Practical implementation of remote continuous glucose monitoring in hospitalized patients with diabetes

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Purpose. Inpatient diabetes management involves frequent assessment of glucose levels for treatment decisions. Here we describe a program for inpatient real-time continuous glucose monitoring (rtCGM) at a community hospital and the accuracy of rtCGM-based glucose estimates.

Methods. Adult inpatients with preexisting diabetes managed with intensive insulin therapy and a diagnosis of coronavirus disease 2019 (COVID-19) were monitored via rtCGM for safety. An rtCGM system transmitted glucose concentration and trending information at 5-minute intervals to nearby smartphones, which relayed the data to a centralized monitoring station. Hypoglycemia alerts were triggered by rtCGM values of ≤85 mg/dL, but rtCGM data were otherwise not used in management decisions; insulin dosing adjustments were based on blood glucose values measured via fingerstick blood sampling. Accuracy was evaluated retrospectively by comparing rtCGM values to contemporaneous point-of-care (POC) blood glucose values.

Results. A total of 238 pairs of rtCGM and POC data points from 10 patients showed an overall mean absolute relative difference (MARD) of 10.3%. Clarke error grid analysis showed 99.2% of points in the clinically acceptable range, and surveillance error grid analysis showed 89.1% of points in the lowest risk category. It was determined that for 25% of the rtCGM values, discordances in rtCGM and POC values would likely have resulted in different insulin doses. Insulin dose recommendations based on rtCGM values differed by 1 to 3 units from POC-based recommendations.

Conclusion. rtCGM for inpatient diabetes monitoring is feasible. Evaluation of individual rtCGM-POC paired values suggested that using rtCGM data for management decisions poses minimal risks to patients. Further studies to establish the safety and cost implications of using rtCGM data for inpatient diabetes management decisions are warranted.

Keywords: blood glucose monitoring, continuous glucose monitoring, diabetes, hyperglycemia, hypoglycemia, inpatients

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In the outpatient setting, appropriate use of real-time continuous glucose monitoring (rtCGM) systems has been associated with clinically significant benefits related to hemoglobin A1C, hypoglycemia avoidance, and improved quality of life.[1,2] rtCGM systems are also beneficial in inpatient settings, and recent studies of hospitalized patients with diabetes have demonstrated that rtCGM use improved time with glucose values in the 70-180 mg/dL target range,[3] lowered mean glucose values,[4] and reduced hypoglycemia.[5] It is important to maintain good inpatient glucose control, as the minimization of hypo- and hyperglycemia have been associated with lower risks of complications and mortality.[6] However, glucose management can be complicated by factors such as illness and hospital logistics and can be limited by the relatively few point-of-care (POC) measurements taken over a 24-hour period.

The use of rtCGM devices in a hospital setting may help address some of

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the challenges in managing inpatient glucose levels. These systems include features that can enable hospital staff to efficiently monitor patients' glucose levels, such as programmable alerts related to existing or impending high and low glucose values or to accelerated rates of glucose concentration change. rtCGM data can be automatically relayed via Bluetooth technology to nearby display devices; from there, connected devices can relay the information over Wi-Fi or cellular networks for remote monitoring and pattern detection. Additionally, it may be possible to use rtCGM as an alternative to standard POC testing, as studies have shown there is reasonable agreement between POC and rtCGM values for adult postoperative surgical patients with diabetes,[7] during cardiac surgery with extracorporeal oxygenation,[8] and during elective abdominal surgery.[9] This could further streamline patient care by decreasing blood sampling procedures. It should be noted that while a growing body of data indicate agreement between POC and rtCGM measurements, inpatient accuracy data generated using venous sampling (the gold standard for evaluating rtCGM accuracy) are still lacking.

Remote monitoring with rtCGM technology has been of interest to healthcare providers during the coronavirus disease 2019 (COVID-19) pandemic. Establishing a remote rtCGM program requires the proper infrastructure and training; however, once this system is in place, centralized availability of rtCGM data has the potential to reduce the number of nursing contacts and patient visits, exposure to transmissible disease, and use of personal protective equipment. While rtCGM devices are not currently approved by the Food and Drug Administration (FDA) for hospital settings, FDA announced in April 2020 it would not object to the use of rtCGM for inpatient management during the pandemic.[10] Multiple studies published in the past year have demonstrated the feasibility of using rtCGM to safely manage diabetes in critically ill patients with COVID-19, and a recent commentary discussed the considerations for implementing rtCGM systems in hospitals.[11-19] A reduction in POC testing frequency following rtCGM implementation was also observed in a preliminary study of patients with COVID-19 in the ICU setting.[13]

Here we describe our experience implementing a remote rtCGM system in a community hospital to monitor non-ICU patients with preexisting diabetes who were admitted for COVID-19. First we discuss the challenges and infrastructure considerations for implementing inpatient rtCGM and remote monitoring in a hospital setting. Next we evaluate the safety and efficacy of utilizing rtCGM as an alternative to POC-guided treatment decisions by assessing accuracy (overall mean absolute relative difference [MARD] and error grid analysis) and by assessing the agreement of insulin dosing decisions for rtCGM versus POC-guided values. Although blood-based glucose measurements ultimately determined the treatment decisions for our patients, evaluation of these aims in the context of our facility protocols will allow our site and others to make informed decisions regarding the utility of rtCGM in the inpatient setting.

KEY POINTS

- Advantages provided by real-time continuous glucose monitoring (rtCGM) have the potential to shift the current inpatient glycemic control paradigm.
- rtCGM performed similarly to point-of-care testing in a small sample (n = 10) of non–critically ill patients with a COVID-19 diagnosis.
- Inpatient rtCGM implementation requires a detailed plan due to current infrastructure limitations.

Methods

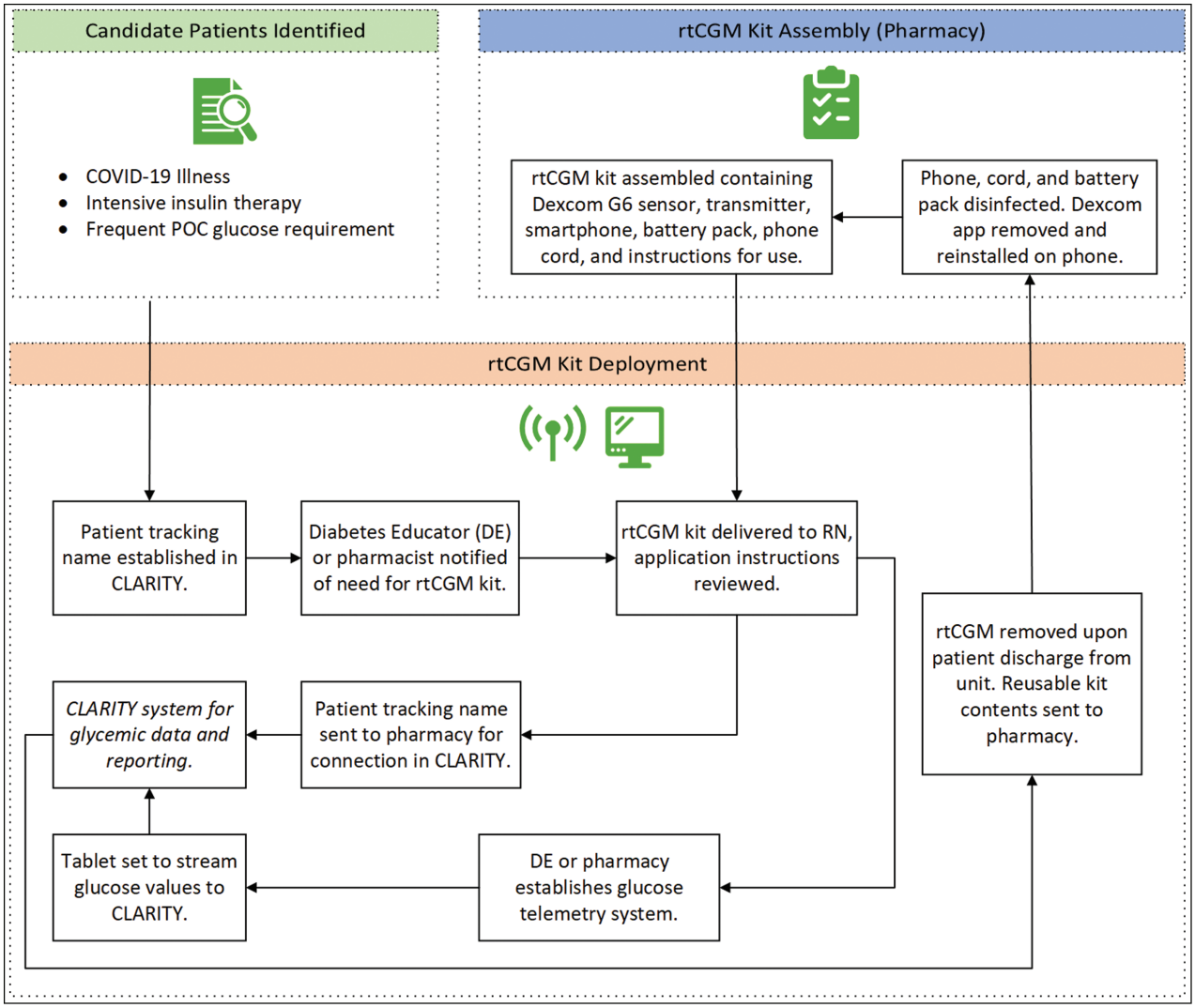
Implementing rtCGM. Use of rtCGM to monitor clinically appropriate patients was approved by the facility incident command in April 2020 as a patient safety performance improvement project. The project was reviewed with the facility's authorized institutional official from the facility's institutional review committee (IRC), and it was determined that the patient safety performance improvement project did not require IRC review.

Our facility's familiarity with rtCGM prior to this project and the pandemic aided rapid adoption of this technology. Under normal circumstances, the implementation process would have occurred over several weeks, with an emphasis on stakeholder involvement and staff education. rtCGM use was further expanded by acquiring manufacturer-donated smartphones and discounted sensors and transmitters.

rtCGM was available as a complimentary therapy for patients with diabetes who were housed in the COVID-19 noncritical care unit and who required at least before-meal and bedtime POC testing. Patients were identified for rtCGM use by prescribers, nursing staff, or pharmacy staff. The workflow diagram is shown in Figure 1. rtCGM kits (see eSupplement for full details) contained a sensor/transmitter (Dexcom G6 CGM System; Dexcom, Inc., San Diego, CA), smartphone, smartphone charging cord, battery pack, and instructions for use. The battery pack was used to power the smartphone when power was not available, and pharmacy staff were responsible for ensuring an adequate battery was maintained.

Each kit had a label corresponding to a prebuilt patient profile in the Dexcom Clarity software (Dexcom, Inc.), which stored rtCGM information. As rtCGM devices were applied to patients, the pharmacy maintained a master list on facility servers that correlated patient identification information with the prebuilt Clarity profile. rtCGM sensors were applied at the discretion

Figure 1. Real-time continuous glucose monitoring (rtCGM) process diagram illustrating keys steps for implementing an rtCGM program in a hospital. Kits are assembled at the pharmacy prior to use. Once a patient is identified, insertion of the rtCGM device is performed by nursing staff. Patient data are tracked in the Clarity system. POC indicates point of care; DE, diabetes educator; RN, registered nurse.



of prescribers, with a diabetes educator and pharmacy personnel working cohesively to handle the logistics to support use. Nursing staff were responsible for sensor application and for ongoing monitoring of the system related to patient care. All patient POC data were available for comparison in patients' electronic medical records (EMRs).

Sensors were applied to the abdomen or upper arm (previous studies have reported similar sensor accuracies for these insertion sites[20,21]), and insertion site was determined secondary to the patient's body habitus or need for frequent repositioning. After sensor application, nursing staff monitored the insertion site twice daily. They also recorded the anticipated date of sensor change and the sensor location as per the established facility policy for inpatients with home sensors. Sensor location and condition of the skin around the insertion site was documented in the EMR

An rtCGM telemetry system for remote patient monitoring in a non-ICU setting has been described previously by Spanakis et al.[22] Similarly, the rtCGM telemetry system in our project consisted of a body-worn sensor/transmitter, a relay point, and a display station. A smartphone located in either the patient's room or the nursing station acted as the relay point, and a tablet located at the nursing station acted as the display station. Patient data were constantly streamed to the tablet, with a new glucose result appearing every 5 minutes. The tablet was set to alarm for rtCGM values of ≤85 mg/dL, which provided nursing staff with an opportunity

to obtain a POC glucose value and evaluate patients for potential hypoglycemia. The tablet display was available for prescribers to monitor rtCGM-based glucose levels. The Dexcom G6 is factory calibrated, and additional calibration was discouraged without first contacting the diabetes educator or pharmacy for assessment. During the period rtCGM was utilized, POC tests were still necessary prior to any treatment or adjustment to therapy. POC testing of fingerstick whole blood samples was performed using the FreeStyle Precision Pro System (Abbott Diabetes Care, Alameda, CA), maintained via manufacturer-recommended quality control practices.

Prior to patient discharge, the sensor/transmitter was removed from the patient and discarded. All other kit components were returned to the pharmacy for cleaning and reuse. Prior to reassigning a smartphone to a new patient, the Dexcom mobile application was removed and redownloaded to pair with the new sensor/transmitter.

Accuracy assessment. Retrospective analysis was conducted on data collected by the Clarity software and through the EMR for patients who received subcutaneous insulin therapy. Patients who were transferred from the COVID-19 critical care unit to the COVID-19 noncritical care unit were monitored via rtCGM; however, only the time on the COVID-19 noncritical care unit was evaluated. POC glucose values were obtained from the EMR and correlated to rtCGM values, which hypothetically would have been available immediately prior, resulting in a pair of rtCGM and POC values.

Accuracy was assessed with the Clarke Error Grid (CEG) and Surveillance Error Grid (SEG). Both characterize the clinical implications of inaccurate rtCGM values. The CEG[23] includes 5 zones (A-E). Measurements in zone A are classified as clinically accurate (within 20% of the reference value), and measurements in zone B are classified as benign (values are outside the range of ±20% but would not lead to inappropriate treatment); values in zones A and B are deemed clinically acceptable, whereas values in zones C, D, and E are deemed potentially dangerous and therefore are clinically significant errors.[23] The SEG[24] places points in several different regions and has been used to evaluate Dexcom G6 accuracy in the past.[25] The overall MARD between rtCGM and POC values was also calculated; however, due to sample size limitations, MARD was not evaluated by glucose range.

Further evaluation was undertaken to determine how actual therapy administered might have been altered had rtCGM values been utilized for treatment decisions. Each rtCGM and POC value pair was reviewed for potential actionability relative to facility insulin protocols (see discussion below) to determine if therapy would have likely been changed based on the rtCGM value and the POC test result. Values that would likely have led to altered treatment decisions were further categorized as hypoglycemic, euglycemic, or hyperglycemic. Hypoglycemic events, defined as any POC test result of <70 mg/dL, were further reviewed to estimate the impact of reliance on the rtCGM value.

Results

Ten patients were monitored via rtCGM (see eSupplement for baseline demographics); 1 patient had type 1 diabetes and the remaining 9 had type 2 diabetes. The mean age of participants was 59 years (range, 44-85 years), 4 participants (40%) were women, and 4 participants (40%) had been transferred from the critical care unit prior to being monitored via rtCGM. Of the monitored patients, 90% used basal insulin therapy, 80% used mealtime insulin therapy, 100% used correctional insulin, 20% used insulin drip prior to subcutaneous insulin, and 70% were concomitantly receiving corticosteroids.

Over the 65 patient-days of rtCGM use, 238 paired rtCGM and POC values were available for evaluation. Figure 2 shows the SEG. There were 212 paired values (89.1%) that were in the "none" risk category, 24 (10.1%) in the "slight, lower" risk category, 1 (0.4%) in the "slight, higher" risk category, and 1 (0.4%) in the "moderate, lower" risk category. The single "moderate, lower" risk value was the first available rtCGM-POC value pair for that particular patient. CEG analysis showed 209 (87.8%), 27 (11.3%), and 2 (0.8%) paired points in the A, B, and D regions, respectively, with none in the C or E regions. The clinically acceptable zones (A + B) contained 236 (99.2%) of the points. Amongst the 238 paired points, the bias was +5.3%, and the MARD was 10.3%.

Table 1 shows the percentage of treatment decisions for which insulin dosing would likely have been identical if based on rtCGM or POC values at various POC ranges. It was determined that "consistent" treatment doses (ie, both POC testing and CGM values would have led to administration of the same insulin dose) would have been advised at 75% of the hypothetical treatment decision junctures. For the remaining 25% of treatment decisions, treatment would likely have been "inconsistent" (ie, POC testing and CGM values would have led to administration of a different insulin dose), and the adjustment would likely have meant decreasing or increasing the insulin dose on the inpatient correctional insulin scale by 1 step. The majority of treatment inconsistencies (44 of 59 [75%]) occurred in the hyperglycemic value group. To further illustrate POC and rtCGM inconsistencies, Figure 3 summarizes the rtCGM-POC pairs recorded for an individual patient. The additional data points provided by the rtCGM system over 3 days are plotted along with the paired points. Among the 9 pairings shown, there were 4 cases of discrepancies in rtCGM and POC values. Three of these events occurred on day 2, and 1 event occurred on day 3. Hypothetically, each of these events would have resulted in different insulin dose adjustments, by one step (1-3 units), on the correctional scale, depending on whether treatment was based on the rtCGM or POC value.

Figure 2. Surveillance error grids. Shown are 238 paired points comparing point-of-care blood glucose values with contemporaneous real-time continuous glucose monitoring–based values, with background colors corresponding to the risk of an inappropriate management decision.

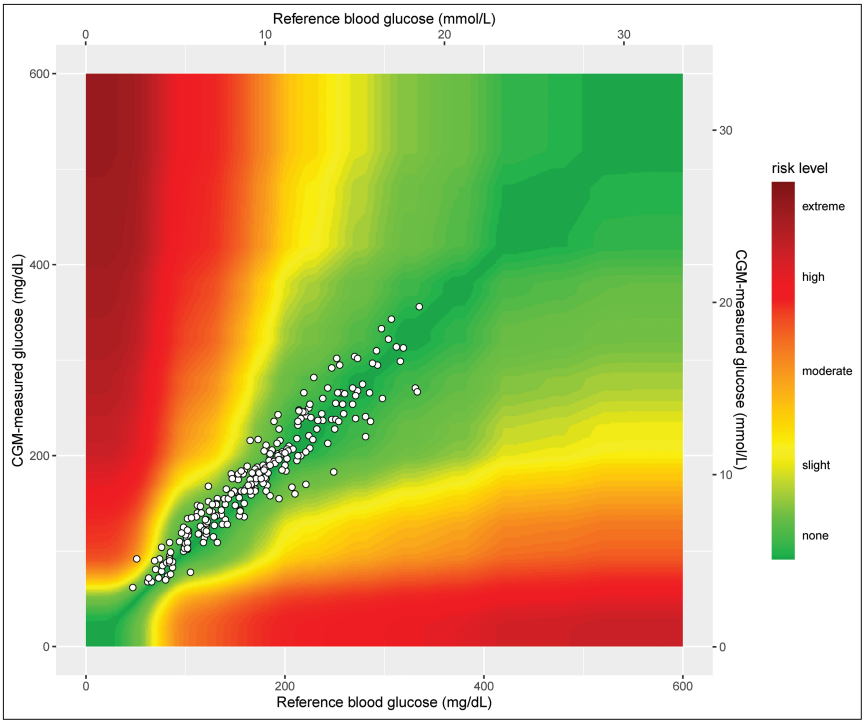


Table 1. Concordance Rates for Treatment Decision Events[a]

Blood Glucose Range	Treatment Consistent[b]	Treatment Inconsistent[b]
≤70 mg/dL	3 (43)	4 (57)
71-180 mg/dL	115 (91)	11 (9)
>180 mg/dL	61 (58)	44 (42)
Total	179 (75)	59 (25)

[a]All data are No. (%) of evaluated hypothetical decisions (*N* = 138).
[b]When both POC testing and CGM values would have led to administration of the same insulin dose, treatment was considered consistent; when values would have led to different insulin doses treatment, was considered inconsistent.

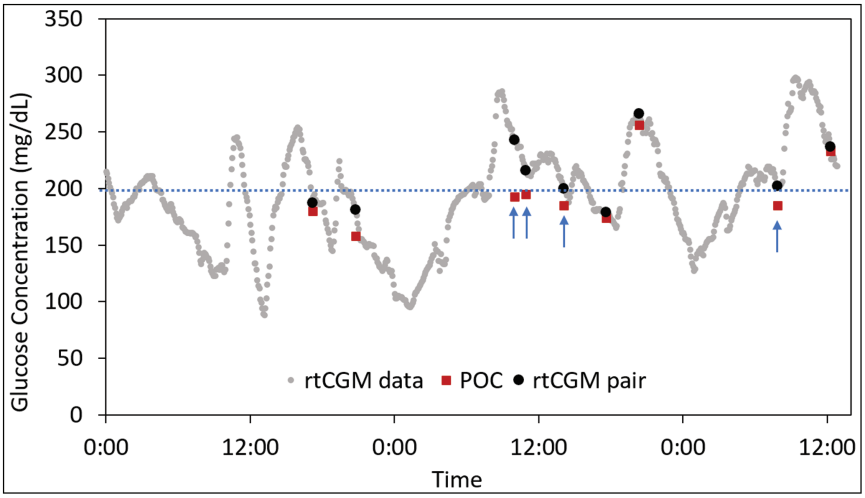
Among the 7 hypoglycemic events identified in Table 1, treatment would have been consistent for 3 of the events. Regarding the remaining 4 hypoglycemic events, treatment was triggered for 2 directly by an rtCGM result of ≤85 mg/dL with a matched POC value that was also hypoglycemic. Both were in a time frame when no POC test was scheduled but was administered, likely secondary to the rtCGM alarm. One was the initial rtCGM reading immediately following insertion, when the rtCGM is more likely to vary, and one was within 2 mg/dL of treatment threshold.

Discussion

Establishing centralized glucose monitoring in a hospital setting could streamline inpatient care and support safe treatment decisions. In this project, implementation of a protocol for rtCGM-based remote monitoring of insulin-requiring patients was found to be feasible. rtCGM data were in agreement with glucose values obtained from POC tests in a manner that would not place the patient in peril (as determined via error grid analysis) or when compared to a facility protocol. Additionally, MARD results were consistent with earlier studies of Dexcom G6 device accuracy in hospital settings.[7,14,26]

While the primary end users of the rtCGM data will be the nursing, pharmacy, and medical teams, coverage of several areas of responsibility is necessary to establish the glucose telemetry system, as highlighted in Figure 1. Our facility utilized both DEs and the pharmacy to leverage the telemetry system for patient monitoring. Involvement of the DEs was especially advantageous, as they were able to bring an enhanced nursing perspective to the implementation process. Depending on facility resources, involvement from other departments may also be appropriate. The flowchart in Figure 1 may help hospital-based pharmacists at other institutions seeking to implement rtCGM for non-ICU patients.

Figure 3. Blood- and real-time continuous glucose monitoring (rtCGM)–based glucose concentrations. Pairs of point-of-care (POC) values (red squares) and rtCGM values (black circles) are shown for an individual patient. Additional rtCGM data points collected over 3 days are plotted (gray circles). Blue arrows indicate inconsistencies in rtCGM and POC values that could lead to different treatment recommendations. Alerts regarding these discrepancies were triggered in the insulin dosing algorithm when rtCGM and POC values were close to a boundary value (horizonal blue line).



Prior to rtCGM use in patients, DEs and the pharmacy collaborated to provide training to nursing staff through frequent ad hoc sessions. After rtCGM devices were deployed in several patients, this training was followed by group education sessions to help streamline rtCGM use. Because the glucose values reported by the rtCGM system will not perfectly match with the results of POC tests currently used for assessment and treatment, this education process is crucial for allowing users to fully optimize the technology and understand the strengths and limitations that exist. As end users become more comfortable with the equipment, this understanding becomes more critical, as there is an option to calibrate the rtCGM if necessary. Determining whether calibration is needed, and who is responsible for making this decision, is important for ensuring that rtCGM and POC values do not become misaligned.

Implementation of inpatient rtCGM use presents several challenges, all of which were compounded by the complexity of installation during a pandemic. One challenge is that the glucose telemetry system is heavily dependent on the facility's wireless communication abilities. If individual areas or patient rooms have weak wireless connection, the system will suffer connectivity issues. Additional connection problems may be encountered as patients are taken from the area for testing or lie on top of their sensor, which could cause signal loss between the transmitter and smartphone. Lying on the sensor may also create pressure-induced artifacts that impact glucose readings.[27] rtCGM devices must be removed during magnetic resonance imaging or computed tomography imaging procedures, creating another potential interruption to the patient monitoring workflow. X-rays, however, are unlikely to affect Dexcom G6 components, and the device may be worn during scans.[28] As this patient population received frequent chest X-rays, communication with the radiology team was important. Signage outside a patient's room identified the location of the sensor and provided instructions to cover the rtCGM to minimize radiographic exposure during the procedure.

Another challenge is the integration of rtCGM data into a patient's EMR, as this data is not automatically uploaded into the EMR. Individual patient information was available in the Clarity system through the tablet; however, data access would require the provider to log into a system separate from the EMR to obtain patient information. Currently, access to the patient's rtCGM data is a rate-limiting step in the monitoring process because of lack of EMR integration. However, in the future, once data are readily retrievable in the EMR, decision makers will have 288 glucose values per day to use for individual patient care. Additionally, there were multiple components to each rtCGM kit, and items such as smartphones were misplaced during the project. To avoid loss of kit components and ensure items are returned to the pharmacy for reuse, individual items should be labeled and a central point should be established to collect kit materials.

Our primary intent in utilizing the rtCGM system was to introduce an additional safety measure for inpatient care by alerting staff when intervention may be needed. As identified in our results, there were 2 instances where the rtCGM triggered an ad hoc POC check, which was able to identify a patient's low glucose level and potentially prevent progression to more severe hypoglycemia. To evaluate the potential of

rtCGM measurements as an alternative to POC-guided treatment decisions, the hypothetical agreement of insulin dosing decisions was compared (Table 1). rtCGM-POC value pairings showed consistent treatment decisions 75% of the time and inconsistent treatment decisions 25% of the time. While treatment decisions are different depending on whether POC or rtCGM values are utilized, based on individual review and error grid analysis, the inconsistencies would have been unlikely to generate negative patient outcomes.

The inconsistency in treatment recommendations stems from the insulin dosing algorithm. The institution-specific algorithm for correctional insulin dosing was based on administration of varied amounts of insulin in response to glucose concentration ranges, with a single insulin dose covering ranges of glucose concentrations that are 50 mg/dL wide. Near the boundary values in the algorithm, glucose level differences as small as 1 mg/dL could result in insulin dose adjustments that varied by 1 to 3 units, depending on whether the patient was on a low-, medium-, or high-intensity correctional scale. In such cases where rtCGM and POC concentrations fell in different ranges, the result might have been different insulin dose recommendations or an inconsistent treatment recommendation. This discrepancy in treatment decision at algorithm boundaries can be seen in Figure 3, wherein POC and rtCGM values fall on opposites sides of a boundary value (the horizonal dotted line at 200 mg/dL). This patient was receiving low-dose correctional scale insulin therapy; for 4 of the 9 pairings (blue arrows), the patient would likely have received an extra unit of insulin had the rtCGM value been used to make the treatment decision.

While the impetus behind our work was the COVID-19 pandemic, the full potential of inpatient rtCGM use has yet to be tapped. As inpatient rtCGM use matures and barriers to implementation are understood or removed, more emphasis will be placed on the clinical opportunities the system affords. POC and laboratory-based tests provide accurate estimates of blood glucose concentrations, but the relatively low frequency of testing often misses important trending information provided by rtCGM. The predictive ability of rtCGM systems will be a primary focus as protocols for rtCGM are developed to move toward a model of proactive prevention of glycemic excursion versus our current reactionary state.

The principal limitations of the project include the small number of patients at a single institution along with the retrospective nature of the work. Further studies should evaluate the safety and cost-effectiveness of utilizing rtCGM data for treatment decisions in a larger number of patients and in varied populations. It should also be noted that the accuracy of rtCGM devices improves after day 1 of sensor insertion.[29] An example of the potential instability in rtCGM values at earlier time points can be observed in a specific measurement taken during this project 145 minutes after rtCGM reading began, which resulted in the "moderate, lower risk" data point on the SEG in Figure 2. In this patient, the POC value was 51 mg/dL and the corresponding rtCGM value was 92 mg/dL. In future studies, a device warm-up period may be necessary prior to using rtCGM measurements to make insulin dosing decisions. This could mitigate the potential impact of varying glucose values at early time points.

Conclusion

Remote monitoring for diabetes management offers a promising alternative to POC testing, with the potential of reducing staff and patient exposure to communicable disease, as well as preventing adverse patient outcomes through safe and timely treatment decisions. A remote rtCGM system is advantageous during a pandemic but can also facilitate patient care under normal circumstances (eg, by avoiding logistical challenges of POC testing and insulin adjustments during meal delivery times). As rtCGM use becomes more common and infrastructure becomes established, troubleshooting the varied challenges (such as those mentioned in the above discussion) will become routine. Specifically, a reduction in the operational steps involved in initiation of rtCGM and integration of rtCGM values into the EMR, followed by development of inpatient protocols, are all necessary to implement rtCGM on a larger scale. As shown in this work, the rtCGM measurement was a reliable comparator to the POC value, and use of rtCGM data to drive therapy administration is unlikely to negatively impact the patient. This project provides the basis to support research on a phased-in approach to utilizing rtCGM for inpatient treatment decisions.

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Disclosures

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