AACE/ACE Consensus Statement

PROCEEDINGS FROM THE
AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLISTS AND
AMERICAN COLLEGE OF ENDOCRINOLOGY
CONSENSUS CONFERENCE ON GLUCOSE MONITORING

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This document represents the official position of the American Association of Clinical Endocrinologists and the American College of Endocrinology. Where there were no randomized controlled trials or specific U.S. FDA labeling for issues in clinical practice, the participating clinical experts utilized their judgment and experience. Every effort was made to achieve consensus among the committee members. Position statements are meant to provide guidance, but they are not to be considered prescriptive for any individual patient and cannot replace the judgment of a clinician.
were reached at the group discussions:

Abbreviations:

AACE = American Association of Clinical Endocrinologists; ACE = American College of Endocrinology; A1C = glycated hemoglobin; BGM = blood glucose monitoring; CDC = Centers for Disease Control and Prevention; CGM = continuous glucose monitoring; CMS = Centers for Medicare and Medicaid Services; FDA = Food and Drug Administration; GM = glucose monitoring; MDR = medical device report; SMBG = self-monitoring of blood glucose

EXECUTIVE SUMMARY

The American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) held a Consensus Development Conference on September 28 and 29, 2014, to evaluate clinical science, utility, and access to blood and continuous glucose monitoring (BGM and CGM). Representatives from leading professional societies, government agencies, industry groups, public advocacy organizations, large employers, and healthcare payers met to consider the current state of knowledge regarding glucose monitoring (GM) and its implementation in clinical practice. The following major conclusions were reached at the group discussions:

- GM has clearly upgraded the quality and safety of diabetes care. This is perhaps best appreciated in patients on intensive insulin therapy.
- The need for GM depends, in part, upon the antidiabetic therapies employed in each patient. Therapies using basal-only insulin require less frequent monitoring than those that incorporate prandial and/or basal insulin in the treatment program. Oral agent therapy may require less monitoring than insulin-based therapies; however, the use of sulfonylureas increases the need for GM due to the risks of hypoglycemia with these agents. CGM may be best for patients with type 1 diabetes on complex insulin regimens; however, it may also be useful in a select group of those with type 2 diabetes, especially those with a need for intensive insulin therapy and high risk of hypoglycemia. Type 2 diabetes CGM candidates may also include patients with long-standing diabetes or severe kidney disease (chronic kidney disease stage 4 or 5).
- Monitoring with glucose oxidase-based systems shows unacceptably high failure rates to meet 2003 ISO standards (17-60%) and 2013 ISO standards (33-85%).
- A proliferation of unbranded and often inaccurate GM systems has occurred in the marketplace, driven by mail-order diabetes suppliers under the Centers for Medicare and Medicaid Services (CMS)-mandated competitive bidding process. Patients typically gain no real savings benefits from unbranded meter use, and safety risks imposed by GM inaccuracies are reported and well known. Switching from branded to unbranded meters and glucose strips is frequently initiated by intermediary profit-driven durable medical equipment (DME) suppliers. Such behavior should be prohibited by regulators and should not be tolerated by prescribers. The U.S. Food and Drug Administration (FDA) needs to enforce existing regulations, during both the approval and the postmarketing surveillance processes. It appears that some manufacturers obtain FDA approval for prototype strips and then later modify their production practices, which no longer meet the initially approved quality. The inability of the FDA to remove these previously approved but now inaccurate strips from the market is a flaw in the regulatory system.
- Although CGM has been shown to be beneficial, it has not been fully accepted as the standard of care in type 1 diabetes by all insurers and prescribers. Many insurance carriers also do not reimburse for adequate quantities of CGM testing supplies for patients with either type 1 or 2 diabetes, despite the recent findings of the Centers for Disease Control and Prevention (CDC) showing that hypoglycemia from antidiabetic medications is the second most common cause of emergency department visits and hospitalizations due to adverse drug reactions in the United States.
- Providing more accurate GM systems and insuring that these systems are appropriately used in patients with diabetes mellitus will improve the risk-benefit ratio for diabetes treatment. (Endocr Pract. 2015;21:522-533)

BACKGROUND

Glucose monitoring (GM) is mandatory for modern diabetes care. While GM is essential, it is not adequate by itself to promote optimal diabetes management. Appropriate action based on GM data is required to effect change. An educated patient collaborating with healthcare professionals can prevent or delay debilitating, and even deadly, complications of this disease. GM is complex and costly and further complicated by issues of access, reimbursement, and durable medical equipment (DME) quality. Cost control measures implemented throughout the healthcare system in the United States have created a renewed interest in the most efficient and effective uses of blood GM (BGM) and continuous GM (CGM) technology to optimize outcomes for patients with diabetes.
Recognizing the need to address these issues and build consensus on GM, the AACE/ACE convened a conference to debate these points on September 28 and 29, 2014, at the Hyatt Regency at Capitol Hill in Washington, DC. Participants included members of healthcare associations, insurance companies, government, patient advocacy groups, pharmaceutical and equipment manufacturing companies, healthcare systems, physicians, educators, and allied healthcare professionals.

Specifically, 4 questions were asked:

1. Which data support GM (as distinct from glycemic control) as a means to prevent diabetic macro- and microvascular complications?
   a) Does the frequency of GM correlate with better outcomes?
   b) Which patients benefit most from structured GM?
   c) Do glucose strip and CGM accuracies correlate with better outcomes?

2. Should the U.S. Food and Drug Administration (FDA) improve postapproval surveillance of glucose strip, glucose meter, and CGM quality?
   a) Does substandard GM technology harm patients? If so, which data 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 postmarketing 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 GM 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 are the most effective ways for the key stakeholders (physicians, allied healthcare professionals, patients, professional associations, educators, investigators, payers, industry, employers, healthcare systems, regulators) to achieve appropriate, evidence-based, cost-effective regulation of GM (BGM and CGM) 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 regulatory action plan for healthcare insurance providers and to identify points of consensus along with alternative interpretations among diverse constituencies representing the major stakeholders in GM in the United States. The intention was to have the broad range of stakeholders jointly examine the evidence from different perspectives. Thus, the conference offered an opportunity for “emergent thinking” and joint discovery with a highly diverse set of viewpoints. The organizers viewed this approach as critical since the action plan will ultimately require concerted action and cooperation among stakeholders based on a consensus interpretation of evidence.

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

Following the Conference, the writing committee developed this consensus statement, based on participant responses to the 4 key questions, presentations of keynote speakers, and open discussions among the pillars.

I. GM AND COMPLICATIONS

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 GM. With the advancement of technology, many meters are now available that allow SMBG throughout the day. We now have advanced technology that allows CGM. Emergent technology now enables GM to interface with insulin administration. Although experts favor frequent GM in most patients with diabetes, many insurance payers, including the CMS, deny appropriate monitoring access due to the cost of possibly an open-ended policy. Understanding the need to form consensus on these issues, participant experts evaluated the available evidence to support GM in people with diabetes.

Consensus participants emphasized that GM is only reasonable if it is actionable. Most major diabetes studies have focused on the long-term outcomes of glucose control, in particular micro- and macrovascular disease. However, an equally important aspect of diabetes care involves prevention of short-term complications, including...
<table>
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<th>Pillar</th>
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|  | Gerardo Moreno, MD, MSHS  
American Geriatrics Society |
|  | Jerry Penso, MD, MBA  
American Medical Group Association |
|  | Gary Puckrein, PhD  
National Minority Quality Forum |
|  | Robert Ratner, MD, FACP, FACE  
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Keynote Speaker  
U.S. Food & Drug Administration, Division of Chemistry and Toxicology Devices |
|  | Kenneth Snow, MD, MBA  
Keynote Speaker  
Aetna |
|  | Pamela Allweiss, MD, MPH  
Centers for Disease Control and Prevention, Division of Diabetes Translation |
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|  | Nathan Carrington, PhD  
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|  | Jacob Drapkin  
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|  | Claudia Graham, PhD, MPH  
Dexcom, Inc |
|  | Brian Levy, MD, FACE  
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hypoglycemia and diabetic ketoacidosis (DKA). Available data support GM, CGM, and advanced technologies to reduce and prevent hypoglycemia. Management plans should be developed by the patient and their diabetes clinician to optimize glucose control and should be based on individual patient preferences and lifestyle. Isolated studies have failed to demonstrate value for GM in achieving glucose control due to poor design and a lack of clinical intervention related to results of GM. More recent trials using structured GM coupled with clinical decision-making demonstrate clear-cut benefits in improving glucose control (1-3).

One of the most commonly used measures to monitor glucose control is glycated hemoglobin (A1c). However, in a large subgroup of people with diabetes, an estimated 15% of A1c values might be misleading. Specifically, certain ethnic groups, people with sickle cell anemia, and patients with severe kidney disease have A1c levels that do not correlate with average glycemia (4). Additionally, in patients with widely variable glucose levels, the A1c will not provide a true picture of detrimental recurrent hypoglycemic episodes. For these patients, frequent GM or continuous GM is virtually the only way to assess glucose control over time (5).

**Frequency**

Participant experts suggested engaged people with type 1 diabetes should perform GM at least 8 times daily. The American Diabetes Association recommends that patients on intensive insulin regimens conduct self-monitoring of blood glucose (SMBG) prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose, and prior to critical tasks (e.g., driving) (6). Frequent GM reduces frequency of hypoglycemia. In a study of people with type 1 diabetes, increased frequency of GM decreased mean A1c across all age groups (7). Although there was no upper limit to the frequency of daily monitoring that offered the most benefit to A1c control, the effect appears to begin to plateau around 7 to 8 times per day (8).

Epidemiologic observational data indicate that SMBG correlates with decreased diabetes-related complications and with all-cause mortality in people with type 2 diabetes (9). Patients with type 2 diabetes and high hypoglycemia risk such as those on multiple daily injections (MDI) of insulin should have glucose monitored at frequency similar to patients with type 1 diabetes. In addition, people with type 2 diabetes who are treated with medications that can cause hypoglycemia (e.g., basal insulin and sulfonylurea), especially the elderly, are more prone to hypoglycemia and should have more frequent monitoring. Although there is a lack of robust data, the consensus of expert opinion suggested GM from 3 to 5 times per day in this population. Because controlled trials in people with type 2 diabetes managed with lifestyle modification or medications with low risk of hypoglycemia are lacking, participant expert opinion suggested that such patients should monitor glucose as clinically indicated, from 1 to 4 times per day. Experts suggested that pregnant, insulin-treated patients should monitor their glucose at least 8 times daily, while those managed with lifestyle modifications or low-hypoglycemia risk medications need less frequent monitoring, perhaps 4 to 6 times per day. Large, randomized trials are needed to validate these expert clinical opinions.

There was considerable discussion about the frequency of GM in all patient populations, but the consensus was that clinical usage must be driven by clinician-patient collaborative agreement on the optimal level of GM.

**CGM**

CGM usage has improved clinical diabetes outcomes by reducing hypoglycemia (1). CGM is recommended in all patients with type 1 diabetes and should be available to all type 2 diabetes on multiple insulin injections, basal insulin, or sulfonylureas. CGM should also be used in all patients who are at risk for hypoglycemia and/or have hypoglycemia unawareness (10).

While studies using CGM in type 2 diabetes are limited, experts in clinical practice realize that it can be useful in identifying and correcting postprandial glycemic excursions (11,12). It was the participant expert opinion that intermittent use of CGM (usually 1-2 weeks) in patients with type 2 diabetes might be more effective than daily glucose fasting glucose in guiding the need for medication adjustment or advancing to new medications.

**Accuracy**

The existing data indicate that accuracy of GM correlates with increased patient confidence in using GM devices, resulting in better adherence, more confident insulin adjustments, and improved quality of life (13). Recognizing this fact, participants expressed a concern that increased accuracy may affect upfront cost and lead insurers to view accurate GM as cost prohibitive. The participant experts identified the 2013 ISO standards for accuracy, precision, and bias as a step in the right direction, with the realization 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 inherent meter bias, as these can affect immediate decision making if confirmatory testing is not performed (14). In particular, the importance of errors in or around the hypoglycemic range was emphasized.

**KNOWLEDGE GAPS**

More data are needed on the long-term efficacy of frequent monitoring and the effect of glucose meters, strips,
and CGM accuracies on outcomes. Participants agreed that much future research is needed on effective and efficient ways to upload, analyze, and visualize glucose data in a standard manner and then effectively use those data to make clinical decisions. Thus, the availability of accurate glucose meters and established ways to effectively use the data to avoid wasting resources are both important factors.

Cost is a major issue in GM, particularly as technology advances. The cost-effectiveness of GM in patients with type 2 diabetes who are managed with lifestyle modification or low-risk medications needs to be investigated. Published studies addressing outcomes related to GM lag far behind ongoing technological advances, and more research is needed. Although there is a dire need to collect more data regarding GM accuracy, it would be unethical to conduct large randomized trials using inaccurate meters. Thus, it is hoped that registry-based postmarketing data may help answer clinical questions that cannot be addressed in controlled trials.

CONCLUSION

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

II. POSTAPPROVAL SURVEILLANCE AND QUALITY

INTRODUCTION

Shortcomings in the pre- and postmarketing surveillance of glucose strip, glucose meter, and CGM quality have been widely recognized. Patients and healthcare professionals are seeking guidance from the FDA regarding accuracy of testing and meter standards, along with clearer labels to help consumers understand the results. What constitutes “substandard” monitoring, however, is not clearly defined. Further, companies producing GM devices are currently permitted to advertise improved clinical outcomes to patients, even if those outcomes have not been demonstrated for their specific technology. Participants described a lack of consistency in the way that FDA postmarket surveillance (which relies heavily on self-reporting by manufacturers) is applied across all manufacturers. Another major concern related to the volume of data to be analyzed is that the FDA is operating under significant budgetary restraints.

Importantly, both stand-alone CGM devices and sensor-augmented insulin pumps are FDA approved as Class III devices. There are clear differences between Class III (premarket Approval [PMA]) and Class II (Premarket Notification [501K]) devices in terms of FDA notifications, manufacturing quality, audits, and documentation. In addition, Unlike Class II manufacturers, Class III device manufacturers are not permitted to develop generic devices. Given the flooding of the U.S. market with generic devices, Class II BGM device manufacturers require additional FDA efforts to assure quality in the postmarketing arena (15,16).

The 2003 ISO standard for blood glucose monitors requires that 95% of blood glucose results be within 15 mg/dL of reference for glucose <75 mg/dL and within 20% of reference for glucose ≥75 mg/dL (17). 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 (18). However, at least 6 studies evaluating the performance of blood GM devices published between 2010 and 2014 have demonstrated that only 40 to 83% met ISO 2003 standards, and only 14 to 67% met ISO 2013 standards (19-24). Many of the less accurate meters are manufactured outside the U.S. and sold at a lower cost. Because DME providers receive fixed reimbursement from insurers, they are financially incentivized to promote these low-cost meters.

The FDA agrees that glucose meters that do not perform as designed pose a risk to patients. The agency receives 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 (25). Despite a requirement to report data on possible patient harm, some lesser known brands report significantly less data than the branded multinational manufacturers. Diabetes Technology Society public meetings have highlighted substantial accuracy issues observed in currently available systems (26). The FDA states that they have tools to effectively ensure that meters and strips perform within labeled levels, including adverse events reports and intermittent inspections of manufacturing facilities. The FDA also has multiple enforcement options including recalls, seizures, safety alerts, warning letters, injunctions, and civil money penalties. Although the FDA can prevent distribution of underperforming meters, they do not have the ability to desanction previously cleared meters on the market, and there is no formal policy at the CMS for the handling of FDA warning letters.

Among FDA options are collaborating with manufacturers to improve AE reporting, development of new methods to analyze medical device report (MDR) data, and the drafting of new guidance for manufacturer reporting.
In the long view, intelligent deployment of harmonized diabetes registries with device numbers, strip lot codes, glucose download data, and hospital encounters could provide a comprehensive “big data” alternative to the expensive postmarketing field testing of BGM and CGM devices.

**KNOWLEDGE GAPS**

- The data to support patient harm from errant BGM are inadequate due to lack of reporting and difficulty in accurately attributing responsibility for adverse events to the strip manufacturer, pharmaceutical company, patient error, or disease progression.
- Reporting of adverse events through the MDR mechanism is erratic and not standardized.
- Information regarding postapproval quality of BGM strips is lacking, particularly data from 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 postmarketing testing of BGM devices. Funding for such surveillance could be derived from manufacturer revenues or government programs including registry development subsidies based on a percentage of total strip sales or other methodology.
- The AACE believes that the FDA should rigorously apply existing enforcement options and expeditiously prohibit the sale and marketing of devices that do not meet acceptable quality standards, including product embargo, if necessary.
- The AACE recommends that requirements and reporting formats for reporting adverse events to the FDA through MDR mechanisms be harmonized and that distribution pathways to insurers be standardized.
- Studies to demonstrate comparative effectiveness should be required and may be facilitated by investment in standardized diabetes data registries.
- Contemporary accuracy standards (e.g., ISO 15197:2013) should be adopted by the FDA and applied to all BGM devices available on the U.S. market to promote accurate SMBG.
- Accuracy results should be part of the product labeling, and manufacturers should be held to the standard on their labeling.
- More education of patients and healthcare professionals is necessary for optimal use of the MedWatch Reporting System.

**III. BALANCING PATIENT ACCESS AND QUALITY OF CARE**

**Medicare Patient Access to BGM Supplies**

The number of patients with diabetes and their medical expenses continue to escalate (27). Two studies have shown positive associations between mandated coverage of strips, meters, or services and more SMBG (28,29). Currently, the CMS views all FDA-approved BGM devices to be of equivalent quality based on 1976 standards, despite the fact that technology has improved dramatically over the last 40 years. In January 2014, the FDA issued draft guidance for BGM and SMBG devices to set standards for quality (30,31). Both draft guidance documents outline stricter standards than previously described with tighter glucose accuracy requirements.

Using the Competitive Bidding Program, Medicare restricts patient access to potentially more expensive, improved technology devices and limits choice for patients and healthcare professionals, based primarily on cost (32). This policy may inhibit patient access to clinically indicated SMBG. A report by the Office of the Inspector General described a 22% reduction in Medicare claims for blood glucose strips, implying that patients may no longer be testing blood glucose as often as recommended, and in some instance, stopping testing completing (33).

Balancing cost with access to SMBG is a challenge that is likely to increase in the future as the overall spending on diabetes care increases. A population-level model recently projected that future direct spending on diabetes care is likely to at least double over the next 25 years. Without changes in public and private insurance coverage, such spending will put our healthcare system and our patients in peril (27).

Over the next quarter century, technologic innovation will be instrumental in minimizing glycemia-related hospitalizations and diabetes complication costs. Unfortunately, device manufacturers view the current Competitive Bidding Process as a barrier to innovation. To the extent that GM accuracy is enhanced by new technology, limiting access to innovation may increase patient risk for adverse glycemic events. Additionally, quarterly attestation documentation requirements for patients and healthcare professionals discourage GM utilization and increase the potential for serious health events in patients with diabetes. Clearly, research studies on optimal ways to efficiently document glucose data, along with their review and appropriate action being taken, are urgently needed. Attestations without clinically relevant purpose do not result in improved care and outcomes and only add to healthcare professionals’ frustration.
**Patient Access to CGM Technology**

CGM technology is not covered as a benefit under the current Medicare program because, at present, there is no benefit category for these devices (34). Successful CGM users with type 1 diabetes under commercial insurance are categorically denied coverage for this technology upon enrollment in Medicare, despite data that showed improved glycemic control in patients with type 1 diabetes mellitus compared to SMBG (35). Hypoglycemia is especially risky in the Medicare population with associated emergency department visits, accidents, seizures, and cardiac events (36). Several prospective studies have shown improved glycemic control with fewer hypoglycemic events in patients with type 1 or 2 diabetes using CGM technology (2,12,37-40). In a contradictory meta-analysis by Langendam et al, there was no difference in hypoglycemic events between CGM and SMBG, although the overall number of hypoglycemic events for all groups in the study was quite small (40). The weight of current evidence suggests that arbitrary Medicare/Medicaid denial of coverage for CGM devices is imprudent in high-risk patients on intensive insulin regimens with a history of hypoglycemic seizures, high cardiac risk, or frequent hospitalizations due to glycemic fluctuations.

**Limited or Lack of Coverage for Sensor-Augmented Insulin Pump Therapy**

The FDA has approved threshold suspend CGM/insulin pump systems. While several private health plans offer coverage, there are notable exceptions of large payers still debating this issue while patients continue to suffer dangerous hypoglycemic events. A small number of private health plans have developed language specific to artificial pancreas systems to address continually advancing technology that is essential to patient care. In the Langendam meta-analysis, glycemic control as measured by A1c level was improved with sensor-augmented insulin pump therapy compared to MDI. There were few hypoglycemic events in this meta-analysis, which prevents conclusions about the hypoglycemia prevention benefit of the sensor augmented insulin pump technology (40). As with CGM devices, Medicare does not have a benefit category for emerging algorithm-based, feedback loop-closing treatment technologies (34).

**RECOMMENDATIONS**

- Contemporary quality standards for glucose measurement need to be incorporated into the BGM competitive bidding process. This process should be modified to assure 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 GM technology demands close collaboration between patients and healthcare professionals. BGM and CGM coverage decisions by payers should place a higher priority on avoidance of long-term complication and hospital costs than on minimizing near-term GM costs. The optimal long-term health needs of the patient are best judged by the treating healthcare professionals.
- Unfettered access to GM technology is not currently provided by many payers. FDA approval of the technology and healthcare professional recommendations should be necessary and sufficient for benefit coverage. Ongoing randomized controlled trials, comparative effectiveness studies, and/or registry follow-up studies should be performed to further elucidate the details of appropriate technology use, including cost-effective approaches to capturing, analyzing, visualizing, and using glucose data to optimize glucose control and quality of life.

**IV. COST-EFFECTIVE USAGE OF GM TECHNOLOGY**

Participants were in general agreement that the ideal health system would provide just the right amount of GM for a given individual as determined by the individual and their healthcare 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 in the near future, so we must create a consensus based on current 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 because the government is the largest payer, and its actions affect every other payer. The sheer number of agencies within the executive branch, each with their own agendas and complex reporting structure, makes it difficult to effect significant change.

An example of a focused response to this challenge is the National Diabetes Clinical Care Commission Act currently under consideration in the House and Senate, which seeks to coordinate actions of agencies related to diabetes and assist them with direction by clinical experts from a sanctioned advisory body (Fig. 1). All stakeholders would benefit from streamlining of regulatory processes involved in access to GM technology. A simple innovation that will ease the current regulatory burden would be a single form for the prescription of GM and documentation of its medical necessity.

One of the most egregious examples of diabetes care distortions occurs when people with type 1 diabetes who...
are glycemically stable on CGM are forced to discontinue CGM when they join Medicare, leaving them more vulnerable to hypoglycemia at the stage of life when it is most dangerous. Participants in the consensus conference agreed that Medicare needs to establish a benefit category for CGM and a benefit structure for advanced diabetes technologies to come.

Communicating best practices of GM to both patients with diabetes and those caring for them is challenging. Telemedicine technology to wirelessly transfer glucose data from patients' meters to care providers has been available for some time. It is also possible to send therapeutic advice to patients based on computerized algorithms or digitized human interpretation of the transmitted glucose data. Such advice could include further guidance on monitoring and changes to therapy. However, there is currently no reimbursement mechanism for such technologic interaction, and the legal status of transmitting computerized advice across state lines is not well defined. There is limited reimbursement for some types of telemedicine, which may include reviewing glucose data, but these programs are still in their infancy and not generally available. With the epidemic increase in diabetes prevalence, a new and more cost-effective approach to disseminate and dispense expert diabetes advice is needed.

In the future, we are hopeful that government-driven funding and informatics protocols can be developed to promote effective use of electronic health record data via large national diabetes registries. Federally mandated technology and strip lot identifiers could then be used to provide informatic links between diabetes technology use and clinically pertinent outcomes. With the implementation of

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**Fig. 1.** The proposed National Diabetes Clinical Care Commission coordinating stakeholders involved in the care of patients living with diabetes and recommending action to U.S. Congress and Secretary of Health and Human Services. **AHRQ** = Agency for Healthcare Research and Quality; **CDC** = Centers for Disease Control and Prevention; **CMS** = Centers for Medicare and Medicaid Services; **DOD** = Department of Defense; **FDA** = Food and Drug Administration; **HRSA** = Health Resources and Services Administration; **IHS** = Indian Health Service; **NIH** = National Institutes of Health; **VHA** = Veterans Health Administration.
effective registries, the strategies to achieve appropriate, evidence-based, cost-effective usage of GM technology should become more apparent.

CONCLUSION

The responses from experts representing government, regulatory, payers, and employers; the pharmaceutical industry; medical, scientific, and professional societies; and patient advocacy and lay organizations were gratifying, with participants providing written answers and data to the 4 questions posed prior to the consensus conference. They had all been provided with the summaries of these materials in advance. This strategy enhanced the quality of open discussions during the conference, and the format offered a unique opportunity for representatives from a broad continuum of patient care fields to discuss different perspectives and form consensus. This conference proved to be a valuable forum for promoting diabetes patient care improvements in future iterations.

The consensus conference provided opportunities to review state-of-the-art GM technology, highlight missing data, and problem-solve among groups with varied, and sometimes competing, perspectives but with the common motivation of improving diabetes patient care. Published guidelines from medical societies constitute an additional source of consensus regarding the best data available at a point in time. Consensus conference-driven education for the public and professionals raises awareness and may generate political will to make improvements in GM regulatory processes.

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Dr. George Grunberger (chair) reports he has received speaker’s honoraria from Novo Nordisk; Salix Pharmaceuticals, Inc; AstraZeneca; Valeritas, Inc; Janssen Pharmaceuticals, Inc; Merck & Co, Inc; sanofi-aventis U.S. LLC; Takeda Pharmaceutical Company Limited; VIVUS Inc; Eisai Co, Ltd; Boehringer Ingelheim GmbH; and Eli Lilly and Company. He has received research support as an investigator for Eli Lilly and Company; AstraZeneca; Novo Nordisk; and Medtronic, Inc.

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REFERENCES


