

Using Flash Continuous Glucose Monitoring in Primary Practice

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■ **IN BRIEF** Obstacles to realizing the clinical benefits of continuous glucose monitoring (CGM) for daily diabetes management are being overcome with more affordable, user-friendly technologies. This article describes a novel category of CGM known as “flash” that may allow more routine use of continuous data for greater numbers of patients treated in primary care.

Modern diabetes management came of age in the late 20th century, when major trials showed the benefit of close glucose control, A1C became the established standard of care, and smaller and more accurate glucose meters enabled regular self-monitoring of blood glucose (SMBG). Yet, even as A1C and SMBG remain cornerstones of diabetes care, the emergence of metrics that could more predictably guide daily glucose levels, together with recent advances in technology, have fueled demand for a fuller characterization of glycemia, including the duration, direction, magnitude, and frequency of glucose fluctuations (1,2). In this milieu, a small subset of patients, mostly with type 1 diabetes treated in specialty clinics, have relied on continuous glucose monitoring (CGM) to better observe real-time glucose values, trend information, and potentially harmful high and low glucose swings known as glycemic variability.

Studies conducted with newer-generation CGM devices affirm the clinical benefit of accessing continuous data regularly; specifically, subjects experienced improved A1C, decreased time spent in hyper- and hypoglycemia, and a lower incidence of severe hypoglycemia (3–14). Nevertheless, overall adoption of

CGM remains at only 8–17%, even among motivated patients using insulin (15–18). Longstanding barriers include cost, concerns about accuracy, alarm fatigue, encumbrances of device wear, lack of standardized data reports, and uncertainty about applying the data to inform treatment decisions (7,19,20). This article revisits these obstacles in the wake of newly introduced flash CGM (FCGM) technology, a novel category of continuous data capture that can be practically implemented in primary care to add context to A1C and provide more actionable information than SMBG alone.

Flash: A New CGM Device Category

Unlike SMBG, which produces a static picture of blood glucose at a single point in time, 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. In 2016, the FreeStyle Libre Pro (Abbott Diabetes Care, Alameda, Calif.) was introduced in the United States, representing a new category of CGM called “flash” or “intermittently scanned” CGM (21). Although employing the same chemical glucose

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oxidase mechanism for glucose measurement as traditional CGM, FCGM uses osmium-based wired enzyme glucose-sensing technology to automatically measure glucose every minute and stores readings at 15-minute intervals. Because this technology does not produce as much drift from blood glucose values as earlier sensors and responds more stably over a longer period, it can be calibrated at the time of manufacturing and does not require recalibration by the patient or clinician. This reduces the burden of calibration for the patient and increases ease of use.

FCGM is now available in two versions. The personal system, FreeStyle Libre, which was approved as a replacement for fingerstick testing by the U.S. Food and Drug Administration (FDA) in September 2017, 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 (22). The earlier-approved FreeStyle Libre Pro system is referred to as a professional device because it is owned by the clinic, and patients wear a sensor temporarily 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 (23,24).

As of this writing, these FreeStyle Libre systems are the only FCGM devices approved by the FDA (24,25). The personal system, introduced abroad in 2014 and obtainable without a prescription in some countries, has generated high interest among patients through international forums and has focused attention on the utility of this device category in the United States, where both the personal and professional systems are available for use separately or in tandem (26,27).

Mechanism of Action

Personal and professional FCGM systems provide different routes for

making therapeutic or behavioral adjustments that affect glucose control. Personal FCGM enables patients to make “fast” adjustments through on-demand readings obtained by scanning, or “flashing,” the glucose sensor with a handheld reader. Patients can look at the display screen to view last-minute values, trend arrows, and graphs showing data from the previous 8 hours. In the case of people with type 2 diabetes who do not perform SMBG routinely, personal FCGM may afford the first opportunity to visualize glucose trending in response to behavior, such as how glucose rises after eating or falls in response to physical activity (28–30). Additionally, personal FCGM may benefit people with type 1 diabetes who are accustomed to using real-time data for diabetes management but find alarms bothersome (31). It may also benefit those with type 1 diabetes who have not used CGM in the past and are testing their blood glucose infrequently. The immediate availability of real-time data can help this population understand for the first time the granularity of how different foods, exercise, and stress affect their diabetes control. On-demand readings can be used for insulin dosing when glucose is not changing rapidly, physical symptoms match the values on the reader, and there is no “check blood glucose symbol” on the home screen (22,32).

The professional version of FCGM, unlike the personal version, is designed exclusively for retrospective review of continuous data patterns, facilitating “slower,” more deliberative adjustment of therapies and behaviors, such as changing insulin-to-carbohydrate ratios. As previously mentioned, patients have no interaction with the device and cannot see glucose readings during wear (33,34). Data can be retrieved only when the health care professional scans the reader over the sensor and uploads the data to the LibreView desktop software (35). At that point, the provider, usually together with the patient, can view a

single-page report, described later in this article, to quickly identify trouble spots such as nocturnal hypoglycemia or decipher A1C values that are higher or lower than would be expected based on SMBG readings alone (36).

Differences Among Currently Available CGM Systems

Addressing known issues affecting CGM uptake—namely, cost, human factors such as wearability and convenience, data display formats, and confidence in using the data for therapy decisions—will be important to encourage the routine use of continuous data (19). Table 1 compares the features of selected CGM systems available in the United States (24,32,37). Although both flash and traditional CGM systems allow users to monitor interstitial glucose levels, there are distinct differences between these technologies that require consideration when evaluating their suitability for individual patients (38).

At the most fundamental level, FCGM does not passively display data continuously (rather, the user must scan the sensor with the reader to see glucose information displayed), nor does it trigger an alarm to alert users to potential hypo- or hyperglycemia. However, a distinct audible tone is generated if a scan occurs when glucose is <70 or >240 mg/dL, projected to be <70 or >240 mg/dL, the display reads “hi” or “lo” (indicating a reading outside of the measuring range of 40–500 mg/dL) or is projected to read “hi” or “lo,” glucose is rapidly changing, or no trend arrow displays. Traditional CGM devices, by contrast, send data continuously to receivers, phones, and/or insulin pumps and feature programmable alerts and alarms that warn patients of current and impending hyper- or hypoglycemia.

Although fingerstick calibration is unnecessary with FCGM, as with latest-generation traditional CGM systems, blood glucose testing is still mandatory in situations of rapidly changing glucose, when clinical

TABLE 1. Comparison of Selected CGM Systems (24,32,37)

System Type	Brand Name	Wear Time	Warm-Up Time	Calibration	Frequency of Glucose Readings	Accuracy (MARD)	Software and/or Device Compatibility
Professional CGM	Freestyle Libre Pro system	Up to 14 days	1 hour	None	Every 15 minutes	12.3%	Data scanned from sensor using Freestyle Libre Pro reader in office
	Medtronic iPro 2 Enlite CGM sensor and iPro2 digital recorder	Up to 6 days	1 hour	None, but at least one blood glucose entry every 12 hours is required for system uploads	Every 5 minutes	13.6%	Data uploaded from sensor recorder using Medtronic CareLink iPro website
	Dexcom G4 Platinum Professional Continuous Monitoring System	7 days	2 hours	Every 12 hours after the 2-hour start-up calibration	Every 5 minutes	13.3%	Data uploaded from sensor using Dexcom STUDIO software
Personal CGM	Freestyle Libre system	Up to 14 days	1 hour	None	Available every minute; automatically records every 15 minutes	9.4%	Data may be uploaded from reader in health care provider's office using Freestyle Libre View software
	Dexcom Platinum G4/G5 sensor with G4 Platinum transmitter	Up to 7 days	2 hours	Every 12 hours	Every 5 minutes	9% when used with most current Dexcom software	Stand alone with Dexcom G4 receiver and compatible with Animas Vibe and Tandem t:slim insulin pumps
	Dexcom Platinum G4/G5 sensor with G5 Platinum transmitter	Up to 7 days	2 hours	Every 12 hours	Every 5 minutes	9% when used with most current Dexcom software	Stand alone with Dexcom G5 receiver, web-based Clarity software (G5 only), and most Apple and Android products and compatible with Tandem t:slim X2 insulin pump
	Dexcom G6 sensor and transmitter	Up to 10 days	2 hours	None	Every 5 minutes	9.8% overall and 9.6% in children 6–17 years of age	Stand alone with most Dexcom G5 receivers and G6 receiver and most Apple and Android products; both G5 and G6 download to web-based Clarity software
	Medtronic Enlite Sensor and MiniLink or Guardian Link transmitter	Up to 6 days	2 hours	Every 12 hours	Every 5 minutes	13.6%	Compatible with Medtronic 530G and 630G insulin pumps
	Medtronic Guardian Sensor 3 sensor and Guardian Link 3 transmitter	Up to 7 days	2 hours	Every 12 hours	Every 5 minutes	10.6% with 2 calibrations/day; 9.6% with 3–4 calibrations/day	Compatible with Medtronic 670G hybrid closed-loop insulin pump system

signs are inconsistent with displayed values, for confirmation of sensor-reported hypoglycemia, and during the system warm-up period (39–41).

The retail price of FCGM systems is currently less than traditional CGM systems, addressing the significant barrier of cost (20). As with the Dexcom G5 system (Dexcom, San Diego, Calif.), FCGM is covered under Medicare for beneficiaries with diabetes who use intensive insulin therapy (three or more injections per day), perform fingerstick glucose testing four times per day, and require frequent adjustment of therapy.

Finally, neither FCGM nor the newer Dexcom G6 (Dexcom, San Diego, Calif.) is affected by acetaminophen interference, which has been a historical barrier to CGM use for some patients (42).

FCGM Accuracy

Patients' continued use of CGM for diabetes management is directly related to their trust in the accuracy and reliability of the data it provides (43,44). The most common numerical metric for assessing CGM accuracy is the aggregate mean absolute relative difference (MARD) between all CGM values and matched reference values. The FDA uses MARD in determining approval of new devices (45). A low MARD percentage indicates that CGM results are closer to the reference readings, whereas a higher MARD percentage indicates larger discrepancies.

A 2015 performance study confirmed the accuracy of FCGM against capillary and venous glucose testing in a wide range of individuals with type 1 or type 2 diabetes (46). Although comparing MARD values among CGM systems is difficult due to a lack of standardization among clinical study methodologies, FDA assessments for product approval indicate comparable accuracy among currently available systems (21,47–49). It is important to confirm sensor readings with blood glucose measurements in situations in which glucose is rapidly

changing or is in the hypoglycemic range (<70 mg/dL) or when symptoms do not match sensor glucose values (39).

CGM Comparison Studies

Recent head-to-head accuracy comparisons between FCGM and selected newer-generation traditional systems indicate similar accuracy. A recent study by Aberer et al. (50) comparing the FreeStyle Libre to the Dexcom G4 Platinum (Dexcom, San Diego, Calif.) and Medtronic Mini-Med 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 in the entire glycemic range were 13.2% ($\pm 10.9\%$), 16.8% ($\pm 12.3\%$), and 21.4% ($\pm 17.6\%$) for the systems, respectively. All three sensors performed less accurately during hypoglycemia and best during hyperglycemia, with the FreeStyle Libre exhibiting the lowest MARD across all glycemic ranges. An earlier study by Bonora et al. (51) comparing only the FreeStyle Libre and Dexcom G4 Platinum sensors to SMBG for up to 14 days showed good overall agreement between the two systems, although the comparative performance varied significantly and inexplicably among individual patients, all eight of whom had type 1 diabetes.

To better understand the performance of the FreeStyle Libre and Dexcom G4 systems during glycemic excursions, Boscari et al. (52) 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). Both sensors functioned with similar accuracy during home use, although the accuracy of both significantly worsened during the excursions due to lag time between plasma and interstitial glucose (52,53). A follow-up study with the new-

er-generation Dexcom G5 Mobile sensor, which, like the FreeStyle Libre, is approved for making diabetes treatment decisions without the need for confirmatory fingerstick testing, found that both systems performed safely and effectively, with an overall at-home MARD of 12.3% (range 5.6–21.4%) for the FreeStyle Libre and 9.8% (range 4.7–18.0%) for the G5 ($P < 0.001$) (54). 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

Efficacy studies of FCGM evaluating glucose control, hypoglycemia, and quality of life substantiate its utility. The IMPACT study by Bolinder et al. (55) comparing FCGM to SMBG in European adults with well-controlled type 1 diabetes ($n = 239$) and awareness of hypoglycemia showed that participants in the FCGM group spent 38% less time in the hypoglycemic range (<70 mg/dL). This reduction was accomplished with no change in total daily insulin dose or deterioration of A1C. Glucose time in range significantly increased in the intervention group; high scores for treatment satisfaction and a scan rate averaging 15 times/day indicated good acceptance of FCGM.

The relationship between glucose control and scanning frequency was explored by Dunn et al. (56), who evaluated de-identified and uploaded data for $>50,000$ FreeStyle Libre system readers with 279,446 sensors (86.4 million monitoring hours by 63.8 million scans). Users scanned an average of 16.3 times/day. When divided into 20 equal-sized groups by scan rate ($n = 2,542$ each), estimated A1C levels decreased ($P = 0.001$) from 8.0% in the group with the lowest scan rate (4.4 times/day) to 6.7% for those with the highest scan rate (48 times/day). Because these

were estimated A1C levels from the downloads and measured A1C levels were not reported, there were no pre-FCGM data to report. Scan rates also correlated with hypoglycemia rates; as scan rates increased, hypoglycemia rates below 70, 55, and 45 mg/dL decreased by 15, 40, and 49%, respectively (all $P < 0.001$).

Two recent single-arm studies without control groups demonstrated significant A1C improvement after FCGM initiation. In the first, Dover et al. (57) prospectively evaluated FCGM in 25 participants with type 1 diabetes and reported improved glucose control, fewer episodes of hypoglycemia, and improved quality of life. The mean A1C fell from $8.0 \pm 0.14\%$ to $7.5 \pm 0.14\%$ (-0.48% , $P = 0.001$) after 16 weeks of FCGM. The number of people with an A1C of $\leq 7.5\%$ more than doubled after FCGM use. Those with a baseline $>7.5\%$ experienced a greater reduction than participants with A1C $<7.5\%$ at baseline ($-0.59 \pm 0.15\%$ vs. $-0.2 \pm 0.11\%$, $P = 0.005$). FCGM data 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. Significant improvements were observed in the Diabetes Distress Scale mean score and other quality-of-life indicators. FCGM use was also associated with a significant increase in the administration of prandial insulin in advance of meals according to recommendation versus immediately before or after.

Ish-Shalom et al. (58) reported similar outcomes in the second single-arm study, which enrolled 31 patients with difficult-to-control type 1 ($n = 6$) or type 2 ($n = 25$) diabetes. Patients treated with a multiple daily injection regimen whose A1C was $\geq 7.5\%$ (baseline average $8.9 \pm 0.26\%$) used FCGM to achieve target glucose levels and minimize hypoglycemia. A1C decreased by $1.33 \pm 0.29\%$ 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 ($1.21 \pm 0.42\%$, $P = 0.009$). Questionnaires completed

by all 31 participants indicated high satisfaction and desire to continue using the device. This finding is in keeping with a study by Olafsdottir et al. (59), in which 58 adults with type 1 diabetes rated their FCGM experience as positive, with average scores from 8.22 to 9.8 on a scale of 0 to 10.

In a large multicenter study of patients with insulin-requiring type 2 diabetes, Haak et al. (60) compared FCGM to standard fingerstick glucose measurement in 224 participants. Baseline A1C was 8.74% in the FCGM group and 8.8% in the SMBG group. A1C reduction in both groups was comparable overall ($-0.29 \pm 0.07\%$ vs. $-0.31 \pm 0.09\%$, respectively). However, patients <65 years of age in the FCGM group showed significant A1C improvement compared to the control group ($-0.53 \pm 0.09\%$ vs. $-0.20 \pm 0.12\%$, $P = 0.0301$). Time in hypoglycemia <70 and <55 mg/dL was reduced by 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 decreased 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 CGM in Primary Practices

Despite a decade-long surge in new diabetes medications and technologies, the proportion of people achieving a target A1C $<7.0\%$ remains about 50% (61). Examination of two waves of data from a subset of respondents to the National Health and Nutrition Examination Survey ($n = 2,677$) found a slight downward trend in the achievement of target A1C, from 52.2% during the period of 2007–2010 to 50.9% during the period of 2011–2014 (62). Explanations for this impasse are largely speculative but include increasingly complex therapies, higher out-of-pocket costs,

a shift from undiagnosed diabetes to diagnosed diabetes among individuals predisposed to poor glycemic control, and the open question of whether A1C is the best marker of glycemic control for individual patients (62–65).

Limitations of A1C

Although A1C, which measures mean glycemic exposure during the 2–3 months before testing, remains the gold standard for assessing population health and complications risk over time, the assay has limitations that may go unrecognized in clinical practice. Accuracy can be affected by the presence of hemoglobinopathies, inter-individual glycation characteristics, and conditions that affect red blood cell life span (66). Moreover, the range of mean glucose concentrations and glucose profiles correlated with a given A1C level is wider than appreciated. The A1c-Derived Average Glucose study, which assessed the relationship between A1C and glucose levels in ~ 500 adults without any known factors affecting A1C, revealed that the 95% predictive interval, or range of corresponding average glucose, increased at each successive A1C level (64,67). Thus, the average glucose of an individual with an A1C of 7% (95% CI 123–185 mg/dL) could in reality be higher than the average glucose of another with an A1C of 8% (95% CI 147–217 mg/dL). Moreover, an average glucose of 154 mg/dL, corresponding to an A1C of 7.0%, can be achieved by blood glucose fluctuating between 120 and 188 mg/dL or between 50 and 258 mg/dL, each requiring markedly different treatment than the other.

A further limitation of A1C is that it does not distinguish people who reach target average glucose levels with frequent glycemic excursions, known as glycemic variability, from those who do so more evenly (68). The role of glycemic variability as an independent risk factor for long-term diabetes complications, including cardiovascular disease, neuropathy, and

retinopathy, is the subject of ongoing study (69–77). More immediately, glycemic variability is a strong predictor of hypoglycemia and poor glycemic control regardless of baseline A1C, with associated decrements in cognitive function and quality of life (11,76,78–80).

The Tipping Point?

Readily accessible and affordable CGM has been a promising, although elusive, pathway toward deciphering the meaning of A1C for individual patients. Calls for more personalized diabetes care by professional diabetes organizations, combined with technological innovations such as FCGM, suggest an imminent tipping point toward wider use of continuous data (19,21,64). According to the American Association of Clinical Endocrinologists (AACE) 2010 consensus statement on CGM (80), obvious candidates for CGM are people with type 1 diabetes who have hypoglycemia or hypoglycemia unawareness or who have an A1C above target. In 2016, AACE refined these criteria, specifying patients >65 years of age with type 1 diabetes and comorbidities or at risk for severe hypoglycemia, as well as those with chronic diabetic kidney disease (81). In 2016, AACE also added insulin-treated patients with type 2 diabetes and pregnant women with diabetes as eligible candidates, with the provision that studies will be required to determine cost-effectiveness (2).

In a 2015 white paper (82), the American Association of Diabetes Educators (AADE) advocated CGM for any person with diabetes who is willing to wear a device, regardless of diabetes type, duration, or patient age. Key purposes cited by the AADE 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 glycemic variability. To these ends, the American

Diabetes Association stressed the need for education, training, and support when prescribing CGM, particularly with respect to data interpretation (1).

Meeting these evolving standards will depend in part on minimizing the burden of learning different approaches to different CGM systems and re-thinking assumptions that continuous data analysis is appropriate only for patients on intensive insulin therapy. Because FCGM poses comparatively few demands on users, it offers an opportunity to address common impediments, such as cost, frequent alarms, and the complexity of data interpretation, when considering CGM options for patients who have monitored blood glucose erratically, unsuccessfully, or not at all (27,39,57,83).

Using FCGM With Data Management Tools

Many researchers, clinicians, and patients advocate a standardized glucose report, similar to an electrocardiogram, as fundamental to wider acceptance of CGM (21). The ambulatory glucose profile (AGP) report developed by Mazze et al. (84) reflects the ongoing effort to create a universal template for more predictable viewing, easier comprehension, and ready interpretation of glucose data. FCGM personal and professional devices were among the first to feature the AGP, which is gradually being incorporated into other CGM systems (84,85).

AGP-enabled software collapses and plots all collected glucose values as if they occurred in a single 24-hour period. The downloadable report, which can be accessed in modular fashion, begins with a statistical summary showing glucose exposure, glucose variability (coefficient of variation [CV] and SD), the proportion of glucose values in the target range (70–180 mg/dL), the percentage of values above or below target (low, serious low, high, or serious high), and the percentage of time CGM is active. Many clinicians are familiar with SD (square root of the variance) as a met-

ric for glucose variability because this has been provided on glucose downloads for >20 years. The problem with SD is that it is not normalized to the mean. CV, on the other hand, is the SD/mean, meaning it is now possible to compare glucose variability values no matter what the mean is.

Beneath this summary, five distribution curves drawn from the aggregated glucose readings provide an at-a-glance picture of a standard day. In the AGP used with FCGM, a 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 spans for 50% of the aggregated glucose values; a wider span (indicated by blue shading) indicates high risk for glycemic variability during the associated time period, whereas a narrower span denotes lower risk. 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 Professional FCGM

Professional FCGM studies can be an effective tool for educating patients about the effects of food choices, exercise, and medications on blood glucose levels and actions that can be taken to improve glycemic control moving forward (86). Because the FCGM sensor can be worn for a full 2-week period without replacement and there is no need for calibration or patient interaction with the device, a professional study affords an uninterrupted and representative view of a patient’s changing glucose levels. For optimum results, patients should be instructed to keep a detailed log of their meals and activities that can be reviewed with the AGP. With minimal training, clinicians can look at the AGP dashboard to visualize and prioritize clinical problems and, through an ongoing process of shared decision-making with patients, introduce

interventions to increase glucose time in range without increasing hypoglycemia (33,87). Use of the standardized report also enhances workflow and communication by allowing the entire diabetes care team to work from the same visualization.

A basic review of the AGP report should include time in range, as well as patterns of hypoglycemia, hyperglycemia, and prandial glucose excursions (87). It is ideal to review results and recommendations face-to-face with patients, using the report as a decision aid to illustrate relationships among glucose data, medication, and other therapeutic or behavioral interventions (34,88). After confirming adequate data (at least 10 days of wear) (37), a patient's daily habits should be reviewed. Asking for 3 days of detailed information before the scheduled appointment and, if possible, a record of unusual days can facilitate this process. Information such as medication regimen, exercise, meals, and/or snacking should be marked directly under the curve on the printed-out AGP sheet. Once the sheet is marked up, asking the patient to briefly describe what he or she sees as possible reasons for glycemic excursions often elicits honest and helpful insights. The daily thumbnail profiles can add further dimension, particularly when regular activities vary from day to day.

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—indicating that, at that time of day, 10% of all glucose levels are <70 mg/dL—adjustments should be made to reduce hypoglycemia. Alternatively, if the light blue area is very wide—conveying high glycemic variability—the patient should be asked if he or she can do anything to adjust factors such as the timing or amount of food intake, timing or dosing of medications, or patterns of exercise that may exacerbate glucose fluctuations. Each time period should

be examined in turn, keeping in mind the following questions:

- Do glucose levels start at target before eating?
- After eating, do glucose levels regularly fluctuate upward or downward?
- Do upward or downward fluctuations happen overnight?
- What normally happens with physical activity?
- Are weekend patterns different?
- Is there an explanation for glucose variability?
- Is there a special situation, such as stress or illness, that requires greater focus?
- Does A1C reflect daily glucose control?






At the end of the consultation, the key messages of the AGP analysis should be summarized so that the patient comes away with one or two specific recommendations (87). In all cases, the first priority should be treating hypoglycemia, denoted by the blue curves touching the 70 mg/dL line or lower. A follow-up appointment should be scheduled within 3–6 months (sooner for pharmacologic intervention than for lifestyle change) to assess progress. Insertion and removal of the FCGM sensor, as well as interpretation of the report by a physician, nurse practitioner, or physician's assistant, are reimbursable by most insurance plans using existing codes. (Readers are referred to AACE's "New and Updated Codes for Continuous Glucose Monitoring (CGM) in 2018" [89]).

Data Visualization Personal FCGM

Unlike professional FCGM, the personal version provides users with observable feedback after the reader is swiped over the sensor. The sensor, about the size of two stacked U.S. quarters, can be swiped through clothing for displays of real-time glucose values, trend arrows, and graphs showing the past 8 hours of data. The sensor should be scanned at least three times per day, 8 hours apart, for

complete data capture, but there is no limit to the number of scans that can be made. From the home screen, users may also add tags to each scan—e.g., carbohydrate intake, insulin, or exercise—or access a glucose history from the past 90 days.



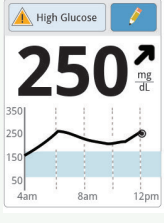
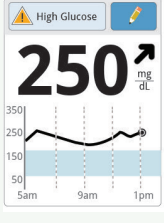
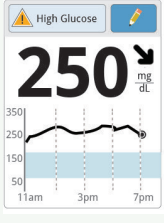
For people accustomed to SMBG, the trend-arrow feature of FCGM is often the most educational, although patients should be advised to use all of the information on the screen when deciding what to do. Arrows for personal FCGM are defined as:

-  rising quickly (>2 mg/dL/minute)
-  rising (1–2 mg/dL/minute)
-  changing slowly (<1 mg/dL/minute)
-  falling (1–2 mg/dL/minute)
-  falling quickly (>2 mg/dL/minute)

Patients who have no experience with continuous data should adopt the use of trend arrows gradually as they gain better understanding of how circumstances such as meals, physical activity, and insulin on board (insulin remaining active from the most recent dose) affect their particular glucose response (90). An example of how trend arrows can help in making treatment decisions is shown in Table 2. Notably, if glucose is rapidly changing, <70 mg/dL, or projected to be <70 mg/dL, or if there is no glucose number or trend arrow, a "check blood glucose" symbol will appear on the home screen, signaling the need to perform SMBG before taking action.

Users who wish to delve deeper than current glucose values and trends can select the "review history" menu option for 7-, 14-, 30-, and 90-day scroll-through reports showing average glucose, time-in-target trends, daily patterns of hypo- and hyperglycemia, low glucose events, and how often the sensor has been scanned. As with the AGP report, these data can be uploaded from the reader in various formats for analysis by patients at

TABLE 2. Sample of Trend Arrow–Guided Decision-Making (90)

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

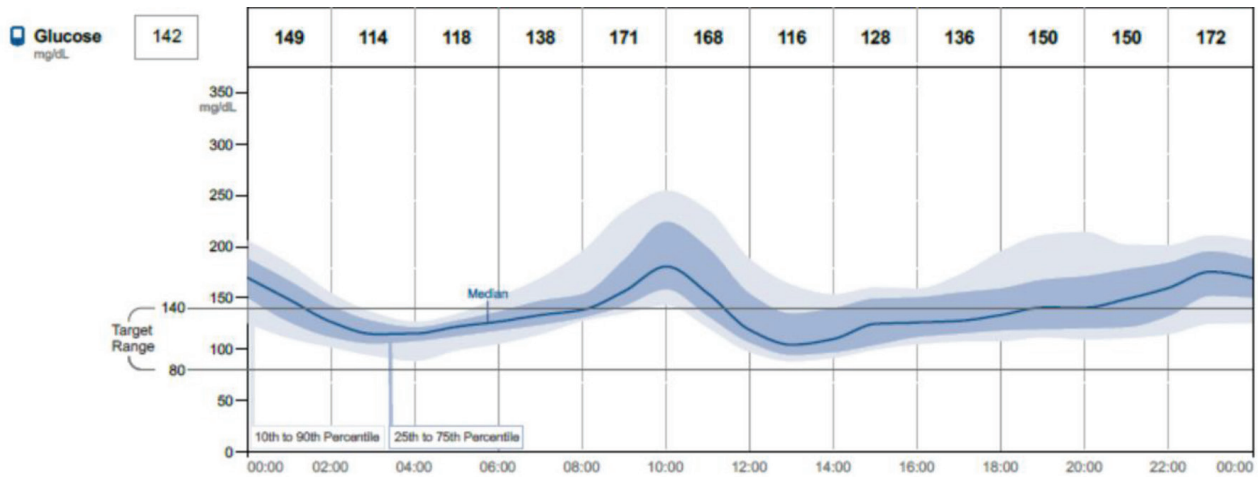
home or with a health care provider during a clinic visit.

Outlook and Case Example

Encouraging clinician and patient acceptance of CGM, used either intermittently or for everyday diabetes management, will depend largely

on dispelling historical biases (38). Measures to overcome real or perceived obstacles, particularly in primary care, must address the following questions: How much time and training will be required to teach patients the basics of device operation? What kind of support will be

necessary for patients to use real-time data effectively? What resources and workflow adaptations will be needed to facilitate retrospective data analysis (by patients and clinicians together or individually)? How well will continuous data translate into actions and behaviors that realize patient-centered



April, 2018

Summary

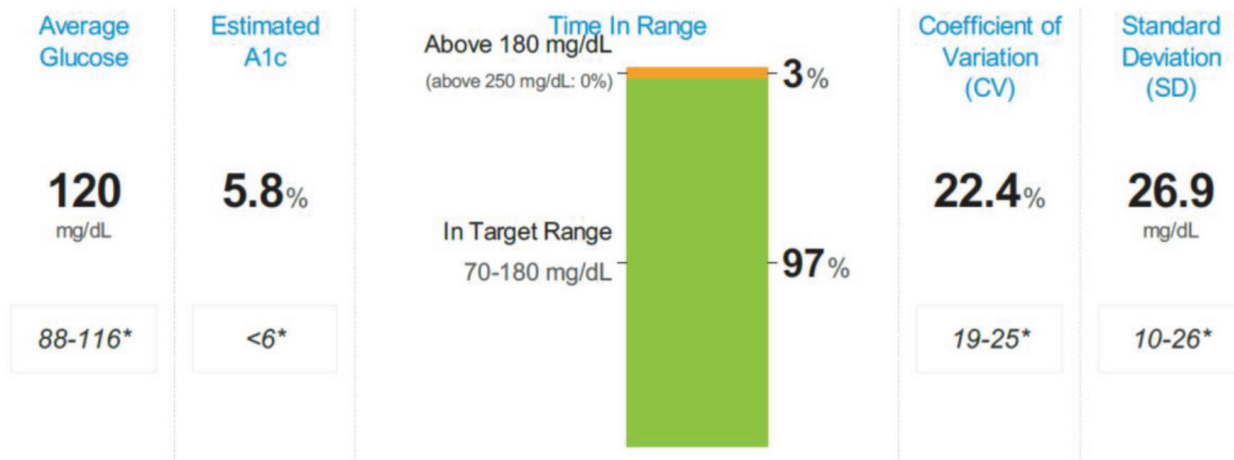


FIGURE 1. AGP profile and follow-up summary report of a 60-year-old man with type 2 diabetes. He was diagnosed with diabetes 3 years ago. His physician prescribed metformin and canagliflozin. With an A1C usually between 6.5 and 7.5%, and 42% of values within the hyperglycemic range as of August 2017, he began 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.

outcomes, including personalized glycemic control, more time in range, greater treatment satisfaction, and better quality of life?

FCGM, which has a track record of successful implementation with minimal training outside the United States, may point the way to feasibility of CGM in primary care (33). Intuitive navigation and data interpretation allow a greater degree of self-management than normally associated with CGM. Figure 1 shows a

case example of a patient with type 2 diabetes who reduced A1C and increased time in range based on FCGM guidance alone.

Summary and Conclusion

Clinical trial and empirical evidence indicate that continuous glucose data analysis, used as an adjunct to A1C, provides more robust and actionable information than SMBG. Although CGM is recognized as a powerful tool for individualizing diabetes care, its

optimal utilization has been stymied by cost and reimbursement issues, limited resources to learn or implement new technology, and user factors such as interference with daily life (7,19). FCGM offers a new avenue. Considered an easy, intuitive monitoring system, FCGM is suitable for a variety of patients, ranging from those not on insulin using SMBG with mixed success to people on intensive insulin regimens who find alarms and other features of traditional systems

challenging. Professional FCGM offers a low-cost and nearly burden-free opportunity for gaining insight into patterns of high and low blood glucose that can be addressed moving forward. For patients who begin with or transition to personal FCGM, the ability to make in-the-moment adjustments based on real-time glucose readings and trends can be motivating and can lead to more rewarding patient-provider interactions.

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