Can You Manage Diabetes Without Glucose Monitoring? Didn’t Think So!

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AACE/ACE Consensus Conference on Glucose Monitoring:
An Update

Agenda

- AACE/ACE Glucose Monitoring Consensus Conference
- Current Issues Regarding Accuracy, Safety and Access to Blood and Continuous Glucose Monitoring Systems
- Questions Addressed at Conference
- Summary of Consensus Conference Findings and Recommendations
- Next Steps
- Q&A

Pillars To Support Action

Pillars, comprised representatives from sectors needed to support a concerted and comprehensive action plan:
- Government/Regulatory, Payors & Employers
- Industry
- Medical/Scientific/Professional & Educational Societies
- Patient/Lay Organizations

Questions Addressed At Conference - 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 rigorous glucose monitoring?
C. Does strip accuracy and/or CGM accuracy correlate with better outcomes?
### Should the FDA improve post-approval surveillance of glucose strip, glucose meter, 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?

### 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
- **B.** Patient access to CGM technology (access by appropriate patients)
- **C.** Limited or lack of coverage for sensor-augmented insulin pump therapy and emerging semi-automated CGM/pump combinations?

### What is the most effective way for the key stakeholders to achieve equitable, evidence-based, cost-effective federal regulation of glucose (blood, continuous) monitoring technology?

### Consensus Process

- There were two teleconferences held for each pillar representatives separately, led by 2 members of the writing group before the meeting itself
- The process was outlined, pillar representatives discussed their answers to the 4 questions posed by the conference and submitted supporting documents to the writing committee
- This allowed for a lot of preparatory work in advance

### 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 rigorous glucose monitoring?
- **C.** Does strip accuracy and/or CGM accuracy correlate with better outcomes?
### Does frequency of glucose monitoring correlate with better outcomes?

- **T1D Exchange Clinic Registry**
  - 20,555 patients with T1D
  - association between number of fingersticks and HbA1c after adjustments for confounders
  - higher number of daily SMBG strongly associated ($p < 0.001$) with lower HbA1c in all age groups and both in pump and MDI users
  - Insurers need to consider that reducing restrictions on number of test strips may improve glycemic control in patients with T1D
  - *Diabetes Care 36:2009-2014, 2013*

- **2015 American Diabetes Association Standards of Medical Care in Diabetes**
  - patients on intensive insulin regimens should perform SMBG prior to meals and snacks, postprandially, at bedtime, prior to exercise, when they suspect hypoglycemia, after treating low glucose until they are normoglycemic and prior to critical tasks (e.g., driving)
  - do the numbers: 8-12x per day

### Usefulness of CGM

- **Does use of CGM result in less hypoglycemia and lower A1c?**
  - 120 patients, T1D, HbA1c < 7.5%, randomized to SMBG vs. CGM, 26 weeks
  - time spent in hypoglycemia less in CGM users ($p = 0.03$)
  - time spent in normoglycemia increased in CGM users ($p = 0.009$)
  - HbA1c lower in CGM users ($p = 0.008$)
  - *Diabetes Care 36:709-710, 2013*

- **Does use of CGM lead to improved glycemic control?**
  - 322 patients, T1D, SMBG vs. CGM, HbA1c 7-10%, 1 year
  - lower HbA1c in CGM users ($p < 0.001$) in adults
  - time spent in normoglycemia increased significantly ($p = 0.02$)
  - *N Engl J Med 359:1464-1476, 2008*
  - *Diabetes Care 32:2047-2049, 2009*

- **Can use of CGM reduce severe hypoglycemia in patients with T1D with hypoglycemia unawareness?**
  - 35 patients with T1D, 1 year, retrospective review of records
  - median rates of severe hypoglycemia reduced from 4 to 0 episodes/patient-year ($p < 0.01$)
  - mean rates of severe hypoglycemia reduced from 8.1 to 0.6 ($p = 0.005$)
  - HbA1c reduced from 8.1 ± 1.2% to 7.6 ± 1.0%
  - *Diabetes Care 36:4160-4162, 2013*

- **100 adults with T2D, not on prandial insulin, effect of intermittent CGM vs. SMBG on HbA1c over 40 weeks**
  - significant HbA1c reduction in the CGM group ($p < 0.0001$)
  - *Diabetes Care 35:32-36, 2012*
**Use of CGM in Medicare Population**

- 38 patients: 31 with type 1 diabetes, average age 70 years (range 65-78), diabetes duration 31 years
- 28 on insulin pump therapy
- 29 using CGM regularly and 25 had both pre- and post-CGM use HbA1c results
- Regular CGM use associated with a decrease in mean HbA1c: 7.6 (0.9)% to 7.1 (0.9)%, (p<0.0001), maintained until the most recent HbA1c (7.2 \[0.8\]%, p=0.0145, average 37 months)
- Fewer reporting severe hypoglycemia (from 79% to 31%, p=0.002), and lower rate of SH (0.37 to 0.12 per year, p=0.0007)

* Endocr Practice 20:1297-1302, 2014

**Glucose Meter Accuracy**

- 12 systems = 83% met the ISO 2003 standards
  - Diab Tech & Therapeut 36:2014
- 43 systems; of 34 evaluated 7 failed to meet ISO 2003 standards
- 5 systems, lot-to-lot variability; only 2 met ISO 2003 standards
- 7 systems, 100 patients, only 3 met ISO 2003, only 1 met ISO 2013 standards
  - J Diab Sci Technol 7:144-152, 2013
- 43 systems; of 34 evaluated 7 failed to meet ISO 2003 standards
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- 7 systems, 100 patients, only 3 met ISO 2003, only 1 met ISO 2013 standards
  - J Diab Sci Technol 7:144-152, 2013
- 27 systems, 18 manufacturers; 16 out of 27 fulfilled minimum accuracy requirements; i.e. more than 40% failed the ISO 2003 standards
  - Diab Sci Technol 12:221-231, 2010

**Summary of Consensus Conference Findings and Recommendations**

- Glucose monitoring has upgraded the quality and safety of diabetes care
- Better glucose monitoring reduces hypoglycemia-related hospitalizations and reduces healthcare costs
- Need for glucose monitoring depends on the anti-diabetic therapies employed
- CGM may be best for patients with type 1 diabetes on complex insulin regimens and in a select group with type 2 diabetes who need intensive insulin therapy and are at high risk of hypoglycemia

**Summary of Consensus Conference Findings and Recommendations**

- Glucose oxidase-based systems show unacceptably high failure rates to meet 2003 ISO standards and even higher failure rates to meet 2013 ISO standards
- A proliferation of unbranded and often inaccurate glucose monitoring systems has occurred, driven by mail order diabetes suppliers under the CMS-mandated competitive bidding process
- Switching from branded to unbranded meters and glucose strips is frequently initiated by intermediary durable medical equipment (DME) suppliers. Such behavior should be inhibited by regulators and should not be tolerated by prescribers

**Summary of Consensus Conference Findings and Recommendations**

- FDA should implement more rigorous pre- and post-marketing surveillance and apply existing enforcement options such as prohibiting the sale and marketing of devices that do not meet current standards for quality, including products made in other countries
- Standardization of adverse event data reported by manufacturers and harmonization of patient data from glucose monitoring devices is needed
- Technological advancements that will improve patient outcomes and reduce healthcare costs are impeded due to the restrictive regulatory climate

**Summary of Consensus Conference Findings and Recommendations**

- Although CGM has shown to be beneficial, it has still not been fully accepted as standard of care in type 1 diabetes by some insurers and prescribers
- Providing more accurate glucose monitoring systems and insuring that these systems are used appropriately in patients with diabetes mellitus will improve the risk-benefit ratio of diabetes treatment
- Productive private/public stakeholder engagement can foster the provision of cost-effective health care and real improvement in patient outcomes.
Building on the Consensus Conference and Maintaining Ongoing Dialogue with Stakeholders

• Consensus Conference is a model for stakeholder engagement
• Demonstrates potential value of a National Diabetes Clinical Care Commission representing a partnership between private sector diabetes experts and diabetes specialists in federal agencies most active in diabetes care
• Legislation re-introduced in 114th Congress and supported by AACE and the entire diabetes community (HR 1192, SR 586); we need 200 co-sponsors to get a hearing (last session got to 183 in the House)
• Commission will provide a formal mechanism for federal agencies to receive consistent and direct clinical expertise and a practical perspective from professionals who work directly with patients with diabetes
• Commission will identify and evaluate current federal quality improvement activities and critical gaps in efforts to support clinicians in providing integrated, high-quality care

Groups Supporting the National Diabetes Clinical Care Commission Act

• Abbott
• Academy of Nutrition and Dietetics
• American Academy of Family Physicians
• American Academy of Ophthalmology
• American Association of Clinical Endocrinologists
• American Association of Diabetes Educators
• American Association of Kidney Patients
• American Clinical Laboratory Association
• American College of Cardiology
• American Diabetes Association
• American Optometric Association
• American Medical Association
• American Pediatric Medical Association
• American Society for Metabolism and Bariatric Surgery
• American Society of Bariatric Physicians
• American Society of Nephrology
• AngioRx
• Bayer Corporation
• Boehringer Ingelheim
• DexCom, Inc.
• diatribe Foundation
• Eli Lilly and Company
• Endocrine Society
• GlaxoSmithKline
• Healthcare Leadership Council
• Health Management Network
• Healthcare Ophthalmology
• Joslin Diabetes Research Foundation
• Lexicon Pharmaceuticals, Inc.
• Merck
• Merck
• National Association of Chain Drug Stores
• National Community Pharmacists Association
• National Kidney Foundation
• Novo Nordisk
• Obesity Action Coalition
• Pediatric Endocrine Society
• Renal Physicians Association
• Results for Life
• Roche Diagnostics
• VIVUS, Inc.
• VSP Vision Care
• YMCA of the USA

Unintended Consequences of the Competitive Bidding Program

• Long-term survival is negatively affected by gaps in SMBG acquisition
• Many more beneficiaries in test markets went to partial SMBG
Unintended Consequences of the Competitive Bidding Program

- more inpatient admissions among test beneficiaries migrating from full to partial SMBG
- more cost for those beneficiaries in test markets

Is This What We Wanted to Happen?

Thank you!

Questions?