Published in final edited form as:
Diabetes Educ. 2010 ; 36(1): 53–62. doi:10.1177/0145721709352010.

Practical Aspects of Real-Time Continuous Glucose Monitors:

The Experience of the Yale Children's Diabetes Program

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Abstract

Real-time continuous glucose monitoring (RT-CGM) provides new dimension to diabetes management. However, there are many challenges to using RT-CGM successfully. This article aims to present how RT-CGM is integrated into diabetes clinical practice at the Yale Children's Diabetes Program (YCDP). The authors provide factors to consider when choosing one of the commercially available RT-CGM systems and a discussion of key strategies for successful use of RT-CGM for families. Careful training and troubleshooting strategies will ensure the most positive experience possible for a family using RT-CGM.

Real-time continuous glucose monitors are the newest commercially available technologies designed to improve diabetes management. As outlined by Hirsch et al in their guidelines on clinical application of continuous glucose monitoring in diabetes management, continuous glucose monitoring can be used concurrently, prospectively, and retrospectively.[1] Real-time continuous glucose monitoring (RT-CGM) not only provides single-point glucose values but also offers information regarding blood glucose trends, including rate and direction of change in blood glucose levels. This is combined with alarms for actual and projected changes in blood glucose concentrations, thus allowing patients to take action before changes become problematic.[1] Retrospective analysis of the data allows for fine tuning of the insulin regimen, as well as the opportunity to review with patients how food choice, activity, and other behaviors impact blood glucose levels.

Whether using multiple daily injections (MDIs) or an insulin pump, RT-CGM can be a very helpful tool in managing diabetes. With MDI therapy, the rapid acting insulin and a patient's food intake or activity plan can be adjusted in response to real-time sensor glucose levels. The long acting insulin can be evaluated using retrospective trend information provided by RT-CGM. Patients using MDI find the event marker feature in the continuous glucose monitor particularly helpful as a way to electronically record insulin doses, activity, illness, and other notes.

Sensor-augmented pump therapy is the use of an insulin pump in conjunction with a real-time glucose sensor. With sensor-augmented pump therapy, patients are able to use both short-term and long-term sensor data to manipulate all aspects of their insulin regimen including both basal insulin delivery and bolus delivery. Regardless of the insulin regimen, RT-CGM allows patients to manage their diabetes more effectively during a myriad of situations, including exercise, illness, and stress. The real-time technology also provides immediate feedback so patients can evaluate the success of their interventions and choices. This article discusses the

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experience of RT-CGM within the Yale Children's Diabetes Program (YCDP): how to integrate RT-CGM into clinical practice, factors for patients to consider when choosing a RT-CGM system, and practical strategies for successful RT-CGM use.

RT-CGM Background

As evidenced in several studies, the median relative absolute difference (RAD), a measure of sensor accuracy comparing sensor readings to reference glucose levels, ranges from 12% to 20%.[2–6] The newest generation of RT-CGM systems is labeled to be within a 20% RAD and does not yet approach the accuracy of current home glucose monitors. However, it is important to note that sensor accuracy has improved over time and that this technology offers a means to improve current diabetes care. Accuracy will continue to improve with technological advancements.

There are only a few studies evaluating the clinical effectiveness of RT-CGM, most of which focus on adults.[7,8] In a randomized study of sensor-augmented pump therapy, Hirsch et al found a greater improvement in A1C in those subjects who used RT-CGM 60% of the time. The improvement in A1C in the sensor group was not accompanied by an increase in severity and/or frequency of hypoglycemia. The control group, however, did have an increased number of symptomatic hypoglycemic events and an increase in the time spent hypoglycemic.[9] Filling the gap in research on RT-CGM in children, the Diabetes Research in Children Network (DirecNet) conducted prospective long-term pilot studies using the Abbott FreeStyle Navigator system (Abbott Park, Illinois) in 57 children with type 1 diabetes aged 4 to 17 years, using MDI or pump therapy.[10,11] A reduction in A1C was found in the baseline >7.0% A1C group and maintenance of A1C in baseline <7.0% group. Hypoglycemia frequency stayed the same in both groups. By the end of the study, the average use of the Navigator system (Abbott) was 80 hours per week, which is still a notable 4 days per week.[10]

Recently, the landmark Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Trial was completed and provided data regarding the use of RT-CGM in adult, adolescent, and pediatric patients. This study showed a statistically significant reduction in A1C with no increase in hypoglycemia for the sensor group aged 25 years and older.[12] Children ages 8 to 14 years saw a modest but not statistically significant reduction in A1C in the sensor group, while no change in A1C was present for adolescents aged 15 to 24 years. Frequency of sensor use varied greatly by age, with 83% of adults, 50% of 8 to 14 year olds, and 30% of 15 to 24 year olds wearing the device at least 6 days per week. As with the other sensor research studies to date, the JDRF trial evidenced that clinical success with RT-CGM appears to be directly related to frequency of use.[12]

Use of RT-CGM in the YCDP

The YCDP has used continuous glucose monitoring technology for many years in its clinical research program. When the Medtronic MiniMed Paradigm REAL-time system (Northridge, California) and DexCom Seven (San Diego, California) RT-CGM devices became commercially available in late 2006, the diabetes team developed a strategy to incorporate this technology into our clinical program.

While about 50 YCDP patients began using a RT-CGM device through their participation in the DirecNet and JDRF continuous glucose monitoring trials, the Yale clinic currently starts approximately 4 patients per month on a sensor system through its newly organized diabetes technology clinic. This clinic is designed to address the unique needs of patients when using both sensor and smart pump technology. While all of the clinicians have gained proficiency in interpreting sensor data and developing strategies to address identified issues, the YCDP has an established core of RT-CGM experts who complete the visits in the technology clinic and

are available for consultation with other clinicians as needed. Initial device training is provided by the device manufacturer's clinical team. Patients are then seen for a follow-up appointment in the technology clinic approximately 1 to 2 weeks after beginning sensor use. This appointment is designed to focus exclusively on any issues regarding technology use and to reinforce initial training. Patients then return to the standard diabetes program for future visits.

The cost of this technology is one of the biggest obstacles to more widespread use of sensors in the YCDP clinic population. Currently, only the Medtronic devices, the MiniMed Paradigm REAL-time system and the Guardian Real Time, are approved by the Food and Drug Administration (FDA) for use in pediatric patients over 7 years old. The other devices must be used off label, which may complicate problems in securing insurance coverage. Reimbursement for RT-CGM has improved as insurance companies develop guidelines for coverage. Overturning the insurance companies' initial denials of coverage has been most successful when parents write an appeal letter describing the daily challenges of diabetes management and how the sensor can help alleviate some of these burdens. Other families are opting to pay out of pocket for the devices. These families are encouraged to speak with representatives from the device companies regarding possible payment plans or bundling of services in order to try to limit out-of-pocket costs.

Data management software packages for the RT-CGM systems vary in user friendliness, but ultimately all provide similar visual displays and reports. The YCDP patients who use the Medtronic MiniMed Paradigm REAL-time system upload their continuous glucose monitoring data to the Internet-based Carelink software (Medtronic). Some patients will bring their printouts to clinic visits, and others will send an e-mail before they arrive so that data may be printed out for their visit. With the DexCom Seven Plus and Abbott FreeStyle Navigator systems, patients are asked to bring printouts of their downloaded data to their appointments. Downloading during follow-up visits, while possible, is not routinely done as it is time consuming and often has a direct impact on clinic and patient flow.

RT-CGM Devices: Current Generation

While the current continuous glucose monitoring systems have varied and unique features, all consist of a subcutaneous glucose oxidase-based electrochemical sensor and a transmitter that sends wireless glucose data to the receiver for storage. With the introduction of real-time continuous glucose monitors, the RT-CGM wearer became an RT-CGM participant, with real-time data and alarms that require a response. Fortunately, the current generation of RT-CGM systems manufactured by DexCom, Abbott, and Medtronic are user friendly. Some important features for families and clinicians to consider when choosing from the 3 commercially available RT-CGM systems are listed in Table 1.

When choosing an RT-CGM system, it is critical to research the differences among devices. Families may need to meet with RT-CGM educators to view and handle the various devices and may benefit from a negotiated trial period with a system, if possible. Each RT-CGM system has advantages and disadvantages, and the following discussion is based solely on the experiences of clinicians and patients at the YCDP. According to YCDP clinicians and patients, the important practical characteristics of RT-CGM devices are the following: the number of components, size of components, length of time the sensor can be worn, sensor insertion process, and user friendliness.

Number of Components, Component Size, and Sensor Duration

The number of components required for RT-CGM can create a "device burden" for users as some systems require patients to carry their insulin administration supplies and blood glucose meter and receiver. It is important for pump users to note that the use of a RT-CGM system

requires a second insertion site. This is an important consideration for younger children who have a smaller surface area available for pump sites and for long-term pump users who have lipodystrophy from years of pump site insertions.

Component size is another consideration. Table 1 displays current data regarding the size of each system's sensor and transmitter. It is important to note that the tape needed to secure the sensor site can increase the amount of skin area used. The length and gauge of the introducer needle can also be very important variables in children and adults with limited body fat.

Each RT-CGM system varies in its labeled sensor duration. In general, patients prefer systems that allow them to wear the sensor for a longer duration. Poor adhesion may shorten the length of sensor wear. Strategies to limit the impact of poor adhesion on sensor longevity are addressed in the next section.

Sensor Insertion

The insertion steps required for a RT-CGM system can dictate whether a family can successfully use the system. The Medtronic Paradigm MiniMed REAL-time system sensor insertion process involves loading the sensor into the inserter, which can feel awkward at first. The Abbott FreeStyle Navigator and DexCom Seven Plus sensors are preloaded into their respective insertion delivery units, and the introducer needles are completely covered, making them more child friendly. Only the Abbott FreeStyle Navigator system sensor insertion offers automatic retraction of the needle, while the Medtronic and DexCom systems require manual removal of the needle.

User Friendliness

All RT-CGM systems perform the task of continuous glucose sensing, yet some require a higher level of participation. Because all 3 devices have advantages and disadvantages, families require education and troubleshooting support in order to use RT-CGM to potential.

Key Strategies for Successful Use of RT-CGM

Despite our recommendations for continuous wear, most YCDP patients only wear their sensors intermittently, similar to what was reported in pediatric patients in the JDRF trial.[12] Patients have expressed several reasons for this discrepancy between recommended and actual use. The most common issues identified by patients include painful or difficult sensor insertion and skin issues including irritation and poor sensor adhesion. Patients and their families also report frustration related to issues of sensor reliability and accuracy as impediments to successful sensor use. Some also report feeling an increased burden as the sensor demands constant attention to diabetes self-management. Key strategies for successful use of RT-CGM include minimizing or avoiding painful or difficult insertion, reducing the incidence of poor adhesion or skin irritation, and considering the reliability of sensor readings, lag time, alarm fatigue, and calibration.

Painful or Difficult Insertion

Each type of RT-CGM system has its own sensor insertion idiosyncrasies so it is critical to give patients the opportunity to review and practice sensor insertions with a trained clinician. It may take repeated teaching sessions before a patient or caregiver feels comfortable with insertion techniques. Sensors should be placed in a "pinchable" area where some body fat can be raised. For those with more subcutaneous fat, it is best to spread the skin until it provides a taut surface for insertion. Some families prefer to use a lidocaine-based cream on the site 45 to 60 minutes prior to insertion. A cool pack can also serve to numb the area just prior to sensor placement, although this may increase the likelihood of bleeding at the insertion site. Only

large quantities of blood will affect sensor performance. If bleeding occurs, it is best to blot the blood with a cotton swab before connecting the transmitter.

Poor Adhesion or Skin Irritation

Many patients complain that sensors will not adhere for their allotted duration. The 2 most common causes of poor adhesion appear to be poor tape adhesion and skin irritation that limits available areas for insertion or causes discomfort while wearing the device. Our diabetes technology team suggests that our patients arm themselves with a "toolbox of tapes," which includes IV 3000 (Smith & Nephew, London, United Kingdom), Tegaderm (3M, St Paul, Minnesota), Coban (a sticky type of ACE bandage) (3M), moleskin, as well as Mastisol (Ferndale Laboratories, Ferndale, Michigan), IV Prep (Smith & Nephew), Skin Tac (Torbot, Cranston, Rhode Island), and a roll-on or spray-on antiperspirant.

Patients who are having difficulty with sensors falling off due to poor adhesion should implement the following procedure: First, the area for insertion should be cleaned as recommended by the sensor manufacturer and then allowed to dry completely. There are data from certain manufacturers that IV Prep (Smith & Nephew) can affect sensor performance. It is best to use alcohol prep pads in the small area where the sensor is inserted. However, IV Prep (Smith & Nephew) can be applied to the remaining area, and it should be allowed to dry as well. A piece of IV 3000 (Smith & Nephew) or Tegaderm (3M) is placed to sandwich the sensor between the tape and the skin. If this still does not prevent site failures, replace the IV Prep (Smith & Nephew) with Mastisol (Ferndale Laboratories) or Skin Tac (Torbot), and again use the IV 3000 (Smith & Nephew) or Tegaderm (3M) to completely cover the sensor site. Coban wrap (3M) works very well to secure the Abbott FreeStyle Navigator sensor site to the arm.

Sweating, especially during sport activities, can lead to early loss of adhesion as well. In this case, patients can apply a roll-on or spray-on antiperspirant (without a deodorant component) to the entire area where the sensor will be worn and then apply the IV Prep (Smith & Nephew), Mastisol (Ferndale Laboratories), or Skin Tac (Torbot), followed by the IV 3000 (Smith & Nephew) tape "sandwich."

Some patients suffer from skin irritation. Causes of irritation can include sensitivity to the tape placed over the sensor area, sensitivity to the tape used to secure the sensor itself, or sensitivity to the transmitter. For those patients who develop a sensitivity to the tape placed over the sensor site, the Yale sensor team asks them to switch brands using either IV 3000 (Smith & Nephew) or Tegaderm (3M). Many patients benefit from partially taping the area rather than blanketing it with a large piece of tape, allowing more skin to be exposed to air. In this case, the clinicians help patients to develop a partial taping strategy that provides strength and stability while using the smallest amount of tape possible.

Other patients develop an irritation to the tape that is attached to the sensor or transmitter itself. In these cases, IV 3000 (Smith & Nephew) or Tegaderm (3M) tape is placed underneath the sensor to provide a barrier between the skin and the transmitter tape. It is important to note that a sensor should not be inserted through this tape barrier. Instead, the barrier must be placed so that the point of insertion is free of any impediment. Irritation from the transmitter itself can be managed with either using a tape barrier between the skin and the transmitter or using moleskin tape to provide a barrier. The moleskin tape is attached to the transmitter so that the soft surface is against the skin.

Reliability of Sensor Readings

Many patients become frustrated when they find that the sensor is not in agreement with their blood glucose meter readings or it gives frequent “false alarms” that interrupt daily activities. The most common causes of these frustrations related to accuracy include unrealistic expectations regarding RT-CGM, poor understanding of “lag time,” alarm fatigue, and ineffective calibration technique.

Lag Time

Sensor readings are based on the average of several readings taken from the interstitial fluid. These levels generally can lag behind blood glucose levels by up to 10 minutes during rapid rise or fall in glucose levels. In human studies, interstitial glucose levels lag behind blood glucose levels by 3 to 13 minutes.[13,14] Patients and family members do not always understand this concept and, consequently, may consider the technology unhelpful at first. A discussion of conceptual underpinnings of RT-CGM is necessary to set realistic expectations for the family. We remind patients that the glucose travels from blood to cells, through the intersitium, and therefore, the readings will rarely be exactly the same. However, this does not mean that the sensor readings are incorrect. Patients are encouraged to designate the first week of RT-CGM use as an observational period, in which they gain a mastery of the mechanics of the device, identify the blood glucose trends, and learn how to interpret retrospective data. Patients and caregivers are reminded that the trends and patterns illuminated by the RT-CGM have always been there but RT-CGM makes them visible. A step-by-step strategy can help families focus. For the first week or 2, it is helpful to identify the behavioral changes that have the greatest impact on blood glucose levels such as how and when to bolus for certain foods and how to manage blood glucose excursions during exercise. The YCDP sensor team advises patients to make adjustments to pump settings no more than every 3 to 5 days. Follow-up visits provide an opportunity to teach more advanced concepts such as interpretation of real-time and retrospective continuous glucose monitoring data.

To ensure safe and proper sensor use, it is critical to underscore that a patient must check the blood glucose level with a blood glucose meter to confirm an alarm or make any diabetes management decisions. Families should be reminded that sensor readings are best used as a trending guide for the time periods between routine blood glucose checks. With time, patients learn to predict their blood glucose patterns based on a myriad of circumstances related to activity, food, stress levels, and health status and report increased confidence in the RT-CGM readings.

Alarm Fatigue

The number and quality of features vary among systems. The Medtronic MiniMed Paradigm REAL-time system offers many features, while DexCom Seven Plus is a simpler, more straightforward device. The Abbott FreeStyle Navigator system has many features that allow for highly customized continuous glucose monitoring but, with inappropriate use, may lead to alarm fatigue.

Alarm fatigue occurs when patients feel overwhelmed by alarms, both accurate alarms and those that are incorrect, known as “false alarms.” Not only do patients become irritated by the constant and sometimes inappropriate interruptions to their daily activities, but many families report that this constant stream of interruptions often leads them to ignore alarms, both true and false, or turn off the alarm feature all together. Many times, alarm fatigue is a result of setting unrealistic alarm thresholds. For families new to RT-CGM, set wide alarm thresholds, and narrow the thresholds over time. A high glucose alarm of 250 mg/dL and a low glucose of 80 mg/dL are safe starting points. If the high alarm rarely sounds, the YCDP clinician or parent will lower this threshold after a week or 2. The low alarm of 80 mg/dL allows for possible

lag time of the sensor glucose reading. Frequent false low alarms can be mitigated by lowering the threshold to 70 mg/dL. Families are instructed to proactively adjust their alarm settings, including the thresholds, volume, and sound quality (beep vs vibrate). Families may also decide to turn off all alarms except the low glucose, particularly during quiet times such as school, sleep, or events, preferring instead to check sensor readings more frequently. Although these may seem like straightforward coping strategies, families may need specific instruction and support from their diabetes providers to prevent alarm fatigue.

Calibration

Proper calibration is the most important action that patients and their families can take to ensure that the sensor data are as accurate as possible. As noted earlier, there is a discrepancy between the blood glucose level and the sensor glucose level that is greatest during times of rapid rate of change in glucose. It is important to regularly reinforce with patients that during times of rapid change in glucose levels such as following meals or rigorous activity, the lag between blood and interstitial glucose levels can be longer. However, thinking of calibration as maintenance of a steady ratio between these 2 values gives value to both sensor data and alarms.

Many patients believe that “more is better” and will enter many more calibration blood glucose readings than is necessary for the sensor to function properly. Each device has a unique calibration strategy so it is important to follow the manufacturer’s instructions for frequency and timing of blood glucose calibration readings. All continuous glucose monitoring systems require calibration using blood from clean, dry fingertips only. Accuracy of the blood glucose meter readings is secured through periodic use of control solution and test strip/meter coding. Regardless of the RT-CGM device used, there are 3 calibration principles the sensor team asks YCDP patients to follow:

1. Quality is more important than quantity. It is better to calibrate less frequently with quality blood glucose readings during periods when blood glucose levels are not changing rapidly than to enter every blood glucose reading into the sensor.
2. Use the sensor data to confirm that a particular blood glucose check is optimal for calibration. Never calibrate when an arrow indicates a rapid rise or fall in blood glucose, and review the 3-hour graph to ensure that the glucose levels have remained relatively stable with no wide swings over the 3 hours.
3. Calibrate routinely rather than wait for the device to require a calibration. The Yale sensor team recommends that patients develop a routine for calibration. An appropriate calibration schedule to begin RT-CGM use includes checking blood glucose fasting, premeal and prebedtime. If these times are not convenient, then patients can try before breakfast and dinner and/or bedtime. It is important to note that the Abbott FreeStyle Navigator system determines when it needs a calibration once it is outside of the initial start-up period. The DexCom Seven Plus and Medtronic MiniMed Paradigm REAL-time systems require a calibration at least every 12 hours so teenagers who like to sleep later in the morning should calibrate the RT-CGM prior to bedtime.

Resources

The JDRF Online Teaching Tool is available to help families learn proper interpretation of real-time sensor data and alarms as well as downloads. This resource can be found at https://studies.jaeb.org/ndocs/extapps/CGMTeaching/.

Summary

RT-CGM is the newest technology available to augment current diabetes care strategies. While the first generation of RT-CGM systems do not replace current blood glucose meters, they still provide valuable data for patients and their families. As with most technological advances, patients need to be aware of the strengths and limitations of RT-CGM systems. Careful training and troubleshooting strategies will ensure the most positive experience possible for a family using RT-CGM.

Acknowledgments

William V. Tamborlane has received funds for his advisory role to Medtronic Inc.

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Table 1

Features of the Real-Time Continuous Glucose Monitoring Systems

	Abbott Free Style Navigator	DexCom Seven Plus	Medtronic MiniMed Paradigm or Guardian Real Time
Range of glucose values	20–500 mg/dL	40–400 mg/dL	40–400 mg/dL
Update of glucose values	Every minute	Every 5 minutes	Every 5 minutes
Sensor duration	Up to 120 hours (5 days)	Up to 168 hours (7 days)	Up to 72 hours (3 days)
Sensor length, angle, and gauge	6 mm, 90°, 21 gauge	13 mm, 45°, 26 gauge	12 mm, 45°–60°, 23 gauge
Transmitter size	2.05″ × 1.23″ × 0.43″	1.5″ × 0.9″ × 0.4″	1.4″ × 1.1″ × 0.3″
Number of components to wear/carry	Receiver, transmitter (home glucose meter built in to receiver)	Receiver, transmitter, and home glucose meter	Receiver, transmitter, and home glucose meter
Warm-up period before glucose readings displayed	10 hours	2 hours	2 hours
Required frequency of calibration	4 times at about 10 hours, 12 hours, 24 hours, and 72 hours after sensor insertion	2 times a day (every 12 hours)	2 times a day (every 12 hours)
Available alarms	High and low glucose alarms; projected high and low glucose alarms	High and low glucose alarms	High and low glucose alarms; Guardian also has projected high and low glucose alarms
Glucose display graphs	2, 4, 6, 12, and 24 hours	1, 3, 6, 12, and 24 hours	Paradigm has 3 and 24 hours; Guardian has 3, 6, 12, and 24 hours
Trending arrows	Yes	Yes	Yes
Capacity to enter events	Insulin, meals, exercise, health, other	Insulin, meals, exercise, and health	Insulin, meals, exercise
Food and Drug Administration (FDA) approval status	Age 18 and older with blood glucose testing using a home glucose meter	Age 18 and older with blood glucose testing using a home glucose meter	Age 7 and older with blood glucose testing using a home glucose meter