

## Introduction

In March 2015, the American Association of Diabetes Educators convened a thought leader summit devoted to continuous glucose monitoring (CGM). The key objective of this event was to identify best practices for managing and educating patients through the use of CGM. Topics of discussion ranged from patient selection and training to efficient data analysis and effective use of personal and professional (blinded) CGM. The summit meeting was supported by all companies currently marketing CGM devices, without product bias.

AADE convened the summit with the goal of improving patient outcomes through more effective use of CGM systems in real-time and on a professional/diagnostic basis. Specifically, the summit was called to:

- Generate a concise set of guiding principles for diabetes educators regarding the use of CGM in patient care
- Provide insight and recommendations to enable industry partners to design better tools and processes to serve patient and provider needs

## Pre-CGM patient selection, device selection, education and training

### I. Patient selection principles

Consistent with consensus statements on CGM issued by the American Association of Clinical Endocrinologists<sup>1</sup> and the Endocrine Society<sup>2</sup>, personal CGM may be appropriate for any person with diabetes who is willing to wear it, regardless of age, type of diabetes or duration of diagnosis.

Professional CGM shows trends and patterns retrospectively or in real time (if a real-time system is used). Patients may deviate from their usual behavior when using a blinded or real-time professional CGM because they know the data will be analyzed, but the data can still shed light on glycemic excursions overnight and between fingerstick glucose tests. Real-time professional CGM offers the additional benefit of providing immediate feedback to the user, who may apply what they learn to hone their diabetes management.

### Benefits and potential risks of CGM use

Benefits of CGM use in appropriate patients:

- Identification and/or confirmation of glycemic excursions, including the impact of high glycemic-index foods, high-fat meals, dawn phenomenon and hormone surges.
- Early warnings for hypoglycemia, particularly those with hypoglycemia unawareness.

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<sup>1</sup> Blevins TC *et al. Endocr Pract.* 2010; 16(5): 730–745.

<sup>2</sup> Klonoff DC *et al. J Clin Endocrinol Metab* 2011; 96: 2968–2979.

- Reassurance for patients and caregivers who are fearful of nighttime hypoglycemia.
- Insight into the effects of physical activity on glucose levels, and ability to better manage glucose levels during exercise.
- Real-time glucose trend data helps patients and caregivers anticipate highs and lows and take action to mitigate glycemic variability.
- Validation of therapy adjustments.
- Empowerment of patients and caregivers to improve decision-making regarding medication choices and insulin doses.
- Enable better diabetes management through better lifestyle choices.

Potential risks and drawbacks of using CGM in inappropriately selected or poorly trained patients:

- Unrealistic expectations, for example, the belief that CGM will eliminate the need for fingersticks glucose measurements.
- Overly-aggressive correction of elevated glucose levels because of the assumption that CGM will keep one 'safe' from severe hypoglycemia.
- Annoying alerts and alarms, which may lead some patients to switch them off or underutilize their CGM system.
- Skin irritation may occur in those sensitive to adhesives.
- For patients with body-image concerns, the sensor may cause emotional discomfort. For some insulin pump users, having a second "site" on the body may be unacceptable or complicate site rotation patterns.
- Costs can make CGM impractical, especially for those without private health insurance or sufficient disposable income to cover out-of-pocket costs.

#### CGM use in specific populations

<i>CGM should be considered for:</i>	<i>CGM may pose challenges for:</i>
Patients with health insurance or those on Medicare who can afford to pay out-of-pocket	Patients for whom CGM is unaffordable
Patients with hypoglycemia unawareness or who would benefit from alarms to avoid severe hypoglycemia	Patients with extreme anxiety/paranoia about hypoglycemia
Patients with suspected eating disorders (may aid in diagnosis and treatment)	Patients with significant body image issues
Pre, peri, and post-pregnancy	Patients with significant visual impairment
Patients interested in improving their diabetes management	Patients who are disengaged with self-care
Most skin types	Patients with unmanageable skin allergies/reactions to adhesive

Athletes or exercisers looking to optimize performance	Athletes who participate in sports that preclude wearing the sensor (wrestlers, for example)

## II. Equipment Selection

CGM product choice should be the result of a robust conversation with each patient. CGM technology is evolving quickly and has a relatively short warranty period compared to insulin pumps. There is potential for a cash upgrade if a new product is launched by the same manufacturer mid-warranty.

Practice regarding the prescription of sensors varies, with some diabetes care providers automatically issuing a prescription for the sensors at the point of pump initiation and others choosing to discuss and prescribe CGM separately from the pump order. Both Medtronic and Dexcom offer personal and professional versions of CGM systems that function independently or integrate with insulin pumps.

Patients tend not to have strong opinions about the exact brand of diabetes management technology unless a close friend or family member has made a specific recommendation. In most cases, patients seek input from their diabetes care professionals to help them make the best choice. It is thus incumbent on diabetes educators to understand the differences between the various systems so that appropriate guidance can be provided.

Attributes of CGM systems to consider, in order of importance (most to least) include:

1. Device accuracy according to clinical research
2. Ease of use/user-friendliness
3. Downloading capability; data reports and ease of data interpretation
4. Ability to customize alarms
5. Loudness of alarms/strength of device vibration
6. Patient perception of device accuracy
7. Quality of the display and number of on-screen report options

Understanding each patient's needs, interests and abilities will help to guide the discussion of the various CGM products. It is usually best to educate the patient on the differences between the systems so that they can make an optimal selection.

### III. Education/Training

#### Pre-CGM initiation

Education and training are required for patients to benefit from CGM. In addition to addressing any questions the patient has, be certain to cover the following prior to CGM initiation:

- The difference between interstitial fluid and capillary glucose, and how this creates lag time
- Device calibration intervals and appropriate use of self-monitoring of blood glucose (SMBG) for insulin dose calculations
- Insulin action time and expected postmeal patterns
- What the patient and clinician hope to achieve from using CGM
- For Dexcom only: acetaminophen contraindication
- Managing emotions around glycemic excursions, including alarm fatigue
- Identifying materials and resources for self-study, including but not limited to: device instructions for use, tutorial videos, articles or books on diabetes self-management (as appropriate)

#### Calibration

A CGM device should be calibrated according to the manufacturer's instructions. Importantly, frequent testers should be informed *not* to enter every fingerstick glucose value into their CGM. This is particularly relevant within the first 24 hours of inserting each new sensor, when the sensor values may differ more from SMBG compared to subsequent days. Medtronic users should be advised to not calibrate in a state of rapid glucose change (as indicated by up or down arrows).

Good SMBG technique to ensure high quality data:

- Test strips should be stored according to manufacturers' instructions and not exposed to extreme temperatures
- Test strips should be used before their expiration date
- Patients must ensure their hands are clean and dry (no lotion or cream on the skin)
- Patients must ensure that the blood sample is sufficient for a test (some glucose meters will return a falsely low value when not enough blood is applied)
- Readings must be entered as calibrations immediately after they are taken.

#### CGM sensor placement

For adults, both Dexcom and Medtronic recommend that CGM sensors be placed in subcutaneous tissue on the abdomen. The back of the upper arm is a preferred off-label Dexcom sensor site for adults, while the upper buttocks (indicated for children aged 2 to 17 using Dexcom) represent another possible area for wear. Lipodystrophy from CGM sensor wear has not been observed in practice. Insertion into an area of hypertrophy does not appear to affect CGM sensor performance.

#### Off-label reuse of CGM sensors

To reduce the cost of using CGM, extend the time between insertion procedures, and cut down on the number of “day 1” inaccuracies, many patients choose to wear a CGM sensor for longer than the approved number of days. Dexcom sensors (indicated for 7 days) are often “re-used” two or three times (14 to 21 days). Medtronic sensors (indicated for 6 days) are sometimes used for up to 12 days or longer. Clinical experience has indicated that Dexcom sensors tend to perform well during the second week of use whereas Medtronic sensors tend not to perform as well when re-used. Given that sensor reuse is common despite label warnings to the contrary, it is important to educate patients on the signs of sensor decay (>20% variation from SMBG, poor signal transmission) as well as symptoms of skin infection/irritation.

#### **IV. Using real-time CGM data**

##### *Use of CGM values for real-time insulin therapy adjustment*

Real-time CGM has three main features: the display of discrete glucose values on-screen, alarms that notify a patient that their glucose level is above or below specified thresholds, and trending information (rising/falling glucose).

Educators should emphasize with patients that triggering alarms does not denote poor control; they merely represent opportunities for correcting problems while they are still relatively minor. Pointing out that “time in-range” is a better reflection of control quality may help patients to put alarms in perspective.

Due to “lag time” inherent in CGM technology, it is generally recommended to set the low alert 10-20 mg/dl above the patient’s true low threshold. Patients should treat mild or pending hypoglycemia with rapid-acting carbohydrate when the CGM alarm sounds, rather than ignoring it or waiting for a subsequent alarm at a lower glucose level. High alerts may be corrected with exercise or insulin, but insulin-on-board should always be taken into account.

Regarding discrete values, patients should not be encouraged to use CGM data as a substitute for SMBG in insulin dosing decisions. However, the reality is that the majority of patients do so anyway. It is the diabetes educator’s responsibility to teach patients the factors that influence sensor accuracy. For example, sensors are less trustworthy on the first day of use and when glucose is rising or falling quickly. Sensor values also lose their reliability when calibration values differ significantly. This behavior makes patient adherence with device calibration procedures all the more necessary and important.

Teaching patients how to factor trend data into therapy decisions can improve outcomes. For example, if glucose is still trending up an hour after a correction bolus has been delivered, it may be appropriate to deliver more insulin or consider whether a pump infusion set should be replaced. A pre-meal downward or upward trend may be addressed with a decrease or increase to the usual bolus dose. A downward trend prior to driving, exercise, test-taking, or medical procedures may necessitate additional carbohydrates and/or a temporary reduction in basal

insulin delivery (for pump users). However, poor numeracy may affect patients' ability to implement adjustments, and diabetes educators are encouraged to provide patients with tailored, simplified advice based on their insulin sensitivity.

### Real-Time Adjustments for Non-Insulin Users

For people with type 2 diabetes, CGM can provide insight into the effects of medications and lifestyle choices. Hypoglycemia may be detected and treated in those using oral hypoglycemic agents. The impact of various forms of food, physical activity and emotional states can be seen immediately. Examining postprandial patterns, in particular, can guide patients in making optimal food choices (including quantities) and timing for exercise.

## **V. Retrospective CGM data analysis**

Few patients analyze data retrospectively themselves, though some will download the data for their healthcare professional to review. To benefit fully from CGM, it is recommended that CGM be downloaded and reviewed at each clinic visit. Diabetes educators can play a major role in retrospective data analysis for patients using CGM.

Without detailed blood glucose logs or the use of event markers on a patient's CGM receiver, it may be difficult to identify the causes of glycemic excursions. For example, many patients do not log carbohydrates consumed to prevent a pending low blood sugar. This, of course, can mask hypoglycemia patterns that should ideally be addressed with proactive insulin adjustments.

In addition to downloading the patient's CGM, blood glucose meter and pump, periodic (3-7 days) of data logging (or event entries into the CGM receiver) prior to clinic visits can be extremely helpful when analyzing CGM data. Tracking food, exercise, insulin/medication, and other events that can impact glucose levels provides context to the CGM reports. Bear in mind that patients may exercise more discretion in their food choices than they would if they were not logging.

Retrospective data review should start with general trends and patterns and hone in on relevant periods and data points. Healthcare providers should take into account that patients may feel vulnerable and under scrutiny in discussions of their CGM data. Be sure to point out successes before focusing on problem areas. Identifying one behavioral or treatment change in a single visit is usually best.

### Clinical goals

Identifying hypoglycemia patterns and confirming basal insulin doses are high priorities for most CGM users. Evaluation/management of postprandial glucose (including discussion of

appropriate bolus timing) and fine-tuning of mealtime insulin doses should also be addressed. Maximizing time spent within one's target glucose range and minimizing standard deviation are important clinical outcomes, but realistic/achievable and individualized goals must be set.

Data analysis programs – overall assessment

As mentioned previously, CGM data is much more robust when combined with details regarding food intake, physical activities, emotional states and insulin/medications. In particular, being able to compare the effects of different types, intensities and durations of exercise could help patients prepare better for physical activity.

Manufacturers' data reporting & analysis programs

	<b>Medtronic CareLink®</b>	<b>Dexcom Studio</b>
Advantages	<ul style="list-style-type: none"> <li>• Combines pump (insulin, carb, BG) data with sensor data</li> <li>• Sensor overlay by meal shows postprandial patterns clearly</li> <li>• Sensor accuracy calculated as MAD%</li> </ul>	<ul style="list-style-type: none"> <li>• Patterns report includes trend graphs, averages, percentage of time in high and low glucose ranges</li> <li>• Highlights areas of greatest clinical risk</li> <li>• Success Report encourages and motivates patients</li> <li>• Can segment data by specific days of the week</li> <li>• Event entries displayed in trend graph reports</li> </ul>
Disadvantages	<ul style="list-style-type: none"> <li>• Different platforms for patients and professionals</li> <li>• Mealtime times/targets require personalization</li> <li>• Events (capture option) are not specific</li> </ul>	<ul style="list-style-type: none"> <li>• PC hard-drive rather than cloud-based data storage</li> <li>• Complex data sharing procedure</li> <li>• Cannot import data from pumps/meters</li> </ul>

\* Note: other programs that integrate CGM, pump, meter and physical activity/notes, such as DIASEND and BLIP (Tidepool), were not included in this report but may be useful resources for collecting and analyzing patient data.

**VI. Overcoming challenges**

### Hesitancy to take the plunge

There are many reasons patients are hesitant to use CGM: Body image issues, fear of pain, lack of confidence in the technology, and lack of understanding of the potential benefits to name a few. Patients who are curious but reluctant to invest time, money and energy into acquiring and using a CGM may benefit from a device trial. For those who prefer to be discreet and not have to explain it to colleagues or classmates, a weekend trial can do the job. In addition, connecting with other CGM users, either in-person or online, can provide an opportunity to ask questions and address concerns in an informal manner.

### Unrealistic expectations

- Appropriate use of SMBG – some patients initially believe that CGM means no more fingersticks; others may come to rely so heavily on the CGM that educators need to reinforce the relevance and necessity of SMBG
- Value of trend data – discuss with patients how to respond appropriately to rising versus falling glucose levels
- Reasonable expectations of the technology – CGM can reduce the frequency and severity of hypoglycemia and hyperglycemia, but it is not a foolproof method for preventing them.

### Over-aggressive correction dosing

Teaching patients (and caregivers) about insulin pharmacokinetics and ways to manage feelings of stress caused by hyperglycemia can reduce intentional and accidental overcorrections. Users must understand the onset, peak and duration of their rapid-acting insulin and know how to apply “insulin-on-board” when determining responses to hyperglycemia.

### Nuisance alerts

An alert represents a trigger point for intervention, not an acceptable glucose target. The ability to set different high and low threshold levels depending on the time of day (for example, a higher threshold for a hypoglycemia alarm overnight) can be helpful. Use of the “snooze” or “repeat” feature on a CGM receiver can reduce the number of alarms that patients hear. It can also be useful to set the high alert well-above the patient’s acceptable target range when first learning the system. The high alert can be tapered down gradually as the patient becomes comfortable with the system and glucose control improves.

Encouraging patients to participate in setting their thresholds for high and low alerts involves them in their care (aiding with “buy-in”) and offers an opportunity to discuss goals for the use of CGM technology. In addition to personalizing the thresholds for alarms, diabetes educators should also discuss rate of change alerts and out-of-range (lost signal) notifications with each patient.

### Data overload/obsession

During routine follow-up appointments, talk through your process/approach to interpreting CGM data with your patients. This can give them a strong sense of perspective and appreciation for pattern analysis and may dissuade them from making impulse-reactions to one-time events. Emphasize to patients that improvement, and not perfection, is the goal. For patients who feel overwhelmed by the constant onslaught of data, taking an occasional break from CGM use is very reasonable.

### Skin issues

Some patients experience allergic reactions, sensitivity or poor adhesion with CGM sensors. A number of options and alternatives can mitigate these issues:

- For patients who develop a rash: Johnson & Johnson Tough Pads (expensive) or Smith & Nephew Opsite Flexifix or Hypafix (less expensive) can be applied to the skin first, with the sensor inserted through the tape.
- For patients with itching: Hypafix, IV-3000 or Molnlycke Mepitac (soft silicone) tape; if moisture is causing itching, apply antiperspirant prior to inserting the sensor (allow it to dry completely before applying the sensor adhesive)
- For tough reactions: use timolol spray (doesn't interfere with sensor) or hydrocortisone lotion an hour prior to sensor insertion; or use Torbots Skin Tac (leaving a small 'doughnut hole' of uncoated skin where the sensor will be inserted)

### Affording CGM

CGM can be costly for patients without adequate insurance coverage or disposable income. Clinicians may appeal denials by insurance companies as many as three times to gain coverage for CGM for patients who have a strong clinical need for the technology. Restrictions on CGM coverage can affect the quality of patient care, and submitting appeals reduces the time healthcare providers educators have to spend with patients. To aid in the appeals process, ask your local clinical representatives from the CGM companies for form letters that can be used in various situations. For patients who cannot obtain coverage but have a significant need for CGM, costs can be mitigated by stretching sensor use or wearing the device only periodically.

## **VII. Considerations for special populations**

### Pediatrics

Parents of children with diabetes need support when using CGM. Emotions can run rampant when a child's glucose level goes high or low. Many parents feel guilty about their child's diabetes and there is a risk of overreacting to high or low glucose levels because of a desire to return them to their target range as quickly as possible.

With very young children, limited areas with sufficient subcutaneous fat tissue may present challenges. Children of all ages, particularly those who are sport-oriented, may have difficulty with sensor adhesion. Timely calibration can be an issue, especially with teens and pre-teens. Children of all ages need a robust plan for managing their diabetes at school. Teachers and school nurses are likely to need additional guidance on how CGM data should be factored into care decisions. Remote monitoring tools (such as Dexcom Share or Nightscout) can give parents insight into what is happening during their child's school day, which can reduce anxiety about diabetes management for all parties. Use of a remote monitoring tool, including Medtronic's My Sentry system, can also provide peace of mind for parents overnight. Adolescents who are resistant to wearing a CGM may be more open to the concept if their parents sign a contract, witnessed by their diabetes educator, stating that parents will not persistently ask about glucose values if the CGM is used.

### Elderly patients

Elderly patients are likely to gain significant benefits from use of CGM because they often live alone, are likely to experience hypoglycemia and may have hypoglycemia unawareness, and often have co-morbidities that predispose them to glucose control problems. Unfortunately, Medicare does not currently cover CGM, which significantly limits over-65s' access to it. When an elderly patient begins using CGM, educators should consider that they may need hands-on training and support to use the system properly. Their caregivers and/or adult children may need education regarding functionality and daily use of the system.

### Athletes

While physically active patients stand to benefit significantly from using CGM, they also present certain challenges. Movement and perspiration can cause problems with sensor adhesion. Educators and patients alike may need to increase their knowledge of physiological changes associated with exercise in people with diabetes. Athletes wishing to use CGM need to consider the practicality of the display screen location: pump screen, mobile device, or separate receiver.

### Pregnancy

Tighter glycemic targets in pregnancy make CGM an excellent tool. Lower and tighter hi/low alert settings may be required. The quality of CGM data depends on the accuracy of SMBG calibration, so educators should ensure that women who become anemic during pregnancy are using a blood glucose meter that has a suitable hematocrit range. There is a debate surrounding the use of the threshold suspend feature on the Medtronic insulin pump during pregnancy due to the need for overall tight glucose ranges and potential for ketosis with repeated bouts of basal insulin disruption. During the third trimester, the sensor should be worn on the hip or upper buttock area. Extra tape may be needed to keep the sensor in place over stretched skin.

### Patients with type 2 diabetes

Behavior change is the major outcome for most patients with type 2 diabetes using CGM. Patients newly diagnosed with type 2 diabetes may use CGM to learn how their glucose responds to various forms of food and physical activity. Diabetes educators may need to

engage with caregivers/significant others to discuss specific goals of using CGM and help patients interpret their data in real time. Primary care doctors should also be made aware of the potential for using CGM in patients with type 2 diabetes.

### Future considerations

	<i>Patients' priorities</i>	<i>Providers' priorities</i>
Device	<ul style="list-style-type: none"> <li>• receiver and manuals in Spanish as well as English</li> <li>• smaller sensor and transmitter</li> <li>• sensor integration with insulin pump infusion sets</li> <li>• SMBG replacement for insulin dosing and development of artificial pancreas</li> <li>• factory calibration to eliminate SMBG</li> <li>• integrated bolus calculator for patients on MDI</li> <li>• choice of remote CGM data display/remote insulin delivery options (smartwatch, smartphone or CGM receiver communicating to insulin pump)</li> </ul>	<ul style="list-style-type: none"> <li>• functional demonstration units so patients can get more of an idea of how CGM works</li> <li>• robust human factor studies to develop more intuitive systems</li> </ul>
Data management:	<ul style="list-style-type: none"> <li>• ability to integrate CGM data and data from other devices in combined reports</li> <li>• intelligent analysis features, such as aligning specific events (meals, boluses, exercise) in order to assess glucose outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• ambulatory glucose profile report</li> <li>• development of a common cross-platform one-page 'at-a-glance' report</li> <li>• printed reports readable in grayscale</li> <li>• available to primary care providers</li> </ul>
Financial	<ul style="list-style-type: none"> <li>• greater insurance coverage</li> <li>• medicare/Medicaid coverage</li> <li>• financial assistance for those in need</li> </ul>	<ul style="list-style-type: none"> <li>• longer timeframe for returning the device after trial (after 2 weeks of use rather than 2 weeks after shipment)</li> <li>• better support for educators concerning reimbursement for time spent on CGM training (both professional development and providing care to patients)</li> </ul>

**[text box] The role of the diabetes educator**

- Diabetes educators play a role in shaping the discussion with each patient about CGM product choice.
- Setting appropriate expectations prior to starting on a CGM is essential to patient success.
- When using CGM data in real-time, patients need education regarding insulin activity time and ‘turnaround time’ for glucose levels to respond. Without support from a diabetes care provider with relevant expertise, enthusiastic patients may make potentially risky therapy adjustments.
- CGM data should be downloaded and analyzed at each clinic visit. Teaching patients the “thought process” that goes into data analysis will help to empower them to self-manage more effectively.
- When moving a patient onto advanced diabetes technology, it is important to consider whether to initiate a pump or sensor first, or both at the same time. In general, a pump should be initiated first for patients who will probably use both a pump and CGM eventually
- Older patients, those with cognitive impairment and those who are not confident with technology may require more healthcare provider support to get started using CGM, but can still benefit from using it
- Many CGM users need professional advice on increasing sensor adhesion or managing sensitivity to device adhesive
- To provide optimal diabetes care, diabetes educators need to lobby for reimbursement for their own professional education as well as reimbursement for CGM devices and patient education on CGM use