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CADTH Reference List

Flash Glucose Monitoring and Continuous Glucose Monitoring for People With Diabetes in Acute Care Settings

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Summary of Abstracts

CADTH

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Key Messages

- Three randomized controlled trials and 13 non-randomized studies were identified regarding the clinical effectiveness and accuracy of continuous glucose monitoring and flash glucose monitoring systems in managing blood glucose levels among people with diabetes in acute care settings.
- One evidence-based guideline was identified regarding the use of continuous glucose monitoring and flash glucose monitoring systems in managing blood glucose levels among people with diabetes in acute care settings.

Research Questions

1. What is the accuracy of continuous glucose monitoring systems and flash glucose monitoring systems compared to arterial, venous, or capillary reference samples among people with diabetes in acute care settings?
2. What is the clinical effectiveness of continuous glucose monitoring systems and flash glucose monitoring systems in managing blood glucose levels among people with diabetes in acute care settings?
3. What are the evidence-based guidelines regarding the use of continuous glucose monitoring systems and flash glucose monitoring systems in managing blood glucose levels among people with diabetes in acute care settings?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were continuous and flash glucose monitoring, and inpatients with diabetes. No methodological search filters were used to limit the results. The search was also limited to English-language documents published between January 1, 2016 and March 2, 2021. Internet links were provided, where available.

Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings section was based on information available in the abstracts of selected publications. Open-access, full-text versions of evidence-based guidelines were reviewed when abstracts were not available and relevant recommendations were summarized.

Table 1: Selection Criteria

Criteria	Description
Population	People (of all ages) with type 1 or type 2 diabetes in acute care settings (e.g., emergency department, intensive care, coronary care)
Intervention	Continuous glucose monitoring systems (e.g., Dexcom G6) and flash glucose monitoring systems (e.g., FreeStyle Libre)
Comparator	Q1: Arterial, venous, or capillary reference samples assessed using any measurement device Q2: Alternative methods of monitoring glucose levels Q3: Not applicable
Outcomes	Q1: Accuracy (e.g., MARD, Clarke error grid, Bland—Altman plots, or agreement with the accuracy standards of the International Organization for Standardization) Q2: Clinical effectiveness (e.g., glucose time-in-range metrics [e.g., time spent in target glucose ranges], glucose variability, glycated hemoglobin, quality of life, safety [e.g., hypoglycemia events, device-related adverse events]) Q3: Recommendations regarding best practices (e.g., appropriate patient populations or clinical settings, guidance suggesting when to use continuous glucose monitoring systems and flash glucose monitoring systems to inform care decisions, specific clinical considerations during the COVID-19 pandemic)
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, evidence-based guidelines

COVID-19 = coronavirus disease 2019; MARD = mean (or median) absolute relative difference.

Results

Seventeen relevant references were identified for this report.[1-17] Three randomized controlled trials[1-3] and 13 non-randomized studies[4-16] were identified regarding the clinical effectiveness and accuracy of continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) systems in managing blood glucose levels among people with diabetes in acute care settings. One evidence-based guideline[17] was identified regarding the use of CGM and FGM systems in managing blood glucose levels among people with diabetes in acute care settings.

Additional references of potential interest that did not meet the inclusion criteria but provided guidance and recommendations or insights on facilitators and barriers to the implementation of CGM or FGM in acute care settings are summarized in Appendix 1. Other articles of potential interest are provided in Appendix 2.

Overall Summary of Findings

Three randomized controlled trials[1-3] and 13 non-randomized studies[4-16] were identified regarding the clinical effectiveness and accuracy of CGM and FGM systems in managing blood glucose levels among people with diabetes in acute care settings. Authors of 3 randomized controlled trials and 2 non-randomized studies found that CGM or FGM devices improved glycemic management compared to point of care (POC) blood glucose testing in ICU and non-ICU settings.[1-3,12,13] Improvements to glycemic management included time

in target glucose range, mean daily glucose values, and reductions in hypoglycemic or hyperglycemic events.[1-3,12,13] In addition, the 2 non-randomized studies also found that CGM was better able to detect hypo- and hyperglycemic events compared to POC testing in non-ICU settings.[12,13] However, authors of 2 other studies found that CGM did not significantly impact glycemic management compared to POC capillary blood glucose testing.[5,16] Even though these studies found that CGM showed improvements in mean daily glucose values compared to POC testing, the findings were non-signficant.[5,16] Three studies reported that CGM devices were useful to minimize health care worker (HCW) contact and minimize the use of personal protective equipment (PPE) for patients who were in isolation for highly contagious diseases such as coronavirus disease 2019 (COVID-19).[4,5,14]

In terms of accuracy, the results were mixed. The evidence largely supported adequate accuracy of CGM devices compared to POC blood glucose testing or standard reference methods.[4,6,8-10,14,15] However, 2 non-randomized studies identified that CGM or FGM devices provided inadequate accuracy compared to POC blood glucose testing (e.g., arterial, capillary, or biochemical serum) in patients with diabetes in the ICU setting.[7,11] Several studies also noted that accuracy tended to deteriorate with glycemic variability such as with hypo- or hyperglycemic events.[11,12,15,16] The authors of 2 non-randomized studies[6,10] evaluated the accuracy of the OptiScanner in ICU patients with diabetes and found that it had adequate accuracy. However, authors of 1 of these studies stated that the OptiScanner should not be used as the sole monitor for glucose management given that recent standards for accuracy were not met.[10] For further details on study characteristics and outcomes, please see Table 2.

The guideline from the Diabetes Technology Society[17] provided various recommendations for the initiation and continuation of CGM and automated insulin dosing (AID) systems during and after hospitalization. A few of these recommendations included initiating CGM in the hospital to minimize nurse contact for POC glucose testing and to also minimize the use of PPE for patients on isolation due to conditions such as COVID-19.[17] More information regarding the logistics of caring for hospitalized patients using CGM and AID systems, as well as continuation of CGM post-discharge, can be found in the full guideline.[17]

Table 2: Summary of Included Studies

First author, year	Study characteristics	Intervention	Comparator	Relevant outcomes assessed	Authors' conclusions
Randomized controlled trials					
Fortmann (2020)[1]	**Population:** Adults with T2DM **Setting:** non-ICU **N** = 110 participants	RT-CGM	POC testing and usual care	Glycemic management (e.g., time spent in target glucose range, hyperglycemia or hypoglycemia)	The RT-CGM group had significantly lower mean glucose, lower and very low percentage of time in hyperglycemia and hypoglycemia compared to usual care; the RT-CGM group also had higher percentage of time in the target glucose range.

First author, year	Study characteristics	Intervention	Comparator	Relevant outcomes assessed	Authors' conclusions
Singh (2020)[2]	**Population:** Patients with T2DM treated with insulin and are at high risk of hypoglycemia **Setting:** non-ICU **N** = 72 participants	RT-CGM using glucose telemetry system	POC blood glucose testing	• Hypoglycemic events • Glycemic management (e.g., time spent in target glucose range)	The RT-CGM group experienced significantly fewer hypoglycemic events, clinically significant hypoglycemic events, and lower percentage of time spent below the target glucose range compared to those in usual care.
Wada (2020)[3]	**Population:** Patients with non-insulin treated T2DM **Setting:** 5 hospitals in Japan **N** = 100 participants	FGM	SMBG	• Glycemic variability • Change in A1C	The FGM group had significant improvement in mean A1C levels compared to SMBG at 24 weeks. A significant decrease in mean glucose levels and time in hyperglycemia was seen in the FGM group.
Non-randomized studies					
Agarwal (2021)[4]	**Population:** Hospitalized patients with COVID-19 using CGM **Setting:** ICU **N** = 11 participants	RT-CGM (Dexcom G6)	POC blood glucose testing	• Accuracy • MARD	CGM showed reasonable accuracy with a MARD of 6.3%. CGM reduced POC testing by about 60% for patients using CII.
Chow (2021)[5]	**Population:** Hospitalized patients with severe COVID-19 and diabetes **Setting:** ICU **N** = 30 participants	RT-CGM (Dexcom G6)	Arterial-line POC blood glucose testing	• Accuracy • Clinical utility	Although results were non-clinically significant, RT-CGM management lead to decreases in mean sensor glucose in 77% of patients and concomitant reductions in daily POC measurements in 50% of patients. It was also noted that PPE use was reduced.
Elder (2020)[6]	**Population:** Critically ill hospitalized burn patients requiring CGM **Setting:** Burn ICU **N** = 10 participants	CGM (OptiScanner)	Yellow Springs Instrument	• Accuracy • MARD	Over 97% of results obtained from the intervention were within 25% of the corresponding comparator values and 100% were within 30% of comparator values. MARD was 9.6%.

First author, year	Study characteristics	Intervention	Comparator	Relevant outcomes assessed	Authors' conclusions
Kotzapanagiotou (2020)[7]	**Population:** Hospitalized pediatric patients aged 4 years and older with an existing diagnosis affecting glucose metabolism **Setting:** Pediatric ICU **N** = 16 participants	FGM (FreeStyle Libre)	Arterial blood gas analysis, capillary blood analysis, and biochemical serum analysis	• Accuracy • MARD	FGM glucose values were consistently lower compared to the comparator values, with MARD being 28.34%, 25.11%, and 18.99% compared to blood gas analyzer, capillary blood glucose meter, and biochemical serum, respectively.
Sadhu (2020)[8]	**Population:** Critically ill hospitalized patients with COVID-19, receiving insulin therapy **Setting:** ICU **N** = 11 participants	CGM (Dexcom G6 and Medtronic Guardian Connect)	POC blood glucose testing	• Accuracy • MARD • CEG • Bland–Altman plots	Both devices showed acceptable accuracy. Compared to POC blood glucose values, the Medtronic device's MARD was 13.1%, with 100% of readings in zones A and B on the CEG. Dexcom G6 MARD was 11.1%, with 98% of readings in zones A and B. Bland–Altman plots for Medtronic had a mean bias of −17.76 mg/dL and −1.94 mg/dL for Dexcom G6.
Ancona (2017)[9]	**Population:** Critically ill hospitalized patients with diabetes **Setting:** ICU **N** = 8 participants	FGM (FreeStyle Libre)	Arterial or capillary POC blood glucose testing	• Accuracy • MARD • CEG • SEG • ISO • CLSI-POCT	The FGM device showed high test-retest reliability and acceptable accuracy when compared with arterial blood glucose measurement. The MARD was 14%; 64.3% and 56.8% of measurements met ISO and CLSI-POCT criteria, respectively.

First author, year	Study characteristics	Intervention	Comparator	Relevant outcomes assessed	Authors' conclusions
Righy Shinotsuka (2016)[10]	**Population:** Adult patients with blood glucose levels > 150 mg/dL, requiring insertion of an arterial and central venous catheter **Setting:** ICU **N** = 88 participants	CGM (OptiScanner R)	Standard reference method	• Glycemic management (e.g., time spent in target glucose range) • Accuracy • MARD • CEG • ISO	Time in target range was lower in the OptiScanner Group compared to the standard method. Based on a MARD of 7.7%, OptiScanner R had adequate accuracy for use in ICU patients. However, because recent standards for accuracy were not met, the OptiScanner R should not be used as a sole monitor.
Wollersheim (2016)[11]	**Population:** Surgical patients requiring CGM **Setting:** ICU **N** = 20 participants	CGM (Medtronic Sentrino)	Intermittent blood glucose monitoring	• Glycemic variability • Accuracy • MARD • CEG • Bland–Altman plot	Glycemic variability and hyperglycemia negatively impacted accuracy. CGM had less than satisfactory accuracy and feasibility. No reductions in dysglycemic events were observed. However, when CGM was used accurately, it identified more hyperglycemic events than the comparator.
Galindo (2020)[12]	**Population:** Patients with T2D requiring insulin **Setting:** non-ICU (general medicine and surgical wards) **N** = NR	FGM (FreeStyle Libre Pro)	Capillary POC blood glucose testing	• Hypoglycemic events • Mean daily blood glucose • Accuracy • MARD • CEG	FGM showed lower mean daily glucose and higher detection of hypoglycemic events, particularly nocturnal and prolonged hypoglycemia compared to POC testing in hospitalized patients with T2DM. CGM's accuracy was lower in the hypoglycemic range.

First author, year	Study characteristics	Intervention	Comparator	Relevant outcomes assessed	Authors' conclusions
Gomez (2020)[13]	**Population:** Patients with T2D requiring insulin **Setting:** non-ICU (general medicine wards) **N** = 34 participants	CGM	Capillary POC blood glucose testing	• Hypoglycemic events • Glycemic management (e.g., time spent in in target glucose range) • Glycemic variability • Mean daily blood glucose • Accuracy • MARD • CEG	The overall incidence of hypoglycemia detected by CGM is low in hospitalized patients with T2DM. Percentage of time in range increased from 72.1% to 89.4%. Increased glycemic variability and decreased mean glucose were associated with hypoglycemic events (< 70 mg/dL).
Reutrakul (2020)[14]	**Population:** Adult COVID-19–positive patients receiving subcutaneous insulin injection **Setting:** non-ICU **N** = 9 participants	CGM (Dexcom G6)	POC blood glucose testing (Accu-Chek Inform II)	• Glucose variability • Clinical utility • Accuracy • MARD • CEG	CGM and POC blood glucose values correlated well with a MARD of 9.77%. POC glucose tests were reduced to 3 per day, likely reducing PPE use. No adverse events were documented.
Cao (2019)[15]	**Population:** Children with diabetes **Setting:** Hospital **N** = 13 participants	FGM	Venous blood glucose monitoring	• Accuracy • MARD	No statistically significant difference in MARD values between FGM and venous blood glucose monitoring. Overall accuracy of the FGM device was good and stable for 14-day wear. However, accuracy was dependent on glucose level and rates of glucose concentration.

First author, year	Study characteristics	Intervention	Comparator	Relevant outcomes assessed	Authors' conclusions
Levitt (2018)[16]	**Population:** Hospitalized patients with T2DM **Setting:** Hospital **N =** 16 participants	Insulin pump and CGM (3 groups)	Capillary POC blood glucose testing	• Glycemic management (e.g., target glucose range) • Hypoglycemic events	No statistically significant difference was found for total daily dose of insulin and percentage of time spent above or below target glucose range. Although not statistically significant, a greater number of hypoglycemic events were detected by CGM than capillary testing. CGM initiation in hospital was feasible.

CEG = Clarke error grid; CGM = continuous glucose monitoring; CII = continuous insulin infusion; CLSI-POCT = Clinical and Laboratory Standards Institute Point of Care Testing; FGM = flash glucose monitoring; A1C = glycated hemoglobin; ICU = intensive care unit; ISO = International Organization for Standardization; MARD = mean absolute relative difference; N = sample size; NR = not reported; POC = point of care; PPE = personal protective equipment; RCT = randomized controlled trial; SEG = surveillance error grid; SMBG = self-monitoring of blood glucose; T2DM = type 2 diabetes mellitus.

References

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-Analyses

No literature identified.

Randomized Controlled Trials

Non-Intensive Care Unit (ICU) Setting

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3. Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. *BMJ open diabetes res*. 2020 06;8(1):06. PubMed

Non-Randomized Studies

ICU Setting

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Non-ICU Setting

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14. Reutrakul S, Genco M, Salinas H, et al. Feasibility of Inpatient Continuous glucose monitoring During the COVID-19 Pandemic: Early Experience. *Diabetes Care*. 2020 10;43(10):e137-e138. PubMed

15. Cao B, Wang R, Gong C, et al. An Evaluation of the Accuracy of a Flash glucose Monitoring System in Children with Diabetes in comparison with Venous Blood Glucose. *J Diabetes Res*. 2019;2019:4845729. PubMed

16. Levitt DL, Spanakis EK, Ryan KA, Silver KD. Insulin Pump and Continuous Glucose Monitor Initiation in Hospitalized Patients with Type 2 Diabetes Mellitus. *Diabetes Technol Ther*. 2018 01;20(1):32-38. PubMed

Guidelines and Recommendations

17. Galindo RJ, Umpierrez GE, Rushakoff RJ, et al. Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline. *J Diabetes Sci Technol*. 2020 11;14(6):1035-1064. PubMed

Appendix 1: Summary of References for Implementation of CGM and FGM in Acute Care Settings

Four relevant clinical practice guidelines[18-21] and 1 consensus statment[22] were identified regarding the use of continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) systems in managing blood glucose levels among people with diabetes in acute care settings; these resources had unclear or incompletely reported methods and hence were placed in the appendix. One systematic review,[23] 4 non-randomized studies,[24-27] and 1 literature review[28] were identified regarding the facilitators and barriers to the implementation of CGM and FGM systems in the acute care setting.

A guideline from the American Diabetes Association[18] recommends that patients using diabetes devices, such as CGM, should have the ability to use these devices in the inpatient setting when proper supervision is available. Another guideline by the American Diabetes Association[19] stated that CGM has not been approved for inpatient or intensive care unit use; however, CGM is permitted for use in some hospitals with established glucose management teams on an individual basis, if both the patients and the glucose management team are well educated in the use of this technology. A guideline from Diabetes UK[20] recommends that CGM or FGM devices such as FreeStyle Libre can be left on the patient during their hospital visit; however, capillary blood glucose testing will still be necessary. In addition, CGM devices should be removed during MRI exams.[20] According to policies and procedures from the Yale New Haven Hospital system,[21] patients should have their ability to use CGM devices evaluated by the admitting providers; if the patient or their caregiver is capable of using their CGM devices in the hospital and if they are capable of self-management, it was recommended that the data from the CGM device should only be used for the patients' own information. Treatment decisions should be based on hospital POC blood glucose meter results and not CGM values, as CGM is not FDA-approved for inpatient glycemic monitoring or management. Moreover, if surgery is planned, health care providers should collaborate with the patient on the use of their insulin pump and/or CGM in the perioperative period.[21] A consensus statement by the Diabetes Technology Society[22] stated that CGM in the ICU and non-ICU settings would be beneficial for glycemic management and could potentially prevent hypo- or hyperglycemic events. However, more research is needed on the clinical effectiveness and safety of this device. In addition, the panel members unanimously agreed that under certain circumstances, patients using CGM in the outpatient setting should be allowed to continue to use these devices in the hospital setting if proper institutional procedures and guidelines are developed.[22]

A systematic review[23] assessing the clinical benefits and accuracy of CGM systems in patients who were critically ill found that CGM devices seemed safe and may positively affect workload and costs. A non-randomized study[24] aimed to describe the implementation of CGM guidance to reduce the frequency of POC glucose testing in the COVID-19 medical ICU and assess nurses' experience throughout this process. Overall, the authors reported that nurse perception of the accuracy and utility of the devices was high.[24] The authors identified that the majority of barriers to implementation were based on contextual factors such as limitations in the physical environment, complexity of setting up the device, hospital firewalls, the need for education and training, and CGM documentation.[24] The authors concluded that outpatient CGM systems can be implemented in the medical ICU using a hybrid protocol implementation science approach.[24] Another non-randomized study[25] aimed to implement CGM data directly

into the electronic health record (EHR) system. The authors of this study found that it was possible to integrate this CGM data into the EHR to allow for health care providers to receive real-time access to CGM data.[25]

Two studies examined different CGM placement. One non-randomized study aimed to compare the accuracy and performance of CGM use on different patient measurement sites in the operating room. The authors found no statistical significance between the measurement sites; however, they did find that that the success rate of measurement was higher in the thigh than the abdomen. In addition, the authors found that CGM systems had lower accuracy compared to arterial POC testing values. The last non-randomized study[27] aimed to compare subcutaneous CGM to IV CGM use in critically ill patients in the intensive care unit (ICU). The authors found that glucose values between the devices were not highly correlated during surgery or ICU stay.[27]

One review[28] of CGM devices in non-ICU settings found that significant investments may be necessary for training hospital staff and developing the proper infrastructure to support inpatient use of CGM systems. Other limitations to the implementation of CGM in the inpatient setting included potential inaccuracies in glucose measurements, sensor lag, and sensor drift.[28]

Clinical Practice Guidelines and Recommendations — Methodology Not Specified

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See: Inpatient Care

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See: Policy, page 2; Continuous Glucose Monitoring (CGM) Systems, page 4 to 5.

Consensus Statements

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Systematic Reviews and Meta-analyses

No Comparator Specified in Abstract

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Non-Randomized Studies

Implementation Studies

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Alternative Comparator

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Reviews

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Appendix 2: References of Potential Interest

Previous CADTH Reports

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See: 5. Clinical Effectiveness, page 93.

Systematic Reviews

Alternative Comparator

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Alternative Population

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Randomized Controlled Trials

Study Protocol

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