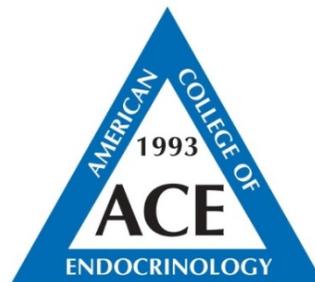




**AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS (AAACE)**  
**AMERICAN COLLEGE OF ENDOCRINOLOGY (ACE)**  
**CONSENSUS CONFERENCE ON GLUCOSE MONITORING**

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## 2014 AACE/ACE Consensus Conference on Glucose Monitoring

### INTRODUCTION

Glucose monitoring is mandatory for modern diabetes care. While glucose monitoring is necessary, it is not adequate by itself to promote optimal diabetes management. Action based on glucose monitoring data is required to affect change. Only an educated patient working with health care professionals can act together to prevent or delay debilitating, and even deadly, complications of this disease. Glucose monitoring is complex, costly, and complicated, surrounded by issues of access, reimbursement, and quality. Cost control measures implemented throughout health care in the United States have created a renewed interest in the most efficient and effective uses of blood glucose monitoring (BGM) and continuous glucose monitoring (CGM) technology to optimize health outcomes for patients with diabetes.

Recognizing the need to address these issues and to build consensus on glucose monitoring, the American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) convened a conference to debate these points on September 28th and 29th, 2014, at the Hyatt Regency at Capitol Hill in Washington, DC. Participants included members of health care associations, insurance companies, government, patient advocacy, pharmaceutical and equipment manufacturing companies, health care systems, physicians, educators, and allied health care professionals.

Specifically, four questions were asked:

- What data support glucose monitoring (as distinct from glycemic control) as a means to prevent diabetic macro- and microvascular complications?
  - a) Does frequency of glucose monitoring correlate with better outcomes?
  - b) Which patients benefit the most from structured glucose monitoring?
  - c) Do glucose strip and CGM accuracy correlate with better outcomes?
- Should the FDA improve post-approval surveillance of glucose strip, glucose meter, and CGM quality?
  - a) Does sub-standard glycemic monitoring technology harm patients? If so, what data exist to support such a claim? Are all manufacturers required to report this data to the FDA?
  - b) What is the current state of affairs at the FDA in post marketing meter and CGM surveillance?
  - c) What enforcement options are available to the FDA, and how are they implemented?
3. Do current private insurance and Medicare policies balance the need to provide patient access to high quality care and effective glucose monitoring and, if not, what policy changes are needed with respect to:
  - a) Patient Access to BGM supplies
    - i. Competitive Bidding Program
    - ii. Limiting glucose strip brand or meter type

- b) Patient access to CGM technology
  - c) Limited or lack of coverage for sensor-augmented insulin pump therapy and emerging semi-automated CGM/pump combinations
4. What is the most effective way for the key stakeholders (physicians, allied health care professionals, patients, professional associations, educators, investigators, payors, industry, employers, health care systems, regulators) to achieve appropriate, evidence-based, cost-effective regulation of glucose (blood, continuous) monitoring technology?

**METHODS AND SCOPE OF CONFERENCE**

The goal of the AACE-ACE Glucose Monitoring Consensus Conference was to develop the evidence base for a comprehensive action plan and to identify points of consensus along with alternative interpretations among constituencies within our four pillars, representing the major stakeholders in glucose monitoring in the U.S. The intention was to have the broad range of stakeholders jointly examine the evidence from different perspectives and with different emphases on priorities. In this sense, the conference was emergent in nature and a process of joint discovery based in terms of the totality of viewpoints. This approach was critical since the action plan will ultimately require concerted action and cooperation among stakeholders based on a consensus interpretation of evidence.

The four pillars and the constituencies that comprise each pillar who participated in the AACE-ACE Glucose Monitoring Consensus Conference are delineated in Table 1. The Medical/Scientific/Professional/Educational Societies pillar comprises professional organizations representing multidisciplinary health care professionals participating in the care of patients with diabetes. The Government/Regulatory/Payers/Employers pillar includes groups that set policy for health care and disease prevention. The Industry pillar encompasses pharmaceutical companies developing glucose monitoring devices and testing strips, large employers concerned with the adverse health impact of diabetes among their employees, and major payors or health care insurance companies. The Patient/Lay Organizations pillar includes lay and professional organizations advocating for diabetes patients.

**Table 1: Glucose Monitoring Consensus Conference Pillar Participants**

PILLAR	PILLAR PARTICIPANTS	
Medical/Scientific Professional/Educational Societies Pillar	Jo Jo Dantone, MS, RDN, LDN, CDE	Diabetes Care and Education Practice Group Academy of Nutrition and Dietetics
	Helena Duncan	College of American Pathologists
	Marion Franz, MS, RDN Guido Freckmann, MD	CDE Academy of Nutrition and Dietetics Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm
	Barry Ginsberg, MD, PhD	Diabetes Technology Consultants
	Louis C. Haenel, IV, DO, FACE, FACOI	American Osteopathic Association
	Aaron J. Kowalski, PhD	JDRLF
	Betty A. Krauss, RDN, CDE	Diabetes Care and Education Practice Group, Academy of Nutrition and Dietetics
	David Marrero, PhD	Diabetes Translational Research Center, Indiana University
	Molly McElwee-Malloy, RN, CDE	American Association of Diabetes Educators

	Gerardo Moreno, MD, MSHS Jerry Penso, MD, MBA Gary Puckrein, PhD Robert Ratner, MD, FACP, FACE David Sacks, MB, ChB, FRCPATH Mitchel Scott, PhD Krishnaswami Vijayaraghavan, MD, MS, FACP, FACC, FNLA Phyllis Zimmer, MN, FNP, FAANP, FAAN Richard Bergenstal, MD  Irl B. Hirsch, MD	American Geriatrics Society American Medical Group Association National Minority Quality Forum American Diabetes Association American Association for Clinical Chemistry Clinical Chemistry, Washington University American College of Cardiology  Nurse Practitioner Healthcare Foundation Park Nicollet International Diabetes Center, Keynote Speaker University of Washington, Keynote Speaker
<b>Government/Regulatory/ Payors/Employers</b>	Pamela Allweiss, MD, MPH  Guillermo Arreaza, MD  Helene D. Clayton-Jeter, OD Sanford Cohen, MD Alberto Gutierrez, PhD  David Knowlton Todd Prewitt, MD William Rogers, MD, FACEP Kimberly Jinnett, PhD, MSPH  Courtney H. Lias, PhD  Kenneth Snow, MD, MBA	Centers for Disease Control and Prevention, Division of Diabetes Translation National Institute of Diabetes, Digestive, and Kidney Diseases, National Institutes of Health US Food and Drug Administration United Healthcare US Food & Drug Administration, Division of Chemistry and Toxicology Devices New Jersey Healthcare Quality Institute Humana Centers for Medicare and Medicaid Services Integrated Benefits Institute, Keynote Speaker US Food & Drug Administration, Division of Chemistry and Toxicology Devices, Keynote Speaker Aetna, Keynote Speaker
<b>Industry</b>	Chris Arapoff Alan Cariski, MD, JD, FACP, FACE Nathan Carrington, PhD Jacob Drapkin Claudia Graham, PhD, MPH Brian Levy, MD, FACE Robert Morin, MD, FACE David Price, MD Melissa Dobson Schooley, JD Steve Scott Mark Swinton, MBA Bruce T. Taylor Ramakrishna Venugopalan, PhD, MBA Duncan Williams	Medtronic Diabetes LifeScan, Inc. Roche Diabetes Care J & J Diabetes Solutions Companies Dexcom, Inc. J & J Diabetes Solutions Companies Bayer HealthCare, LLC Dexcom, Inc. Medtronic Abbott Diabetes Care Abbott Diabetes Care Roche Diagnostics Diabetes Care Animas Corporation, a J&J Company Abbott Diabetes Care
<b>Patient/Lay Organizations</b>	Bennet Dunlap, MSHC Larry Ellingson, RPh  Manny Hernandez Jeff Hitchcock Cynthia Rice, MPP Larry Smith  Kelly Close	StripSafely National Diabetes Volunteer Leadership Council Diabetes Hands Foundation Children with Diabetes JD RF National Diabetes Volunteer Leadership Council diatribe.org, Keynote Speaker

The AACE-ACE Glucose Monitoring Consensus Conference took place September 28-29, 2014 in Washington, DC at the Hyatt Regency on Capitol Hill. The conference agenda is outlined in

Figure 1.

**Figure 1: AACE-ACE Glucose Monitoring Consensus Conference Agenda**

SUNDAY, SEPTEMBER 28, 2014		
General Session - Keynote Speakers   Moderator: Dr. George Grunberger		
1:00 pm – 1:10 pm	Welcome Dr. R. Mack Harrell, AACE President	Regency C
1:10 pm – 1:20 pm	AACE Perspective Dr. George Grunberger, AACE President Elect Chair, Consensus Conference on Glucose Monitoring	
1:20 pm – 1:40 pm	State of the Art of Glucose Monitoring Technology Dr. Richard Bergenstal, Park Nicollet International Diabetes Center	
1:40 pm – 2:00 pm	Clinical Applications of Glucose Monitoring Dr. Irl Hirsch, University of Washington School of Medicine	
2:00 pm – 2:20 pm	Post-Marketing Surveillance Dr. David Klonoff, Diabetes Technology Society	
2:20 pm – 2:40 pm	Overall Economic Impact of Glucose Monitoring Dr. William Herman, Michigan Center for Diabetes Translational Research	
2:40 pm – 2:55 pm	Break	
2:55 pm – 3:15 pm	Regulator's Viewpoint Dr. Courtney Lias, Division of Chemistry and Toxicology Devices, FDA	Regency C
3:15 pm – 3:25 pm 3:35 pm – 3:55 pm	Payors' Viewpoint: Private Insurance – Dr. Kenneth Snow, Aetna Large Employers - Dr. Kimberly Jinnett, Integrated Benefits Institute	
3:55 pm – 4:15 pm	Industry Viewpoint Ms. Khatereh Calleja, AdvaMed Mr. Richard Price, AdvaMed	
4:15 pm – 4:35 pm	Patients' Viewpoint Mrs. Kelly Close, Close Concerns	
4:35 pm – 5:00 pm	Conclusion and Monday Agenda Dr. George Grunberger, Chair	
5:00 pm – 6:00 pm	Reception	
6:00 pm	Dinner on your own	Regency B

The conference began with introductory remarks from the AACE president, Dr. Harrell, a summary of AACE's perspective on glucose monitoring, and several keynote talks giving the perspectives of different stakeholders. Pillar breakout sessions were scheduled on the morning of the second day. During these breakout sessions, participants within each pillar individually presented their answers to each of the 4 questions using oral statements, hardcopy handouts, and/or slide presentations. Every participant was given 5 minutes to respond to each question. This was followed by general discussion and debate, moderated by the co-chairs. For each question, an effort was made to establish points of consensus among participants, as well as to identify alternative viewpoints and knowledge gaps requiring additional research. The proceedings were recorded. To capture salient aspects and conclusions in real time, a team of

medical writers and conference leaders integrated information and discussions.

On the afternoon of the second day, the pillars met together for “among-pillar discussions” so that all participants could evaluate and debate the conclusions reached by the individual pillars. The co-chairs assigned to each pillar briefly summarized the points of consensus and alternate views, followed by robust discussion of the evidence pertinent to each question, involving all participants. This facilitated the emergence of consensus across pillars.

Immediately after the conference, a primary writing team analyzed the meeting’s transcripts and completed this document summarizing the conference proceedings, along with points of consensus and alternative views. The writing committee identified points of affirmation where the data and related discussions supported previously accepted or validated practices. In addition, new points of emergence arose from the dynamic and multi-disciplinary nature of the conference. Both the affirmative and emergent conclusions were sufficient to form the basis for actionable recommendations.

#### **FOUR QUESTIONS ADDRESSED**

***QUESTION 1: What data support glucose monitoring (as distinct from glycemic control) as a means to prevent diabetic macro- and microvascular complications?***

- a) Does frequency of glucose monitoring correlate with better outcomes?***
- b) Which patients benefit the most from structured glucose monitoring?***
- c) Do glucose strip and CGM accuracy correlate with better outcomes?***

Several modern studies have demonstrated the importance of glucose control to reduce both short- and long-term complications. One of the major tools to improve glycemic control is glucose monitoring. With the advancement of technology, many meters are now available that allow patients to self-monitor throughout the day. We also now have technology, which allows continuous glucose monitoring (CGM). New technology enables glucose monitoring to interface with insulin administration. Although there is a general expert opinion to use frequent glucose monitoring in most patients with diabetes, many insurance payors, including CMS, deny access to patients who could benefit due to the cost of such a program. Underscoring the need to form consensus on these issues, participant experts discussed the available evidence to support glucose monitoring in people with diabetes.

Consensus participants emphasized that glucose monitoring is only reasonable if it is actionable. Many of the major diabetes studies have focused on the long-term outcome of glucose control, in particular micro and macrovascular disease. However, an important aspect of controlling diabetes is preventing short-term complications, including hypoglycemia and diabetic ketoacidosis (DKA). Available data support glucose monitoring, CGM, and advanced technologies to reduce and prevent hypoglycemia. Management plans should be developed individually with the patient and their clinician to optimize glucose control and should be chosen according to patient preference and lifestyle.

Some studies failed to demonstrate value for glucose monitoring in obtaining glucose control due to problems in design as well as a lack of clinical action related to results of glucose monitoring. More recent trials using structured glucose monitoring coupled with clinical decision-making demonstrate a benefit in improving glucose control.

One of the most commonly used measures to monitor glucose control is hemoglobin A1c. In a large group of people with diabetes, ranging from 14%-25%, A1c is not accurate and should not be used. For example, A1c levels in people with sickle cell anemia, those of several ethnic

groups, those with severe kidney disease, and others do not correlate with average glycemia and may be misleading. For these patients, frequent glucose monitoring is virtually the only way to assess glucose control over time.

### **Frequency**

People with type 1 diabetes who are engaged in their care should have glucose monitoring offered at least 8 times daily. Frequency of glucose monitoring reduces hypoglycemia. In a study of people with type 1 diabetes, increased frequency of glucose monitoring decreased mean A1c across age groups. Although there was no upper limit to the frequency of daily monitoring that offers benefit to A1c control, the benefit plateaus around 7-8 per day. Epidemiologic observational data indicate that self-monitoring of blood glucose (SMBG) correlates with decreased diabetes-related complications and with all-cause mortality in people with type 2 diabetes.

People with type 2 diabetes who are on multiple insulin injections, with a high risk of hypoglycemia, should have glucose monitored at least 8 times daily, similar to type 1 diabetes. People with type 2 diabetes who are on medications that can cause hypoglycemia (like basal insulin and sulfonylurea), especially the elderly, are more prone to hypoglycemia and should have more frequent monitoring. Due to the lack of available robust data, the opinion ranged in suggesting glucose monitoring from 3-5 times per day in this population. Because of the lack of controlled trials in people with type 2 diabetes who are being managed with lifestyle modification or medications with low risk of hypoglycemia are also lacking, it was the participant expert opinion that these patients should monitor glucose from 1-4 times per day. Similarly, for women with diabetes who are pregnant, managed with insulin the participant expert opinion was that glucose should be checked at least 8 times daily and for those managed with lifestyle modification or medications with low risk of hypoglycemia approximately 4-6 times daily. Large, randomized trials are needed to validate these expert clinical opinions.

There was considerable discussion about the frequency of glucose monitoring in different patient populations, but a consensus was reached that clinical usage must be driven by clinician-patient agreement on the optimal level of glucose monitoring.

### **CGM**

Usage of CGM has improved outcome through reduction of hypoglycemia. CGM is recommended in all patients with type 1 diabetes and should be offered to all type 2 diabetes on multiple insulin injections, basal insulin, or sulfonylureas. CGM should also be used in all patients who have hypoglycemia unawareness. It was the participant expert opinion that CGM may be offered to patients with type 2 diabetes who may benefit through lifestyle and specific changes in their management plan.

### **Accuracy**

Data support the fact that accuracy of glucose monitoring correlates with better outcomes. Recognizing the importance of accuracy of the glucose meters, participants expressed a concern that requirement for increased accuracy may affect cost and lead to glucose monitoring becoming cost-prohibitive. The participant experts accepted the 2013 ISO standards for accuracy, precision, and bias, with the exception that the standard applied at low glucose levels may need to be more stringent to avoid clinically inappropriate decisions. Participants also noted that values that are far out of range are more problematic than meter bias, as these can affect immediate decision making if no confirmatory testing is performed.

### **Knowledge Gaps**

More data are needed on the long-term efficacy of frequent monitoring, as well as the data on the effect of accuracy of glucose meters and strips and CGM on outcomes. Cost is a major issue in glucose monitoring, particularly as technology advances. Cost-effectiveness of glucose monitoring in patients with type 2 diabetes who are managed with lifestyle modification or medications with low risk of hypoglycemia needs to be investigated. Published studies addressing outcomes related to glucose monitoring lag far behind ongoing technological advances, and more research is needed. Although there is a dire need to have more data on the accuracy of glucose monitoring, it would be unethical to conduct large randomized trials using inaccurate meters. Thus, it is hoped that “big data” may assist in answering those clinical questions that cannot be addressed in controlled trials.

## **Conclusion**

Glucose monitoring is essential to diabetes care, particularly for reducing hypoglycemia, provided it is structured. Implementing clinical actions based on data gained during glucose monitoring is critical for diabetes control. There seems to be a relationship between higher frequency of glucose monitoring and better glycemic control. The consensus of the participant experts calls for a wider use of glucose monitoring and CGM and calls for studies that can address efficacy and cost.

### ***QUESTION 2: Should the FDA improve post approval surveillance of glucose strip, glucose meter, and CGM quality?***

- a) Does sub-standard glycemic monitoring technology harm patients? If so, what data exist to support such a claim? Are all manufacturers required to report this data to the FDA?***
- b) What is the current state of affairs at the FDA in post-marketing meter and CGM surveillance?***
- c) What enforcement options are available to the FDA and how are they implemented?***

## **Introduction**

Shortcomings in the surveillance of glucose strip, glucose meter, and CGM quality have been clearly recognized. Patients and health care professionals are seeking stricter guidance from the FDA regarding accuracy of testing and meter standards, along with clearer labels to help patients understand the results. What constitutes “substandard” monitoring, however, is not clearly defined. Further, companies producing glucose-monitoring devices are currently permitted to claim improved clinical outcomes to patients, even if those outcomes have not been demonstrated. Additional concerns include a lack of consistency in the way that post-market surveillance (which relies heavily on self-reporting by manufacturers) is applied across manufacturers and the volume of data to be analyzed.

The 2003 ISO standard minimum accuracy criteria for blood glucose monitors requires that 95% of glucose results be within 15 mg/dL of reference for glucose <75 mg/dL and within 20% of reference for glucose ≥75 mg/dL. The 2013 ISO standard requires that 95% of glucose results <100 mg/dL be within 15 mg/dL of reference and within 15% of reference for glucose ≥100 mg/dL. However, at least six studies evaluating the performance of blood glucose monitoring devices published between 2010 and 2014 have demonstrated that only 40%-83% met ISO 2003 standards, and only 14-67% met ISO 2013 standards. Most of the less accurate meters are manufactured outside the US and sold at a lower cost.

The FDA agrees that glucose meters that do not perform as designed pose a risk to patients, since they receive at least 30,000 reports/year of cases of patient harm, including suspected device-associated deaths, serious injuries, and malfunctions for glucose meters and CGMs. Despite a requirement to report data on possible patient harm, some lesser known brands report few or no such data versus the larger branded multinationals. Diabetes Technology Society public meetings have highlighted substantial accuracy issues observed in currently available systems. The FDA states that they have tools to effectively assure that meters and strips perform within labeled levels, including adverse events reports and inspections of manufacturing facilities. FDA also has multiple enforcement options including recalls, seizures, safety alerts, warning letters, injunctions, and civil money penalties. However, they do not have the ability to remove clearance of previously cleared meters on the market, though they can prevent distribution of such meters.

Ongoing improvements include collaborating with manufacturers to improve AE reporting, development of new methods to analyze medical device report (MDR) data, drafting new guidance for manufacturer reporting, and development of a new surveillance program to test strips and meters in market.

#### **Knowledge Gaps:**

- The data to support patient harm are inadequate due to lack of reporting and difficulty in accurately attributing responsibility for adverse events to the strip manufacturer versus pharmaceutical company versus patient error.
- Manufacturers are required to report adverse events through the MDR mechanism, but reporting is done variably and is not standardized.
- Information regarding post-approval quality of blood glucose monitoring strips is lacking, particularly those obtained from non-US manufacturers of mail order strips and devices.

#### **Conclusions:**

- The FDA is to be commended for their recognition of the need for independent and ongoing pre- and post-marketing testing of blood glucose monitor devices. This could be funded by industry based on a percentage of total strip sales or other methodology.
- AACE recommends periodic ongoing post-marketing manufacturer inspections and audits, both within and outside the country.
- AACE believes that the FDA should rigorously apply existing enforcement options and expeditiously prohibit the sale and marketing of devices that do not meet their ongoing evaluation of quality, including embargoing products if necessary.
- AACE recommends that requirements and reporting formats for reporting adverse events to the FDA through MDR mechanisms be harmonized.
- Studies to demonstrate comparative effectiveness should be required.
- ISO 15197:2013 standards should be applied to all blood glucose monitoring devices to ensure accuracy of SMBG.
- Accuracy results should be part of the product labeling, and manufacturers should be held to that standard.
- More education for patients and healthcare professionals is necessary for optimal use of the MedWatch Reporting System.

***QUESTION 3: Do current private insurance and Medicare policies balance the need to provide patient access to high quality care and effective glucose monitoring, and if not, what policy changes are needed with respect to:***

***a) Patient access to BGM supplies***

- i. Competitive bidding program*
- ii. Limiting glucose strip brand or meter type*
- b) Patient access to CGM technology**
- c) Limited or lack of coverage for sensor-augmented insulin pump therapy and emerging semi-automated CGM/pump combinations**

### **Medicare patient access to BGM supplies**

CMS views all FDA cleared blood glucose monitoring devices to be of equivalent quality based on 1976 standards, in spite of the fact that technology has improved dramatically over the last 40 years. Using the Competitive Bidding Program to limit glucose strip costs, Medicare restricts access to more expensive improved technology devices and limits choice for patients and health care professionals based primarily on cost. Device manufacturers view this practice as a barrier to innovation. To the extent that accuracy is improved by new technology, limiting access to new technology may increase patient risk for adverse events. Additionally, attestation documentation requirements for patients and health care professionals discourage the utilization of glucose monitoring, and increase the potential for serious health risks for the patient with diabetes.

### **Patient access to CGM technology**

CGM technology is not covered as a benefit under the current Medicare program as there is no benefit category for these devices. Successful CGM users with type 1 diabetes, under commercial insurance, are categorically denied coverage for this technology upon enrollment in Medicare. Hypoglycemia is especially risky in the Medicare population with associated ER visits, accidents, seizures, and cardiac events. Several prospective studies have shown improved glycemic control with fewer hypoglycemic events in patients with type 1 diabetes utilizing CGM technology. Arbitrary denial of coverage for these devices seems imprudent in these high-risk patients.

### **Limited or lack of coverage for sensor augmented insulin pump therapy etc.**

The FDA has approved threshold suspend CGM/insulin pump systems, however, all payors currently deny coverage for this technology deeming it as experimental. In addition, as with CGM devices, Medicare does not have a benefit category for these emerging technologies.

### **Knowledge gap:**

Technology advances much faster than our ability to plan and complete randomized controlled trials that assess outcomes. In 2014, the FDA approval process for advanced glucose monitoring technology is rigorous and should suffice for coverage decisions.

### **Summary**

Contemporary quality standards need to be incorporated into the competitive bidding process. The bidding process should be modified to ensure the availability of the highest quality products at the best price.

Diabetes care requires a highly individualized treatment plan. As part of this planning, selection of glucose monitoring technology demands close collaboration between patients and health care professionals. Therefore, coverage determination by payors should place a higher priority on the optimal health needs of the patient as determined by their health care professionals.

### **Conclusion**

Access to glucose monitoring technology is not currently provided to an acceptable degree by payors. FDA approval should be a reliable indication for benefit coverage. Ongoing randomized controlled trials or comparative effectiveness studies would be appropriate.

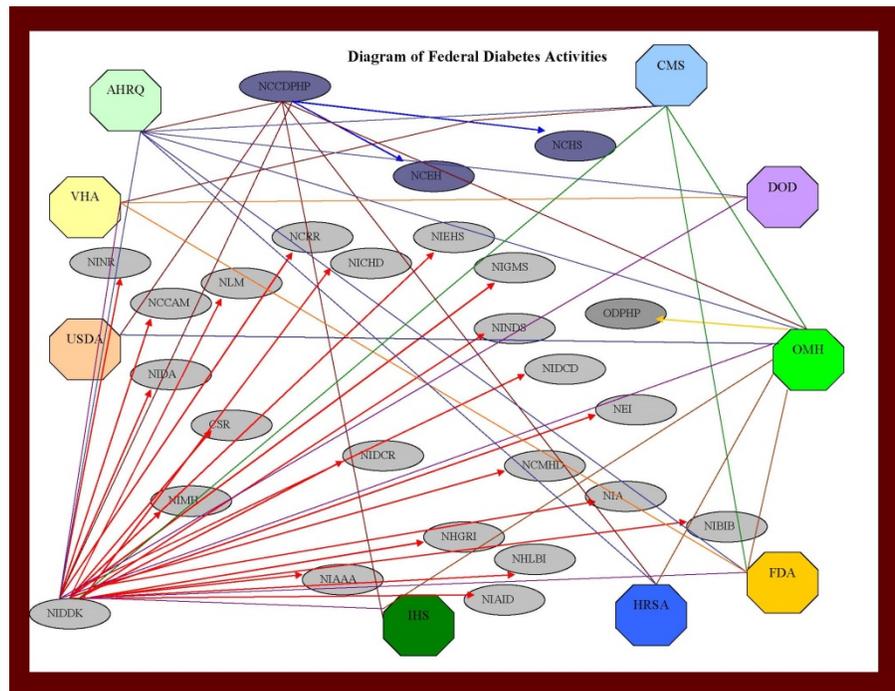
**QUESTION 4: What is the most effective way for the key stakeholders (physicians, allied health care professionals, patients, professional associations, educators, investigators, payors, industry, employers, health care systems, regulators) to achieve appropriate, evidence-based, cost-effective usage of glucose (blood, continuous) monitoring technology?**

The consensus conference provided an opportunity to present the state-of-the-art, highlight missing data, and problem-solve among groups with varied, and sometimes competing perspectives, but each with the motivation of improving diabetes patient care. Published guidelines from medical societies are an excellent source of consensus regarding the best data available at a point in time. Education for the public and professionals raises awareness and may create the political will to make improvements in glucose monitoring processes. Stakeholders were in general agreement that the ideal system would provide just the right amount of glucose monitoring for a given individual as determined by the individual and their health care professional. Unfortunately, the current system creates distortions in which some people who need more monitoring are denied access, while others may be sent supplies in excess of need in the absence of sufficient controls to prevent fraud and abuse. It is not likely that we will have randomized clinical trials to answer the question, so we must create a consensus based on limited data, clinical experience, and expert opinion. Underlying all of these considerations is the recognition of the reality of finite resources and the need to make hard choices among competing interests.

It is extremely important to address diabetes-related processes at the Federal government level, since the government is the largest payor and its actions affect every other payor. The sheer number of agencies with their own agendas and complex reporting structure makes it difficult to affect significant change.

An example of a response to this is the National Diabetes Clinical Care Commission Act that seeks to coordinate all agencies related to diabetes and assist them

with the direction of clinical experts as a sanctioned advisory body. All stakeholders would benefit from streamlining of processes involved in access to glucose monitoring technology. Innovations that may ease this burden include a single type of form for prescription of glucose monitoring and documentation of its medical necessity.



One of the most egregious distortions among stakeholders occurs when people with type 1 diabetes who are stable on CGM are forced to stop CGM when they go on Medicare, leaving them more vulnerable to hypoglycemia at exactly the stage of life when it is most dangerous. Stakeholders unanimously agreed that Medicare needs to establish a benefit category for CGM and advanced medical technologies to come.

In the future, big data can hopefully be harnessed to obtain more definitive answers regarding the relationship between quality and intensity of BGM and CGM to diabetes outcomes. When that occurs, the strategies to achieve appropriate, evidence-based, cost-effective usage of glucose (blood, continuous) monitoring technology will become more apparent.