Using Pattern Management to Improve Glycemic Control

Supported by an educational grant from Novo Nordisk Inc.
Program Objectives

• 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
Need for Improved Glucose Control in the United States

- US diabetes prevalence may double or triple by 2050
- Preventing or delaying the onset of diabetic complications is essential
- Effective BG control reduces the incidence of complications
- Overall BG control is improving in the US, but 43% of the overall population with diagnosed diabetes has an A1C that exceeds the current ADA goal of <7%

ADA = American Diabetes Association.

Pattern Management: A Tool for Improving Glycemic Control

• Proactive, comprehensive approach to BG management

• Reviews several days of BG readings in conjunction with food intake, activity, doses of insulin and/or other glucose-lowering medication, and other factors

• Promotes diabetes self-management

• Can be used with any treatment regimen and any route of medication delivery

Goals of Pattern Management

• Attain and maintain target BG goals
• Reduce BG fluctuations
• Optimize diabetes self-management
• Reduce likelihood of developing diabetes complications
• Improve overall health and well-being

Elements of Pattern Management

- Accurate self-monitoring of BG (SMBG) on an agreed-upon schedule
- Accurate and consistent recordkeeping
- Application of knowledge about the effects of food, activity, medications, and other factors on BG values

How Pattern Management Differs From the Use of Sliding-Scale Insulin

• Proactive vs reactive approaches
• Sliding-scale insulin a one-time reaction to 1 elevated BG reading
• Sliding-scale insulin addresses the problem for a single point in time
• Use of sliding-scale insulin is not evidence-based
• Aim of pattern management is to prevent problem from recurring

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

Key Questions for Health Care Providers When Reviewing Data

• Is the patient storing and administering medication(s) correctly?
• Does something happen at the same time each day?
• Are there BG readings for key times of the day?
• Are there BG readings for the peak times of each medication (if applicable)?
• What lifestyle factors might be affecting glucose control?

Checkpoint 1

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.
Glucose Monitoring Schedules

• SMBG may be performed more often than usual while gathering pattern management data

• Frequency depends on treatment regimen, lifestyle considerations, and patient’s motivation

• To detect patterns, it is desirable to have readings for same time of day on several consecutive or closely spaced days

• Patient and health care provider should develop SMBG schedule together

## Designing the Data Log

<table>
<thead>
<tr>
<th>Day, Notes</th>
<th>Before Bkfst</th>
<th>After Bkfst</th>
<th>Before Lunch</th>
<th>After Lunch</th>
<th>Before Dinner</th>
<th>After Dinner</th>
<th>Before Bed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thursday BG Walk after dinner</td>
<td>109 (3 U RAIA)</td>
<td>284</td>
<td>208 (5 U RAIA)</td>
<td>195</td>
<td>169 (6 U RAIA)</td>
<td>128</td>
<td>108 (12 U LAIA)</td>
</tr>
<tr>
<td>Friday BG Bagel at bkfst</td>
<td>111 (3 U RAIA)</td>
<td>315</td>
<td>292 (5 U RAIA)</td>
<td>205</td>
<td>173 (6 U RAIA)</td>
<td>149</td>
<td>123 (12 U LAIA)</td>
</tr>
<tr>
<td>Saturday BG Small lunch</td>
<td>99 (3 U RAIA)</td>
<td>279</td>
<td>216 (5 U RAIA)</td>
<td>135</td>
<td>121 (6 U RAIA)</td>
<td>137</td>
<td>118 (12 U LAIA)</td>
</tr>
</tbody>
</table>

Bkfst = breakfast; LAIA = long-acting insulin analog; RAIA = rapid-acting insulin analog.

Automated Glucose Monitoring Systems for Pattern Management

For patients with access to and accepting of electronic technology, automated BG monitoring and recording systems may offer a modest advantage in glycemic control compared with a conventional approach.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>80</td>
<td>205</td>
</tr>
<tr>
<td>Diabetes type</td>
<td>2</td>
<td>1 and 2</td>
</tr>
<tr>
<td>Baseline A1C, mean</td>
<td>7.6%</td>
<td>9.1%</td>
</tr>
<tr>
<td>BG monitoring, intervention group</td>
<td>Internet-based system with electronic feedback every 2 weeks, office visit every 3 months</td>
<td>Integrated glucose meter and electronic logbook</td>
</tr>
<tr>
<td>BG monitoring, control group</td>
<td>Paper logbook, office visit every 3 months</td>
<td>Conventional glucose meter and paper logbook</td>
</tr>
<tr>
<td>Time of final observation</td>
<td>30 months</td>
<td>66 weeks</td>
</tr>
<tr>
<td>Mean A1C change from baseline, intervention vs control group; P-value</td>
<td>$-0.8%$ vs $-0.1%$; $P = 0.022$</td>
<td>$-0.36%$ vs $+0.32%$; $P = 0.006$</td>
</tr>
</tbody>
</table>

Case 1: Patient Profile

- 70-year-old African American male
- Retired postal clerk
- Widower, lives with daughter and her family
- Height, 72 in; weight, 166 lb; BMI, 22.5 kg/m²
- 6-year history of type 2 diabetes
- A1C, 8.1%
- Other health issues: hypertension, hyperlipidemia, glaucoma, chronic renal insufficiency
- Current insulin regimen (using needle and syringe)
  - 7 units regular insulin, taken immediately before breakfast
  - 5 units regular insulin, taken immediately before dinner
  - 34 units long-acting insulin analog at bedtime

BMI = body mass index.
Case 1: Initial BG Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Units</th>
<th>Pre-</th>
<th>2 H</th>
<th>Units</th>
<th>Pre-</th>
<th>2 H</th>
<th>Bed-</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insulin</td>
<td>bkfst</td>
<td>PP</td>
<td>Insulin</td>
<td>lunch</td>
<td>PP</td>
<td>time</td>
<td>Insulin</td>
</tr>
<tr>
<td>4/13</td>
<td>7 Reg</td>
<td>84</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5 Reg</td>
<td>148</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/14</td>
<td>7 Reg</td>
<td></td>
<td>189</td>
<td>5 Reg</td>
<td>144</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td>4/15</td>
<td>7 Reg</td>
<td>88</td>
<td></td>
<td>5 Reg</td>
<td>213</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td>4/16</td>
<td>7 Reg</td>
<td>153</td>
<td></td>
<td>5 Reg</td>
<td>197</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td>4/17</td>
<td>7 Reg</td>
<td>180</td>
<td></td>
<td>5 Reg</td>
<td>230</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td>4/18</td>
<td>7 Reg</td>
<td>92</td>
<td></td>
<td>5 Reg</td>
<td>118</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td>4/19</td>
<td>7 Reg</td>
<td>98</td>
<td></td>
<td>5 Reg</td>
<td>168</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>34 LAIA</td>
</tr>
<tr>
<td>4/20</td>
<td>7 Reg</td>
<td>98</td>
<td></td>
<td>5 Reg</td>
<td>168</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Red = exceeds current ADA goal.
PP = postprandial; Reg = regular.

Case 1: Patient’s Concerns About Current Diabetes Care Plan

• Unhappy with present BG control
• Frustrated because he requires his daughter’s assistance to draw up insulin into syringes
• Does not wait the recommended 30–45 minutes before taking his regular insulin to eat his breakfast and dinner
• Has not worked with a diabetes educator for a long time
• Has many questions regarding his food intake
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
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.
### Case 1: Follow-Up BG Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Units Insulin</th>
<th>Pre-bkfst</th>
<th>2 H PP</th>
<th>Units Insulin</th>
<th>Pre-lunch</th>
<th>2 H PP</th>
<th>Units Insulin</th>
<th>Pre-dinner</th>
<th>2 H PP</th>
<th>Bed-time</th>
<th>Units Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/1</td>
<td>5 RAIA</td>
<td>86</td>
<td>121</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/2</td>
<td></td>
<td></td>
<td>5 RAIA</td>
<td>99</td>
<td>123</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/3</td>
<td></td>
<td></td>
<td></td>
<td>3 RAIA</td>
<td>124</td>
<td>149</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/4</td>
<td>5 RAIA</td>
<td>101</td>
<td>127</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/5</td>
<td></td>
<td></td>
<td>5 RAIA</td>
<td>130</td>
<td>151</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/6</td>
<td></td>
<td></td>
<td></td>
<td>5 RAIA</td>
<td>130</td>
<td>151</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/7</td>
<td>5 RAIA</td>
<td>101</td>
<td>135</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
<tr>
<td>7/8</td>
<td></td>
<td></td>
<td>5 RAIA</td>
<td>124</td>
<td>146</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32 LAIA</td>
</tr>
</tbody>
</table>

**Orange** = at high end of ADA-recommended range.

Case 1: Fine-Tuning the Treatment Plan

• At follow-up visit with primary health care provider, Richard reports having more energy and renewed confidence
• A1C has decreased from 8.1% to 7.6%
• Following review and discussion of new BG log data:
  – Richard will increase his bedtime dose of long-acting insulin analog from 32 to 36 units
  – He will reduce the dose to 34 units if 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.
What Is Continuous Glucose Monitoring?

- Important pattern management tool
- Ongoing, minimally invasive sampling of interstitial fluid glucose
- Calibrated with SMBG readings
- Provides real-time information about current glucose concentrations
- Identifies upward and downward trends
- Warns of hypo- or hyperglycemia
- Can benefit patients with type 1 or type 2 diabetes
- Equipment consists of professional and personal devices

Introduction to Professional CGM

- Professional (retrospective) CGM equipment owned by health care provider or facility
- Patients unaware of results until downloaded and analyzed by health care provider
- Used in patients with type 1 or type 2 diabetes who are not at their A1C target, have recurrent hypoglycemia or hypoglycemia unawareness, or are pregnant
- Intended to be used on an episodic basis
- Requires little setup time on patient’s part
- Patients generally wear sensor for 3–5 days, keep food and activity logbook, and then return to office
- Equipment does not have alerts to indicate hyperglycemia or hypoglycemia
- Insurance reimbursement more readily available than for personal CGM

Professional CGM: Responsibilities of Clinicians and Medical Staff

<table>
<thead>
<tr>
<th>Timing</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>First visit</td>
<td>• Have patient sign waiver agreeing to accept financial responsibility for equipment</td>
</tr>
<tr>
<td></td>
<td>• Set up CGM device</td>
</tr>
<tr>
<td></td>
<td>• Educate patient and reinforce instructions</td>
</tr>
<tr>
<td></td>
<td>– Outline SMBG frequency and calibration requirements using compatible BG meter</td>
</tr>
<tr>
<td></td>
<td>– Explain importance of logkeeping and return visit</td>
</tr>
<tr>
<td></td>
<td>• Provide patient with log to record food, medication, and activity</td>
</tr>
<tr>
<td></td>
<td>• Insert device sensor and start up system</td>
</tr>
<tr>
<td></td>
<td>• Schedule return visit for patient (usually in 3–7 days, depending on device)</td>
</tr>
</tbody>
</table>

| Return visit | • Remove sensor from patient and download data                                   |
|             | • Set preferences for individual target values and generate report               |
|             | • Interpret report and discuss treatment plan with patient                      |
|             | • Reinforce the effects of food, activity, and medications on BG levels          |
|             | • Provide patient with copy of report as an educational tool                    |
|             | • Clean and disinfect CGM equipment                                             |

Introduction to Personal CGM

- Device is owned by patient
- Glucose values are visible continuously
- Typically used by patients with type 1 diabetes who are not at their A1C target
- In addition to hyperglycemia and hypoglycemia alarms, systems may have alarms indicating a rapid rate of glucose change and predictive alarms that calculate whether high or low glucose thresholds will be crossed
- Setup requirements include programming customized glucose targets and alarm thresholds

Personal CGM: Follow-Up
Requirements and Resources

• Medical office should be proactive in arranging for clinician to interpret personal CGM data for patient
• Interpretation can take place by telephone, via Internet report, or in a face-to-face appointment
• Manufacturers can provide educational materials and one-on-one guidance
• Manufacturer Web sites offer educational printouts, online tutorials, user guides, and toll-free customer service telephone numbers

CGM System Components

- Sensor: measures interstitial glucose levels
- Transmitter: sends data to receiver
- Receiver: displays and stores data, can be linked to personal computer
- Integrated insulin pump: MiniMed Paradigm® REAL-Time Revel™ only
- Integrated BG meter: FreeStyle Navigator® only*


*Sale indefinitely suspended, April 2010.
# Reports Generated by Professional CGM Software*

<table>
<thead>
<tr>
<th>Report</th>
<th>Description*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor Summary</td>
<td>Comprehensive overview of patient’s BG profile, including summary of continuous data and meter readings, post- and premeal glucose levels, and periods of lows and highs</td>
</tr>
<tr>
<td>Sensor Modal Day</td>
<td>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</td>
</tr>
<tr>
<td>Sensor Daily Details</td>
<td>Complete overview of effects of insulin, meals, and exercise on patient’s glucose levels</td>
</tr>
<tr>
<td>Sensor Modal Time Periods</td>
<td>Analyzes daily continuous glucose levels in each of 6 key time periods (mealtimes and 3 optional periods determined by the user)</td>
</tr>
<tr>
<td>Sensor Data</td>
<td>Displays item-by-item records of all the downloaded recorder and meter data in the patient file</td>
</tr>
<tr>
<td>Log Book</td>
<td>Presents table of events (eg, insulin doses, meals, exercise) in chronological order with corresponding glucose values and comments. Supplements patient’s handwritten diary</td>
</tr>
</tbody>
</table>

*These reports are generated by Solutions® Software for the CGMS® iPro™ Continuous Glucose Recorder. The reports generated by CareLink® Pro software provide similar information in different formats. CareLink® Pro software is generally used for patients who use insulin pumps.

Medtronic. iPro™ Solutions® Software. 2008.
Medtronic. CareLink® Pro Reports. 2011.
AACE Consensus Statement: Patients Recommended for Personal CGM

• Those with type 1 diabetes and
  – Hypoglycemia unawareness or frequent hypoglycemia
  – A1C over target, or with 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

AACE = American Association of Clinical Endocrinologists.  
AACE Consensus Statement: Other Recommendations

• Patients who might be good candidates for personal CGM, for whom a 2–4 week trial period is recommended
  – Youth who frequently monitor their BG levels
  – Committed families of children <8 years of age, especially if 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

Personal CGM Systems Currently Approved by the FDA

FreeStyle Navigator®
Abbott Diabetes Care

DexCom™ SEVEN® PLUS
Dexcom, Inc.

MiniMed Paradigm® REAL-Time Revel™
Medtronic Diabetes

Guardian® REAL-Time
Medtronic Diabetes

## Major Differences Among Approved Personal CGM Systems*

<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>Transmitter/sensor size</td>
<td>2.05 × 1.23 × 0.88 in</td>
<td>1.5 × 0.9 × 0.4 in</td>
<td>1.4 × 1.1 × 0.3 in</td>
<td>1.4 × 1.1 × 0.3 in</td>
</tr>
<tr>
<td>Transmitter/sensor weight</td>
<td>0.48 oz</td>
<td>0.24 oz</td>
<td>&lt;0.25 oz</td>
<td>&lt;0.25 oz</td>
</tr>
<tr>
<td>Transmitter power source</td>
<td>1 silver oxide battery that lasts 30 d</td>
<td>Integrated battery that lasts 1 yr</td>
<td>Rechargeable, lasts 14 d</td>
<td>Rechargeable, lasts 14 d</td>
</tr>
<tr>
<td>Transmission range (wireless)</td>
<td>≤10 ft</td>
<td>≤5 ft</td>
<td>≤6 ft</td>
<td>≤6 ft</td>
</tr>
<tr>
<td>Calibration needed</td>
<td>10, 12, 24, and 72 h after inserting sensor</td>
<td>Every 12 h</td>
<td>2 and 6 h after inserting sensor, then every 12 h</td>
<td>2 and 6 h after inserting sensor, then every 12 h</td>
</tr>
<tr>
<td>BG range</td>
<td>60–300 mg/dL</td>
<td>40–400 mg/dL</td>
<td>40–400 mg/dL</td>
<td>40–400 mg/dL</td>
</tr>
</tbody>
</table>

## 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>
</tr>
</tbody>
</table>

*Information current as of February 2011. †Not currently available for purchase.

Overall Shortcomings of Approved CGM Systems

• Current CGM systems are less accurate than BG meters
• The need for home calibration of personal CGM systems may contribute to inaccuracy
• There is a physiologic lag between BG measured by SMBG and interstitial glucose measured by CGM
• Patients may overreact to changing glucose values, leading to insulin stacking or overtreatment of hypoglycemia

AACE Recommendations for CGM Product Improvement

- Improved accuracy in measuring glucose (perhaps through use of implantable sensors)
- More uniform integration of personal CGM devices with insulin pumps
- More intuitive software for downloading CGM results
- More comfortable sensors (perhaps noninvasive)
- More affordable systems, encouraging reimbursement for broader spectrum of patients

The accurate statement about CGM is that:

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.
STAR 1: Patient Selection Is Essential

- First prospective, randomized, controlled study to assess efficacy and safety of CGM
- 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

<table>
<thead>
<tr>
<th>Mean A1C Change From Baseline, %</th>
<th>All Patients</th>
<th>Adults</th>
<th>Adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGM + CSII + SMBG (n = 66)</td>
<td>-0.71</td>
<td>-0.69</td>
<td>-0.79</td>
</tr>
<tr>
<td>CSII + SMBG (n = 72)</td>
<td>-0.56</td>
<td>-0.64</td>
<td>-0.37</td>
</tr>
</tbody>
</table>


CSII = continuous subcutaneous insulin infusion; NS = not statistically significant.
JDRF CGM Study: Main Results

- N = 322 adults and children (≥8 yr) with type 1 diabetes and A1C of 7.0%–10.0%
- Randomized to use CGM + SMBG (CGM group) or SMBG (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

JDRF = Juvenile Diabetes Research Foundation; MDI = multiple daily injection.

Effects of Sustained CGM in the JDRF CGM Study

• The effects of CGM over 12 months were studied in patients ≥25 years old with a baseline A1C of <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

Decrease in Severe Hypoglycemia in the JDRF CGM Study

• Clinically meaningful decreases in the rate of severe hypoglycemia events were observed between months 1–6 and 7–12 in the overall population of patients ≥25 years and in both cohorts

• CGM provides the ability to achieve target A1C levels much more safely than previously reported

Severe Hypoglycemia Events, Patients ≥25 Years

- A1C <7% (n = 34): Months 1–6 = 23.6, Months 7–12 = 0
- A1C 7%–10% (n = 49): Months 1–6 = 20.5, Months 7–12 = 12.1
- Total Population (n = 83): Months 1–6 = 21.8, Months 7–12 = 7.1

P = NS

STAR 3: Consistently Better Outcomes With CGI + CSII

- Patients randomized to receive CGM + CSII + SMBG (CGM group) or MDI + SMBG (control group) for 1 year
- Change from baseline was significantly greater in the CGM group for all patients, adults, and children
- Robust improvements in A1C in the CGM group attributed to synergistic effects of CGI and CSII

![Graph showing A1C change from baseline at 1 year](image)

**Mean A1C Change From Baseline, %**

<table>
<thead>
<tr>
<th>Group</th>
<th>Value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGM + CSII + SMBG (n = 247)</td>
<td>-0.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>MDI + SMBG (n = 248)</td>
<td>-1.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Adults</td>
<td>-0.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Children</td>
<td>-0.4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

STAR 3 = Sensor-Augmented Pump Therapy for A1C Reduction 3 study.

Safety and Tolerability of CGM

- CGM is contraindicated in patients with impaired vision or hearing (unless a responsible caregiver is always available)
- Patient should follow manufacturer’s instructions about sensor placement and insertion
- Local reactions, including bleeding, erythema, edema, ecchymosis, cellulitis, and abscess, may occur at the sensor insertion site
- Severe hypoglycemia is the adverse effect of greatest concern; its risk may diminish over time
- Diabetic ketoacidosis occurs rarely

Ongoing Support Is Essential to Address Psychosocial Issues

- Patient selection is essential for successful CGM, but even carefully selected patients require ongoing support from health care providers.
- Because it is a constant reminder that they have diabetes, some persons choose to wear the sensor intermittently, compromising the benefits of CGM.
- Some patients eventually decide that the technical demands of CGM outweigh its benefits.
- To derive maximum benefit from the system, patients need to learn:
  - Not to react to every excursion from target BG levels.
  - How to respond proactively to developing BG trends.

Cost-Effectiveness of CGM

- Cost-effectiveness of CGM was calculated using data from the JDRF CGM study.
- The daily estimated cost of CGM was $13.85 and the annual cost was $4335.
- Consistent use of CGM was projected to reduce the direct and indirect costs of diabetes by decreasing the risk of microvascular and macrovascular complications.
- Lifetime cost savings were greater in the cohort whose baseline A1C was <7% than in the cohort whose A1C was 7–10% because of a longer postbaseline life expectancy (~37 years vs ~27 years, respectively).

Coverage for CGM is increasing rapidly as additional data supporting its efficacy and safety become available.

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 likelihood of reimbursement.

JDRF. CGM coverage policies for select health plans. 2011.

<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.

SC = subcutaneous.

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
Answer to Checkpoint 4

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.
Case 2: Patient Profile

- 47-year-old white female
- Office manager at large children’s daycare center
- Married, 2 children in college
- Height, 65 in; weight, 165 lb; BMI, 27.5 kg/m²
- 5-year history of type 2 diabetes
- A1C, 8.7%
- Other health issues: hypertension, hyperlipidemia
- Current glucose-lowering regimen
  - DPP-4 inhibitor at breakfast
  - Metformin XR 2000 mg with dinner
  - 50 units of LAIA at bedtime, administered with insulin pen
- Comprehensive health insurance plan through private carrier

DPP-4 = dipeptidyl peptidase-4.
# 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>Bed-time</th>
<th>Units Insulin</th>
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</thead>
<tbody>
<tr>
<td>1/17</td>
<td>100 mg</td>
<td>82</td>
<td></td>
<td>123</td>
<td></td>
<td>2000 mg</td>
<td></td>
<td></td>
<td></td>
<td>50 LAIA</td>
</tr>
<tr>
<td>1/18</td>
<td>100 mg</td>
<td>220</td>
<td></td>
<td></td>
<td></td>
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<td>117</td>
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<td>50 LAIA</td>
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<tr>
<td>1/19</td>
<td>100 mg</td>
<td>86</td>
<td></td>
<td></td>
<td></td>
<td>2000 mg</td>
<td>262</td>
<td></td>
<td></td>
<td>50 LAIA</td>
</tr>
<tr>
<td>1/20</td>
<td>100 mg</td>
<td>115</td>
<td></td>
<td>2000 mg</td>
<td>121</td>
<td>50 LAIA</td>
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<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>50 LAIA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/22</td>
<td>100 mg</td>
<td>91</td>
<td></td>
<td>254</td>
<td>2000 mg</td>
<td>50 LAIA</td>
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<tr>
<td>1/23</td>
<td>100 mg</td>
<td></td>
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<td>123</td>
<td>50 LAIA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Red** = exceeds current ADA goal.  
Met = metformin.  

Case 2: Patient’s Initial Concerns

- Unhappy about current BG control
- Frequently experiences fatigue
- Frustrated by inability to lose weight
- Prepares meals that are consistent with meal plan, but “sometimes” snacks during workweek
- Long workdays leave little time for exercise
- Finds it difficult to perform SMBG after meals due to schedule and fatigue
- Willing to undergo professional CGM to gain more insight into her diabetes self-management
- Confirmation that professional CGM is covered by insurance carrier
Case 2: First Office Visit for Professional CGM

- Glucose sensor is inserted using insertion device
- CGM recorder is synchronized with Gail’s BG meter
- Recorder is connected to glucose sensor
- Electronic wand is used to start communication between recorder and iPro™ Solutions® software and place 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
Case 2: Second Office Visit for Professional CGM

- Glucose sensor and iPro™ Recorder are removed
- Data are downloaded from recorder and BG meter
- Reports are generated and printed
- Health care provider interprets results for Gail

Sample Sensor Daily Details Report*

*This is a sample report and does not show data for the patient in this case.

Medtronic. iPro™ Solutions® Software. 2008.
Case 2: Interpreting Gail’s Professional CGM Results

- Nocturnal hypoglycemia occurred on 2 of 3 nights
- Postprandial glucose levels exceeded ADA target (<180 mg/dL) after all lunches, 2 of 3 dinners, and all 3 snacks
- Premeal glucose levels were consistently within target range (70–130 mg/dL)

*This is a sample report and does not show data for the patient in this case.

Sample Sensor Modal Day Report*

Medtronic. iPro™ Solutions® Software. 2008.
Case 2: Regimen Changes in Response to CGM Results

• Immediate changes
  – Dose of LAIA reduced from 50 to 25 units
  – All snacks eliminated, all food portions weighed or measured
  – Postprandial SMBG performed at least once a day

• Changes at 3 months
  – Dose of long-acting insulin reduced from 25 to 10 units
  – Patient lost 8 pounds and reports having more energy
  – A1C 7.9%

• At 6 months
  – Patient lost 5 more pounds (BMI, 25.3 kg/m²)
  – A1C 7.1%
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.
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Additional CE Activities

Information about additional continuing education activities on topics related to diabetes is available at:

(for Web-based, multimedia activities)

These activities are complimentary.