QUESTION

Should inpatient glycemic surveillance and management programs leveraging EHR data vs. standard care be used for hospitalized people at risk for hypoglycemia?	
POPULATION:	hospitalized people at risk for hypoglycemia
INTERVENTION:	inpatient glycemic surveillance and management programs leveraging EHR data
COMPARISON:	standard care
MAIN OUTCOMES:	Patients with hypoglycemia ≤70 mg/dl; Episodes of hypoglycemia <70 mg/dl; Hypoglycemia (≤70 mg/dl) – episodes per patient; Hypoglycemia (≤54 mg/dl) – episodes - randomized controlled trial; Hypoglycemia (≤54 mg/dl) – episodes - observational study; Severe hypoglycemia; Time in range (60 - 180 mg/dl); Death; Hemoglobin A1C; Myocardial Infarction; Stroke; Loss of consciousness/Seizure;
SETTING:	Inpatient
PERSPECTIVE:	Clinical recommendation - Population perspective
BACKGROUND:	Hypoglycemia in hospitalized patients with diabetes is a significant problem leading to morbidity, longer hospital stays and higher health care costs. Inpatient glycemic surveillance and programs that utilize electronic health record data may be used to reduce the risk for inpatient hypoglycemia in those at risk (both with and without diabetes) and should be considered given potential benefits.
CONFLICT OF INTERESTS:	None Note: No financial COI. Panel members have been involved in building programs leveraging EHR data within their institutions. Have published on the experiences.

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Uncontrolled diabetes in hospitals is a significant problem, and both hyperglycemia and hypoglycemia are very common. Hypoglycemia in the hospital is likely to extend hospital stays and prevent safe discharge.** Several studies indicate that hypoglycemia is dangerous, costly and associated with adverse outcomes, increase length of stay and poor recovery and mortality risk (1, 2, 3, 4). Therefore, this is a very high priority problem.	Patients at risk for hypoglycemia, including those without diabetes, are the subjects where this question is indicated. Patients who are admitted to the hospital often have impaired hypoglycemia awareness (4). Medical conditions that have the potential to compromise glucose counter-regulation and hypoglycemia awareness increase the risk for hypoglycemia in hospitalized patients, independently of their diabetes status. Hospitalized patients may have the worse outcomes in relation to hypoglycemia and hypoglycemia risks. However, these findings may not be fully captured in research studies. Management systems leveraging electronic health record data have advanced and become more sophisticated and enable the providers to detect hypoglycemia and monitoring it in real-time using various flowsheets. In view of the increasing concerns for patient safety due to hypoglycemia this is a priority question. There is great variability in the available management systems based on EHRs in different health care systems, with great variability of quality between products. The Centers for Medicaid and Medicare (CMS) will include hypo- and hyperglycemia as a priority quality measure in the inpatient setting beginning in 2023. Reporting will start in 2022 and will be a requirement in 2023 with possible consequences such as financial penalties for institutions where there are excessive hypo- and hyperglycemia rates.

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● Moderate ○ Large ○ Varies ○ Don't know		The panel highlighted that CMS has made hypo- and hyperglycemia a priority quality measure in the inpatient setting, with <40 mg/dl as the cut-off, for patients who are on insulin who have hypoglycemia. This creates an issue for determining the size of desirable effects, in particular based on the other cut-offs (e.g. <70 mg/dl and <54 mg/dl). The panel discussed that most systems use <40mg as criterion for severe hypoglycemia for inpatients, which will be a changed metric with CMS as noted above. The literature data reviewed reveals the heterogeneity of inpatient glycemic management programs leveraging EHR data making comparison between them not feasible.

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with standard care	Risk difference with inpatient glycemic management programs leveraging EHR data
Patients with hypoglycemia ≤70 mg/dl	4401 (5 observational studies)	⨁⨁◯◯ LOW [a]	**OR 0.55** (0.39 to 0.77)	Study population	

				188 per 1,000	**75 fewer per 1,000** (105 fewer to 37 fewer)	Additional studies that were identified did not have a control group and were excluded from the meta-analysis.
Episodes of hypoglycemia <70 mg/dl	0 (2 observational studies)	⨁◯◯◯ VERY LOW [b,c]	-	We did not find a difference between the intervention group and control (OR: 0.11; 95% CI: 0.01 to 1.98; I2 = 73.18%).		
Hypoglycemia (≤70 mg/dl) – episodes per patient	54 (1 observational study)	⨁◯◯◯ VERY LOW [d,e]	-	The mean hypoglycemia (≤70 mg/dl) – episodes per patient was **0** episodes per patient	MD **0.4 episodes per patient fewer** (0.79 fewer to 0.01 fewer)	
Hypoglycemia (≤54 mg/dl) – episodes - randomized controlled trial	0 (1 RCT)	⨁◯◯◯ VERY LOW [c,f]	-	We did not find a difference between the intervention group and control (OR: 2.00; 95% CI: 0.18 to 22.46; I2 = N/A).		
Hypoglycemia (≤54 mg/dl) – episodes - observational study	0 (1 observational study)	⨁◯◯◯ VERY LOW [b,c]	-	We did not find a difference between the intervention group and control (OR: 0.30; 95% CI: 0.01 to 7.35; I2 = N/A).		
Severe hypoglycemia	4716 (3 observational studies)	⨁◯◯◯ VERY LOW [g]	**OR 0.11** (0.03 to 0.34)	Study population		
				33 per 1,000	**30 fewer per 1,000** (32 fewer to 22 fewer)	
Time in range (60 - 180 mg/dl)	179 (1 RCT)	⨁⨁⨁◯ MODERATE [f]	-	The mean time in range (60 - 180 mg/dl) was **0** % of time spent in range	MD **3.3 % of time spent in range more** (3.22 more to 3.38 more)	
Death	214 (1 observational study)	⨁◯◯◯ VERY LOW [b,c]	**OR 3.00** (0.31 to 29.30)	Study population		
				9 per 1,000	**18 more per 1,000** (6 fewer to 209 more)	
Hypoglycemia ≤54 mg/dl - not reported	-	-	-	**-**	**-**	
Hemoglobin A1C - not reported	-	-	-	**-**	**-**	
Myocardial Infarction - not reported	-	-	-	**-**	**-**	
Stroke - not reported	-	-	-	**-**	**-**	
Loss of consciousness/Seizure - not reported	-	-	-	**-**	**-**	

a. 4 studies at high risk of bias and majority of evidence is not randomized.
b. Concerns about comparability of one of the studies.
c. Very serious concerns about imprecision due to very wide CI that includes substantial benefits and harms.
d. Serious concerns about adequacy and length of follow-up.
e. Small sample size.
f. Serious concerns about the random sequence generation, deviations from intended interventions, selective reporting, and other source of bias.
g. 2 studies at high risk of bias.

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 standard care	Risk difference with inpatient glycemic management programs leveraging EHR data
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Hypoglycemia (≤54 mg/dl) – episodes - randomized controlled trial	0 (1 RCT)	⨁◯◯◯ VERY LOW [c,f]	-	We did not find a difference between the intervention group and control (OR: 2.00; 95% CI: 0.18 to 22.46; I2 = N/A).	
Hypoglycemia (≤54 mg/dl) – episodes - observational study	0 (1 observational study)	⨁◯◯◯ VERY LOW [b,c]	-	We did not find a difference between the intervention group and control (OR: 0.30; 95% CI: 0.01 to 7.35; I2 = N/A).	
Severe hypoglycemia	4716 (3 observational studies)	⨁◯◯◯ VERY LOW [g]	**OR 0.11** (0.03 to 0.34)	Study population	
				33 per 1,000	**30 fewer per 1,000** (32 fewer to 22 fewer)

ADDITIONAL CONSIDERATIONS

The panel noted that due to the prevalence of very few events reported, there is serious imprecision regarding determining mortality and other undesirable outcomes. Therefore, there is very low certainty regarding undesirable effects.

Given the low event rate, a high value cannot be assigned to these undesirable outcomes.

Time in range (60 - 180 mg/dl)	179 (1 RCT)	⨁⨁⨁◯ MODERATE [f]	-	The mean time in range (60 - 180 mg/dl) was **0** % of time spent in range	MD **3.3 % of time spent in range more** (3.22 more to 3.38 more)
Death	214 (1 observational study)	⨁◯◯◯ VERY LOW [b,c]	**OR 3.00** (0.31 to 29.30)	Study population	
				9 per 1,000	**18 more per 1,000** (6 fewer to 209 more)
Hypoglycemia ≤54 mg/dl - not reported	-	-	-	**-**	**-**
Hemoglobin A1C - not reported	-	-	-	**-**	**-**
Myocardial Infarction - not reported	-	-	-	**-**	**-**
Stroke - not reported	-	-	-	**-**	**-**
Loss of consciousness/Seizure - not reported	-	-	-	**-**	**-**

a. 4 studies at high risk of bias and majority of evidence is not randomized.
b. Concerns about comparability of one of the studies.
c. Very serious concerns about imprecision due to very wide CI that includes substantial benefits and harms.
d. Serious concerns about adequacy and length of follow-up.
e. Small sample size.
f. Serious concerns about the random sequence generation, deviations from intended interventions, selective reporting, and other source of bias.
g. 2 studies at high risk of bias.

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		The certainty of evidence for these outcomes was very low, with a high degree of imprecision and concerns for risk of bias. There will likely be a substantial difference in literature pre-COVID compared to post-COVID. In the COVID period, the FDA allowed the expanded use of continuous glucose monitoring (CGM) in the inpatient setting which has generated substantial literature on the application of this tool to hospitalized patients with COVID infection. Most of the literature published has been generated from academic centers where the use of CGM in hospitalized patients was implemented early with a variety of protocols.

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 and providers in the hospital (where insulin is generally the preferred treatment) are fearful of iatrogenic hypoglycemia, and value its reduction.** Extreme lability of glycemia is common in hospitalized insulin-treated patients. Frequent monitoring and finger sticks may increase diabetes stress. Insulin is used in general wards as well as in the ICUs (5). Longer stays are common and unwelcome (6).	The inpatient setting includes a very heterogenous population at risk of hypoglycemia, whether recently diagnosed with hypoglycemia or acutely ill (incapacitated patients). There are no differences in the values placed on the avoidance of hypoglycemia and its complications across patient types.

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		NOTE: ADD what is INT in remaining questions.

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	**The resources required to reduce hypoglycemia via an inpatient glycemic management program are high.** EHR-linked insulin treatment in the hospital is time consuming, burdens staff and is costly (7). **Inpatient hypoglycemia is very common as patients may have not finished eating due to limited food availability, need to go to procedures (e.g., x-ray), and additional staff may be needed to prevent or treat hypoglycemia. Systematic care limits some these problems. Resources and staff may not always be optimal** Systematic EHR-linked insulin treatment may cost many thousands of dollars for set up and require significant time for training staff (months). Costs and time needed will depend on what system is used and how comprehensive it is (8). Cardona et al. set up a glucommander post CABG and estimated costs. Cost saved was $3654 per patient (9).	Resource use for an effective glycemic management system may result in savings by reducing complications and reducing length of stay during a hospital admission. The panel recognized the high costs and resources for initial systems setup, including time required for training and education for the major stake holders in the hospital. The panel noted that although there is probability of downstream potential savings, there remains uncertainty as to the number of patients need to be treated to achieve these savings. However, if the intervention leads to substantial reductions in costly hypoglycemia episodes and hospital length of stay, the costs to setup the systems may be overall balanced out. In addition to the initial setup of these systems, there is a need for continuous education and operationalization of the workflow required for use of the systems, including orientation for incoming personnel. Therefore, ongoing costs, likely moderate, are expected. The system costs have to be considered with the overall outcomes for patients, to determine costs vs. savings. While inpatient hypoglycemia being addressed by an inpatient glycemic management system is important, it is also paramount to consider hyperglycemia (and its subsequent management with insulin) as a potential cause of hypoglycemia, thus the two should not be addressed separately.

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	**There is moderate evidence showing cost-saving – but more study is needed.** As noted above in Cardona et al. - not including installation and training - there is a moderate cost saving (9).	The panel noted that the cost-effectiveness will vary depending on the size of the institution and the number of patients with diabetes mellitus admitted each year. In addition to cost of installing computer software, there is the additional cost of ongoing training for physicians, nurses, pharmacists. This may be unaffordable for small hospitals with a relatively low volume of diabetes patients. In contrast, this may be cost-effective in larger institutions with a high volume of patients with diabetes because length of stay and complication rates related to hyperglycemia and hypoglycemia might be reduced.

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**	There will be funds from hospital for data analysis for the quality indicator reporting requirement by CMS. Hypoglycemia-related electronic clinical quality measures (eCQM) will become one of the new indicators that hospitals can choose for reporting. Small hospitals may be able to use the funds towards implementation of the glycemic management programs leveraging EHR data.

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**	The panel outlined that there are systems for post-operative patients and that issues in accuracy and identification of hypoglycemia as well as hyperglycemia exist. The use of the inpatient glycemic management programs leveraging EHR data facilitates the ability to monitor glycemic trends in the inpatient setting. In large institutions or multiple-hospital health systems, glycemic management programs leveraging EHR data are already in place (i.e. as a standard of care). In smaller community hospitals the systems already being implemented will not be as common. Hospital staff (physicians, nurses, etc.) generally accept these systems. Importantly, a systematic approach is considered state-of-the-art. In small community hospitals the administration and use of the systems may be more manageable with specific workflow (e.g. care providers responsible for system set up, training, etc.) for use of the systems. Panel noted that the intervention is probably acceptable, with expected variability between settings.

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**No research evidence identified**	The costs of an inpatient glycemic management system developed to reduce hypoglycemia vary widely, with little data regarding their use. Some health systems will not be able to afford the training and costs of EHR-linked systems (mostly used in academic medical centers/larger hospitals). Some paper systems may also work – but there are few if any head-to-head comparisons of the different systems. All the hospitals using these systems will need to establish training protocols and policies as well as a method to implement them/update overtime. These systems are mostly established and used in referral centers. Thus, it is crucial that access to health care in such institution be available to patients. The prevalence/frequency of hypoglycemia in people with diabetes is estimated at 30-50% for patients on medical wards as well as in intensive care units – making such systems important to implement. These systems should be feasible given real-world experience and examples. The panel discussed that proper implementation and use of the systems is important to improve care. The panel noted experiences in large, academic medical centers with implementation failure of the systems – demonstrating the significant needs to utilize such systems It is crucial to designate champions for implementation/use of the systems to address troubleshooting and overcome challenges with feasibility. Staff training is important.

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 recommend inpatient glycemic surveillance and management programs leveraging EHR data be used for inpatients at risk for hypoglycemia. (strong recommendation, very low certainty evidence) (1⊕○○○)

Remarks:

- The panel defined leveraging EHR data as having specific hospital staff utilizing glycemic data collected within the electronic medical record (from all admitted patients) to identify those at risk for and those having hypoglycemic and hyperglycemic episodes, and then utilizing that data to develop mechanisms for managing these adverse outcomes.

Justification

Although the panel judged the certainty of evidence to be very low overall for desirable and undesirable effects, the panel found that the desirable anticipated effects were moderate when high value was placed on reducing identifying and reducing severe hypoglycemia in hospitalized patients. The panel issued a strong recommendation in light of very low certainty evidence, considering episodes of severe hypoglycemia to be a life-threatening situation. The panel determined that cost considerations (for implementation and utilization of glycemic surveillance programs) and time considerations (for training and re-training staff) were the primary concern regarding use of glycemic surveillance and management programs leveraging EHR data for inpatients at risk for hypoglycemia, and acknowledged that costs and benefits may differ in different health care settings. However, the panel also noted that significant reductions in inpatient severe hypoglycemia would lead to reductions in costly hospital lengths of stay and hypoglycemia-related comorbidities.

Subgroup considerations

None

Implementation considerations

Inpatient glycemic surveillance systems vary greatly but typically include collecting real-time glycemic data from the EHR (including finger stick data, laboratory drawn data, and possibly CGM data if available) and putting this information into a database format that can be readily analyzed for pertinent findings and patterns. This allows for daily reports (stop light/traffic light charts, etc) that will help trained hospital staff in identifying those patients that require changes in their clinical management to avoid both hypo- and hyperglycemia. Setting up such a system requires integration between glucometers throughout the hospital, as well as the main hospital laboratory, and the EHR – so that daily reports can be easily created and dispersed among hospital staff. Specialized hospital staff must be trained to interpret and troubleshoot the program, and nursing staff and other clinical staff must be trained in how to make pertinent clinical management changes in a timely manner based upon the data received and reviewed.

The panel considered the crucial importance of correct setup of these systems, which include training of providers, nurses, MD, pharmacists, APPs (advanced practitioners) and the need to designate system champions and analysts for ongoing training, troubleshooting and management of the system. The panel realized the importance of continued training, but also for training incoming staff during their orientation.

The panel recommended that CMS-related outcomes quality indicators be set up to allow required reporting. The systems can be beneficial regardless of the type of diabetes and /or the presence of diabetes diagnosis, as hypoglycemia can occur in any hospitalized patient. Thus, all patients are at increased risk of hypoglycemia when hospitalized. Notably, monitoring hyperglycemia should also be included in these systems, since often hypoglycemia occurs as a result of hyperglycemia. The panel notes that the hypoglycemia eCQM is one of the measures that hospitals may choose to report, though will not be required for all.

Monitoring and evaluation

This recommendation should be monitored with respect to the new CMS requirements in the United States that will be implemented in 2022 & 2023.

Research priorities

Additional research on implementation of glycemic management surveillance systems, and appropriate quality measures/cut-offs (e.g. whether only <40 mg/dL) are needed.

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