QUESTION

Should initiation of CGM in the inpatient setting vs. not using CGM be used for select people at high risk for hypoglycemia?	
POPULATION:	select people at high risk for hypoglycemia
INTERVENTION:	initiation of CGM in the inpatient setting
COMPARISON:	not using CGM
MAIN OUTCOMES:	Episodes of hypoglycemia ≤70 mg/dl; Patients with hypoglycemia ≤54 mg/dl; Episodes of hypoglycemia <54 mg/dL; Time below range (<54mg/dL); Time below range (<70 mg/dL); Time in range (70-180 mg/dL); Hemoglobin A1C; Death; Myocardial Infarction; Stroke; Severe hypoglycemia; Loss of consciousness/Seizure;
SETTING:	Inpatient
PERSPECTIVE:	Clinical recommendation - Population perspective
BACKGROUND:	In several situations, particularly ICU patients for COVID-19 there is a need to monitor patients who have diabetes or become diabetic because of the underlying COVID-19 and a need to protect care givers and minimize risk of viral spread. CGM is a very useful tool for this situation. It is being used frequently in some hospitals to minimize and clarify the need for fingerstick glucose testing and it has an advantage in these unstable cases to anticipate insulin needs using trend arrows.
CONFLICT OF INTERESTS:	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: Grazia Aleppo

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**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 ± 33.9 vs 176.6 ± 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)	The panel noted that there has been increased use of CGM in inpatient settings, although not currently approved. There is a current EUA for CGM during COVID pandemic. During COVID-19 pandemic, the use of CGM increased to minimize contact with patients. Prevention of hypoglycemia in the inpatient setting is a priority.

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

[a]Mean (±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

- ○ Trivial
- ○ Small
- ● Moderate
- ○ Large
- ○ Varies
- ○ Don't know

RESEARCH EVIDENCE

Outcomes	№ 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	

ADDITIONAL CONSIDERATIONS

Panel noted some indications of improvement based on ability to detect hypoglycemia and improved time in range outcomes.

Studies focused on time in range/control versus capturing hypoglycemia outcomes. Few events and very imprecise effect estimates.

Noted that the studies are not capturing the true value of use in the inpatient setting, which is identifying changing values (BG trends) and alerts.

Note to SR team: *Fill out no. of participants for IRR outcomes in SoF.*

Methods: Check consistency in judgement of moderate for effect sizes.

				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

- ○ Large
- ○ Moderate
- ● Small
- ○ Trivial
- ○ Varies
- ○ Don't know

RESEARCH EVIDENCE

Outcomes	№ 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	
				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	-	-	-	-	-

ADDITIONAL CONSIDERATIONS

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.

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.

Accuracy concerns can be overcome by validating CGM for each patient with POC checks.

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).
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i. Serious concern about imprecision due to wide CI that has benefits and harms.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies		

Values

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	**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). **Singh et al. (Diabetes Care, 2020).** RT-CGM/GTS can decrease hypoglycemia among hospitalized high-risk insulin treated patients with type 2 diabetes (6). **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).	

Balance of effects

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ 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

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	**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. (Diabetes Care, 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. (J Diabetes Sci Technol, 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. (Diab Tech & Therapeut, 2018).** Nurses were extensively counseled on CGM calibration and troubleshooting by study investigators (3). **Singh et al. (J Diabetes Sci Technol, 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. (Diabetes Care, 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. (Diabetes Metab 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).	Offset in costs through savings of reduced hypoglycemia events/length of stay, but there was uncertainty about this. Cost of integration into EMR a major cost here. Subscribing to data aggregator as well. For individual patient care, CGM equipment results in less use of hospital equipment. Less nursing /medical assistant time required for BG checks.

Certainty of evidence of required resources

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Very low ● Low ○ Moderate ○ High ○ No included studies		

Cost effectiveness

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ 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	No research evidence identified	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	No research evidence identified	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).

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	No research evidence identified	Reducing nurse workload, as well as exposure to patients with potentially infectious diseases (i.e. during COVID). Some hospitals are already using inpatient CGM, despite no FDA approval yet. (Emergency Use Authorization, due to COVID-19) Staff trust of the device/CGM result, e.g. whether reliable measurement, was highlighted as a consideration for acceptability. For patients, complexity of adding an additional device during hospitalization, which would be handled by nurses. However, CGM versus use of lancing device (for finger sticks) may be more acceptable. CGM would result in less disruption to patients during sleep. Alerts and alarms, especially warning trends for hypoglycemia as well as data collection for healthcare providers.

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**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).	Current CGM devices are difficult to connect to hospital electronic medical records (EMR). Much work being done in the field to allow hospitals to adopt these and integrate into their own systems. Closed loop, smart pumps, depend on accurate CGM. Integrated systems. 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.

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
○	○	○	●	○

CONCLUSIONS

Recommendation

We suggest initiation of CGM in the inpatient setting for select inpatients at high risk for hypoglycemia. (conditional recommendation, very low certainty of evidence) (2⊕◯◯◯)

Remark:

- This should be done via a hybrid approach where CGM use is combined with periodic POC-BG testing to validate the accuracy of CGM on a continuous basis
- Inpatient CGM use is not currently FDA-approved, but currently has enforcement discretion. It has been extensively used in hospitals recently due to Emergency Use Authorization during the COVID-19 pandemic.

Justification

The balance of effects probably favors CGM use in the inpatient setting for select patients at high risk for hypoglycemia, based on very low certainty evidence. The panel placed high value on acceptability by healthcare providers and patients. Although resource requirements may be large, impact on improved resource utilization and cost-effectiveness was not known (e.g. considering potential savings).

Subgroup considerations

There are patients that may not be appropriate for inpatient CGM use due to concerns regarding CGM accuracy. These would include vasoconstricted patients (including those that are severely dehydrated, volume depleted, or requiring vasopressor therapy); patients that are edematous or with anasarca; patients with diabetic ketoacidosis. Patients must also be willing and able to follow hospital CGM protocols. 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.

There are also patients that would especially benefit from the initiation of inpatient CGM – this includes those with hypoglycemia unawareness, renal failure, that are elderly, that have T1DM; also patients requiring enteral feeding with hyperglycemia, steroid-related hyperglycemia.

Implementation considerations

Different CGM devices are available. Differentiate from having a formulary with one device only. If patient already has CGM at home, could have access to their data from outpatient setting. Having a system to integrate all of the apps/companies to have data available in the inpatient setting regardless of device, and linkage to EHR system to have access to data. Recommendation focus is on inpatient setting, whether to use CGM for inpatient management/hospital care. Not necessarily going to continue with CGM use after discharge (not the focus of this question).

There are significant resources needed to implement use of CGM in the hospital setting. Protocols, education, and integration into EHR are all necessary for implementation. The panel identified the following as necessary aspects of CGM implementation:

- Appropriate patient selection
- Identification and documentation of presence or absence of a subcutaneous insulin pump.
- 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 on which to base treatment changes.
- 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.

Monitoring and evaluation

Monitoring of FDA approval of CGM devices in the hospital setting. Currently has Emergency Use Authorization during COVID-19 pandemic.

Research priorities

New research evidence will become available from studies conducted during COVID-19 pandemic.

Research evidence specifically on patient selection is needed, to inform definition of inpatients at high risk of hypoglycemia.

Research evidence on whether or not inpatient CGM should be used for dosing insulin is a priority.

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