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Consensus Statement on Inpatient Use of Continuous Glucose Monitoring

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Abstract

In June 2016, Diabetes Technology Society convened a panel of US experts in inpatient diabetes management to discuss the current and potential role of continuous glucose monitoring (CGM) in the hospital. This discussion combined with a literature review was a follow-up to a meeting, which took place in May 2015. The panel reviewed evidence on use of CGM in 3 potential inpatient scenarios: (1) the intensive care unit (ICU), (2) non-ICU, and (3) transitioning outpatient CGM use into the hospital setting. Panel members agreed that data from limited studies and theoretical considerations suggested that use of CGM in the hospital had the potential to improve patient clinical outcomes, and in particular reduction of hypoglycemia. Panel members discussed barriers to widespread adoption of CGM, which patients would benefit most from use of this technology, and what type of outcome studies are needed to guide use of CGM in the inpatient setting.

Keywords

continuous glucose monitor, diabetes, glucose, hospital, hypoglycemia, inpatient

In June 2016, Diabetes Technology Society convened a panel of US experts in endocrinology in New Orleans, Louisiana to discuss the current and potential future uses of CGM in the inpatient setting. This was a follow-up discussion to a previous meeting discussion held in May 2015 in Burlingame, California.[1] Panelists addressed current use of CGM in the hospital, potential future use, and current gaps in knowledge regarding inpatient use of this technology. Three cochairs, Dr Robert Rushakoff, Dr Guillermo Umpierrez, and Dr Amisha Wallia, each served as a moderator for discussion of CGM use in the (1) intensive care unit (ICU), (2) non-ICU, and (3) in the hospital as a continuation of home CGM. The focus of each discussion was to review the available evidence for CGM use in the proposed settings, discuss which patients would benefit most from use of this technology, propose studies needed to answer important outcome questions, review barriers to use, and propose next steps for adopting CGM technology in the hospital.

Background

Currently CGMs are FDA approved in the outpatient setting as an adjunctive device to complement information obtained from standard home blood glucose monitoring devices and to aid in detecting hyper- and hypoglycemic episodes. In December 2016, one device, the G5 Mobile (Dexcom, San Diego, CA), was approved for outpatients to make diabetes treatment decisions without confirmation by capillary blood glucose testing.[2] Use of this technology in the inpatient setting is of increasing interest. Information obtained from CGM includes glucose concentration, trajectory of glucose change (increasing, decreasing, or stable) and rate of glucose change (slow, fast, or steady). These data is used to facilitate

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short and long-term therapy adjustments and limit glycemic excursions.

CGMs sample glucose subcutaneously by way of interstitial fluid or intravascularly from venous or arterial blood. Glucose is measured in interstitial fluid using the glucose oxidase method or through fluorescence or it is measured intravenously through fluorescence, mid-infrared spectroscopy, or hydrogel methods.[3,4] Therefore, CGM devices can be invasive (intravascular devices), minimally invasive (subcutaneous), or even noninvasive (transdermal CGMs). Sampling and measurement frequencies typically range from 1 to 15 minutes and most commonly are every 5 minutes.

More than 15 continuous or semi-CGM devices have been described.[5] Devices vary by measurement method (fluid sampled), probe site, and sampling frequency. Numerous CGM devices have been studied in the inpatient setting. In Europe, there are currently four CGMS approved for intravenous (IV) use in hospitals: (1) GlucoClear by Edwards Life Sciences (Irvine, CA, USA), (2) Glysure System by Glysure (Abingdon, Oxfordshire, UK), (3) Eirus by Maquet Getinge Group (Rastatt, Germany), and (4) Optiscanner 5000 by Optiscan (Hayward, CA, USA), plus one CGMS approved for subcutaneous use in hospitals: Sentrino Continuous Glucose Management System by Medtronic (Northridge, CA, USA). One CGM system is FDA approved for use in US hospitals (GlucoScout, International Biomedical, Austin, TX, USA).

CGM Use in the ICU

Moderator: Robert J. Rushakoff, M.D

Is There a Role for CGM in the Intensive Care of Patients? Achieving optimal glucose target ranges in critically ill patients is now considered standard of care. Intermittent measurements of blood glucose by point-of-care testing technology is the only means of assessing glycemic control and adjusting insulin therapy in the ICU available for routine clinical practice. Panelists agreed that use of CGM in the ICU has the potential for improving glucose control, possibly in a safer and more effective/cost efficient manner. A recent systematic review examined the evidence on accuracy and clinical benefits of CGM in critically ill patients.[6] Although the majority of evidence for use of CGM in the hospital setting has been in the ICU, these studies have concentrated mainly on accuracy rather than on outcomes. Two tables comparing clinical trials of CGM use in the ICU (by adult patients and by pediatric patients) were reviewed by the experts and are included in this Consensus Statement (Table 1 and Table 2).

From an accuracy standpoint, there were numerous concerns discussed. Technological limitations that impede accuracy in subcutaneous continuous glucose sensors include buildup of tissue deposits (biofilm), the need for regular calibration due to sensor drift, measurement lag, and substance interference (acetaminophen, maltose, ascorbic acid, dopamine, mannitol, heparin, uric acid, and salicylic acid). Intravascular CGMs carry risks of thrombus formation, catheter occlusion or biofilm, and catheter-related infections.[23,24] Acetaminophen is commonly used in the hospital setting and may cause a CGM to overestimate glucose. There is a risk of overdosing insulin if the CGM is used to calculate the insulin dose after acetaminophen use. Patients wearing a device that may be impacted by acetaminophen should have the device removed if acetaminophen is to be given to the patient in the hospital. Concerns regarding accuracy in critically ill patients with impaired tissue perfusion remain.[5] It is worth noting that the studies included very few glucose values in the hypo- or hyperglycemic extremes. In the hypoglycemic range, sensor accuracy often breaks down. Furthermore, most of the studies included patients without diabetes, and few were performed in patients with type 1 diabetes, where excursions are more likely to occur. Despite these concerns, studies performed have shown acceptable device accuracy and no particular safety signals in neither adult[12-15,25] nor pediatric[21] populations.

The definition of "adequate" glucose control in the ICU continues to be a matter of debate. In 2009, the NICE-SUGAR study reported that a tight glucose target (81-108 mg/dL, <4.5-6.0 mmol/L>) in the ICU was associated with higher mortality rates than a moderate glucose target (140-180 mg/dL).[26] Following the results of the NICE-SUGAR study, target glucose control in the ICU has been redefined. Currently, most hospitals target glucose ranges of 140-180 mg/dL (7.8-10.0 mmol/L) in the ICU, with an acceptable target level of 110 mg/dl (6.1 mmol/L) in certain populations and locations.[27,28] Although strict control is no longer targeted, consensus exists that lower glycemic targets are beneficial if hypoglycemia (glucose <70 mg/dl <3.9 mmol/L>) can be avoided. The Society of Critical Care Medicine has published guidelines recommending a moderate target range of 110-150 mg/dL (6.1-8.3 mmol/L).[29] There are, however, data from the surgical ICU showing favorable outcomes with lower glycemic targets (<110 mg/dl <6.1 mmol/L>), as long as hypoglycemia is avoided.[30] There is strong evidence that hypoglycemia and hyperglycemia are associated with worse outcomes in the ICU population and that good glucose control is associated with better outcomes. To date, there are few outcomes studies using CGM in the ICU setting. Outcomes that have been examined in CGM studies include the rate and severity of hypoglycemic events, glycemic variability, and percentage time in target range (proportion of time glucose values fall within a specified range).[5] Most normal ranges for metrics of CGM measurement (such as percentage time in range and glycemic variability) in the literature are based on outpatient data and these amounts might not apply to the inpatient setting.

Intensive insulin therapy—which is required to achieve lower glucose ranges—can result in higher frequencies of hypoglycemic events, thus limiting the potential benefits of intensive glucose control.[31] Panel members agreed that if CGM could help identify and prevent hypoglycemic events in the ICU, then the technology could be a valuable tool by

Table 1. Clinical Trials of Adult CGM Use in the ICU.

Author, year	Population	Sample size	# of sites	Type of CGM	Performance measurement	Comparator
De Block et al, 2006[7]	MICU	50	1	Glucoday	Reliability	Arterial
Holzinger et al, 2009[8]	MICU	50	1	System Gold	Accuracy and reliability	Arterial by blood gas analyzer
Rabiee et al, 2009[9]	SICU/BICU	19	1	Dexcom	Accuracy and reliability	Capillary POC and lab
Holzinger et al, 2010[10]	ICU-mechanically ventilated	24	1	Guardian	% of time at glucose <110, glycemic control, mortality	CGMS Gold (blinded)
Kopecky et al, 2013[11]	Postcardiac surgery	12 intervention/12 control	1	Guardian	Glycemic control	Computer (eMPC) algorithm alone
Boom et al, 2014[12]	MICU/SICU	78 intervention/78 control	1	Navigator	Accuracy	Arterial by blood gas analyzer
Kosiborod et al, 2014[13]	Cardiac ICU	21	1	Sentrino	Accuracy and reliability	Central venous POC or lab
Leelarathna et al, 2014[14]	Neurosurgical ICU	24	1	Navigator	Accuracy	Standard IV insulin protocol
Punke et al, 2015[15]	SICU	14	1	Sentrino	Accuracy	Arterial by blood gas analyzer
Gottschalk et al, 2016[4]	Extracorporeal cardiac life support	25	1	Sentrino	Accuracy	Arterial by blood gas analyzer
Umbrello et al, 2014[16]	MICU	6	1	Optiscanner 5000	Glucose control	None
Sechterberger et al, 2015[17]	Cardiac ICU	8	1	Navigator	Accuracy	Arterial by blood gas analyzer
Nohra et al, 2016[18]	SICU	23	1	Optiscanner 5000	Accuracy	Yellow Springs Instrument
Wollersheim et al, 2016[19]	MICU	20	1	Sentrino	Accuracy	Arterial or venous
Schierenbeck et al, 2017[20]	Cardiac ICU	26	1	Freestyle Libre	Accuracy	Arterial by blood gas analyzer
Schierenbeck et al, 2017[20]	Cardiac ICU	26	1	Eirus System	Accuracy	Arterial by blood gas analyzer

Abbreviations: BICU, burn intensive care unit; eMPC, enhanced model predictive control; MICU, medical intensive care unit; POC, point of care; SICU, surgical intensive care unit.

Table 2. Clinical Trials of Pediatric CGM Use in the ICU.

Author, year	Population	Sample size	# of sites	Type of CGM	Performance measurement	Comparator
Bridges et al, 2010[21]	ICU	47	1	Guardian	Accuracy	iSTAT POC
Prabhudesai et al, 2015[22]	ICU	19	1	Guardian	Accuracy	Lab glucose

introducing greater safety into intensive insulin algorithms. A relatively large randomized controlled trial in 124 mechanically ventilated ICU patients demonstrated decreased rates of severe hypoglycemia in a real-time CGM group (1.6 vs 11.5% in a control group, $P = .031$) despite similar mean glucose levels. The absolute risk of hypoglycemia was reduced by 9.9% (95% CI 1.2-18.6).[10] Similarly, smaller studies in select populations have shown trends toward lower rates of hypoglycemic events with intensive glycemic control achieved when CGM was deployed to the ICU.[11] In contrast, a study of 156 ICU patients using subcutaneous CGM identified no difference in the number of hypoglycemic episodes (plasma glucose <40 mg/dL <2.2 mmol/L>) in patients managed with CGM vs intermittent glucose monitoring performed on arterial blood measured on a point-of-care (POC) blood glucose monitor.[12] Similarly, in a study of 35 patients,

there was no difference in the rate of hypoglycemic events with the use of subcutaneous CGM in the ICU setting. Comparisons between studies are difficult, however, given the lack of standardization of glucose metrics and differences between patient groups.[32] Panel members agreed that larger, randomized control studies need to be designed to answer outcome questions.

Despite inconsistent published outcomes data regarding hypoglycemic events, panel members agreed that CGM in the intensive care setting makes intuitive sense. Data indicate that ICU patients have a blunted counter regulatory response to hypoglycemia.[33] Furthermore, the ICU setting would make it difficult to detect hypoglycemia via usual symptomatic signs or complaints. For instance, intubated patients cannot express to nursing staff that they feel hypoglycemic, and altered mental status could be due to many other factors besides hypoglycemia. Intermittent glucose monitoring has the potential to miss both hyperglycemic and hypoglycemic events that would be detected on CGM. Many experts felt that knowledge of glucose measurements in-between testing intervals could reveal new glycemic patterns that could influence management decisions. Parallels between CGM use could be made with any other type of continuously measured parameter in ICU patients, such as pulse oximetry or arterial blood pressure. Intuitively, continuous "glucometry" could provide practitioners with more useful data for informing management decisions than intermittent glucose testing alone could provide.

Panel members agreed that there are significant management concerns with use of CGM in the ICU setting. Although endocrinologists may be involved in their care, patients in the ICU are managed by the critical care team with limited specialty training in diabetes or CGM use. In the absence of additional training, critical care teams might be unable to interpret the data and might dose insulin too frequently (insulin "stacking") based on the trend data. Panel members agreed that the success of CGM largely depends on correct interpretation of the data and the ability to make consistent dosing adjustments based on the data trends. Despite these concerns, studies using CGM-specific computer algorithms have been successful in guiding insulin dosing decisions. The use of an enhanced model predictive control algorithm (eMPC) showed reliability and trends toward less hypoglycemia as compared to a standard algorithm in a cardiothoracic ICU setting.[11] Other studies have evaluated professional ease of use with CGM systems. In a cardiothoracic ICU setting where the Sentrino CGM was used, it was found that 100% of critical care professionals found the Sentrino easy to use after 2 patients.[13] This preliminary evidence suggests that CGM systems can be used successfully by practitioners outside the field of endocrinology if they have appropriate training/experience. CGM-specific insulin protocols may help facilitate accurate and safe and effective use of this technology.

From a hospital administration perspective, use of CGM must not be cost-prohibitive. There might be costs "saved" with implementation of a CGM process. Studies have shown that CGM use can reduce nursing workload. In patients requiring hourly blood glucose monitoring in the ICU, it took nursing staff 4.72 minutes to obtain a glucose measurement and adjust insulin doses. In this study, 2 hours of direct nursing time was spent per patient per day to achieve tight glycemic control.[34] Time saved on hourly blood glucose monitoring could translate into significant time and cost savings. A recent European study demonstrated a 12 euro/patient savings with CGM use versus standard monitoring.[12] In a 24-hour time period, nurses in the control group spent 36 minutes obtaining point-of-care glucose measurements. Despite the added workload of CGM sensor placement and calibration, nurses in the intervention group (CGM) spent significantly less time on glucose monitoring than those in the point-of-care group, which translated to a 19-minute reduction in nursing workload.[12] The use of CGM could result in lower costs because of the need for fewer point-of-care glucose measurements, particularly for those patients on intravenous insulin where values are typically monitored hourly. However, many new costs need to be considered as well. CGM systems will need to be maintained. Sensors will need to be purchased and professionals trained in proper insertion. Depending on a patient's hospital length-of-stay, a sensor may need to be replaced multiple times. Computerized insulin infusion protocols may need to be developed and professionals trained in their use. Our experts pointed out that if cost is prohibitive for use of CGM in all ICU patients, then perhaps CGM use could be restricted to select, high-risk populations more likely to benefit.

Which Patients in the ICU Would Benefit Most From Use of CGM? Panel members agreed that use of CGM at this time may not be feasible for every ICU patient. However, there are populations of high interest who may benefit from further study of CGM because they are at high risk for glucose variability and hypoglycemia, and they include (1) any patients receiving insulin, especially intravenous insulin, (2) postcardiac surgery patients, (3) neonatal ICU patients, (4) post-transplant patients, (5) patients receiving glucocorticoids, (6) patients with end-stage renal or liver disease, (7) traumatic or vascular brain injury, and (8) those with hypoglycemia unawareness.

Consensus Reached by the Panelists. Current recommendations regarding use of CGM in the ICU setting are limited by a number of factors. Most studies on CGM in critically ill patients have focused on accuracy rather than on clinical outcomes. In addition, the panelists felt that randomized controlled trials might be challenging because of the difficulty in blinding the caregivers as to which subjects receive CGM compared to those who do not, and innovative study design approaches need to be developed. Finally, studies to date have been largely single-site rather than multicenter in nature. Funding opportunities for future studies might be limited as well.

Table 3. Clinical Trials of Adult CGM in the Non-ICU.

Author, year	Population	Sample size	# of sites	Type of CGM	Performance measurement	Comparator
Burt et al, 2013[36]	General ward	26	1	System gold	Performance measurement	Comparator
Rodríguez et al, 2010[37]	General ward-ACS	16	1	Guardian	Glycemic control, time to BG <140	Capillary POC q 4 hours
Gómez et al, 2015[38]	General ward	38	1	iPro-2	Accuracy	Capillary POC 7 times/day

Abbreviation: ACS, acute coronary syndrome.

Additional factors to consider before endorsing CGM use in the ICU relate to decision support and staff training. For instance, who will be examining and interpreting the CGM data? Who will be making treatment decisions based on the CGM data? Designing decision support systems to aid staff in making decisions, particularly with regards to insulin therapy adjustment, would be needed. Furthermore, the information technology department of the hospital would need to integrate CGM data within their EMR's insulin dosing software. How will CGM data be communicated to the nurse? This question is particularly—more important when CGM is used outside of the ICU, but still may require a hardware interface like that used for vital signs. Finally, staff would have to be trained on proper placement, care, and calibration of the devices.

Nonetheless, panel members agreed that use of CGM in the ICU setting could result in improved clinical outcomes by allowing for intensive glycemic control with significantly less risk of hypoglycemia. It makes intuitive sense that continuous measurement of glucose or "glucometry" can provide practitioners with not only a greater number of data points per day, but more useful glycemic information including direction and rate of glucose change. This additional information can help professionals anticipate glucose excursions and intervene prior to the development of a hypo- or hyperglycemic event. Panelists believed that CGM can be an important tool in the hospital but do not yet have enough evidence to support its immediate introduction into the ICU. Well designed, larger, multicenter studies are needed to answer important outcome questions. Moving forward, studies should concentrate on clinical outcomes, such as mortality, infection rates, patient length of stay, hypoglycemia rates, and glycemic control. Glucometrics need to be standardized to allow for meaningful comparisons between studies. Finally, patients who would benefit from CGM need to be defined.

What Is the Role of CGM in the Non-ICU Setting?

Moderator: Guillermo Umpierrez, MD

Hyperglycemia and diabetes are common in medical and surgical patients admitted to non-ICU settings.[35] About 25% of such patients have a prior diagnosis of type 2 DM, the majority of whom will require insulin administration during the hospitalization. Given rapidly changing factors in the hospital (varying nutritional status, steroid use, renal function, and poor appetite) patients are at significant risk for both hyperglycemia and hypoglycemia. Panel members agreed there is evidence to suggest that use of CGM in the non-ICU setting has the potential to detect hyper- and hypoglycemic events, that would otherwise be missed with standard POC testing. A table comparing clinical trials of CGM use in the non-ICU setting by adult patients was reviewed by the experts and is included in this Consensus Statement (Table 3). A study of 26 hospitalized patients with type 1 and type 2 diabetes reported increased detection of both hypo- and hyperglycemic events with use of CGM versus POC monitoring. Patients were maintained on basal-bolus therapy in conjunction with CGM use.[36] There was no difference in mean daily glucose concentration between the CGM and POC readings; however, in the CGM group there were 88 postprandial hyperglycemic excursions detected as opposed to the POC monitoring, in which 61 episodes were noted. Moreover, CGM identified 10 hypoglycemic events, only one of which was detected on POC monitoring.[39] In another study of 38 patients with either known type 2 diabetes or hyperglycemia on basal-bolus insulin, CGM use was compared to POC glucose testing. There were no differences in mean daily glucose, premeal, fasting, or 2-hours postprandial glucose levels between the 2 groups. However, CGM detected a higher number of hypoglycemic events than POC (55 vs 12, $P < .01$). More than 50% of the hypoglycemic events occurred between dinner and breakfast; suggesting that these episodes would be missed by standard POC testing. A sizable percentage of these hypoglycemia episodes were asymptomatic (26.3%).[38] However, because they were based on outpatient paired BG monitor-sensor data, these asymptomatic hypoglycemic events could also have been false alerts.

Consensus Reached by the Panelists. The quality of data on the use of CGM in the non-ICU setting is limited in comparison to the ICU. Nonetheless, many of the potential advantages for using CGM in the ICU were also felt to be applicable in the non-ICU environment. For instance, panelists believed that CGM could more effectively identify trends toward hypoglycemia and hyperglycemia, allowing for earlier intervention than would be possible with blood glucose testing. While CGM in the ICU could likely be easily adopted by critical

care personnel (who have to train in the use of complex devices), in the non-ICU setting endocrinology specialists would likely have to be consulted to assist.

Should Home CGM Devices Be Continued in the Inpatient Setting?

Moderator: Amisha Wallia, MD, MS

Subcutaneous CGMS use in patients with type 1 diabetes in the outpatient setting is growing and varies by age—as low as 4% in the adolescent population and in selected subgroups (age ≥26 years) up to 21%.[40] The percentage of patients with diabetes admitted to the hospital who are using CGM in the outpatient setting is unknown.[40] It is well documented that continued outpatient use of CGM improves glycemic control, and recent studies suggest that use of CGM is associated with increased patient satisfaction, decreased fear of hypoglycemia, and improved quality of life.[41,42] As the majority of patients who use CGM in the outpatient setting find it helpful, it is reasonable to assume that many patients admitted to the hospital would choose to continue use of CGM in the inpatient setting. Continued use of outpatient CGM in the hospital could increase patient satisfaction. Patient knowledge of impending hypoglycemia could also aid hospital staff in treating these events quicker and in a safer manner. Asking patients to remove a CGM device in the hospital could potentially contribute to decreased patient satisfaction. Even with the recent FDA decision approving a primary indication for the Dexcom G5 Mobile for insulin dosing for outpatients, CGM use in the hospital is not FDA approved. Making decisions based on these data in the inpatient setting would be considered off-label use. There are significant concerns regarding accuracy of CGM data in hospitalized patients given possible physiologic interferences that can affect a CGM's performance (eg, hypoxemia, vasoconstriction, edema, and medications such as acetaminophen). In these cases, especially where calibration is needed, clear safety and quality protocols need to be in place for safe use. Also, during diabetic ketoacidosis rapidly changing glucose levels and fluid/electrolyte shifts may impede the utility of CGM.[43]

There is very little data available on transitioning outpatient CGM devices to the inpatient setting and studies demonstrating accuracy and safety of these devices are needed. Institutions must determine within their infrastructure if they have the capacity to continue use of these devices safely and put measures in place to decrease potential liability. Currently there is no billing code or coverage to bill for CGM interpretation in the inpatient setting. If hospitals receive payments for bundled services, then they will require evidence of economic benefit before deploying inpatient CGM.

The roundtable discussion concentrated on the following three questions:

1. What are the potential safety concerns with continuing use of outpatient CGM in the hospital, and how can these concerns be addressed?

There are safety concerns regarding accurate calibration of CGM devices. Current real time FDA approved CGM devices require timed calibration with a blood glucose meter for accuracy. Specific rules should be in place regarding use of a patient's home meter in calibrating the CGM device. Calibration with the patient's home meter, which might be inaccurate, would compromise accuracy of the CGM data.[39] Experts agreed that real time CGMs should be calibrated using the hospital blood glucose meter twice daily and documented in the chart. Since CGM data is not currently approved by FDA as being adequately accurate for inpatient insulin dosing, it is important to ensure that insulin dosing decisions are not being made based only on CGM glucose data. Patients should continue to receive POC glucose monitoring prior to meals and insulin boluses should be documented by nursing based on those values. Protocols need to be in place for patients to alert nursing with an aberrant CGM value, prompting the nurse to confirm the value prior to making an insulin dosing decision. In instances where the patient wishes to bolus sooner than 4 hours from the last bolus based on CGM trends, then this bolus must be discussed with the hospital staff overseeing the patient's care. Finally, for sensor integrated pumps, the automatic threshold suspend features should be turned off in the hospital.

Safety concerns also arise with regard to interpretation of the data. Given the magnitude of data output, inexperienced professionals might make inappropriate dosing decisions or act too quickly. CGMs are often used in conjunction with insulin pumps, and will require policies that include use of both technologies in the inpatient setting. Such policies will be needed when patients are admitted to the hospital with the recent approved but not yet marketed 670G Hybrid Closed Loop System by Medtronic (Northridge, CA, USA).[44] Panelists agreed that these patients should be followed by an endocrinologist, or an advanced practitioner specifically trained in insulin pump and CGM use. If there is no such provider available (as in some small rural hospitals), then consideration must be given regarding transfer of the patient to a facility familiar with use of these devices. If transferring the patient is not an option and experienced hospital staff are not available, then the devices should be removed. To ensure safety across the hospital stay, educational programs must be in place to ensure that nursing and other ancillary personnel have a basic understanding of these devices and feel capable of communicating glucose data and trend data to on-call professionals.

2. How can liability be decreased at an Institutional level?

There are many potential legal liabilities which should be addressed at an institutional level. Each institution must weigh the risk and benefits of inpatient CGM use based on their hospital infrastructure. Use of these devices in a hospital setting may not be feasible at institutions that do not have adequate ancillary support in the form of

endocrinology/diabetes services, nursing expertise, or diabetes educators. Panel members agreed that patients should be required to sign patient safety waivers, similar to documentation used with insulin pumps, to illustrate the risks and benefits to the patient with continued use. Waivers should specify that professionals have the right to remove the CGM from the patient in cases where they feel the device is not being used properly, the patient is not safe to use the device in the hospital, the patient is receiving an MR image, CT scan or diathermy treatment, or the device poses risk to the patient.

Many panelists raised concerns with allowing patients to continue using this technology in the hospital if they cannot demonstrate an ability to manage/set up/maintain the CGM. There are no proposed criteria for testing a patient's ability to do this. There should be rules in place regarding whether CGM use can be continued in patients who require more intensive care (eg, acute transfer to an ICU setting). CGM data may be particularly useful in the delirious or encephalopathic patient who cannot voice hypoglycemic symptoms. However, there may be increased liability with continued use of these devices in such patients. There may be certain admitting diagnoses/services (eg, psychiatry) where CGM use would be inappropriate. There should be agreement within an institution regarding specific acuities/diagnoses in which CGM use would be contraindicated. Waivers should specify that patients must have their own CGM supplies available to reinsert the device as needed. If the patient lacks appropriate supplies, then the device must be removed.

Methods also need to be in place for recording the CGM data in the hospital and uploading pertinent CGM data into medical records. Institutions must determine what portion of the CGM data should be recorded and archived and how best to do this in the medical record. Unless CGM devices are downloaded on a daily basis, then documentation will largely be done by the nursing staff and in endocrinology notes after reviewing the data on a daily basis. There will need to be a process in place for educating floor nurses on the basic principles of CGM use so they are able to document continued use of the device and feel comfortable verifying information from the CGM provided to them by the patient. An unresolved issue relates to how nurses can document on each shift that a patient wearing a CGM (like anything attached to the body) has no signs of infection. A policy is needed for this assessment, because if the device is heavily taped, then the nurse cannot make an adequate assessment. The nurse might pull back the tape and end up removing the CGM by mistake.

A significant concern regarding continued use of commercial outpatient CGM devices in the inpatient setting is whether these glucose data are being adequately protected. Cybersecurity is a significant concern, and there is the possibility that the integrity or availability of CGM data could be compromised. Hospital CGM data must be stored securely for both medical safety and legal liability reasons. Hospitals might not feel safe allowing continued use of a device that has not been certified to meet a standard for cybersecurity.[25]

Table 4. Principles for Research on CGM in Inpatient Settings.

1. CGM needs to be compared to intermittent blood glucose monitoring (standard of care).
2. Glycemic outcomes and glucometrics should be standardized among studies and include number of hypoglycemic events, level of hypoglycemia, time in target range, and glucose variability to allow for comparisons of studies.

Table 5. Types of Research Studies Needed for CGM in Inpatient Settings.

1. Accuracy studies of potential interferences on CGMs performance (eg, vasoconstriction, dehydration, edema, hypoxemia, and certain medications).
2. Clinical outcome studies in low-risk and high-risk populations (eg, inpatient mortality, infection rates, patient length of stay, and satisfaction).
3. Computer-based algorithm studies incorporating CGM.
4. Cost studies of CGM to the institution, its effects on nursing workload, and provider ease of use.
5. Safety studies demonstrating institutional models of device use in the hospital through patient liability forms, nursing education models, processes of patient reporting, nursing documentation, and means of documenting CGM data in the medical record.

3. What additional studies need to be done/what needs to happen to make continuing CGM use in the hospital safe and desirable to hospital administration?

The panelists developed two principles for research on CGM in inpatient settings (Table 4). The panelists recommended that five types of research should be conducted to provide information about the potential benefits of CGM in inpatient settings. See Table 5.

Consensus Reached by the Panelists. CGM use in the outpatient setting is increasing and will continue to increase. Panel members unanimously agreed that continuation of outpatient CGM in the hospital should be considered under specific circumstances if proper institutional procedures and guidelines are developed. Patients will expect to be allowed to continue use of this technology in the inpatient setting and protocols must be in place to allow their safe and continued use. We feel that continued CGM use in the hospital has the potential to improve outcomes by assisting professionals with identifying hypoglycemic and hyperglycemic events. In addition to the possibility of improved outcomes, continued use of these devices will increase patient satisfaction. Well-powered studies are needed to examine outcomes and accuracy with these devices. Institutions must decide whether continued use of these devices can be safe and effective, and methods must be in place to decrease liability. Institution-specific

care processes are needed as models before this practice can be widely adopted.

Abbreviations

ACS, acute coronary syndrome; BICU, burn intensive care unit; CGM, continuous glucose monitoring; eMPC, enhanced model predictive control algorithm; MICU, medical intensive care unit; POC, point of care; SICU, surgical intensive care unit.

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Declaration of Conflicting Interests

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