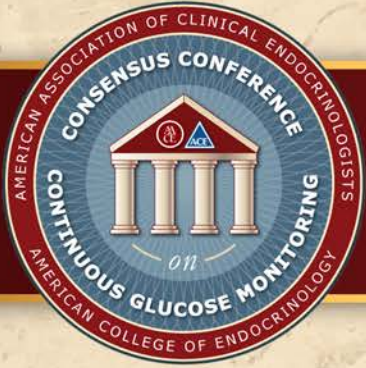




AACE/ACE CONSENSUS CONFERENCE ON CONTINUOUS GLUCOSE MONITORING

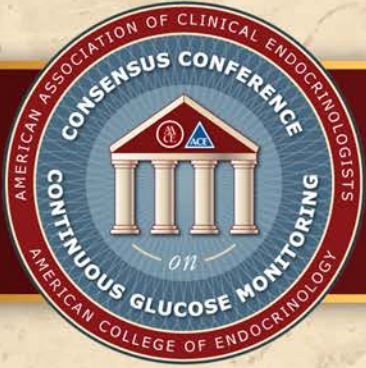
FEBRUARY 20, 2016

HYATT REGENCY AT CAPITOL HILL | WASHINGTON, DC



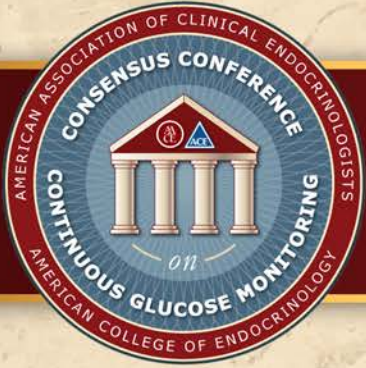
Task Force & Writing Committee

- George Grunberger, MD, FACP, FACE, AACE President
- Vivian Fonseca, MD, FRCP, FACE, Chair
- Henry Anhalt, DO, FACE
- Timothy Bailey, MD, FACP, FACE, ECNU
- Thomas Blevins, MD, FACE, FNLA, ECNU
- Satish Garg, MD
- Yehuda Handelsman, MD, FACP, FNLA, FACE
- Irl B. Hirsch, MD
- Eric A. Orzeck, MD, FACP, FACE
- Victor L. Roberts, MD, MBA, FACP, FACE
- William Tamborlane, MD



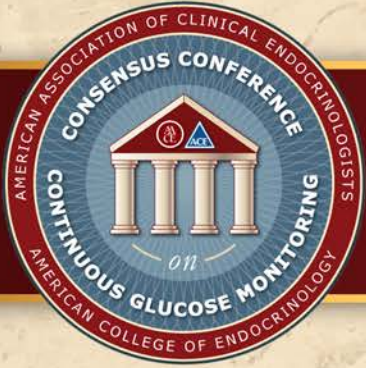
Conference Mission

To bring together all relevant stakeholders, what we call the Pillars, to discuss evidence supporting the development of clinical recommendations for the management of patients with diabetes utilizing Continuous Glucose Monitoring (CGM) technology.



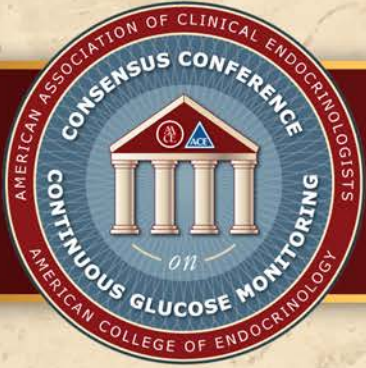
Conference Process

- General Session
 - Welcome & Introductions
 - AACE Perspective
 - Keynote Speaker
 - Pillar Breakout Instructions
- Pillar Breakout Sessions
- Lunch
- Pillar Forum



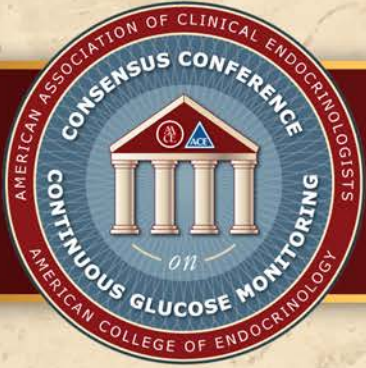
Deliverable

- Consensus Conference Statement
 - Introduction
 - Question-oriented evidence base
 - Consensus Conclusions
 - Recommendations
- Publication in *Endocrine Practice*



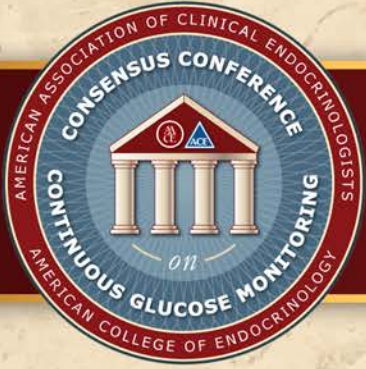
Conference Participants

- Conference Writing Committee
- Pillars Participants
- Sponsor Representatives
- Registered Attendees



Corporate Support

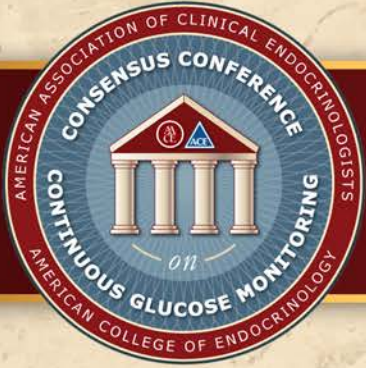




Bruce Buckingham, MD

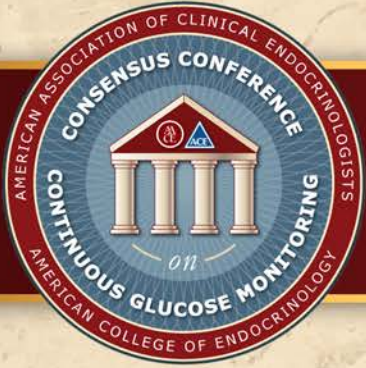


Professor of Pediatrics
(Endocrinology) at the Lucile
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Hospital, Stanford School of
Medicine



Pillars

- Medical, Scientific, Professional, Educational Societies
- Patients/Lay Organizations
- Government/Regulatory, Payers, & Large Employers
- Industry Organizations



Medical, Scientific, Professional, Educational Societies

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Phyllis Arn Zimmer, MN, FNP, FAANP, FAAN

American Board of Internal Medicine (ABIM)

Diabetes Care and Education Group

Institute for Diabetes-Technology GmbH at Ulm University

Diabetes Technology Consultants

American Academy of Physician Assistants

Diabetes Care and Education Group

University of Virginia School of Medicine

American College of Osteopathic Internists

Indiana University Department of Medicine

American Geriatrics Society

American Diabetes Association

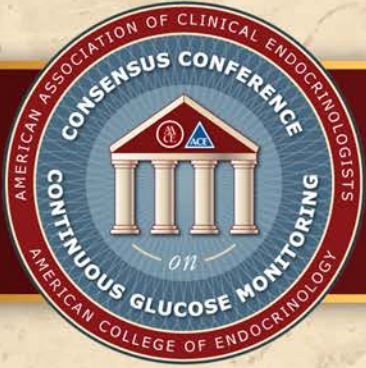
JDRF

Academy of Nutrition and Dietetics

American Association of Diabetes Educators

American Association of Diabetes Educators

Nurse Practitioner Healthcare Foundation



Patient/Lay Organizations

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Larry Smith

Diabetes Patient Advocacy Coalition

T1D Exchange

The diaTribe Foundation

National Patient Safety Foundation & Institute
for Safe Medication Practices

Diabetes Patient Advocacy Coalition

Taking Control of Your Diabetes

ACE Foundation Board of Regents Member

Children with Diabetes

Diabetes Mine

The diaTribe Foundation

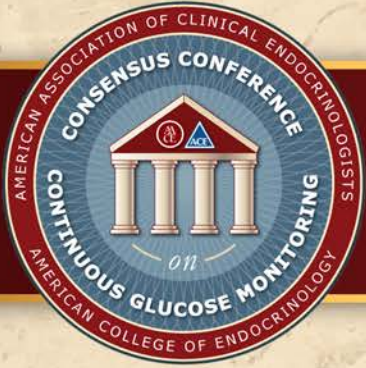
National Diabetes Volunteer Leadership Council

National Patient Safety Foundation & Institute
for Safe Medication Practices

The diaTribe Foundation

JDRF

National Diabetes Volunteer Leadership Council



Government/Regulatory, Payers, & Large Employers

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Centers for Disease Control and Prevention

National Institutes of Health

U.S. Food and Drug Administration

National Quality Forum

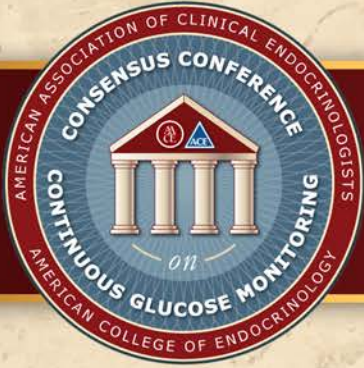
UnitedHealthcare

U.S. Food and Drug Administration

Federal Aviation Administration

Healthcare Leadership Council

National Institutes of Health



Industry Organizations

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David Price, MD

Jimmy Ren, PhD

Eli Lilly and Company/Lilly USA

Medtronic Diabetes

DexCom, Inc.

Insulet Corporation

Roche Diabetes Care, Inc.

Novo Nordisk, Inc

J & J Diabetes Care Companies

Abbott Diabetes Care

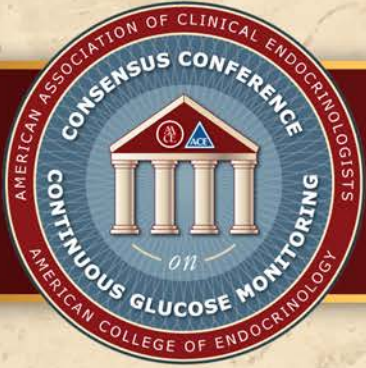
Eli Lilly and Company/Lilly USA

Novo Nordisk, Inc.

DexCom, Inc.

J & J Diabetes Care Companies

Continued



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AstraZeneca

AstraZeneca

Medtronic Diabetes

Boehringer Ingelheim Pharmaceuticals, Inc.

Ascensia Diabetes Care

Lexicon Pharmaceuticals

Ascensia Diabetes Care

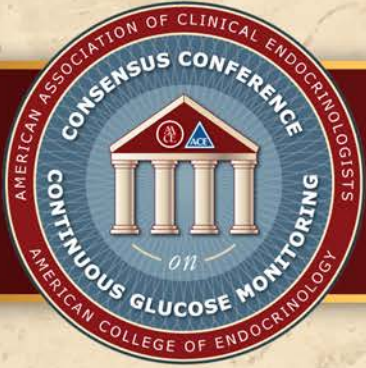
Roche Diabetes Care, Inc.

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J & J Diabetes Care Companies

Medtronic Diabetes

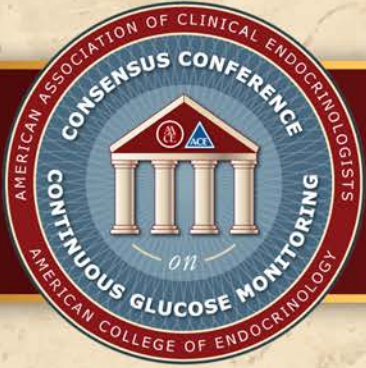
Insulet Corporation



Question 1

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

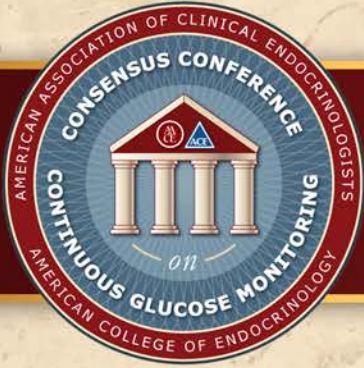
- a. What data support the use of CGM for either personal or professional use?
- b. What patient populations are best served by this technology based on the research?
- c. What are the implications on the healthcare system of not addressing glycemic variability which results in short-term acute hypos/hospitalizations, and long-term complications/hyperglycemia?
- d. Is it necessary to review data in different groups to determine the impact on improved control of diabetes, and not necessarily only a lower A1C, but a better quality of life?



Question 2

What CGM data are relevant and how should it be reported?

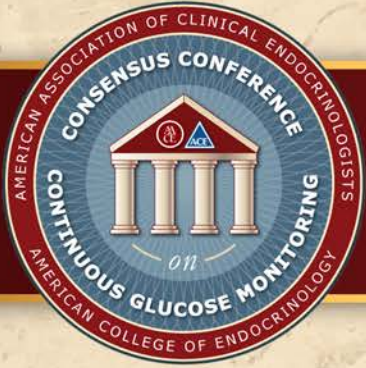
- a. What information from CGM technology is critical for patients and physicians to manage diabetes and improve outcomes?
- b. What key metrics should be considered: time-in-range, percent time above/below range, etc.
- c. Would standardized reporting support patient management, physician utilization, and training of physicians and patients?
- d. What data are necessary? How should it be standardized, i.e., should data be broken into different times such as fasting, post-prandial, bedtime, hypoglycemic episodes and their times?
- e. Can unnecessary data distract from key findings? If so, should a series of algorithms be developed to assist with a focused and meaningful analysis and interpretation?



Question 3

How should the data and reporting be interpreted?

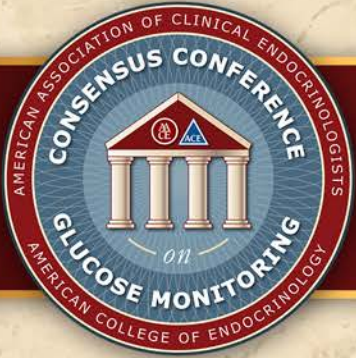
- a. Are there standard metrics that could inform therapy adjustment, such as should A1C be reported with a risk index based upon CGM glucose profile or Time In Range report?
- b. Should additional patient descriptors based on standardized CGM reporting be included such as, “hypo unaware,” “hyper unaware,” “high variability?” What are the most important factors physicians need to focus on when interpreting CGM data?
- c. Who should interpret that data to utilize it in an effective way? Who should be authorized to interpret the standardized CGM report that will allow it to be a part of permanent medical record and billable service? Is specified training or certification necessary? Should the provider interpretation of the data be standardized as well?
- d. What is the impact of blood glucose monitoring? What would be the impact of CGM on patients’ frequency of blood glucose monitoring?
- e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess meaningful use of CGM in their patients and justify decisions on continued need/coverage?



Question 4

What clinical data are currently available to support expanded CGM coverage by payers as it pertains to Questions 1-3? What additional data are needed?

- a. Professional CGM and patient types
- b. Personal CGM and patient types
- c. Other
- d. What other clinical needs would CGM need to address to improve blood glucose self-management and patient engagement for both clinical and economic outcomes improvements? Who would be the target patient audience supported by the data? Do some patient types need further study?
- e. In view of recent scientific evidence and progress in CGM technology:
 - What are the current gaps in CGM reimbursements?
 - Reimbursement of technology itself
 - Reimbursement for clinician time supervising CGM
 - In what priority should these gaps in reimbursement be addressed?



Pillar Breakout Sessions

Pillar	Room
Medical, Scientific, Professional & Educational Societies	Columbia A
Patient/Lay Organizations	Columbia C
Government/Regulatory, Payers, & Large Employers	Congressional CD
Industry Organizations	Columbia B



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