

QUESTION

Should continuation of personal CGM in the inpatient setting vs. discontinuation of CGM be used for people at high risk for hypoglycemia who are already using it?

POPULATION:	inpatients who are already using it
INTERVENTION:	continuation of personal CGM in the inpatient setting
COMPARISON:	discontinuation of CGM
MAIN OUTCOMES:	Hypoglycemia ≤ 70 mg/dl; Severe hypoglycemia; Hypoglycemia ≤ 54 mg/dl; Hemoglobin A1C; Death; Myocardial Infarction; Stroke; Loss of consciousness/Seizure;
SETTING:	Inpatient
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	<p>Endocrine Society conflict of interest management policies were applied and the following panel members were recused as a result of risk of conflicts of interest:</p> <p>Grazia Aleppo</p> <p>During the consensus conference when this question was discussed, it was revealed that a panel member had participated in an advisory board for a relevant company in violation of the COI policy. They were excused from the call and removed from the panel. They did not take place in the voting for this recommendation, but did participate in part of the discussion.</p>

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Hypoglycemia is common in the hospital setting and several studies have demonstrated the detection of hypoglycemia and asymptomatic hypoglycemia by CGM which was missed with traditional point-of-care (POC) testing. Galindo et al. (Diabetes Care, 2020). The overall MARD was 14.8%, ranging between 11.4% and 16.7% for glucose values between 70 and 250 mg/dl and higher for 51-69 mg/dl (MARD 28.0%). The percentages of glucose readings within 15%/15 mg/dL, 20%/20 mg/dL, and 30%/30 mg/dL were 62%,76%, and 91%, respectively. Error grid analysis showed 98.8% of glucose pairs within zones A and B. (1) Gomez et al. (J Diabetes Sci Technol, 2015). No differences in average daily glucose levels were observed between CGM and POC (176.2 \pm 33.9 vs 176.6 \pm 33.7 mg/dl, P = .828). However, CGM detected a higher number of hypoglycemic episodes than POC (55 vs 12, P < .01). Glucose measurements were clinically valid, with 91.9% of patients falling within the Clarke error grid A and B zones. (2)Levitt et al. (Diab Tech & Therapeut, 2018). Group 1 had lower mean capillary glucose levels, 144.5 - 19.5 mg/dl, compared with groups 2 and 3,191.5 - 52.3 and 182.7 - 59.9 mg/dl (P1 vs. 2+3 = 0.05). CGM detected 19 hypoglycemic episodes (glucose<70 mg/dl) among all treatment groups, compared with 12 episodes detected by capillary testing, although not statistically significant. No significant differences were found for the total daily dose of insulin or percentage of time spent below target glucose range (<90 mg/dl), in target glucose range (90-180 mg/dl), or above target glucose range (>180 mg/dl). On the diabetes treatment satisfaction questionnaire-change, group 3 reported increased hyperglycemia and decreased hypoglycemia frequency compared with the other two groups, although the differences did not reach statistical significance. (3)Singh et al. (J Diabetes Sci Technol, 2020). CV % 30.28 vs 27.15. Results from this pilot study suggest a nonstatistically significant trend toward lower hypoglycemia, including nocturnal hypoglycemia, in patients monitored by GTS. This was observed without an increase in hyperglycemia. Based on the observed hypoglycemia event rate, sample size calculation revealed that 270 patients (135 patients in each group) would be necessary to meet 80% power with a P-level of <.05. CGM use in the hospital setting is of increasing interest. The ability to have access to significantly more glucose data could be beneficial as it could prevent hypoglycemic and hyperglycemic excursions. Availability of using alarms for hypoglycemia prevention could lead to increased detection and earlier intervention. (4)</p>	<p>This question was a priority as individual hospitals are currently setting their own protocols regarding continuation of CGM use.</p> <p>Hypoglycemia awareness and prevention of hypoglycemia are important concerns in the inpatient setting.</p> <p>The panel noted that there has been increased use of CGM in inpatient settings, although not currently approved. During COVID-19 pandemic, the use of CGM increased to minimize contact with patients.</p>

Table 2. Primary and Secondary Outcomes^a.

	Intervention (N = 6)	Standard of care (N = 7)	P-value
Hypoglycemic events, N	2	6	NR
Nocturnal hypoglycemic events, N	1	3	NR
Hypoglycemia event rate, N episodes/per patient—per day under CGM	0.07 (±0.11)	0.20 (±0.23)	.31
≥ 1 hypoglycemic event, n (%)	2 (33.33)	4 (57.14)	.60
Patients with blood glucose <54 mg/dL, N (%)	0 (0)	3 (42.86)	.19
Percent of time spent			
<54 mg/dL	0	0.29 (±0.47)	.19
<70 mg/dL	0.30 (±0.39)	2.44 (±3.86)	.54
70-179 mg/dL	64.24 (±14.56)	62.31 (±27.80)	.94
≥180 mg/dL	35.47 (±14.71)	35.25 (±29.38)	.94
>300 mg/dL	3.28 (±5.65)	5.52 (±12.64)	1.00
Percent of nocturnal time spent			
<54 mg/dL	0	1.09 (±1.40)	.24
<70 mg/dL	1.39 (±0)	5.06 (±3.47)	.28
Mean glucose, mg/dL	168.57 (±22.97)	170.54 (±49.68)	1.00
SD, mg/dL	51.53 (±15.66)	44.87 (±8.54)	.53
CV, %	30.28 (±6.67)	27.15 (±5.22)	.73

^aMean (±SD).

Abbreviations: CGM, continuous glucose monitoring; CV, coefficient of variation; Intervention, monitored by GTS (glucose telemetry system); N, number; NR, not reported; Standard of care, monitored by point-of-care blood glucose.

Gu et al. (Diabetes Metab, 2017). When data from 81 patients (40 SAP, 41 MDI) were analysed, 21 patients using SAP therapy, compared with six using MDI therapy, achieved their glycaemic targets within 3 days, and their time to reach their glucose targets was significantly shorter (3.7±1.1 vs 6.3±3.1 days for MDI; P<0.001), while three MDI patients failed to reach glycaemic targets within 14 days. SAP vs MDI patients experienced significantly less hypoglycaemia [sensor glucose<50mg/dL (2.8mmol/L): 0.04% vs 0.32%, respectively; P<0.05] and significantly less hyperglycaemia [sensor glucose>180mg/dL (10mmol/L): 21.56% vs 35.03%, respectively; P<0.05]. (5)

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS																				
<ul style="list-style-type: none"> <input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>No research evidence identified</p> <p>Indirect Evidence from Q8:</p> <table border="1"> <thead> <tr> <th rowspan="2">Outcomes</th> <th rowspan="2">No of participants (studies) Follow-up</th> <th rowspan="2">Certainty of the evidence (GRADE)</th> <th rowspan="2">Relative effect (95% CI)</th> <th colspan="2">Anticipated absolute effects* (95% CI)</th> </tr> <tr> <th>Risk with not using CGM in the inpatient setting</th> <th>Risk difference with initiation of CGM in the inpatient setting</th> </tr> </thead> <tbody> <tr> <td>Episodes of hypoglycemia ≤70 mg/dl follow-up: 5 days</td> <td>0 (3 RCTs)</td> <td>⊕○○○ Very low^{a,b,c}</td> <td>-</td> <td colspan="2">We did not find a significant difference between the intervention group and control (IRR = 0.73; 95% CI: 0.20 to 2.72; I2= 73.00%).</td> </tr> <tr> <td>Patients with hypoglycemia ≤54 mg/dl</td> <td>13 (1 RCT)</td> <td>⊕○○○ Very low^{c,d}</td> <td>OR 0.10 (0.00 to 2.42)</td> <td colspan="2">Study population</td> </tr> </tbody> </table>	Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)		Risk with not using CGM in the inpatient setting	Risk difference with initiation of CGM in the inpatient setting	Episodes of hypoglycemia ≤70 mg/dl follow-up: 5 days	0 (3 RCTs)	⊕○○○ Very low ^{a,b,c}	-	We did not find a significant difference between the intervention group and control (IRR = 0.73; 95% CI: 0.20 to 2.72; I2= 73.00%).		Patients with hypoglycemia ≤54 mg/dl	13 (1 RCT)	⊕○○○ Very low ^{c,d}	OR 0.10 (0.00 to 2.42)	Study population		<p>Patients already using it would be at higher risk of hypoglycemia, therefore the anticipated absolute effects may be larger, but there was not any direct evidence.</p> <p>Inherently, more data points from CGM would help with predicting or detecting hypoglycemia.</p> <p>Patient / family satisfaction likely enhanced when personal CGM allowed to continue in the inpatient setting.</p>
Outcomes	No of participants (studies) Follow-up					Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)														
		Risk with not using CGM in the inpatient setting	Risk difference with initiation of CGM in the inpatient setting																			
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Patients with hypoglycemia ≤54 mg/dl	13 (1 RCT)	⊕○○○ Very low ^{c,d}	OR 0.10 (0.00 to 2.42)	Study population																		

				429 per 1,000	359 fewer per 1,000 (429 fewer to 216 more)
Episodes of hypoglycemia <54 mg/dL	0 (1 RCT)	⊕⊕⊕⊕ Moderate ^e	-	There were fewer events in the intervention groups compared with control (IRR = 0.11; 95% CI: 0.03 to 0.37; I2= N/A)	
Time below range (<54mg/dL) follow-up: 14 days	153 (2 RCTs)	⊕⊕⊕⊕ Moderate ^f	-	The mean time below range (<54mg/dL) was 0 % of time spent	MD 0.57 % of time spent fewer (1.02 fewer to 0.11 fewer)
Time below range (<70 mg/dL) follow-up: 14 days	247 (3 RCTs)	⊕○○○ Very low ^{g,h,i}	-	The mean time below range (<70 mg/dL) was 0 % of time spent	MD 0.89 % of time spent fewer (2.32 fewer to 0.55 more)
Time in range (70-180 mg/dL) follow-up: 7 days	101 (3 RCTs)	⊕○○○ Very low ^{c,g}	-	The mean time in range (70-180 mg/dL) was 0 % of time spent	MD 4.06 % of time spent more (5.79 fewer to 13.91 more)
Hemoglobin A1C - not reported	-	-	-	-	-
Death - not reported	-	-	-	-	-
Myocardial Infarction - not reported	-	-	-	-	-
Stroke - not reported	-	-	-	-	-
Severe hypoglycemia - not reported	-	-	-	-	-
Loss of consciousness/Seizure - not reported	-	-	-	-	-

- a. Serious concerns about risk of bias because 2 trials are at high risk of bias and 1 raises some concerns.
- b. Serious concerns about inconsistency due to a substantially large I2 estimate that is unlikely explained by chance (p=0.02) and no overlap of CI of 2 studies. One possible source of heterogeneity is the comparator group in Levitt, 2018 (unblinded CGM vs blinded CGM).
- c. Very serious imprecision due to a very wide CI that has appreciable benefits and harms.
- d. Serious concerns about risk of bias due to an overall high risk of bias in the trial.
- e. A single small study.
- f. Serious concerns about risk of bias due to multiple issues with reporting.
- g. Serious concern about risk of bias because 2 trials are at overall high risk of bias.
- h. Serious concern about inconsistency due to a substantially large I2 estimate that is unlikely explained by chance (p=0.01) and poor overlap of CI- between 2 studies.
- i. Serious concern about imprecision due to wide CI that has benefits and harms.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

RESEARCH EVIDENCE

ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>No research evidence identified.</p>	<p>Panel noted accuracy as a concern, with false positives and false negatives (e.g. in patients with transfusions, etc.), and site of measurement as a factor in accuracy (e.g. ischemic limb). Hospital metrics/issues for using CGM accurately. Criteria for patient eligibility to continue CGM necessary, as well as validation patient's CGM device is in good working order.</p> <p>Variable undesirable effects/concerns about accuracy depending on the patient: trivial concerns in some and small in others. Panel noted lack of data to make a judgement.</p> <p>Accuracy concerns can be overcome by validating CGM for each patient with POC checks. Before treating hypoglycemia would want POC confirmation to confirm it. Not intended to be used for dosing without POC confirmation.</p>
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Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>No research evidence identified</p>	<p>There was indirectness of evidence and uncertainty about absolute effects. The panel discussed that we do not know for sure whether continuation of CGM would be better/worse in this patient population if direct evidence was available.</p>

Values
Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input checked="" type="radio"/> Probably no important uncertainty or variability <input type="radio"/> No important uncertainty or variability 	<p>Patients value reductions in hypoglycemia, including in the hospital setting. Gomez et al. (J Diabetes Sci Technol, 2015). Our preliminary results indicate that the use of CGM in type 2 patients hospitalized in the general ward provides accurate estimation of blood sugar levels and is more effective than POC for the detection of hypoglycemic episodes and asymptomatic hypoglycemia (2). Singh et al. (J Diabetes Sci Technol, 2020). Half of the hypoglycemic episodes occurred overnight. POC BGM usually performed infrequently, at most four to six times per day and rarely overnight. This highlights an important benefit of RT-CGM as it decreases the interval of time glucoses are unmonitored, leading to decreased risk of undetected hypoglycemia (4).</p> <p>Singh et al. (Diabetes Care, 2020). RT-CGM/GTS can decrease hypoglycemia among hospitalized high-risk insulin treated patients with type 2 diabetes (6).</p> <p>Gu et al. (J Diabetes Sci Technol, 2015). Compared with POC, FreeStyle Libre CGM showed lower mean daily glucose and higher detection of hypoglycemic events, particularly nocturnal and prolonged hypoglycemia in hospitalized patients with T2D. CGM's accuracy was lower in the hypoglycemic range (5).</p> <p>Levitt et al. (Diab Tech & Therapeut, 2018). Diabetes treatment satisfaction questionnaire change (DTSQc) - results are reported on a scale from -3 to +3, with negative numbers corresponding to dissatisfaction and positive numbers corresponding to satisfaction. Subjects from all three groups reported equivalent treatment convenience. Although not achieving statistical significance, groups 2 and 3 were less likely to want to continue their current treatment compared with group 1 (3).</p>	<p>The panel discussed that patients in general are wanting to continue use of their CGM, stay in good control, and participate in staying in control.</p> <p>It was viewed as important to keep patients with diabetes (and / or their families) feel in control during hospitalization.</p>

Balance of effects
Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favors the comparison <input type="radio"/> Probably favors the comparison <input type="radio"/> Does not favor either the intervention or the comparison <input checked="" type="radio"/> Probably favors the intervention <input type="radio"/> Favors the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 		Based on indirect evidence, with moderate desirable effects and small undesirable effects.

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Large costs <input type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>There are significant costs to consider with respect to use of inpatient CGM (including cost of technology itself, costs of integration into electronic medical record and costs of training staff). However, these costs may be offset by reductions in hospital length of stay and reductions in hypoglycemia. More study is needed in this regard.Galindo et al. (<i>Diabetes Care</i>, 2020). POC BGM is labor intensive, costly, and prone to errors and mismatched measurements. There is a need for an improved method to monitor glycemic control in the hospital setting. CGM utilization has expanded significantly (1). Gomez et al. (<i>J Diabetes Sci Technol</i>, 2015). The use of this technology has generated concern because of its high cost and because data on its accuracy and safety in inpatients are limited; therefore, its use is not currently recommended by international guidelines. The present results provide a basis for further investigation (2). Levitt et al. (<i>Diab Tech & Therapeut</i>, 2018). Nurses were extensively counseled on CGM calibration and troubleshooting by study investigators (3). Singh et al. (<i>J Diabetes Sci Technol</i>, 2020). Important to explore novel methods of inpatient glucose monitoring. Costs related to CGM devices and supplies are another practical limitation to CGM use in the hospital (4). Singh et al. (<i>Diabetes Care</i>, 2020). Cost of training nursing staff on GTS and providing technical support as needed, selecting a commercially available internet network with consistent signal to ensure minimal interruption in glucose transmission between iPhone and iPad, and securing the devices with an antitheft iPad case at the nursing station and a locked safe box wired to a permanently affixed object at the bedside (6). Gu et al. (<i>Diabetes Metab</i> 2017). SAP vs MDI therapy in hospitalized patients with T2DM significantly reduced the time required to achieve glycaemic targets, and such systems may be a cost-effective way to improve glucose control and reduce hospital stays in T2DM patients. While the study did not include a cost-effectiveness analysis of SAP and MDI therapies in hospitalized patients, the approach described here can reduce hospital stays, decrease medical service fees and/or the labour force (physicians, healthcare providers, other hospital staff) associated with hospitalization, while increasing the number of available hospital beds; thereby reducing overall medical costs for both hospitals and patients (5).</p>	<p>Resource use was less of a concern as patients are already trained in use of the device, and are bringing in own device. Patients are asked to sign a document for continued use.</p> <p>The panel noted there are still resource requirements for staff resources, training (e.g. skin assessments, cleaning of wands, where battery located, etc.). There are resources involved in ensuring competency of use. Without standardized use of CGM, resource use may be significant (EMR documentation for CGM data vs. lab, etc.).</p> <p>The panel noted there may be potential savings with reduced hypoglycemia, length of stay, not having staffing for finger prick tests, etc., but the resource requirements were unknown.</p> <p>Resource requirements were still considered large because of the hospital needs, but less than initiation of in-hospital CGM as patients are bringing in their own devices.</p>

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 		

Cost effectiveness
Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favors the comparison <input type="radio"/> Probably favors the comparison <input type="radio"/> Does not favor either the intervention or the comparison <input type="radio"/> Probably favors the intervention <input type="radio"/> Favors the intervention <input type="radio"/> Varies <input checked="" type="radio"/> No included studies 	No research evidence identified	

Equity
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	No research evidence identified	<p>In this question, patients are already using CGM; also affects equal access.</p> <p>Panel noted that the impact on health equity was not known for this intervention. Depending on setting and resources, in terms of costs as well as staffing/training (e.g. community hospital vs. academic centers).</p>

Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	No research evidence identified	<p>Use of CGM provides more data points for healthcare providers, to use as checking of trends, including at night and therefore the intervention is probably acceptable.</p> <p>For patients during sleep, CGM was viewed as more acceptable.</p> <p>Reducing nurse workload, as well as exposure to patients with potentially infectious diseases (i.e. during COVID).</p> <p>Some hospitals are already using inpatient CGM, despite no FDA approval yet. (Emergency Use Authorization, due to COVID-19)</p> <p>Staff trust of the device/CGM result, e.g. whether reliable measurement, was highlighted as a consideration for acceptability.</p> <p>Given current situation/setting, it is acceptable for hospitals, but barriers must be overcome (i.e. resources invested).</p>

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Insulin pump and CGM initiation are feasible during hospitalization, although they are labor intensive. Levitt et al. (Diab Tech & Therapeut, 2018). Insulin pump and CGM initiation are feasible during hospitalization, although they are labor intensive. Diabetes treatment satisfaction questionnaire change (DTSQc) - results are reported on a scale from -3 to +3, with negative numbers corresponding to dissatisfaction and positive numbers corresponding to satisfaction. Subjects from all three groups reported equivalent treatment convenience. There were trends toward group 3 feeling as if they were spending more time hyperglycemic than with their home treatment regimen compared with groups 1 and 2. The lower satisfaction noted in groups 2 and 3 may be due to the difficulty of initiating an insulin pump and/or CGM device during hospitalization and associated frequent alarms (11 pump alarms and 25 CGM alarms; Table 3). These alarms occurred in the context of hospitalized patients with multiple comorbidities, diagnostic testing, and other disruptions, likely contributing to alarm fatigue (3).</p>	<p>For patients, there is required knowledge about use of device. Similar to insulin pump issue, hospitals may need policy with criteria about continuation of use of CGM.</p> <p>Assessment of capability is critical to successful continued use in the inpatient setting. Providers must incorporate evaluation of patient, however, there is a feasibility concern about completing the assessments for all patients given the volume of patients that would be using CGM. For patients coming in with own CGM, there is a need to ensure it is working.</p> <p>Hospitals do not have the supplies for patients' own CGM. For those who run out of supplies in emergent situation, hospital would not be able to provide them. There are also certain situations (e.g. MRI) that would have contraindication for use. Each CGM also has a time period over which patients need to test again after removal, which would impact acceptability.</p> <p>With respect to logistics, each hospital must be able to record data from CGM for use of the data. There may need to be integration with EMR as well.</p> <p>For CGM with closed loop systems, these are not integrated into the hospital system for auto stop/suspend mode. This makes it challenging for writing/changing orders. Hospitals need a policy for this.</p> <p>It is feasible to implement CGM in patients at high risk of hypoglycemia if there is a willingness to spend the funds on infrastructure, training, etc. The responsibility would fall to health care providers who would have to be trained in proper techniques for inserting CGM and understanding how to interpret the data. Because of issues such as lag time, compression hypoglycemia, etc. CGM in hospital would likely be used to trend glucose data and detect impending hypoglycemia. Validation of CGM accuracy currently needs to be corroborated for each patient against POC glucose measurements. Clinical decisions may require confirmation with POC glucose measurement.</p>

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know

CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

We suggest continuation of personal CGM in the inpatient setting rather than discontinuation for inpatients who are already using personal CGM. (conditional recommendation, very low certainty of evidence) (2@○○○)

Remarks:

- Inpatient CGM use is not currently FDA-approved, but has an exemption due to the COVID-19 pandemic.

Justification

The balance of effects probably favors continuation of CGM use in the inpatient setting for patients who are already using personal CGM, based on very low certainty and indirect evidence. The panel placed high value on acceptability by healthcare providers and patients. Although resource requirements may be large, cost-effectiveness was not known (e.g. considering potential savings). CGM is becoming standard of care for pediatric type 1 diabetes in the ambulatory setting in many areas. Patients and their families rely on CGM to feel safe, particularly at night. Patient/family dissatisfaction with discontinuing a pre-existing CGM already in use in the ambulatory setting was therefore taken into account by the panel. The panel also notes that during the COVID-19 pandemic, the use of CGM increased to minimize contact with patients and reduce sleep interruption.

Subgroup considerations

There are many patient considerations that would not be appropriate for continuing CGM, including decreased mentation of patient and ability / willingness to follow hospital CGM protocols, patients undergoing MRI, diminished perfusion, patients on vasopressors, for example. Clinicians must consider substances known to interfere with CGM accuracy - including high-dose vitamin C and hydroxyurea. Patients with extremes of both hyper- and hypoglycemia should have their CGM result corroborated with POC blood glucose checks.

Implementation considerations

Significant resources are needed to implement continued use of CGM in the hospital setting. Protocols, education, integration into EHR need to reinforce several crucial aspects, including:

- Appropriate patient selection
- Identification and documentation of pre-existing CGM, and presence or absence of a subcutaneous insulin pump.
- Verification that CGM is in working order
- Clear guidance for use of CGM values, emphasizing that CGM is to be used as an early warning device and trend indicator, rather than a definitive value to base treatment changes on.
- Delineation of roles and responsibilities of patient, nurse, physician, pharmacy, and subject matter experts familiar with CGM.
- Guidance on how / where to document CGM findings, in an area distinct from laboratory / POC BG readings.
- Guidance for when to involve a physician, consult a CGM expert, and when verification of CGM readings is indicated.
- Order sets allowing for appropriate use of CGM
- Nursing / healthcare provider education about the different types of devices patients may bring in (e.g., CGMs with and without alarms).
- The panel recognizes that the implementation burden is significant. However, implementation and expense are less for continuing pre-existing CGM than for initiating new CGM in the hospital setting.

Monitoring and evaluation

Hospital teams need to monitor future changes and FDA approval for inpatient CGM use (currently has Emergency Use Authorization during COVID-19 pandemic). Hypoglycemia ADEs and incident reports involving CGMS and / or insulin pumps are needed. Patient / provider comfort and satisfaction with continuing personal CGM in the inpatient setting should be monitored as well.

Research priorities

Research evidence specifically on patient selection is needed (e.g. those who would benefit most/not benefit).

The panel notes that there is a lack of direct RCT evidence for this intervention, but recruitment for RCTs may be problematic, given the concerns for patients already using CGM not willing to discontinue. Implementation studies and cost-effectiveness studies should be a priority.

REFERENCES SUMMARY

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