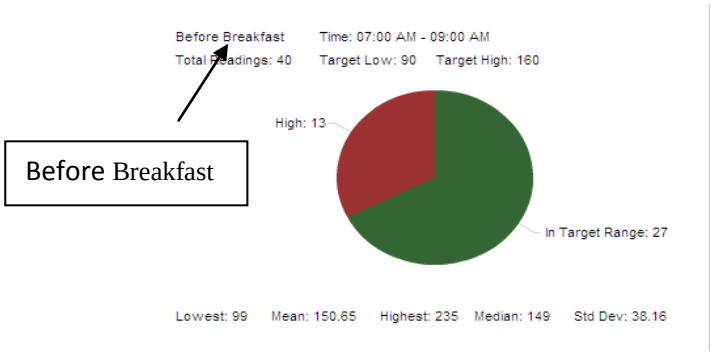

When the glucose data is grouped by Time Period, horizontal lines are shown for the median (50$^{th}$ percentile) (longer lines), and for the 25$^{th}$ and 75$^{th}$ percentiles (shorter lines). In the example shown, slightly more than 50% of the night-time glucoses are within target and slightly less than 50% are higher than target.

Data points are still color coded red (high), green (target) and blue (low) with the ranges that were set in CADS during setup and identification of the ideal A1c for this specific patient.

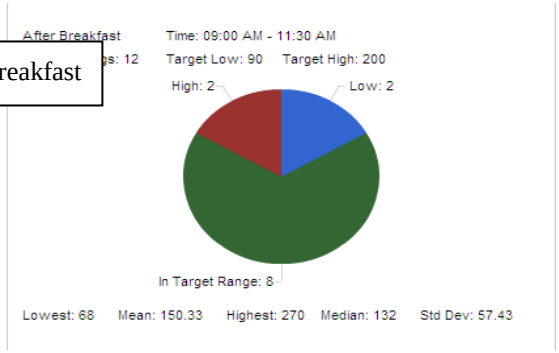
Remember that all these ranges can be set by the provider, so that the ranges are specific to the individual circumstances of each of the patients. These values can be adjusted in Analysis Setup at any point while using the program.



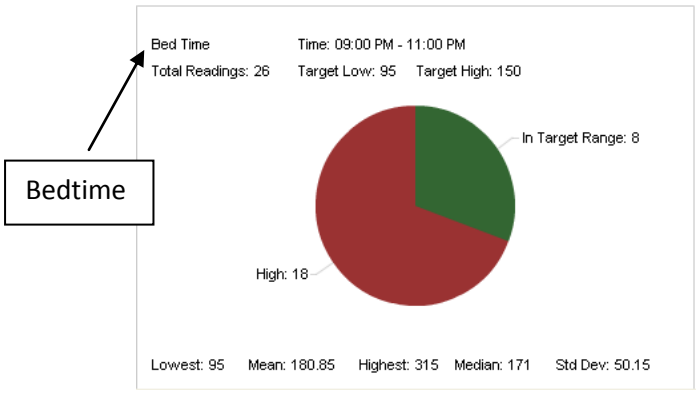
Pie Charts can be created as another way to display the patterns of BG over time and by meals.




Before Breakfast




After Breakfast


Bedtime
Bed Time
Time: 09:00 PM - 11:00 PM
Total Readings: 26
Target Low: 95
Target High: 150
In Target Range: 8
High: 18
Lowest: 95
Mean: 180.85
Highest: 315
Median: 171
Std Dev: 50.15

## BIBLIOGRAPHY

Algorithms and Guidelines
- AACE/ACE
- ADA
- VA/DOD

CADS system

Analysis of SMBG data


1. **AACE Algorithm**

https://www.aace.com/sites/default/files/GlycemicControlAlgorithm.pdf

https://www.aace.com/sites/default/files/GlycemicControlAlgorithmPPT.pdf

https://www.aace.com/sites/default/files/Diabetes_Algorithm_120909_PC_final_animated.ptt

2. **ADA/EASD**
http://care.diabetesjournals.org/content/29/8/1963.full.pdf+html

**3. VA/DOD guideline** short version:

http://www.healthquality.va.gov/diabetes/DM2010_SUM-v4.pdf

**4. VA/DOD guideline** long version**:**

http://www.healthquality.va.gov/diabetes/DM2010_FUL-v4e.pdf

5. **AACE guideline 2011**

https://www.aace.com/sites/default/files/DMGuidelinesCCP.pdf

**CADS**:

Rodbard D, Vigersky RA. Design of a Decision Support System to Help Clinicians Manage Glycemia in Patients with Type 2 Diabetes Mellitus. J Diab Sci Tech. 2011 (Mar); 5 (2): 402-411 and on-line Appendix.

**Analysis and Interpretation of SMBG Data:**

Rodbard, D. Optimizing Display, Analysis, Interpretation and Utility of Self-Monitoring of Blood Glucose (SMBG) Data for Management of Patients with Diabetes. Journal of Diabetes Science and Technology, 1 (1): 62 - 71, 2007.

**CURRENT ISSUES WITH TZDs**

GSK re Rosiglitazone (Avandia), with Risk elimination program:

http://www.gsk.com/media/pressreleases/2011/2011_pressrelease_10024.htm

FDA re withdrawal of Pioglitazone (Actos) in France and Germany:

http://www.fda.gov/Drugs/DrugSafety/ucm259150.htm

http://care.diabetesjournals.org/content/34/4/916.long

# Trouble Report

**Note: This form can be submitted anonymously without the name of the provider, or patient, or both.**

1. Name of Clinician: (optional)
2. Date:
3. Facility: WRNMMC, WHASC, UH
4. Patient Identifier: (optional)
5. Nature of the Problem
6. Severity of the Problem
7. Is there any risk to the patient, or likely to be any risk to any other patient as a result of this problem?