Using Pattern Management to Improve Glycemic Control

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Using Pattern Management to Improve Glycemic Control is supported by an educational grant from Novo Nordisk Inc. This program has been accredited by the American Association of Diabetes Educators (AADE) for nurses, dietitians, and pharmacists.
The following program is a recorded presentation by Deborah Hinnen.

Deborah Hinnen, RN, ARNP, BC-ADM, CDE, FAAN, FAADE has been a diabetes educator for over thirty years. As a clinical nurse specialist and education coordinator, she currently works at Mid America Diabetes Associates as coordinator of a multidisciplinary team. The centerpiece of their program is a three day comprehensive self-management course that serves nearly 1000 people with diabetes per year.

Ms. Hinnen is involved extensively with the American Association of Diabetes Educators (AADE), having served as their national President in 1993-94. She was awarded their prestigious Distinguished Service Award in the summer of 2001. She has also served on the national board of directors for the American Diabetes Association, and was an associate editor for *Diabetes Spectrum*. She continues to volunteer with many other organizations. Her faculty positions are with the Pharmacy Department at University of Kansas, Creighton and University of Nebraska and Graduate Nursing Department at Wichita State University and the Physicians Assistant Program at Wichita State. Ms. Hinnen was inducted as a Fellow into the American Academy of Nursing in 2003 and as a Fellow into the AADE in 2010.

Her career has focused on diabetes patient and professional education with many publications in both areas. In addition to diabetes efforts, she served as a Trustee for Butler Community College, a college with seven sites and more than 14,000 students.
After completing this educational activity, participants should be able to:

• Define the components of pattern management

• Explain why pattern management is a powerful, practical tool for optimizing glucose control

• Discuss the process of establishing effective blood glucose (BG) monitoring schedules, setting up BG logs, and helping patients to interpret their BG data and modify their treatment regimens in response to these data

• Describe how professional and personal continuous glucose monitoring (CGM) devices can be used to assist selected patients with pattern management
The prevalence of diabetes, which currently affects 25.8 million people in the United States, has recently been projected to double or triple by 2050. This prediction underscores the importance of preventing the onset of diabetes whenever possible and of preventing or delaying the onset of diabetic complications in those individuals who develop diabetes. Many outcomes studies have established the connection between effective BG control and a reduced incidence of diabetic complications. Although a recent analysis of National Health and Nutrition Examination Survey data have shown that overall glucose control is improving in the United States, 43% of the overall US population with diagnosed diabetes has an A1C that exceeds the American Diabetes Association (ADA) goal of less than 7%. Furthermore, the proportions of patients with suboptimal BG control are much higher in some ethnic groups. Given the high, and increasing, prevalence of diabetes in the United States, the link between suboptimal BG control and the development of complications, and the frequency of inadequate BG control, there is an urgent need for effective, workable, and flexible strategies for improving glycemic control.
Pattern management is a proactive, comprehensive approach to BG management that considers all aspects of current diabetes therapy.

It consists of the review of several days of BG readings to identify patterns of recurring problems. It examines BG values in combination with food intake, activity levels, doses of insulin and/or other glucose-lowering medication, illness, stress, and other factors that can contribute to changes in BG levels.

Pattern management promotes diabetes self-management by teaching individuals with diabetes to recognize patterns in their BG readings, identify problems, and modify their treatment regimen or resolve issues to optimize their BG levels. Instead of reacting to each BG value, patients are taught to look at several days of BG readings.

Pattern management is most often used for persons treated with insulin, but all individuals with diabetes can benefit from pattern management. It can be used for patients who receive their diabetes medication by any route (eg, oral, injection, insulin pump) and for patients with type 1, type 2, or gestational diabetes.
Goals of pattern management are to attain and maintain target BG goals, reduce fluctuations in BG, and optimize diabetes self-management. The ultimate goals of pattern management are to keep A1C values in target range, reduce the likelihood of developing complications of diabetes, and to improve the patient’s overall health and well-being.
Pattern management has 3 major elements. The first is accurate self-monitoring of BG (SMBG) on a schedule determined by the patient and health care provider. The second is accurate and consistent recordkeeping. The third is application of knowledge about the effects of food, activity or exercise, medications, illness, stress, and other factors on BG values.
Pattern management differs from the use of sliding-scale insulin because pattern management is a proactive rather than a reactive approach to BG management.

Administration of sliding-scale insulin is an antiquated approach consisting of a one-time reaction to a single elevated BG reading. Although it appears to address the problem for a single point in time, it does not prevent the problem from arising again. Administration of sliding-scale insulin is not evidence-based. Not addressing basal needs and underdosing at mealtime lead to the need to give more insulin at the next meal.

The aim of pattern management is to identify the reasons for changes or fluctuations in BG levels, enabling the patient and health care provider to take action and prevent the problem from recurring.
There are several major prerequisites for performing pattern management effectively. First, the individual should be committed to achieving the goals of pattern management and understand that the development of sound pattern management skills may require substantial time and effort.

To be able to carry out pattern management, an individual should have intact cognitive function. Additionally, the person should have, or be willing to acquire, sound self-care skills. These include healthy eating, engaging in appropriate types of physical activity, taking prescribed medications consistently, performing SMBG and other types of monitoring, reducing the risks of developing complications of diabetes, and healthy coping.

Strong problem-solving skills is another important prerequisite for effective pattern management. One aspect of problem-solving is learning how to make self-adjustments to the treatment regimen. The individual should be able to adjust a single parameter at a time to determine how changes in diet, physical activity, or medication affect BG levels. Good math skills are a must. Patients who are candidates for basal/bolus insulin therapy should understand why this regimen is useful, how it works, and the basics of adjusting therapy.

Patient Characteristics Needed for Effective Pattern Management

- Commitment to achieving goals of pattern management
- Intact cognitive function
- Sound self-care skills
- Strong problem-solving skills
  - Self-adjusting the treatment regimen
  - Changing a single parameter at a time
  - Good math skills

The following are basic questions to ask when evaluating BG readings for pattern management:

- Does something happen at the same time every day (e.g., a high glucose reading after breakfast)?
- Are there available BG readings for key times of the day (e.g., fasting, pre-meal, post-meal)?
- Are there BG readings for the peak times of each medication (if applicable)?
- What lifestyle factors might be affecting glucose control?
- Is the patient storing and administering medication(s) correctly?

An accurate statement about pattern management is that it:

a. is limited to patients who use multiple daily injections of insulin or an insulin pump
b. requires the use of a BG meter with special software
c. requires intact cognitive function and sound self-care skills
d. is similar in approach to the use of sliding-scale insulin
Answer to Checkpoint 1

The correct answer is c.

An accurate statement about pattern management is that it requires intact cognitive function and sound self-care skills.

The correct answer is c.

An accurate statement about pattern management is that it requires intact cognitive function and sound self-care skills.
Generally, the frequency of SMBG depends on the intensity of the patient’s treatment regimen, lifestyle considerations, and motivation to perform SMBG. For some patients, the reimbursement policies of their insurance provider may affect SMBG frequency. For example, Medicare Part B covers 100 test strips and lancets per month for patients who use insulin and 100 test strips and lancets every 3 months for persons who do not. However, Medicare will allow additional test strips and lancets if a patient’s provider demonstrates medical necessity.

When gathering data for pattern management, SMBG is often performed more than usual. To detect any patterns that might exist, it is desirable to have readings for the same time of day on several consecutive or closely spaced days.

To optimize the patient’s involvement in the process, the patient and health care provider should develop the SMBG schedule together. A commonly used, realistic schedule involves checking the BG before and 2 hours after meals plus at bedtime for 3 consecutive days. It is beneficial if the patient keeps a corresponding food record. From the patient perspective, 3 days of intense monitoring and recordkeeping is reasonable and the patterns that typically emerge provide effective feedback for dose adjustment or food-related changes.
This chart shows the BG log entry for Luisa, a Hispanic female with an 8-year history of type 2 diabetes who has recently transitioned to multiple daily injection (MDI) insulin therapy. She is 33 years old, has a body mass index (BMI) of 32.9 kg/m², and works as an accountant. Her immediate goals are to lower her A1C of 7.7% and lose weight. Because she demonstrates a solid understanding of nutrition and makes careful food choices, Luisa and her health care provider agree that she will focus on measuring her BG before and after each meal and at bedtime for 3 days. She will also keep a food record and keep a log of any extended period of physical activity.

The process of pattern management usually includes a careful review of several days of patient-compiled data related to:

- BG values, measured according to a schedule agreed to by the patient and health care provider
- Food, including the type, quantity, and timing of food eaten, making special note of skipped meals or foods not included in the patient’s diet plan (eg, high-fat foods)
- Any period of exercise or unusual physical activity
- Any other event (eg, acute illness) that could affect BG values
- Any glucose-lowering medications taken

The process of data collection will be most successful when the patient and health care provider decide together what data should be gathered and the format in which it should be presented. A system perceived by the patient as being too complex or too burdensome is unlikely to be successful. Although many currently available glucose meters have the capacity to download recent BG values, this information alone is not sufficient for effective pattern management.
Regular SMBG and accurate data recording in a paper logbook is an effective pattern management method for most patients. However, the results of some studies suggest that, for patients who have access to and are accepting of electronic technology, automated BG monitoring and recording systems—along with the opportunities they may provide for additional interaction with a health care provider—may offer a modest advantage in glycemic control compared with a conventional approach. This table summarizes data from 2 randomized studies that investigated the effects of different automated systems on glycemic control, as measured by the difference in the mean A1C level from baseline to the final observation in patients who used an automated system (intervention group), compared with patients who used a conventional system (control group).

The study of Cho et al included 80 patients with type 2 diabetes. The mean baseline A1C was 7.6%. The intervention group used a conventional BG meter but entered data into an Internet-based system. Based on these data, patients received electronic feedback from a health care provider every 2 weeks and had an outpatient office visit every 3 months. Patients in the control group entered their data in a paper logbook and also had an office visit at 3-month intervals. After 30 months, the mean A1C reduction was 0.8% in the intervention group and 0.1% in the control group, a statistically significant difference.

The Laffel et al study included 205 patients with type 1 or type 2 diabetes. The mean baseline A1C was 9.1%. The intervention group used an integrated glucose meter and electronic logbook and the control group used a conventional glucose meter and paper logbook. After 66 weeks, the mean A1C decreased by 0.36% in the intervention group and increased by 0.32% in the control group, a statistically significant difference.
Richard is a 70-year-old African American male who presents for an initial appointment with his primary health care provider. He is a retired postal clerk and lives with his daughter and her family. He is 72 inches tall, weighs 166 pounds, and has a BMI of 22.5 kg/m².

Richard has a 6-year history of type 2 diabetes. His most recent A1C was 8.1%.

Other health issues are hypertension, hyperlipidemia, glaucoma, and chronic renal insufficiency.

His current insulin regimen is 7 units of regular insulin taken immediately before breakfast, 5 units of regular insulin taken immediately before dinner, and 34 units of a long-acting insulin analog at bedtime. He uses a syringe to inject his insulin doses.
To prepare for the first appointment with his primary health care provider, Richard kept a BG log for 8 days, performing SMBG twice daily.

Comparison of Richard’s BG values with current ADA target values identified several areas of concern. All prebreakfast values were within the recommended range of 70 to 130 mg/dL, but 3 of 4 predinner values exceeded this range. Examination of 2-hour postprandial values showed that 2 of 4 postbreakfast and 2 of 4 postdinner levels exceeded the target peak postprandial level of less than 180 mg/dL.

These patterns suggest that 34 units of a long-acting insulin analog provided adequate nighttime coverage, but that the premeal doses of regular insulin were causing Richard to exceed his postprandial target values half of the time. The high predinner values on 3 of 4 days suggested that the 7 units of regular insulin taken before breakfast did not provide sufficient coverage through the afternoon hours.
At his initial appointment, Richard expresses several concerns about his diabetes care plan.

He says that he is unhappy with his overall level of BG control.

Because of visual impairment due to glaucoma, he is unable to draw up his exact insulin dose with a syringe and insulin vial and depends on his daughter to draw up his doses for him. He says that he feels frustrated because he seems to be losing his independence.

He explains that although he knows he should take his regular insulin 30 to 45 minutes before breakfast and dinner, he has started injecting it immediately before eating because he forgets to take it at the recommended time and does not want to disrupt the family routine.

He says that he has not worked with a diabetes educator since shortly after he was diagnosed with diabetes and that he has many questions about his food intake. He finds lunchtime especially difficult, since the other members of the family are away from home and he needs to prepare his own meal.
### Case 1: New Treatment Plan

- Substitute rapid-acting insulin analog for regular insulin at breakfast and dinner
- Add rapid-acting insulin analog at lunchtime
- Replace vial and syringe with prefilled, disposable insulin pens
- Meet with diabetes educator to learn carbohydrate-counting skills

Based on his BG data and the concerns he has expressed, Richard and his primary health care provider develop a new treatment plan.

A rapid-acting insulin analog is substituted for regular insulin at breakfast and dinner. As a result of this substitution, Richard needs to take his premeal insulin 5 to 10 minutes rather than 30 to 45 minutes before beginning a meal.

Rapid-acting insulin analog is added at lunchtime to address the problem of high predinner BG values.

Prefilled, disposable insulin pens for Richard’s rapid-acting and long-acting insulin analogs replace the vial-and-syringe method of insulin delivery. Switching to insulin pens allows Richard to dial up his own insulin doses accurately, despite his impaired vision.

Richard also agrees to meet with a diabetes educator to learn carbohydrate-counting skills and develop a workable meal plan.
Case 1: Meeting With Diabetes Educator

- Richard masters CHO-counting skills
- He and diabetes educator develop nutritionally appropriate, workable meal plan
- Insulin:CHO ratio is developed and revised
  - Begins by taking 1 unit of rapid-acting insulin analog per CHO choice (1 unit:15 g CHO)
  - When postprandial BG values remain high, switches to 1.5 units per CHO choice (1 unit:10 g CHO)

CHO = carbohydrate.

Richard meets with a diabetes educator and learns how to count carbohydrates. The diabetes educator also helps him develop a meal plan that focuses particularly on lunch, the meal he prepares for himself. The lunch plan includes foods that Richard enjoys, provide the appropriate balance of nutrients, and are easy for him to prepare.

Richard begins his new regimen by taking 1 unit of rapid-acting insulin analog per carbohydrate choice (that is, 1 unit of insulin to 15 grams of carbohydrate). He keeps a detailed food diary and records his pre- and postmeal BG values for 1 week.

When he returns to the dietitian, all of his premeal BG values are within the target range, but many of his postprandial levels are above 180 mg/dL. Therefore, Richard’s insulin-to-carbohydrate ratio is changed to 1.5 units per carbohydrate choice (that is, 1 unit of insulin to 10 grams of carbohydrate).
To prepare for his follow-up appointment with his primary health care provider, Richard keeps another 8-day BG log, again performing SMBG twice daily.

This log represents a marked improvement from Richard’s initial log. All postprandial BG values are well under the ADA target of less than 180 mg/dL.

Review of premeal values shows that prebreakfast BG levels are within the target range of 70 to 130 mg/dL. However, 1 of 3 prilunch levels and 1 of 2 predinner levels are 130 mg/dL, at the upper limit of the recommended range.

This overall pattern suggests that using the ratio of 1 unit of rapid-acting insulin analog per 10 grams of carbohydrate is providing Richard with adequate mealtime coverage. However, his bedtime dose of 32 units of long-acting insulin analog is not providing adequate coverage throughout the day.
At his follow-up visit with his primary health care provider, Richard reports that he has had more energy in the last several weeks than he has had in a long time. Both his ability to dial up his own insulin doses and his ability to prepare nutritionally balanced lunches have given him a renewed sense of confidence and independence. In fact, he has become so confident in the kitchen that he is now preparing the family dinner on 2 nights of the week.

Since his initial visit, Richard’s A1C has decreased from 8.1% to 7.6%.

Richard and his health care provider review his BG log, noting the problem with his prelunch and predinner BG values. They decide that Richard will increase his bedtime dose of long-acting insulin analog from 32 to 36 units. The health care provider advises Richard to monitor his prebreakfast levels carefully over the next week, and to reduce his bedtime insulin dose to 34 units if he finds that his prebreakfast BG levels are below 90 mg/dL.
The accurate statement about the use of BG monitoring in pattern management is that:

a. patients must be willing to perform SMBG at least 4 times per day
b. it is desirable to have readings for the same time of day on several consecutive or nearly consecutive days
c. using automated BG monitoring and recording systems does not result in increased glycemic control compared with a conventional system
d. using automated BG monitoring and recording systems greatly improves glycemic control compared with a conventional system
The correct answer is b.
The accurate statement about the use of BG monitoring in pattern management is that it is desirable to have readings for the same time of day on several consecutive or nearly consecutive days.
CGM is a potentially important tool for pattern management. CGM is the sampling of a patient’s interstitial fluid glucose in an ongoing, minimally invasive way. The CGM system is calibrated with readings obtained from SMBG. It provides real-time information about current glucose concentrations, thus providing short-term feedback about the effectiveness of diabetes interventions, such as insulin administration. It provides much more information about upward and downward trends than can be obtained from SMBG. It also provides warnings when glucose concentrations become dangerously high or low.

To date, most CGM clinical trials have enrolled patients with type 1 diabetes, but CGM can also benefit patients with type 2 diabetes, as well as patients who are pregnant.

There are 2 types of CGM devices: professional and personal systems.
Professional, or retrospective, CGM equipment is owned by the health care provider or facility. Patients are unaware of monitoring results until they are downloaded and analyzed by the health care provider.

Professional CGM is primarily used for patients with type 1 or type 2 diabetes who are not at their A1C target, have recurrent hypoglycemia or hypoglycemia unawareness, or are pregnant. Professional CGM is intended to be used on an episodic basis and requires little setup time on the patient’s part.

Patients have an office visit, receive instruction, wear a sensor for 3 to 5 days, keep a food and activity logbook, and then return to the office.

Unlike personal CGM, professional CGM does not have alerts to warn patients about the presence of hyperglycemia or hypoglycemia.

Insurance reimbursement is more readily available for professional CGM than for personal CGM.

The picture on this slide shows the Medtronic iPro™, the only system now manufactured specifically for professional CGM. In addition, one of the systems currently approved for personal CGM, the DexCom™ SEVEN® PLUS, can be adapted for professional monitoring.
This table summarizes the responsibilities of clinicians and medical staff when CGM is performed.

At the first visit, the patient should sign a waiver agreeing to accept financial responsibility for the CGM equipment. After the CGM device has been set up, the clinician should educate the patient about the CGM procedure, outlining the frequency of testing and how to calibrate the system using a compatible BG meter. The clinician should explain the importance of logkeeping and of the return visit. The patient should receive a log to record food intake, medication, and activity. The CGM sensor should be inserted and the system started up. A return visit should be scheduled for the patient, usually in 3 to 7 days. The exact timing of the return visit depends on the CGM system that is being used.

When the patient arrives for the return visit, the sensor should be removed from the patient and the data downloaded. After setting preferences for individual target BG values, the patient’s report should be generated. The clinician should interpret the report and discuss a treatment plan with the patient based on the report’s content. It is also important to reinforce the effects of food, activity, and medications on BG levels. The clinician should provide the patient with a copy of the report as an educational tool and ensure that the CGM equipment has been cleaned and disinfected.

Office staff responsible for reimbursement should understand national and local payer policies for CGM reimbursement and determine whether an individual patient’s insurer requires prior authorization for CGM. They should submit claims for reimbursement, track these submissions, and appeal claims if they are denied.
A personal CGM device is owned by the patient. Glucose values are visible continuously, allowing for immediate therapeutic adjustments based on real-time glucose results. For this reason, personal CGM is also referred to as “real-time CGM.”

Personal CGM is typically used by patients with type 1 diabetes who are not at their A1C target and are able to use and understand the information supplied by the system, have hypoglycemia or hypoglycemia unawareness, and/or are pregnant. Any patient who could benefit from the continuous feedback of glucose readings and/or the hyperglycemia and hypoglycemia alarms in personal CGM devices would also be a potentially good candidate for this technology.

Some personal CGM devices have alarms that indicate a rapid rate of glucose change using trend markers or arrows. Some also have “predictive alarms,” which calculate whether high or low glucose thresholds will be crossed, depending on the rate of change and the current glucose level.

The setup requirements for personal CGM are more intensive than those for professional CGM. They include programming customized glucose targets and alarm thresholds.

Currently, 4 personal CGM devices approved by the US Food and Drug Administration are available in the United States.
Patients who are most successful with personal CGM engage in regular follow-up with their health care provider.

The medical office should be proactive in arranging for the clinician to interpret the patient’s CGM data. This interpretation can be provided over the telephone, via the Internet, or in a face-to-face appointment.

As needed, device manufacturers can provide educational materials, one-on-one guidance, or information about industry certification of products.

Manufacturer Web sites offer additional information, including educational printouts, online tutorials, product user guides to supplement face-to-face training, and toll-free customer service telephone numbers.
The basic components of a CGM system are a sensor, a transmitter, and a receiver. The sensor, which consists of a very narrow plastic tube enclosing a catheter, measures interstitial glucose levels. It is inserted just under the skin of the abdomen or upper arm using an insertion device. The sensor catheter has an electrode impregnated with glucose oxidase. Once the sensor is inserted into the subcutaneous tissue, the reaction between the glucose oxidase on the electrode and the interstitial fluid glucose produces hydrogen peroxide. This reaction converts the interstitial glucose into an electrical current proportional to the glucose concentration at the insertion site.

A transmitter attached to the sensor sends information to the receiver via radio waves, and no cable is necessary. The transmitter is attached to the skin with adhesive.

A receiver displays real-time glucose values and trends. It also stores information for later use, and long-term data can be downloaded to a personal computer so that they can be viewed on a large screen or printed out.

All CGM systems can be used with insulin pumps, but the MiniMed Paradigm® REAL-Time Revel™ is the only available system with an integrated insulin pump.

The FreeStyle Navigator® is currently the only system with an integrated BG meter. In April 2010, Abbott Diabetes Care announced that it had indefinitely suspended the sale of new FreeStyle Navigator® kits as well as replacement transmitters and receivers.
This table describes the 6 types of reports that can be generated by Solutions® Software for the CGMS® iPro™ Continuous Glucose Recorder. The iPro™ Recorder is currently the only professional CGM system approved for use in the United States. The reports generated by CareLink® Pro software for the iPro™ Recorder provide similar information, but in different formats. CareLink® Pro software is generally used for patients who use insulin pumps.

The **Sensor Summary** provides a comprehensive overview of the patient’s BG profile, including a summary of continuous data and meter readings, post- and premeal glucose levels, and periods of lows and highs. The **Sensor Modal Day** report shows continuous data, or “tracings,” from each day of the monitoring period overlapped in a single graph. Upper and lower limits of target range are shown by a dashed line. The **Sensor Daily Details** report provides a complete overview of the effects of insulin, meals, and exercise on the patient’s glucose levels. The **Sensor Modal Time Periods** report analyzes daily continuous glucose levels in each of 6 key time periods (mealtimes and 3 optional periods determined by the user). The **Sensor Data** report displays item-by-item records of all downloaded recorder and meter data in the patient file. The **Log Book** presents a table of events, such as insulin doses, meals, and exercise, in chronological order, with corresponding glucose values and comments. It is intended to supplement the patient’s handwritten diary.
The American Association of Clinical Endocrinologists (AACE) issued a consensus statement on CGM in September 2010.

On the basis of available evidence, the AACE recommends personal CGM for patients with type 1 diabetes and the following characteristics:

- Hypoglycemic unawareness or frequent hypoglycemia
- A1C over target from excess glycemic variability
- Requiring A1C lowering without increased hypoglycemia
- In the preconception period or pregnancy

- Children and adolescents with type 1 diabetes whose A1C is <7.0%
- Youth with type 1 diabetes whose A1C is ≥7% and who are able to use device on a near-daily basis

The AACE has identified 2 additional groups of primary candidates for CGM. The first is children and adolescents with type 1 diabetes whose A1C levels are less than 7%. The rationale for this recommendation is that these patients and their families are typically highly motivated.

The second group is youth with type 1 diabetes who have A1C levels of 7% or greater and are able to use the device on a near-daily basis.
In its consensus statement, the AACE also identifies 2 groups of patients as good candidates for personal CGM, for whom a trial period of 2 to 4 weeks is recommended. These groups are:

- Youth who frequently monitor their BG levels
- Committed families of young children (younger than 8 years), especially if the patient is having problems with hypoglycemia

Intermittent use of professional CGM may be useful for youth with type 1 diabetes who are experiencing changes to their diabetes regimen or have problems with:

- Nocturnal hypoglycemia/dawn phenomenon
- Hypoglycemia unawareness
- Postprandial hyperglycemia

This slide shows the 4 personal CGM systems approved for use in the United States:

- FreeStyle Navigator®, manufactured by Abbott Diabetes Care
- DexCom™ SEVEN® PLUS, manufactured by Dexcom, Inc.
- MiniMed Paradigm® REAL-Time Revel™, manufactured by Medtronic Diabetes
- Guardian® REAL-Time, manufactured by Medtronic Diabetes

As previously mentioned, Abbott Diabetes Care has suspended the sale of new Freestyle Navigator® kits and supplies.
This table summarizes some important differences among approved personal CGM systems. The 2 Medtronic systems (MiniMed Paradigm® REAL-Time Revel™ and Guardian® REAL-Time) are identical with regard to the features shown here.

Although all of the transmitter/sensor devices are small, lightweight, and discreet, the transmitter/sensor of the FreeStyle Navigator® is larger and heavier than the other devices. It also has a greater transmission distance.

The system transmitters have different power sources. The FreeStyle Navigator® has a silver oxide battery that lasts 30 days, the DexCom™ SEVEN® PLUS has an integrated battery that lasts about 1 year, and the Medtronic systems have rechargeable transmitters that can be used 14 days without recharging.

A major differentiator is the calibration requirements of the various systems. The FreeStyle Navigator® must be calibrated at 10, 12, 24, and 72 hours after the sensor is inserted. The DexCom™ SEVEN® PLUS requires calibration at 12-hour intervals. The Medtronic systems must be calibrated 2 and 6 hours after insertion and then every 12 hours.

The range of glucose concentrations within which the devices function is 60 to 300 mg/dL for the FreeStyle Navigator® and 40 to 400 mg/dL for the other systems.
This table shows some other differences among approved personal CGM systems.

The sensor needs to be changed every 3 days with the 2 Medtronic systems, every 5 days with the FreeStyle Navigator®, and every 7 days with the DexCom™ SEVEN® PLUS.

The FreeStyle Navigator® is the only system with a built-in BG meter. With the other systems, BG readings from any meter can be entered manually. In addition, DexCom™ SEVEN® PLUS users can upload BG data from a OneTouch® Ultra® meter by connecting the devices with a cable. Users of either Medtronic system can transfer data wirelessly with a OneTouch® UltraLink™ meter.

The MiniMed Paradigm® REAL-Time Revel™ is the only device that functions as both an insulin pump and a CGM system.

Each CGM system uses proprietary software. Only the Data Manager® 3 software used with the DexCom™ SEVEN® PLUS system is compatible with a Macintosh computer.

### Major Differences Among Approved Personal CGM Systems* (Cont)

<table>
<thead>
<tr>
<th>Feature</th>
<th>FreeStyle Navigator®</th>
<th>DexCom™ SEVEN® PLUS</th>
<th>MiniMed Paradigm® REAL-Time Revel™</th>
<th>Guardian® REAL-Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor duration</td>
<td>5 d</td>
<td>7 d</td>
<td>3 d</td>
<td>3 d</td>
</tr>
<tr>
<td>BG meter interaction</td>
<td>Built-in BG meter</td>
<td>BG readings from any meter can be entered manually; cable can be used to upload data from OneTouch® Ultra® meter</td>
<td>BG readings from any meter can be entered manually; OneTouch® UltraLink™ meter communicates wirelessly with system</td>
<td>BG readings from any meter can be entered manually; OneTouch® UltraLink™ meter communicates wirelessly with system</td>
</tr>
<tr>
<td>Communication with insulin pump</td>
<td>No</td>
<td>No</td>
<td>Functions as insulin pump and CGM system</td>
<td>No</td>
</tr>
<tr>
<td>Software</td>
<td>CoPilot™; not Mac compatible</td>
<td>Data Manager® 3; Mac compatible</td>
<td>CareLink®; not Mac compatible</td>
<td>CareLink®; not Mac compatible</td>
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Currently, all CGM systems are approved only as adjunctive devices to SMBG. This is partly because the accuracy of approved CGM devices is not equivalent to that of BG meters. The need for home calibration of personal CGM systems may contribute to this inaccuracy.

Another problem is that there is a physiologic lag of about 5 to 10 minutes between BG and interstitial glucose values, and this is accentuated when glucose levels are undergoing rapid change. This discrepancy may cause patients to overact to changes in glucose levels, resulting in insulin stacking or overtreatment of hypoglycemia. Therefore, patients should calibrate sensors when BG levels are stable.
The AACE has offered several recommendations for making CGM more useful and acceptable to patients and clinicians.

First, the accuracy of CGM systems needs to be improved. One approach for eliminating the discrepancy between interstitial and BG levels is to use a sensor implanted in a peripheral vein. Various types of implantable sensors are now under investigation.

More uniform integration of personal CGM devices with insulin pumps would allow patients to choose the CGM system and the insulin pump of their choice, without concerns about compatibility issues.

The availability of more intuitive software would make the process of downloading CGM results less frustrating for patients.

More comfortable sensors might make the long-term use of CGM more acceptable. Noninvasive sensors that rest on the skin are now under investigation.

Finally, CGM systems should become more affordable, especially since this would encourage insurers to provide reimbursement for a broader spectrum of patients.
The accurate statement about CGM is:

a. CGM samples glucose levels in peripheral blood
b. patients with type 1 diabetes and hypoglycemia unawareness are primary candidates for CGM
c. all currently approved CGM systems have a built-in insulin pump
d. currently approved CGM systems are more accurate than most BG meters
The correct answer is **b**.
The accurate statement about CGM is that patients with type 1 diabetes and hypoglycemia unawareness are primary candidates for CGM.
The initial Sensor-Augmented Pump Therapy for A1C Reduction (STAR) 1 Study was the first prospective, randomized, controlled clinical trial to assess the efficacy and safety of CGM. This 26-week, multicenter study included adults and adolescents with type 1 diabetes and A1C ≥7.5%.

Overall, decreases from baseline were similar in CGM and control groups (graph).

In patients who were ≥60% compliant with CGM use, addition of CGM to CSII + SMBG regimen resulted in significantly greater A1C reduction.

Key finding: identification of appropriate patients is essential.

The most important finding of the study is that the addition to CGM of a regimen of insulin pump therapy and SMBG resulted in a significantly greater A1C reduction among patients who were at least 60% compliant with the CGM regimen. This result has been replicated in several subsequent studies. CGM can result in clinically meaningful improvements in glycemic control as long as patients use it regularly. The challenge is that some patients find personal CGM too difficult or too inconvenient to use consistently. Therefore, identification of appropriate patients is essential to the success of CGM therapy.

Another important finding of STAR 1 is that CGM is generally safe in both adults and adolescents. Compared with baseline, both groups experienced a statistically significant but small increase in the number of hypoglycemic events during the study. Severe hypoglycemic events occurred in 3 patients in the CGM group and 11 patients in the control group. This difference was statistically significant.
The Juvenile Diabetes Research Foundation (JDRF) is sponsoring a large study to investigate the efficacy and safety of personal CGM in different populations. This slide shows key results from the first phase of the study. This multicenter, 26-week phase included 322 patients who had baseline A1C levels of 7% to 10% despite CSII or MDI therapy. Patients were randomly assigned to receive CGM (CGM group) or home monitoring with a BG meter (control group), with CSII or MDI therapy.

- Significant A1C change from baseline only in patients ≥25 years old (Graph A)
- Significantly higher proportion of patients in CGM group had A1C ≤7% among ≥25 yr cohort (Graph B) and 8–14 yr cohort

The investigators concluded that CGM improves A1C levels and may enhance the management of type 1 diabetes in adults who have the motivation to use this technology and the capability to incorporate it into their own daily diabetes management. They also observed that further work is needed to identify and address the lack of effectiveness of CGM in children and adolescents.
Another phase of the JDRF CGM Study investigated the effects of using CGM for 1 year. This analysis included only patients who were 25 years or older and used CGM over the entire study period. Patients were stratified according to their baseline A1C value: less than 7% or 7%–10%.

A1C remained essentially stable in the <7% A1C cohort and decreased significantly between baseline and month 12 in the A1C 7%–10% cohort.

The graph shows that patients whose baseline A1C was less than 7% had a relatively stable A1C over the study period. In contrast, patients with a baseline A1C of 7% to 10% had a statistically significant mean A1C reduction of 0.4% at week 26.

Another important finding of this analysis was that the median amount of time per day with glucose in the range of 71 to 180 mg/dL increased significantly from baseline to 12 months, reflecting a decrease in both hypoglycemia and hyperglycemia. Similar trends were observed both in patients whose baseline A1C was less than 7% and in those whose baseline A1C was 7% to 10%.
Another important finding of the analysis of 12-month data from the JDRF CGM study was that rates of severe hypoglycemia decreased markedly between months 1 through 6 and months 7 through 12 in adults 25 years of age or older. Severe hypoglycemia was defined as an event that required assistance from another person to administer rescue actions.

As this graph shows, the number of severe hypoglycemia events per person-years decreased in the total population, patients whose baseline A1C was less than 7%, and patients whose baseline A1C was between 7% and 10%. These decreases were clinically meaningful although not statistically significant.

The investigators suggested that the decline in severe hypoglycemic events during the second 6 months of the study may have resulted from learning from prior experience, including appropriate setting of the low alarms, glucose targets, and titration of basal and bolus insulin doses. They concluded that the benefits of CGM can be sustained for at least 12 months in motivated adults with type 1 diabetes practicing intensive diabetes management. In such individuals, CGM provides the ability to achieve target A1C levels much more safely than previously reported.
The STAR 3 Study was a 1-year multicenter study in which 485 patients were randomized to receive CGM plus CSII plus SMBG (CGM group) or MDIs of insulin plus SMBG (control group) for 1 year. At baseline, patients were between the ages of 7 and 70 years and had an A1C between 7.4% and 9.5%. Patients in both groups were stratified by age into 2 cohorts: 7 to 18 years and 19 to 70 years. The primary endpoint was the mean change from baseline in the A1C level at 1 year.

The graph shows that the mean A1C at 1 year decreased from baseline for all patients except children in the control group. The change from baseline was statistically greater in the CGM group than in the control group among all patients, adults, and children.

The investigators attributed the robust improvements in A1C values observed in the CGM group to the synergistic effects of CGM and CSII.

Rates of severe hypoglycemia per 100 person-years were similar in the 2 groups: 13.31 in the CGM group and 13.48 in the control group.
Because successful operation of a CGM system requires adequate vision and hearing, use of the device is contraindicated in patients whose impaired vision or hearing does not allow full recognition of the monitor signals and alarms, unless a responsible caregiver is always available.

Patients should follow manufacturer’s instructions about sensor placement and insertion to ensure that the device functions properly and to minimize the risk of local reactions.

Local reactions, including bleeding, erythema, edema, ecchymosis, cellulitis, and abscess, may occur at the sensor insertion site. These reactions are usually of mild or moderate intensity.

Severe hypoglycemia is the adverse effect of greatest concern during use of a CGM system. Data from the JDRF study suggest that the risk of severe hypoglycemia diminishes over time, as patients become more familiar with the system.

Diabetic ketoacidosis is a rare adverse effect in users of CGM devices.
Studies such as STAR 1 have shown that careful patient selection is essential for effective use of personal CGM devices. However, even carefully selected patients require ongoing support from health care providers to address common psychosocial issues related to personal CGM.

Body image concerns are a major issue for many patients. Because it is a constant reminder that they have diabetes, some patients start to wear the sensor/transmitter unit less and less frequently, compromising the benefits of CGM. Health care providers need to reinforce the importance of wearing the device consistently. They can help patients to select insertion sites that meet the technical requirements of their device but are still comfortable and discreet.

After the initial period when they receive intensive training and support from health care providers and representatives of their device manufacturer, patients may decide that the ongoing technical demands of CGM outweigh its benefits. Health care providers must offer continuing education and support to patients. They should also ensure that patients are familiar with the wide array of educational resources—many of them Internet based—provided by device manufacturers.

An important role of healthcare providers is helping patients to understand when they should take corrective action in response to a BG excursion and when they should wait for additional data. In addition, many patients who have managed their diabetes by retrospectively reviewing data from a BG log need ongoing assistance in learning how to respond proactively to developing BG trends.
The cost-effectiveness of CGM has been investigated using data from the JDRF CGM study. Cost-utility analyses were conducted for all participants with a baseline A1C of less than 7% and for adults over age 25 years with a baseline A1C of 7% to 10%.

Based on current costs, the investigators calculated that the daily cost of CGM was $13.85. The annual estimated cost, based on 6 days of CGM per week, was $4335.

The most compelling finding of the analysis was the calculation that consistent use of CGM markedly reduced the direct and indirect costs of diabetes by decreasing the risk of developing microvascular and macrovascular complications. As shown in the graph, ongoing use of CGM resulted in total cost savings of $87,386 in patients whose baseline A1C was less than 7% and of $58,787 in patients whose baseline A1C was 7% to 10%. Cost savings were notably greater in patients with a lower baseline A1C because their estimated additional life expectancy from baseline was about 37 years, in contrast to about 27 years for patients in the higher A1C cohort.
Coverage for CGM is increasing rapidly as additional data supporting its efficacy and safety become available, but different payers have different reimbursement criteria.

Currently, US Centers for Medicare & Medicaid Service carriers reimburse only for professional CGM.

In addition to providing coverage for professional CGM, many large, private US health plans provide some coverage for personal CGM, especially for patients with type 1 diabetes who
- Are at least 25 years old
- Have recurrent severe hypoglycemia or hypoglycemia unawareness

The JDRF Web site maintains a list of personal CGM reimbursement policies for select health plans.

Proper, precise diagnostic coding can improve the likelihood of reimbursement.

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JDRF. CGM coverage policies for select health plans. 2011.
The Current Procedural Terminology (CPT) codes used for CGM are 95250 and 95251. Neither code can be billed more frequently than every 30 days.

As shown in the table, 95250 is the more comprehensive code, describing ambulatory CGM of interstitial tissue fluid via subcutaneous sensor for at least 72 hours, along with sensor placement, hookup, calibration of monitor, patient training, sensor removal, and printout of recording. It is usually used with an evaluation and management code for the office visit. For returning patients, this code will be in the 99213 to 99215 range. The modifier -25 must be appended to the evaluation and management code to show that this code is being billed with code 95250. The modifier indicates a significant, separately identifiable evaluation and management service provided by the same physician on the same day of the procedure or other service. Professional CGM can be billed either on the day the sensor is inserted or when removed. Personal CGM is billed when data are downloaded.

Code 95251 describes ambulatory CGM of interstitial tissue fluid via subcutaneous sensor for at least 72 hours; interpretation and report. This code can be used for professional or personal data collection and does not have to take place in the context of a face-to-face meeting. If this code is billed at a time separate from another evaluation and management service, such as an office visit, no modifier is needed.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>95250*</td>
<td>Ambulatory CGM of interstitial tissue fluid via SC sensor for ≥72 h; sensor placement, hookup, calibration of monitor, patient training, sensor removal, and printout of recording</td>
<td>Usually used with an evaluation and management code for the office visit. For returning patients, this code will be in the 99213 to 99215 range. The modifier -25 must be appended to the evaluation and management code to show that this code is being billed with code 95250. The modifier indicates a significant, separately identifiable evaluation and management service provided by the same physician on the same day of the procedure or other service. Professional CGM can be billed either on the day the sensor is inserted or when removed. Personal CGM is billed when data are downloaded</td>
</tr>
<tr>
<td>95251*</td>
<td>Ambulatory CGM of interstitial tissue fluid via SC sensor for ≥72 h; interpretation and report</td>
<td>Can be used for professional or personal data collection and does not have to take place in the context of a face-to-face meeting. If this code is billed at a time separate from another evaluation and management service, such as an office visit, no modifier is needed</td>
</tr>
</tbody>
</table>

*Cannot be billed more frequently than every 30 days.

An important finding of clinical studies of CGM is that:

a. CGM with intensive insulin therapy and SMBG is consistently superior to intensive insulin therapy and SMBG
b. CGM is beneficial only for patients whose A1C is already at the ADA goal of <7%
c. CGM substantially increases the risk of severe hypoglycemia over time
d. CGM is generally more effective in adults than in children
The correct answer is d.

An important finding of clinical studies of CGM is that CGM is generally more effective in adults than in children.
Gail is a 47-year-old white female who presents for an initial appointment with her health care provider. She is the office manager at a large children’s daycare center and lives with her husband, an engineer. Their 2 children are away at college. She is 65 inches tall, weighs 165 pounds, and has a BMI of 27.5 kg/m².

Gail has a 5-year history of type 2 diabetes. Her most recent A1C was 8.7%. Three months earlier, her A1C was 8.2%.

Other health issues are hypertension and hyperlipidemia, for which she takes medication.

Her current glucose-lowering regimen consists of 100 mg of a dipeptidyl peptidase-4 inhibitor at breakfast, metformin XR 2000 mg with dinner, and 50 units of a long-acting insulin analog at bedtime, administered with an insulin pen.

She has a comprehensive health insurance plan through a private carrier.
To prepare for the first appointment with her primary health care provider, Gail kept a BG log for 1 week, performing SMBG twice daily.

Comparison of Gail’s BG values with current ADA target values identified an area of concern. All premeal values and the one available bedtime value were within the recommended range of 70 to 130 mg/dL. However, all 3 of the available postprandial values were substantially above the ADA goal of less than 180 mg/dL.

The patterns revealed by Gail’s BG log showed that changes needed to be made to her overall regimen. But more data were needed to determine the changes that should be made.

### Case 2: Initial BG Log

<table>
<thead>
<tr>
<th>Date</th>
<th>DPP-4 Inh.</th>
<th>Pre-bkfst</th>
<th>2 H PP</th>
<th>Pre-lunch</th>
<th>2 H PP</th>
<th>Met. XR</th>
<th>Pre-dinner</th>
<th>2 H PP</th>
<th>Bedtime</th>
<th>Insulin</th>
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</thead>
<tbody>
<tr>
<td>1/17</td>
<td>100 mg</td>
<td>82</td>
<td>123</td>
<td>2000 mg</td>
<td></td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/18</td>
<td>100 mg</td>
<td>220</td>
<td></td>
<td>2000 mg</td>
<td>117</td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>86</td>
<td></td>
<td>2000 mg</td>
<td>262</td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/20</td>
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<td>115</td>
<td></td>
<td>2000 mg</td>
<td>121</td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/21</td>
<td>100 mg</td>
<td>89</td>
<td></td>
<td>2000 mg</td>
<td>123</td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/22</td>
<td>100 mg</td>
<td>91</td>
<td></td>
<td>2000 mg</td>
<td>254</td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/23</td>
<td>100 mg</td>
<td>119</td>
<td></td>
<td>2000 mg</td>
<td>123</td>
<td></td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Red = exceeds current ADA goal.*

*Met = metformin.*

At her initial appointment with her health care provider, Gail expresses several concerns. She says that she is unhappy with her overall level of BG control. In addition, she reports feeling fatigued most of the time.

She says that she feels frustrated by her inability to lose weight, even though she follows her meal plan conscientiously. She explains that she practices strict portion control and takes almost all of her lunches to work with her. When questioned about snacking, she admits that she “sometimes” snacks during the workweek on baked goods that parents and colleagues bring to the daycare center.

Gail reports that long workdays provide little opportunity for exercise. Because of her work schedule and her fatigue, she says that she rarely checks her postmeal BG levels. Therefore, she does not know whether the elevated values shown on her BG log were routine or unusual for her.

Gail’s health care provider explains that professional CGM is an effective way of identifying opportunities for better diabetes self-management. After further discussion, Gail says that she would like to undergo CGM. Once she receives confirmation that professional CGM is covered by her health care insurance, Gail makes an appointment with her health care provider to have a sensor inserted and receive detailed instructions.
At Gail’s first office visit for professional CGM, the glucose sensor is inserted into the subcutaneous tissue of her abdomen using an insertion device. The CGM recorder is synchronized with Gail’s BG meter and then connected to the glucose sensor. An electronic wand is used to start communication between the recorder and iPro™ Solutions® software and place the recorder in “receive” mode.

Gail is given paper log sheet and given specific instructions to:

- Follow her normal weekday routine
- Perform 4 fingersticks each day
- Use the log sheet to record daily activities (eg, meals, snacks, exercise, taking oral medication, injecting insulin)
- Return to the office in 3 days

At Gail’s first office visit for professional CGM, the glucose sensor is inserted into the subcutaneous tissue of her abdomen using an insertion device. The CGM recorder is synchronized with Gail’s BG meter and then connected to the glucose sensor. An electronic wand is used to start communication between the recorder and iPro™ Solutions® software and place the recorder in "receive" mode.

Gail is given a paper log sheet to complete over the next 3 days. She also receives specific instructions to follow her normal weekday routine, perform 4 fingersticks each day, and use the log sheet to record her daily activities, including meals, snacks, exercise, taking oral medication, and injecting insulin. Her health care provider stresses the importance of returning for her next office visit in 3 days.
Three days later, Gail has her second office visit for professional CGM. After the glucose sensor and iPro™ Recorder are removed, data are downloaded from the recorder and from Gail’s BG meter. The Solutions® software reports described earlier in this activity are generated and printed. The health care provider then interprets the results for Gail.

This slide shows a sample Sensor Daily Details report for a 3-day evaluation period. It is an example of one of the reports that Gail reviews with her clinician. Note that the report shown here does not present actual data for Gail.

The Sensor Daily Details report presents 24-hour data for up to 6 days, using a different color for each day’s tracings. As discussed previously, it provides a complete overview of the effects of insulin, meals, and exercise on the patient’s glucose levels.
Review of Gail’s CGM reports identified 3 important patterns. Nocturnal hypoglycemia occurred on 2 of the 3 nights.

Postprandial glucose levels exceeded the ADA target of less than 180 mg/dL after all lunches, 2 of 3 dinners, and all 3 snacks.

Finally, as anticipated by Gail’s earlier BG log, premeal glucose levels were consistently within the ADA target range of 70–130 mg/dL.

The Sensor Modal Day report generated by the CGM software made these recurring patterns very evident. As described earlier, this report shows continuous data, or “tracings,” from each day of the monitoring period overlapped in a single graph.

Note that the Sensor Modal Day report shown on this slide is a sample and does not present data for the patient in this case. The sample report presents data for 6 days, using a different color for each day’s tracings.
In response to her CGM results, Gail and her health care provider agreed on several changes to her regimen. Gail was overinsulinized with basal insulin. To decrease the risk of nocturnal hypoglycemia, her bedtime dose of long-acting insulin was significantly reduced from 50 to 25 units. She eliminated all snacks, and either weighed or measured all portions of food. She performed postprandial SMBG at least once a day.

After 3 months, Gail’s dose of long-acting insulin was further reduced, from 25 to 10 units. She had lost 8 pounds and reported having more energy. Her A1C was 7.9%.

Six months after undergoing professional CGM, Gail had lost a total of 13 pounds, giving her a BMI of 25.3 kg/m². Her A1C was 7.1%. Her short-term goal was to lose 5 more pounds, bringing her within a normal weight range for the first time since the birth of her second child.
Pattern management consists of performing SMBG on an agreed-upon schedule, accurate recordkeeping, and applying knowledge about the effects of food and other factors on BG levels.

Pattern management is a proactive, comprehensive approach to diabetes self-management.

Health care providers should work with patients to establish effective SMBG schedules, set up BG logs, interpret BG data, and modify their treatment plans in response to these data.

Professional and personal CGM helps carefully selected patients to improve their BG control by allowing them to identify patterns associated with BG excursions, alerting them to hypoglycemia and hyperglycemia, and facilitating the recordkeeping process.

Summary

- Pattern management consists of performing SMBG on an agreed-upon schedule, accurate recordkeeping, and applying knowledge about the effects of food and other factors on BG levels.
- Pattern management is a proactive, comprehensive approach to diabetes self-management.
- Health care providers should work with patients to establish effective SMBG schedules, set up BG logs, interpret BG data, and modify their treatment plans in response to these data.
- Professional and personal CGM helps carefully selected patients to improve their BG control by allowing them to identify patterns associated with BG excursions, alerting them to hypoglycemia and hyperglycemia, and facilitating the recordkeeping process.