Pattern Management: Effective Use of a Powerful Tool

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Pattern Management: Effective Use of a Powerful Tool 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, pharmacists, and dietitians.
The following program is a taped presentation by Deborah Hinnen.

Deborah Hinnen, RN, ARNP, BC-ADM, CDE, FAAN 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, 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.

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.
The goal of this program is to provide information to assist in the effective use of pattern management for people with diabetes.

After completing this educational activity, participants should be able to:

- Describe major obstacles that patients with diabetes face in meeting glycemic targets
- Explain why pattern management (PM) is a valuable tool for achieving and maintaining glycemic targets
- Discuss how PM is implemented for patients who use conventional methods of blood glucose (BG) monitoring and record-keeping
- Describe the components of continuous glucose monitoring systems (CGMSs) and systems that are currently available
- Summarize key data on the efficacy and safety of CGMSs
- Discuss how PM is used in connection with CGMSs
The program objectives are slightly different for pharmacy technicians and are listed on this slide.
Major randomized clinical trials have shown that maintaining the glycosylated hemoglobin (A1C) level at near-normal levels reduces the risk of diabetes complications. The Diabetes Control and Complications Trial (DCCT) and the Kumamoto study demonstrated that maintaining the A1C at ~7% (through the use of intensive insulin therapy) delayed or prevented the development of microvascular complications, including retinopathy, nephropathy, and neuropathy, in patients with type 1 and type 2 diabetes, respectively. Similarly, the United Kingdom Prospective Diabetes Study (UKPDS) showed using insulin, oral agents, or both to keep the median A1C at ~7% significantly lowered the risk of microvascular complications.

The DCCT/Epidemiology of Diabetes Interventions and Complications (EDIC) study was an 11-year follow-up to the DCCT. The EDIC study revealed a significant association between a history of consistently meeting glycemic target goals and a reduced risk of macrovascular and microvascular complications. As reported in September 2008, a 10-year follow-up to the UKPDS also documented prolonged benefits of meeting glycemic targets. As shown in this slide, patients in the sulfonylurea plus insulin group had a significantly lower risk for many end points, and patients in the metformin group also had a significantly reduced risk of any diabetes-related end point, diabetes-related death, death from any cause, and myocardial infarction.
Heisler et al examined several obstacles to meeting glycemic target goals in a survey-based study of demographically diverse adults who were receiving treatment for diabetes at 1 of 5 health care facilities in southeastern Michigan. Patients were divided into 5 groups on the basis of their most recently documented A1C value. They were asked what their most recent A1C was, what different A1C levels signify (in terms of meeting established glycemic targets), and how well they understood how to manage their diabetes. They were also asked to rate their diabetes self-efficacy by reporting on how many of the past 7 days they had taken their medications as prescribed, followed their eating plan, and monitored their BG.

As this slide shows, the great majority of patients in each group did not have accurate knowledge of their most recent A1C. The highest rate of correct responses was in patients with an A1C of <7% (18.8% of patients), and the lowest rate was in patients with an A1C of 9% to 10% (4.9% of patients). Patients who knew this value were more likely to know the significance of the value than other patients and to report a good understanding of diabetes self-management. However, these patients did not demonstrate better diabetes care self-efficacy than other patients.

The investigators concluded that knowledge of one’s last A1C values appears to be useful but not sufficient for translating increased understanding of diabetes care into the increased confidence and motivation necessary to improve patients’ diabetes self-management. Strategies to provide information must be combined with other behavioral strategies to motivate and help patients effectively manage their diabetes.
Many persons are knowledgeable about the treatment of diabetes and highly motivated to practice conscientious self-management but experience situations that make it difficult to maintain their glycemic goals. These include individuals with irregular mealtimes, inconsistent levels of physical activity, acute illness, the need for multiple medications for other medical conditions, stress, beginning or modifying intensive insulin therapy (IIT) regimen, pursuing an A1C target of <7%, and nocturnal hypoglycemia, hypoglycemia unawareness.

Although many insulin-treated persons are better at meeting glycemic targets after they transition to intensive insulin therapy (IIT), maintaining target BG levels when beginning or significantly modifying an IIT regimen can be challenging.

Individual patients, in an effort to prevent or delay the onset of diabetes-related complications, may elect to pursue an A1C target of <7%. Despite the potential benefits of this approach for selected patients, these individuals may be at an increased risk for hypoglycemia. In addition, nocturnal hypoglycemia and hypoglycemia unawareness are persistent problems for many patients.
Self-monitoring of blood glucose (SMBG) is essential for maintaining BG levels at target ranges in patients treated with insulin, but regular BG monitoring does not translate directly to meeting glycemic targets. According to the American Diabetes Association (ADA), SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved. Results of SMBG can be useful in preventing hypoglycemia and adjusting medications, diet, and physical activity. The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient. SMBG is especially important for insulin-treated patients to monitor for and prevent asymptomatic hypoglycemia and hyperglycemia.

However, the accuracy of SMBG is instrument and user dependent, making it important to evaluate each patient’s monitoring technique, both initially and then at regular intervals. Furthermore, optimal use of SMBG requires proper interpretation of the data. Patients should be taught how to use SMBG data to adjust food intake, exercise, or drug therapy to achieve specific glycemic goals, and these skills should be examined periodically.
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 oral 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 to resolve issues to optimize their BG levels.

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, and gestational diabetes.
Goals of PM are to attain and maintain target BG goals, reduce fluctuations in BG, and optimize diabetes self-management. The ultimate goals of PM are to 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 SMBG on a schedule determined by the patient and health care provider. The second is accurate and consistent record-keeping. The third is application of knowledge about the effects of food, activity, medications, illness, stress, and other factors on BG values.
There are several major prerequisites for performing PM effectively. First, the individual should be committed to achieving the goals of PM and understand that the development of sound PM skills may require substantial time and effort.

To be able to carry out PM, 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 PM. 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. 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.
The following are basic questions to ask when evaluating BG readings for PM:

- Is the patient storing and administering prescribed medication(s) correctly?
- 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, premeal, postmeal)?
- Are there BG readings for the peak times of each medication (if applicable)?
- What lifestyle factors might be affecting glucose control?

Pattern management differs from the use of sliding-scale insulin because PM is a proactive rather than a reactive approach to BG management.

Administration of sliding-scale insulin is a one-time reaction to a single elevated BG reading. Although it addresses 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 PM 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.
Estimated average glucose (eAG) values can be an important PM tool.

The A1C-Derived Average Glucose (ADAG) Study was an international study sponsored by the ADA, European Association for the Study of Diabetes (EASD), and the International Diabetes Federation (IDF). Study results were published in *Diabetes Care* in August 2008. The objective of the study was to define the mathematical relationship between A1C and eAG and to determine if A1C could be reliably reported as eAG. The study included 507 subjects: 268 with type 1 diabetes, 159 with type 2 diabetes, and 80 without diabetes. The study affirmed the existence of a linear relationship between A1C and average BG levels. This slide shows A1C values and corresponding eAG values, as well as the formula used to calculate eAG levels. The ADA Web site includes a calculator that automatically transforms A1C to eAG levels, as well as many useful educational materials for health care providers and their patients. Now that the relationship between A1C and eAG levels has been demonstrated and defined, health care providers can report A1C results to patients in the same units that patients use for self-monitoring, a process that should benefit clinical care and facilitate the process of PM.

Although many patients who practice SMBG already see an “average glucose” value on their BG meter, their eAG value is unlikely to match their average BG level. Because persons with diabetes often perform SMBG when their BG values are low (upon awakening and before meals), the average of the readings of their meter is likely to be lower than their eAG, which represents an average of their glucose levels 24 hours a day, including postmeal periods of higher BG levels, when individuals are less likely to test.

### Estimated Average Glucose (eAG)

<table>
<thead>
<tr>
<th>A1C Value</th>
<th>Corresponding eAG Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>126</td>
</tr>
<tr>
<td>6.5</td>
<td>140</td>
</tr>
<tr>
<td>7</td>
<td>154</td>
</tr>
<tr>
<td>7.5</td>
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<td>183</td>
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<td>8.5</td>
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</tr>
<tr>
<td>9.5</td>
<td>226</td>
</tr>
<tr>
<td>10</td>
<td>240</td>
</tr>
</tbody>
</table>

Formula: $28.7 \times A1C - 46.7 = eAG$

http://www.diabetes.org/professional/eAG.
Now, let’s answer this checkpoint question.

Prerequisites for effective PM include all of the following EXCEPT:

a. SMBG
b. Intact cognitive function
c. Willingness to use an insulin pump
d. Sound self-care skills
Answer to Checkpoint 1

The correct answer is c.

Effective PM does not depend on the method of insulin delivery. Pattern management can also benefit persons with diabetes who do not use insulin.

The correct answer is c.

Effective PM does not depend on the method of insulin delivery. Pattern management can also benefit persons with diabetes who do not use insulin.
Under routine circumstances, 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 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.

The efficient utilization of those strips can still allow pattern management. For example, a person taking oral agents might test fasting and 2 hours after meals 2 days per week and use about 100 test strips in 3 months. This is a much more effective use of the test strips than testing 1x/day for 3 months.

When gathering data for PM, SMBG will often be performed more often than usual.

To detect any patterns that might exist, it is desirable to have readings for the same time of day on several consecutive days.

To optimize the patient’s involvement in the process, the patient and health care provider should develop the SMBG schedule together.
This chart represents the basic log entry for Barbara, a patient who has a 5-year history of type 2 diabetes and has recently begun IIT. She is 57 years old, has a body mass index (BMI) of 30 kg/m², and works in a call center. Her immediate goals are to reduce her A1C of 8.4% (eAG level, 194 mg/dL) and lose weight. Because she demonstrates a solid understanding of nutrition and has been generally adherent with her meal plan, Barbara and her health care provider have agreed that she will focus on measuring her BG before and after each meal and at bedtime for 3 days and report any deviations from her meal plan and any extended period of physical activity.

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

- Blood glucose 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 diabetes 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 PM.
James is a 62-year-old African American male who presents for an initial appointment with his family physician. He works part time at his township’s road department, is married with 3 grown children and 7 grandchildren, and participates in many family and volunteer activities.

He was diagnosed with type 2 diabetes 15 years ago and began to experience symptoms of retinopathy about 2 years ago.

He took oral medications until 2 years ago, when he began using regular insulin (5 units before breakfast and dinner) and 32 units of a long-acting insulin analog (LAIA) at bedtime.

He is 70 inches tall, weighs 158 pounds, and has a BMI of 23 kg/m². His A1C is 7.6% and his eAG level is 171 mg/dL.
James says that he is unhappy that he often fails to meet his BG target values. In addition, because he is an active person, he wants more flexibility in his lifestyle.

He reports that he often forgets to take his regular insulin 30 to 45 minutes before meals. He either injects the insulin right before eating or does not take it at all.

Because of his retinopathy, he has a difficult time drawing up his exact insulin dose with a syringe and insulin vial and has his granddaughter do it for him when she is at home. He says he feels frustrated because he seems to be losing his independence.

He describes his carbohydrate-counting skills as “poor” and says that he feels “lost” when his wife is out of the house and he needs to prepare his own meals.

**Case 1: Therapeutic Challenge**

- Unhappy with present BG control
- Wants more flexibility in his lifestyle
- Often forgets to take regular insulin 30–45 minutes before meals
- Depends on granddaughter to draw up insulin dose
- Has limited CHO-counting skills

CHO = carbohydrate.
In preparation for his first appointment, James kept a log of his BG levels for 1 week, performing SMBG 2 or 3 times a day.

As this log shows, all of James’s postbreakfast and postdinner and 3 of his 4 postlunch 2-hour postprandial BG values exceeded ADA guidelines of <180 mg/dL. Two of his 4 prelunch values were below the range of 70 to 130 mg/dL prescribed by the ADA guidelines. These patterns show that regular insulin was causing James to exceed his postprandial target values and was lowering his prelunch values too much.
To begin to realize his goals of meeting his glycemic targets and gaining more flexibility in his lifestyle, James agreed to make some medication and dietary changes.

Because his health insurance covers treatment with insulin analogs, James’s physician discussed the benefits of switching from regular insulin to rapid-acting insulin delivered via disposable pen. James expressed a preference for initially covering only his breakfast and dinner with a rapid-acting insulin analog (RAIA) and said that he would be willing to add a lunchtime dose if needed. Following instruction, James demonstrated proficiency in manipulating the pen and administering an injection with it. He was very pleased that he would no longer have to rely on his granddaughter to draw up his insulin. At the recommendation of his physician, James agreed to reduce his bedtime dose of long-acting insulin from 32 to 30 units.

After learning the skill of carbohydrate counting with the registered dietitian, certified diabetes educator, James demonstrated a good understanding of carbohydrate counting. He agreed to begin by taking 1 unit of RAIA per 15 grams of carbohydrate. Based on assessment, his energy needs were calculated as being 2000 calories per day, with 50% (1000 calories) from carbohydrate. Based on the formula of 4 calories in each gram of carbohydrate, his meal plan called for 250 grams of carbohydrate, divided as 60 grams at breakfast, 60 at lunch, 25 at his mid-afternoon snack, 75 at dinner, and 30 at his bedtime snack.

So that his new regimen could be fine-tuned, James agreed to keep a detailed 3-day log of BG readings and food intake in preparation for his next appointment.
As a reminder, glycemic recommendations of the ADA are preprandial BG values of 70 to 130 mg/dL and peak postprandial BG values <180 mg/dL (peak glycemic excursions is ~1-1/2 hrs after eating). Recommendations of the American Association of Clinical Endocrinologists (AACE) are fasting BG values <110 mg/dL and 2-hour postprandial BG values <140 mg/dL. As agreed with his health care provider, James was following ADA guidelines.

One month after his last visit, James returned with his BG and food log. As demonstrated by the first page of the log, he was now proficient in estimating the carbohydrate content of his meals and giving the correct insulin dose based on each meal’s carbohydrate content.

Analysis of his BG ranges showed a mixed picture. His fasting BG values, which ranged between 98 and 110 mg/dL, were at goal. His 2-hour postprandial breakfast values ranged between 120 and 150 mg/dL, which were also at goal. The fact that there was no more than a 40-point difference between his preprandial and 2-hour postprandial BG indicates that his insulin:carbohydrate ratio of 1:15 worked well for him and his glycemic variability is minimal. His before-dinner BG ranged between 160 and 185 mg/dL, and thus were nearly at goal.

James was very pleased with his new insulin regimen and the ease of using an insulin pen device, but was dissatisfied with his predinner BG values. He suggested adding a premeal injection of RAIA at lunchtime and his health care provider agreed with the idea.
When James returned to his provider 1 month later with a new log of his BG readings and food intake, all of his BG values were within goal range. He also reports that he has more energy.

**Case 1: Improved Outcomes**

- After 1 month, patient’s BG values were within goal range
  - Predinner: 90–130 mg/dL
  - 2-hr postdinner: 120–153 mg/dL
- Patient reports increased energy
Robert is a 56-year-old white male who presents to the emergency department (ED) of an urban hospital. He works at a lumberyard. He was recently divorced and has 2 grown sons. On weekends, he and his brother sell baseball memorabilia at flea markets throughout the state. He says that he has always enjoyed a “meat and potatoes” diet and often eats out.

Robert was diagnosed with type 2 diabetes 4 years ago. He also has hypertension and hypercholesterolemia. He is currently taking pioglitazone 45 mg/day.

He is 6 feet, 1/4 inch tall, weighs 195 pounds, and has a BMI of 26.4 kg/m². His A1C is 10.1% and his eAG level is 243 mg/dL.
On the Sunday evening when his brother brought him to the ED, Robert reported polydipsia, polyphagia, and polyuria. His BG value was 353 mg/dL.

Per ED protocol, Robert was given a correction dose of a RAIA and IV fluids. His BG level at the time of his discharge from the ED was 141 mg/dL, and he said that he was less thirsty.

Before leaving the hospital, Robert made an appointment to come to the outpatient department the following Wednesday for further evaluation and treatment.
During his first outpatient visit, Robert and his physician agreed that he would follow BG goals recommended by the ADA (preprandial, 70–130 mg/dL; peak postprandial, <180 mg/dL).

Robert participated in survival skills diabetes education, which included:

- SMBG
- Insulin administration using a pen device
- Signs, symptoms, and treatment of hypoglycemia
- When to contact his doctor
- What to do before his first meeting with the department’s dietitian

Robert learned to use an insulin pen so he could inject a LAIA at an initial dose of 18 units (0.2 unit of basal insulin per kg of body weight per day). He stated that bedtime would be the most convenient time for him to take the insulin and agreed to check and record his BG values 2 to 4 times per day. He was scheduled to return to the outpatient clinic in 5 days for further medical management and diabetes education.
Review of Robert’s initial BG log during his second outpatient visit showed that none of his levels were at goal and that his weekend levels were particularly high. He attributed his out-of-range results on the weekend to the limited food choices available at the flea market where he had a booth for 2 days.

Robert’s health care provider discussed the possibility of intensifying his insulin regimen to help him reach his BG targets, but Robert said that he was not ready for that step. His bedtime dose of LAIA was increased to 25 units. The dietitian discussed Robert’s weekend food options with him, urging him to eat as many meals as possible away from the flea market, and to try to limit his consumption of fatty foods, such as french fries.

Before leaving, Robert made an appointment to return in 1 month.
When Robert presented his 3-day BG log at his third outpatient visit, his health care provider was pleased to see that both his preprandial and postprandial values had come closer to target levels over the past month. Robert said that he had been eating more meals at home, making better food choices when eating out, and following his meal plans most of the time. Before they entered the flea market grounds over the weekend, Robert and his brother prepared turkey and tuna sandwiches and also took fresh fruit and unsalted pretzels with them.

Despite this progress, only Robert’s average prebreakfast BG level (127 mg/dL) was at goal (70–130 mg/dL). After discussing various options with his physician, he agreed to start on mealtime insulin, injecting 4 units of RAIA before breakfast and dinner. It was decided that he should not take insulin at lunch because of the heavy lifting and high level of physical activity required by his job.

Robert made an appointment to return to the clinic in a month, and to bring another 3-day BG log with him. He said he could not commit to recording all of the foods he ate during that period, but agreed to record any major deviations from his meal plan or other events that might have affected his BG level.
Review of Robert’s latest BG log during his fourth outpatient visit showed that most of his BG values were now at goal. The comments he added to the log also demonstrated an understanding of the effect of food choices and activity levels on his BG control. At this point, his A1C had dropped to 7% (eAG level, 154 mg/dL).

Robert’s one concern at this visit was that his weight had increased from 195 pounds at his initial visit to 205 pounds, giving him a BMI of 27.8 kg/m². Robert’s health care provider explained that weight gain is a common side effect of pioglitazone and insulin. She suggested that they consider discontinuing the pioglitazone if weight gain continued to be an issue.

To help him fine-tune his meal plan and make lower-fat choices when eating out, Robert made an appointment to meet with the registered dietitian the following week. He was asked to check BG after lunch to verify that those values were near target even though he wasn’t taking pre-lunch insulin.
Here is another checkpoint question.
To optimize PM, the patient log should consist of:

a) Several complete days of BG values before and 2 hours after meals and at bedtime
b) BG values and other data agreed on by the patient and health care provider
c) A printout of BG values from the patient’s meter
d) A detailed log, documenting all foods consumed and their CHO content
The correct answer is b.
Although it is helpful to have as much data as possible on BG values, food choices, and events likely to affect glycemic control, the basis for effective PM is a collaborative relationship between the patient and health care provider.
Continuous glucose monitoring (CGM) is a potentially important tool for PM. Continuous glucose monitoring is the sampling of the glucose level in a patient’s interstitial fluid. This is an ongoing, minimally invasive way to evaluate glucose. The CGMS 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 is indicated for adults and children with both type 1 and type 2 diabetes. Some models are designed specifically for children aged 7 to 17 years of age.
All except one of the currently available CGMSs have 3 components: a sensor, transmitter, and monitor. 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 applicator or self-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 monitor via radio waves, and no cable is necessary. The transmitter is attached to the skin with adhesive.

A monitor displays and stores information on glucose levels. It displays real-time glucose values and trends. The monitor stores information for later use, and long-term data can be downloaded to a personal computer so that data can be viewed on a large screen or printed out. Available systems have a variety of alarms to warn users of actual or anticipated hyperglycemia or hypoglycemia.

All CGMSs can be used with insulin pumps, but the Medtronic MiniMed Paradigm® CGMS is the only available device that has an insulin pump integrated into the system. With the Paradigm, monitor functions are incorporated within the insulin pump.
At the present time, 5 CGMSs have been approved by the US Food and Drug Administration (FDA) and are available for use. With 4 of these systems—the Guardian® REAL-Time CGMS, Paradigm® REAL-Time Insulin Pump and CGMS, SEVEN™ CGMS, and FreeStyle Navigator® CGMS—real-time data are directly accessible to patients. With the CGMS® iPro™ Recorder, on the other hand, patients wear the device for 3 days, after which health care providers or diabetes educators review the data and discuss them with their patients.

Medtronic MiniMed manufactures the Guardian® REAL-Time CGMS, Paradigm® REAL-Time Insulin Pump and CGMS, and CGMS® iPro™ Recorder. Both the Guardian and Paradigm systems have models designed specifically for children aged 7 to 17 years.

DexCom manufactures the SEVEN™ CGMS. This is an updated version of the DexCom STS® CGMS.

Abbott manufactures the FreeStyle Navigator® CGMS.
The transmitter, sensor, and monitor for the Medtronic MiniMed Guardian® REAL-Time CGMS are shown on this slide. The sensor is inserted at a 45-degree angle using the Sens-serter® insertion device, although manual insertion is also possible. The start-up initialization time is 2 hours. Calibration is required 2 hours after initial insertion, 6 hours following insertion, and then every 12 hours. An alarm sounds if the calibration value is not entered. Users can set alarms for 8 different glucose thresholds, and a predictive alarm can be set to warn the user 5 to 30 minutes before the glucose limit has been reached. Alarms can also be set to warn the user about rates of change from 1.1 mg/dL per minute to 5 mg/dL per minute. Directional trends can be displayed using 3-, 6-, 12-, and 24-hour graphs. The user can enter insulin administration, carbohydrate consumption, SMBG values, and exercise events. The user can choose from vibrating or audible alarms. The transmitter is waterproof, but it should not be exposed to hot water.

A separate system is available for pediatric patients aged 7 to 17 years of age.

Additional Notes
The monitor for the Medtronic MiniMed Guardian® REAL-Time CGMS was approved by the FDA in June 2006 and the transmitter was approved in February 2007. The monitor weighs 2.8 ounces, its overall size is 3 inches by 2 inches, and the screen size is approximately 1.8 inches by 0.75 inch. Together, the transmitter and sensor are 1.64 inches long, 1.4 inches wide, and 0.37 inches high. The sensor cannula has a diameter of 14 mm. Transmitter batteries are rechargeable, provide ≥14 days of use per charge, and have an expected life of 1 year. The monitor uses 1 AAA battery. The monitor has separate snooze alarms to alert the user to high and low glucose values.
The Medtronic MiniMed Paradigm® system, which is pictured on this slide, differs from other available CGMSs because the system integrates CGM and insulin pump functions in 1 system. Two insulin pumps are available—model 522, which has a maximum capacity of 176 units of insulin, and model 722, which can hold up to 300 units of insulin. Model 522 is intended for persons who use up to 50 units of insulin per day, and model 722 is intended for those who use more than 50 units per day. As with the Guardian® system, the sensor is inserted at a 45-degree angle using a Sens-serter® insertion device, although manual insertion is also possible. The start-up initialization time is 2 hours. Calibration is required 2 hours after initial insertion, 6 hours following insertion, and then every 12 hours. An alarm sounds if the calibration value is not entered. Users can set alarms for different glucose thresholds, and a predictive alarm can alert the user 10, 20, or 30 minutes before an anticipated low or high value. Directional trends can be displayed using 3- and 24-hour graphs, and glucose data can be reviewed for the last 24 hours. The user can select audible and/or vibrating alarms. The transmitter is waterproof, but should not be exposed to hot water.

As with the Guardian® system, a separate system is available for pediatric patients aged 7 to 17 years of age.

Additional Notes
The Medtronic MiniMed Paradigm® system was approved by the FDA in March 2006. Monitor functions are incorporated within the insulin pump. Together, the transmitter and sensor are 2 inches long and 1.5 inches wide. The sensor cannula has a diameter of 14 mm. The transmitter battery has an estimated life of 9 months, and the insulin pump/monitor uses 1 AAA battery. The monitor has separate snooze alarms to alert the user to high and low glucose values.
The Medtronic CGMS® iPro™ Continuous Glucose Recorder differs from the other CGMSs described in this activity because the patient has no direct interaction with the device. The CGMS® iPro™ Recorder is intended to help health care providers and their patients design an individualized diabetes treatment program based on detailed glycemic profiles. This device may be especially valuable for patients who experience dangerous glycemic lows and highs, those who experience hypoglycemia unawareness, those who have elevated A1C levels, women with diabetes who are pregnant, and women with gestational diabetes.

During an initial office visit, the health care provider inserts the glucose sensor into the patient’s abdomen. The sensor has the same specifications as those used with other CGMSs manufactured by Medtronic (Guardian® and Paradigm®). The health care provider then synchronizes the meter time to match the time on the office computer using Medtronic Solutions® software, connects the glucose sensor to the data recorder, and provides the patient with a log sheet and instructions.

During the 3 days the patient wears the recorder, the patient takes 4 fingersticks per day and records meals, periods of exercise, administration of insulin and/or other medications, and other relevant information on the log sheet.

During the follow-up office visit, the health care provider removes the system from the patient, uploads CGMS® iPro™ Recorder data and BG meter data onto the computer, manually enters log sheet information, and uses Solutions® software to generate reports to discuss with the patient.
The DexCom SEVEN™ CGMS is pictured in this slide. The sensor is inserted at a 45-degree angle using the DexCom SEVEN™ Applicator insertion device. The start-up initialization time is 2 hours. Calibration is required every 12 hours using the OneTouch® Ultra® Meter. There are 3 alarms, one for a user-set high value, one for a user-set low value, and one preset for a value of 55 mg/dL. Directional trends can be displayed using 1, 3, or 9-hour graphs. The system has a vibrating and an audible alarm. The transmitter can be exposed to water for up to 30 minutes.

**Additional Notes**

The DexCom SEVEN™ CGMS was approved by the FDA in June 2007. The monitor weighs 2.9 ounces, its overall size is 3 inches by 2.5 inches, and the screen size is approximately 1.9 inches by 1.5 inches. Together, the transmitter and sensor are 1 inch long and 0.75 inch wide. The sensor cannula has a diameter of 13 mm. The transmitter has a nonreplaceable battery and the monitor has a battery that needs to be recharged every 5 days for 3 hours.

An earlier version of this device, the 3-day STS® CGMS, was approved by the FDA in March 2006.
The Abbott FreeStyle Navigator® is shown on this slide. The sensor is inserted at a 90-degree angle with an automatic inserter. The start-up initialization time is 10 hours. Calibration is required at 10, 12, 24, and 72 hours after insertion. No calibration is required during the last 2 days of the 5-day wear cycle. Users can set alarms for low and high glucose values, and predictive low/high alarms can be set for 10, 20, or 30 minutes before an event is expected to occur. Directional glucose arrows indicate the rate and direction of change. Glucose data can be reviewed for the previous 24 hours. The user can select audible or vibrating alarms. The transmitter can be submerged in up to 3 feet of water for 30 minutes.

**Additional Notes**

The Abbott FreeStyle Navigator® was approved by the FDA in March 2008. The overall monitor size is 3 inches by 5 inches. Together, the transmitter and sensor are 2 inches long and 1 inch wide. The sensor cannula has a diameter of 5 mm. The transmitter uses a watch battery that should be replaced monthly, and the monitor uses 2 AAA alkaline batteries. The monitor has a snooze alarm that provides silence for 1 hour.
Kovatchev et al recently reported the results of a study that compared the accuracy of 4 CGMSs: the Medtronic MiniMed Guardian®, DexCom STS®, Abbott FreeStyle Navigator®, and Menarini GlucoDay®. The DexCom STS unit used in this study has a 3-day sensor, while the newer DexCom SEVEN® has a 7-day sensor. The GlucoDay unit, which is manufactured by Menarini Diagnostics, is currently approved for use in several Western European countries but not in the United States. Therefore, GlucoDay data are not presented here. The Guardian, DexCom STS, and Navigator systems were evaluated in 14 patients with type 1 diabetes.

Many of the comparisons made in this complex study were based on a continuous glucose error grid analysis, which assigns each glucose reading to 1 of 5 clinically meaningful zones. Zone A corresponds to clinically accurate readings, zone B to benign errors, zone C to overcorrection errors, zone D to failure to detect clinically significant BG or rate of change, and zone E to erroneous readings.

As shown on this slide, the 3 monitors demonstrated similarly high levels of accuracy during euglycemia, with nearly all of the readings falling within zone A and virtually none falling within zones C to E. During hypoglycemia, 84.4% of Guardian readings and 97.0% of Navigator readings fell within zones A and B. There were insufficient data to perform the analysis for DexCom STS readings. During the study, all 3 sensors experienced periods of transient loss of sensitivity, particularly during hypoglycemia. The percentage of such unreliable data points was 6.9% for the Guardian, 29.8% for the DexCom, and 16.8% for the Navigator.

The investigators concluded that the clinical accuracy of the 3 sensors was similar during euglycemia and higher for the Navigator during hypoglycemia (because of the higher percentage of readings within zones A and B).
Deiss et al conducted a 3-month randomized clinical trial which showed that the use of CGM could improve short-term glucose management in patients with type 1 diabetes. The study enrolled 81 children aged 8 through 18 years and 81 adults who were adherent to intensified insulin therapy but had A1C levels $\geq 8.1\%$ (eAG level, 186 mg/dL). Patients were randomly assigned to receive continuous monitoring with the Guardian® CGMS (continuous group), monitoring with the Guardian system for 3-day periods every 2 weeks (biweekly group), or conventional SMBG (control group).

As shown on this slide, the reduction in A1C values between baseline and 1 month and baseline and 3 months was significantly greater in the continuous group than in the control group. At 3 months, A1C reductions $\geq 1\%$ were reported by 50% of patients in the continuous group, 37% of those in the biweekly group, and 15% in the control group. Almost all patients in the continuous and biweekly groups reported making insulin, dietary, or lifestyle adjustments based on real-time data.

Severe hypoglycemia was reported in 2 patients. One patient in the biweekly group had severe hypoglycemia while not wearing the device. A patient in the continuous group experienced severe hypoglycemia despite a confirmatory SMBG value and corrective carbohydrate intake.
Results of The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study have recently been published. This randomized multicenter clinical trial was the first study to investigate the effects of CGM over 26 weeks. The study assigned 322 adults and children who were already receiving intensive therapy for type 1 diabetes to a CGM group or to a control group performing home monitoring with a BG meter. The patients, who had baseline A1C levels ranging from 7% to 10%, were stratified by age into 8–14-year-old, 15–24-year-old, and ≥25-year-old subgroups. Patients in the CGM group received a DexCom SEVEN®, Medtronic MiniMed Paradigm®, or Abbott FreeStyle Navigator® monitoring system. The primary outcome was the change in A1C level at 26 weeks.

At 26 weeks, changes in A1C levels in the 2 study groups varied markedly according to age group. Among patients aged ≥25 years, there was a significant between-group difference that favored the CGM group (mean difference in change, −0.53%; \( P < 0.001 \)). Among patients in the CGM group who were ≥25 years old, there were improvements in virtually all measures of glycemic control compared with the control group. As shown on this graph, significantly more patients in the CGM group achieved the target A1C level of <7% as recommended by the ADA \( (P = 0.005) \), and significantly more had a relative reduction of ≥10% in the mean A1C level compared with baseline \( (P = 0.003) \). In contrast, among patients aged 15 to 24 years, the mean decrease in A1C levels was −0.2% in both study groups and there were no significant intergroup differences on any secondary glycemic measure. Among patients aged 8 to 14 years, the mean A1C decrease was 0.37% in the CGM group versus 0.22% in the control group; this difference was not significant. However, more patients in the CGM group had a relative reduction of ≥10% in the A1C level from baseline \( (P = 0.04) \) and more had A1C levels of <7% \( (P = 0.01) \). 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.
Reportable adverse events included severe hypoglycemia (defined as an event that required assistance from another person to administer oral carbohydrate, glucagon, or other resuscitative actions), hyperglycemia resulting in ketoacidosis, unexpected study- or device-related events, and serious adverse events regardless of cause.

As shown on this slide, the rate of severe hypoglycemia in the study was low (between 7.3% [n = 12] and 9.6% [n = 15]) and did not differ significantly between the 2 study groups. However, the trial was not powered to detect such a difference. Other reportable adverse events in the CGM group were cellulitis related to sensor use (n = 2), anxiety and depression (n = 1), and seizure not caused by hypoglycemia (n = 1). Other reportable adverse events in the control group were diabetic ketoacidosis (n = 1), dizziness during blood draw (n = 1), and kidney laceration (n = 1).

The study compared the mean number of minutes per day that patients spent at 2 levels of hypoglycemia: ≤70 and ≤50 mg/dL. Among adults ≥25 years of age, the mean minutes per day that the CGM group spent with BG levels ≤70 mg/dL were 89 at baseline and 60 at week 26; for the control group, values were 80 minutes at baseline and 81 minutes at week 26. The mean minutes per day that the CGM group spent with BG levels ≤50 mg/dL were 32 at baseline and 11 at week 26; for the control group, these values were 22 minutes at baseline and 23 minutes at week 26. These differences between the CGM group and the control group were not statistically significant.
Because successful operation of a CGMS requires adequate vision and hearing, use of the device is not recommended for patients whose impaired vision or hearing does not allow full recognition of the monitor signals and alarms, or who do not have a caregiver who can perform this function for them.

The patient should avoid injecting insulin or placing an insulin pump infusion set within 3 inches of a sensor.

Patients may experience mild to moderate local reactions. Erythema, edema, and ecchymosis have been reported at the sensor insertion site and at the transmitter attachment site. Additionally, bleeding has been reported at the sensor site.
In 2007, the estimated total cost of diabetes in the United States was $172 billion. Direct medical costs, including institutional care, outpatient care, and outpatient medications and supplies, accounted for about $116 billion. Indirect costs, including mortality, reduced performance at work, and permanent disability, represented another $58 billion.

A matched population analysis showed that the annual medical costs for a person with diabetes totaled $11,744 in 2007, compared with $5095 for a similar person without diabetes. Thus, the medical costs for a person with diabetes were 2.3 times greater than those for a comparable person without diabetes.

Another analysis has shown that the cost of diabetes care is related to A1C values. Gilmer et al calculated the cost of the diabetes care that 1694 adults received between 1999 and 2002. As shown on this slide, standardized costs over this 3-year period were 11% higher for patients with an A1C value of 10% (eAG level, 240 mg/dL; $26,408) compared with the costs for patients with an A1C of 6% (eAG level, 126 mg/dL; $23,873). The cost of medical care was significantly higher when the A1C value was ≥7.5% (eAG level, 169 mg/dL) and escalated with every 1% rise in A1C.

Since it has been shown to reduce A1C levels, CGM may have the potential to reduce the direct and indirect costs of diabetes. However, cost-effectiveness data are not currently available.
Real-time CGM is expensive, with an average daily cost of $5–$10, depending on the longevity of the glucose sensor. Continuous glucose monitoring is not currently reimbursed by Medicare or Medicaid. Some private insurers consider CGM medically necessary for certain patients with type 1 diabetes. For example, Aetna covers up to two 72-hour CGM monitoring sessions per year (with a CGMS® iPro™ Recorder or older recording device) for persons who have repeated hypoglycemia or hyperglycemia at the same time each day despite conventional insulin dose adjustment or for those with hypoglycemia unawareness. Aetna also covers long-term CGM as an adjunct to SMBG in persons who have had recurrent episodes of severe hypoglycemia (BG <50 mg/dL) despite appropriate insulin regimen modifications and compliance with frequent SMBG (≥4 fingersticks per day). Some private insurers base their positions on 2 statements contained in the ADA’s Standards of Medical Care in Diabetes—2008. The first is: “CGM may be a supplemental tool to SMBG for selected patients with type 1 diabetes, especially those with hypoglycemia unawareness.” The second is: “Although continuous glucose sensors would seem to show great promise in diabetes management, as yet no rigorous controlled trials have demonstrated improvements in long-term glycemia.” Also cited is this statement from the AACE 2007 diabetes guidelines: “Arrange for CGM for patients with T1DM with unstable glucose control and for patients unable to achieve an acceptable A1C level; CGM is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.”

As noted above, 3 days of patient evaluation with a CGMS® iPro™ Recorder (or older device of this type) is covered by Medicare and many private insurers.
Despite the demonstrated advantages of CGMSs, several important psychosocial issues need to be addressed if the patient is to derive maximum benefit from the system.

Because it is a constant reminder that they have diabetes, some individuals prefer to wear the system intermittently. As a rule, intermittent use is most appropriate for persons with type 2 diabetes.

Thorough patient education and consistent support at the beginning of CGMS use is an important means of reducing patient anxiety. It is important for health care providers to recognize that many individuals feel overwhelmed by the vastly increased amount of data and information that they are suddenly receiving.

At the beginning of CGMS use, patients tend to react to every excursion from target BG levels. Some experts recommend that patients take no action in response to alarms during the first 3 to 7 days of system use.

Patients who have been accustomed to managing their diabetes by retrospectively reviewing data from a BG log benefit from education in prospectively recognizing developing patterns.

Continuous glucose monitoring is particularly valuable for detecting unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.

As demonstrated most definitively by The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study, currently available CGMSs improve A1C values. The results of some studies suggest that currently available devices may also reduce the time spent in hypoglycemia and the incidence of severe hypoglycemia.

Continuous glucose monitoring systems have great value as teaching tools, providing patients and health care providers with better insight into BG fluctuations and the probable reasons for these fluctuations. For example, readings stored in a CGMS can be downloaded to a personal computer and printed out for review. Many patients find this graphic depiction of the changes in their BG levels easier to understand than the numbers in a traditional logbook. Therefore, a CGMS can be an important component of pattern management.
Currently available CGMSs have several major disadvantages. Because these devices must be calibrated with readings obtained with fingerstick BG measurements, patients need to have good SMBG skills and continue to do glucose monitoring.

Moreover, available systems measure interstitial glucose, not BG, and there is a physiologic lag for equilibration of glucose between the blood and interstitial fluid compartment. To optimize the accuracy of CGM, the patient must calibrate the device during steady-state conditions. After meals, the glucose level will often increase by >3 mg/dL per minute. This, together with the physiologic lag in equilibration that is often in the range of 10 to 15 minutes, can lead to differences between glucose levels in the blood and interstitium of 30 to 45 mg/dL. Similarly, when the glucose is falling rapidly, the interstitial glucose generally lags behind the blood. Therefore, the actual BG could be quite low, even when the interstitial glucose is normal. Thus, when the glucose is falling, such as after exercise, the patient needs to perform SMBG to clarify whether to treat.

If patients are to derive maximum benefit from CGMSs, they need to receive comprehensive education and support as they begin to use their systems so that psychosocial issues can be addressed.

Finally, real-time CGMSs are not reimbursed by Medicare or Medicaid, although reimbursement is generally available for the CGMS® Pro™ Recorder. Some private insurers provide coverage for real-time systems, but only for a small subset of patients with type 1 diabetes.
An important finding of The Juvenile Diabetes Research Foundation CGM Study is that:

a) Patients with type 2 diabetes had the lowest incidence of adverse events
b) Patients of all ages were highly compliant with the study regimen
c) Two-year follow-up data showed persistent benefits of CGM
d) Mean changes in A1C levels varied greatly by age group
The correct answer is d.
For the primary end point of change in A1C from baseline to week 26, the only significant difference between patients in the CGMS and control groups was in the subgroup of patients aged ≥25 years of age.
Anna is a 56-year-old Hispanic female who presents for an initial appointment with her primary care provider. She works full time as a legal secretary and has a 40-minute commute to and from work. She is married to a middle school teacher, has 2 married children, and 2 grandchildren (ages 6 and 8). She spends much of her time on the weekends babysitting her grandchildren, and reports having little time or enthusiasm for exercise because of her work and family responsibilities.

She has an 18-year history of type 2 diabetes and also has hypertension, hyperlipidemia, and osteoarthritis.

Until 6 months ago, she took a biphasic insulin analog before breakfast and dinner, most recently 24 units before breakfast and 33 units before dinner. Although she appreciated the convenience of that regimen, her BG levels were increasingly out of bounds and she agreed with her health care provider’s suggestion that she begin IIT. She currently takes 9 units of a RAIA before meals (2 units per carbohydrate choice) and 41 units of a LAIA at bedtime.

She is 65 inches tall, weighs 183 pounds, and has a BMI of 30 kg/m². Her A1C is 8.7% and her eAG level is 203 mg/dL.
Anna says that although she understands why it was important for her to transition to IIT, she has seen little improvement in her A1C level since beginning her basal/bolus regimen, going from 9.3% (eAG level, 220 mg/dL) to 8.7% (eAG level, 203 mg/dL). She states that she does not understand her present regimen well enough to derive full benefit from it.

Anna says that she has been very concerned about developing hypoglycemia since she started using insulin. She admits that she often overtreats it, resulting in high BG values. She finds her evening drive home especially stressful, fearing that she will become hypoglycemic if a traffic problem extends her commute.

Anna says that one of the lawyers in her office, who has type 1 diabetes, has recently purchased a CGMS and has been very pleased with it. Anna is unsure whether persons with type 2 diabetes can also benefit from CGM, but thinks that such an approach might be helpful to her.

Anna’s physician explains that some patients with type 2 diabetes do use and report a benefit from CGM. However, ongoing costs of these systems are currently high and health insurance rarely covers these devices for patients with type 2 diabetes.

Anna replies that she might be willing to pay for the system herself, considering the peace of mind and health benefits it might provide. Her physician suggests that they resume their discussion about CGM after Anna has met with the certified diabetes educator at the diabetes center and deals with some immediate issues related to her glycemic control.

Anna makes an appointment with the diabetes educator for the following week. In preparation for the appointment, Anna is asked to keep a BG log, measuring her BG 4 times a day and noting any unusual events that might have affected her values.
Anna’s physician had suggested that she use the BG values recommended by the ADA. Thus, her target preprandial BG value ranged from 70 to 130 mg/dL and her target peak postprandial BG value was <180 mg/dL.

Based on these targets, nearly all of Anna’s BG values were out of range. Particularly noteworthy was her overtreatment of an episode of hypoglycemia on Tuesday.

Over the next 4 weeks, Anna met with a certified diabetes educator each week. During this time, Anna fine-tuned her carbohydrate-counting skills and learned about the appropriate treatment of hypoglycemia and the prevention of hypoglycemia. As the BG log showed, those effects were still apparent at dinnertime.

After discussion with Anna, her physician and diabetes educator suggested that she modify both her meal plan and her IIT regimen. Her RAIA dosage was changed to 11 units before breakfast, 9 units before lunch, and 13 units before dinner. Her bedtime insulin dose was changed to 45 units of a LAIA. The registered dietitian gave Anna a diet plan that emphasized a variety of carbohydrate choices, explaining that that approach might reduce her risk of morning hypoglycemia.

To check to see whether this new regimen would result in fewer excursions from her target values, Anna was asked to prepare another 3-day glucose log in preparation for her next appointment. To gain further insight into the efficacy of this new regimen, the diabetes educator suggested that Anna monitor and record her 2-hour postprandial values as well as those she had already been measuring.

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**Case 3: Initial BG Log**

Treatment: 9 Units RAIA before meals, 41 units LAIA at bedtime

<table>
<thead>
<tr>
<th>Day</th>
<th>FBG</th>
<th>2 h After Bkfst</th>
<th>Before Dinner</th>
<th>Bedtime</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td>208</td>
<td>140</td>
<td>165</td>
<td>260</td>
</tr>
<tr>
<td>Tues</td>
<td>135</td>
<td>50</td>
<td>385</td>
<td>207</td>
</tr>
<tr>
<td>Wed</td>
<td>120</td>
<td>184</td>
<td>183</td>
<td>232</td>
</tr>
</tbody>
</table>

*Took insulin before breakfast and ate only 1/2 cup of egg substitute and no carbohydrate. Overtreated hypoglycemia by drinking 16 oz of juice.

FBG = fasting blood glucose.
When Anna and her certified diabetes educator reviewed her most recent BG log, they noted substantial improvement in her overall patterns. All of her BG values during the early part of the day and at bedtime were at goal. However, many of her afternoon and evening values, although considerably reduced, exceeded her target values.

Anna attributed this continuing problem to 2 factors. There were always “goodies” to eat in the staff kitchen of her law firm. Although she usually packed her own lunch, following her meal plan closely, she often found it impossible to resist a cookie or some pretzel sticks when she walked past the kitchen. In addition, her concern about hypoglycemia during the drive home from work often prompted her to eat a high-carbohydrate, high-fat snack, such as crackers and peanut butter, before getting into her car.

At this point Anna again raised the question of whether CGM might benefit her. Over the next few weeks, she learned about CGMSs from her diabetes educator and physician.
As Anna explored the benefits of CGM with the help of her physician and certified diabetes educator, she became convinced that this device would help her to manage her diabetes more effectively.

She was particularly impressed with data showing that many patients experience fewer BG fluctuations when they have access to CGM. For example, this slide documents a patient's interstitial glucose levels over several days at the start of CGM (left panel) and after 3 months of CGM (right panel). At the start of treatment, about 53% of the patient’s BG values were out of the target range; after 3 months, this proportion had dropped to about 37%. It was evident to Anna that CGM could help her control her excursions into hyperglycemia and especially into hypoglycemia.

It was also evident to her that CGM, along with her recently increased knowledge of medical nutrition therapy, would help her to meet several of her personal goals. Especially important were the ability to begin an exercise program without fear of severe hypoglycemic episodes and to start losing weight.

Anna decided to buy a CGMS after wearing an CGMS® iPro™ Recorder for 3 days. As she reviewed the iPro data with her health care provider, she gained new insight into the situations and times of day during which she was most likely to have BG values that were out of range. Once she received her own CGMS, she learned how to program the monitor quickly. As her skills developed, she received excellent support from her local health team and from a representative of the device manufacturer. She also found the written documentation that came with the system clear and easy to follow.
Anna soon learned to avoid several mistakes common to new users of CGMSs. At first, in her eagerness to keep to her routine schedule, she tried to calibrate her system right after breakfast. When her glucose readings seemed implausible, she consulted her documentation and learned that she needed to calibrate her system after her BG level had stabilized. Anna adjusted to this situation by getting up 30 minutes earlier.

When she first began to use her system, Anna also made the mistake of responding to a postprandial hyperglycemia alarm by hastily giving herself a bolus dose of rapid-acting insulin. The graphics on this slide illustrate this common problem and its consequences. The top panel shows the download from a glucose sensor and the bottom panel indicates insulin doses taken. Each blue bar represents a bolus. At breakfast, the glucose reading was 140 mg/dL and the patient took bolus 1. In response to postprandial hyperglycemia, Anna took boluses identified by arrows 2, 3, and 4, leading to hypoglycemia.

Another issue involved setting the low-glucose alarm. Because of Anna's anxiety about hypoglycemia, she originally programmed her monitor to alert her when her glucose value fell to 90 mg/dL. However, Anna soon learned that this value was too high, and that her alarm was frequently sounding. Eventually she decided to keep the alarm set for 80 mg/dL.
Three months after acquiring her CGMS, all of Anna’s BG readings are within their target ranges and her A1C has fallen to 7.4% (eAG level, 166 mg/dL). Anna has started attending a water aerobics class and walking with a coworker at lunchtime, and has lost 8 pounds.

Anna says that she intends to use her CGMS indefinitely. However, she also thinks that using her system for 3 months has taught her more about the management of her type 2 diabetes than she had learned in her first 18 years with the disease. She especially appreciates the help that the system has given her in anticipating hypoglycemic episodes and treating but not overtreating them. Additionally, the real-time data that she receives from her system is a powerful inducement to avoid impulse snacking at work.

Although Anna’s health care provider has mentioned that some patients with type 2 diabetes prefer to wear their CGMSs intermittently, so that they are not constantly reminded that they have diabetes, Anna feels that regular use is best for her, at least while she is focusing on weight reduction.
• Short- and long-term clinical trials have shown that maintaining BG values within target ranges reduces the incidence of many complications of diabetes. However, patients face a number of obstacles to keep their BG levels within target, including knowledge deficits, limited self-efficacy, and lifestyle factors.

• Pattern management is a valuable tool for achieving and maintaining target BG values for a wide range of patients with diabetes.

• Effective PM in patients using conventional methods of BG monitoring and record keeping and in those using CGM depends on consistent collaboration between the patient and health care provider and alertness to factors that might affect BG control.

• Real-time CGMSs consist of a sensor, transmitter, and monitor. Monitor functions may be integrated into an insulin pump. A device that records BG values for later downloading and review is also available.

• Currently available data suggest that CGM is effective, safe, and well tolerated, but longer-term data are needed.