Continuous Glucose Monitoring
The Third Era of Diabetes Management

Brian Horner, M.S., and H. Peter Chase, M.D.

The Diabetes Control and Complications Trial conclusively demonstrated the effectiveness of intensive diabetes management for lowering the kidney, nerve, and cardiovascular complications of Type 1 diabetes (1, 2). A crucial aspect of intensive diabetes management is self-monitoring of blood glucose (SMBG), which is usually done two to four times per day. The use of relatively infrequent SMBG levels may soon be supplemented or replaced by continuous glucose monitoring (CGM) levels, which are available every 1–5 minutes throughout the day. During the past 5 years, CGM technology has been significantly refined, and current second-generation continuous glucose monitors possess improvements, particularly in accuracy, over the previous devices (Figure 1).

The main advantage of continuous glucose monitors over SMBG is the ability to constantly deliver glucose values in real time. Such real-time continuous glucose monitoring (RT- CGM) devices provide both the clinician and patient or family with much more information about daily glucose profiles and glycemic excursions than does SMBG. In addition, audible alarms for high and low glucose levels increase safety for the patient and act as "behavior modification" to encourage the patient to maintain glucose levels in his or her target range. Because of these capabilities, the expanded use of RT-CGM could change the current clinical paradigm for glucose monitoring in patients with Type 1 diabetes. The goal of this article is to offer practical, stepwise information to clinicians about how the current and soon-to-be-available RT-CGM technology may be effectively incorporated into the clinical care of individuals with Type 1 diabetes.

Overview of Real-Time Continuous Glucose Monitoring

During the past 50 years, individuals with diabetes have used numerous methods and devices to measure their glucose levels. Technological advances have created three major historic eras of glucose testing. Before 1978, diabetes management relied on dipstick measurements of glucose in a patient's urine. Thereafter, the development of home-based, and eventually portable, blood glucose strips and monitors allowed more accurate and convenient measurement of glucose levels. Compared with the current and previously used methods of glucose measurement, RT-CGM represents a "third era" in diabetes management, as depicted in Figure 2. Expanded use of RT-CGM will once again revolutionize how patients and physicians monitor glucose levels and manage diabetes.

RT-CGM devices incorporate a sensor that measures glucose levels every 1–5 minutes over 3–7 days. The mechanism of sensor action and the medium in which glucose is measured vary somewhat between devices; however, most current and soon-to-be-available RT-CGM devices measure glucose in the interstitial subcutaneous fluid. The interstitial fluid is accessed in a variety of ways, most commonly through a subcutaneously placed, enzyme-coated sensor (3, 4).

The glucose levels measured by an RT-CGM sensor are displayed on a pocket-sized monitor, or, for the Paradigm Real Time device (Medtronic MiniMed), on the screen of an insulin pump. Most devices also record and store glucose values for later analysis. The availability of real-time glucose values also enables RT-CGM devices to generate alerts for hypoglycemia and hyperglycemia, and, in some cases, to display information on glucose trends with the use of directional arrows.

The literature contains several thorough reviews of first-generation CGM technology, including a RT-CGM device (GlucoWatch, Cygnus Inc.) and a retrospective, blinded CGM study (Continuous Glucose Monitoring System, Medtronic MiniMed) (5–7). In addition to reviewing studies on CGM accuracy and usability, these reports have addressed general indications for CGM and specific information related to individual devices. Characteristics of four second-generation RT-CGM de-
The top two photos (Medtronic/MiniMed, Northridge, California) show the Paradigm (722) Real Time System (on left), in which the sensor communicates glucose levels to the face of the pump, and the Guardian RT system (on right), in which the sensor communicates with a receiver. The bottom left shows the FreeStyle Navigator (investigational system currently under FDA review; Abbott Diabetes Care, Alameda, California) sensor, transmitter, and receiver. The bottom right shows the DexCom STS Continuous Glucose Monitoring System (DexCom, Inc., San Diego, California) receiver, sensor with applicator, and transmitter.

...
similar system components and electronic platform. A typical RT-CGM system consists of three main components: a glucose sensor that measures glucose levels, a communication link (transmitter) that transmits glucose readings from the sensor to the monitor unit, and a pocket-sized monitor unit that displays glucose readings, generates alerts for hypoglycemia and hyperglycemia, and records all values for later analysis.

RT-CGM devices also have the capability to interface with a personal computer through a connection unique to each manufacturer’s device. Device-specific software programs can be used to download glucose values stored in the monitor unit and to generate reports to aid the patient and the clinician with diabetes management. Although the hardware, software, and operating-system specifications required for the interface between the RT-CGM device and the personal computer will vary between devices, most personal computers capable of using at least Microsoft Windows 2000 should be able to support an interface with RT-CGM devices.

Given that RT-CGM devices rely heavily on the use of both hand-held electronics and personal computers, patients and clinicians need a certain level of comfort and proficiency with both technologies. Although hand-held electronics (such as cell phones, personal digital assistants, and electronic games) and personal computers are nearly ubiquitous in the home and workplace, lack of user knowledge and comfort with these devices must still be a concern for clinicians who intend to use RT-CGM in the management of diabetes. After ample training, patients must be proficient at navigating through and using all RT-CGM device functions. If patients will be asked to download and review their own RT- CGM data at home, they must also possess the computer skills and knowledge to do so. Clinicians must be familiar with all RT-CGM device functions to adequately educate the patient and family and to troubleshoot problems and errors with them during use of the device.

Clinical Approach to the Use of RT-CGM

One of the most important aspects of effectively integrating RT-CGM into diabetes clinical practice is thorough patient education at the outset. The approach to, and extent of, patient education needed for the use of RT-CGM is not unlike that needed before the use of continuous subcutaneous insulin infusion (CSII; insulin pump therapy). Adequate education increases the likelihood of successful RT-CGM use. Such education must include hands-on training on how to use the specific device and its features, how RT-CGM differs from point-in-time testing, and how data obtained from RT- CGM should be used and interpreted.

Regardless of the RT-CGM device used, several standard educational elements must be addressed with all patients and their families. These include the following:

- The purpose of wearing the RT-CGM device and goals of use (what it can and cannot do)
- Sensor insertion and device connections
- Device-specific calibration procedures
- How to use specific functions of the device
- How to properly use and protect the RT- CGM device
- How to interpret and respond to real-time glucose values, alarms, and trend information
- A review of insulin action and guidance for making dose adjustments based on RT- CGM readings

Figure 3 presents a sample educational checklist for training the patient and family in the use of an RT- CGM device.
<table>
<thead>
<tr>
<th>RT-CGM DEVICE</th>
<th>FDA APPROVED&lt;sup&gt;a&lt;/sup&gt;</th>
<th>SENSOR MECHANISM</th>
<th>POSSIBLE LOCATIONS FOR SENSOR WEAR</th>
<th>INITIAL CALIBRATION TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guardian RT Continuous Glucose Monitoring System / Paradigm Real Time System</td>
<td>Yes</td>
<td>Enzyme-coated, subcutaneously placed, indwelling sensor</td>
<td>Abdomen, hip, buttock, thigh</td>
<td>2 hours</td>
</tr>
<tr>
<td>Freestyle Navigator Continuous Glucose Monitor</td>
<td>No</td>
<td>Enzyme-coated, subcutaneously placed, indwelling sensor</td>
<td>Posterior arm, abdomen, hip, buttock</td>
<td>10 hours</td>
</tr>
<tr>
<td>Dex-Com STS</td>
<td>Yes</td>
<td>Enzyme-coated, subcutaneously placed, indwelling sensor</td>
<td>Abdomen</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

RT-CGM indicates real-time continuous glucose monitoring; FDA indicates Food and Drug Administration.

<sup>a</sup>FDA approved for use in patients who are at least 18 years old.

<sup>b</sup>Sensor lifespan of 72 hours is based on the initial FDA application. However, new data are showing that sensors may last 5–7 days.

Once the patient has used the device for a period of time, the clinician should meet with the patient and family again to review the RT-CGM data and to suggest any necessary changes to the patient's diabetes management. Downloading the glucose values stored in the monitor into the device-specific software package allows the clinician to review and analyze the patient's glucose readings. This review is easily done using the numerous reports that can be generated by the given software package. Reports of RT-CGM data can illustrate a patient's glucose profile over several days, thus aiding the patient and clinician in identifying glucose trends or patterns that require corrective action. We have found that patients and families easily understand concise, graphic reports, such as modal day plots, or simple statistics, such as the percent-ages of glucose readings within, above, and below a patient's target range. Individual patients and their families and clinicians usually favor one of the specific reports. Figure 4 shows examples of reports that can be generated from RT-CGM data, along with an accompanying analysis.

Figure 5 illustrates a sample RT-CGM analysis scheme. A single review of RT-CGM data may reveal several distinct glycemic trends and patterns that require changes to diabetes management. However, the clinician and the patient and family must understand that not all apparent problems can be corrected at once. We believe that having the patient and family focus on one change in diabetes care per week is generally acceptable to them and can lead to improved glycemic control. This approach prevents the patient and family from becoming overwhelmed with the large amount of data available from the RT-CGM device. It also gives time to observe the result of the previous change before making another change. The RT-CGM device works as a "behavior modifier," and as patients and families see patterns, they make behavior changes themselves (e.g., more nutritious snacks, more exercise). After using the RT-CGM device for 1–3 months, most patients and families begin to make insulin dose modifications on their own as well. Some of the most frequent modifications patients might make include the following:

- Change in long-acting insulin dose or CSII basal rates
- Change in insulin-to-carbohydrate ratio (for one or more meals)
- Change in timing of meal insulin doses or CSII insulin boluses (e.g., administering dose 15 or more minutes before meals rather than after)

Given the capabilities and expanding use of RT-CGM, it is logical to ask how long a pa-
<table>
<thead>
<tr>
<th>CALIBRATIONS PER 72-HOUR LIFESPAN OF SENSOR</th>
<th>FREQUENCY OF GLUCOSE READINGS</th>
<th>HYPO- AND HYPERGLYCEMIC ALARMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Every 5 minutes</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Every 1 minute</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Every 5 minutes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

The overall bias between paired sensor and SMBG values was less than 15 mg/dl at low glucose levels (50 and 80 mg/dl) and less than 15% at glucose levels of 100, 150, and 200 mg/dl (8). In addition, subjects who were able to view glucose values in real time over 6 days decreased the amount of time spent in the hypoglycemic and hyperglycemic ranges and increased the amount of time spent in the euglycemic target range (8).

The National Institutes of Health funded an independent study group (The Diabetes Research Network in Children, or "DirecNet") to evaluate the accuracy of the various CGM systems. At this time, only one of the three CGM companies (Abbott Diabetes Care; the Navigator device) has allowed DirecNet to do accuracy studies. Thus, independent accuracy data (not analyzed by the CGM company) are primarily available for the Navigator. The DirecNet group reported a median relative absolute difference between paired Navigator sensor readings and laboratory reference values of 13% and 10% during euglycemia (71–180 mg/dl) and hyperglycemia (>180 mg/dl), respectively, for 30 pediatric subjects during an inpatient hospital stay (9).

In the same 30 subjects monitored during outpatient use of the Navigator, the investigators found a median relative absolute difference between paired Navigator sensor readings and SMBG reference values of 14% and 12% during euglycemia and hyperglycemia, respectively (9). For glucose levels in the hypoglycemic range (<70 mg/dl), the median absolute difference between the Navigator and reference glucose values was 14 mg/dl during an inpatient stay and 15 mg/dl with outpatient use (9). Throughout a 7-week outpatient study period, the 30 subjects receiving real-time glucose values increased the number of Navigator-measured glucose values in the euglycemic target range of 71–180 mg/dl from 53% to 61% and had a slight decrease in glycosylated hemoglobin (HbA1c) levels (from 7.0 ± 0.5% to 6.8 ± 0.6%) (10).

Patients and their families must have methods to keep track of and use the information provided by RT-CGM devices. DirecNet recently released pilot data on the utility of the DirecNet Applied Treatment Algorithm (DATA) (11). The DATA provides guidelines on therapy adjustments for responding to hypoglycemic and hyperglycemic alarms, glucose trends, and continual glucose readings in real time. For example, a premeal insulin dose (in-
FIGURE 3.

PATIENT EDUCATION FOR REAL-TIME CONTINUOUS GLUCOSE MONITORING

I. RT-CGM Basics

Patients are educated about, and must demonstrate an understanding of, the following basic RT-CGM concepts:

- The RT-CGM device consists of a sensor worn under the skin, a transmitter (communication link) that sends glucose readings to a receiver, and a receiving/recording/display unit.
- The RT-CGM device will measure, record, and display glucose levels at specified intervals.
- The RT-CGM sensor and device components must be worn continuously for glucose levels to be measured and recorded.
- The RT-CGM device measures glucose levels in the interstitial subcutaneous fluid (ISF) as opposed to blood.
- Glucose values displayed in real time are used by the patient to detect recurring patterns, observe impending trends, and make some daily diabetes management decisions.\(^a\)
  
  —Current RT-CGM technology is not a complete substitute for point-in-time blood glucose testing.
- Fingerstick, point-in-time blood glucose measurements are still required under certain circumstances:
  
  —RT-CGM device calibration
  —Verification of hypo- and hyperglycemic RT-CGM device readings or symptoms
  —Verification of unusual trends or glucose patterns detected by the RT-CGM device
- Values stored by the RT-CGM device can be downloaded and viewed by a clinician to help identify glucose fluctuations that may signal a needed change to diabetes management.

II. Use of the RT-CGM Device

Patients are educated about, and must demonstrate proficiency in, the following procedures as they relate to the specific RT-CGM device being used:

- Site selection, site preparation, and subcutaneous sensor insertion
- Attachment, connection, and activation of all device components

- Device setup:
  
  —Time, date, and glucose measurement settings
  —Hypo- and hyperglycemic alarm thresholds
- Device operation\(^b\)
  
  —Navigation of device menus
  —Use of device-specific functions (e.g., meal, exercise, medication markers)
  —Acknowledgment of alarms
- Calibration schedule, process, and related procedures
- Use of an associated standard home glucose monitor for RT-CGM device calibration and verification of questionable or extreme device readings
- Proper use, wear, and protection of the RT-CGM device

III. Use of RT-CGM for Daily Diabetes Management

Patients are educated about, and must demonstrate an understanding of, how to use the RT-CGM device and the information it provides to manage and adjust their diabetes care on a daily basis.\(^c\) The following areas are covered:

- The proper response or treatment for impending or true hypo- and hyperglycemic alarms
- The proper response or treatment for noneuglycemic values indicated by the CGM device
- The proper response or treatment for hypo- and hyperglycemic glucose trends
- The proper way for the patient to make safe and prudent insulin dose adjustments based on RT-CGM readings
  
  —This should include a review of insulin action, time of insulin activity, and recommended basal, food bolus, and correction bolus insulin dosages.

---

\(^a\)Device-specific educational materials such as diagrams, slides, and instructional videos are helpful in this portion of the patient-education session.

\(^b\)A demonstration RT-CGM device, separate from the one being used by the patient, is helpful for familiarizing patients with the overall use, functions, features, and "button-pushing" of the device.

\(^c\)Patient education in this area may be easily accomplished by requiring the patient to use a predetermined set of recommendations or instructions, such as the DirecNet Applied Treatment Algorithm (DATA) (11), for each of the above scenarios.
A1. The modal day plot indicates numerous periods of hyperglycemia throughout the day. The most distinct and recurring pattern of hyperglycemia occurred during the nighttime hours (box) and probably indicates the need for an increase in the basal insulin dose covering that time period.

A2. The frequency of this patient's hyperglycemia is further illustrated by the values in the summary statistics table. Of particular interest are the highest glucose values recorded at each time and the large percentage of glucose values above the target range (70–180 mg/dl [3.9–10.0 mmol/liter]).
FIGURE 4. (continued)
SAMPLE REPORTS GENERATED FROM REAL-TIME CONTINUOUS GLUCOSE MONITORS

B. Modal day plot (each line represents 1 day) and accompanying pie charts from 5 days of RT-CGM data obtained from an 8-year-old girl using CSII.

B1. The modal day plot indicates a recurring pattern of postprandial hyperglycemia after breakfast (box). This hyperglycemia might be corrected with an increased mealtime insulin dose (increased insulin-to-carbohydrate ratio or appropriate adjustment to sliding-scale dosage).

B2. The post-breakfast pie chart clearly indicates the abundance of hyperglycemic values in this time period compared with the low proportion of hyperglycemic values in the post-lunch pie chart. This concise visual comparison of undesirable versus acceptable postprandial glucose profiles is easy for patients to understand and learn from.

the likely evolution in the assessment of glycemic control in patients with Type 1 diabetes. In the current standard of care, HbA1c is the gold-standard measurement for long-term glycemic control. Although other factors, such as the avoidance of frequent hypoglycemic and hyperglycemic episodes, are also important, the exact frequency and duration of glucose excursions can be difficult to quantify reliably on a daily basis. The use of RT-CGM to obtain frequent glucose measurements over several days allows easy recording of glucose excursions. The percentages of glucose values in a patient's hypoglycemic, euglycemic, and hyperglycemic ranges may become an increasingly useful measurement of glycemic control in conjunction with HbA1c. It is important to note that an increase in the percentage of glucose values within the target range may well reduce the number of hypo-
C. Isolated modal day plot and accompanying diary excerpt from 1 day of RT-CGM data obtained from a 17-year-old male patient using CSII.

C1. Single Day Modal Day Plot

C1. The modal day plot illustrates a dangerously prolonged period of hypoglycemia (box). The patient reported being asleep during this period of hypoglycemia, which occurred after a social event extending late into the previous night. An isolated graph of an extreme hypo- or hyperglycemic episode is a valuable tool for educating patients. Such graphs emphasize the importance of recognizing and quickly treating these conditions.

C2. Glucose Value Logbook

<table>
<thead>
<tr>
<th>TIME</th>
<th>GLUCOSE VALUE</th>
<th>TIME</th>
<th>GLUCOSE VALUE</th>
<th>TIME</th>
<th>GLUCOSE VALUE</th>
<th>TIME</th>
<th>GLUCOSE VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:56 AM</td>
<td>75</td>
<td>6:56 AM</td>
<td>60</td>
<td>8:56 AM</td>
<td>56</td>
<td>10:56 AM</td>
<td>47</td>
</tr>
<tr>
<td>5:06 AM</td>
<td>62</td>
<td>7:06 AM</td>
<td>57</td>
<td>9:06 AM</td>
<td>55</td>
<td>11:06 AM</td>
<td>47</td>
</tr>
<tr>
<td>5:16 AM</td>
<td>58</td>
<td>7:16 AM</td>
<td>57</td>
<td>9:16 AM</td>
<td>54</td>
<td>11:17 AM</td>
<td>47</td>
</tr>
<tr>
<td>5:26 AM</td>
<td>57</td>
<td>7:26 AM</td>
<td>58</td>
<td>9:26 AM</td>
<td>52</td>
<td>11:27 AM</td>
<td>46</td>
</tr>
<tr>
<td>5:36 AM</td>
<td>57</td>
<td>7:36 AM</td>
<td>59</td>
<td>9:36 AM</td>
<td>51</td>
<td>11:37 AM</td>
<td>46</td>
</tr>
<tr>
<td>5:46 AM</td>
<td>56</td>
<td>7:46 AM</td>
<td>60</td>
<td>9:46 AM</td>
<td>52</td>
<td>11:46 AM</td>
<td>46</td>
</tr>
<tr>
<td>5:56 AM</td>
<td>56</td>
<td>7:56 AM</td>
<td>60</td>
<td>9:56 AM</td>
<td>50</td>
<td>11:57 AM</td>
<td>45</td>
</tr>
<tr>
<td>6:06 AM</td>
<td>57</td>
<td>8:06 AM</td>
<td>59</td>
<td>10:06 AM</td>
<td>43</td>
<td>12:06 AM</td>
<td>45</td>
</tr>
<tr>
<td>6:16 AM</td>
<td>60</td>
<td>8:16 AM</td>
<td>58</td>
<td>10:16 AM</td>
<td>43</td>
<td>12:17 AM</td>
<td>45</td>
</tr>
<tr>
<td>6:26 AM</td>
<td>60</td>
<td>8:26 AM</td>
<td>57</td>
<td>10:26 AM</td>
<td>44</td>
<td>12:27 AM</td>
<td>44</td>
</tr>
<tr>
<td>6:36 AM</td>
<td>61</td>
<td>8:36 AM</td>
<td>57</td>
<td>10:36 AM</td>
<td>44</td>
<td>12:37 AM</td>
<td>49</td>
</tr>
<tr>
<td>6:46 AM</td>
<td>61</td>
<td>8:46 AM</td>
<td>57</td>
<td>10:47 AM</td>
<td>44</td>
<td>12:47 AM</td>
<td>78</td>
</tr>
</tbody>
</table>

C2. The excerpt from the glucose value logbook illustrates the exact duration and severity of the prolonged hypoglycemic episode. This detailed list of timed glucose values reinforces the importance of preventing such dangerous episodes.
FIGURE 5.
SAMPLE ANALYSIS SCHEME FOR REAL-TIME CONTINUOUS GLUCOSE MONITORING

1. Identify hypoglycemic and hyperglycemic excursion patterns of concern from RT-CGM reports
2. Prioritize the severity of the identified excursion patterns
3. Identify possible causative events for the highest priority glucose excursions
   - Does the excursion occur after a meal or snack?
     - Evaluate and adjust meal/snack carbohydrate-insulin ratio
   - Does the excursion occur during or after exercise/physical exertion?
     - Evaluate and adjust basal insulin dose and food intake before and after exercise
   - Does the excursion occur between known activities such as meals, snacks, or physical activity?
     - Excursion may indicate the need for basal rate adjustment or change to correction bolus
4. Reevaluate RT-CGM reports in approximately 1 week. Did the decided upon corrective action improve the highest priority glycemic excursion?
   - No
     - Reevaluate the potential cause of the glycemic excursion and alter recommended corrective action as needed
   - Yes
     - Repeat the above process with next-highest priority glycemic excursion

RT-CGM indicates real-time continuous glucose monitoring.

glycemic episodes that previously contributed to a “good” HbA1c value. This, in turn, may result in slightly higher HbA1c levels for some patients. Educating patients about this possibility and the continued importance of striving for a near-normal glycemic profile will be required.

Future improvements to RT-CGM technology may eventually produce a device that can completely replace point-in-time SMBG testing as the primary method for home glucose monitoring. To completely replace SMBG, RT-CGM devices should not rely on calibration from another blood glucose measuring device but should be self-calibrating, and they must be capable of delivering reliable, accurate, real-time glucose levels to patients without interruption. Although the accuracy of current and soon-to-be-available RT-CGM devices is improving substantially compared with previ-
TABLE 2.
COSTS OF TWO CURRENTLY AVAILABLE RT-CGM SYSTEMS

<table>
<thead>
<tr>
<th>RT-CGM SYSTEM</th>
<th>SYSTEM DESCRIPTION</th>
<th>SYSTEM AND COMPONENT COST BREAKDOWN</th>
</tr>
</thead>
</table>
| Dex-Com STS              | System consists of a transcutaneous sensor attached to a transmitter. The transmitter sends glucose information to a wireless receiver unit that displays real-time glucose values. | ▪ Start-up kit (receiver, transmitter, 2 sensors): $800.00  
▪ Replacement transmitter: $250.00 (needed after 6 months)  
▪ Single-use sensors: $35.00 each  
▪ Download and management software: not available |
| Medtronic MiniMed       | System consists of a transcutaneous sensor attached to a transmitter. The transmitter sends glucose information to a Medtronic MiniMed Paradigm 522 or 722 insulin pump. The insulin pump acts as the receiver and displays real-time glucose values and trend information. The RT-CGM system is not available for use without the insulin pump as the receiver. | ▪ Receiver: Insurance or patient may purchase a Medtronic MiniMed Paradigm 522 or 722 insulin pump that acts as the receiver.  
▪ Start-up kit (transmitter + 10 sensors): $999.00  
▪ Additional single-use sensors: $35.00 each  
▪ Download and management software: free via secure web portal |
| Paradigm Real-Time System |                                                                                   |------------------------------------------------------------------------------------------------------|

RT-CGM indicates real-time continuous glucose monitoring.

Nous first-generation models, all such devices require periodic calibration from a conventional home glucose monitor and can fail to deliver real-time readings under certain conditions. Therefore, it is unlikely that any current or soon-to-be-available RT-CGM device will completely replace point-in-time blood glucose testing.

Additional Issues and Practical Solutions
Disparity between RT-CGM glucose readings and point-in-time SMBG readings. Because of differing glucose concentrations in blood and interstitial fluid (ISF), a disparity may arise between an RT-CGM glucose reading and a conventional home glucose monitor reading when the tests are done at the same time. This disparity may result in part from the 4- to 10-minute lag time between the blood glucose level and the ISF glucose level, whereby the blood glucose level generally precedes the ISF glucose level (12). The lag time is usually most disconcerting during periods of rapid change in glucose levels. Patients and families may incorrectly assume that the lag time indicates device inaccuracy. Therefore, clinicians should stress that RT-CGM device accuracy is dependent on proper calibration and that calibration values should be entered only when glucose values are relatively stable and not showing a rapid increase or decrease.

The few patients to date who have had nocturnal seizures while using a CGM device had been hypoglycemic for 2 or more hours before the seizure. This finding may make the issue of lag time of the CGM as the patient becomes hypoglycemic less of an issue.

One of the three CGM companies (Abbott Diabetes Care; the Navigator device) has included "pending-hypoglycemia" alarms in addition to the hypoglycemia alarm. Thus, if a glucose level is declining rapidly, an alarm will sound to indicate a predicted low glucose level.

A major problem with the first-generation CGM devices was the high incidence of false-positive (and -negative) alarms for hypoglycemia. Families objected to hearing low-alert alarms when the blood glucose level was not low. All CGM devices are less accurate at detecting hypoglycemic than hyperglycemic glucose levels. However, the second-generation devices are a definite improvement. Unfortunately, many young people sleep through the alarms, and innovative ways to awaken patients or alert family members are needed.
Costs and reimbursements. The one-time and ongoing costs for RT-CGM device components, associated computer hardware and software, and the clinician's time remain a significant concern with the use of RT-CGM in clinical practice. The initial costs for the patient and family and the clinician depend largely on the specific type of RT-CGM system being used. Initially, RT-CGM systems are likely to be marketed to, and purchased by, individual patients or families. The costs to the clinician include time and the cost of purchasing the computer hardware and software needed to download the device and analyze the stored glucose values. Table 2 summarizes the costs of two currently available RT-CGM systems and their associated components.

Regardless of the specific device and cost model, health insurance reimbursement for RT-CGM devices and clinical evaluation of results is likely to play a major role in the clinical use of RT-CGM. In a recent report, Aubry discussed common criteria, policies, and processes used by insurers in considering a coverage decision, and thus reimbursement, for medical technology such as RT-CGM (13). Any such reimbursement for RT-CGM will most likely be for CPT codes 95250 (CGM sensor insertion, device setup, 72-hour wear, and download of results) and 95251 (clinical interpretation of CGM results). It may take several years before health maintenance organizations recognize the value of RT-CGM and agree to fund the devices even in part. Adequate funding for the health-care provider will probably be delayed even longer. Such funding will depend on large patient studies that show the value of RT-CGM in reducing and maintaining lower HbA1c levels and thus reducing the risk of complications.

Conclusion

The use of CGM devices will increase over the next few years, initially in combination with SMBG levels. Use of CGM devices will lead to the third era of diabetes management. As diabetes care providers gain further experience and expertise in using RT-CGM in clinical practice, recommendations and standards for use will continue to evolve. Issues such as clinicians' acceptance of the technology, patients' compliance with RT-CGM-based treatment regimens, health-insurance reimbursement, and the long-term usability of the technology have yet to be solved. Further studies of these and other issues related to RT-CGM are needed.

Mr. Horner is currently a medical student at the University of Colorado School of Medicine in Denver. Dr. Chase is Professor of Pediatrics at the University of Colorado School of Medicine and Past Executive and Clinical Director of the Barbara Davis Center for Childhood Diabetes at the University of Colorado Health Sciences Center in Denver. This study was supported in part by the Children's Diabetes Foundation at Denver.

References


