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CONTRACTING ORGANIZATION: Diabetes Technology Society
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POST MEETING REPORT
THIRD ANNUAL CLINICAL DIABETES TECHNOLOGY MEETING
APRIL 20-21, 2007
SAN DIEGO, CALIFORNIA

The Third Annual Clinical Diabetes Technology Meeting was presented by the Diabetes Technology Society at the San Diego, California, Marriott Mission Valley Hotel on April 20-21, 2007. The attendance was 378 healthcare providers and scientists. The first day of the meeting covered Technologies for Diabetes Monitoring and the second day covered Technologies for Diabetes Therapy.

On April 20, 2007, which was the Technologies for Diabetes Monitoring day, the first presentation was made by Christopher Saudek, M.D. on the topic, "The Impact of Self Monitoring of Blood Glucose on Glycemic Control". This clinician emphasized the benefits of glucose monitoring to achieve glycemic targets. Bruce Buckingham, M.D. presented an overview on Continuous Glucose Monitoring. He described how metabolic monitoring with continuous glucose monitoring can provide information about nutritional and metabolic status that is unavailable with spot glucose testing. William Clarke, M.D. discussed the concept of "Glycemic Variability" which means that acute fluctuations in blood glucose levels can be as harmful for the circulation as prolonged severe hyperglycemia. Glycemic variability can be best measured through continuous glucose monitoring technology. Howard Wolpert, M.D. discussed "Establishing a CGM Program" and pointed out how important it is to utilize the data provided by continuous glucose monitoring to determine therapy of diabetes. He provided examples of glycemic patterns that can be discerned through this monitoring technology. Darrell Wilson, M.D. spoke on the use of CGM to Improve Control and Prevent Hypoglycemia: Case Studies" and gave examples of how continuous glucose monitoring can provide insight into patient behavior and assist in determining drug and diet therapy. He described the work of the multicenter research group DirecNET.

Edward Dougherty, M.S., M.A., Jay Dunigan, and Claudia Graham, Ph.D., M.P.H., M.B.A. together described the policies of government payers and insurance payers for determining coding, coverage, and payment for new monitoring technologies, such as

continuous glucose monitoring in a series of brief presentations plus a panel discussion entitled "Reimbursement of CGM". They emphasized the need for physicians to communicate with these payers to effect establishment of favorable policies for the use of new technologies. Robert Gabbay, M.D., Ph.D. described the benefits to research and patient care by establishing hospital databases in his presentation entitled, "Databases and Diabetes: Potential and Reality". Timothy Bailey, M.D., FACE discussed "Software to Manage Diabetes" and showed how data management software can provide insights into glycemic control where the amount of data is so great that a caregiver cannot assimilate all the information at one time. David Sacks, M.D. spoke on "Hemoglobin A1c and Mean Blood Glucose (MBG) to Diagnose and Manage Diabetes" and described the technology for measuring Hemoglobin A1c and the value of this analyte. He discussed the international climate for changing the normal range for this marker of longterm glycemia. Walter Palmas, M.D., M.S. described a 4-year large multisite telemedicine program organized by Columbia University and SUNY Upstate in his presentation entitled, "Telemedicine for Diabetes Management" the day concluded with a panel of patients who wear continuous glucose monitors. In this session entitled, "Patient Panel: Living With Continuous Glucose Monitoring" four patients who have used three different continuous glucose monitors, between them, discussed benefits and drawbacks of having access to real-time glucose values and how this technology has improved their glycemic control.

On April 21, 2007, which was the Technologies for Diabetes Therapy day, the first presentation was made by Michael Goldberg, M.D and Jeffrey Joseph, D.O. on "Hospital Management of Diabetes". They explained the benefits of intensive glycemic control in the hospital and presented algorithms and targets for achieving improved control. Debra Armstrong, R.N., CCRN and Andrea Gasper, M.S., PA-C presented a lecture on Pens, Pumps, and Dosing Software: the Latest Devices which reviewed the latest products and how they can be used to improve compliance, and in some cases even outcomes, through improved compliance. Stephen Gitelman, M.D. and Howard Wolpert, M.D. gave a presentation entitled "Insulin Pump Therapy: Case Studies" in a set of four patients: two adults and two children. They used audience response questions to illustrate how various types of insulin boluses may be necessary for atypical meals or exercise patterns. Scott

Lee, M.D. spoke on "Sensor Augmented Pump: Looking at Clinical Outcomes" and explained how a partnership between the patient and physician can help a type 1 patient to collect the most information and make the best decisions using advanced sensor-pump control. He discussed how to collect and utilize the realtime data that the sensor-augmented pump provides. Jean-Louis Selam, M.D. presented a discussion of potential advantages and risks of insulin delivery via the inhaled route. A panel discussion of Medical Management of Type 2 Diabetes followed. Leann Olansky, M.D. discussed possible choices of oral agents when it is time to initiate therapy. COL Robert Vigersky, M.D. discussed insulin regimens for transitioning from oral agents to insulin. Anne Peters, M.D., CDE reviewed indications for the use of GLP-1 Agonists. Finally, S. Sethu Reddy, M.D., M.B.A., FRCPC, FACP, FACE presented an overview of the mechanisms, clinical indications, and outcomes of therapy with DPP-4 Inhibitors. A panel discussion among the four endocrinologists followed the individual presentations. A panel discussion on management of obesity followed. COL Gaston Bathalon, Ph.D. discussed nutrition therapy in the military and civilian communities. Erik Dutson, M.D. discussed the potential for bariatric surgery to serve as a cure for type 2 diabetes in obese patients. Dr... Dutson also reviewed how robotic surgery could make future abdominal surgeries simpler and faster. The meeting concluded with a panel discussion on the future of diabetes technologies. The panel participants were Jeffrey Joseph, D.O. (Chair) and participants included David Rodbard, M.D., Susan Braithwaite, M.D, FACP, FACE John Walsh, P.A., CDE. The panel members reviewed possible settings for real time continuous glucose monitoring and closed loop control of glycemia.

The Clinical Diabetes Technology Meeting highlighted areas of blood glucose monitoring and drug delivery that are of great value to patients with diabetes, and can also be modified to be used for warfighters who require metabolic monitoring in the field and occasional receipt of parenteral drugs. The dual uses of these "diabetes technologies" technologies will become increasingly apparent as the products become established in the diabetes community and then move out to other groups who can benefit from them.

Friday/Saturday
April
20-21, 2007

Third Annual

CLINICAL DIABETES TECHNOLOGY MEETING

A PRACTICAL COURSE FOR CLINICIANS TAUGHT BY CLINICIANS

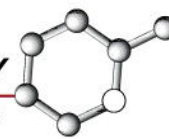
**Marriott Hotel
San Diego Mission Valley**

Presented by:



DIABETES TECHNOLOGY SOCIETY

Applying science and engineering to fight diabetes



Developed in cooperation with:

- Barbara Davis Center for Childhood Diabetes
- Stanford University, Department of Pediatrics
- Yale University, Department of Pediatrics
- University of California at San Francisco, Diabetes Center
- Pennsylvania State University, Department of Medicine
- Technologies for Metabolic Monitoring Research Program
- Mills-Peninsula Health Services
- Medical Education Collaborative

Meeting supported by educational grants from:

- Abbott Diabetes Care
- Amylin-Lilly
- Bayer Healthcare: Diabetes Care
- LifeScan, Inc.
- Medtronic MiniMed
- Merck & Co., Inc.
- Novo Nordisk A/S
- Pfizer, Inc.
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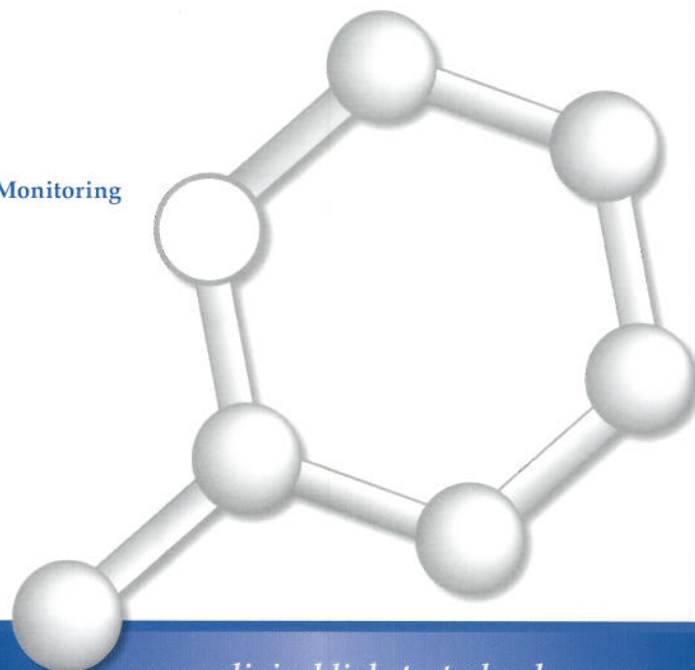
Planning Committee:

- **David Klonoff, M.D., FACP, Chair**
Diabetes Research Institute, Mills-Peninsula Health Services, San Mateo, California, and Department of Medicine, University of California at San Francisco; Editor, *Journal of Diabetes Science and Technology*
- **Robert Gabbay, M.D., Ph.D.**
Department of Medicine, Pennsylvania State University, Hershey, Pennsylvania
- **Satish Garg, M.D.**
Departments of Pediatrics and Medicine, Barbara Davis Center for Childhood Diabetes, University of Colorado, Aurora, Colorado
- **Stephen Gitelman, M.D.**
Department of Pediatrics, University of California at San Francisco, San Francisco, California
- **Jeffrey Joseph, D.O.**
Artificial Pancreas Center and Department of Anesthesiology, Thomas Jefferson University, Philadelphia, Pennsylvania
- **Robert Vigersky, M.D.**
Diabetes Institute, Walter Reed Army Medical Center, Washington, DC
- **Stuart Weinzimer, M.D.**
Department of Pediatrics, Yale University, New Haven, Connecticut
- **Darrell Wilson, M.D.**
Department of Pediatrics, Stanford University, Palo Alto, California
- **Howard A. Wolpert, M.D.**
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

FRIDAY, APRIL 20, 2007

Technologies for Diabetes Therapy

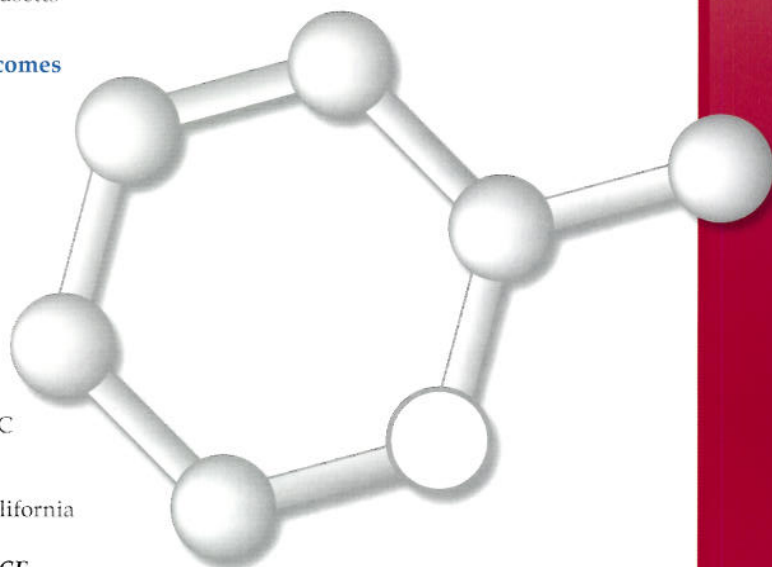
- 08:00 Welcome: First Day**
David Klonoff, M.D., FACP
 Mills-Peninsula Health Services, San Mateo, California and
 UCSF, San Francisco, California
- 08:05 The Impact of Self Monitoring of Blood Glucose on Glycemic Control**
Christopher Saudek, M.D.
 Johns Hopkins University, Baltimore, Maryland
- 08:45 Continuous Glucose Monitoring Overview**
Bruce Buckingham, M.D.
 Stanford University, Palo Alto, California
- 09:25 Glycemic Variability**
William Clarke, M.D.
 University of Virginia, Charlottesville, Virginia
- 10:05 Break (Refreshments Provided)**
- 10:30 Establishing a CGM Program**
Howard Wolpert, M.D.
 Joslin Clinic/Harvard University, Boston, Massachusetts
- 11:10 Use of CGM to Improve Control and Prevent Hypoglycemia: Case Studies**
Darrell Wilson, M.D.
 Stanford University, Palo Alto, California
- 11:50 Reimbursement of CGM: Panel Discussion**
Edward Dougherty, M.S., M.A.
 B&D Consulting LLC, Washington DC
Jay Dunigan
 Abbott Diabetes Care, Londonderry, New Hampshire
Claudia Graham, Ph.D., M.P.H., M.B.A.
 Medtronic Diabetes, Northridge, California
- 12:30 Lunch (Provided)**
- 13:40 Databases and Diabetes: Potential and Reality**
Robert Gabbay, M.D., Ph.D.
 Pennsylvania State University, Hershey, Pennsylvania
- 14:20 Software to Manage Diabetes**
Timothy Bailey, M.D., FACE
 North County Endocrine, Escondido, California
- 15:00 Hemoglobin A1c and Mean Blood Glucose (MBG) to Diagnose and Manage Diabetes**
David Sacks, M.D.
 Harvard University, Boston, Massachusetts
- 15:40 Break (Refreshments Provided)**
- 16:05 Telemedicine for Diabetes Management**
Walter Palmas, M.D., M.S.
 Columbia University, New York, New York
- 16:45 Patient Panel: Living With Continuous Glucose Monitoring**
- 17:45 Adjourn**



SATURDAY, APRIL 21, 2007

Technologies for Diabetes Therapy

- 08:00 **Welcome: Second Day**
David Klonoff, M.D., FACP
 Mills-Peninsula Health Services, San Mateo, California and UCSF, San Francisco, California
- 08:05 **Hospital Management of Diabetes**
Michael Goldberg, M.D.¹ and Jeffrey Joseph, D.O.²
¹University of Medicine & Dentistry of New Jersey, Camden, New Jersey
²Thomas Jefferson University, Philadelphia, Pennsylvania
- 08:45 **Pens, Pumps, and Dosing Software: the Latest Devices**
Debra Armstrong, R.N., CCRN¹ and Andrea Gasper, M.S., PA-C^{1,2}
¹VA San Diego, California
²California Diabetes and Endocrine Associates, La Mesa, California
- 09:25 **Insulin Pump Therapy: Case Studies**
Stephen Gitelman, M.D.¹ and Howard Wolpert, M.D.²
¹UCSF, San Francisco, California
²Joslin Clinic/Harvard University, Boston, Massachusetts
- 10:05 **Break (Refreshments Provided)**
- 10:30 **Sensor Augmented Pump: Looking at Clinical Outcomes**
Scott Lee, M.D.
 Loma Linda University, Loma Linda, California
- 11:10 **Inhaled Insulin**
Jean-Louis Selam, M.D.
 Diabetes Research Center, Tustin, California
- 11:50 **Lunch (Provided)**
- MEDICAL MANAGEMENT OF TYPE 2 DIABETES**
- 13:00 **Initiating Therapy**
Leann Olansky, M.D.
 Cleveland Clinic, Cleveland, Ohio
- 13:20 **Transitioning from Oral Agents to Insulin**
Robert Vigersky, M.D.
 Walter Reed Army Medical Center, Washington, DC
- 13:40 **GLP-1 Agonists**
Anne Peters, M.D., CDE
 University of Southern California, Los Angeles, California
- 14:00 **DPP-4 Inhibitors**
S. Sethu Reddy, M.D., M.B.A., FRCPC, FACP, FACE
 Merck & Co., Inc., North Wales, Pennsylvania
- 14:20 **Panel Discussion**
by Drs. Olansky, Vigersky, Peters, and Reddy
- 15:00 **Break (Refreshments Provided)**
- MANAGEMENT OF OBESITY**
- 15:25 **Nutrition Therapy**
COL Karl Friedl, Ph.D.
 US Army, TATRC, Fort Detrick, Maryland
- 15:45 **Medical Therapy**
Ken Fujioka, M.D.
 Scripps Clinic, San Diego, California
- 16:05 **Surgical Therapy**
Erik Dutson, M.D.
 UCLA, Los Angeles, California
- 16:25 **Panel Discussion**
by Drs. Friedl, Fujioka, and Dutson
- 17:00 **Future of Diabetes Technology: Panel Discussion**
Christopher Saudek, M.D., Chair
 Johns Hopkins University, Baltimore, Maryland
Susan Braithwaite, M.D, FACP, FACE
 University of North Carolina,
 Chapel Hill, North Carolina
- 17:45 **Adjourn**
- David Rodbard, M.D.*
 American Institutes for Research, Silver Spring, Maryland
John Walsh, P.A., CDE
 North County Endocrine, Escondido, California



Third Annual Clinical Diabetes Technology Meeting: April 20 & 21, 2007 Marriott Mission Valley Hotel, San Diego, California

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NO ACTUAL OR POTENTIAL CONFLICT

Debra Armstrong, R.N., CCRN
Timothy Bailey, M.D., FACE
Bruce Buckingham, M.D.
William Clarke, M.D.
Edward Dougherty, M.S., M.A.
Erik Dutson, M.D.
COL Karl Friedl, Ph.D.
Robert Gabbay, M.D., Ph.D.
Stephen Gitelman, M.D.
Walter Palmas, M.D.
David Rodbard, M.D.
Christopher Saudek, M.D.
Robert Vigersky, M.D.
Darrell Wilson, M.D.

DISCLOSED RELATIONSHIP(S) WITH INDUSTRY

Jay Dunigan – Employee of Abbott Diabetes Care.

Andrea Gasper, M.S., PAC – Consultant to Abbott Diabetes Care, Smiths Medical.

Ken Fujioka, M.D. – Grant support from Orexigen, Glaxo (GSK), Abbott (Knoll), Amylin, BMS, Johnson & Johnson, Ortho-McNeil, Amgen, Merck, Sanofi, Novartis; Consultant to Abbott (Knoll), Johnson & Johnson, Ortho-McNeil, Amgen, Merck; Speaker for Glaxo (GSK), Abbott (Knoll), Auxilium.

Michael Goldberg, M.D. – Grant support from PDL BioPharma, Baxter, Glucon; Speaker for Merck, PDL BioPharma.

Claudia Graham, Ph.D., M.P.H., M.B.A. – Employee of Medtronic MiniMed.

Jeffrey Joseph, D.O. – Grant support from Medtronic Diabetes Abbott Diabetes, St. Jude Medical, LifeScan; Consultant to St. Jude Medical; Speaker for Abbott Diabetes; Major Stock Shareholder of Medtronic, Johnson & Johnson.

David Klonoff, M.D., FACP – Grant support from Bidel, C8 MediSensors, MannKind, Novo Nordisk, Pfizer, Sankyo; Consultant to C8 MediSensors, Medingo, M2 Medical.

Scott Lee, M.D. – Grant support from Medtronic; Consultant to Medtronic; Speaker for Medtronic.

Leann Olansky, M.D. – Consultant to Takeda; Speaker for Takeda, Lilly, Merck, Novartis, Pfizer, Amylin.

Anne Peters, M.D., CDE – Grant support from Abbott; Consultant to Abbott, Aventis, Amylin, Lilly, Takeda; Speaker for Abbott, Aventis, Amylin, Lilly, Takeda.

S. Sethu Reddy, M.D., M.B.A., FRCPC, FACP, FACE - Employee of Merck & Co.

David Sacks, M.D., Ch.B. - Advisory panel for Metrika; Speaker for Beckman Coulter, Prous Science.

Jean-Louis Selam, M.D. - Consultant to Pfizer, Novo-Nordisk.

John Walsh, P.A., CDE - Grant support from Smiths Medical; Consultant to Bayer; Speaker for Smiths Medical, DexCom; Advisory Board Member for Roche Diagnostics, LifeScan, Animas.

Howard Wolpert, M.D. – Grant support from Medtronic MiniMed; Consultant to Abbott Diabetes Care.

Continuous Glucose Monitoring Overview

Bruce Buckingham, M.D.

Stanford University, Palo Alto, California

Continuous glucose monitoring is now available from several companies. In this presentation an overview of these devices will be presented. Issues common to all subcutaneous glucose sensors will be discussed, such as the lag time between interstitial and blood glucose levels and how this affects perceived sensor accuracy and the detection of hypoglycemia. Use of sensor for managing diabetes in "real-time" will be reviewed as well as retrospective analysis of CGM results for recognition of glycemic trends. The potential for using CGM technology in development of a closed-loop artificial pancreas will also be briefly reviewed.

Glycemic Variability

William Clarke, M.D.

University of Virginia, Charlottesville, Virginia

Recent evidence suggests that glycemic variability may contribute significantly to the morbidity associated with both Type 1 and Type 2 diabetes. Indeed glycemic variability, especially extreme hyperglycemic excursions has been shown to contribute to oxidative stress which is the chief underlying mechanism of glucose mediated vascular injury. In addition, hypoglycemic extremes are associated with the development of hypoglycemia associated autonomic failure, and cognitive dysfunction, depression and anxiety, are associated with both hypo- and hyper-glycemic extremes.

Assessing and quantifying glycemic variability is difficult since traditional statistics such as mean, standard deviation, and variance require data which is normally distributed while the blood glucose scale is skewed towards hyperglycemia. Standard deviation has an inherent bias towards hyperglycemia and is a poor predictor of severe hypoglycemia. MAGE, and M-value metrics are also weak predictors of hypoglycemia. Risk Analysis, which uses logarithmically transformed blood glucose data, permits the calculation of the Low Blood Glucose Index (LBGI), the High Blood Glucose Index (HBGI) and the Average Daily Risk Range (ADRR). LBGI is based on the frequency and extent of low glucose determinations and can predict 40-60% of the variance in significant future hypoglycemia. HBGI is strongly associated with HbA1c and postprandial glucose excursions. ADRR evaluates the risk of extreme BG fluctuations and minimizes the significance of variability of glucose within the target range. Continuous glucose sensing adds the dimension of time to the assessment of glycemic variability. Temporal analyses include of rate of glucose change and the risk associated with temporal variability.

Obviously new strategies are needed to reduce glycemic variability. Initially these will include more attention to the frequency of glucose monitoring and the effects of insulin, food and exercise on individual glycemic patterns. Medications such as pramlintide and exenatide have been shown to reduce hyperglycemic excursions in Type 1 and Type 2 diabetes respectively. Recent information suggests that the use of continuous glucose sensors with minimal physician guidance can be associated with reduced glycemic variability. Future treatment options including islet cell transplantation and closed loop "Artificial Pancreas" control of blood glucose offer the promise of reduced glucose extremes as well as lower HbA1c levels.

Establishing a CGM Program

Howard Wolpert, M.D.

Joslin Clinic/ Harvard University, Boston, Massachusetts

Real-time continuous glucose monitoring (RT-CGM) provides detailed information on glucose patterns and trends, and promises to be a major advance in diabetes care. To derive full potential benefit from RT-CGM the patient needs to be skilled in diabetes self-management. The talk will cover several key concepts and issues that need to be addressed in training patients to use RT-CGM. This includes: 1) The impact of the physiologic lag between interstitial and capillary blood glucose levels on sensor calibration accuracy and the detection/ treatment of hypoglycemia, and the related importance of using fingerstick measurements for treatment decision-making when the glucose level is changing rapidly i.e. conditions when physiologic lag can lead to a marked discrepancy between blood and interstitial glucose; and 2) The increased risk among RT-CGM

Establishing a CGM Program - Howard Wolpert, M.D. continued

users for hypoglycemia related to blind postprandial bolusing, and the related importance of considering the glucose trend, 'insulin on board', as well as the impact of the glycemic index of different foodstuffs on postprandial glucose patterns in patient decision-making about whether to take supplemental boluses to correct postprandial hyperglycemia. The talk will also cover considerations in patient selection: individuals with unresolved barriers to optimization of glycemic control (such as fear of weight gain manifesting as insulin restriction) or fear of hyperglycemia/complications (with frequent hypoglycemia from excessive bolusing) are not good candidates for this technology. To use continuous glucose data safely and effectively patients need to have advanced diabetes management skills, and the widespread adoption of RT-CGM into diabetes care will need to be coupled to comprehensive self-management education.

Use of CGM to Improve Control and Prevent Hypoglycemia: Case Studies

Darrell Wilson, M.D.

Stanford University, Palo Alto, California

This presentation will highlight case studies where CGM data has been used to decrease hypoglycemia and improve diabetes control in patients. Additionally, algorithms will be reviewed which use both the pre-meal glucose concentration and slope of recent glucose changes to adjust pre-meal insulin boluses in real time. Dr. Wilson will also discuss other algorithms designed to help patients review 3 to 5 days of recent CGM data to prospectively adjust both the basal insulin patterns as well as modify a patient's approach to post prandial hyperglycemia.

Databases and Diabetes: Potential and Reality

Robert Gabbay, M.D., Ph.D.

Pennsylvania State University, Hershey, Pennsylvania

Numerous studies indicate a gap between evidence-based recommendations for care in clinical outcomes. Barriers reported by physicians include inefficiencies in data gathering. Information technology provides a potent solution to this problem. Diabetes registries are increasingly being utilized as a critical feature for population-based disease management. Searchable registries provide an opportunity to identify high risk patients for more intensive intervention, individuals who have not had appropriate screening tests for reminders to improve process measures and feedback to physicians on performance. As translational research in clinical trials become an important focus for academic institutions, the power of registries for patient recruitment is significant.

The Penn State Diabetes Center Diabetes Registry provides real time data on over 10,000 patients within 18 Primary Care and Endocrinology clinics in a geographically dispersed rural area. Electronic feeds from hospital-based laboratory systems and identification of eligible patients based on bearing DRG codes (250.xx on two occasions) populate the core aspects of the registry. Other data fields such as last eye and monofilament exam, ACE/ARB, use aspirin, diabetes education, self-care goals, etc. are indicated on flow sheets printed at the time of visit by clinic staff and providers.

The presentation will focus on some of the effective uses of registries in this environment and many of the lessons learned in implementation of such a system into the work flow of Primary Care clinics. Success or failure of registries are often more dependent on these issues than the actual technology aspects of the software. Use of registries for clinical trials can help build the business model for sustainability.

Software to Manage Diabetes

Timothy Bailey, M.D., FACE

North County Endocrine, Escondido, California

Diabetes software has been developed and used since the advent of memory-capable glucose meters. All leading glucose meter brands now offer some solution for uploading glucose values from them. The density and quantity of diabetes-generated data is increasing enormously with the added information available from insulin pumps (insulin doses and carbohydrates) and continuous glucose monitoring. The adoption rate of diabetes software in any form among doctors, educators, and patients alike has lagged behind expectations. This has occurred despite awareness of the technology and its benefits. The many reasons for this and available solutions will be discussed, focusing on overcoming technical pitfalls and logistical barriers. The wealth of information now available to patients and providers should be more fully exploited to allow us to offer our patients state-of-the-art care. Practical approaches for various patient types will be discussed and demonstrated.

Hemoglobin A1c and Mean Blood Glucose (MBG) to Diagnose and Manage Diabetes

David Sacks, M.D.

Harvard University, Boston, Massachusetts

Measurement of glycated hemoglobin (GHb) as hemoglobin A1c (HbA1c) is used extensively in individuals with diabetes mellitus to monitor long-term glycemic control. Moreover, two large prospective randomized clinical trials, namely the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that HbA1c is a marker for the risk of developing complications in type 1 and type 2 diabetes, respectively. The current American Diabetes Association (ADA) recommendations are that HbA1c be measured at least twice a year in patients who are meeting treatment goals and every 3 months in patients whose therapy has changed or who are not meeting glycemic goals. The HbA1c test is thus an integral and fundamental component of diabetes management.

GHb consists of hemoglobin A1a (HbA1a), HbA1b and HbA1c. More than 30 different methods are commercially available to measure GHb. These factors have led to considerable variation in results reported by different laboratories. In the United States, the NGSP has reduced interlaboratory variation using a standardization process based on the DCCT reference method. More recently, the International Federation for Clinical Chemistry (IFCC) developed a reference method for HbA1c using mass spectrometry. HbA1c values by the IFCC method are significantly lower (~1.5 - 1.9% across the relevant HbA1c range) than NGSP results. These findings have generated considerable debate as to how HbA1c should be reported.

A large multicenter international study is currently underway to address this concern. The goal is to determine whether HbA1c correlates with mean blood glucose (MBG) in an individual. If a mathematical relationship between HbA1c and MBG is established, HbA1c could be reported in the same units as the patients' self monitoring results.

Telemedicine for Diabetes Management

Walter Palmas, M.D., M.S.

Columbia University, New York, New York

The Informatics for Diabetes Education & Telemedicine (IDEATel) Project is a randomized controlled trial sponsored by the Center for Medicare and Medicaid Services (CMS).

Goals: The overall goal is to implement and evaluate a large scale electronically delivered telemedicine disease management program to a population of medically underserved Medicare beneficiaries with diabetes. The research aims are to evaluate the impact of the telemedicine case management intervention on diabetes outcomes, to evaluate the cost effectiveness of telemedicine as a method for delivering disease management services, and to assist CMS in policy formation regarding whether to reimburse health care providers for electronically delivered health care services.

Telemedicine for Diabetes Management - Walter Palmas, M.D., M.S. continued

Methods: IDEATel was originally designed as a four year project, and has been extended by the funding agency to a total duration of eight years. Subject enrollment began December 1, 2000 and 1,665 participants were enrolled in the initial phase. In order to compensate for attrition an additional group of 504 new participants were recruited in the second phase. Newly enrolled participants will remain in the study for two years. Those participants who have already been enrolled, and wish to continue to participate, will remain in the study for a total duration of five years. The study is being conducted in one urban and one rural location, namely, New York City and upstate New York. Within each of these two blocks (urban, rural) approximately half of the participants are randomized to intervention and half to usual care.

One Year Results: In the intervention group (n= 5,844), mean HgbA1c improved over one year from 7.35% to 6.97% and from 8.35% to 7.42% in the subgroup with baseline HgbA1c >7% (n= 5,353). In the usual care group (n= 5,821) mean HgbA1c improved over one year from 7.42% to 7.17%. Adjusted net reductions (one-year minus baseline mean values in each group, compared between groups) favoring the intervention were as follows: HgbA1c, 0.18% (p= 0.006), systolic and diastolic blood pressure, 3.4 (p= 0.001) and 1.9 mm Hg (p < 0.001), and LDL cholesterol, 9.5 mg/dL (p < 0.001). In the subgroup with baseline HgbA1c >7%, net adjusted reduction in HgbA1c favoring the intervention group was 0.32% (p= 0.002). Mean LDL cholesterol level in the intervention group at one year was 95.7 mg/dL. The intervention effects were similar in magnitude in the subgroups living in New York City and upstate New York. In conclusion, telemedicine case management improved glycemic control, blood pressure levels, and total and LDL cholesterol levels at one year of follow-up.

Telemedicine management was acceptable to patients and their primary care providers. In spite of low computer literacy, study participants made full use of the video-conference, self-monitoring and data uploading features. These findings have important implications for ongoing policy discussions and will influence research in this field.

Hospital Management of Diabetes

Michael Goldberg, M.D.¹ and Jeffrey Joseph, D.O.²

¹University of Medicine & Dentistry of New Jersey, Camden, New Jersey

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The goal of the talk is to familiarize the practicing physician with the outcome studies in the ICU and OR setting that support the concept of tight Glucose control. To this end, this talk will review several of the studies, focusing on the outcome benefit. This will be followed by a description of glucose monitoring and administration in the perioperative arena. Included in the talk will be results of studies at our own institution focusing on practice parameters and changes that can be instituted.

Pens, Pumps, and Dosing Software: the Latest Devices

Debra Armstrong, R.N., CCRN¹ and Andrea Gasper, M.S., PA-C^{1,2}

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Insulin delivery systems continue to evolve for the benefit of both type 1 and type 2 diabetics using insulin. For the young and old alike, these advances in technology have increased accuracy, ease of handling, convenience and safety.

Pens come with a variety of features. From prefilled disposable to reuseable, insulin pens can be used for infants, the visually impaired, and those with reduced manual dexterity. The newest generation of pens produced by Lilly, Aventis, Novo Nordisk and Amylin offer a variety of features that may include dosing windows with digital readout, pens that can deliver less than 1 unit, and the Memoir by Lilly that offers dose memory, date and time with backlighting.

The stability of in-pen insulin has increased as has the ease of storage. Insulin pens can deliver a wide variety of insulins, from short acting to extended acting, as well as the non-insulin incretins Symlin and Byetta.

Pens, Pumps, and Dosing Software: the Latest Devices - Debra Armstrong, R.N., CCRN and Andrea Gasper, M.S., PA-C continued

Although all current insulin pumps employ some sort of smart pump technology, they have a variety of unique features.

The Animas IR-1250 is the smallest full-feature pump. It allows for 0.025u basal increments/ 0.050u bolus increments which make this pump well suited for the insulin sensitive or pediatric patient. The pump can be used as a carb counter by uploading favorite foods from the CalorieKing food database. EzManager Plus Software allows data from pump to be downloaded to a PC.

The MiniMed Paradigm 522 and 722, differ only by insulin reservoir size, 176u and 300u, respectively. The Paradigm RT continuous monitor is an optional upgrade that provides continuous glucose data to the pump. The BD glucose meter, if used, communicates blood glucose data directly to the pump. There is also an optional a wireless remote for the pump. ParadigmPAL software allows for PC downloads as well as the web-based Medtronic CareLink.

The Insulet OmniPod, available in select markets, should be fully launched nationwide by late 2007. The OmniPod is a small, lightweight, disposable insulin pump. There is no tubing; insulin is filled directly into the pump. Automated cannula insertion is initiated from a wireless PDA. The handheld device has an integrated FreeStyle glucose meter. OmniPod can be worn for up to 80 hours, after that insulin delivery is suspended.

The Disetronic Accu-Chek Spirit is an integrated system that includes an insulin pump, PDA and glucose meter. Boluses can be programmed into the PDA and delivered wirelessly, or they can be keyed into the pump directly. The insulin reservoir is the largest at 315u. Display is available in 12 languages. Pump data downloadable to PC via Accu-Chek Pocket Compass Software.

The Deltec Cozmo, when used in combination with the CoZmonitor FreeStyle glucose meter, is referred to as the CozMore. For providers, there is a Therapy Effectiveness Scorecard and a Basal Rate Test program. The Hypo Manager, helps patients manage hypoglycemia. The Disconnect feature directs patients before and after disconnecting to deliver missed basal rate. There is also a CozFoods database. CoZmanager 2.0 software allows for data download to PC.

Insulin Pump Therapy: Case Studies

Stephen Gitelman, M.D.¹ and Howard Wolpert, M.D.²

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This session will cover a series of case discussions involving insulin pump therapy. Problems and pitfalls relating to both pediatric and adult diabetes management will be covered in an interactive format with the audience.

Sensor Augmented Pump: Looking at Clinical Outcomes

Scott Lee, M.D.

Loma Linda University, Loma Linda, California

Sensor augmented insulin pump therapy is a convergence of two technologies, continuous insulin infusion therapy, and real-time continuous interstitial glucose monitoring (RT-CGM). Frequent self-monitoring of blood glucose (SMBG) is a critical component of intensive therapy with insulin pumps and assists patients in their estimation of insulin dosing, food intake and exercise. SMBG, however, cannot be performed frequently enough to reliably detect every glycemic excursion. Continuous glucose monitoring (CGM) can be used to improve glucose control by capturing clear trends in the patients' glycemic profiles that are not easily identified by intermittent SMBG alone. More recently, continuous glucose monitoring has given patients the added ability to view their glucose real-time, as well as review graphs of recent trends in their glycemic control. The application of real-time alarms warns users of impending hypo- and/or hyperglycemia, thereby potentially allowing for either preventative or, if need be, corrective action.

Sensor Augmented Pump: Looking at Clinical Outcomes - Scott Lee, M.D. continued

We have reported that with a sensor augmented insulin pump patients with type 1 diabetes achieved significantly better reductions in A1c levels compared to patients maintained on MDI without an increased incidence of severe hypoglycemia.

Several features which played an integral role in the sensor augmented pump system and may possibly explain the benefit seen in the study group. These include: 1) the algorithmic dosing support system (bolus calculator), 2) the ability to view glucose real time and detect trends in the direction and velocity of glycemic change, 3) the sensor alarms/alerts to prompt therapeutic intervention when glucose levels are out of target range, as well as 4) the weekly feedback from the online data management program which overlays food, insulin, sensor and fingerstick information.

Based on our experience we suggest the following criteria for sensor augmented pump therapy which is similar to insulin pump criteria:

- Inadequate glycemic control, defined as A1c above target ($> 7\%$).
- "Dawn phenomenon," with glucose levels greater than 8-9 mmol/L ($> 144-162$ mg/dL) in the morning.
- Marked daily variations in glucose levels.
- History of hypoglycemia unawareness or of hypoglycemic events requiring assistance.
- Need for flexibility in lifestyle.
- Pregnancy or intention to become pregnant.

Patients considering combined insulin pump therapy and real time glucose monitoring system must be willing and able to meet the demands of pump therapy, such as the need to change the infusion set regularly and to monitor blood glucose at least 4 times a day.

Inhaled Insulin

Jean-Louis Selam, M.D.

Diabetes Research Center, Tustin, California

Inhalation of insulin is the first and only effective non invasive method of insulin delivery. Though needle injections are not the only nor the major burden of diabetes, suppression of all or a majority of injections should improve acceptance, especially in Type 2, and flexibility of treatment, especially in type 1 diabetes. Several projects have now reached large clinical trial application, but only Exubera inhaled insulin (Pfizer) has recently been made available to patients. Most insulins have a bioavailability of 8-10 %, and pharmacokinetics are intermediate between those of fast acting analogs and regular insulin. Type 1 efficacy trials, all unfortunately designed as non inferiority studies, have shown similar efficacy to various conventional or intensified subcutaneous insulin regimens. Type 2 trials have shown superiority to oral medications and non inferiority to insulin. However, data versus most recent insulins only or CSII and in pediatric Type 1 patients, and versus bedtime insulin in Type 2 oral failures are missing. Pfizer safety data show frequent though mild and transient throat irritation at time of inhalation, leading to patient withdrawal in only 1% personal cases, and a non progressive, mild and reversible loss of some lung function, including FEV1 (40 ml difference between groups at 2 yr for a baseline of 3 L) and DLCO, though only significant in 1% cases. A longer than 2 year experience is however needed and is in progress to eliminate potential local toxicity and carcinogenicity. Indeed, regular lung function tests are requested in the labelling of current commercial inhaled insulin, and inhaled insulin is contraindicated in smokers and not recommended in unstable or underlying lung conditions e.g. asthma and COPD. Though promising, this new treatment has a major drawback: its high cost which may, like insulin pens in the US, inappropriately refrain its usage.

Initiating Therapy

Leann Olansky, M.D.

Cleveland Clinic, Cleveland, Ohio

There are a number of therapies FDA approved for initial therapy for Type 2 diabetes and some therapies not yet approved as initial therapy that might be the best choice for some patients. The best initial therapy needs to be individualized based on aims of therapy, co-morbidities, risk for complications, risk of side effects and economic considerations. When economic considerations are primary, the tendency is to use older agents that are now generic but this may not be the most economic approach in the long term. The UKPDS study demonstrated a significant reduction in the development of microvascular complications with using sulfonylurea, insulin or metformin. In contrast, the insulin increasing therapies failed to demonstrate a significant reduction in myocardial infarctions while use of metformin succeeded despite considerably fewer subjects treated with metformin.

None of the older agents used in the UKPDS provided a durable control as monotherapy but the recent ADOPT study demonstrates the durability of rosiglitazone compared to metformin or glyburide as initial monotherapy in a similarly drug naïve group of Type 2 diabetic subjects. If TZDs are added earlier rather than later patients could be maintained on simpler regimes facilitating long term adherence to the therapeutic regime. Reductions in progression and reductions in cardiovascular complications ultimately are likely to be the most cost effective initial diabetes therapies.

The PROACTIVE trial demonstrated secondary reduction in cardiovascular end points of death, MI and stroke with the addition of pioglitazone to traditional therapies previously only seen in statin trials (16% reduction in the composite endpoint of death, MI and stroke over 3 years $p=.027$). The downside of TZD therapy is weight gain and edema and an increase in cases of CHF. The combination of rosiglitazone and metformin has been FDA approved as initial therapy for type 2 diabetes and minimizes both weight gain and edema, making heart failure less likely as well. The lipid changes of these 2 agents are complimentary added to the potential benefit of this approach.

Theoretically incretin-based therapy should also provide durable control of glycemia but this therapy has not been available long enough to be sure that this approach will provide durable control. Weight stability or weight loss is the promise of incretin therapy with DPP-4 and GLP-1 mimetic therapy respectively and this is an important aspect to this approach. Ultimately, no one agent can be recommended as initial therapy for all type 2 diabetes at this time but the long-term issues of reduced cardiovascular risk and a durable therapeutic effect make those agents that provide these benefits most likely the cost-effective options for initial therapy.

Transitioning from Oral Agents to Insulin

Robert Vigersky, M.D.

Walter Reed Army Medical Center, Washington, DC

Patients with Type 2 diabetes have both secretory and functional abnormalities of insulin which are present even prior to diagnosis. The beta cell progressively loses its capacity to make insulin, while insulin resistance generally persists over the course of the disease. Thus, early success in managing hyperglycemia with single or combinations of oral hypoglycemic agents often fail in the 5-10 years following diagnosis. The mechanism of this failure is unclear. While, in general, the secretory failure does not appear to be related to the particular agent, there are data suggesting that insulin, thiazolidinediones (TZD), and glucagon-like peptide 1 (GLP-1) analogs may preserve beta cell function while certainly insulin secretagogues, e.g. sulfonylureas, may promote the loss of the beta cells' secretory ability.

The armamentarium of non-insulin hypoglycemic agents has exploded in the last 12 years. There are now 7 classes of agents: sulfonylureas, biguanides, alpha-glucosidase inhibitors, thiazolidinediones, meglitinides, GLP-1 analogs, and DPP-IV inhibitors. Most produce a 1% improvement in A1c and the addition of an agent in a different class results in a similar and additive outcome (up to triple therapy). One of the most difficult questions facing a clinician whose patient has not reached their A1c goal despite being on 2 or 3 non-insulin hypoglycemic agents is: do I add an additional non-insulin agent or do I initiate insulin therapy.

Transitioning from Oral Agents to Insulin - Robert Vigersky, M.D. continued

The theoretic advantages of adding a 3rd or 4th non-insulin hypoglycemic agent include the chance of better compliance if injections are avoided, reduced risk of hypoglycemia, less weight gain, and maintenance of beta cell mass. On the other hand, there are disadvantages of this approach including an increased risk of adverse events, the complexity of dose adjustments, the development of contraindications, e.g. pregnancy, renal insufficiency, or liver disease, lack of efficacy, and cost. To complicate matters more, the addition of insulin can be supplemental to an existing non-insulin regimen (e.g. basal insulin like glargine or detemir; bedtime insulin like NPH or Lente; or pre-mixed insulin) or can be used to replace the regimen *in toto* (prandial insulin t.i.d. with basal insulin or pre-mixed insulin). There are only a handful of randomized controlled trials that address these issues⁽¹⁻⁴⁾. Most show that the rates of hypoglycemia and weight gain are greater with insulin (whether added or substituted) whereas lipids changes and cost are generally better with insulin. Given the combinations and permutations available, definitive algorithms are unlikely to be forthcoming and clinicians must individualize therapy performing a risk-benefit-cost analysis based on a thorough knowledge of the mechanism of each agent, their patient's needs/desires, and what is available on the patient's health plan formulary.

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DPP-4 Inhibitors

S. Sethu Reddy, M.D., M.B.A., FRCPC, FACP, FACE

Merck & Co., Inc., North Wales, Pennsylvania

The prevalence of type 2 diabetes mellitus worldwide is on the rise, consistent with trends in obesity.

The challenge of achieving effective blood glucose control is illustrated by several trials in patients with type 2 diabetes. In the STENO-2 study, achieving goal HbA1c (<6.5%) was infrequently achieved with conventional or intensive therapy, and proved more elusive than attaining therapeutic targets for blood pressure and lipid management.¹ UKPDS has demonstrated that glycemic control progressively worsens over time, despite intervention with metformin, sulfonylureas and insulin.² More recently, ADOPT showed that despite differences in the time to treatment failure with monotherapy few patients were at HbA1c levels of <7% by the year 4 evaluation (40% rosiglitazone, 36% metformin, 26% glyburide).³

The need for additional glucose control provides a rationale for developing new therapies and combination regimens. It is important that such regimens not only improve glycemic control but also consider the potential accumulation of unwanted effects such as weight gain, edema, and hypoglycemia, all of which may impact on acceptance of the regimen by patients.

Dipeptidyl peptidase-4 (DPP-4) inhibitors increase serum concentrations of the intact, endogenously produced incretins, GLP-1 and GIP, by reducing their degradation by DPP-4. Sitagliptin is an orally active, potent and highly-selective DPP-4 inhibitor with a 24-hour duration of action supporting once-daily administration. Sitagliptin is the first DPP-4 inhibitor in the world to be approved for the management of patients with type 2 diabetes.

In Phase III clinical trials, sitagliptin 100 mg once-daily has demonstrated clinically effective reductions in A1C, FPG and PPG both as monotherapy and as add-on treatment to existing regimens such as metformin and pioglitazone. Typically, more than twice the number of patients achieved a goal HbA1c of less than 7% in the sitagliptin arm compared to the placebo arm.

DPP-4 Inhibitors - S. Sethu Reddy, M.D. continued

In these trials, sitagliptin has also improved various markers of β -cell function such as the proinsulin/insulin ratio and the HOMA- β index. In a noninferiority trial comparing sitagliptin with glipizide in add-on combination use with metformin, sitagliptin provided similar glycemic control to glipizide while providing modest weight loss compared to weight gain with glipizide and a lower incidence of hypoglycemia. Sitagliptin has also been studied in initial co-administration therapy with metformin with substantial reductions in A1C observed with this combination treatment.

In these studies, sitagliptin has been well tolerated, with a generally neutral effect on body weight.

There is intense research into development of other DPP-4 inhibitors as well as agents in the GLP-1 family.

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Medical Therapy

Ken Fujioka, M.D.

Scripps Clinic, San Diego, California

Treatment of the obese diabetic patient has changed dramatically in past few years. The mechanisms of why these patients struggle with weight control and glucose homeostasis appear to be related. Conversely it is well known that weight loss in the diabetic is one of the best things a patient can do for their disease management.

Currently there are two long term approved medications weight loss. A third may have been approved at the time of this symposium. There are also several medications that are used “off label” for their weight loss capabilities in the diabetic population. This talk will review the mechanisms of how these medications work, their expected weight loss, and potential complications.

A practical approach to using medications that produce weight loss will be emphasized with didactic information mixed with cases of typical obese diabetic patients.

Surgical Therapy

Erik Dutson, M.D.

UCLA, Los Angeles, California

The incidence of morbid obesity in the United States has been rising steadily over the last 30 or more years, and currently affects an estimated 35 million Americans. The growing recognition of the safety and efficacy of surgical management of this disease has resulted in the geometric increase in the number of surgical procedures performed annually. Approximately 13,000 procedures were performed in 1998 versus approximately 250,000 performed in 2006. Type 2 Diabetes is rampant in this population, and studies have shown up to 76 percent resolution after surgery. The rise in incidence of surgical management of morbid obesity mirrors the dissemination of advances in surgical technology and technique, most notably the employment of minimally-invasive approaches such as laparoscopy and robotic surgery.

This talk focuses on inclusion criteria for bariatric surgery, reported effects on glycemic control, and the techniques used in the operating room in video format. The techniques employed continue to evolve, and future directions of advanced surgical technology, including so-called computer-assisted, or robotic, surgery will be discussed.

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- Deadline to submit: June 29, 2007
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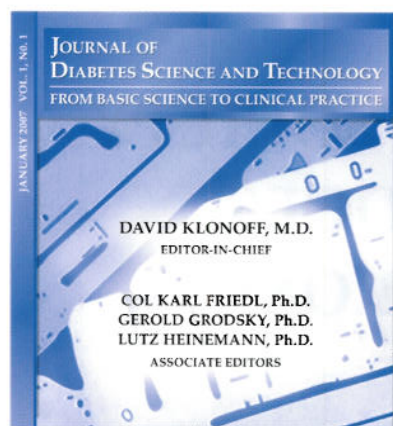
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