



Topic Brief: Continuous Glucose Monitoring on Work-related outcomes in Adults with Diabetes

Date: 8/21/2019

Nomination Number: 869

Purpose: This document summarizes the information addressing a nomination submitted on 7/30/2019 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: Continuous glucose monitoring (CGM) can help people with diabetes self-manage blood glucose and improve glucose control. Research has mainly focused on clinical outcomes, and not on its impact on work-related outcomes.

Program Decision: The EPC Program will not develop a new systematic review because we did not find enough primary studies addressing the concerns of this nomination.

Key findings

- We found three systematic reviews that addressed quality of life in people with diabetes type 1 and 2; and resource utilization in people with diabetes type 2.
- We found twelve primary studies that addressed other outcomes. Ten focused on people with diabetes type 1, and three on people with diabetes type 2. Two studies assessed the effect of CGM on absenteeism.

Background

- More than 30 million people in the United States have diabetes. Type 2 diabetes accounts for about 90% to 95% of all diagnosed cases of diabetes; type 1 diabetes accounts for about 5%.¹
- Hypoglycemia, fear of hypoglycemia, and diabetes complications can lead to loss of productivity of working adults including absenteeism and presenteeism.²
- An analysis found that per-year absenteeism for a small employer was about 6 days for diabetes and costs were estimated to be from \$1,621 for diabetes. A large employer (1,000 employees) could face absenteeism rates of 65 days for diabetes. Annual costs for a large employer could range from approximately \$17,000 for diabetes.³
- Continuous glucose monitors (CGM) provide people with diabetes with readings on what their glucose levels are at the moment and typically whether they are trending into the territory of hypoglycemia, a dangerous drop in sugar that can lead to a serious medical emergency.⁴

- It is theorized that use of CGM can help people with diabetes control their blood sugars and improve clinical and work-related outcomes. A recent review found presenteeism attributed to diabetes is mainly caused by hypoglycemia, diabetic neuropathy, and mood disorders. Limited information suggests that improving glycemic control, adjusting treatment regimen by evaluating the impact on work, providing psychological support, and developing suitable work accommodations may reduce presenteeism.⁵
- CGM is covered by Medicare for people with diabetes who are on three or more insulin injections per day, checking their blood glucose multiple times per day, and require frequent adjustments of their insulin based on the blood glucose results.

Nomination Summary

- The nominator was interested in the impact of continuous glucose monitoring (CGM) on work-related outcomes for people with diabetes type 1 and 2. Findings of a systematic review could support a business case for employers to invest in CGM, and spur research about use and support of CGM in the workplace.

Scope

1. What is the effectiveness and harms of continuous glucose monitoring for adults with diabetes type 1?
2. What is the effectiveness and harms of continuous glucose monitoring for adults with diabetes type 2?

Table 1. Questions and PICOTS (population, intervention, comparator, outcome, timing and setting)

Questions	1. CGM in adults with diabetes type 1	2. CGM in adults with diabetes type 2
Population	Adults with type 1 diabetes mellitus	Adults with type 2 diabetes mellitus on multiple injections insulin each day
Interventions	Continuous glucose monitoring	Continuous glucose monitoring
Comparators	Self-monitored blood glucose monitoring	Self-monitored blood glucose monitoring
Outcomes	Quality of life Self-efficacy Out of pocket cost Resource utilization (office visits, ER visits, hospitalization) Absenteeism Presenteeism Workability	Quality of life Self-efficacy Out of pocket costs Resource utilization (office visits, ER visits, hospitalization) Absenteeism Presenteeism Workability
Timing	All	All
Setting	Outpatient	Outpatient

Assessment Methods

See Appendix A.

Summary of Literature Findings

We found two systematic reviews that addressed part of the nomination scope. We identified twelve primary studies in our targeted literature search, too few to recommend an AHRQ EPC systematic review on this topic.

One systematic review⁶ addressed quality of life (QoL) in people with type 1 and type 2 diabetes. An in-process systematic review⁷ addressed QoL and resource utilization in people with type 2 diabetes. We found no reviews on work-related outcomes, such as presenteeism and absenteeism.

Ten primary⁸⁻¹⁷ focused on people with type 1 diabetes. Outcomes studied included hospitalizations, unplanned office visits, absenteeism, CGM satisfaction, hypoglycemia-related confidence in social situations, and quality of life. Five publications were on cost-effectiveness.

Three primary studies^{16, 18, 19} focused on people with type 2 diabetes. Outcomes included cost and self-efficacy. One of the studies included people with diabetes type 1 and 2; it was a qualitative study about people’s perceptions of work while using CGM.¹⁶

Table 2. Literature identified for each Question

Question	Systematic reviews (7/2016-8/2019)	Primary studies (7/2014-8/2019)
Question 1: CGM in adults with diabetes type 1	Total: 1 <ul style="list-style-type: none"> • Other-1⁶ 	Total: 3 <ul style="list-style-type: none"> • RCT¹⁴ • Cohort-1⁸ • Crossover-1^{11,13} • Qualitative-1¹⁶ • Cost-effectiveness^{9,10,12,15,17} Clinicaltrials.gov: 0
Question 2: CGM in adults with diabetes type 2	Total: 2 <ul style="list-style-type: none"> • Other-2^{6,7} 	Total: 2 <ul style="list-style-type: none"> • RCT¹⁹ • Cohort-1¹⁸ • Qualitative-1¹⁶ Clinicaltrials.gov: 0

Abbreviations: CGM=continuous glucose monitoring; RCT=randomized controlled trial

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

While this topic is important and could potentially impact support for CGM for people with diabetes, we found too few studies to recommend an AHRQ EPC systematic review.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years July 2016 to August 2019 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
 - AHRQ Evidence Reports <https://www.ahrq.gov/research/findings/evidence-based-reports/index.html>
 - EHC Program <https://effectivehealthcare.ahrq.gov/>
 - US Preventive Services Task Force <https://www.uspreventiveservicestaskforce.org/>
 - AHRQ Technology Assessment Program <https://www.ahrq.gov/research/findings/ta/index.html>
- US Department of Veterans Affairs Products publications
 - Evidence Synthesis Program <https://www.hsrp.research.va.gov/publications/esp/>
 - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program <https://www.healthquality.va.gov/>
- Cochrane Systematic Reviews <https://www.cochranelibrary.com/>
- PROSPERO Database (international prospective register of systematic reviews and protocols) <http://www.crd.york.ac.uk/prospéro/>
- PubMed <https://www.ncbi.nlm.nih.gov/pubmed/>
- McMaster Health System Evidence <https://www.healthsystemevidence.org/>
- Joanna Briggs Institute <http://joannabriggs.org/>

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed, PsycInfo, CINAHL, and Scopus from the last five years July 2014 to August 2019 on parts of the nomination scope not addressed by earlier identified systematic reviews. We reviewed all identified titles and abstracts for inclusion and classified identified studies by question and study design to estimate the size and scope of a potential evidence review.

Search strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to August 16, 2019

Date searched: August 19, 2019

Searched by: Robin Paynter, MLIS

1	Blood Glucose Self-Monitoring/	6225
2	Monitoring, Ambulatory/	7787
3	and/1-2	335
4	(contin* adj2 glucose).ti,ab,kf.	4950
5	or/3-4	5054
6	employment/ or return to work/ or workplace/	65722
7	(absent* or business or career or cost or costs or emergency or employee* or employed or employment or employer* or hospitali?ation* or job or jobs or livelihood or occupation* or office or "out of pocket" or presenteeism or profession or "quality of life" or QoL or QALY or self* or utilise or utilising or utilisation or utilize or utilized or utilization or visit* or work*).ti,ab,kf.	3972278
8	or/6-7	3986265
9	and/5,8	1470
10	limit 9 to (adaptive clinical trial or clinical trial, all or clinical trial or comparative study or controlled clinical trial or equivalence trial or pragmatic clinical trial or randomized controlled trial)	288
11	limit 10 to yr="2014 -Current"	139

<https://clinicaltrials.gov/ct2/results?cond=continuous+glucose+monitoring&term=&cntry=&state=&city=&dist=>

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes
1b. Is the nomination a request for an evidence report?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	More than 30 million people in the United States have diabetes. Type 2 diabetes accounts for about 90% to 95% of all diagnosed cases of diabetes; type 1 diabetes accounts for about 5%. ¹
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. Hypoglycemia, fear of hypoglycemia, and diabetes complications can lead to loss of productivity of working adults including absenteeism and presenteeism. ² A recent review found presenteeism attributed to diabetes is mainly caused by hypoglycemia, diabetic neuropathy, and mood disorders. There are very limited evidences, but available information suggests that improving glycemic control, adjusting treatment regimen by evaluating the impact on work, providing psychological support, and developing suitable work accommodations may effectively reduce presenteeism. ⁵
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. The total direct and indirect estimated cost of diagnosed diabetes in the United States in 2012 was \$245 billion. ²⁰ An analysis found that per-year absenteeism for a small employer was about 6 days for diabetes and costs were estimated to be from \$1,621 for diabetes. A large employer (1,000 employees) could face absenteeism rates of 65 days for diabetes. Annual costs for a large employer could range from approximately \$17,000 for diabetes. ³
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other	A new review would be partly duplicative.

evidence review is not available on this topic	<p>We found one systematic review developed for the Washington State Health Care Authority⁶ that addressed quality of life for questions 1 and 2; and one in-process systematic review⁷ addressing quality of life for question 2.</p> <p>We found on in-process systematic review that addressed resource utilization in type 2 DM.⁷</p> <p>We found no reviews that assessed work-related outcomes.</p>
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	<p>Guidance for candidates for CGM are clear. However it is unclear whether CGM also impacts work-related outcomes and costs, and thus whether coverage of CGM could be extended to other populations including those with renal impairment, athletes, people with type 2 diabetes, and those on oral diabetes medications.²¹</p> <p>The joint AACE/ACE statement notes that CGM is likely to reduce costs by alerting patients of hyper or hypoglycemia and avoiding hospitalization or ER utilization, but more studies of the economic impact are needed before expanding the use of CGM. They also note that cost-effectiveness studies are needed to further document healthcare cost reductions related to CGM.²¹</p>
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	No.
5. Primary Research	
<p>5. Effectively utilizes existing research and knowledge by considering:</p> <ul style="list-style-type: none"> - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies) 	<p>A new systematic review is not feasible.</p> <p>We found 10 primary studies addressing type 1 diabetes:</p> <ul style="list-style-type: none"> • Charleer et al.⁸ Outcomes included hospitalizations, absenteeism and quality of life. • Hommel et al.¹¹ Outcomes included unscheduled visits, diabetes-related hospitalizations, and days off of work. • Scharf et al.¹⁶ People with diabetes type 1 or 2 on insulin therapy. Fewer and shorter interruptions at work, increased concentration and workability. • Chaugule et al.⁹ The IMS CORE Diabetes Model (v.9.0) was used to assess the long-term (50 years) cost-effectiveness of real-time CGM compared with self-monitored blood glucose (SMBG) alone for a cohort of adults with poorly-controlled type 1 diabetes mellitus (T1DM). The incremental cost-effectiveness ratio for the base case CGM vs SMBG was \$33,789 CAD/quality-adjusted life-year (QALY). It assumed a Canadian willingness-to-pay threshold of \$50,000 CAD per QALY • Polonsky et al.¹⁴ CGM satisfaction was associated with most of the QOL outcomes but not with glycemic outcomes.

	<ul style="list-style-type: none"> • Conget et al.¹⁰ From the societal perspective, sensor-augmented pump (SAP) with low glucose suspend increased total costs with a resultant incremental cost-effectiveness ratio (ICER) of 21,862/QALY. Considering the willingness-to-pay threshold of 30,000/QALY in Spain, SAP with low glucose suspend represents a cost-effective option from both the national health system and societal perspectives. • Nicolucci et al.¹² SAP with automated insulin suspension resulted in an incremental cost effectiveness ratio (ICER) of 44,982 per QALY gained. • Olafsdottir et al.¹³ Compared with SMBG, CGM use improved hypoglycemia-related confidence in social situations and confidence in more broadly avoiding serious problems due to hypoglycemia. Persons also reported greater confidence in detecting and responding to decreasing blood glucose levels (thereby avoiding hypoglycemia) during CGM use and indicated greater confidence that they could more freely live their lives despite the risk of hypoglycemia. • Roze et al.¹⁵ The CORE Diabetes Model was used to simulate disease progression in a cohort of people with baseline characteristics taken from a published meta-analysis. Use of the sensor-augmented pump was associated with an incremental cost-effectiveness ratio of 367,571 SEK per quality-adjusted life year gained, which is likely to represent good value for money in the treatment of Type 1 diabetes in Sweden. • Wan et al.¹⁷ The total 6-month costs were \$11,032 (CGM) vs. \$7,236 (control). For adults with T1D using multiple insulin injections and still experiencing suboptimal glycemic control, CGM is cost-effective at the willingness-to-pay threshold of \$100,000 per QALY. <p>We found three studies addressing people with type 2 diabetes.</p> <ul style="list-style-type: none"> • Sierra et al.¹⁸. Use of professional CGM. Total annual costs • Bailey type 2 self-efficacy. People using CGM demonstrated higher rates of self-monitoring, goal setting, and self-efficacy to self-monitor. • Scharf et al.¹⁶ People with diabetes type 1 or 2 on insulin therapy. People using CGM had fewer and shorter interruptions at work, increased concentration and workability. <p>ClinicalTrials.gov. 0</p>
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Abbreviations: AHRQ=Agency for Healthcare Research and Quality; AACE=American Association of Clinical Endocrinologist; ACE=American College of Endocrinology; CGM=continuous glucose monitoring; DM=diabetes mellitus; ICER=incremental cost effectiveness ratio; SAP=sensor-augmented pump; QALY=quality adjusted life year; SMBG=self-monitored blood glucose