



**AACE/ACE Consensus Conference on Continuous Glucose Monitoring  
February 20, 2016, Hyatt Regency at Capital Hill, Washington, DC**

**Conclusion Summary**

Continuous glucose monitoring (CGM) has been commercially available since the early 2000s but has not been widely adopted in the management of diabetes. In light of advances in CGM technology and a growing body of evidence supporting CGM benefits, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) convened a public consensus conference to review available CGM data and develop strategies for overcoming barriers to CGM use and access. Representatives from medical and scientific societies, patient advocacy organizations, government, health insurance providers, and device and pharmaceutical manufacturers met to discuss 4 key questions related to CGM use. Together, the conference reached the following conclusions:

**Q1. How would patients, physicians, and payers benefit from expanded use of personal and professional CGM?**

- Extensive data from randomized controlled and other trials support the use of CGM in many people, particularly children and adults with type 1 diabetes
- Numerous advances in CGM technology have improved the accuracy and reliability of these devices
- Data from small-scale randomized trials and retrospective or prospective observational studies suggest CGM may have similar benefits in insulin-using patients with type 2 diabetes and women with gestational diabetes
- Acute and chronic diabetes complications are debilitating and expensive, and CGM has the potential to reduce health-related costs
  - Threshold suspend in systems integrating CGM with insulin pumps reduces the incidence of severe hypoglycemia, thereby decreasing the need for emergency medical services and/or hospitalization
  - Alarms on stand-alone CGM devices can also predict and prevent hypoglycemia by alerting patients to impending low glucose values, facilitating prompt corrective action

- CGM use helps patients safely maintain target hemoglobin A1C levels, and it is well established that reduced glycemic exposure reduces the risk of long-term diabetes complications and associated healthcare costs
- More studies of the economic impact of CGM use are needed. Currently available data based on quality adjusted life years (QALY) may be inaccurate because health-related quality of life (HRQOL) surveys are insensitive to the effects of CGM

## **Q2. What CGM data are relevant and how should they be reported?**

- The primary display of all CGM devices should highlight actionable data, such as:
  - Current glucose level
  - Glucose trend arrows
- The primary downloadable report of all CGM devices should highlight the above-listed actionable data and the following:
  - Time in range
  - Time above/below range
  - Hypoglycemic risk with the low blood glucose index (LBGI) or similar risk index
- The threshold for hypoglycemia alerts should be <70 mg/dL. Additional alerts at lower values may be useful as a hard-preset alarm
- CGM data reports should primarily track patterns of hypoglycemia and hyperglycemia
- CGM data should be put in context with other system variables such as meals, treatments, exercise, illness, insulin boluses, and artificial pancreas algorithm activity
  - Systems should permit integration with commonly used step counters, heart rate monitors, and mobile device apps that track meals, exercise, etc., to minimize manual entry by patients
- Standardized metrics and reporting among available CGM devices would facilitate understanding by patients and clinicians and promote wider adoption of CGM technology
- Ease of downloading CGM data is essential for utilization by clinicians; current download systems need improvement, particularly in areas of simplicity and download speed
  - Future systems could include automatic uploads to data clouds to facilitate remote access by clinicians and caregivers

## **Q3. How should the data and reporting be interpreted?**

- Patients manage their own diabetes on a day-to-day basis and their health and safety depends on access to CGM data
  - Professional use refers to CGM devices owned by the physician's office and used intermittently to assess glycemic patterns for therapeutic decision-

- making, while personal use refers to CGM devices owned by patients who use it for making real-time adjustments to diabetes management
- Whether CGM is used intermittently (personal or professional use) or continuously (personal use), patients should generally be able to see and react to glucose data
- CGM without data display (i.e., masked CGM) has demonstrated benefit when used intermittently in conjunction with advice from clinicians. It is also of great value in clinical trials to clarify the action of investigational medications, and CGM results may be used as endpoints in the evaluation of medication efficacy and safety
- Pattern recognition software that identifies the highest risk patterns could facilitate interpretation and utilization of data by clinicians
- CGM reports should be interpreted by trained clinicians but should include summary pages designed to be understood by patients
- Clinicians should receive adequate training in the use and interpretation of CGM
  - CGM training should be made widely available to clinicians involved in diabetes management
  - Clinician training should include delivery of patient education on CGM
  - Certification should not be required, as this would hinder wider adoption of CGM technology

**Q4. What clinical data are currently available to support expanded CGM coverage by payers as pertains to questions 1 and 3? What additional data are needed?**

- Robust data support CGM-associated improvements in A1C and reduced risk of hypoglycemia in patients using intensive insulin therapy
  - Cost-effectiveness studies are needed to further document healthcare cost reductions associated with CGM
- CGM is likely to provide significant benefits to the following patient populations, although additional studies are needed:
  - Patients older than 65 years on intensive insulin therapy
  - Gestational diabetes and women with diabetes who are or are planning to become pregnant
  - Patients with kidney disease
  - Patients with diagnosed hypoglycemia unawareness
- CGM provides benefits only to those patients willing and able to use it, but as wearability, reliability, and accuracy continue to improve, so should patient acceptance
- As factory-calibrated CGM devices become commercially available and approved for stand-alone use for insulin dosing, savings from reduced use of traditional blood glucose monitors will likely offset the cost of CGM devices
  - Factory calibration will also reduce common calibration errors from self-monitoring of blood glucose (SMBG) due to blood sample contamination and other patient-driven factors

- Reimbursement should be expanded to cover clinician time spent reviewing and interpreting CGM data and advising patients outside of as well as during patient visits
  - Advancements in data delivery, through cloud-connected devices, standardized reports, and other improvements in efficiency-related factors should increase clinician efficiency in the review and interpretation of CGM data, facilitating better patient care
- Patients, clinicians, and other interested parties should continue working together to address statutory barriers to expanded CGM coverage