Flash Continuous Glucose Monitoring: Implications for Use of Continuous Data in Daily Diabetes Management

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ABSTRACT

Full realization of the benefits of continuous glucose monitoring (CGM) depends on addressing barriers such as cost, accuracy, burdens of daily use, and uncertainty about applying the data. Lack of systematic education has also hampered widespread adoption among patients and health care professionals. This article describes the practical application of an affordable and intuitive category of CGM called “flash” that requires users to scan the sensor with a handheld reader for on-demand access to continuous data. The data may be used for in-the-moment therapy adjustment, retrospective review of glucose patterns, and observation of glucose trending in response to behavior. Higher rates of flash CGM scanning have been associated with increased time in the glycemic target range and reduced time in hyper- and hypoglycemia. Growing interest in this technology suggests new opportunities for helping more patients incorporate CGM into their daily self-care.

The health care improvement goal of excellent quality and patient experience at reasonable cost has translated to new expectations of glucose measurement. A1C is the reigning standard for assessing long-term diabetes complications risk, but as a measure of average glucose level over 2–3 months, this laboratory assay cannot capture daily glucose change and is subject to inaccuracies in individual patients (1). Self-monitoring of blood glucose (SMBG) is typically used to supplement A1C because episodic fingerstick checking allows patients to assess their response to factors immediately affecting daily glucose change. However, interrelated issues of education, logistics, and reimbursement often impede patient engagement with a structured monitoring schedule (2–6).

In the past decade, continuous glucose monitoring (CGM) has emerged as an adjunct to A1C that could potentially help meet glycemic goals (7–10). CGM technology provides near-continuous data by measuring the glucose concentration in the body’s interstitial fluid and extrapolating blood glucose levels for real-time or retrospective analysis.

Clinical trials have affirmed the benefit of accessing continuous data on a regular basis. Specifically, study participants have experienced improved A1C, decreased time spent in hyper- and hypoglycemia, and lower incidences of severe hypoglycemia (11–22). These benefits are derived from the ability of CGM, compared to A1C and SMBG, to more fully communicate real-time glucose values, trend information, and potentially harmful high and low glucose swings known as glycemic variability (2,23). Users wearing traditional devices can receive alerts to actual or predicted episodes of hypoglycemia and hyperglycemia and review display arrows reflecting the rate and direction of glucose change.
Despite these advantages, CGM use remains at only 8–17% even among motivated patients with type 1 diabetes (24–27). Longstanding barriers have included high cost, concerns about accuracy, alarm fatigue, encumbrances of wearing a mechanical device, uncertainty about applying the data, and the continuing need for SMBG to dose insulin (15,28–30). Additionally, systems to date have been education-intensive, and few clinicians or patients receive systematic training on how to respond to readings, either in the moment or retrospectively (28).

This article examines evolving CGM use in the wake of newly introduced flash CGM (FCGM) technology. This novel category of continuous data capture can add context to A1C, eliminate the need for routine fingerstick monitoring, and provide “teaching moments” amenable to wider patient engagement with CGM-guided diabetes management.

**Flash: A New CGM Device Category**

FCGM is available in two versions, personal and professional. The personal system, FreeStyle Libre (Abbott Diabetes Care, Alameda, Calif.), was approved as a replacement for fingerstick checking by the U.S. Food and Drug Administration (FDA) in September 2017. It affords on-demand observation of real-time and trend data, as well as retrospective review of complete profiles by patients at home or providers in their clinics (31). The earlier approved FreeStyle Libre Pro system (Abbott Diabetes Care, Alameda, Calif.) is referred to as a professional device because patients wear it without being able to see glucose values until their provider uploads the data for review during an office visit. Both versions include a disposable sensor worn on the back of the arm for up to 14 days (32).

Although employing the same chemical glucose oxidase mechanism for glucose measurement as traditional CGM, FCGM uses wired enzyme glucose sensing technology to automatically measure glucose every minute and records readings at 15-minute intervals. It is calibrated at the time of manufacturing and does not require recalibration by patients or clinicians. Additionally, there is no separate transmitter that must be reused with sensors. These features reduce patient burden and enhance ease of use.

**Mechanism of Action**

Personal and professional FCGM provide different perspectives for making therapeutic or behavioral adjustments that affect glycemic control (33–35). Personal FCGM enables patients to make “micro” adjustments through information obtained by scanning, or “flashing,” the glucose sensor with a handheld reader or phone app. The sensor, about the size of two stacked U.S. quarters, can be wiped through clothing for displays of last-minute glucose values, trend arrows, and graphs showing the last 8 hours of data. There is no limit to the number of scans that can be taken over the duration of a sensor use.

For many patients who do not perform SMBG regularly, personal FCGM may afford the first opportunity to observe glucose trending in response to behavior, such as how glucose rises after eating or falls after exercise (36–38). Personal FCGM may also benefit people with insulin-requiring diabetes who rely on continuous data for glucose management but struggle with certain aspects of traditional CGM systems, such as alarms (39). Candidates include people with newly diagnosed diabetes using SMBG with mixed success, as well as those on intensive insulin regimens who do not have impaired awareness of hypoglycemia. Sensor readings can be used for insulin dosing unless glucose is changing rapidly, physical symptoms do not match the values on the reader, or there is a “check blood glucose” alert on the home screen (32). In such situations, confirming sensor values with fingerstick checks is vital because changes in plasma glucose precede changes in interstitial glucose and thus provide an earlier warning of impending hypo- or hyperglycemia.

The professional version of FCGM, unlike the personal version, is designed only for retrospective review of glycemic patterns that inform “macro” adjustments of therapies and behaviors, such as introducing a new medication or changing a patient’s insulin-to-carbohydrate ratio. As previously mentioned, patients have no interaction with the device and cannot see glucose readings during wear (40,41). Data can be retrieved only when the health care professional scans the reader over the sensor and uploads the information to the LibreView desktop software (42). At that point, the clinician or educator, usually together with the patient, can view a single-page report, described later in this article, to quickly identify trouble spots such as postprandial hyperglycemia or explain A1C values that are higher or lower than would be expected based on SMBG readings alone (1).

**Device Selection**

Patients who have had no experience with CGM may most likely rely on their diabetes care team to recommend a particular system (43). Factors to consider when matching CGM technologies to patients’ individual needs include accuracy, convenience, data display formats, cost, and the learning curve for both patients and clinicians (44). Selecting a continuous monitoring device should be a deliberate decision that balances the operational and design differences among systems with the clinical, treatment, and lifestyle needs of the patient. Device attributes for guiding the selection are presented in Table 1 (45–47).

The chief distinction between FCGM and traditional CGM is that FCGM does not passively send continuous data to receivers, phones, or a pump. Instead, users must actively
## Table 1. Features of Selected CGM Systems (45–47)

<table>
<thead>
<tr>
<th>CGM System</th>
<th>Wear Time</th>
<th>Warm-up Time</th>
<th>Calibration Frequency</th>
<th>Accuracy (MARD)</th>
<th>Software and/or Device Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freestyle Libre Pro</td>
<td>Up to 14 days</td>
<td>1 hour</td>
<td>Every 15 minutes</td>
<td>9.4%</td>
<td>Data may be uploaded from reader in provider’s office using Freestyle LibreView software.</td>
</tr>
<tr>
<td>Medtronic iPro 2 Enlite CGM sensor and iPro2 digital recorder</td>
<td>Up to 6 days</td>
<td>1 hour</td>
<td>Every 12 hours</td>
<td>13.6%</td>
<td>Data uploaded from sensor recorder using Medtronic CareLink iPro website.</td>
</tr>
<tr>
<td>Dexcom G4 Platinum professional system</td>
<td>7 days</td>
<td>2 hours</td>
<td>Every 12 hours</td>
<td>13.3%</td>
<td>Data uploaded from sensor using Dexcom STUDIO software.</td>
</tr>
<tr>
<td>Dexcom G6 sensor and transmitter</td>
<td>Up to 10 days</td>
<td>2 hours</td>
<td>Every 5 minutes</td>
<td>9.8% overall and 9.6% in children 6–17 years of age</td>
<td>Stand alone with most Dexcom G5 receivers and compatible with Tandem t:slim X2 insulin pumps.</td>
</tr>
<tr>
<td>Medtronic Enlite sensor and Medtronic MiniLink or Guardian Link transmitter</td>
<td>Up to 6 days</td>
<td>2 hours</td>
<td>Every 12 hours</td>
<td>13.6%</td>
<td>Compatible with Medtronic 530G and 630G insulin pumps.</td>
</tr>
<tr>
<td>Medtronic Guardian Sensor 3 sensor and Guardian Link transmitter</td>
<td>Up to 7 days</td>
<td>2 hours</td>
<td>Every 12 hours</td>
<td>10.6% with 2 calibrations/day, 11.5% with 3 calibrations/day, 12.6% with 4 calibrations/day</td>
<td>Compatible with Medtronic 670G hybrid closed-loop insulin pump system.</td>
</tr>
</tbody>
</table>

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scan their sensor with a reader to see their glucose information displayed. For some patients, repeated scanning could potentially increase engagement with CGM-driven diabetes management (48). FCGM also differs from traditional CGM in that the U.S. version of the device does not feature programmable alerts and alarms that warn patients of current or impending hyper- or hypoglycemia. This aspect offers an acceptable option for patients interested in acquiring continuous data but who are concerned about false or frequent alarms (44). Despite having no alarms, the FCGM system provides a distinct audible tone when alerts to perform fingerstick checks are displayed. This may occur during scanning when glucose is <70 or >240 mg/dL, projected to be <70 or >240 mg/dL, identified as “hi” or “lo” or projected to be “hi” or “lo,” or rapidly changing or when no trend arrow displays. SMBG remains a required action under conditions of rapidly changing glucose, when clinical signs are inconsistent with displayed values, for confirmation of sensor-reported hypoglycemia, and during the 1-hour warm-up period while the device is adjusting to the body (49).

The retail price of FCGM is currently less than that of traditional systems (29). As with the Dexcom G5 system (Dexcom, San Diego, Calif.), FCGM is covered under Medicare for people using insulin who meet eligibility criteria (see below) (50). Finally, FCGM is not affected by acetaminophen interference in contrast with many newer-generation CGM devices (51).

FCGM Accuracy
Patients’ continued use of CGM for diabetes management is directly related to their trust in the accuracy and reliability of data (52–54). Whereas ISO (International Organization for Standardization) 15197 is the accepted accuracy standard for SMBG devices, mean absolute relative difference (MARD) is the most common metric used to assess the performance of CGM systems. This metric shows on average how far away the sensor reading is from a reference blood glucose value across all glucose ranges. MARD values are expressed as a percentage; the lower the percentage value, the more accurate the system.

A 2015 performance study using the aggregate MARD between all sensor values and matched reference values reported good accuracy of FCGM against capillary and venous glucose measurements in a wide range of patients with type 1 or type 2 diabetes (55). Although comparing MARD values among CGM systems is difficult because of a lack of standardization among clinical study methodologies and differences between older and newer generation devices, FDA assessments for product approval indicate comparable accuracy among currently available systems (30,56–58).

CGM Comparison Studies
Head-to-head accuracy comparisons between FCGM and selected newer-generation traditional systems have shown similar accuracy. A recent study by Aberer et al. (59) comparing the FreeStyle Libre with the Dexcom G4 Platinum and Medtronic MiniMed 640G (Medtronic Diabetes, Northridge, Calif.) systems over 12 hours (24 hours after sensor insertion) during mimicked real-life conditions such as meals, exercise, and hypo- and hyperglycemia, found that MARDs overall were 13.2% (±10.9%), 16.8% (±12.3%), and 21.4% (±17.6%), respectively (59). All three sensors performed less accurately during hypoglycemia and best during hyperglycemia, although comparative performance among systems can vary significantly and inexplicably among patients (60). It is therefore important to confirm sensor readings with blood glucose measurements in situations where glucose is rapidly changing or in the hypoglycemic range (<70 mg/dL) or when symptoms are inconsistent with the value on the display screen (49).

To document the performance of the FreeStyle Libre and Dexcom G4 systems during glycemic excursions, Boscari et al. (61) collected accuracy data from 22 adults with type 1 diabetes both at home and during a single 6-hour hospital admission to induce glycemic excursions (early post-meal hyperglycemia followed by a quick decrease in blood glucose). The sensors functioned with comparable accuracy during home use, but the accuracy for both systems decreased in the hypoglycemic range owing to the lag time between plasma and interstitial glucose (62). A follow-up study (63) with the newer-generation Dexcom G5 Mobile sensor (Dexcom, San Diego, Calif.), which like the FreeStyle Libre is approved for making diabetes treatment decisions without the need for confirmatory fingerstick checking, found that both systems performed safely and effectively, with an overall at-home MARD of 12.3% for the FreeStyle Libre and 9.8% for the G5 (P <0.001) (63). However, the MARD increased during hypoglycemia and decreased during hyperglycemia with both systems, again pointing to the need for confirming CGM with SMBG when results are in the hypoglycemic range or inconsistent with symptoms.

Effectiveness and Utility
A consistent finding of all trials of personal CGM is that frequent checking or scanning of the device is essential for successful outcomes (30). Dunn et al. (48) evaluated de-identified data for 50,831 FreeStyle Libre system readers with 279,446 sensors (86.4 million hours of readings and 63.8 million scans). Scan rate per reader was determined and readers were sorted into 20 equal-sized, rank-ordered user groups distinguished by scan frequency. Estimated A1C and other glucose parameters were calculated for each group. Analysis revealed an average scan rate of 16.3 times/day. Estimated A1C levels decreased (P = 0.001) from 8.0% in the group with the lowest scan rate.
showed that the number of hypoglycemic episodes (<72 mg/dL) dropped from 17 in the first 2 weeks of use to 12 in the final 2 weeks. The second study by Ish-Shalom et al. (67) reported similar outcomes in patients with difficult-to-control type 1 (n = 6) or type 2 (n = 25) diabetes. A1C decreased by 1.33 ± 0.29% after 8 weeks, and for those who continued using FCGM after the 12-week study period (n = 27), the change was sustained for 24 weeks (1.21 ± 0.42%, P = 0.009). Questionnaires completed by all 31 participants indicated high satisfaction and desire to continue using the device.

In a large multicenter study of patients with type 2 diabetes (n = 224) on intensive insulin therapy, Haak et al. (68) compared FCGM to standard fingerstick checking. A1C reductions in the FCGM and SMBG groups were comparable overall (−0.29 ± 0.07% in the intervention group vs. −0.31 ± 0.09% in the control group); however, patients <65 years of age in the FCGM group showed significant A1C improvement compared to the control group (−0.53 ± 0.09% vs. −0.20 ± 0.12%, P = 0.0301). Times in hypoglycemia <70 mg/dL and <55 mg/dL were reduced 0.47 ± 0.13 hours/day (43%) and 0.22 ± 0.07 hours/day (53%), respectively, for FCGM versus SMBG users. Nocturnal hypoglycemia <70 mg/dL declined by 54% in the FCGM group (P = 0.0001), and time in hypoglycemia was reduced by 56% (P = 0.0083) for patients ≥65 years of age. Treatment satisfaction was higher in FCGM users, and no device-related serious adverse events were reported.

**Opportunities for Diabetes Education**

To meet the triple aim of providing high-quality patient experience, wider population health, and reduced cost of care, it will be necessary to break the gridlock of suboptimal glycemic control, defined as an A1C >7.0%, for almost 50% of patients diagnosed with diabetes (8,9,69). In part, this will come about by optimizing continuous data to “unmask” specific glucose dynamics behind A1C, which remains the gold standard for estimating the risk of long-term complications and mortality but does not reveal intra- and inter-day variations that may lead to hypoglycemia or postprandial hyperglycemia. Furthermore, the range of average glucose corresponding to an A1C level increases at each successive increment such that the average glucose of an individual with an A1C of 7.0% (95% CI 123–185 mg/dL) could in fact be higher than the average glucose of another with an A1C of 8% (95% CI 147–217 mg/dL) (70). The presence of hemolytic anemia, hemoglobinopathy, and inter-individual variations in red blood cell life span also may falsely raise or lower results. If unrecognized by patients and their health care providers, these limitations of A1C interpretation have the potential to set up a cycle of discouragement and disengagement when targets remain unmet despite patients’ best efforts at daily self-management (71).

**Role of Continuous Glucose Data**

Easier, more intuitive monitoring technologies such as FCGM portend a shift toward wider use of continuous glucose data to better decipher A1C and guide daily adjustments in therapy (2,23,28,30,72). The more often glucose is within the target range the better the A1C is likely to be because these two variables are highly correlated (73). In a 2015 white paper, the American Association of Diabetes Educators advocated CGM for any person with diabetes who is willing to wear a device, regardless of diabetes type, duration, or the age of the patient (43). Main purposes cited by the expert panel were identifying glycemic excursions, validating therapy adjustments, observing and modulating the effects of physical activity and meals on glucose levels, and using trend information to prevent or mitigate issues associated with fluctuation of blood glucose known as glycemic
variability, a strong predictor of hypoglycemia and poor glycemic management (19,74–84).

Glucose metrics that play a role in meeting these goals—including time in range, time in hypoglycemia, time in hyperglycemia, and glucose variability—are best calculated by CGM (30,71). Because FCGM poses comparatively fewer demands than traditional CGM, it offers an opportunity to head off historical obstacles when introducing continuous data, especially to patients who have performed SMBG erratically, unsuccessfully, or not at all (48,66). The rest of this article will describe mechanical and data features of FCGM to help guide patients in using this technology for daily diabetes self-management.

FCGM Mechanics and Initiation
The FreeStyle Libre system consists of a handheld reader and fully disposable sensor designed for upper arm wear (85). The sensor can be applied to the upper arm with one hand by pushing the applicator down firmly on the prepared site (swabbed with alcohol and air dried). The patient initiates the sensor with the reader and can begin obtaining glucose readings after 1 hour. The sensor may be worn for up to 14 days.

Before starting personal FCGM, patients are advised to review all of the product instructions and other educational materials provided with the product and on the manufacturer’s website. Scanning frequently can help patients see how carbohydrate intake, medication, illness, exercise, or stress affect readings. Optimal scanning times can be established, and the clinician or educator can address the issue of over-responding to above-target post-meal CGM readings. Taking rapid-acting insulin at close intervals, commonly referred to as “insulin stacking,” is a well-known cause of hypoglycemia, and correction doses are rarely required within 2 hours of a meal dose.

Direct questioning can help determine whether patients using rapid-acting insulin understand the principles of mealtime and correction dosing. Questions may include: “How much time do you wait to eat after taking your mealtime insulin?”, “How long do you wait between insulin doses to avoid insulin stacking?”, “How often do you check your glucose before bed?”, and “When should you eat a bedtime snack?” Showing patients the Notes feature (a pencil symbol in the upper right corner of the reader home screen) can encourage systematic tracking of insulin, food, and other factors affecting glucose levels. Food and rapid-acting insulin notes, if saved, will be available for review by the clinician or educator.

There are several situations in which sensor readings alone should not be used for making treatment decisions. These include rapidly changing glucose levels indicated by trends arrows pointing straight up or down, sensor readings in the hypoglycemic range, or when symptoms do not match sensor readings. In these instances, confirmatory blood glucose checking should be performed.

Potential skin reactions should also be discussed upon initiation of personal or professional FCGM. In one study by the manufacturer, mild skin irritations were reported in 5 of 48 patients (85). When the sensor is applied, a small filament is inserted, usually painlessly, just under the skin and held in place with an adhesive pad. To avoid irritation, patients may select a different site on the back of the arm when replacing the sensor. There is no need to stretch or pinch the skin. The waterproof sensor can be worn while bathing, showering, swimming in depths <3 feet for under 30 minutes, or exercising.

Considerations for Professional FCGM
Because the FCGM sensor can be worn for up to 14 days without replacement and there is no need for calibration or patient interaction with the device, a professional study affords a detailed view of a patient’s changing glucose levels. The use of professional FCGM will vary from practice to practice depending on size, logistics, and resources. Training one member of the team to specialize in professional FCGM start-ups, application, downloading, and report generation can facilitate workflow. Nonmedical staff can confirm a patient’s insurance status and schedule follow-up. Payer policy and criteria should be confirmed in the event that multiple professional FCGM studies are required to follow a patient’s progress over the course of a given year.

Start-ups and downloads of professional FCGM are usually accomplished in two visits. At the first, the health care professional counsels the patient about the reasons and procedures for using professional FCGM and inserts the sensor. After the 14-day wear period, the patient returns for sensor removal, report downloading, and data interpretation by a qualified health care professional (see Using FCGM With Data Management Tools below).

Reimbursement
As evidence of increasing acceptance of CGM, a Current Procedural Terminology code (95249) was recently designated for procedures surrounding personal use devices worn for at least 72 hours, including sensor placement, calibration (if applicable), patient training, and a printout of the recording. In the case of professional CGM, coverage usually includes sensor application and patient counseling at the first visit, and removal of the sensor and report downloading at the second visit (code 95250). Report interpretation is covered separately (code 95251).

As mentioned previously, Medicare patients with type 1 or type 2 diabetes may be eligible for coverage of nonadjunctive personal CGM if they currently perform at least four fingersticks per day with a home blood
Preload glucose meter; they use insulin, either with multiple daily injections or an insulin pump; and they will need to make frequent adjustments in insulin doses based on CGM readings (50).

Data Visualization With Personal FCGM
Patients using the personal version of FCGM carry the reader to scan the sensor for nearly immediate feedback. The sensor must be scanned at least three times a day, 8 hours apart, for complete data capture. From the home screen, the user may add tags to each scan (e.g., carbohydrates consumed, insulin taken, or exercise performed) or access a glucose history from the past 90 days (see below). It should be noted that when >8 hours pass between scans, the oldest data are overwritten by the most recent data. For this reason, people who wake during the night are encouraged to scan to maintain a continuous report. Additionally, because FCGM does not feature automatic alarms for nocturnal hypoglycemia, checking current sensor glucose and trend arrow data before sleep is recommended.

Patients accessing FCGM data in real-time should be urged to use all of the information on the display screen when making treatment decisions. For many people, however, the trend-arrow feature of FCGM is often the most illuminating (86). The directionality of trend arrows enables users to anticipate future glucose concentrations. This foresight can be used to proactively adjust therapy and prevent hypo- or hyperglycemia (87).

Patients who have no experience with continuous data might elect to incorporate trend arrow–guided decision-making gradually as they gain improved understanding of how circumstances such as meals, physical activity, and insulin on board affect their individual glucose response. Arrows for personal FCGM are defined as:

- ↑ rising quickly (>2 mg/dL/minute);
- → changing slowly (<1 mg/dL/minute);
- ↓ falling (between 1 and 2 mg/dL/minute); and
- ↓ falling quickly (>2 mg/dL/minute).

An example of how trend arrows can help in making treatment decisions is shown in Table 2.

Users seeking additional insight into current glucose values and trends can select the “review history” menu option for 7-, 14-, 30-, and 90-day scroll-through reports of average glucose; time-in-target trends; daily patterns of hypo- and hyperglycemia; low glucose events; and frequency of scanning.

Using FCGM With Data Management Tools
Teaching patients with diabetes the thought process behind continuous glucose data analysis can lead to more strategic and independent glucose management (23,30). To this end, the ambulatory glucose profile (AGP) facilitates interpretation and comprehension of continuous glucose data. FCGM personal and professional devices were among the first to feature the AGP, which is now available with other CGM systems as well (88,89).

AGP software collapses and plots all collected glucose values as if they occurred in a single 24-hour period. The resulting graph has been incorporated in a standardized report, which has been endorsed by the American Association of Clinical Endocrinologists for continuous glucose data reporting (Figure 1). This standardized report begins with a statistical summary showing glucose exposure, glucose variability (coefficient of variation [CV] and standard deviation [SD]), the proportion of glucose values in target range (70–180 mg/dL), the percentage of values above or below target (low, serious low, high, and serious high), and the percentage of time CGM is active. Beneath this summary, the AGP is displayed with five distribution curves drawn from the aggregated glucose readings to provide an at-a-glance picture of a standard 24-hour period. The dark blue line represents the median curve and would be mostly flat under optimal conditions. The curves immediately above and below the median curve (25th and 75th percentiles) depict the daily, nightly, and postprandial excursions for 50% of the aggregated glucose values; a wider span (indicated by blue shading) indicates higher risk for glycemic variability during the associated time period, whereas a narrower span denotes lower risk. The dashed curves represent the 10th and 90th percentiles, showing data above or below 80% of all the data (indicated by gray shading), conveying “occasional excursions.”

AGP With Personal and Professional FCGM
The AGP is a robust tool for educating patients about the effects of food choices, exercise, and medications on glucose levels (90). With minimal training, clinicians can look at the AGP to visualize and prioritize clinical problems and, through an ongoing process of shared decision-making with patients, introduce interventions to increase time in range without increasing hypoglycemia (40,91).

A basic report review should include time in range, as well as patterns of hypoglycemia, hyperglycemia, and prandial glucose excursions (91). Results should be shared face-to-face with patients, if possible, using the report as a decision aid to draw connections between glucose data, medication timing and dosing, eating, and other factors affecting glucose change (Figure 2) (41,92). Information such as medication regimen, meals, exercise, and snacking should be noted directly under the curve on the printed AGP sheet. Once the sheet is marked up, asking the patient to briefly describe what he or she sees as possible reasons for glyce-
TABLE 2. Sample of Trend Arrow–Guided Decision-Making (87)

<table>
<thead>
<tr>
<th>Patient Profile</th>
<th>Scanning Time</th>
<th>What Display Shows</th>
<th>What the Patient Does</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kate has a target of 100 mg/dL and a correction factor of 1:50. This means she would take 1 unit of insulin to lower her glucose about 50 mg/dL.</td>
<td>After breakfast</td>
<td>Kate sees a reading of 250 mg/dL trending rapidly downward. There is also a high glucose message and the “check blood glucose” symbol.</td>
<td>Seeing the symbol, Kate performs a blood glucose check before deciding what to do.</td>
</tr>
<tr>
<td></td>
<td>Before lunch</td>
<td>Kate’s glucose is 250 mg/dL and rising.</td>
<td>Before eating, Kate adds 50 mg/dL to her current reading given the rising trend arrow (250 + 50 = 300). She subtracts her target (300 – 100 = 200) and divides by her correction factor (200 + 50 = 4). Kate takes 4 units of insulin in addition to her calculated meal dose.</td>
</tr>
<tr>
<td></td>
<td>After lunch</td>
<td>Ninety minutes later, Kate’s glucose is the same. The trend arrow and graph show a continued rise.</td>
<td>Kate does not take a correction dose because it is within 2 hours of her meal dose. This could lead to “insulin stacking” and low glucose. The insulin she took for her meal may still be active. Kate decides to wait and scan again later.</td>
</tr>
<tr>
<td></td>
<td>Before dinner</td>
<td>Kate’s current glucose is 250 mg/dL. The trend arrow and graph indicate her glucose is going down.</td>
<td>Kate asks herself what might be causing her glucose to go down and what she might do to prevent a low glucose, deciding to take less insulin before her meal. She subtracts 50 mg/dL from the current value because of the falling trend arrow (250 – 50 = 200) and then subtracts her target of 100 mg/dL (200 – 100 = 100). She divides this by her correction factor (100 + 50 = 2). Kate takes 2 units of insulin in addition to her calculated meal dose.</td>
</tr>
</tbody>
</table>

**FIGURE 1.** AGP report. The AGP is a visual report that collapses all glucose readings from several days or weeks as if they occurred in a single 24-hour period, making it easier to visualize glycemic patterns. The median (dark blue line) shows the middle of the data; the 25th and 75th percentile curves (blue shading), or interquartile range, represent 50% of all the data; the 10th and 90th percentile curves (gray shading) signify 80% of all data. The 10th and 90th percentiles showing data above or below 80% of all the data (indicated by edges of gray shading) convey “occasional excursions.”
mic excursions often generates useful insights.

Actions should be prioritized according to patterns of hypoglycemia, hyperglycemia, and glucose variability. For example, if the 10% lower line is touching the 70 mg/dL target line—a signal that, at that time of day, 10% of all glucose levels are <70 mg/dL—steps should be taken to reduce hypoglycemia; if the light blue area is very wide, conveying high glycemic variability, factors that may contribute to glucose fluctuations, such as the timing or amount of food intake, timing or dosing of medications, or patterns of exercise, should be considered for each time period.

Questions should include:
- Are pre-meal glucose levels at target?
- Do glucose levels rise or fall dramatically after eating?
- Do upward or downward fluctuations occur overnight?
- Is there an explanation for glucose variability?

**FIGURE 2.** AGP report notes for a 24-year-old woman who has had type 1 diabetes for 2 years and is beginning FCGM. Her A1C is 7.8%. A) Statistical summary shows high average glucose and high CV (>33%) with 51% above target. B) There is no specific pattern, with wide variability all day. Review of individual days shows the following issues. C) Fasting hypoglycemia occurs from too much correction dose at bedtime; miscalculated carbohydrate intake at breakfast (thought it was 15 g but was actually 35 g) resulted in noontime hyperglycemia that was not treated; correction dose insulin was not provided until 3:00 p.m., and appropriate prandial insulin was provided at 4:00 p.m. D) The patient missed 18 units of glargine the night before; mealtime and correction doses did not lower glucose normally without basal insulin. E) Patient received a good basal insulin dose (18 units glargine), keeping glucose flat overnight, but her 8:00 a.m. coffee resulted in a spike; she needs to give prandial insulin even for black coffee.
• What typically happens with exercise?
• Are patterns different on weekends?
• Are there circumstances such as stress or unusual travel that require special attention?
• Is A1C consistent with daily glucose management?

At the end of the consultation, the key lessons of the AGP analysis should be summarized so that the patient comes away with one or two achievable recommendations (91). In all cases, the first priority should be treating hypoglycemia, indicated by the blue curves touching the 70 mg/dL line or lower. Timely follow-up is important to determine next steps, with a shorter interim for therapy adjustment than for lifestyle change recommendations.

Outlook and Case Example
Educators have an important role to play in encouraging wider acceptance of CGM, used either intermittently or for everyday diabetes management. Success will depend in part on dispelling long-held preconceptions based on traditional devices (44). Using both FCGM and the AGP, educators can more easily integrate retrospective continuous data analysis into busy practice settings and support patients so that they gain confidence in their ability to translate on-demand continuous data into appropriate action. FCGM, as an affordable option embraced by the international patient community with minimal training, may point the way to feasibility of CGM for more patients in the United States (40). Figure 3 provides a case example of an individual with type 2 diabetes who increased time in range and reduced A1C based on FCGM guidance alone.

Summary and Conclusion
Clinical trial and empirical evidence attest that continuous glucose data analysis, used as an adjunct to A1C, provides more instructive and actionable information than SMBG. Although CGM is recognized as a robust tool for refining diabetes management, cost and reimbursement issues, scant resources to learn or implement new technology, and human factors of usability have hampered its wider use (15,28).

FCGM offers an easy, intuitive, and flexible option for appropriate patients with type 1 or type 2 diabetes (64,68). Candidates include people with newly diagnosed diabetes using SMBG with mixed success, as well as those on intensive insulin regimens who do not have impaired awareness of hypoglycemia.

Real-world data associate higher rates of FCGM scanning with improved glycemic markers, including increased time in range and reduced time in hyper- and hypoglycemia, and further evaluation is expected to build momentum toward incorporating continuous data strategies into daily self-care (48). Alternatively, professional FCGM offers a low-cost and nearly burden-free opportunity to understand patterns of high and low glucose that can be addressed in a timely fashion.

Duality of Interest
I.B.H. has received research support from Medtronic Diabetes and consulting income from Abbott Diabetes Care, Becton Dickinson, Bigfoot, and Roche. E.N. has received honoraria for participating on the speakers boards of Astra Zeneca and Janssen Pharmaceuticals and consulting income from Senseonics. No other potential

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FIGURE 3. A) AGP profile and B) follow-up summary report of a 60-year-old man with type 2 diabetes. He was diagnosed with diabetes 3 years ago. His physician prescribed metformin and canagliflozin. With an A1C usually between 6.5 and 7.5%, and 42% of values within the hyperglycemic range as of August 2017, he began using personal FCGM the following December. His medication therapy remained the same. When he returned to the clinic in April 2018, 97% of his glucose values were within target range, and his estimated A1C was 5.8%. He attributed this improvement to controlling his rice intake based on feedback from FCGM.

- What typically happens with exercise?
- Are patterns different on weekends?
- Are there circumstances such as stress or unusual travel that require special attention?
- Is A1C consistent with daily glucose management?

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References
1. Rubinow KB, Hirsch IB. Reexamining Funding conflicts of interest relevant to this article were reported.
35. Close K, Brown A. Abbott’s FreeStyle Libre transforming glucose monitoring through utter simplicity, fingersticks aside! Diatribe January 9, 2015. Available from diatribe.org/abbott-freestyle-libre-
transforming glucose-monitoring through utter-simplicity—fingersticks. Accessed 3 March 2018


54. Clarke W, Kovatchev B. Statistical tools to analyze continuous glucose monitor data. Diabetes Technol Ther 2009;11(Suppl. 1):S45–S54


73. Bergenstal RM. Glycemic variability and diabetes complications: does it matter? Simply put, there are better glycemic markers! Diabetes Care 2015;38:1615–1621
74. Hirsch IB, Brownlee M. Beyond hemoglobin Alc: need for additional markers of risk for diabetic microvascular complications. JAMA 2010;303:2291–2292
80. Qu Y, Jacober SJ, Zhang Q, et al. Rate of hypoglycemia in insulin-treated patients with type 2 diabetes can be predicted from glycemic variability data. Diabetes Technol Ther 2012;14:1008–1012