



DIABETES MELLITUS INTERAGENCY COORDINATING COMMITTEE (DMICC)

January 20, 2014 Meeting Abstracts

Report and Discussion of the American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Conference on Glucose Monitoring

George Grunberger, MD, FACP, FACE, President-elect of the American Association of Clinical Endocrinologists (AACE), and Chair, Consensus Conference on Glucose Monitoring

AACE and the American College OF Endocrinology (ACE) held a Consensus Development Conference on September 28 and 29, 2014, in Washington, DC, to evaluate clinical science, utility, and access to blood and continuous glucose monitoring. 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 and its implementation in clinical practice. Participants agreed that while glucose monitoring is mandatory to diabetes care, it is not in itself adequate to promote optimal diabetes management. Appropriate action based on data gained through careful monitoring is needed to optimize care. Recognizing the need to build consensus on this issue, the participant experts reached the following conclusions during the conference:

- Glucose monitoring has upgraded the quality and safety of diabetes care and is perhaps best appreciated in patients on intensive insulin therapy.
- The need for glucose monitoring depends, in part, upon the anti-diabetic therapies employed in each patient. CGM may be best for patients with type 1 diabetes on complex insulin regimens and may also be useful to a select group with type 2 diabetes, especially those with a need for intensive insulin therapy and high risk of hypoglycemia.
- Intermittent monitoring with glucose oxidase-based systems shows 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 especially by mail order diabetes suppliers under the Centers for Medicare and Medicaid Services (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. US Food and Drug Administration (FDA) needs to enforce existing regulations, during both the approval and the post-marketing surveillance processes.

- Although CGM has shown to be beneficial, it has still not been fully accepted as standard of care in type 1 diabetes by all insurers and prescribers. Many insurance carriers also do not reimburse for adequate testing supplies for patients with either type 1 or type 2 diabetes, despite the recent findings of the Centers for Disease Control and Prevention (CDC) showing hypoglycemia from anti-diabetic medications is the second most common cause of emergency department (ED) visits and hospitalizations due to adverse drug reactions in the United States.
- 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

Stayce E. Beck, PhD, Supervisory Biologist, Center for Devices and Radiological Health, Office of *in Vitro* Diagnostics and Radiological Health

FDA regulates devices according to the risk of the intended use of the device. Glucose meters are considered moderately risky and are cleared through the 510(k) program according to substantial equivalence. In January of 2014, the FDA proposed updated studies for glucose meter clearance through draft guidance documents.

Aaron Kowalski, Ph.D., JDRF Chief Mission Officer, and Vice President, Research

Two issues at the heart of the AACE Consensus Conference on Glucose Monitoring were (1) lack of access to necessary quantities of diabetes testing supplies and (2) reduced access to higher quality blood glucose meters and supplies. These issues are important because of the clinical and patient impact that they have today. Glucose monitoring is the bedrock of diabetes treatment. They are also important with respect to future diabetes technologies. Access to high quality blood glucose meters is necessary for the calibration of low-glucose suspend systems – a first step towards an artificial pancreas – as well as future artificial pancreas device systems.

Improving diabetes clinical outcomes, however, goes beyond access to a sufficient number of strips and access to high quality meters. The current approach to diabetes technologies is one size fit all. That is, the primary means for judging the success of diabetes therapies has been measurement of changes in the HbA1c level. While diabetes is a disease of high-blood sugar and HbA1c is a measure elevated blood sugar levels over time, the needs and the clinical goals of people with type 1 diabetes (T1D) are not all the same – nor should they be – and often include metrics in addition to the A1c. In older adults, the goal is typically to reduce hypoglycemia. In teens, the goal may be to avoid diabetic ketoacidosis. With respect to diabetes technologies, we are seeing a shift towards a more personalized view of diabetes care, however, payers are reluctant to adopt a broader view. Reticence on the part of payers, including the Centers for Medicare & Medicaid Services (CMS), impacts investment in diabetes technologies and slows our path forward.

Despite robust clinical evidence supporting the efficacy of continuous glucose monitoring (CGM) in individuals with T1D, CMS continues to deny Medicare beneficiaries access to CGM. Medicare's position on CGM also negatively impacts beneficiary access to technologies that include or rely on CGM such as sensor-augmented pumps and low-glucose suspend systems. Medicare beneficiary lack of access to CGM and related technologies is problematic. Older adults, who typically have had T1D for a long duration, are at increased risk for severe hypoglycemia making access to CGM a necessity.

With respect to low-glucose suspend systems, or sensor augmented pumps that suspend insulin delivery automatically when individuals are unable to respond to low-glucose warning alarms, commercial health plans have resisted providing coverage to their beneficiaries. One reason is that these systems do not lower HbA1c. These devices, however, are not intended to reduce HbA1c. Rather, they are intended to reduce hypoglycemia without increasing HbA1c. Data from randomized controlled trials supports the efficacy of low-glucose suspend systems in reducing hypoglycemia without adversely impacting HbA1c. Finally, with hypoglycemia as a key barrier to treatment in T1D, access to technologies that reduce hypoglycemia is critical.

PARTICIPANT LIST

Speakers

Dr. George Grunberger (AACE)

Dr. Stayce E. Beck (FDA)

Dr. Aaron Kowalski (JDRF)

Participating DMICC Members

Dr. Tibor Roberts (NIDDK, DMICC
Executive Secretary)

Dr. Judith Fradkin (NIDDK, DMICC Chair)

Dr. Jane Atkinson (NIDCR)

Dr. Larissa Avilés-Santa (NHLBI, via
telephone)

Dr. Kasia Bourcier (NIAID)

Dr. Ann Bullock (IHS, via telephone)

Dr. Chhanda Dutta (NIAID)

J. Nadine Gracia (OMH, via telephone)

Dr. Gilman Grave (NICHD)

Dr. Alberto Gutierrez (FDA, for Mary
Parks)

Dr. Rex Robison (NLM, via telephone)

Dr. Sharon Saydah (CDC, for Ann Albright)