

AACE/ACE CONSENSUS CONFERENCE ON CONTINUOUS GLUCOSE MONITORING

FEBRUARY 20, 2016

HYATT REGENCY AT CAPITOL HILL | WASHINGTON, DC

**QUESTION 1. HOW WOULD PATIENTS,
PHYSICIANS, AND PAYERS BENEFIT
FROM EXPANDED USE OF PERSONAL
AND PROFESSIONAL CGM?**

Question 1a. What data support the use of CGM for either personal or professional use?

- Lower A1C in pediatric and adult patients with T1D (T1D Exchange, STAR3, JDRF, Vigersky 2012 [T2D], Adamson 2015, Bailey 2007, O'Connell 2009, Pickup 2011; Deiss 2006, Garg 2006, Kovatchev 2007)
- Reduced hypoglycemia (ASPIRE, JDRF, Battelino 2011, Zick 2007)
- Identification of hypoglycemia in elderly and other patients with hypoglycemia unawareness (Hay 2003; Gehlaut 2015, Chico 2003)
- Reduced fear of hypoglycemia (Chamberlain 2015)
- Identification of time in target BG range (Bode 2005)
- Fewer school days missed for children (Hommel 2014)
- Reduced macrosomia in pregnant patients (Murphy 2008)
- CGM superior to SMBG and sensor-augmented pumps superior to MDI (meta-analysis; Yeh 2012)
- Closed loop systems achieve superior glucose control and reduce hypoglycemia (closed loop references)
- Benefits depend on wearing the system >50% of the time (STAR 3)

Question 1a. What data support the use of CGM for either personal or professional use? Cont.

Support

- Intermittent CGM shown to help identify strengths and weaknesses in T2D glycemic control regimens (Vigersky 2012, Blackberry 2014)
- Unmasked CGM useful for professional use

Gaps

- Masked CGM does not teach patients cause-effect relationships
- Majority of HCPs are not skilled at data interpretation

Question 1a. What data support the use of CGM for either personal or professional use?

- Numerous studies support personal CGM (JDRF, STAR)
- Reductions in time out of glucose target range vs SMBG (GLADIS; New 2015)
- Anecdotal reports of patient experience with CGM (Pickup 2016)

Counter-evidence/Gaps

- Professional CGM is not well supported by data

Question 1a. What data support the use of CGM for either personal or professional use?

- Published data from last decade support use of CGM alone or in sensor-augmented insulin pump therapy as adjunct to SMBG
 - Improved glucose control
 - Prevents/reduce hypoglycemia (especially low-glucose suspend devices)
 - Time-in-range
- More advanced sensors and algorithms can be used for non-adjunctive glucose monitoring, especially in T1D patients
- Trend analysis

Question 1a. What data support the use of CGM for either personal or professional use?

- CGM helps reduce A1C and hypoglycemia
- CGM associated with improved glycemic outcomes in T1D
- CGM associated with improved glycemic outcomes in T2D managed with or without intensive insulin therapy
- Compared with SMBG, CGM significantly reduces A1C and periods of hypoglycemia and hyperglycemia

Question 1b. Which patient populations are best served by this technology based on the research?

Populations Likely to Benefit

- All T1DM, (most have uncontrolled glycemia plus at risk for severe hypo and DKA)
 - Children and adults who use CGM frequently will benefit (JDRF, STAR 3)
- Patients with HAAF and/or nocturnal hypoglycemia
- Older adults with T1D or insulin-controlled T2D
- Pregnant patients
- T2D at risk for hypoglycemia and associated CV events
- Anyone with DM willing to wear CGM
- Athletes
- CGM also useful with MDI therapy

Gaps/No evidence of benefit

- Type 2 Patients not using insulin (Vigersky 2012)

Question 1b. Which patient populations are best served by this technology based on the research?

- T1D
- No RCT in T2D, but those with history of display of history of severe hypoglycemia could be considered candidates
- Patients with frequent hypoglycemia
- Pancreatic diabetes

Question 1b. Which patient populations are best served by this technology based on the research?

Populations Evidenced to Benefit

- Adult T1D patients
- Patients with hypoglycemia unawareness
- Preconception/pregnant patients with T1D
- Older adults at risk for hypoglycemia*
- Insulin-using T2D
- Athletes and physically active people
- Commercial drivers, heavy equipment operators, pilots and safety sensitive populations
- Hospitalized patients

Lack of evidence of benefit

- Teenagers
- Young children (low rates of use, but benefits similar to adults if used for ≥ 6 weeks)

*NIDDK has issued an FAO to address this issue.

Question 1b. Which patient populations are best served by this technology based on the research?

- All patients with diabetes
 - Patients who are most likely to benefit
 - Intensive insulin therapy
 - Hypoglycemia unawareness
 - Others at increased risk of hypoglycemia
 - Patients over the age of 65
 - Renal failure

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Question 1c. What are the implications on the healthcare system of not addressing glycemic variability that results in short-term acute hypoglycemic episodes/hospitalizations, and long-term complications/hyperglycemia?

- Long term care for geriatric patients with multiple co-morbidities
- Glycemic variability is associated with DM complications and high costs (Nalysnyk 2010, Jacobsen 2015)
- Cost of hypoglycemia-associated hospital admission: \$18,000 average per admission; \$120 million annual yearly expenditures (Geller 2014)
- A1C >10% associated with higher estimated hospitalization costs (Menzin 2012)
- Maintaining optimal/improved A1C reduced total direct medical costs (Cranor 2003, Jacobsen 2004)
- Reduced use of healthcare resources and improved QOL (Hommel 2014)
- Hypoglycemia-associated cognitive decline can lead to medication errors and risk of falls (Rizzo 2010)
- Reduced costs associated with severe hypoglycemia and DKA, long-term complications, and reduced use of SMBG
- Less burden on HCPs to manage hyper- and hypoglycemia emergencies

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Question 1c. What are the implications on the healthcare system of not addressing glycemic variability that results in short-term acute hypoglycemic episodes/hospitalizations, and long-term complications/hyperglycemia?

- CGM use could reduce costs associated with DM complications, especially in older patients (CMG Medicare Act preamble)
 - 42% of Medicare fee for service spending is on people with DM
 - Costs for hypoglycemia inpatient admission: \$17,564 per visit
 - >97,000 ER/hospital admissions for hypoglycemia (Geller 2014)
 - CGM has added value in outcomes-based reimbursement
- A1C is crude and fails to capture periods of success and areas of challenge, while CGM allows insights into diet, behavior, and medications
- Data in T2D showing greater therapeutic adherence with CGM may substantiate the cost savings in this population

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Question 1c. What are the implications on the healthcare system of not addressing glycemic variability that results in short-term acute hypoglycemic episodes/hospitalizations, and long-term complications/hyperglycemia?

Implication

- Significant increase in diabetes healthcare costs when CGM is not used
 - Acute care
 - Hospitalizations
- ICER = \$98,679/QALY (Huang et al 2010)
- Eliminating copays improves adherence to medications (Choudhry 2010)

Gaps

- No compelling clinical evidence that glycemic variability modifies micro- and macrovascular complications
 - Need properly powered intervention studies

Government/Regulatory, Payers & Large Employer Pillar

Question 1c. What are the implications on the healthcare system of not addressing glycemic variability that results in short-term acute hypoglycemic episodes/hospitalizations, and long-term complications/hyperglycemia?

- **Diabetes acute complications are costly**

Hypoglycemic & Hyperglycemic Crisis

Element	Approx. Cost /episode (\$USD)
Ambulance Transport	\$1,704 ^{5^}
Emergency Room Visit	\$1,579 ^{6†}
Hospitalization	\$20,606 ^{6†}
Inpatient cost for Hypoglycemic Coma	\$37,536 ^{3^}

[^]Type 1 and type 2 diabetes combined.
[†]Type 2 diabetes . Figure adjusted for inflation.
[^]Applies to all hypo cases, regardless of diabetes type.

- 1) 2015 AACE/ACE Consensus Statement. *Endocrine Practice* 2015;21.
- 2) Leese GP, Wang J, Broomhall J, et al. Frequency of severe hypoglycemia requiring emergency treatment in type 1 and type 2 diabetes: a population-based study of health service resource use. *Diabetes Care*. 2003;26:1176-80.
- 3) National and regional estimates on hospital use for all patients from the HCUP Nationwide Inpatient Sample (NIS), 2009. <http://hcupnet.ahrq.gov/HCUPnet.jsp> Accessed January 28, 2012.
- 4) Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States*, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.
- 5) Centers for Medicare and Medicaid Services (CMS). Ambulance Fee Public Use Files. CMS website. <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/afspuf.html>.
- 6) Dollars updated to 2014 value. Quilliam BJ, Simeone JC, Osbay AB, Kogut SJ. The incidence and costs of hypoglycemia in type 2 diabetes. *Am J Manag Care* 2011;17:673-80.

At-Risk Patients and the Financial Burden

11.8%

of adults with Type 1 experience one or more severe hypoglycemic events (seizure or loss of consciousness) within the last 12 months¹

36%

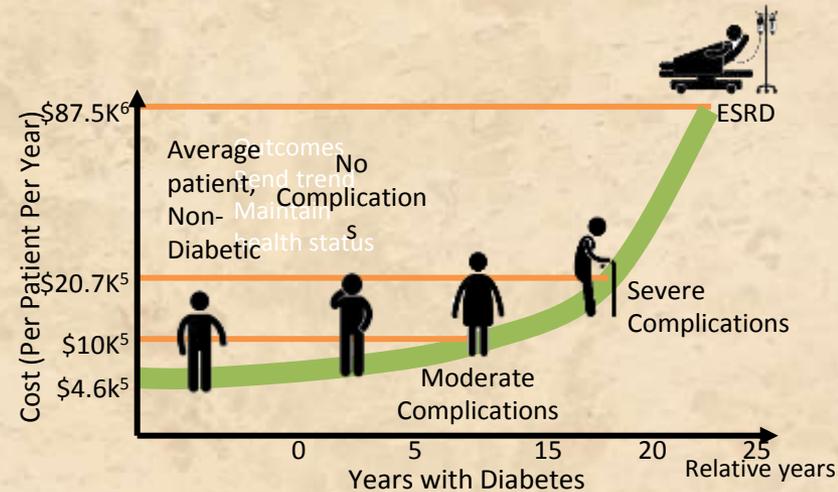
of Type 2 patients treated with insulin reported experiencing self-treated hypoglycemia during the previous 30 days²

97,648

insulin related hypoglycemia and errors (IHEs) ED visits annually in the US³

\$502.5M

Total annual hospitalization cost attributed to insulin related hypoglycemia and errors in the US^{3,4}



- 1) Weinstock RS, Xing D, Maahs DM, et al. Severe Hypoglycemia and Diabetic Ketoacidosis in Adults with Type 1 Diabetes: Results from the T1D Exchange Clinic Registry. *J Clin Endocrinol Metab.* 2013 Aug;98(8):3411-9.
- 2) Brod M, Rana A, Barnett A. Impact of self-treated hypoglycaemia in type 2 diabetes: a multinational survey in patients and physicians. *Current Medical Research & Opinion* Vol. 28, No. 12, 2012, 1947–1958
- 3) Geller AI, Shehab N, Lovegrove MC, et al. National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations, *JAMA Intern Med.* 2014;174(5):678-686. doi:10.1001/jamainternmed.2014.136.
- 4) Quilliam BJ, Simeone JC, Ozbay AB, Kogut SJ. The incidence and costs of hypoglycemia in type 2 diabetes *Am J Manag Care* 2011;17:673-80.
- 5) United HealthCare/i3 Innovus, *The United States of Diabetes, Challenges and Opportunities in the Decade Ahead*
- 6) 2012 USRDS Annual Data Report
- 7) Weinstock RS, Xing D, Maahs DM, et al. Severe Hypoglycemia and Diabetic Ketoacidosis in Adults with Type 1 Diabetes: Results from the T1D Exchange Clinic Registry. *J Clin Endocrinol Metab.* 2013 Aug;98(8):3411-9.
- 8) Cengiz, E, et al. Severe Hypoglycemia and Diabetic Ketoacidosis among youth with Type 1 Diabetes In the T1D Exchange Clinic Registry. *Pediatric Diabetes*, 2013.

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Question 1d. 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?

Yes

- STAR3 clearly showed that CGM works differently in different groups
- QOL, fear of hypoglycemia and glycemic variability should be tested as well as A1C
- Reduction of hypoglycemic events might be shown in patients with hypoglycemia unawareness

No

- More important than studying different groups is recognizing whether a given patient will be able to use CGM consistently and frequently enough to see its benefits
- Stratifying people into different subpopulations is not supported by clinical evidence and so may hurt rather than help access to CGM

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Question 1d. 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?

- QOL is the goal of therapy
 - Less burden of therapy
 - Caregivers
 - Spouses
 - Less fear of hypoglycemia

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Question 1d. 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?

Yes

- Studies should measure QOL, burden of care, and fear of hypoglycemia
 - Families with young children where a member uses CGM
 - Patients who live alone who are at risk of severe hypoglycemia
 - Hypoglycemia unawareness
 - Preconception, pregnancy, and immediately postpartum women
 - Elderly

No

- Psychosocial stresses associated with using CGM

Question 1d. 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?

- **We believe in compound metrics**
- **These should be standardized.**