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Sutter West Bay Medical Group

# *CGM Facilitates Telehealth Services for Diabetes Management*

webinar

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## **Sutter West Bay Medical Group**

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**Webinar, July 29, 2020**

*“I think [patients] can feel much more relaxed knowing that they’re going to get alerts or alarms. They know where their blood glucose is, throughout the day, and it can really help them feel more comfortable managing their diabetes.”*

— **Karen Earle, M.D.**, Chief, Division of Endocrinology, and Medical Director, Center for Diabetes Services, California Pacific Medical Center, and Chief, Division of Medical and Surgical Specialties, Sutter West Bay Medical Group

Continuous glucose monitoring (CGM) provides significant benefits to diabetes patients and their providers. With government restrictions and personal preferences limiting in-person office visits during the COVID-19 pandemic, providers are finding real time CGM (RT-CGM) especially helpful in the new age of telehealth. In particular, Sutter West Bay Medical Group has found Dexcom’s advanced G6 RT-CGM system and CLARITY cloud-based data sharing software are effective tools to enhance remote care for people with diabetes.

Dr. Karen Earle, chief of California Pacific Medical Center’s division of endocrinology, medical director for the Center for Diabetes Services, and chief of the Division on Medical and Surgical Specialties at Sutter West Bay Medical Group, recently discussed her clinic’s success with the Dexcom G6 RT-CGM system in providing care for diabetes patients in the age of COVID-19. Deborah Greenwood, Ph.D., a nurse, diabetes care and education specialist, and medical science liaison on Dexcom’s clinical education team, moderated the discussion and provided technical details in response to participant questions.

## **Benefits of CGM**

Key to diabetes treatment is keeping patients “in the target range,” where glucose levels are between 70 and 180 mg/dL ideally 70% of the time. When checking those levels is dependent on patients doing multiple fingersticks, information available to the provider will have gaps. In fact, said Dr. Earle, “Most patients are only checking maybe one, two, or three times a day.” As a result, reported glucose levels may appear to be in the target range, but details are missing. Said Dr. Earle, “If you were to go ahead and put a continuous glucose monitor on that patient, you’re going to see a very different pattern of blood glucose levels throughout the day.”

She provided an example of one patient whose self-reported numbers were in range (dots in Figure 1), but CGM monitoring (line in Figure 1) showed the patient was actually experiencing hypoglycemia overnight and hyperglycemia after breakfast and dinner.

The American Diabetes Association (ADA) now recommends CGM for both type 1 and type 2 diabetes patients treated with multiple daily doses of insulin as useful for lowering A1C and/or reducing hypoglycemia in adults who are not meeting glycemic targets. ADA also recommends CGM should also be considered for all children and adolescents with type 1 diabetes to improve glucose management.

There are two types of CGM: Intermittently scanned CGM (IS-CGM) and real time CGM (RT-CGM). Both involve use of a sensor, attached to the patient's body, a transmitter that sends data to either a receiver, reader, or a compatible smartphone.

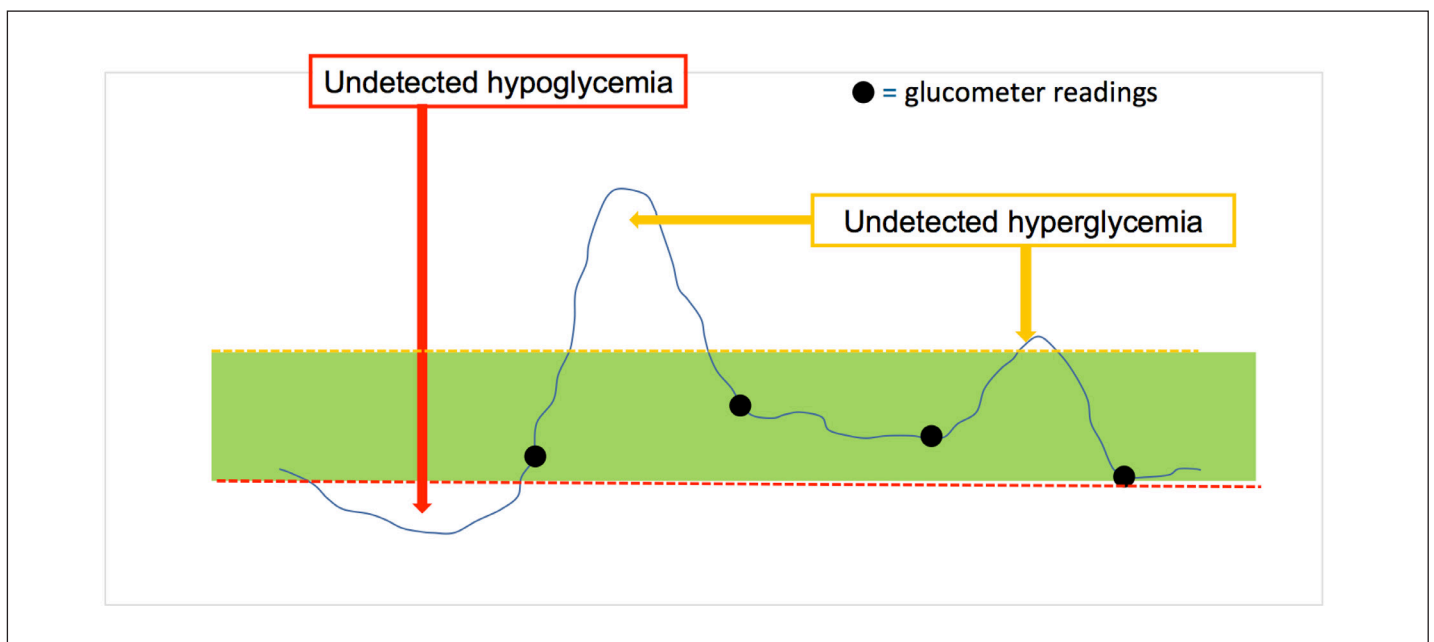
With an IS-CGM, the patient is required to scan the sensor with the reader or compatible smartphone several times over the course of the day. Every eight hours is

recommended. If the patient follows that protocol, a full 24 hours of data can be captured, but that assumes the patient does scan every eight hours. There are two commercially available IS-CGM systems. One with and one without alarms. The newest versions of IS-CGM now include alerts triggering an individual to scan to see their glucose level.

With RT-CGM, the patient is not responsible for scanning. The RT-CGM transmitter is in constant contact with the receiver or compatible smartdevice (phone, watch, etc.) and can send alarms or alerts when necessary without any action by the patient as long as the smart device is within 20 feet of the patient.

In randomized clinical trials, RT-CGM has been shown to reduce A1C and time spent in hypoglycemia and hyperglycemia, increase time in range, and provide overall improvement in quality of life. Dr. Earle, however, sees special benefits to RT-CGM. While the significant increase in glucose data available from RT-CGM may require some adjustment and a change in how patients think about their diabetes management at first, Dr. Earle

**Figure 1: BGM Vs. CGM**



observed, “Once they get used to it, I think they can feel much more relaxed knowing that they’re going to get alerts or alarms. They know where their blood glucose is, throughout the day, and it can really help them feel more comfortable managing their diabetes.”

## The Dexcom G6 RT-CGM System

Dexcom’s G6 RT-CGM System falls within the FDA’s new classification for Integrated Continuous Glucose Monitoring – Class II with Special Controls. A key benefit of the Dexcom G6 is its accuracy; it has an overall mean absolute relative difference (MARD) of 9.0%, a metric that assesses the average amount the sensor readings differ from YSI (Yellow Springs Instruments) laboratory glucose values. Unlike earlier RT-CGMs in which accuracy could be affected if the patient was taking acetaminophen, the Dexcom G6 is not affected by standard or maximum doses of acetaminophen (up to 1000 mg every six hours).

Other key benefits of the G6 RT-CGM include its ability to work alone or in conjunction with other devices (such as an insulin pump), a slimmer profile than prior CGM versions, a simple 1-touch sensor insertion process, and a sensor that is effective for up to 10 days. Patients can also customize their alert schedules with the G6 RT-CGM, and the device is factory calibrated and does not require fingerstick calibration.

As well, the system has a predictive “Urgent Low Soon” alert, which tells patients not just when they’re having a hypoglycemic event, but when the system detects that they are *predicted to have* a sensor glucose value < 55mg/dL. This allows the patient to take action and avoid hypoglycemia, which, as Dr. Earle noted, “is a huge benefit to our patients.” And, of course, use of the G6 RT-CGM means patients no longer need to do regular finger sticks, which is “a huge improvement in that quality of life when they’re not sticking their finger all the time.”

## Proven Benefits of RT-CGM

While there have been many different clinical trials related to CGM, Dr. Earle focused on two.

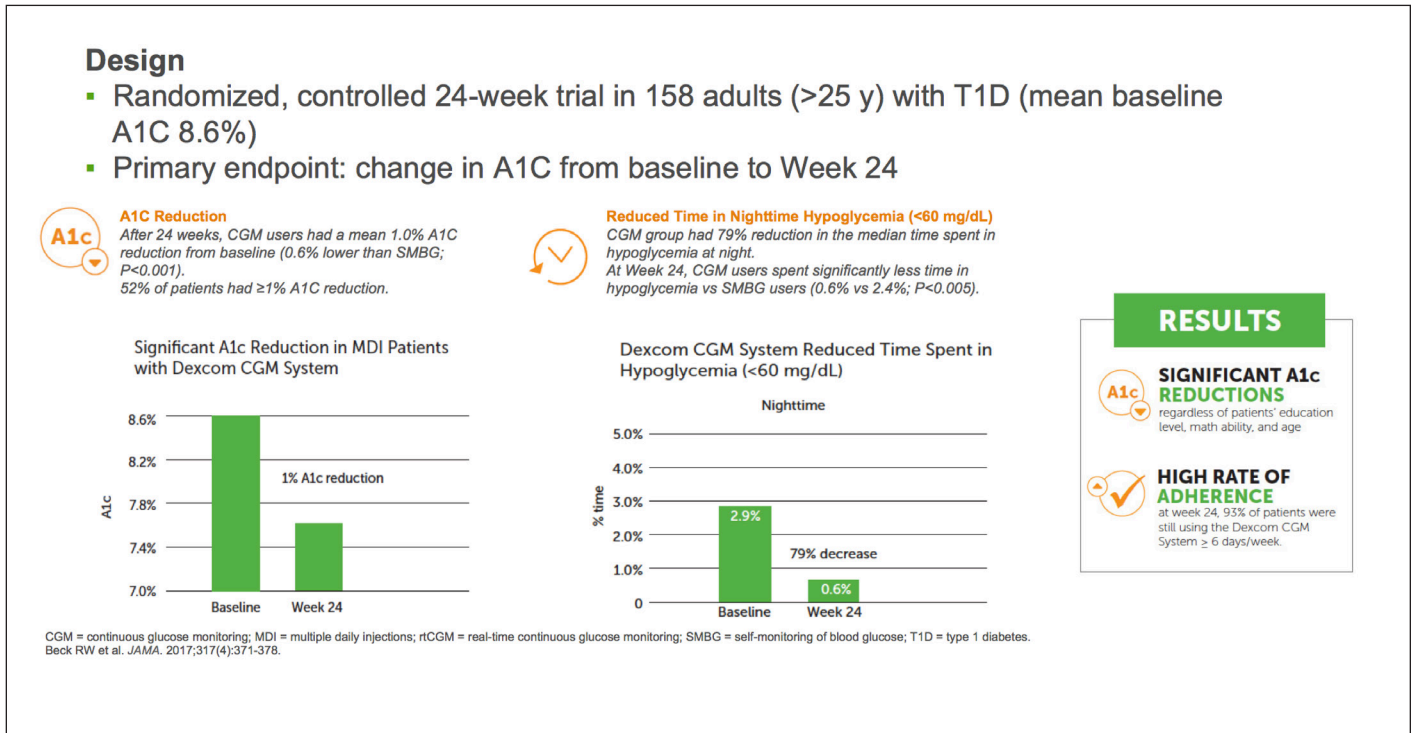
The DiaMonD study compared the Dexcom RT-CGM with standard blood glucose checking in people with type 1 diabetes. The randomized, controlled, 24-week trial involved 158 adults over age 25, with an average A1C of 8.6. The focus of the study was the change in A1C from baseline to week 24. Patients that were on the Dexcom RT-CGM system achieved, overall, about a one percent A1C reduction from baseline over the course of this trial. Dr. Earle pointed out that going from “eight-and-a-half to a seven-and-a-half is a huge improvement for our patients and potentially lowering their risk of complications from their diabetes.”

The other significant finding of this study was a 79% reduction in time in hypoglycemia, especially at nighttime. Nighttime hypoglycemia is one of the biggest fears of type 1 diabetes patients on insulin, as well as the spouses who sleep next to them. Again, Dr. Earle called this “a huge improvement for these patients.” Finally, patients participating in the study really liked the CGM system and, as a result, they were able to use it continuously. “So across the board,” Dr. Earle advised, “our patients could benefit from using CGM.” (Figure 2)

Next, Dr. Earle turned to the WISDM—Wireless Innovation for Seniors with Diabetes Mellitus—study. She noted that there may be a concern among practitioners about whether older patients can correctly utilize CGM technology. This six-month, multi-center, randomized, controlled trial indicates they can.

The study, published in JAMA, enrolled approximately 200 patients. All participants went through a screening phase in which they checked their glucose levels with a blinded CGM (Dexcom’s G4 Professional version),

**Figure 2: DLaMonD (T1D) Study: Dexcom rtCGM System vs SMBG in T1D**



which meant the provider saw the reported glucose levels retrospectively, but patients did not. Thereafter, participants were randomly split into two groups. The control group checked their blood glucose with fingersticks and continued to utilize the blinded G4 Pro system at four intervals (8, 16, and 26 weeks) to measure glucose metrics. The intervention group used the Dexcom G5 RT-CGM and received real-time glucose information, trend arrows and patterns.

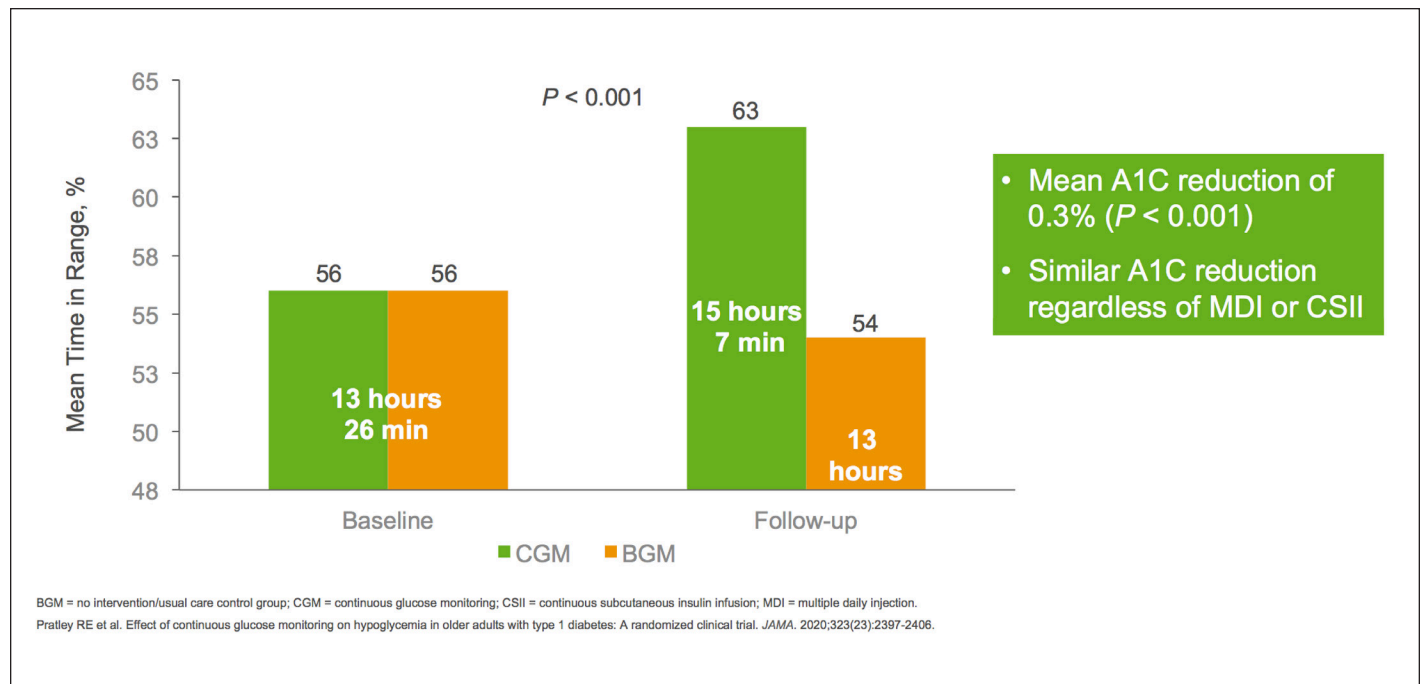
Both groups had similar baseline levels of time spent in hypoglycemia (<70 mg/dL). By week 8, however, those using the Dexcom G5 saw significant decreases in the amount of time spent in hypoglycemia. That reduction was sustained through week 16, along with even further reductions by week 26. In comparison, the control group saw only minor reductions through weeks 8 and 16, significantly less than the intervention time in severe hypoglycemia (<54 mg/dL) was also dramatically reduced in patients using the Dexcom

G5 RT-CGM as compared with the study participants without access to RT-CGM data.

At baseline, both of the participant groups in the WISDM study spent a little more than half their day in the target range of 70-180 mg/dL. Over the course of the study, the G5 RT-CGM participants increased their time in range significantly—from 13.5 to 15 hours per day. Dr. Earle noted this “correlates with an A1C reduction of about 0.3%.” Further, the reduction in A1C was seen whether patients were on multiple daily injections (MDI) of insulin or insulin pumps. So, it was clear the A1C reduction was not due to the insulin delivery method, but the use of the RT-CMG (Figure 3).

Further, utilization of the RT-CGM in this study was quite high—83% of the patients wore the sensor more than six days a week. Said Dr. Earle, “Just because someone’s above 60 [years old] does not mean they will not benefit from technology and will not be able to use the technology.”

**Figure 3: Secondary Outcomes: Time in Range 70-180 mg/dL**



### Use of RT-CGM for Telehealth

Like many other providers, Dr. Earle and clinic staff scrambled to find alternatives to in-person visits once COVID-19 hit the US in March 2020. A quick pivot to telehealth/video visits highlighted the challenges of getting the data to help patients manage diabetes when both the patient and the doctor are remote. Further, as some patients were unwilling to go to a laboratory, recent information on A1C levels was unavailable. “And so,” said Dr. Earle. “I was really dependent on using some of this technology and being able to utilize this information remotely.”

Enter Dexcom’s CLARITY platform, which allows patients to see their own retrospective data on their phone or computer and to share CGM data with their diabetes care team. Briefly, clinics set up a secure account on CLARITY where they house all the patient data. Then a share code is generated from the clinic and sent to the patient via email or through the Dexcom G6 app. Once the patient accepts sharing, then all of

their data are available and accessible to authorized staff in near real-time. In addition, the patient can share data with up to 10 family members or friends with the Follow app. Sharing data can be very helpful for parents to follow their school age children during the day to manage their insulin doses remotely.

While the data can be viewed in myriad of interactive reports, Dr. Earle focused on two reports she finds particularly helpful. First is the Overview Report, which provides the average glucose level, time in range, and the percentage of time the patient used the sensor over the selected data period (Dr. Earle generally generates a 14-day report). The Overview Report also highlights patterns identified by the CLARITY software, such as particular times of day where highs or lows are common, which can be very helpful to providers thinking about changes in medication.

Also useful, says Dr. Earle, is the CLARITY Trends Report, which provides a holistic view of the data set. For example, if a patient is spending too much

time in either high or low glucose levels, the Trends Report can show the time of day those problems are happening which can support the need for changes in health behaviors or medications. As shown in Figure 4, Dr. Earle remarked, “You can see between midnight and 3:00 a.m., this patient’s kind of struggling. ... We need to figure out what’s happening between midnight and 3:00 a.m. that’s causing this big glucose variability for this patient.”

Noting the many different ways to view data in CLARITY, Dr. Earle acknowledged that every provider might have a difference preference. However, she stated, “Personally, I find that time in range graphs and then this Trends Report to be the two pieces of information that are most useful when I’m making clinical decisions.”

## Other Issues Related to Using CGM

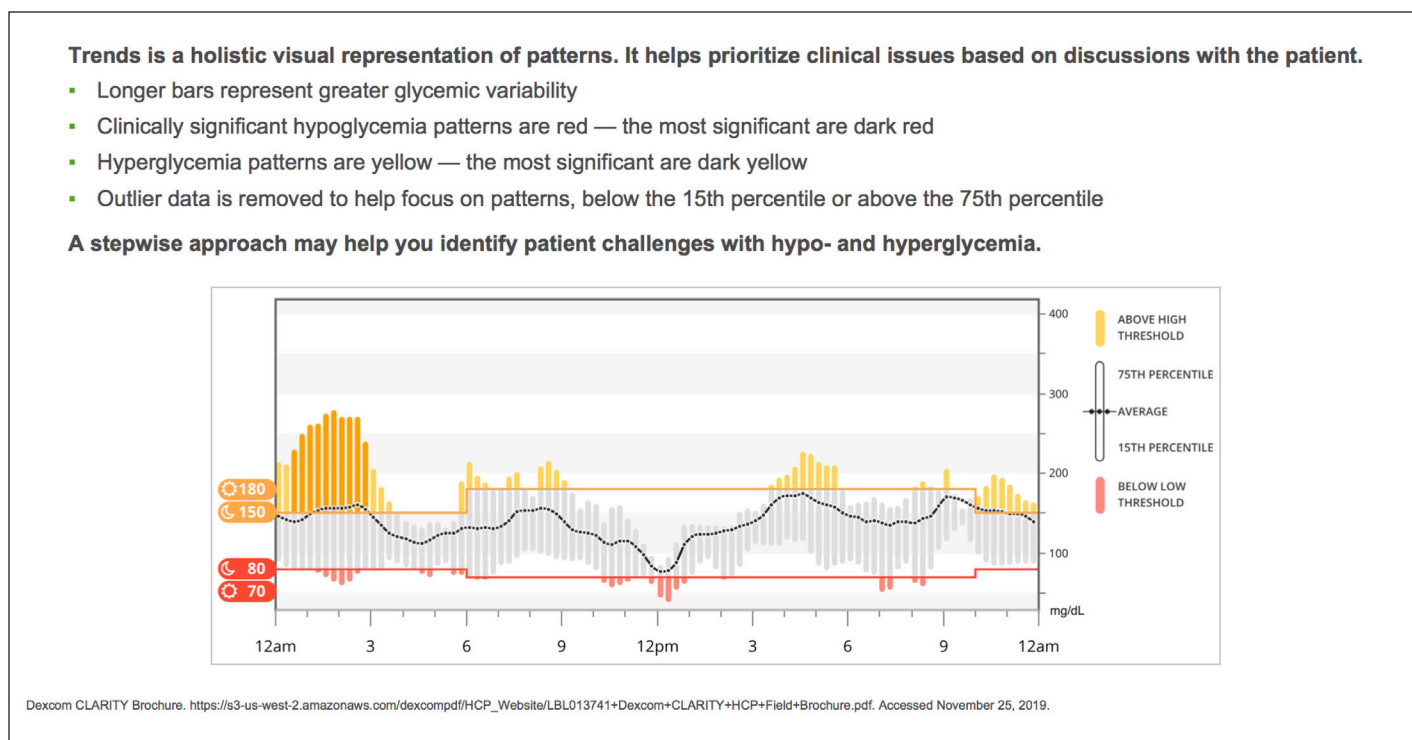
Dr. Earle also highlighted some practical issues related to the use of CGM. She discussed proper Medicare coding to ensure payment for CGM-related services,

including training the patient how to use the CGM, provider interpretation of CGM data (which is in addition to the charge for the office visit), and, if using the professional version of the Dexcom CGM, putting that unit on the patient. The Dexcom G6 RT-CGM is reimbursed by Medicare and, while there are criteria for coverage, people with type 1 and type 2 diabetes on multiple daily doses of insulin may qualify.

In terms of clinical use, Dr. Earle noted that the day before a telehealth visit, her staff will contact the CGM patient, ask questions about their use of the system, and make sure their data has been shared in the CLARITY clinic software. Then, staff will take a screenshot of the Overview and Trend Reports, which are clipped to Dr. Earle’s notes so the data are available to her before she sees the patient. “My video visits are 20 minutes long,” said Dr. Earle, “so I don’t want to spend 10 minutes getting the data. I want to have it right there from the time that I start.”

Her staff scans the full report into the electronic medical record, Epic, so that information is available

## Figure 4: Trends Report



for review when needed. In addition, Dr. Earle has CLARITY on her computer so she can look at reports in real time if needed, as well as compare reports over time. Her clinic has all their patients in one CLARITY account. That way, no matter which provider is in the office or on call, if a patient calls with an issue, the provider can access that patient's CGM records.

## RT-CGM for Type 2 Diabetes

As most providers think of CGM as being associated with type 1 diabetes, Dr. Earle ended her presentation with a case study involving a type 2 diabetes patient to highlight how RT-CGM can be used in those cases.

The 58-year-old male patient was on a combination of metformin (2000 mg per day), basal insulin glargine (60 units per day), and mealtime insulin lispro (10 units) with both breakfast and dinner. In the first 30 days of using the RT-CGM his regimen stayed the same, and the trend report indicated that he was experiencing high glucose levels all throughout the day. Overnight, he was running in the low 200s. He was spiking after breakfast and, after dinner, experienced another, smaller, spike. Using the CGM made it clear according to Dr. Earle: "This regimen is not working for him and we need to make some changes."

While there were many options, including an increase in insulin, Dr. Earle decided to add a 0.75 mg weekly dose of Trulicity (a GLP1 receptor agonist), and mealtime lispro was reduced to five units. A comparison of CLARITY trend reports from before the change in medication and at a two-week follow-up showed some improvement, but not enough. So, they increased weekly Trulicity to 1.5mg, and, because the dinner spike had improved, eliminated the dinner time lispro. The patient also was advised to reduce the glargine by five units if his blood glucose levels were dropping overnight. In this regard, Dr. Earle noted, "It's really important that patients have some autonomy so

they can be looking at their numbers on their own and decide if they need more or less insulin."

Another comparison of Trend Reports after the second medication change showed significant improvements across the board (Figure 5).

The patient now spends far more time in range. A1C was reduced from 8.7% to 7.4%, and average glucose dropped by over 50 points. A smaller standard deviation shows the patient has less glucose variability. Now, as the patient would prefer not to have to take so many injections, he is working with a dietician to lower the carb content of his breakfast, which could allow them to eliminate the breakfast lispro.

"So, again, a big success story," said Dr. Earle, adding, "This is a really nice case of how utilization of CGM helps to figure out which area of the day was most problematic and which medication was most likely to make the improvements necessary to get that A1C down."

The Dexcom G6 Professional unit can also be very helpful for type 2 diabetes patients who might not want to wear a sensor all the time and/or for when there is no insurance coverage. When type 2 patients are not to goal and blood glucose levels look like they're in range yet A1C is above 8, said Dr. Earle, "you know something's going on and you need to figure out where the problem is." The patient wears the G6 Pro sensor for 10 days, and the data is uploaded to the office CLARITY account to be reviewed at a follow-up appointment. Changes can be made to medications or health behaviors and the patient can follow up with an additional professional sensor session to see the effects. Dr. Earle noted, "The G6 Professional is a fabulous way to kind of figure out what's happening." The G6 Professional CGM version is also covered by Medicare whether an individual is using insulin or not.



**Figure 5: T2D Case**



According to Dr. Earle, one of the best features of the Dexcom G6 RT-CGM system “is that the accuracy is good enough that you can use it to dose insulin.” She noted that the G6 RT-CGM provides two pieces of information: glucose value and a trend arrow. She said, “If you don’t have both of those pieces of information, then need to to check a fingerstick to confirm what your blood sugar is before you do a dose.” Another

possible need for a finger stick comes when the patient’s symptoms don’t match what they see on the CGM or if they have question about their CGM value before taking a big dose of insulin, but those times are infrequent, said Dr. Earle. She stated, “Most of the time and most of my patients are dosing their insulin based on the CGM and they’re doing brilliantly with that combination.”



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