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Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline

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Abstract

This article is the work product of the Continuous Glucose Monitor and Automated Insulin Dosing Systems in the Hospital Consensus Guideline Panel, which was organized by Diabetes Technology Society and met virtually on April 23, 2020. The guideline panel consisted of 24 international experts in the use of continuous glucose monitors (CGMs) and automated insulin dosing (AID) systems representing adult endocrinology, pediatric endocrinology, obstetrics and gynecology, advanced practice nursing, diabetes care and education, clinical chemistry, bioengineering, and product liability law. The panelists reviewed the medical literature pertaining to five topics: (1) continuation of home CGMs after hospitalization, (2) initiation of CGMs in the hospital, (3) continuation of AID systems in the hospital, (4) logistics and hands-on care of hospitalized patients using CGMs and AID systems, and (5) data management of CGMs and AID systems in the hospital. The panelists then developed three types of recommendations for each topic, including clinical practice (to use the technology optimally), research (to improve the safety and effectiveness of the technology), and hospital policies (to build an environment for facilitating use of these devices) for each of the five topics. The panelists voted on 78 proposed recommendations. Based on the panel vote, 77 recommendations were classified as either strong or mild. One recommendation failed to reach consensus. Additional research is needed on CGMs and AID systems in the hospital setting regarding device accuracy, practices for deployment, data management, and achievable outcomes. This guideline is intended to support these technologies for the management of hospitalized patients with diabetes.

Keywords

automated insulin dosing, continuous glucose monitor, COVID-19, guideline, hospital

Introduction

Continuous glucose monitors (CGMs) are becoming an important technology for improving glycemic outcomes in diabetes. The opportunity for a patient (or by way of wireless communication, a caregiver, or relative) to see real-time glucose concentrations tested automatically and continuously is transforming the practice of diabetes care.

Recent generations of these devices offer improved accuracy, smaller form factors, extended sensor life, and new data presentation software for translating data into increasingly useful metrics on various mobile platforms. Some new factory-calibrated CGMs have eliminated the need for finger-stick blood glucose (BG) testing by users (except at certain times per individual product instructions, such as soon after insertion, when there appear to be errors or no readings at all, when the CGM value does not match how the patient feels, or when an icon indicates the need for testing BG).

CGMs for monitoring glucose concentrations and automated insulin dosing (AID) systems, which contain a CGM controlling a continuous subcutaneous insulin infusion (CSII) system (also known as an insulin pump), are cleared (class II) or approved (class III) by the United States Food and Drug Administration (FDA) for home use (by prescription) by people who have diabetes. However, many clinicians believe that CGMs have the potential to be utilized by hospitalized patients in a variety of situations.

Escalating interest in utilizing CGMs and AID systems in a hospital setting has resulted in a need for guidance on the continuation of these technologies in the hospital setting. This interest has been stimulated by four trends in the application of CGM technology, including (1) improvements in the technology and human factors of CGMs, (2) an increasing number of patients wearing these devices in ambulatory settings, (3) growing interest by clinicians to understand and interpret their hospitalized patients' glucose concentrations, and (4) an accumulation of published reports describing use of these products in investigational settings. Diabetes Technology Society (DTS) previously organized guidance on the use of CGMs in the hospital as "Consensus Statement on Inpatient Use of Continuous Glucose Monitoring,"[1] published in 2017. Because of recent increasing interest in this topic, coupled with advances in technology, DTS recognized a need for an updated consensus guideline on the use of CGMs and AID systems in an acute-care setting.

On April 23, 2020, DTS, led by Dr David Klonoff, convened the Continuous Glucose Monitor and Automated Insulin Dosing Systems in the Hospital: Consensus Guideline Panel. This international panel consisted of experts in diabetes technology from the United States, Europe, and Australia. The purpose of this meeting was to provide guidance for clinicians on how and when to best use both subcutaneous CGMs and AID systems, as well as to promote clinical research utilizing these devices.

The panel was planned in late 2019 before the first case of Coronavirus Disease 2019 (COVID-19) was reported. Two weeks prior to the panel meeting, two CGM companies announced that during the pandemic, the FDA had told them that the Agency would not object if these companies provided devices and technical support to hospitals who ordered CGMs for off-label use.[2,3] Because some healthcare systems were interested in validating CGMs for use in their hospitals to preserve personal protective equipment (PPE) supplies and to minimize patient/provider contact, there was additional urgency for the panel to develop new clinical guidance. Panelists discussed how the pandemic has impacted inpatient glucose monitoring and how an

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urgent need has arisen for alternative approaches to this monitoring.[4] The traditional approach of testing capillary BG every one to two hours in patients who are receiving intravenous insulin in an intensive care unit (ICU) as well as frequent BG testing in non-ICU wards for patients receiving subcutaneous insulin is not workable during the pandemic. Other methods are needed to decrease nurse contact with the patient for assisted monitoring of BG (AMBG)[5] in order to (1) decrease risk of contagion from exposure to patients, (2) save time from donning and doffing PPE wherever possible, and (3) preserve limited supplies of PPE.[4] Despite limited guidance, established studies, or widespread support from the clinical community to use CGMs in acute care,[6] some healthcare professionals (HCPs) in the hospital diabetes community have recently begun to prescribe CGMs in the hospital setting for investigational or off-label use for COVID-19 patients.[7]

The Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline Panel included professionals from a variety of backgrounds. Members included experts in the use of CGMs from adult endocrinology, pediatric endocrinology, obstetrics and gynecology, advanced practice nursing, diabetes care and education, clinical chemistry, bioengineering, and product liability law. The expert panel included representatives from academia and government and observers from government (FDA), and industry (Abbott Diabetes Care, Dexcom, Glytec, Medtronic, and Roche Diagnostics). One member represented the College of American Pathologists, one represented the Endocrine Society, and one represented the Association of Diabetes Care and Education Specialists.

The expert panel discussed the following five topics: (1) continuation of home CGMs after hospitalization, (2) initiation of CGMs in the hospital, (3) continuation of AID systems in the hospital, (4) logistics and hands-on care of hospitalized patients using CGMs and AID systems, and (5) data management of CGMs and AID systems in the hospital (Table 1). Panelists reviewed available evidence on the inpatient use of diabetes technology, and discussed potential opportunities, potential barriers, and recommendations associated with the use of these devices in the hospital setting.

Recommendations were proposed by the panelists and then reviewed by the entire panel for favorability. Recommendations receiving at least 80% favorable votes were classified as strong recommendations, proposals receiving 60%-79% favorable votes were classified as mild recommendations, and proposals receiving less than 60% favorable votes were classified as recommendations that failed to receive consensus support.

For each of the five topics of this guideline (Table 1), six categories of recommendations (two for clinical practice, two for future research, and two for hospital policies) were developed for the main stakeholders of CGM and AID system technology in the hospital. These types of recommendations included (1) and (2) strong and mild recommendations that clinicians (HCPs or nursing) should do to utilize the technology optimally, (3) and (4) strong and mild recommendations that researchers and manufacturers need to do to improve the safety and effectiveness of the technology, and (5) and (6) strong and mild recommendations that hospitals need to do to build an environment for facilitating use of these devices. We define "should" as a statement of good practice and "need" as a necessary step to ensure patient safety or proper fulfillment of a procedure. These recommendations are intended to promote the best use of CGMs and AID systems in the hospital.

Table 1. The Five Topics Discussed at the Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Panel.

Topic 1: Continuation of home continuous glucose monitors after hospitalization
Topic 2: Initiation of continuous glucose monitors in the hospital
Topic 3: Continuation of automated insulin dosing systems in the hospital
Topic 4: Logistics and hands-on care of hospitalized patients using continuous glucose monitors and automated insulin dosing systems
Topic 5: Data management of continuous glucose monitors and automated insulin dosing systems in the hospital

Background

CGMs were developed for the outpatient setting, and their transition for use in hospitals has been the subject of ongoing scholarship, research, and consensus guidelines. The first CGM became commercially available in 1999.[8] CGM technology has greatly improved since then and several revolutionary developments in CGM technology have taken place over the past five years. These advances have all significantly reduced patients' burden of diabetes care. The result has been improved patient satisfaction and self-care behaviors, increased clinician awareness, and a significant increase in CGM adoption, mostly by patients with type 1 diabetes mellitus (T1DM), but also in some patients with type 2 diabetes mellitus (T2DM).[9] Software for analyzing continuous glucose data streams has permitted the development of new CGM-based glycemic metrics, which, compared to hemoglobin A1c, illustrate multidimensional patterns of glycemia more directly and with greater granularity.[10] Improvements in CGM technology have also permitted integration with CSII systems to create AID systems. With the increasing popularity of AID systems that depend on CGMs, hospital HCPs will increasingly encounter patients who will want to utilize their CGMs and AID systems for inpatient diabetes care.

AID systems are becoming more advanced and are more frequently utilized for outpatients to successfully achieve glycemic outcomes in diabetes by facilitating increased time in range (TIR) and decreased time in hypo- and hyperglycemia. Two AID systems are currently cleared or approved by the FDA for home use in people with diabetes: 670G (Medtronic,

Northridge, CA, USA) and Tandem Control IQ (Tandem Diabetes Care, Inc., San Diego, CA, USA). Some patients utilizing these AID systems and/or their physicians wish to continue the AID systems even during a hospitalization, believing that the benefits of commercial AID systems outweigh potential risks in this setting and noting that product use would not be off label if a patient is self-managing using the device even if the patient is in the hospital while doing it.

CGM sensors can be invasive (intravascular blood sampling or sensing devices that remove blood), minimally invasive (subcutaneous placement of a sensor), or noninvasive (transdermal CGMs that do not puncture the skin). They are measuring in different compartments, which can lead to different values.[11] The frequency of receiving a signal by a CGM ranges from every 1 to 15 minutes, most commonly every 5 minutes. Invasive CGMs that are intended only for hospital use include two systems cleared by the FDA. They are (1) the GlucoScout (International Biomedical, Austin, TX, USA)[12] and (2) the OptiScanner 5000 (OptiScan Biomedical Corporation, Hayward, CA, USA).[13] Both devices track glycemic patterns of blood that is withdrawn from the venous system of adults.[13] In Europe, four CGMs have been CE Marked for measuring venous blood in hospitalized patients: (1) GlucoClear (Edwards Life Sciences, Irvine, CA, USA),[14] (2) Glysure System (Glysure, Abingdon, Oxfordshire, UK),[15] (3) Eirus (Maquet Getinge Group, Rastatt, Germany),[16] and (4) Optiscanner 5000.[13] The Optiscanner 5000 has received FDA clearance, but the Glucoclear, Glysure System, and Eirus products all have not received FDA clearance. The Glucoclear and Eirus products have been discontinued, and Glysure Ltd. went out of business in 2018. The Optiscanner 5000 is available in the United States and Europe. One CGM with a subcutaneous sensor was available in Europe for measuring glucose in hospitalized patients: Sentrino Continuous Glucose Management System (Medtronic, Northridge, CA, USA).[17] However, at this time, Sentrino is not a commercial product. There are no commercially available noninvasive CGMs in the United States.

In the hospital special issues can arise that can impair proper function of CGMs. No CGM is labeled to allow for exposure to X-rays, computed tomographic (CT) scans, magnetic resonance imaging (MRI), diathermy, radiation therapy, or other types of radiation. Typically, the device is removed or covered with a lead shield during these procedures. Some sites have covered their CGMs with a lead shield and have not reported adverse events. Emerging data suggest that there may be no need for removal of the Dexcom G6 sensor (Dexcom, San Diego, CA, USA) during X-rays, CT scans, radiation therapy, or when electrocautery is used during surgical procedures.[18-20] There were no data errors observed when FreeStyle Libre Pro sensor was exposed to chest X-rays, CT, radiotherapy, and MRI.[21] The panel expected that each manufacturer will continue to determine and report the impact of imaging studies and electrocautery on their particular devices.

An attractive feature of CGMs is that they can measure glucose concentrations automatically and sound an alarm for readings that are outside of a prespecified safe target range. Five subcutaneous home-use CGMs are currently available with the potential for hospital use: FreeStyle Libre 14-day system,[22] FreeStyle Libre 2[23] (both Abbott Diabetes Care, Chicago, IL, USA), Dexcom G6,[24] Medtronic Guardian Sensor 3[25] (Medtronic Diabetes, Northridge, CA, USA), and Eversense (Senseonics, Inc., Germantown, MD, USA).[26] Table 2 presents these devices' glucose sensing methods, technical features, and known interferences from chemical substances.[27-37]

Table 2. List of Currently Available Subcutaneous CGM Devices and their Interferences.

CGM system	Glucose sensing methods	Technical features[4]	Known interferences from chemical substances
Abbott Diabetes Care FreeStyle Libre 14 day system[28]	GO + Redox Sensing Membrane	No required calibration; warm-up 1 hour; 14 days of sensor wear; range 40-500 mg/dL; no predictive alerts; requires scanning at least every 8 hours	Ascorbic acid Salicylic acid
Abbott Diabetes Care FreeStyle Libre 2[29,30]	GO + Redox Sensing Membrane	No required calibration; warm-up 1 hour; 14 days of sensor wear; range 40-400 mg/dL; no predictive alerts; optional alarms for hypoglycemia, hyperglycemia, and signal loss; requires scanning at least every 8 hours	Ascorbic acid
Dexcom G6[31,32]	GO + Perm-selective membrane coating	No required calibrations; warm-up 2 hours; 10 days of sensor wear; range 40-400 mg/dL; hypoglycemia predictive alerts	Hydroxyurea
Medtronic MiniMed Guardian Sensor 3[34,35]	GO	Requires 2-4 calibrations/day; warm-up 2 hours; 7 days of sensor wear; range 40- 400 mg/dL; predictive alerts	Acetaminophen
Senseonics Eversense[36,37]	Nonenzymatic electrochemical fluorescent-based polymer	Required 2 calibrations/day; implantable; warm-up 24 hours; 90-180 days of sensor wear; predictive alerts for hypoglycemia and hyperglycemia; conditional MRI compatibility	Mannitol Tetracycline

GO, glucose oxidase; MRI, magnetic resonance imaging.

Continuation of Home CGMs After Hospitalization

Chair: Robert J. Rushakoff, MD
University of California, San Francisco, CA, USA

Potential Opportunities

Patient Considerations

Standalone CGMs and AID systems are typically used in the outpatient setting. If a patient wearing either of these technologies is hospitalized, then policies are needed to continue these technologies. Some hospitals have policies for removing personal use devices like CGMs, CSII systems, and AID systems from patients when they are admitted. It is within the FDA's authorized use for a patient to use their own device for self-management while in a hospital. What is not authorized is when a hospital wants to use the CGM for their own testing purposes as well as in patients who do not have diabetes.

This section focuses on continuing a CGM already started before a patient arrives at the hospital and a subsequent section focuses on initiating a CGM in the hospital. Anyone with diabetes who is using a CGM and who is not cognitively impaired is a candidate to continue with this device in the hospital.

Benefits of CGMs

Several studies have demonstrated that CGMs in ambulatory settings improve patients' satisfaction,[38,39] as well as control (eg, better TIR and time in hypo- and hyperglycemia).[40,41] Continuation of an outpatient CGM during a hospitalization could improve patient satisfaction and efficacy of glycemic monitoring by assisting the patient and the hospital staff to identify glucose patterns, and predict future glycemia with trend arrows and rate of change,[42] and potentially prevent severe hypo- and hyperglycemic events.[43] This would be particularly relevant if staffing shortages exist or a patient is no longer aware of hypoglycemia. Accordingly, asking patients to remove their CGMs in the hospital could potentially contribute to decreased patient satisfaction and quality of care. CGM use in ICU and non-ICU settings has several superior features over intermittent point-of-care (POC) testing for glucose monitoring during continuous insulin infusion and subcutaneous insulin therapy, and possibly is a safer and less costly approach that can reduce workload. Additionally, CGM technology could potentially replace many uses of POC capillary BG testing in the hospital.[43] However, if CGM readings turn out to be inaccurate, then more confirmatory testing would be needed and that could increase workload.

Pregnancy

The use of CGMs in pregnant patients with T1DM has been associated with improvement in both maternal and fetal outcomes in five areas, including (1) time in glycemic target range without increase in hypoglycemia, (2) lower incidence of large-for-gestational-age babies, (3) fewer neonatal ICU admissions, (4) reduced neonatal hypoglycemia, and (5) decreased length of stay (LOS).[44,45] The use of CGMs in pregnancy is considered off-label in the United States, but not in Europe. In recent years, patients and HCPs have identified real-time continuous glucose monitoring as a helpful adjunct. Although there is ongoing interest in the use of CGMs in pregnancy, there are limited data about its use in the acute-care setting. If an HCP intends to use such a device, then it would be important to avoid placing it near areas of potential obstetric surgery.

Potential Barriers

Studies on substances that interfere with current subcutaneous CGMs are shown in Table 2. The panel agreed that CGM results should be interpreted cautiously in patients using select drugs known to cause interference with CGM sensing technologies. For these situations, panelists recommended using more accurate glucose testing, such as laboratory analyzers or AMBG[5] using hospital BG monitors (BGMs; which, unlike home-use BGMs, require special cleaning and disinfection procedures). Even though these devices are factory-calibrated and a limited set of studies have reported acceptable accuracy in critically ill patients,[46] several potential scenarios in the hospital (eg, interfering substances, hypoxia, acidosis, and hypotension) would require very careful use of this technology. The panel did not feel that current CGMs can now replace capillary POC finger stick monitoring or other FDA-cleared methods for monitoring BG in the hospital.

Recommendations for Continuation of Home CGMs After Hospitalization

Clinical Practice

Strong Recommendations

- HCPs **should** consult with an inpatient diabetes team if available, when continuing or initiating a CGM or AID system.
- HCPs **should** avoid relying on CGM data for glycemic management decisions in patients with severe hypoglycemia or hyperglycemia (ie, BG $<$ 40 mg/dL or $>$ 500 mg/dL).

- HCPs **should** avoid using CGMs for management of (1) diabetic ketoacidosis until glucose is in the CGM measurement range, and then CGMs should be used adjunctively or (2) situations with rapidly changing glucose levels and fluid/electrolyte shifts.
- HCPs **should** avoid continuing or initiating CGMs to patients with skin infections near the sensor site or placing sensors in areas with significant edema as well as patients treated with vasoactive agents or poor tissue perfusion.
- HCPs **should** use a CGM checklist for elective procedures during the preoperative visits to ensure proper documentation of devices and real-time data reporting.
- HCPs **should** advise pregnant women to continue the use of a CGM during a hospitalization to identify glucose trends and prevent hypo- or hyperglycemia.
- HCPs **should** instruct patients to bring supplies with them to the hospital for the duration of any preplanned admission or elective procedures.
- HCPs **should** check capillary BG or serum BG concentrations after procedures for non-critically ill patients and venous/arterial blood for critically ill patients to ensure the patient's CGM is functioning properly.
- HCPs **should** use trend arrows and rate of change to help prevent extreme glycemic excursions and (when a CGM is used adjunctively) to help determine when a BG test is required.
- HCPs **should** set alarm thresholds for inpatient glycemic targets, such as predicting hypoglycemia (typically BG < 80-85 mg/dL) or predicting hyperglycemia.
- Nursing **should** document CGM and/or CSII system information in the electronic health record (EHR) for all admissions or elective procedures.

Research

Strong Recommendations

- Researchers **need** to provide more data to support definitive recommendations on improved outcomes for continuation of home/ambulatory CGM use after hospitalization.
- Researchers **need** to conduct studies on the roles of CGM and POC BG testing and identify the optimal features of telemetry to inform nursing staff about actionable CGM patterns.
- Researchers **need** to perform further studies to assess the accuracy of CGMs during pregnancy, labor and delivery, and the peripartum period.
- Researchers **need** to study the impact of lag time on glucose measurements (ie, situations with rapid changes in the glucose concentration) in the hospital.

Hospital Policies

Strong Recommendations

- Hospitals **need** to develop standard CGM data reports and workflows.
- Hospitals **need** to implement policies for testing capillary BGs and calibrating CGMs if the CGM requires calibration.
- Hospitals **need** to develop a system for automatic staff notification for CGM alarms that predict impending or current hypoglycemia or hyperglycemia.
- Hospitals **need** to develop specific guidelines for using CGMs and AID systems for their affiliated nursing homes and skilled nursing facilities.

Initiation of CGMs in the Hospital

Chair: Guillermo E. Umpierrez, MD, CDE
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Potential Opportunities

COVID-19

The current COVID-19 pandemic created the need for innovative approaches for glycemic monitoring in the hospital.[4] Coincidentally, two weeks before this meeting, the FDA stated that they would exercise enforcement discretion and they would not object to the use of CGMs in the hospital during the crisis.[2,3] This policy was intended for the factory-calibrated CGMs manufactured by Abbott Diabetes Care and Dexcom. Subsequently, these two manufacturers provided CGM supplies to hospitals to help monitor glucose remotely. Immediately afterward, several institutions started the process of implementing CGM use and realized that there was a need for training, implementation, and resource utilization and not all hospitals have this expertise. The announcement also resulted in new reports on the use of CGMs in the hospital. During the panel discussion, there was a recognition that this "exceptional" situation did not indicate "label approval" for CGM use in the hospital by regulatory bodies. Collaborative efforts from Emory University and DTS have recently provided examples of practical implementation of CGMs and use of diabetes technology in the hospital through creation of a website that contains information about original articles, commentary, news, and protocols related to COVID-19 and diabetes[47] (covidindiabetes.org). Small pilot studies have provided unconfirmed evidence of the feasibility of remote glucose monitoring during this global crisis.[40]

ICU Patients

There is strong evidence from large, prospective, and randomized studies indicating that optimal glucose management

results in improved outcomes, reduced complications, and a decreased LOS.[48,49] In the ICU setting, therapy with intravenous insulin infusion allows clinicians to maintain narrow glycemic targets. The panelists reviewed studies using CGMs in the ICU in adult populations (Table 3) [50-83] and pediatric populations (Table 4) [84-88].

In the ICU, bedside POC glucose using factory-calibrated BGMs (performed every one to two hours) has been recommended as the preferred method to assess glycemic management and to guide hyperglycemia treatment with intravenous insulin infusion. POC BG testing has drawbacks. This testing method is labor-intensive. Also, POC testing does not provide (1) a full 24-hour glycemic profile, (2) predictions of hypoglycemic events, or (3) alarms for asymptomatic hypo- or hyperglycemia. Although the use of POC glucose testing, compared to central laboratory glucose testing, is approximately as convenient and generates faster results, another drawback is that it costs more. Estimated mean total costs (including equipment, supplies, and labor) can be up to $5.13 per POC test in a high-test-volume nursing unit, and up to $16.49 per POC test in a low-test-volume nursing unit, compared to $3.78 for central laboratory glucose testing.[89] Moreover, the accuracy of POC glucose meters is not optimal, with only 6 of 18 glucose monitor systems (representing 90% of commercially available meters and intended for outpatient use) meeting regulatory accuracy requirements[17] in a recent study. In 2018, the FDA cleared the first POC glucose meter—the StatStrip Glucose (Nova Biomedical, Waltham, MA, USA)—for all hospitalized patients, including critically ill patients, to test capillary, venous, and arterial blood specimens.[90] However, not all hospitals use this system to measure BG. While definitive validation of CGM accuracy in ICU patients is still forthcoming, there remains a potential role for CGMs to measure glucose concentrations in this population.[46,91,92]

Non-ICU Patients

Studies using older CGM technology that required regular recalibration have shown minimal differences in mean daily glucose, premeal, fasting, or two-hour postprandial glucose levels between CGM and POC BG testing. In a pilot study, CGMs detected a higher number of hypoglycemic events compared to POC BG testing, particularly nocturnal or asymptomatic hypoglycemia.[93] Few studies have been published on the use of newer factory-calibrated CGMs in non-ICU settings.[94]

A recent study of patients with T2DM admitted to general medicine and surgery wards and managed with basal-bolus insulin therapy compared the FreeStyle Libre Pro (Abbott Diabetes Care, Alameda, CA, USA)[95] to POC BG testing.[96] This CGM system is a variant of the FreeStyle Libre 14-day system, where glucose readings are available to the HCP but not to the patient. The FreeStyle Libre Pro CGM, compared to POC BG testing, showed a tendency toward lower mean glucose with an estimated mean glucose difference of 12.8 mg/dL (confidence interval [CI] 8.3-17.2). Accordingly, CGMs, compared to POC BG testing, were more sensitive at detecting hypoglycemic events. The overall mean absolute relative difference was 14.8%. The percentage of glucose concentrations within the ±15% or 15 mg/dL, ±20% or 20 mg/dL, and ±30% or 30 mg/dL (where for CGM concentrations ≤100 mg/dL, the units of the range were mg/dL and for CGM concentrations >100 mg/dL, the units of the range were percent) was 62%, 76%, and 91%, respectively. A Clarke error grid analysis showed acceptable clinical accuracy with 98.0% of glucose concentrations falling into Zones A (75.1%, $n = 1184$) and B (23.7%, $n = 374$).[96] Panelists reviewed CGM studies in the non-ICU in adult populations (Table 5). [40, 43, 93, 96-103] Evidence suggests that initiating the use of CGMs in the non-ICU settings provides better glycemic monitoring, compared to standard 3-4 times daily POC BG testing, with improved detection and potential prevention of hypo- and hyperglycemic events. Most of these events, particularly nocturnal and asymptomatic hypoglycemia, might otherwise be missed. Ongoing hospital CGM studies listed on ClinicalTrials.gov[104] may provide some guidance (Table 6).

Glucose Telemetry

The hospital should possess the physical infrastructure to download the patient's CGM data for the retrospective review of patterns in glycemia. CGM data can be automatically delivered to the nursing station by way of automatic downloading into a monitor at the nursing station. A recently published manuscript evaluated whether such a system for presenting CGM data, called the "Glucose Telemetry System," can decrease hypoglycemia in the general wards/non-ICU setting.[43] This report is the first interventional randomized controlled trial (RCT) study of CGM technology to improve outcomes in the non-ICU setting. The study included patients with T2DM, who were at high risk for hypoglycemia. Participants were randomized to either the "Glucose Telemetry System" (intervention group) or to POC BG testing (control group). For patients in the "Glucose Telemetry System," nurses were instructed to proceed with hypoglycemia prevention actions if the low-glucose alerts were activated (for a setting of BG < 85 mg/dL). Participants in the control group were placed on "blinded" CGMs, which were only used to collect glucometric data. Overall, the subjects in the "Glucose Telemetry System" experienced fewer events of hypoglycemia (BG < 70 mg/dL) and clinically significant hypoglycemia (BG < 54 mg/dL) compared to the POC BG group. The outcomes of the intervention versus control groups for these two

Table 3. CGM Studies in the ICU in Adult Populations.

Authors	Population	CGM type	CGM manufacturer	Performance measurement	Comparator
Goldberg et al[50]	ICU (*n*: 22)	CGMS	Medtronic MiniMed	Accuracy	Capillary by POC
Vriesendorp et al[51]	OR, SICU (*n*: 8)	CGMS and GlucoDay	Medtronic MiniMed and A. Menarini Diagnostics (A. Menarini Diagnostics Ltd., Florence, Italy)	Accuracy and feasibility	Arterial by blood gas analyzer
Corstjens et al[52]	MICU (*n*: 45)	System Gold	Medtronic MiniMed	Accuracy	Arterial by blood gas analyzer, YSI (YSI 2300 STAT Plus glucose and lactate analyzer, YSI Life Science, Yellow Springs, OH, USA) and POC
De Blocket al[53]	MICU (*n*: 50)	Glucoday	A. Menarini Diagnostics	Reliability	Arterial
Price et al[54]	Mixed ICU (*n*: 17)	Guardian	Medtronic MiniMed	Accuracy	Arterial by blood gas analyzer and POC
Holzingeret al[55]	MICU (*n*: 50)	System Gold	Medtronic MiniMed	Accuracy and reliability	Arterial by blood gas analyzer
Rabiee et al[56]	SICU/Burn (*n*: 19)	Dexcom STS	Dexcom	Accuracy and reliability	Capillary by POC and serum by Lab
Yamashita et al[57]	ICU (*n*: 50)	STG 22	Nikkiso Co., Ltd. (Tokyo, Japan)	Accuracy	Arterial by blood gas analyzer
Logtenberg et al[58]	Cardiac surgery ICU; (*n*: 30)	Paradigm	Medtronic MiniMed	Accuracy and glycemic control	Capillary, arterial, and venous by POC
Holzinger et al[59]	ICU, mechanical ventilation (*n*: 24)	Guardian	Medtronic MiniMed	Glycemic control (% time at glucose $<$ 110 mg/dL), LOS, mortality	Arterial by blood gas analyzer and blinded Medtronic MiniMed System Gold CGM
Jacobs et al[60]	ICU (*n*: 29)	Guardian RT	Medtronic MiniMed	Accuracy and feasibility	Capillary by POC
Brunner et al[61]	MICU (*n*: 174)	Guardian & System Gold	Medtronic MiniMed	Accuracy and reliability	Arterial by blood gas analyzer
Lorencio et al[62]	ICU (*n*: 41)	Guardian	Medtronic MiniMed	Accuracy	Arterial by blood gas analyzer
Kalmovich et al[63]	Perioperative cardiac surgery (*n*: 32)	System Gold Blinded	Medtronic MiniMed	Accuracy and feasibility	Venous by blood gas analyzer
Kopecký et al[64]	Cardiac ICU; *n*: 24	Guardian RT	Medtronic MiniMed	Accuracy and glycemic control	Arterial by blood gas analyzer and computer (enhanced model predictive control) algorithm alone
Leelarathna et al[65]	Neurosurgical ICU (*n*: 24)	FreeStyle Navigator	Abbott Diabetes Care	Glycemic control	Arterial by blood gas analyzer
Rodríguez-Quintanilla et al[66]	CCU (*n*: 16)	Guardian RT	Medtronic MiniMed	Time to normoglycemia	Venous and capillary by POC
Schuster et al[67]	SICU (*n*: 24)	Guardian	Medtronic MiniMed	Accuracy	Capillary by POC
Boom et al[68]	MICU/SICU (*n*: 156)	FreeStyle Navigator	Abbott Diabetes Care	Accuracy and glycemic control	Arterial by blood gas analyzer, and POC
Kosiborod et al[17]	Cardiac ICU (*n*: 21)	Sentrino	Medtronic MiniMed	Accuracy and reliability	Central venous by POC or lab
Umbrello et al[69]	MICU (*n*: 6)	OptiScanner 5000	OptiScan Biomedical	Glycemic control	Central venous by blood gas analyzer or lab (reported elsewhere)
Van Hooijdonk et al[70]	ICU (*n*: 50)	Sentrino	Medtronic MiniMed	Accuracy and reliability	Arterial by blood gas analyzer
Sechterberger et al[71]	Cardiac ICU (*n*: 8)	FreeStyle Navigator	Abbott Diabetes Care	Accuracy	Arterial by blood gas analyzer
Punke et al[72]	SICU (*n*: 14)	Sentrino	Medtronic MiniMed	Accuracy	Arterial by blood gas analyzer

(continued)

Table 3. (continued)

Authors	Population	CGM type	CGM manufacturer	Performance measurement	Comparator
De Block et al[73]	MICU (*n*: 35)	GlucoDay S	A. Menarini Diagnostics	Accuracy and glycemic control	Arterial by blood gas analyzer and blinded microdialysis-based CGM
Ballesteros et al[74]	MICU (*n*: 18)	Soft Sensor	Medtronic MiniMed	Accuracy	Capillary by POC
Nohra et al[75]	SICU (*n*: 23)	Optiscanner 5000	Optiscan Biomedical	Accuracy	Central venous by YSI
Wollersheim et al[76]	MICU (*n*: 20)	Sentrino	Medtronic MiniMed	Accuracy and feasibility	Arterial, central venous, or venous by blood gas analyzer
Gottschalk et al[77]	Extracorporeal cardiac life support (*n*: 25)	Sentrino	Medtronic MiniMed	Accuracy	Arterial by blood gas analyzer
Righy Shinotsuka et al[78]	ICU (*n*: 88)	OptiScanner 5000	Optiscan Biomedical	Accuracy	Arterial by YSI
Schierenbeck et al[79]	Cardiac ICU (*n*: 26)	Freestyle Libre Subcutaneous-CGM vs Eirus Intravascular	Abbott Diabetes Care and Maquet Getinge Group	Accuracy	Arterial by blood gas analyzer and capillary by POC
Song et al[80]	OR, ICU (*n*: 22)	Guardian	Medtronic MiniMed	Accuracy and reliability	Arterial by blood gas analyzer
Rijkenberget al[81]	Mixed ICU (*n*: 155)	FreeStyle Navigator	Abbott Diabetes Care	Accuracy and reliability	Arterial by blood gas analyzer
Ancona et al[46]	ICU (*n*: 8)	FreeStyle Libre CGM	Abbott Diabetes Care	Accuracy and feasibility	Arterial by blood gas analyzer or capillary by POC
Bochicchio et al[82]	ICU (*n*: 243)	OptiScanner 5000	OptiScan Biomedical	Accuracy	Arterial, central venous, or venous by YSI
Nukui et al[83]	Acute stroke (*n*: 39)	FreeStyle Pro CGM	Abbott Diabetes Care	Accuracy and efficacy	Capillary by POC

CGM, continuous glucose monitoring; ICU, intensive care unit; LOC, length of stay; MICU, medical ICU; OR, operating room; POC, point of care; SICU, surgical ICU.

Table 4. CGM Studies in the ICU in Pediatric Populations.

Author	Population	Type of CGM	CGM manufacturer	Performance measurement	Comparator
Bridges et al[84]	ICU (*n*: 47)	Guardian	Medtronic MiniMed	Accuracy	Arterial, venous, and capillary by iSTAT POC and lab
Steil et al[85]	Cardiac ICU (*n*: 311)	Guardian	Medtronic MiniMed	Accuracy and hypoglycemia prevention	Arterial by POC and lab
Prabhudesai et al[86]	ICU (*n*: 19)	Guardian	Medtronic MiniMed	Accuracy	Arterial by lab
Kotzapanagiotou et al[87]	ICU (*n*: 16)	FreeStyle Libre	Abbott Diabetes Care	Accuracy	Arterial by blood gas analyzer capillary by POC, biochemical serum by lab
Sopfe et al[88]	Stem cell transplantation (*n*: 29)	FreeStyle Libre Pro	Abbott Diabetes Care	Accuracy	Central venous by lab

CGM, continuous glucose monitoring; ICU, intensive care unit; POC, point of care.

levels of hypoglycemia were, respectively, 0.67 versus 1.69 events/patient, $P = .024$ (BG < 70 mg/dL) and 0.08 versus 0.75 events/patient, $P = .003$ (BG < 54 mg/dL). There was a reduction in percentage of time in hypoglycemic range (BG < 70 mg/dL and <54 mg/dL) in the glucose telemetry system group compared to POC group (0.40% vs 1.88%, $P = .002$ and 0.05% vs 0.82%, $P = .017$).

Potential Barriers

Minimally Invasive CGMs

As discussed in previous consensus reports[1,105] during the past 20 years, many studies have been published on the initiation of subcutaneous CGMs in critically ill patients (Tables 3 and 4). However, most of those studies were

Table 5. CGM Studies in the Non-ICU in Adult Populations.

	Patient population	CGM type	CGM manufacturer	Performance measurement	Comparator
Dungan et al[97]	T1DM and T2DM (*n*: 58), on intravenous or subcutaneous insulin	iPro system	Medtronic MiniMed	Accuracy	Capillary by POC
Burt et al[98]	T1DM and T2DM, on basal bolus insulin (*n*: 26)	System Gold	Medtronic MiniMed	Accuracy and glycemic control	Capillary by POC
Schaupp et al[99]	T2DM, on basal bolus insulin (*n*: 84)	iPro2 system	Medtronic MiniMed	Accuracy	Capillary by POC
Gómez et al[93]	T2DM, on basal bolus insulin (*n*: 38)	iPro2 system	Medtronic MiniMed	Glycemic control and hypoglycemia detection	Capillary by POC
Spanakis et al[100]	T2DM, on insulin therapy (*n*: 5)	Dexcom G4 CGM with Share2 application	Dexcom	Glucose telemetry system feasibility	None
Singh et al[101]	T2DM, on basal-bolus insulin (*n*: 13)	Dexcom G4 Platinum CGM	Dexcom	Feasibility and prevention of hypoglycemia	Blinded CGM
Nair et al[102]	Surgical ward (*n*: 10)	Dexcom G6 Blinded	Dexcom	Accuracy	Capillary by POC
Shehav-Zaltman et al[40]	T1DM on CSII (*n*: 1) and T2DM on basal bolus (*n*: 3), COVID-19 wards (*n*: 5)	Guardian	Medtronic MiniMed	Feasibility	None
Galindo et al[96]	T2DM, on basal-bolus insulin (*n*: 97)	FreeStyle Libre Pro CGM	Abbott Diabetes Care	Accuracy and hypoglycemia detection	Capillary by POC
Singh et al[43]	T2DM, on basal-bolus insulin (*n*: 72)	Dexcom G6	Dexcom	Prevention of hypoglycemia	Blinded CGM
Ushigome et al[103]	Diabetes (unknown type) with COVID-19 (*n*: 1)	Dexcom G4 Platinum	Dexcom	Safety and effectiveness	Lab

CSII, continuous subcutaneous insulin infusion; POC, point of care; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

Table 6. Ongoing Hospital CGM Studies Listed on ClinicalTrials.gov.

Dexcom intervention trial (NCT03877068)
CGM in Hospitalized Veterans/ Glucose Telemetry System (NCT03508934)
Scripps Digital Diabetes (NCT04269655)
Green Line from Hospital to Territory (GreenLightHT) (NCT03764709)
Use of Wearables for Early Detection of Complications After Major Acute Abdominal Surgery (NCT04257344)
DRIVE—Perioperative Period (DRIVE-Periop) (NCT04033705)
Flash Glucose Measurement in Patients on Total Parenteral Nutrition (NCT03871660)
Early Glargine (Lantus) in Diabetic Ketoacidosis Management in Children with Type 1 Diabetes (NCT03107208)
Reducing Emergency Department Visits and Improving Glucose Control in Uncontrolled Type 2 Diabetes Using CGM Sensors at Hospital Discharge (NCT04277780)
CGM in Hospitalized Patients with Diabetes (NCT04230694)
Remote Continues Glucose Monitoring During the COVID-19 Pandemic in Quarantined Hospitalized Patients (CGM-ISO) (NCT04430608)
The Use of a Continuous Glucose Monitoring System (Dexcom G6) in Hospitalized Patients for Acute Care (NCT04385862)
Wireless Assessment of Respiratory and Circulatory Distress - Continuous Glucose Monitoring (WARD-CGM) (NCT04473001)
Reliability of the Freestyle Libre CGM in the Inpatient Setting During the COVID-19 Surge (NCT04417270)

Table is up-to-date as of August 8, 2020.
CGM, continuous glucose monitoring.

intended to focus only on accuracy data and not clinical outcomes. In addition, it is difficult to reach conclusions from these reports because of different study designs and small sample sizes. A recent systematic review by van

Steen et al analyzed 32 studies that assessed the accuracy of CGMs in the ICU. These authors reported moderate-to-good accuracy especially with intravascular devices.[106] The authors included only five RCTs for efficacy assessment and recognized methodological limitations.[106] Panelists noted that there is currently insufficient data to provide definitive recommendations on improved outcomes based on reports in the medical literature.

It is unclear whether CGMs will be able to fully replace POC BG testing and be approved as nonadjunctive use for treatment decisions in acute care. Panelists had concerns with the accuracy of subcutaneous CGM values for the first hours after insertion to make treatment decisions or even during the first one to two days of use. Panelists also had concerns with the unintentional added burden on nursing when (1) a CGM has overreported low glucoses values and these false low values have required POC confirmation, (2) new CGM technology must be learned during a crisis, and (3) time is needed for troubleshooting. In addition, skin-related issues have been mentioned in 19% of articles about recent CGMs.[107-109]

Invasive CGMs

Although these systems were not the focus of the guideline, the panelists briefly considered the role of invasive CGMs. They noted that few intravascular invasive sensors are cleared for ICU patients. Also, compared to subcutaneous CGM sensors, intravascular sensors tend to have three main disadvantages. First, these systems are invasive and some are associated with vascular complications, such as thrombosis, catheter occlusion, biofilm formation, or intravascular catheter-related infections.[110] Second, they impose a higher implementation resource and care burden to patients and the ICU system. Third, they are not intended for non-ICU settings. Therefore, intravascular CGMs, compared to subcutaneous CGMs, are less attractive options.

Recommendations for Initiation of CGMs in the Hospital

Clinical Practice

Strong Recommendation

- HCPs **should** consider prescribing CGMs to reduce the need for frequent nurse contact for POC glucose testing and the use of PPE for patients on isolation with highly contagious infectious diseases (eg, COVID-19).

Mild Recommendation

- HCPs **should** avoid initiating CGMs in patients with severe hypoglycemia or hyperglycemia (ie, BG < 40 mg/dL or > 500 mg/dL) or during periods of rapid glucose fluctuations.

Research

Strong Recommendations

- Researchers **need** to provide data to support initiation of CGMs for improving patient-centered outcomes.
- Researchers **need** to provide data on hospital outcomes when initiating CGMs in the hospital, including improved glycemic outcomes, detection and/or reduction of hypoglycemia and hyperglycemia, reduction of ICU LOS, and cost-effectiveness.
- Researchers **need** to conduct studies on long-term benefits for initiating CGMs in the hospital after discharging patients with newly diagnosed diabetes or recurrence of diabetic ketoacidosis (DKA) or other complications of diabetes.
- Manufacturers **need** to develop educational tools for patients, hospital staff, and HCPs.

Hospital Policies

Strong Recommendations

- Hospitals **need** to develop plans, including process maps, protocols, staff educational resources, and order sets for prescribing CGM use during hospitalizations before implementing a CGM.
- Hospitals **need** to provide educational tools for patients, nurses, house staff, and attending physicians when a patient in the hospital starts on a CGM.

Continuation of AID Systems in the Hospital

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Potential Opportunities

Improved Glycemic Outcomes

Evidence about the potential glycemic benefits of continuing AID systems from the outpatient into the inpatient setting is limited, and currently it is possible only to extrapolate data from studies of AID systems initiated during a hospital stay. Several such studies of initiating AID systems in the hospital have been performed in medical or surgical patients as well as in patients on hemodialysis or women in the peripartum/postpartum period.[111-118] In the largest of these studies,[111] Bally et al reported that initiation of AID system technology in the hospital for patients receiving noncritical care achieved a higher percentage of TIR when compared to standard hospital management. The times in range were, respectively, 65.8 (±standard deviation 16.8)% vs 41.5 (±16.9)%, with a difference of 24.3 (±2.9)% (95% CI 18.6-30.0; $P < .001$). Mean glucose levels were lower in the AID

system arm compared to the group treated with conventional subcutaneous insulin delivery (with the differences being 154 [±29] mg/dL vs 188 [±43 mg/dL], $P < .001$) and there was no significant difference in time spent in hypoglycemia, <54 mg/dL or <70 mg/dL. AID systems have also been found to improve TIR in women in the peripartum/postpartum period[112] and patients on hemodialysis.[113] AID system management has reduced surgical site infections resulting in shorter postoperative hospitalizations.[114] In a single-center observational study that was performed in an ICU setting, use of AID system management compared to standard sliding-scale insulin therapy led to a decreased frequency of blood sampling, reduced time required for achieving glycemic targets, and a decreased nursing workload per admission of diabetes management from 68 (±25) minutes (AID system) to 33 (±21) minutes (sliding scale) ($P < .001$).[115] In a randomized, parallel-group trial, inpatients with T2DM in the United Kingdom received fully closed-loop insulin delivery without meal-time boluses, which was found to be safe and effective.[116] In a two-center open-label, RCT of fully AID in the United Kingdom and Switzerland, this method was found to improve glycemic outcomes for inpatients receiving nutritional support.[117]

Glycemic management in hospitalized patients aims to avoid both hypoglycemia and hyperglycemia. Since patients with diabetes are often in a compromised state of health and at risk for hypoglycemia because of interrupted nutrition, inadvertent insulin overdosages associated with intensive insulin therapy, or unexpected improvements in insulin sensitivity, hypoglycemia can be a serious problem for these patients. Special AID systems that can deliver both insulin and glucose have been created exclusively for inpatient use. A clinical study in Japan compared two such systems (differing in size and weight, but not algorithms) manufactured by Nikkiso Co., Ltd., and used for perioperative glycemic management. The newer (STG-55) and older (STG-22) AID system models[119] both achieved similar glycemic control without hypoglycemia, leading the investigators to conclude that the newer (as well as smaller and lighter) system could potentially be used in routine practice for perioperative glycemic management.[118] A study in Denmark assessed an intravenous AID infusion system delivering both insulin and glucose based on a proprietary controller (Admetsys, Boston, MA, USA).[120]

COVID-19

With the COVID-19 pandemic, increased mortality has been associated with hyperglycemia both in patients diagnosed with diabetes prior to admission and those diagnosed with diabetes during their admission.[121] There is a paucity of high-quality data about optimal monitoring and therapy and associated outcomes in these patients. The need for improved glycemic management for COVID-19 patients may accelerate the development of future novel glucose monitoring technologies in the hospital setting, including possibly closed-loop control for intensively treated patients. During the pandemic, AID systems, if utilized, can also perhaps reduce the risk of nursing exposure, the time needed for donning and doffing for any needed BG monitoring, and the use of limited supplies of personal protective equipment.

Patient Satisfaction

Evidence about the potential benefits of using of AID systems in the inpatient setting is limited. Even for the more traditional non-AID CSII system, the available data are based on retrospective studies, because no randomized clinical trials have been performed.[122] One of these studies reported that outpatients on CSII systems, who had reasonable control (mean hemoglobin A1c 7.5%),[123,124] were sufficiently confident to continue self-managing their diabetes and use their own CSII systems during a hospitalization. Many of these CSII system users reported higher patient satisfaction (86%) when they were allowed to continue wearing their CSII system during their inpatient stay.[125] Similar outcomes are likely to be found with the use of AID systems. Asking hospitalized patients with diabetes to remove their AID system could result in decreased patient satisfaction, especially if their diabetes care is managed by healthcare professionals, who have limited experience with inpatient and outpatient diabetes management. Furthermore, a patient who must surrender their AID system upon hospitalization might express dissatisfaction with nocturnal POC BG testing.

Potential Barriers

Patient-Related Factors

Although AID systems can be beneficial, five types of factors may preclude their use in the inpatient setting.[122,123,126] They can be divided into the following categories: (1) patient-related, (2) hospital-related, (3) device-related, (4) medication-related, and (5) surgical procedure-related. Examples of patient-related conditions in which AID systems should not be used are physical or psychiatric conditions, which can make patients incapable of self-managing an AID system in the hospital. Contraindications to CSII system and AID system therapy in the hospital are presented in Table 7. Patients should be able to self-manage their AID systems and provide their pump settings to the treating HCPs in case the AID system may need to be discontinued. Patients with severe metabolic decompensations, such as DKA,[122] acute kidney injury, post-transplant T1DM patients in acute rejection, or those with severe sepsis and hypovolemia, which may lead to tissue hypoperfusion, should also probably not use AID systems in the hospital. Skin infections may represent another contraindication, especially if they are extensive, because they may preclude CGM or pump placement. However, it is still unclear

Table 7. Contraindications to CSII System and AID System Therapy in the Hospital.

Impaired level of consciousness (except during short-term anesthesia)
Patient's inability to correctly demonstrate appropriate CSII system settings
Critical illness requiring intensive care
Psychiatric illness that interferes with a patient's ability to self-manage diabetes
Diabetic ketoacidosis and hyperosmolar hyperglycemic state
Refusal or unwillingness to participate in self-care
Lack of CSII system supplies
Lack of trained health care providers, diabetes educators, or diabetes specialists
Patient at risk for suicide
Health care decision

AID, automated insulin dosing; CSII, continuous subcutaneous insulin infusion.
Table has been reproduced with permission from Umpierrez and Klonoff, Diabetes Care, 2018.[122] "Insulin pump therapy" in the title of the table has been changed to "CSII system and AID system therapy". "Pump" in the second and seventh bullets has been changed to "CSII system".

whether the above conditions can significantly affect the function of AID systems and more research is needed in this area.

Hospital-Related Factors

Examples of hospital-related factors are situations where there are no policies in place that can safeguard the use of AID systems in the inpatient setting and delineate the roles of the patients, nurses, and HCPs.[123,126] Because only limited information is currently available about the use of AID systems in the hospital, further research is needed in order to provide evidence-based recommendations.[126] Another potential obstacle to the use of AID systems in the inpatient setting is the lack of nurses and HCPs who are adequately trained in the use and interpretation of data from the AID systems. However, it is unclear whether AID systems do or do not lead to increased workload for nursing and/or HCPs.

Device-Related Factors

Limitations related to device use include clinical scenarios where AID systems cannot be used because of a device malfunction or insufficient medical supplies, either for the continuous insulin infusion set or for the CGM components. A CGM can become compressed during a prolonged period of a prone position, such as with sleep or prone ventilation, and produce a false low reading, which could also pose another limitation to their use.[127,128] For AID systems that require the patient to select a meal-time bolus dose recommended by a bolus calculator, unexpected failure to reach postprandial glycemic targets could be due to manufacturer-specific pump settings resulting in a different dose recommendation by each pump brand.[129]

Medication-Related and Meal-Related Factors

Medications, such as glucocorticoids, which can cause severe insulin resistance and uncontrolled hyperglycemia, may present a challenge for some AID systems, but others may adapt well to changes in insulin resistance during periods of illness.[130] Other challenging scenarios are nutritional interruptions, which are very common in a busy hospital environment.[130] Nutrition in the inpatient setting is more complicated than in the ambulatory environment. Patients may have nausea, vomiting, or other conditions that can affect nutrient absorption and therefore create irregular patterns in the glucose values. Insulin is not always administered at the right time before the meal is delivered. Meals can be interrupted or delayed and tube feedings and parenteral nutrition (either peripheral or total) can be suddenly discontinued. Although the above scenarios are not absolute treatment-related contraindications, they represent challenging situations for AID system use in the hospital. HCPs should also be aware about the potential interactions of certain medications with subcutaneous CGMs (Table 2). Additional studies are required to determine the effects, if any, of multiple doses and combinations of potentially interfering medications on CGM accuracy.

Surgical Procedure-Related Factors

Surgical procedures can create additional barriers to the use of AID systems in the inpatient setting.[122,124,131] Surgical procedures can be broadly divided into two different categories, elective or urgent. Elective surgeries can provide sufficient time for preadmission preparation. The endocrinology clinician or diabetes team would coordinate care between the different subspecialties that are involved such as the anesthesiology, and surgical and inpatient diabetes teams (if they are available and different from the primary endocrinologist) about the upcoming surgical procedure. The panel recognized that many hospitals do not have a diabetes team or inpatient diabetes educator. Patients need to be instructed to insert the sensor and the insulin cannula away from the operative field and change the sites one day prior to the surgery. Urgent surgeries do not allow for such planning. In the immediate preoperative period, for either elective or urgent surgical procedures, the inpatient diabetes team should be notified, if this has not been done earlier. Consent must be obtained from the patient about the use of an AID system during surgery. Temporary higher glycemic targets may be needed to allow slightly higher glucose values during surgery to decrease the risk of hypoglycemia in an unconscious patient. Ideally, the anesthesiology team would need to be familiar with the use of an AID system during the intraoperative period so the team can control or suspend the pump if necessary because the unconscious patient will not be able to adjust the settings themselves. However, it is unclear whether it would be realistic to expect an anesthesiologist to learn the

operation of an AID system and there is no data about anesthesiologists operating AID systems during surgery. The basal insulin delivery rate is determined by an AID system controller. If the team members are able to manage the AID system, then they should also have easy access and proximity to the AID system intraoperatively. The use of an AID system during surgery is not recommended if the insulin requirements are expected to fluctuate significantly intraoperatively. In that case intravenous insulin delivery with insulin dosing software instead of subcutaneous insulin delivery would be more appropriate with either an intravenous or subcutaneous glucose sensor. AID systems can be continued during the operation if there are no concerns regarding device malfunction. However, there are no good data available on the safety or maximum safe duration of closed-loop control during anesthesia. Even with control by an AID system, BG concentrations should be monitored intraoperatively.

Recommendations for Continuation of AID Systems in the Hospital

Clinical Practice

Strong Recommendations

- HCPs **should** prescribe AID systems only for appropriate candidates, who will need to have adequate knowledge and skills for using AID systems.
- HCPs **should** reassess a decision periodically to transition use of outpatient AID systems into the hospital in order to ensure that AID system continues to represent the best treatment option for each patient.
- HCPs **should** prepare an alternative plan for diabetes management in case it becomes inappropriate for a patient to continue using an AID system in the hospital.
- HCPs **should** discontinue AID systems in critically ill hospitalized patients (such as those with hypovolemia or sepsis).
- HCPs **should** recognize glycemic patterns due to CGM compression, which can cause false low readings.

Mild Recommendation

- HCPs **should** avoid initiating an AID system during a hospitalization.

Research

Strong Recommendations

- Researchers **need** to conduct studies about whether continuing AID systems in the hospital is beneficial to improve glycemic management or clinical outcomes.
- Researchers **need** to provide data on hospital outcomes when using AID systems in the hospital, including improved glycemic outcomes, detection and/or reduction of hypoglycemia, reduction of ICU LOS, and cost-effectiveness.
- Manufacturers **need** to research whether all types of CGMs and AID systems can be used during radiological/imaging studies or diathermy.

Hospital Policies

Strong Recommendations

- Hospitals **need** to develop institution-specific protocols and order sets for the proper use of AID systems during a hospitalization.
- Hospitals **need** to require that patients using AID systems bring with them sufficient supplies for these devices during a hospitalization.
- Hospitals **need** to develop protocols for using AID systems during elective procedures and surgeries.

Recommendation Not Reaching Consensus

- HCPs **should** switch AID systems from "auto" mode to "manual" mode when a patient is admitted to the hospital wearing an AID system.

Logistics and Hands-On Care of Hospitalized Patients Using CGMs and AID Systems

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Potential Opportunities

Expectations for Patients and Hospital Staff and Practical Considerations for Use of CGMs and AID Systems in the Acute Care Setting

Continuation of CGM use can be a helpful adjunct to management in the acute care setting and can increase patient satisfaction. However, because CGMs are not currently cleared by FDA for the inpatient environment, a policy addressing practical considerations for use of CGMs and AID systems in hospitalized patients is needed.

Potential Barriers

Necessary Hospital Responsibilities

It is important that key tasks, roles, and responsibilities, related to work system domains (technology/data, tasks, personnel, structure/organization, and environment), are addressed for safe and effective implementation.[132] Below are listed potential responsibilities delineated by team members. It is helpful for diabetes team members to be

I_____currently have a continuous glucose monitor and/or insulin pump in place and wish to maintain this therapy during my admission to the Hospital. I understand and agree as follows:

Patient's Continuous Glucose Monitor

1. I may continue to wear my continuous glucose monitor (CGM) during my hospital stay but my blood glucose will also be monitored using a hospital-approved blood glucose meter and treatment decisions will be based on these results.
2. I will keep a back-up supply of all CGM supplies including, without limitation, sensors and dressings.
3. I will change the CGM sensor every 7-14 days depending on the device instructions.
4. I will notify my nurse immediately if my CGM indicates my glucose reading is trending out of target (i.e., trending low or high) so that my blood glucose can be tested to confirm the trending and appropriate treatment initiated according to the prescriber's order.
5. I will allow my nurse to assess the sensor site every shift.
6. If I need any surgery or procedure, then the hospital might need to remove my sensor. If I elect to leave my CGM sensor on during any surgery or procedure it may present a risk of damage to my CGM sensor during the surgery or procedure.
7. If I need an MRI scan, then I will remove the sensor prior to the procedure so that the transmitter and receiver can be either secured by staff or sent home with a designated family member/significant other.
8. If I need an X-ray or CT scan, then my CGM will be covered by a lead apron.
9. Any of my CGM supplies stored by hospital staff will be returned to me prior to my discharge.

Patient's Automated Insulin Dosing System

1. I can manage my own automated insulin dosing system (insulin pump and continuous glucose monitors) and the medical condition for which the automated insulin dosing system is prescribed.
    a. If my physical or mental condition changes, my caregivers at the hospital may re- assess my capability to manage my own pump. If it is determined that I can no longer safely manage my pump, the hospital will remove the pump and administer insulin by injection or IV as determined by my provider.
    b. Hospital personnel will not operate my pump, except in the above-described situation.
2. Only family members/significant others who usually assist me with the operation of my pump will do so during my hospital stay. I will keep a back-up supply of all insulin pump supplies including, without limitation, insertion sets, infusion tubing and dressings.
3. My insulin will be kept in my personal medication bin and my nurse will get it for me when needed for an insulin infusion set change.
4. I will change my insulin infusion set every 48-72 hours (2-3 days) or earlier as needed.
5. If I change my insulin pump settings, I will immediately communicate that with my health care team.
6. I will only make changes to the basal rate, unless in auto mode, after discussion with my provider. I will notify my nurse immediately if I have any problem with my insulin pump.
7. If I need any surgery, procedure, radiation therapy, or diagnostic imaging (e.g. MRI or x- rays), the hospital may need to disconnect my insulin pump and an alternative insulin regimen will need to be prescribed.

Figure 1. *(continued)*

8. If I need diagnostic imaging (e.g. MRI or x-rays), I may need to remove the pump prior to the procedure, and it will be secured by staff outside of the imaging area.
9. Regarding the CGM part of my automated insulin dosing system, if I need an MRI scan, then I will remove the sensor prior to the procedure so that the transmitter and receiver can be either secured by staff or sent home with a designated family member/significant other. If I need an X-ray or CT scan, then my CGM will be covered by a lead apron.
10. The hospital staff will monitor my blood glucose with a hospital-approved blood glucose meter.
11. I will report all bolus doses of insulin to my nurse for documentation purposes.
12. I will allow my nurse to assess the insertion site every shift.
13. If my blood glucose values are erratic and cannot be controlled, my insulin pump may be discontinued, and an alternative insulin regimen will be provided for me.
14. Prior to being discharged from the hospital, I will confirm with my nurse that the pump is working correctly and that there are no problems with medication delivery or the delivery site on my body. In the event that there are problems, they will be corrected prior to my discharge from the hospital.
15. Any of my unused insulin and pump supplies that I have brought with me to the hospital will be returned to me prior to my discharge.
16. My physicians and other health care providers may terminate my use of the insulin pump if they observe any contraindication to its use or for any reason that they believe medically necessary.

By signing below, I acknowledge that I have read, understood, and agreed to the above and that all of my questions have been answered.

Patient Signature: _____

Nurse/Provider Signature: _____

Nurse/Provider Print Name: _____

Unit/Service: _____

Date & Time: _____

Figure 1. Continuous glucose monitors or automated insulin dosing system sample patient agreement.
CGM, continuous glucose monitoring; CT, computed tomography; MRI, magnetic resonance imaging.

interchangeable (eg, subspecialty consultant with pharmacist or nurse with patient care technician). Furthermore, it is appropriate to predefine tasks, person assignments, policies, procedures, and a clear organizational structure (eg, determination of committee reporting) around monitoring and interpretation of data, to facilitate use of CGMs and AID systems.

Necessary Patient Responsibilities

Patients who wish to continue use of CGMs or AID systems in the acute care setting should read a detailed set of information and should review and sign a patient agreement about hospital policy. The panel developed a sample patient agreement for the use of CGMs or AID systems in the hospital presented in Figure 1. This agreement is meant to be an example for a subcutaneous non-implanted sensor. Each institution must develop their own agreement and they should consider manufacturer labeling.

CGMs may be used for guidance about the direction and magnitude of changes in glucose concentrations. The patient should notify hospital staff if they are observing glucose excursions out of range or if they experience symptoms of hypoglycemia. The patient should bring all supplies (infusion sets, sensors, receiver, and so on) needed for continuation of home use for the duration of a hospitalization and be

responsible for maintenance of their device and changing sites as directed during a hospitalization. Device supplies may be stored per hospital policy and will be returned to the patient upon discharge.

Necessary HCP Responsibilities

Inpatient caregivers must (1) confirm that it is appropriate for a patient to continue using a CGM or an AID system, (2) discuss hospital policy with the patient, and (3) review an agreement with the patient. After the patient agreement is signed, the HCP should place an order for inpatient use of a CGM or an AID system. A patient's ability to safely continue use of a CGM or an AID system (which may change during the hospitalization) must be regularly assessed by nursing staff and HCPs.[133] Daily documentation per institutional policy will be needed throughout the hospitalization. If there is concern for patient's ability to use a CGM or an AID system, then the caregiver will recommend an alternative treatment plan.

Necessary Nursing Responsibilities

In collaboration with other inpatient HCPs, it is important for nursing to assess the patient's suitability for using a CGM or an AID system and review hospital policies with the patient. It is also important for nursing to assess the insertion site and document site changes in the EHR.

Treatment decisions based on CGM data linked to insulin dosing software might lead to unwanted outcomes unless the safety and efficacy of the system in the acute care setting can be clearly established. For patients using AID systems in the hospital who are going to be transitioned to and/or discharged with subcutaneous multiple-dose insulin therapy, if the insulin dosing information (from "auto" mode) is not available in the EHR, then an estimate of insulin requirements might be inaccurate and could lead to dysglycemia following discharge.

Standard approaches to documentation are also needed. The panel recognized a spectrum of practice for nursing documentation and institutional requirements. Nursing should document all AID system device settings, including any insulin boluses in "manual" mode, in the inpatient progress notes and/or in the patient's bedside log, which is scanned into the EHR. Additionally, the frequency that this information is documented (ie, every shift vs daily) may vary based on individual hospital resources and policies.

Specialty Consultation

When using CGMs or AID systems in the acute care setting, specialty consultation, if available, is required and the request for consultation should be documented. While some institutions have inpatient diabetes support available for in-person consultation and ongoing management, the panel recognizes there are circumstances in which inpatient diabetes expertise may not be readily available. The panel suggested consideration for telemedicine consultation with a diabetes specialist if necessary. It is useful to document the patient's ability to use the technology to assist with glucose management.

Recommendations for Logistics and Hands-On Care of Hospitalized Patients Using CGMs and AID Systems

Clinical Practice

Strong Recommendations

- HCPs **should** inquire about and document the medication and supplement history of patients who use CGMs to determine whether there are any agents that can interfere with glucose measurements.
- HCPs **should** ensure that off-label use of CGMs and AID systems is consistent with medical practice and appropriate precautions have been taken to protect patients.
- Nursing **should** document hands-on training of CGM use and AID system therapy through a technology certification program.
- Nursing **should** confirm that the patient is appropriate to continue using a CGM or an AID system and also review the agreement and hospital policy with the patient.
- Nursing **should** inspect the insertion site every shift with attention to skin integrity and signs of erythema or infection, and should document site changes.
- Nursing **should** know device basics, institutional policies, HCPs' roles, and whom to contact if questions arise.
- Nursing **should** administer a patient competency assessment or survey to assess patient ability to safely assist with managing a CGM or an AID system.
- Nursing **should** set expectations and clarify that there will be a need to continue checking POC capillary glucose even when using a CGM.
- Nursing **should** measure POC BG concentrations to confirm or supplement CGM readings (usually a minimum of four times daily: before each of three meals and at bedtime if patients are eating, or every six hours if patients are fasting) as well as at patient request; however, the CGM glucose, trend arrows, and rate of change may be used to help determine if and when a BG test is required.

Research

Strong Recommendations

- Researchers **need** to conduct further studies on the best logistics and hands-on care for patients using CGMs and AID systems to achieve the best outcomes.
- Manufacturers **need** to research interoperable components for AID systems that are compatible with hospital EHRs.

Hospital Policies

Strong Recommendations

- Hospitals **need** to provide interpreter services to translate CGM and AID system agreements.
- Hospitals **need** to state in their policy and patient agreement documents that treatment decisions will be based on hospital-calibrated BGM readings (or laboratory readings) and not on CGM readings, barring a need to isolate a patient with a severe and highly contagious infection.
- Hospitals **need** to maintain their CGM and AID system policy and patient agreement documents in easily accessible electronic files stored in the EHR order set for CGMs and AID systems.
- Hospitals **need** to develop policies for when to discontinue or temporarily suspend the use of CGMs and AID systems.
- Hospitals **need** to survey their HCPs, nursing, and patients to improve outcomes and satisfaction.

Data Management of CGMs and AID Systems in the Hospital

Chair: James H. Nichols, PhD, DABCC, FAACC
Vanderbilt University Medical Center, Nashville, TN, USA

Potential Opportunities

Policies and Procedures

As previously noted, there is a distinction between CGM glucose values and laboratory glucose values, and CGM data are currently not part of the laboratory information system. Rather, CGM data are analogous to ICU vital sign monitoring data rather than lab values like serum potassium and sodium. Because of this distinction, it is important to consider where in the medical records these data should reside and how they should be displayed, such as in reports, tables, or graphs. Given this known difference between CGM glucose values and lab glucose values,[134] criteria should also be developed on when to check or cross-reference CGM values with a POC or laboratory glucose test. A related question is whether or not clinical decisions should be made on the basis of CGM data, or whether clinicians should always obtain a laboratory or POC glucose test for treatment decision-making. Finally, criteria should be established as to whether a minimum number of laboratory or POC BG tests must be performed while patients are using CGMs or AID systems in the hospital. Manufacturers of some CGMs have recommended a calibration frequency, but those recommendations are intended for outpatient use, and might not be adequate for inpatient use.

As part of the standardization of summary metrics, we should also develop clear criteria for values or trends that require a clinical intervention. The panel discussed creating a framework for clinical action based on CGM data. This includes understanding what data and trends are actionable, as well as what the appropriate clinical interventions might be. Critical values are considered to be imminently life-threatening test results that require immediate contact by the ordering HCPs. CGMs can trend the rise and fall of glucose concentrations, and can predict critical hypo- or hyperglycemia. Data management systems can be set to alarm when CGM glucose trends reach or cross certain critical values. These alarms should lead to clinician and patient notification so that appropriate actions may be taken in a timely fashion.

The panel noted that data and security are major concerns in Germany and the rest of Europe. In Europe, every manufacturer uses a different data scheme and interface to download their data, which can be confusing.

Information Technology Infrastructure

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects health information, promotes transparency, trust, and patient welfare in medical practice. Since CGMs and AID systems collect protected health information (PHI), when they are used by institutions and clinicians to make medical decisions, institutions have a responsibility to treat it like all other PHI, meaning they must ensure the integrity, security, and appropriate availability of that data. Documenting CGM results and data in the EHR designates it as part of the medical record, and it becomes subject to HIPAA. The Information Technology (IT) department is needed to assist with licenses to download the data, and install the software into each hospital system.

Healthcare facilities should adopt the Unique Device Identifier (UDI) system to track devices in the EHR. In 2013, the FDA issued guidelines for the implementation of a global UDI system to adequately identify and track medical devices across their lifecycle, from distribution to patient use.[135] The UDI final rule established a timeline for all qualifying medical devices in the United States to be compliant with UDI labeling by 2022.[136] Diabetes technologies like BGMs, CGMs, CSII systems, and AID systems are all required to bear a UDI. Institutions should rapidly move toward UDI adoption and integration into the EHR, and ensure that CGM and AID system data are associated with the correct UDI for safety and quality assurance.

Data

Panelists recognized that there is limited evidence on how CGM data are integrated into EHRs at this time. With the

near-universal adoption of EHRs among inpatient facilities in the United States,[137] integrating device data into the EHR is important for quality and consistency. Several groups have explored the integration of these data into the EHR,[138-140] but many questions still remain regarding best practices for the acquisition, storage, display, and use of those data.

Distinctions should be made when recording CGM data in the EHR, since CGM data differ from laboratory glucose results. CGMs measure glucose within interstitial fluid, while laboratory instruments measure glucose in plasma, serum, or whole blood. This means that CGM data may not agree with laboratory glucose measurements collected at the same time.[134] While individual CGM data points may be less precise than lab instrumentation-generated values, a major advantage offered by CGMs is the presentation of multiple data points over time. These create an opportunity to evaluate glucose patterns as well as trends in the rate of change, percent of time spent hypo- or hyperglycemic or within target range, and estimate stability/instability of the glucose concentration over time. These summary patterns may be more valuable than individual data points and provide a synthesis of the patient's overall glycemic status.

Data Patterns

As EHR integrations of CGM data become more common, HCPs with a wider variety of backgrounds in training and experience with CGM data interpretation will have access to this data. Some might be less familiar with its use and interpretation. It is important that standardized, clear, and interpretable summary metrics be established in order to facilitate the clinical use of CGM data in the hospital setting.

When considering how to integrate device data, the first decision is how to source data. There are two main options: (1) obtaining the data directly on a platform provided by the manufacturer (eg, Abbott, Dexcom, or Medtronic) and (2) obtaining the data from a third-party aggregator, eg, Tidepool (Tidepool, Palo Alto, CA, USA) or Glooko (Glooko, Inc., Mountain View, CA, USA). Each of these approaches has advantages and disadvantages, as well as associated costs and technical requirements. It may be reasonable to use a hybrid approach, connecting directly with a few manufacturers that have significant market share, and then using an aggregator to capture other devices.

The next decision is what data to extract. There are several options for extracting, storing, and displaying CGM data, and at varying levels of complexity (Table 8). Static reports (view-only documents, typically PDFs) are the simplest, and some CGM manufacturers have already developed mechanisms to bring the CGM reports found on their provider platforms into the EHR. Structured summary data are predefined and standardized, and can be added to existing data tables in the EHR for charting, trending, and so on. Structured continuous data refer to the hundreds of daily individual BG measurements, and are the most complex to manage, but potentially offer the most flexibility and control.

Data storage and display will be dictated by the type of data extracted from the device. Reports and structured summary data can be stored in native EHR data tables, but continuous glucose readings would likely overwhelm those tables, and would best be stored in a separate environment. In terms of displaying the data, this can be accomplished in a variety of ways described in Table 8.

A consensus list of core data elements should be developed and standardized across all models and manufacturers. Data standards and ontologies are critical for ensuring interoperability across information systems.[141] A core set of data elements and definitions developed and applied by the entire CGM industry would facilitate storage and use of CGM data. Finally, core data elements would ideally be submitted to the appropriate governing bodies for inclusion in existing healthcare ontologies and common data models, such as Systematized Nomenclature of Medicine—Clinical Term, Logical Observation Identifiers Names and Codes, and Observational Medical Outcomes Partnership.

Patient-reported outcomes (PROs) are any reports of the status of a patient's health condition that come directly from the patient, without interpretation of the patient's response by a clinician or anyone else.[142] PROs can be leveraged for research, clinical care, and quality improvement. While several groups are actively working on the development of PROs in diabetes, there is still significant work to be done.[143] The development, dissemination, and implementation of diabetes technology-specific PROs will enable a more holistic approach to patient care and research.

Atypical Scenarios

Guidelines should address the use of CGMs and AID systems for diagnoses other than diabetes, where glucose monitoring is valuable. In pediatrics, several clinical situations require close monitoring of BG concentrations and tight glycemic control, such as the titration of glucose infusion rates in premature infants on total parenteral nutrition. Early detection of hypoglycemia in infants with inborn errors of metabolism (eg, fatty acid oxidation disorders, ketotic hypoglycemic disorders, and disorders of gluconeogenesis) could be another critical use for CGMs in the hospital setting. In these diseases, infants are often allowed to become hypoglycemic as a challenge in order to draw critical diagnostic labs. CGM measurements could make that process less stressful for parents and HCPs and safer for patients.

Table 8. CGM Data Integration Complexity Across Three Key Domains.

Data extraction (from least to most complex)	Data storage (from least to most complex)	Data display (from least to most complex)
1. Static, standard reports	1. Web storage, linked to EHR	1. Text and graphic reports
2. Custom reports	2. Native EHR data tables	2. Structured data fields with native analytics
3. Structured summary data	3. External storage and computing environment	3. Embedded analytics displayed from a web service
4. Structured continuous data		4. Native integration of manufacturer analytics platform
5. Device metadata		

EHR, electronic health record.

Economic Analysis

Panelists had concerns with the costs of some CGMs and AID systems being a limiting factor (ie, batteries, sensors, transmitters, and/or a monitor or smartphone), but found that some CGMs are affordable. Panelists considered questions about the reimbursement for these devices. Who is responsible for covering their costs and consumable components? What if the patient has a device from one manufacturer, but the hospital only stocks supplies from a different manufacturer? Panelists also discussed the economic implications of CGM and AID system use in hospitalized patients. Inpatient hypo- and hyperglycemia, which might prove to be reduced with structured CGM or AID system programs, have been associated with increased LOS, readmissions, and costs.[48,144] In patients undergoing cardiac surgery, studies suggested potential cost saving with intensive glycemic management (targeting 100-140 mg/dL).[145] Finally, panelists acknowledged the need for well-powered studies comparing the use of CGMs vs POC BGMs on hospitalization costs.[146]

Potential Barriers

Regulatory Considerations

The Clinical and Laboratory Improvement Amendment of 1988 (CLIA) sets a minimum quality standard for any laboratory test performed in the United States for patient care or clinical decision making. Externally attached patient-dedicated monitoring devices like pulse oximetry capnography are not subject to CLIA.[147] CGMs and AID systems are also automatic monitoring devices that are wearable and continuously or intermittently detect glucose concentrations in interstitial fluid or tissue fluid. There is no sample collection and analysis in a separate instrument that can be calibrated or validated with a quality control sample. As such, a CGM is more of a monitoring device than a laboratory instrument, and should not be subject to CLIA.

Although CGMs and AID systems should not be subject to CLIA, quality control is still an important consideration for inpatient CGM and AID system use. Previous consensus panels have stressed the need for clear safety and quality protocols to be in place.[1] There is known variation between sensors, both between brands and within brands. Also, calibration errors can lead to significant deviations in glucose values. Currently, some hospitals using CGMs require a patient agreement, which outlines that the patient can still use their CGM, but hospital BGM testing is still mandatory. See Figure 1 for a sample agreement. In Germany, laboratory quality control guidelines require twice-daily internal testing and quarterly external testing for hospital lab meters.[148] This is a prerequisite for the use of data for diagnostic or therapeutic decisions. With CGMs, there is no sample and no control materials, so these procedures cannot be applied to CGMs, which is why some BG monitoring is still mandatory in the hospital. One possible path forward is for manufacturers to develop a mechanism to perform quality control procedures for CGMs. Otherwise, CGMs in the hospital may be limited to adjunctive use only.

Off-label use of prescription drugs and devices is common in modern medical practice, and has been recognized as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine" by the United States Supreme Court.[149] A manufacturer may not market unapproved uses of a medical device, but a physician may in their independent judgment decide to use a cleared device in an off-label manner. While off-label use is seen as accepted practice, it does not shield physicians from liability, and there is potential tort exposure. Whether a hospital would also be liable under those circumstances would probably depend on what sort of control it exerted over the physician. If it is for an employed physician, then the hospital might be liable for the physician's actions under a theory of respondeat superior, which is a doctrine that states that an employer is responsible for the acts of an employee. If the physician is an independent contractor, then hospital liability for the physician's actions would be more difficult to establish. One way to evaluate the liability or legal risk of off-label use is to consider whether or not that action may expose the practitioner to a claim of negligence or malpractice. Negligence can be thought of as a breach in duty (eg, to a patient), or as the failure to act reasonably in light of foreseeable consequences.

Data Privacy and Security

Another potential risk is around the data itself, and whether they are being stored and protected with the proper precautions for PHI. Overall, this should not be seen as an obstacle, provided it is consistent with standard practice. Tracking UDIs may also be an appropriate risk-mitigation step that can address some safety and quality concerns. Software whose sole purpose is to store and summarize data may not be considered a medical device, but there are still privacy and cyber-security concerns with these products.[150,151]

Document retention policies are important in order to protect HCPs and hospitals from possible legal actions. In situations where the hospital is developing custom institutional ("home-brewed") software, it is important to follow cybersecurity risk management standards and realize that not all insurance policies cover cyber security breaches related to custom-developed software. Risk management teams should be in close communication with their insurance brokers to ensure appropriate coverage for that type of activity.

Finally, it may be important to develop maturity models for diabetes technology. Maturity models are tools developed in the information technology field to provide guidance to organizations for assessing their current level of development in a particular topic, as well as a roadmap for systemic and structured improvement.[152] Healthcare IT maturity models have been developed to cover a variety of topics, ranging from continuity of care and healthcare analytics, to telemedicine and mobile technology.[153] Diabetes technology integration would greatly benefit from a maturity model to help guide implementation at healthcare institutions in a systematic way.

Recommendations for Data Management of CGMs and AID Systems in the Hospital

Clinical Practice

Strong Recommendation

- HCPs **should** develop a set of core data elements and definitions for CGM data for inclusion in common data models and the EHR.

Mild Recommendation

- Nursing **should** contact an HCP immediately when CGM results cross critical value thresholds set by the institution.

Research

Strong Recommendations

- Researchers **need** to conduct further studies on the best data management practices of CGMs and AID systems.
- Researchers **need** to develop and validate robust glucose telemetry systems for both ICU and non-ICU populations.
- Researchers **need** to develop a diabetes technology maturity model that helps institutions understand the requirements to successfully integrate diabetes-related data and technology.
- Researchers **need** to develop, disseminate, and validate CGM- and AID system-specific PRO measures to improve patient care.
- Manufacturers **need** to research methods for quality control for CGMs and AID systems, which is critical as part of inpatient use of CGMs and AID systems.
- Manufacturers **need** to research optimally expanded device labeling in order to overcome clinical inertia and align practice with regulatory policy.
- Manufacturers **need** to research systems for integration of CGM data following initial upload into the cloud (eg, the Eversense CGM) subsequently into the EHR.
- Manufacturers **need** to research secure communication systems for protecting data from wireless wearables, telemedicine systems, and Bring-Your-Own-Device portable computers used by HCPs (also known as "data in motion").

Mild Recommendation

- Researchers **need** to develop computerized insulin decision support system that will integrate with CGMs.

Hospital Policies

Strong Recommendations

- Hospitals **need** to develop appropriate security protocols, dedicated data storage, visualization tools, and adequate cyber insurance coverage (also known as "data at rest").
- Hospitals **need** to integrate AID system data into the EHR system for nursing and HCPs to have easy access to this information.
- Hospitals **need** to determine the number of laboratory or POC BG tests that must be performed while patients are using CGMs or AID systems in the hospital.
- Hospitals **need** to adopt the UDI system for healthcare facilities to track devices in the EHR.
- Hospitals **need** to identify CGM data reports in the patient's EHR to distinguish them from laboratory glucose results.
- Hospitals **need** to present clear criteria to clinicians to identify data that will require intervention.
- Hospitals **need** to implement CGM- and AID system-specific PROs to improve patient care.
- Hospitals **need** to develop a universal platform for their EHRs that can be used by all CGMs to present core data elements, summary glucometrics, consistent formats, and uniform interfaces across all CGM products.
- Hospitals **need** to arrange for CGM results to be automatically uploaded into the EHR.
- Hospitals **need** to manage CGM data with the same safety and security measures as all other PHI.
- Hospitals **need** to develop policies for CGM and AID system use with atypical scenarios outside of diabetes, when glucose monitoring is valuable.

Conclusion

This consensus guideline for subcutaneous CGMs and AID systems was created to provide recommendations to clinicians, researchers, and hospitals for promoting the safe and effective use of CGMs and AID systems in the hospital

Table 9. Seventy-eight Proposed Recommendations for the Guideline Voted on by the Panel.

Continuation of home continuous glucose monitors after hospitalization

Clinical Practice: Strong Recommendations

- HCPs **should** consult with an inpatient diabetes team if available, when continuing or initiating a CGM or AID system.
- HCPs **should** avoid relying on CGM data for glycemic management decisions in patients with severe hypoglycemia or hyperglycemia (ie, BG $<$ 40 mg/dL or $>$ 500 mg/dL).
- HCPs **should** avoid using CGMs for management of (1) diabetic ketoacidosis until glucose is in the CGM measurement range, and then CGMs should be used adjunctively or (2) situations with rapidly changing glucose levels and fluid/electrolyte shifts.
- HCPs **should** avoid continuing or initiating CGMs to patients with skin infections near the sensor site or placing sensors in areas with significant edema as well as patients treated with vasoactive agents or poor tissue perfusion.
- HCPs **should** use a CGM checklist for elective procedures during the preoperative visits to ensure proper documentation of devices and real-time data reporting.
- HCPs **should** advise pregnant women to continue the use of a CGM during a hospitalization to identify glucose trends and prevent hypo- or hyperglycemia.
- HCPs **should** instruct patients to bring supplies with them to the hospital for the duration of any preplanned admission or elective procedures.
- HCPs **should** check capillary BG or serum BG concentrations after procedures for noncritically ill patients and venous/arterial blood for critically ill patients to ensure the patient's CGM is functioning properly.
- HCPs **should** use trend arrows and rate of change to help prevent extreme glycemic excursions and (when a CGM is used adjunctively) to help determine when a BG test is required.
- HCPs **should** set alarm thresholds for inpatient glycemic targets, such as predicting hypoglycemia (typically BG $<$ 80-85 mg/dL) or predicting hyperglycemia.
- Nursing **should** document CGM and/or CSII system information in the EHR for all admissions or elective procedures.

Research: Strong Recommendations

- Researchers **need** to provide more data to support definitive recommendations on improved outcomes for continuation of home/ambulatory CGM use after hospitalization.
- Researchers **need** to conduct studies on the roles of CGM and POC BG testing and identify the optimal features of telemetry to inform nursing staff about actionable CGM patterns.
- Researchers **need** to perform further studies to assess the accuracy of CGMs during pregnancy, labor and delivery, and the peripartum period.
- Researchers **need** to study the impact of lag time on glucose measurements (ie, situations with rapid changes in the glucose concentration) in the hospital.

Hospital Policies: Strong Recommendations

- Hospitals **need** to develop standard CGM data reports and workflows.
- Hospitals **need** to implement policies for testing capillary BGs and calibrating CGMs if the CGM requires calibration.
- Hospitals **need** to develop a system for automatic staff notification for CGM alarms that predict impending or current hypoglycemia or hyperglycemia.
- Hospitals **need** to develop specific guidelines for using CGMs and AID systems for their affiliated nursing homes and skilled nursing facilities.

Initiation of continuous glucose monitors after hospitalization

Clinical practice: strong recommendation

- HCPs **should** consider prescribing CGMs to reduce the need for frequent nurse contact for POC glucose testing and the use of PPE for patients on isolation with highly contagious infectious diseases (eg, COVID-19).

Clinical practice: mild recommendation

- HCPs **should** avoid initiating CGMs in patients with severe hypoglycemia or hyperglycemia (ie, BG $<$ 40 mg/dL or $>$ 500 mg/dL) or during periods of rapid glucose fluctuations.

Research: Strong Recommendations

- Researchers **need** to provide data to support initiation of CGMs for improving patient-centered outcomes.
- Researchers **need** to provide data on hospital outcomes when initiating CGMs in the hospital, including improved glycemic outcomes, detection and/or reduction of hypoglycemia and hyperglycemia, reduction of ICU LOS, and cost-effectiveness.
- Researchers **need** to conduct studies on long-term benefits for initiating CGMs in the hospital after discharging patients with newly diagnosed diabetes or recurrence of diabetic ketoacidosis or other complications of diabetes.
- Manufacturers **need** to develop educational tools for patients, hospital staff, and HCPs.

Hospital Policies: Strong Recommendations

- Hospitals **need** to develop plans, including process maps, protocols, staff educational resources, and order sets for prescribing CGM use during hospitalizations before implementing a CGM.
- Hospitals **need** to provide educational tools for patients, nurses, house staff, and attending physicians when a patient in the hospital starts on a CGM.

(continued)

Table 9. (continued)

Continuation of automated insulin dosing systems in the hospital

Clinical practice: strong recommendations	Clinical practice: mild recommendation
• HCPs **should** prescribe AID systems only for appropriate candidates, who will need to have adequate knowledge and skills for using AID systems. • HCPs **should** reassess a decision periodically to transition use of outpatient AID systems into the hospital in order to ensure that AID system continue to represent the best treatment option for each patient. • HCPs **should** prepare an alternative plan for diabetes management in case it becomes inappropriate for a patient to continue using an AID system in the hospital. • HCPs **should** discontinue AID systems in critically ill hospitalized patients (such as those with hypovolemia or sepsis). • HCPs **should** recognize glycemic patterns due to CGM compression, which can cause false low readings.	• HCPs **should** avoid initiating an AID system during a hospitalization.

Research: Strong Recommendations

- Researchers **need** to conduct studies about whether continuing AID systems in the hospital is beneficial to improve glycemic management or clinical outcomes.
- Researchers **need** to provide data on hospital outcomes when using AID systems in the hospital, including improved glycemic outcomes, detection and/or reduction of hypoglycemia, reduction of ICU LOS, and cost-effectiveness.
- Manufacturers **need** to research whether all types of CGMs and AID systems can be used during radiological/imaging studies or diathermy.

Hospital Policies: Strong Recommendations

- Hospitals **need** to develop institution-specific protocols and order sets for the proper use of AID systems during a hospitalization.
- Hospitals **need** to require that patients using AID systems bring with them sufficient supplies for these devices during a hospitalization.
- Hospitals **need** to develop protocols for using AID systems during elective procedures and surgeries.

Recommendation Not Reaching Consensus

- HCPs **should** switch AID systems from "auto" mode to "manual" mode when a patient is admitted to the hospital wearing an AID system.

Logistics and hands-on care of hospitalized patients using continuous glucose monitors and automated insulin dosing systems

Clinical Practice: Strong Recommendations

- HCPs **should** inquire about and document the medication and supplement history of patients who use CGMs to determine whether there are any agents that can interfere with glucose measurements.
- HCPs **should** ensure that off-label use of CGMs and AID systems is consistent with medical practice and appropriate precautions have been taken to protect patients.
- Nursing **should** document hands-on training of CGM use and AID system therapy through a technology certification program.
- Nursing **should** confirm that the patient is appropriate to continue using a CGM or an AID system and also review the agreement and hospital policy with the patient.
- Nursing **should** inspect the insertion site every shift with attention to skin integrity and signs of erythema or infection, and should document site changes.
- Nursing **should** know device basics, institutional policies, HCPs' roles, and whom to contact if questions arise.
- Nursing **should** administer a patient competency assessment or survey to assess patient ability to safely assist with managing a CGM or an AID system.
- Nursing **should** set expectations and clarify that there will be a need to continue checking POC capillary glucose even when using a CGM.
- Nursing **should** measure POC BG concentrations to confirm or supplement CGM readings (usually a minimum of four times daily: before each of three meals and at bedtime if patients are eating, or every six hours if patients are fasting) as well as at patient request; however, the CGM glucose, trend arrows, and rate of change may be used to help determine if and when a BG test is required.

Research: Strong Recommendations

- Researchers **need** to conduct further studies on the best logistics and hands-on care for patients using CGMs and AID systems to achieve the best outcomes.
- Manufacturers **need** to research interoperable components for AID systems that are compatible with hospital EHRs.

(continued)

Table 9. (continued)

Logistics and hands-on care of hospitalized patients using continuous glucose monitors and automated insulin dosing systems

Hospital Policies: Strong Recommendations

- Hospitals **need** to provide interpreter services to translate CGM and AID system agreements.
- Hospitals **need** to state in their policy and patient agreement documents that treatment decisions will be based on hospital-calibrated BGM readings (or laboratory readings) and not on CGM readings, barring a need to isolate a patient with a severe and highly contagious infection.
- Hospitals **need** to maintain their CGM and AID system policy and patient agreement documents in easily accessible electronic files stored in the EHR order set for CGMs and AID systems.
- Hospitals **need** to develop policies for when to discontinue or temporarily suspend the use of CGMs and AID systems.
- Hospitals **need** to survey their HCPs, nursing, and patients to improve outcomes and satisfaction.

Data management of continuous glucose monitors and automated insulin dosing systems in the hospital

Clinical practice: strong recommendation

- HCPs **should** develop a set of core data elements and definitions for CGM data for inclusion in common data models and the EHR.

Clinical practice: mild recommendation

- Nursing **should** contact an HCP immediately when CGM results cross critical value thresholds set by the institution.

Research: strong recommendations

- Researchers **need** to conduct further studies on the best data management practices of CGMs and AID systems.
- Researchers **need** to develop and validate robust glucose telemetry systems for both ICU and non-ICU populations.
- Researchers **need** to develop a diabetes technology maturity model that helps institutions understand the requirements to successfully integrate diabetes-related data and technology.
- Researchers **need** to develop, disseminate, and validate CGM- and AID system-specific PRO measures to improve patient care.
- Manufacturers **need** to research methods for quality control for CGMs and AID systems, which is critical as part of inpatient use of CGMs and AID systems.
- Manufacturers **need** to research optimally expanded device labeling in order to overcome clinical inertia and align practice with regulatory policy.
- Manufacturers **need** to research systems for integration of CGM data following initial upload into the cloud (eg, the Eversense CGM) subsequently into the EHR.
- Manufacturers **need** to research secure communication systems for protecting data from wireless wearables, telemedicine systems, and Bring-Your-Own-Device portable computers used by HCPs (also known as "data in motion").

Research: mild recommendation

- Researchers **need** to develop computerized insulin decision support system that will integrate with CGMs.

Hospital Policies: Strong Recommendations

- Hospitals **need** to develop appropriate security protocols, dedicated data storage, visualization tools, and adequate cyber insurance coverage (also known as "data at rest").
- Hospitals **need** to integrate AID system data into the EHR system for nursing and HCPs to have easy access to this information.
- Hospitals **need** to determine the number of laboratory or POC BG tests that must be performed while patients are using CGMs or AID systems in the hospital.
- Hospitals **need** to adopt the Unique Device Identifier system for healthcare facilities to track devices in the EHR.
- Hospitals **need** to identify CGM data reports in the patient's EHR to distinguish them from laboratory glucose results.
- Hospitals **need** to present clear criteria to clinicians to identify data that will require intervention.
- Hospitals **need** to implement CGM- and AID system-specific PROs to improve patient care.
- Hospitals **need** to develop a universal platform for their EHRs that can be used by all CGMs to present core data elements, summary glucometrics, consistent formats, and uniform interfaces across all CGM products.
- Hospitals **need** to arrange for CGM results to be automatically uploaded into the EHR.
- Hospitals **need** to manage CGM data with the same safety and security measures as all other PHI.
- Hospitals **need** to develop policies for CGM and AID system use with atypical scenarios outside of diabetes, when glucose monitoring is valuable.

AID, automated insulin dosing; BG, blood glucose; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; EHR, electronic health record; HCP, health care practitioner; ICU, intensive care unit; LOS, length of stay; POC, point of care; PPE, personal protective equipment; PRO, patient-reported outcome.

environment. Through a consensus process, an international expert panel voted on 78 recommendations. Seventy-seven of the recommendations were classified as either strong or mild, and one failed to reach consensus (Table 9). The panel's recommendations are intended to support clinical practice, future research, and improved hospital policies, to facilitate the use of these tools. The success of this guideline will be the impact to clinicians, researchers, manufacturers, and hospitals in the management of hospitalized patients with diabetes.

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