THE ROLE OF BLOOD GLUCOSE MONITORING IN DIABETES MANAGEMENT

CONTRIBUTING AUTHORS

RUTH S. WEINSTOCK, MD, PHD, FACE, FACP
SUNY Distinguished Service Professor; Chief, Division of Endocrinology, Diabetes and Metabolism, Department of Medicine; and Medical Director, Clinical Research Unit and Joslin Diabetes Center at Upstate
Upstate Medical University
Syracuse, NY

GRAZIA ALEPPO, MD, FACE, FACP
Professor of Medicine
Northwestern University Feinberg School of Medicine
Chicago, IL

TIMOTHY S. BAILEY, MD, FACE, FACP, CPI
President and Chief Executive Officer
AMCR Institute
Escondido, CA, and Clinical Associate Professor
University of California San Diego School of Medicine
San Diego, CA

RICHARD M. BERGENSTAL, MD
Executive Director
International Diabetes Center, Park Nicollet/HealthPartners
Minneapolis, MN

WILLIAM A. FISHER, PHD
Distinguished Professor Emeritus and Adjunct Research Professor
Department of Psychology, Western University
London, Ontario, Canada

DEBORAH A. GREENWOOD, PHD, RN, BC-ADM, CDCES, FADCES
President and Owner
Deborah Greenwood Consulting
Sacramento, CA

LAURA A. YOUNG, MD, PHD
Associate Professor of Medicine and Director, Endocrinology Fellowship Program
University of North Carolina School of Medicine
Chapel Hill, NC

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Dear ADA Journal Subscriber:

I am pleased to present to you “The Role of Blood Glucose Monitoring in Diabetes Management,” the latest in the American Diabetes Association’s (ADA’s) Clinical Compendia Series. Produced by ADA and supported by unrestricted educational grants from Ascensia and Lifescan, this valuable resource reviews the continuing importance of blood glucose monitoring (BGM) in diabetes management, even in this age of rapid technological advancements.

In her introduction, lead author Ruth S. Weinstock, MD, PhD, FACE, FACP, of Upstate Medical University in Syracuse, NY, notes that, although home BGM revolutionized diabetes self-management four decades ago, the more recent advent of personal continuous glucose monitoring (CGM) systems has raised questions regarding its role moving forward. She and her team of expert co-authors then set out to answer those questions, explaining why BGM remains a useful and cost-effective source of glycemic data for many people with diabetes.

The authors review key issues related to the optimal use of BGM. They discuss the high level of accuracy of modern glucose meters and how that accuracy is measured, and they review current recommendations regarding the frequency and timing of BGM for people with different types of diabetes and therapeutic regimens. They offer specific strategies for making the best use of BGM to improve glycemic management and therapeutic outcomes, as well as tips for overcoming common barriers. They then position BGM in today’s high-tech diabetes landscape, describing the complementary uses of BGM and CGM, as well as the latest blood glucose–related innovations, including Cloud-based data management, mobile apps, insulin calculators, and remote and automated counseling systems. The authors conclude that BGM is, and will continue to be, an important tool in diabetes management, even as technologies continue to evolve.

Sincerely,

Robert A. Gabbay, MD, PhD 
Chief Scientific & Medical Officer 
American Diabetes Association

2451 Crystal Drive 
Suite 900 
Arlington, VA 22202 
1-800-DIABETES (342-2383) 
diabetes.org 
@AmDiabetesAssn
THE ROLE OF BLOOD GLUCOSE MONITORING IN DIABETES MANAGEMENT

ABSTRACT | The introduction of home blood glucose monitoring (BGM) 40 years ago revolutionized diabetes self-management, providing valuable glucose data that have helped many people with diabetes (PWD) improve their glycemic management. In the early 2000s, personal continuous glucose monitoring (CGM) systems also became available, raising questions regarding the future role of BGM. However, for some PWD, particularly many with type 2 diabetes who do not take medications associated with increased hypoglycemia risk, BGM remains more easily accessible and more affordable than CGM and can adequately meet their needs. In addition, PWD who use CGM still need to periodically use BGM. This publication reviews key issues related to the optimal and most cost-effective use of BGM. The authors address the accuracy of modern glucose meters and the recommended frequency of monitoring for people with different types of diabetes and therapeutic regimens. They suggest strategies for using glycemic data to inform therapy adjustments, as well as ways to overcome common barriers to BGM use. They then review the use of BGM in patients who also use CGM and describe the latest related technological innovations, including Cloud-based data management, mobile applications, insulin calculators, and remote and automated counseling systems. The authors conclude that BGM remains an important tool in diabetes management, even as diabetes management technologies continue to evolve.

The introduction of home blood glucose monitoring (BGM) in the late 1970s and regulatory clearance of the first meter for this purpose in 1980 revolutionized the self-care of people with diabetes (PWD) (1–3). Although often referred to as “self-monitoring of blood (or plasma) glucose,” this form of glucose monitoring will be referred to by the more succinct “BGM” in this compendium. Knowing one’s current glucose reading and being able to examine and better understand glucose patterns enable PWD to adjust their food intake, activity, and medications to achieve their glycemic goals.

Over the past 40 years, glucose meters have become ever smaller, more accurate, and more widely available (3). Today, they require less blood and provide readings more rapidly, and the lancets used to perform fingersticks cause less discomfort than ever before. BGM has provided valuable data that have helped many PWD reach their glycemic targets.

In the early 2000s, personal continuous glucose monitoring (CGM) devices became available and are now being used more commonly, especially...
for PWD treated with intensive insulin therapy (3). The increasing accessibility of CGM has raised questions regarding the future role of BGM in the management of diabetes.

For most PWD, CGM is more expensive than BGM. For PWD who do not require frequent daily glucose monitoring to achieve their glycemic goals, particularly those with type 2 diabetes who are not taking medications that commonly cause hypoglycemia, BGM remains more easily accessible and more affordable than CGM and, for many, can fulfill their glucose self-monitoring needs. In addition, PWD who use CGM still need to periodically use BGM, as will be discussed.

In this monograph, we review issues that are crucial to understand to ensure the optimal and most cost-effective use of BGM. These issues include the accuracy of available glucose meters; the recommended frequency of BGM for PWD who have different types of diabetes and whose diabetes management follows different therapeutic approaches; strategies for using BGM to reach glycemic targets; barriers to BGM use and ways to overcome them; the use of BGM in PWD who also use CGM; and technological innovations such as Cloud-based glucose data management systems, mobile applications (apps), insulin calculators, and remote and automated counseling systems that incorporate BGM to improve care.

Overall, BGM remains an important tool for PWD, even as diabetes management technologies continue to evolve. It is our hope that the information presented in this compendium will assist health care providers (HCPs) in guiding their patients on the most appropriate and cost-effective use of BGM.

**BGM Accuracy**

Introduced in the 1970s (1,2), capillary BGM replaced urine glucose monitoring and in-office glucose checking, which were neither timely nor actionable. Frequent BGM was the crucial intervention, along with more frequent insulin dosing, of intensive treatment in the landmark Diabetes Control and Complications Trial (4). Capillary glucose measurements gave people with diabetes and those caring for them data to understand variations in glucose levels, with the potential to optimize basal and prandial insulin dosing.

Initial glucose meters were cumbersome and imprecise, and expectations were largely aspirational (5). However, over the years, both accuracy and usability have greatly improved (3). Here, we describe the key measures of accuracy, review the factors contributing to it, and discuss its impact on various stakeholders.

**How Accuracy Is Measured**

Accuracy is a concept comprising both trueness and precision. Trueness is defined as “closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value,” whereas precision is defined as “closeness of agreement between indications or measured quantity values obtained by replicate measurements” (6). A device with high degrees of both trueness and precision would be said to be highly accurate because it would likely produce individual results that would be consistently in close agreement with an accepted reference method.

The error grid is a longstanding tool in the evaluation of BGM accuracy. First developed by Clarke et al. (7), it has subsequently been modified by Parkes et al. (8) and others. In this approach, BGM results are plotted against reference results, with grid regions defined to reflect the potential risk severity of incorrect treatment triggered by the measurement error (Figure 1). Device performance is typically reported as the percentage of glucose values in lower-risk zone A or zones A and B. Higher percentages indicate better performance. Because most current meters attain nearly 100% of results in these lower-risk zones, this method has become less useful for comparing glucose meters.

![Sample error grid. Reprinted with permission from ref. 8.](image-url)
Guidance from the U.S. Food and Drug Administration (FDA) and the International Organization for Standardizations has been used to set minimum standards for regulatory clearance of glucose meters. These guidelines have become increasingly strict. In 2016, the FDA published criteria for meters for personal use, stating that 95% of results should be within ±15% of the comparator method, and 99% of results should be within ±20% of the comparator across the entire claimed measuring range (9). Devices for point-of-care professional use should achieve 95% of results within ±12% of the comparator method for blood glucose levels >75 mg/dL and within ±12 mg/dL for levels <75 mg/dL; they should also achieve 98% of values within ±15% of the comparator method for blood glucose levels >75 mg/dL and ±15 mg/dL for levels <75 mg/dL across the entire claimed measuring range (10).

Testing within-run and intermediate precision is required to show that, among multiple meters and glucose strip lots measuring a single sample, over time and with multiple devices, results are consistent. These results are best expressed as coefficient of variation, which is calculated from mean and standard deviation (SD). The effects of potential interfering substances and other factors, such as hematocrit and altitude, are expressed as bias (in mg/dL and percentages).

Accuracy data are reported to and reviewed by the FDA before a meter is cleared. However, there is no post-marketing surveillance other than monitoring of reported adverse events with use of the device.

Factors Contributing to Accuracy
For a holistic understanding of accuracy, it is useful to borrow terminology from laboratory science and separate glucose measurement errors into three distinct categories: pre-analytical, analytical, and post-analytical errors. Pre-analytical errors are those that occur before the device makes a measurement; post-analytical errors are those happening after a measurement is made. Many tests of meter accuracy are performed under ideal laboratory conditions and thus may reflect only the analytical accuracy of the device. Most errors found in laboratory testing other than BGM have been reported to be either pre-analytical (46–68%) or post-analytical (18–47%). Indeed, only 7–13% of errors may occur during the analytical phase (Table 1) (11).

### Pre-Analytical Factors
Early meters required users to either blot or wipe the glucose strip at a precise time interval. They also required the correct entry of a lot-specific test code. Furthermore, both underfilling and overfilling the glucose strip could have altered test results. Fortunately, these potential sources of pre-analytical error have been mostly eliminated in newer meters by either auto-correction or error detection.

However, poor surface preparation of the capillary sampling site continues to contribute to pre-analytical errors. Despite the known importance of cleansing the site, many users are unaware of or neglect this step. Both fruit handling (12) and the use of some body lotions (13) have been associated with pseudo-hyperglycemia. Additionally, glucose strips damaged by inappropriate storage conditions and the dilutional effect of extraneous fluid at the testing site have been associated with pseudo-hypoglycemia (14). The impact of these factors has increased because of the smaller sample volume required by newer meters.

Thus, although technological advances have addressed many of the pre-analytical sources of reduced accuracy, comprehensive patient education remains important to address remaining pre-analytical issues.

### Analytical Factors
Glucose measuring technology has advanced in many ways to meet the demand for greater accuracy. Glucose oxidase has been the most important enzyme used to measure glucose. However, as sensors changed from optical to fully electrochemical, alternative enzymes

### TABLE 1 Examples of Glucose Meter Measurement Errors

<table>
<thead>
<tr>
<th>Pre-Analytical</th>
<th>Analytical</th>
<th>Post-Analytical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor skin surface preparation</td>
<td>Environmental (e.g., temperature, humidity, altitude)</td>
<td>Poor user numeracy</td>
</tr>
<tr>
<td>Use of incorrectly stored or expired test strips</td>
<td>Interfering substances (e.g., ascorbic acid, acetaminophen, maltose)</td>
<td>Misunderstanding because of incorrect glucose units (mg/dL vs. mmol/L)</td>
</tr>
<tr>
<td></td>
<td>Degradation of manufacturers’ quality standards</td>
<td>Missing and fabricated glucose values in manual log</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Software processing errors</td>
</tr>
</tbody>
</table>
have been used. Although these other enzymes have generally improved performance, one—GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone)—led to harmful hypoglycemia resulting from inappropriate treatment of pseudo-hyperglycemia when maltose, galactose, and xylose were detected nonspecifically as glucose (15).

Other potential sources of error that must be assessed in glucose meters include altitude, hematocrit, ascorbic acid, and acetaminophen. All devices must include results of these tests in their labeling.

In addition to better chemistry, advances in manufacturing techniques, proper storage and distribution, and quality processes to monitor these factors remain crucial to ensuring accuracy. To date, there is no regulatory requirement that manufacturers of cleared meters proactively demonstrate the continued accuracy of their devices after initial clearance.

The Diabetes Technology Society’s comparative study (16) evaluated 18 meters and glucose strips acquired through the retail channel in 1,032 subjects with a total of 5,584 data pairs. This study expanded on previous studies (17) and evaluated all 18 meters at each of three research sites. During each of three substudies, each site evaluated six meters. In each of two subsequent studies, six additional meters were tested in round-robin format such that each site verified all meters. Only six of the 18 meters met accuracy standards (similar to, but slightly more lenient than, current regulatory standards) in all three substudies. These data suggest that real-world meter performance may frequently differ from that initially reported by manufacturers and support the need for post-marketing surveillance to ensure reliable meter accuracy.

Post-Analytical Factors
Visual inspection and comparison of a result with a color chart was commonplace with early meters, and this practice limited accuracy. Essentially all glucose meters now display data digitally to users, but despite this greater clarity, there remain several situations in which the device user may inaccurately interpret the result presented. For example, depending on locale, meters present data in either mg/dL or mmol/L. In the past, users could change the measurement units (although, occasionally, device settings unpredictably changed). Manufacturers no longer allow users to change data units, but someone using a meter that displays results in mmol/L (e.g., a meter acquired in Canada) but who is accustomed to mg/dL units (e.g., someone residing in the United States) might incorrectly interpret 10.0 mmol/L as 100 mg/dL (or vice versa). Low numeracy has also been reported to be a barrier for some users (18).

The advent of meters that store a digital record of glucose results confirmed the persistent suspicion of many clinicians regarding logbooks (19): missing, phantom (“dry-lab”), and incorrectly transcribed readings are quite common. This problem persists today in clinics where manual logbooks are still reviewed.

In addition to missing, fabricated, and incorrectly recorded data, there is short- and long-term potential to underuse or even misuse BGM data. To address this issue, structured BGM (20,21), described in more detail on pages 6-7, has been proposed as a technique to make BGM data more actionable. A further development has been meter connectivity, allowing BGM data to be transmitted via smartphone to the Cloud for enhanced remote medication management.

Innumerable mobile apps that can now accept BGM data and provide insulin dosing advice represent an additional source of post-analytical errors. Unfortunately, these apps vary considerable in quality (22). They also require configuration by programming in a patient’s insulin-to-carbohydrate (I:C) ratio (the number of grams of consumed carbohydrate that 1 unit of insulin will cover), insulin sensitivity factor (ISF; the blood glucose lowering in mg/dL to be expected per unit of insulin delivered), and duration of insulin action, and often sophisticated input from users (e.g., carbohydrate counting). These apps, and other BGM-related innovations, are discussed in more detail starting on p. 18.

Why Accuracy Matters and to Whom
Although it may seem intuitively obvious that more accurate BGM is advantageous, access to any means of BGM is such a formidable barrier in low-resource settings (23) that a broader perspective is needed. Type 1 diabetes, pregnancy, and use of a CGM device that benefits from calibration are all compelling examples of circumstances requiring high BGM accuracy. However, people with type 2 diabetes who are not taking medications likely to cause hypoglycemia may accrue benefit even from less-expensive devices with lower accuracy ratings. In recognition of this, one major manufacturer of meters introduced a semi-quantitative system using a smartphone camera (24). This approach allows a
mobile app to photograph a glucose strip and provide an estimated glucose level range, rather than a specific value, and does not require users to purchase a meter. Likewise, a study of a meter that displayed color-coded glucose range data (in addition to a glucose value) demonstrated a salutary effect, particularly in people with low numeracy (25).

For PWD, meter accuracy affects not only insulin dosing decisions, but also confidence in their meter. For example, if glucose is checked multiple times within a short interval and the results differ, trust in the meter may decline. Additionally, accurate BGM is required for calibration of some CGM systems and is also needed for confirmation of CGM results or as a backup for people who use a CGM system. Table 2 summarizes groups of PWD who would benefit from greater BGM accuracy (26).

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RECOMMENDATIONS FOR BGM USE

BGM via capillary blood historically has been considered a cornerstone of diabetes self-care. Touted as a key part of patients’ daily routine, when performed regularly, it can guide insulin dosing and help patients judge whether their noninsulin medications and lifestyle changes are having favorable effects. When the desired results are not achieved, BGM values can be used by PWD and their care team to guide medication adjustments and further lifestyle modifications.

Over the past several decades, BGM technology has evolved, making routine checking more affordable and accessible, and many providers universally recommend daily BGM for all PWD. However, with the advent of newer noninsulin therapeutics that do not cause hypoglycemia and the recognition that daily BGM may be of little value in people with optimally managed type 2 diabetes has come a push to adopt a selective approach to BGM in people with diabetes. In the following sections, we discuss current recommendations for BGM in people living with diabetes (26,29), which are also summarized in Table 3.

One way to determine who might benefit most from routine BGM is to consider individual patient factors such as insulin use, pregnancy, hypoglycemia history, hypoglycemia unawareness, and blood glucose levels that are difficult to normalize. Although our intent is to convey best practices supported by high-quality data, it is important to recognize that, in many cases, there is no one correct answer and that a personalized approach to BGM is recommended.

People with Type 1 Diabetes

Although the use of CGM is increasing, some people living with type 1 diabetes will choose to continue with daily BGM exclusively. Reasons some patients may decide to continue to use BGM include higher costs of CGM systems, unacceptability of being connected to a device, and overload with regard to the quantity of data CGM provides (30).
The Role of Blood Glucose Monitoring in Diabetes Management

Given the day-to-day glycemic variability that people with type 1 diabetes typically experience, recommended BGM frequency per day will vary by person and anticipated daily activities. At a minimum, it is recommended that people with type 1 diabetes who are not using CGM perform BGM 4 times/day (before meals and at bedtime). Other times people with type 1 diabetes should check their blood glucose level include before exercise, during prolonged exercise, occasionally after meals, and whenever they have signs or symptoms of hypoglycemia. For people who have hypoglycemia unawareness, performing BGM before activities that require clear cognition (e.g., driving, caring for children, or operating heavy machinery) should be the norm. More frequent BGM is also needed during acute illness or times of stress. Thus, for most people with type 1 diabetes who are not using CGM, performing BGM 4–10 times/day as needed is recommended. It is essential, however, to recognize the need to personalize this recommendation for each person based on the presence of complications and variability in daily life.

Another situation in which people with type 1 diabetes must perform BGM is to calibrate certain CGM systems. Although newer systems do not require such calibration, some people still may be using older CGM models that do or the Medtronic 670G system with the Guardian sensor, which also requires BGM calibration a minimum of twice daily. Additionally, PWD who are using CGM may need to perform BGM on occasion to confirm extreme hyperglycemia or hypoglycemia measured via CGM or when they suspect CGM sensor or transmitter malfunction.

### People with Type 2 Diabetes

#### Those Who Do Not Use Insulin

The role of BGM for people with type 2 diabetes who are not using insulin is one of the more contested issues in diabetes management. Some previous trials have shown benefit of BGM on glycemic outcomes (31–34), whereas others have shown no such benefit (35–38) in this population.

Of the studies that have shown benefit, using a structured approach and ensuring that both PWD and providers review the results has proven to be the most efficacious strategy. Examples of structured approaches include paired checking and intermittent, frequent checking over a period of several days before a clinical visit (39). These studies have been rigorous, controlled clinical trials with close participant follow-up; thus, the beneficial results may be difficult to realize in busy, real-world clinical practice settings.

Although BGM may increase patients’ awareness of glucose values, which can support healthy lifestyle choices, it is also important to consider the burden that BGM places on PWD. In large meta-analyses of BGM in people with type 2 diabetes who were not using insulin, a benefit of BGM on glycemic management was found in the short term (≤6 months), but when assessed after 1 year of routine BGM, that benefit was

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**TABLE 3** BGM Frequency by Type of Diabetes and Treatment Regimen: General Recommendations

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>Type 1 Diabetes</th>
<th>Type 2 Diabetes</th>
<th>GDM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regimens without insulin, sulfonylurea, or meglitinide</td>
<td>N/A</td>
<td>For most PWD, BGM is not recommended. Consider using it, though, when altering treatment, symptoms of hyperglycemia develop, or acute illness occurs; in some instances, intermittent use can assist with self-management.</td>
<td>4 times/day until optimal glycemic control is achieved, then 1–2 times/day</td>
</tr>
<tr>
<td>Regimens with sulfonylurea, meglitinide, or basal insulin</td>
<td>N/A</td>
<td>Recommended as needed to detect, treat, and prevent hypoglycemia; when symptoms of hyperglycemia develop; or when acute illness occurs. Consider also when altering treatment or when A1C is above goal. For some PWD, intermittent use can assist with self-management. Generally recommended 0–3 times/day</td>
<td>4 times/day until optimal glycemic control is achieved, then 1–2 times/day</td>
</tr>
<tr>
<td>Basal-bolus insulin regimen</td>
<td>4–10 times/day</td>
<td>Up to 6–10 times/day</td>
<td>4–10 times/day</td>
</tr>
</tbody>
</table>

*These recommendations are based on published guidelines and the expert opinion and clinical experience of the authors. NA, not applicable.*
no longer significant (40–42). A recent large, pragmatic trial of PWD who were not using insulin and had A1Cs that reflected moderate to ideal glycemic management demonstrated that, in a real-world setting, once-daily BGM did not improve glycemic outcomes or quality of life compared to no BGM throughout an entire year (43).

Increasingly, national organizations are encouraging providers and PWD to rethink the need for routine BGM in people with type 2 diabetes who are meeting or near their A1C targets when using medications that do not cause hypoglycemia. It is still reasonable to encourage people with type 2 diabetes who are experiencing hypoglycemia or severe hyperglycemia, using therapies within the sulfonylurea and meglitinide classes, acutely ill, using steroids, or far from meeting their glycemic targets to perform BGM, as discussed in the next section, until optimal glycemic management has been attained. Regardless of the views of specific providers and PWD on this issue, BGM is only truly valuable to PWD when they are provided feedback on the meaning of the values they obtain and guidance on how to make health behavior changes when needed.

**Those Who Use Insulin**

For people with type 2 diabetes who require basal insulin, BGM is recommended during basal dose titration and at any time when hypoglycemia is a concern. During dose titration, blood glucose values should be monitored in the morning while fasting and again at bedtime.

Because newer basal insulin formulations lead to less glucose variability, the frequency of BGM may be reduced when a stable dose of basal insulin has been determined. However, people using basal insulin should always have a meter and glucose strips available given the potential for hypoglycemia. If a person’s fasting glucose is within target range but the A1C value is still above goal, BGM before and after meals should be considered to check for postprandial hyperglycemia.

For most people with type 2 diabetes using a basal-bolus regimen, BGM should occur at least 4 times/day, similar to people with type 1 diabetes.

**Women with Gestational Diabetes**

BGM has proven efficacy in women with gestational diabetes mellitus (GDM). Most approaches include asking pregnant women at the time of GDM diagnosis to perform BGM several times daily to establish patterns of hyperglycemia. Such women are often asked to perform BGM initially at least 4 times/day, including in the morning while fasting and 1–2 hours after meals. From these data, providers can identify women who require pharmacologic therapy.

BGM values paired with food diaries can also guide dietary change recommendations, which are foundational to the treatment of GDM. Once glycemia is optimally managed, it is reasonable to decrease the frequency of BGM. This recommendation is based on trial data showing that women who performed BGM 4 times/day had babies with similar birth weights and a similar incidence of macrosomia as women who carried out BGM once every other day.

In summary, although CGM is gaining in popularity among all people with diabetes, BGM will remain an important component of diabetes self-care for many people. The engagement of both PWD and their diabetes care team in interpreting and acting on blood glucose data is crucial in all cases for BGM to be of optimal value.

**USING BGM DATA TO ACHIEVE TREATMENT GOALS**

For BGM to make a meaningful difference in diabetes self-management, both PWD and their diabetes care team must have the skills, understanding, and ability to change health behaviors and adjust pharmacologic therapies in response to glucose data (29,44,45). Focusing on BGM data is particularly important when glucose goals are not being met; for people who are using insulin therapy or starting or titrating glucose-lowering medications; for tracking adverse events; when changes are being made to the care regimen (including eating pattern and physical activity); when a new condition, change in condition, or instability develops; or during times of illness or stress (46,47). Table 4 identifies specific opportunities for learning from BGM data collected at different times of day (29,47,48). Additionally, PWD can be taught that BGM is a great tool for making insulin dose decisions, determining their potential risk for or the presence of hypoglycemia, getting feedback with regard to the
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As previously noted, a structured approach to BGM has been shown to improve outcomes (39,49). This approach, also called “structured testing” or “structured checking,” can be individualized by implementing different checking “profiles.” Examples of these profiles are described in Table 5 (50). The design of the profile can be determined based on the desire to collect specific mealtime data (e.g., checking before and after the largest meal of the day) or in an exploratory nature to understand overall glycemic patterns. The structured data then create an opportunity for informed decision-making.

**Pattern Management**

Understanding pattern management is the key to effective BGM (47). Searching for patterns in blood glucose data is like being a detective trying to find clues that reveal trends and thereby identify opportunities to improve glycemic management. There are three factors to consider when engaging in pattern management: 1) recognition that BGM will identify the effects of food choices, physical activity, stress, and medications on daily glucose values; 2) PWD and their diabetes care providers both need education on how to interpret individual glucose values and patterns to

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**TABLE 4** Information PWD and Their Diabetes Care Providers Can Learn from BGM Performed at Different Times of Day (29,47,48)

<table>
<thead>
<tr>
<th>Time of BGM</th>
<th>How Can the Data Be Used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting</td>
<td>• Determine the effect of the evening medication</td>
</tr>
<tr>
<td></td>
<td>• Evaluate and titrate the basal insulin dose</td>
</tr>
<tr>
<td></td>
<td>• Determine the effect of physical activity (from the previous afternoon/evening)</td>
</tr>
<tr>
<td></td>
<td>• If above goal, evaluate for:</td>
</tr>
<tr>
<td></td>
<td>• Dawn phenomenon</td>
</tr>
<tr>
<td></td>
<td>• Rebound from nocturnal hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>• Impact of evening meal/snacks, including late-night food intake</td>
</tr>
<tr>
<td>Before meals</td>
<td>• Assess basal insulin dose requirements</td>
</tr>
<tr>
<td>After meals</td>
<td>• Assess mealtime insulin dose requirements</td>
</tr>
<tr>
<td></td>
<td>• Assess proper timing of insulin administration</td>
</tr>
<tr>
<td></td>
<td>• Identify the need for additional medications to target postprandial hyperglycemia</td>
</tr>
<tr>
<td></td>
<td>• Assess the effectiveness of changes in the amount and composition of meals and snacks and/or physical activity in moving blood glucose into the target range</td>
</tr>
<tr>
<td>Bedtime</td>
<td>• Assess the impact of pre-dinner medication</td>
</tr>
<tr>
<td></td>
<td>• Assess the impact of dinner and evening snacks and late afternoon/evening exercise</td>
</tr>
<tr>
<td>2:00 a.m.</td>
<td>• Identify overnight hypoglycemia</td>
</tr>
</tbody>
</table>

**TABLE 5** Examples of BGM Structured Checking Profiles

<table>
<thead>
<tr>
<th>Profile</th>
<th>Example</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paired checking</td>
<td>BB AB BL AL BD AD BT</td>
<td>• Checking glucose before and after the same meal for 7 days in a row</td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>• Used to evaluate the change in glucose levels from pre- to post-meal</td>
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<td>T</td>
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</tr>
<tr>
<td>7-Point profile</td>
<td>BB AB BL AL BD AD BT</td>
<td>• Checking glucose 7 times/day, for 3 days in a row</td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>• Provides an overall picture of glucose values before a clinic visit</td>
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<tr>
<td>Staggered profile</td>
<td>BB AB BL AL BD AD BT</td>
<td>• Checking glucose before and after one meal per day</td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>• Staggering the mealtimes provides more data and a clearer picture of glucose levels and patterns</td>
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</table>

*AB, after breakfast; AD, after dinner; AL, after lunch; BB, before breakfast; BD, before dinner; BL, before lunch; BT, bedtime.*
inform adjustments to therapies or lifestyle behaviors; and 3) tools such as paper logbooks or digital apps are needed to collect, analyze, and interpret data (47). Many glucose meters come with their own apps that synchronize directly with the device, allowing users to log events (e.g., carbohydrate intake, physical activity, and insulin doses) along with BGM data.

Living with diabetes 24/7, year in and year out, is challenging. Understanding the value of pattern management can help PWD take charge of their self-management and play an active role in decision-making regarding their diabetes treatment. Understanding their own BGM data can motivate them to make healthier choices and build their self-confidence. Working with a certified diabetes care and education specialist to learn about BGM and pattern management is important at the time of diagnosis and annually thereafter, as well as whenever there is a change in medication or their condition or when glycemic goals are not being met (51,52).

Early clues from random BGM values or conversations with PWD can help to identify a glucose profile that will best reveal trends in various situations. Searching for patterns requires BGM values collected at the same time of day for a minimum of 3–4 days. One framework for interpreting BGM data (47) sets out a simple three-step process: 1) obtain at least 3–4 days of data, 2) identify patterns, and 3) collaborate with the PWD to individualize diabetes care and education based on the data collected (Table 6).

When reviewing BGM data, certain patterns should be given higher priority than others. First, focus on episodes of hypoglycemia. After hypoglycemia has resolved, review glucose values that are above the target range. When post-meal glucose values are rising above target range, consider whether changes to both medication and health behaviors may be needed. When focusing on health behaviors, review food portions, carbohydrate counting, and the quality of food consumed.

The following case studies describe different structured checking profiles and how BGM data can be reviewed to make health and treatment decisions.

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**TABLE 6 Three-Step Process for Evaluating BGM Data and Sample Questions to Help Identify Opportunities for Improvement**

<table>
<thead>
<tr>
<th>Issues to Explore</th>
<th>Step 1: Obtain 3–4 Days of Data</th>
<th>Step 2: Identify Patterns</th>
<th>Step 3: Collaborate to Individualize Diabetes Care and Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy coping</td>
<td>Are life stressors affecting self-care?</td>
<td>Is the person stress-eating?</td>
<td>What new techniques might the person try to reduce stress levels?</td>
</tr>
<tr>
<td>Healthy eating</td>
<td>Is the person counting carbohydrates?</td>
<td>Are meal and snack portion sizes consistent?</td>
<td>Can changes be made to the amount of carbohydrate at mealtimes? Snacks?</td>
</tr>
<tr>
<td>Physical activity</td>
<td>Is physical activity documented (time of day, intensity, duration, and type)?</td>
<td>Is physical activity irregular?</td>
<td>Can physical activity be planned and more regular?</td>
</tr>
<tr>
<td>Medication-taking</td>
<td>Are medications taken as prescribed?</td>
<td>Is the diabetes medication adequately covering glucose peaks after meals?</td>
<td>Could a different type or dose of medication be taken?</td>
</tr>
<tr>
<td>BGM</td>
<td>Is more BGM needed?</td>
<td>Are BGM strips expired?</td>
<td>Can the pattern of BGM be negotiated?</td>
</tr>
<tr>
<td>Problem-solving</td>
<td>Have there been lifestyle changes?</td>
<td>Have you observed meter use?</td>
<td>What changes is the person willing to make?</td>
</tr>
<tr>
<td>Risk reduction</td>
<td>If hypoglycemia is noted, what is the usual treatment?</td>
<td>Are medications expired?</td>
<td>Could the treatment regimen be simplified?</td>
</tr>
</tbody>
</table>

Adapted from ref. 47.
**CASE 1: M.V.**

M.V. is a 50-year-old woman with type 2 diabetes for 11 years, who is taking metformin 1,000 mg twice daily and glipizide 10 mg before breakfast and dinner. Her BMI is 25 kg/m², her most recent A1C was 8.5%, and she notes feeling tired most of the time. She has not been checking her glucose.

After discussion, she agrees to perform a 7-point profile for 3 days before her next clinic visit so you can get a better idea of her glucose levels throughout the day. The data she shares at her next appointment are displayed in Table 7.

**TABLE 7** Case 1: 3-Day, 7-Point Glucose Profile (mg/dL)

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</thead>
<tbody>
<tr>
<td>Monday</td>
<td>125</td>
<td>201</td>
<td>150</td>
<td>256</td>
<td>129</td>
<td>259</td>
<td>203</td>
</tr>
<tr>
<td>Tuesday</td>
<td>130</td>
<td>249</td>
<td>174</td>
<td>241</td>
<td>122</td>
<td>263</td>
<td>214</td>
</tr>
<tr>
<td>Wednesday</td>
<td>129</td>
<td>223</td>
<td>142</td>
<td>203</td>
<td>126</td>
<td>281</td>
<td>199</td>
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<tr>
<td>Thursday</td>
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AB, after breakfast; AD, after dinner; AL, after lunch; BB, before breakfast; BD, before dinner; BL, before lunch; BT, bedtime.

**What questions do you ask?**

Start by asking M.V. what she notices and what information she can share with you. Solicit her opinion regarding what is working and what she believes may need to change. Ask her about her food choices and portion sizes and about her physical activity.

M.V. states that she is taking her medication as directed. She says she is unable to walk after breakfast or lunch because of work and that she does not feel the need to change her eating habits.

**What patterns do you see?**

M.V.’s pre-breakfast values are all within her target range. However, her post-meal values are above range, as are those at bedtime. The only times during the day that she is in the target range are before breakfast and before dinner.

You learn that M.V. takes a walk every day 3 hours after lunch, which lowers her pre-dinner glucose level into the target range.

---

**What do you suggest?**

These BGM data suggest that M.V. needs more medication to manage her post-meal glucose excursions. Using a shared decision-making approach, you can discuss the pros and cons of appropriate medication options with her and arrive at a plan.

**CASE 2: K.B.**

K.B. is a 67-year-old woman who has lived with type 2 diabetes for 14 years. She is taking metformin 1,000 mg/day and 24 units of insulin glargine, which she reports taking every night at her 9:00 p.m. bedtime. Her BMI is 32 kg/m².

She has been checking her fasting glucose levels several times per week, and all of her values have been <130 mg/dL. However, her A1C continues to be above goal and is currently 8.3%. She has never checked her glucose at other times of the day.

You ask her about her meals and activity and learn that her biggest meal of the day is at dinner. Together, you decide that K.B. will take a “paired checking” structured approach to BGM, checking her glucose before and 2 hours after dinner nightly for 1 week and then return for a follow-up appointment. Her BGM data are displayed in Table 8.

**TABLE 8** Case 2: 1 Week of Paired Checking Glucose Values Before and 2 Hours After Dinner (mg/dL)

<table>
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<tbody>
<tr>
<td>Monday</td>
<td>131</td>
<td>255</td>
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<td>Tuesday</td>
<td>128</td>
<td>181</td>
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<td>Wednesday</td>
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<td>Sunday</td>
<td>134</td>
<td>277</td>
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AB, after breakfast; AD, after dinner; AL, after lunch; BB, before breakfast; BD, before dinner; BL, before lunch; BT, bedtime.

**What questions do you ask?**

What does K.B. notice about her glucose values? Ask her about her food choices and portion sizes at dinner.

K.B. says she has been using an online weight loss program and has been focusing on using the plate method at mealtimes. Although she does eat pasta and other carbohydrate-containing foods, she says her portion sizes are small.
What patterns do you see?
All of K.B.’s post-dinner glucose values are above her target of <180 mg/dL.

What do you suggest?
K.B. needs more medication to manage her post-meal glucose excursions. Together, you consider adding a glucagon-like peptide-1 receptor agonist to her regimen to assist with both weight loss and glycemic management. You might also suggest that K.B. use BGM to check before and after other meals to see if her glucose levels are consistently out of range at any other times.

What questions do you ask?
What does P.R. notice about his glucose values? Was this week typical for him, including the food he ate and his physical activity?

CASE 3: P.R.
P.R. is an 80-year-old man who has been living with type 2 diabetes for 26 years. His A1C is typically in range, at <7.0%. He has been taking 36 units of insulin degludec at bedtime and 8 units of rapid-acting insulin before each meal. He states that he has been “feeling low” during the day. Sometimes he checks his glucose, but other times, he just drinks juice or eats a snack without checking. He performs BGM infrequently, but when he does, it is typically before breakfast and before bed.

He agrees to your request that he check his glucose before and after 1 meal/day for 1 week, alternating meals, as well as whenever he feels as if his glucose is low. The BGM results he brings to his follow-up visit are displayed in Table 9.

What patterns do you see?
The first pattern you address is the two episodes of hypoglycemia after lunch on Wednesday and Sunday.

What do you suggest?
P.R. should reduce his pre-meal insulin dose at lunch. Together you discuss whether he would be willing to adjust his pre-meal insulin doses based on the size of the meal he is going to eat and his anticipated physical activity. You also ask if he would be willing to check his glucose before and after lunch to help identify the best insulin dose for him at that meal.

You refer P.R. to a diabetes care and education specialist to review carbohydrate counting and portion sizes and to review BGM to develop a plan for insulin management. Using CGM could also be considered.

Solution-Focused Questioning
Assessment of blood glucose management requires frequent discussions with PWD. A questioning approach is commonly used. Often, questions can make PWD feel blamed or shamed for out-of-range glucose values, elevated A1C levels, or decisions they have made, and this perceived negativity can seem to devalue the hard work of living with a chronic condition. One alternative is to consider a more solution-focused approach (53).

In this type of approach, questions focus on what is going well for the person and are chosen to identify existing strengths. For example, instead of asking about breakfast glucose values by saying, “Why are your after-breakfast numbers so high?” consider asking, “Can you share with me an example of your typical breakfast?” From there, you can have a conversation based on the data. If the person is

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</tbody>
</table>

AB, after breakfast; AD, after dinner; AL, after lunch; BB, before breakfast; BD, before dinner; BL, before lunch; BT, bedtime.

What questions do you ask?
What does P.R. notice about his glucose values? Was this week typical for him, including the food he ate and his physical activity?

P.R. states that he typically eats a late breakfast and often has a small lunch. He likes to garden, and he typically does that in the afternoon, often after lunch. His lunch is frequently just a handful of nuts, some berries and a diet coke. He has been on a fixed dose of prandial insulin for the past several years, but he says his appetite has changed lately.

You also ask what type of symptoms he has when his glucose values drop to <70 mg/dL and how he treats his low glucose. P.R. says that he usually feels sweaty and hungry, and then he feels shaky and lightheaded. He prefers to drink juice and keeps juice boxes in the refrigerator.

What patterns do you see?
The first pattern you address is the two episodes of hypoglycemia after lunch on Wednesday and Sunday.

What do you suggest?
P.R. should reduce his pre-meal insulin dose at lunch. Together you discuss whether he would be willing to adjust his pre-meal insulin doses based on the size of the meal he is going to eat and his anticipated physical activity. You also ask if he would be willing to check his glucose before and after lunch to help identify the best insulin dose for him at that meal.

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In this type of approach, questions focus on what is going well for the person and are chosen to identify existing strengths. For example, instead of asking about breakfast glucose values by saying, “Why are your after-breakfast numbers so high?” consider asking, “Can you share with me an example of your typical breakfast?” From there, you can have a conversation based on the data. If the person is
eating a high-carbohydrate breakfast, you might ask, “What changes would you be willing to consider to bring your after-breakfast glucose levels into the target range?”

Another strategy would be to focus on a time of the day when glucose values are in range and ask questions about those times, again to identify strengths. For example, “I see your before-dinner numbers are within your target range most of the time. How did you achieve that?” With this type of question, you are strengthening your relationship with the person by building trust and acceptance. This method also helps PWD identify their own strengths and what is working well for them. In theory, this approach will help PWD do more of the things that are working well for them and less of those that are not working well (54).

In summary, a structured approach to BGM can help PWD and their diabetes care team accurately interpret glucose data, recognize patterns, and work together to make informed treatment decisions to improve diabetes management.

OVERCOMING BARRIERS TO BGM

It is well established that BGM can serve as a basis for self-management that is effective in achieving and maintaining positive glycemic outcomes (55,56). However, it is also well established that PWD do not always perform BGM as recommended and that those who do may not take appropriate self-management actions based on their blood glucose data. In the previous section, we focused on ways to assist PWD in making optimal use of BGM to achieve their treatment goals. Here, we look at how to overcome the numerous barriers that may hinder a person’s success in that endeavor.

BGM Is Behavior

To help PWD overcome barriers to BGM, it is essential to understand that BGM is behavior. As such, it is influenced by individuals’ store of actionable BGM information, motivation to act on this information, and behavioral skills for acting on it effectively. Data collected by carrying out BGM as recommended can serve as the basis for self-management actions that result in improved diabetes health outcomes, contributing to a virtuous feedback loop (Figure 2).

The impact of BGM information and motivation will often be limited by a person’s BGM behavioral skills. Moderating factors such health literacy and ability to acquire and pay for supplies to check glucose may influence the amount of BGM data collected, a person’s motivation and ability to carry out BGM with the recommended frequency, and, ultimately, health outcomes.

Information and BGM

PWD may have information deficits that interfere with BGM (57). Some may believe that their body can “feel” when their blood glucose is within their target range; some may not be aware of glucose checking patterns that can provide meaningful information; and others may believe that their A1C results tell them everything they need to know to manage their diabetes.

Motivation and BGM

Personal and social motivation can also influence BGM (57). Personal motivation for BGM rests on a person’s perception of the overall costs and benefits of BGM. PWD who believe that BGM has important payoffs will be inclined to carry out monitoring as recommended, whereas those who believe that BGM has costs that outweigh the benefits are not as likely to consistently carry out BGM. Social motivation for
BGM rests on a person’s perception that significant others—spouses, children, diabetes care and education specialists—support their BGM efforts and endorse their interest in engaging in shared decision-making. Thus, a supportive partner, or an indifferent physician, can influence BGM performance.

Personal and social motivation to carry out BGM are often in competition with the impetus to engage in other activities that are incompatible with strictly following BGM recommendations. Many, if not most, PWD will regard BGM as having important benefits and social support, but sometimes less important benefits and less social support than other aspects of their lives (e.g., maintaining concentration at work or enjoying a meal with friends).

**Behavioral Skills and BGM**

Performing BGM as recommended places substantial behavioral skills demands on PWD (57). In the context of busy day-to-day life, simply remembering to perform BGM at meaningful intervals may be a challenge. Financing supplies to check glucose within complex, changing, or limited insurance coverage poses additional challenges. Maintaining access to such supplies when needed and discreetly, painlessly, and effectively lancing one’s finger or positioning a sensor, can also be challenging. Still other behavioral skills demands involve knowing how to talk to a busy HCP about problems with BGM or interpreting and using its results.

**Moderating Factors and BGM**

Personal characteristics of PWD and their environment can have direct and indirect impacts on BGM (57). These factors include inadequate insurance coverage, limited health literacy, burden of disease associated with diabetes (e.g., impaired eyesight, impaired dexterity, and overall medication burden), and comorbid conditions. Overall, optimal BGM will be achieved by well-informed, engaged, behaviorally skilled PWD and will be maintained when they experience positive health outcomes.

**Assisting Patients in Overcoming Obstacles to BGM**

Optimal BGM needs to be taught, rehearsed, refined, and reinforced by well-informed, well-motivated, and behaviorally skilled clinician educators. A diversity of interventions—including BGM device education, smartphone coaching keyed to blood glucose results, and counseling approaches linked to readiness to change—may all be effective in increasing a person’s frequency of BGM and changing patterns of checking glucose (55,58,59). In the realistic context of the busy and resource-limited clinical practice setting, means for assisting PWD in overcoming barriers to BGM must be both brief and effective and must focus on those with the greatest need.

**Triage the Need for BGM Coaching**

BGM counseling should target individuals who are experiencing difficulties in achieving their glycemic goals. Such difficulties can involve inadequate or uninformative testing, inability to translate results into self-management actions, or the need to change the therapeutic regimen.

**Follow Principles of Effective BGM Counseling**

Principles of efficient and effective BGM counseling are inspired by the procedures of and evidence base supporting Motivational Interviewing (59,60). For people identified as potentially benefiting from improved BGM practices, the following counseling approaches may prove helpful.

**Acknowledge the Challenge**

Many PWD are defensive and fearful of provider censure for variable performance of BGM. Legitimizing an individual’s struggle with the demands of BGM can be the first step in improving its practice. Consider asking, “Almost all of my patients find BGM to be a challenge. How is it going for you?”

**View PWD as the Experts**

Although clinicians are the experts in diabetes medical management, PWD are the experts in what would have to happen to improve their BGM. Change strategies that originate with PWD—as opposed to those proposed by clinicians—are often much better suited to individuals’ situations and therefore more likely to be adopted (59,60). Motivational Interviewing–inspired questions such as the following can be helpful in eliciting change strategies from PWD.

* “Can you help me understand what BGM is like for you?”
* “On a scale of 1 to 10, how important is it for you to stick to the BGM pattern we’ve discussed?” Most people will respond with a high number. Those who give a low importance rating are essentially telling the provider that they lack the information, ability, or motivation to practice BGM.
• “Why do you say 10 (or 9 or 8 or 7) and not lower?” This paradoxical question and its answer provide an opportunity for the individual to rehearse reasons for the importance of BGM.

• For those who rate importance as a 6 or lower, the most important question to ask is, “What would it take—what would have to happen—for you to rate the importance of following the BGM pattern we’ve discussed as, say, a 7 or an 8 or a 9?” Here the individual—the expert in what it would take to make BGM personally important—may tell you exactly what it would take, and this can become the core of the counseling intervention. The person—not the provider—has offered a strategy to suit the situation. This suggestion is followed by a discussion regarding how to make it happen.

• “On a scale of 1 to 10, where 1 is ‘not at all confident’ and 10 is ‘completely confident,’ how confident are you—how sure are you—that you can monitor your blood glucose in the way that we’ve discussed?” A lower confidence rating generally means that a person lacks the behavioral skills to implement the recommended pattern of testing or lacks motivation or resources to do so.

• For those who report their self-confidence high (from 7 to 10), consider asking another paradoxical question: “Why did you say 10 (or 9 or 8 or 7) and not lower?” This question gives people an opportunity to rehearse their strengths by explaining why they feel confident about performing BGM.

• For those rating their confidence as a 6 or lower, the most important question to ask is, “What would it take—what would have to happen—for you to be, say, a 7 or an 8, or a 9 in confidence that you could follow the BGM pattern we’ve talked about?” Here the individual—the expert in what it would take to increase his or her self-confidence in BGM performance—can tell the clinician exactly what it would take to do so. This can become the core of the counseling intervention. Again, the person—not the provider—has offered a strategy to suit the situation. This suggestion is followed by a discussion regarding how to make it happen.

Set Incremental, Achievable Goals
Based on an exchange like the one described above, diabetes care providers and PWD can negotiate incremental, achievable BGM goals. Change is rarely an all-or-nothing event, and identifying and achieving an incremental goal (i.e., structured pre- and post-meal testing for 1 meal/day to assist with food choices or improved insulin dosing) can be the first step toward achievement of broader goals negotiated in future counseling exchanges.

Embracing the Spirit of Collaborative Problem-Solving
This approach to helping people with diabetes overcome obstacles to BGM is meant to suggest an overall collaborative spirit of BGM counseling that will enable diabetes care providers to triage PWD and identify those who can benefit from counseling, empathize and legitimize their struggles, elicit strategies for improvement, and negotiate achievable goals.

Attention to BGM performance and its use to inform and facilitate meaningful self-management action is part of an ongoing support process. In subsequent encounters, providers should check in concerning the attainment of negotiated goals and potentially suggest a more challenging BGM goal moving forward. For PWD who have achieved their goal, implement a relapse prevention discussion; ask how they achieved their success, and identify specific practices they can implement as needed in the future. For those who have not met the negotiated goal, process their struggle to attain the goal and elicit an alternative strategy for achieving it or modify the goal to make it more achievable. Repeat this process until BGM performance is stable, all the while continuing to empathize with the struggles, elicit solutions to emerging challenges, and reinforce successes.

The approach to diabetes self-management and BGM counseling described here is summarized in Figure 3. Clinicians interested in a more in-depth discussion of this approach are encouraged to consult references 57–60. Keep in mind that the specific steps and wording provided here are only illustrations. Many clinicians have had effective BGM support discussions by simply asking, “How’s it going for you?” and “What would have to happen to make it work better?” Most importantly, remember that PWD are your allies and experts in facilitating their own behavior change.
USE OF BGM IN CGM USERS

Convenience and accuracy are characteristics of CGM that lead many to think CGM will, to a great extent, displace BGM. CGM systems are small and getting even smaller with each new generation, as well as becoming increasingly accurate. Although CGM is not as accurate as the most accurate BGM systems, it surpasses the accuracy of many glucose meters available today (16,61).

Importantly, the recent, rapid uptake of CGM is also the result, in part, of scientific data showing improved clinical outcomes of reduced hypoglycemia and improved A1C levels using CGM compared to BGM or usual care (62–67). Furthermore, an impactful recent meta-analysis of randomized controlled trials demonstrated that CGM improves glucose outcomes by increasing glycemic time in range (TIR) and decreasing time below range, time above range, and glucose variability in both type 1 and type 2 diabetes compared to usual care that included BGM (68).

In its 2020 Standards of Medical Care in Diabetes—2020 (29), the American Diabetes Association (ADA) states that, “when used properly, real-time and intermittently scanned continuous glucose monitors in conjunction with insulin therapy are useful tools to lower A1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness, and/or have episodes of hypoglycemia . . . and in conjunction with insulin therapy . . . to lower A1C levels and/or reduce hypoglycemia in adults with type 2 diabetes who are not meeting glycemic targets.” There is also considerable support for a broad range of intermittent use of CGM over time (using either personal devices owned by PWD or professional CGM systems owned by medical clinics) for evaluating CGM metrics and glucose patterns for PWD who use BGM but have not achieved their glucose targets.

Despite the availability of high-quality CGM systems that can facilitate improvements in glucose management, uptake of this technology in clinical practice, while growing steadily, is still only about 50–75% in pediatric endocrine practices and 35–50% in adult endocrine practices for individuals with type 1 diabetes (69) and much lower for those with type 2 diabetes treated in primary care. The main barriers to uptake are cost, reluctance of patients to wear a CGM glucose sensor, and high time demands for implementation into usual clinical workflows coupled with inadequate reimbursement for the extra time spent. Another likely barrier to use of CGM in the primary care setting is a
lack of clinician awareness regarding the availability of these systems and the potential benefits they may provide. In addition, some PWD find the CGM alarms for fluctuating glucose and the increased volume of data collected via CGM to be stressful, and others may experience difficulties with skin irritation at sensor sites.

Some have asked whether the availability of newer CGM systems that do not require calibration and are cleared for nonadjunctive insulin dosing (i.e., not requiring confirmation of glucose levels via BGM) might signal “the end of fingersticks” (70). However, despite the trend of increasing indications for CGM use and guidance to use BGM only when indicated (43) to minimize unnecessary health care costs, in practice, most PWD are taught how to use a glucose meter as part of routine self-management education, even if it is to be used only intermittently (as is often the case in type 2 diabetes). Still, the ability to perform BGM remains important even for PWD who use CGM because data are not available during CGM system warmup periods, and there will be instances in which CGM systems malfunction or require calibration. PWD also need to be able to verify their glucose status when they are asymptomatic and are concerned that their CGM reading is not accurate.

Interpreting BGM and CGM Data for Clinical Decision-Making

There are some principles in the use of BGM and CGM that may enhance the effective use of each type of glucose monitoring. Forty years ago, PWD insisted, often to their skeptical medical teams, that they wanted to perform their own glucose monitoring at home, even if that meant using the crude lancet devices and slow and only moderately accurate glucose meters of that era. More recently, some clinicians have worried that CGM generates a potentially overwhelming level of data that may be confusing to PWD. Once again, however, many PWD are making it clear that they find such information helpful and that they find the emerging terminology around the concept of TIR easy to understand (71).

Efforts to standardize (72,73) and organize (74) CGM data to facilitate interpretation have led to the
establishment of 10 core CGM metrics for clinical care; CGM targets for times below, in, and above glycemic ranges; and a recommended single-page CGM report known as the ambulatory glucose profile (AGP) as a starting point for CGM-informed clinical care. The ADA has included these recommendations in its 2020 Standards of Care (29).

**AGP Report for CGM**

A 2-week AGP report is usually generated from CGM data at face-to-face or remote telehealth visits with PWD who use CGM systems. As shown in Figure 4A, the AGP is a three-panel, one-page report showing the 10 core CGM metrics and CGM targets in the first panel. A clinician or patient can review the Time in Ranges color bar to see if the recommended TIR target of glucose in the range of 70–180 mg/dL for >70% of readings is being met while also keeping the time-below-range metrics of <70 mg/dL and <54 mg/dL to the recommended <4% and <1% of readings, respectively. This graphic display shows whether there is room for improvement. The second panel of the AGP shows a 2-week glucose profile previously known as a “modal day” or “standard day” data depiction. This panel identifies at a glance where in the 24-hour period there is room for improvement. Recommendations are to mitigate any periods of hypoglycemia first and then tackle any hyperglycemia or excessive glycemic variability. The third panel depicts each of the daily glucose profiles from the 10–14 days of CGM use that make up panel 2. Reviewing these daily views helps to sort out whether there are differences in glycemic outcomes between weekends and weekdays or if any particular day of the week stands out as needing attention. Clinicians and PWD alike have generally embraced this one-page report that allows for a dialog about the collected data and facilitates shared decision-making on next steps toward improving glycemic management.

**AGP Report for BGM**

Although BGM had a 20-year head start on CGM, there has not been a similar concerted effort until now to generate a consensus BGM report similar to the one that has been so helpful in encouraging the uptake of CGM, despite the fact that the original AGP report conceived by Mazze et al. (75) in 1987 was developed for BGM data. Figure 4B shows a sample AGP report generated by an expert panel at the International Diabetes Center, using BGM rather than CGM data. Where possible, it follows the CGM version of the AGP (Figure 4A), including three graphic panels in a one-page report. Although 14 days is the default standard for the CGM AGP that includes several thousand glucose values, the AGP for BGM compiles 90 days of data with an average 2.2 checks/day and a few hundred total glucose checks summarized. The metrics are partly BGM-oriented, with the ability to calculate and display the average pre- and post-meal glucose values if the individual manually marks these time points. The BGM targets relate to the desired fasting, pre-meal, and post-meal glucose readings. In addition, there is the familiar color bar of glucose ranges, but for the BGM report, this is not called “Time in Ranges.” Rather, they are called “BGM Values in Ranges” because since these are intermittent BGM samples and do not cover the entire day. Instead, the percentage of values that were in the standard glucose ranges are displayed, along with the number of glucose checks that actually comprise each range. The glucose profile in the middle panel shows all of the glucose values at the times they were taken, color-coded to indicate in-range, below-range, or above-range values. In addition, the median line and interquartile range are included only when there are enough data to generate these summary metrics. This approach will often lead to gaps in the AGP graphic, but this is a teaching point to indicate that, with BGM, there are times (usually overnight) during which there is uncertainty regarding glycemic status. Finally, like the CGM report, the AGP BGM report ends with 2 weeks of individual day graphs so the clinician can see whether there are patterns of days with fewer tests performed that cannot be discerned from the combined data in panel 2.

**Intermittent Use of BGM and CGM**

Having a standardized and systematic approach to displaying BGM and CGM data makes for a smoother transition in glucose analysis when moving from BGM to CGM use or when using BGM and CGM intermittently. Are there data supporting the intermittent use of both methods of glucose monitoring in the management of type 1 or type 2 diabetes? This topic was nicely reviewed from the perspectives of PWD, HCPs, and health systems by Ziegler et al. (76), who concluded that the question of intermittent monitoring requires much more discussion.

For most individuals with type 1 diabetes, use of CGM is recommended on a continuous basis as much as is financially and socially acceptable (77). Many individuals with type 2 diabetes who are not on a multiple daily injection (MDI) insulin therapy regimen but who have not achieved their glycemic targets...
might also consider intermittent use of CGM and BGM. Professional CGM systems may facilitate this strategy for such patients. In this type of intervention, clinic-owned CGM systems are provided to PWD for 10- to 14-day wear periods, either blinded or providing real-time glycemic data. The data are then also evaluated retrospectively during a clinic or telehealth visit to assess the current state of management and look for glucose patterns. In addition, PWD can use a real-time CGM system intermittently, such as for 10–14 days once every 2–3 months, to get the value of real-time reinforcement of good food and exercise choices.

**Logical Cases and Positive Anecdotal Experience**

The most logical cases in which to use BGM and CGM intermittently are those in which PWD seem to value the data from CGM but do not want or cannot afford to wear a sensor continuously. In such cases, PWD can get the CGM-derived AGP and daily views during intermittent CGM use to help identify the times of day when there is room for the most improvement (i.e., very low or very high glucose levels) and then target those time periods with intermittent BGM. For example, if the person whose data is represented in Figure 4A could only afford or only wanted intermittent CGM use, that person could focus BGM between 3:00 and 7:00 a.m. and again between 7:00 and 8:00 p.m. to minimize potentially dangerous hypoglycemia and hyperglycemia, respectively, until another intermittent CGM AGP could be generated. Having the PWD direct BGM according to the previous CGM AGP can provide motivation for making lifestyle changes. It can also help to overcome clinical inertia, leading to shared decision-making regarding any necessary therapeutic changes.

One clinical scenario in which intermittent use of CGM seems particularly beneficial anecdotally is to provide a detailed glucose profile when considering adding a glucagon-like peptide 1 receptor agonist or basal insulin to a regimen of metformin and a sulfonylurea (usually reducing or stopping the sulfonylurea in the process). A second scenario in which intermittent CGM may be beneficial is to facilitate intensification from a basal insulin regimen. Often in such cases, there is a classic stair-step pattern of rising glucose after each meal until a person is very hyperglycemic at night, requiring large doses of basal insulin to try to normalize glucose levels by morning. In such instances the picture afforded by the CGM-derived AGP is so clear that PWD may agree to add mealtime insulin and adjust their basal insulin doses downward to smooth out the glucose profile. We refer to these scenarios as logical cases and anecdotal experiences because we currently lack randomized trials or even cohort-matched studies in real-world settings to confirm for larger numbers of PWD that intermittent CGM and BGM is an effective strategy (78).

More data are also needed on the appropriate use of BGM, CGM, and intermittent use of either or both in the real-world primary care setting. In 2018, an Italian team studied BGM in >13,000 individuals with type 2 diabetes from 21 clinical centers and concluded that, regardless of PWD’s therapeutic regimen, BGM was poorly utilized (defined as mostly fasting BGM, no structured BGM checking that might reveal glucose patterns, and overall very little BGM checking that would be helpful in guiding glycemic management) (79). One recent review of both BGM and CGM concluded that we will probably continue to see a mix of BGM and CGM use and, in many cases, a combined use of both monitoring methods (80). Both CGM and structured BGM can generate data to assist with pattern recognition and inform lifestyle changes and medication adjustments.

**INNOVATIONS IN BGM**

The use of BGM has been found to assist many PWD in achieving their glycemic targets (50,81,82). Traditional glucose meters display and store glucose measurements within the device. These data need to be retrieved before they can be analyzed by users or clinicians to guide treatment. Innovative technologies such as digital health apps that display and summarize individual blood glucose measurements and incorporate additional relevant data such as insulin doses, meals/snacks, and physical activity, can further support self-management while decreasing disease burden and benefitting overall diabetes care (83). Integration of BGM with insulin calculators, automated insulin titration software, and remote coaching are further developments that will be reviewed in this section.

**Diabetes Apps and Data Management**

**Regulations and Recommendations**

More than 1,500 mobile apps support diabetes management, many of which incorporate BGM. Digital health apps used for diabetes management include options that focus on nutrition, physical activity, glucose monitoring, insulin titration, and insulin delivery. These apps are generally intended to improve health outcomes by coaching PWD, supporting healthy eating...
and weight management, encouraging BGM, and helping with interpretation of glucose data and identification of glycemic patterns (22).

Although the field of digital health apps has been developing rapidly, regulations and guidelines have lagged behind. Mobile apps are still largely unregulated unless they meet the definition of a medical device for therapeutic or diagnostic purposes. Recently, however, regulatory agencies in the United States and abroad have recognized the rapid growth of this market and have released guidelines and policies (22). Many European countries assess whether a product meets the standards set by the E.U. Medical Device Directive (84). In the United States, the FDA in 2019 released an updated version of its Policy for Device Software Functions and Mobile Medical Applications (85).

The FDA requires evidence of safety, performance, and clinical effectiveness, using a risk-based approach (22,85,86). Mobile apps that provide insulin dose calculations are considered medical devices; those that track, record, or make behavioral suggestions about fitness, health, or wellness (e.g., dietary logs, calorie counters, and activity monitors) are not considered medical devices (85). FDA-cleared glucose meter–connected apps are described in Table 10.

Although digital health apps have great potential to benefit PWD, they can generate challenges for clinicians. HCPs need to understand not only the potential benefits, but also the potential risks with regard to data confidentiality, security, accuracy, and reliability (22). Readers are referred to a recently published consensus report from the Diabetes Technology Working Group of the ADA and the European Association for the Study of Diabetes for a detailed review of this topic and recommendations for the use of this technology in clinical practice (22).

### Table 10: FDA-Cleared Glucose Meter–Connected Apps

<table>
<thead>
<tr>
<th>Brand</th>
<th>Description and Compatible Meter(s)</th>
<th>Automatic Synchronization?</th>
<th>Apple/Android Compatibility?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contour Diabetes (Ascensia Diabetes Care)</td>
<td>Contour Next One meter&lt;br&gt;• Testing reminders&lt;br&gt;• Customizable graph view&lt;br&gt;• Color-coded glucose levels&lt;br&gt;• Alerts for critically high or low blood glucose levels&lt;br&gt;• Compatible with Apple Health&lt;br&gt;• Ability to share reports with HCP</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dario (Dario Health)</td>
<td>Dario Blood Glucose Monitoring System&lt;br&gt;• Digital logbook with trends&lt;br&gt;• Automatic unlimited test strips refills&lt;br&gt;• Carbohydrate counter&lt;br&gt;• Hypoglycemic alerts shared to up to four people via text message and GPS&lt;br&gt;• Three levels of subscription (basic, pro, and premium)</td>
<td>Yes</td>
<td>Yes, including Apple Watch</td>
</tr>
<tr>
<td>Glooko (Glooko)</td>
<td>Compatible with &gt;70 meters and numerous insulin pumps and CGM devices&lt;br&gt;• Testing reminders&lt;br&gt;• Medication reminders&lt;br&gt;• Customizable reminders&lt;br&gt;• Customizable graph view&lt;br&gt;• Compatible with Apple Health, iHealth, and Fitbit&lt;br&gt;• Can synchronize with HCP practice accounts&lt;br&gt;• Ability to share reports with HCP</td>
<td>Yes, for Bluetooth-enabled meters</td>
<td>Yes</td>
</tr>
<tr>
<td>iHealth Gluco-Smart (iHealth Labs)</td>
<td>iHealth Gluco and Align glucose meters&lt;br&gt;• Offers free Cloud data storage&lt;br&gt;• Medication reminders&lt;br&gt;• Ability to share reports with HCP</td>
<td>Yes</td>
<td>Yes, including Apple Watch</td>
</tr>
<tr>
<td>Lifescan OneTouch Reveal (Lifescan)</td>
<td>OneTouch Verio Flex meter&lt;br&gt;• Color-coded logbook and dashboard&lt;br&gt;• Customizable graph view&lt;br&gt;• Automatic notifications for repeated hypoglycemia or hyperglycemia values&lt;br&gt;• Ability to share reports with HCP</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*continued on next page*
**TABLE 10 continued from previous page**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Description and Compatible Meter(s)</th>
<th>Automatic Synchronization?</th>
<th>Apple/Android Compatibility?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livongo (Livongo Health)</td>
<td>Livongo cellular-enabled meter • Testing reminders • Custom alerts to automatically notify friends/family after an out-of-range reading • Live coach available 24/7 via text or call for out-of-range readings • Ability to share reports with HCP • Expert coaching (by a CDCES) to advise on lifestyle, diabetes, and blood pressure • Available primarily through employers or health care systems</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>mySugr (mySugr/Roche Diabetes Care)</td>
<td>Bluetooth-enabled Accu-Chek meters • Ability to share glucose data with others via text message • Customizable reports • Accu-Chek bolus advisor • Can synchronize with HCP practice accounts • Clinicians’ online portal home page</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>One Drop (One Drop)</td>
<td>One Drop meter • Medication reminders • One Drop Personal Diabetes Assistant, allowing logging of other relevant data • Automated decision support • Built-in food database with macronutrient and calorie counter • Scans barcodes on packaged foods • One Drop Predictive Insights machine learning algorithm • Tracks activity with a smartphone’s pedometer • Compatible with Apple Health, Google Fit, and FitBit • Ability to share reports with HCP • Personal diabetes coach option with CDCES: SugarRx (additional cost/month)</td>
<td>Yes</td>
<td>Yes, including Apple Watch</td>
</tr>
<tr>
<td>Patterns for POGO (Intuity Medical)</td>
<td>POGO Bluetooth-enabled meter • Reminders and alerts via push notifications, text, or email for low and high glucose • Testing schedule reminders • Medication schedule reminders • Sharing Circle: invite friends/family to view data and receive glucose alerts • Personal coaching with a CDCES (added cost per month) • Compatible with Fitbit, Strava, Apple Health, and MyFitnessPal • Ability to share reports with HCP</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

CDCES, certified diabetes care and education specialist; GPS, global positioning system.

**Cloud-Based Solutions**

Busy practitioners are often presented with multiple BGM communications from PWD, who use many different meters and may send in handwritten data logs or use meter-specific proprietary proprietary downloading software and nonstandardized data reports. In addition, the lack of integration of these reports with HCPs’ electronic medical record (EMR) systems makes the documentation of glucose levels cumbersome. These problems have led to the development of Cloud-based, device-agnostic diabetes data management systems, the largest of which are Glooko (known in Europe as Diasend-Glooko) and Tidepool. Both provide users with standardized reports that can assist in BGM pattern recognition and facilitate shared decision-making.

The Glooko platform (https://glooko.com, Glooko) is available to practices by subscription (87). It allows rapid in-clinic or remote uploading of data from >70 different glucose meters and numerous insulin pumps and CGM systems (Figure 5) and potential integration into EMR systems. The Tidepool platform (https://tidepool.org, Tidepool Project), run by a nonprofit organization, provides free software for PWD and clinicians to upload, share, and review data from >25 meters, as well as most insulin pumps and CGM devices (Figure 6). Tidepool has a “copy as text” feature, enabling copying and pasting of BGM data into clinic notes (88).
FIGURE 5 Glooko BGM log. A) Overview of blood glucose values with color-coded dots, from low to high (red = <70, green = 70–180, and orange = >180 mg/dL). Bottom panel shows glucose mean and SD. B) Overlay of 14 days of blood glucose values graphed by time of day showing median, lowest and highest averages, and percentiles (25–75% and 10–90%). Bottom panel shows glucose mean and SD, number of glucose readings/day, and percentages of glucose levels in the target range (green; 70–180 mg/dL), above range (orange; >180 mg/dL and >250 mg/dL), and below range (red; <70 mg/dL and <54 mg/dL).
FIGURE 6 Tidepool BGM log. A) Blood glucose values with color-coded dots, from low to high (red = <54, orange = <70, green = 70–180, lilac = >180, and purple = >250 mg/dL). B) Overlay of 14 days of blood glucose values graphed by time of day with average bars depicting 3-hour blocks, in green if blood glucose is 70–180 mg/dL. On the right panel is a “copy as text” feature, average glucose value with SD, and average daily readings in range (green; 70–180 mg/dL), above range (lilac; >180 mg/dL and purple; >250 mg/dL), and below range (orange; <70 mg/dL and red; <54 mg/dL).
Although diabetes apps have tremendous potential (89), barriers exist for many individuals. These include low literacy and numeracy levels, inability or challenges with regard to using smartphone or other smart devices (e.g., older adult or those with impaired vision or hearing); costs, low digital (i.e., computer or Internet) literacy, limited Internet access, and insufficient broadband Internet service or “dead zones” in urban and rural settings (22,83,90).

### Insulin Dose Calculators

Successful diabetes self-management enables PWD to achieve their glycemic goals and is especially important for those on insulin therapy (45). Intensive insulin therapy requires the completion of multiple complex daily tasks. These include monitoring glucose levels before meals and at bedtime; counting carbohydrates and calculating insulin doses for each meal or using fixed insulin doses with carbohydrate-consistent meals; adjusting insulin doses to correct hypoglycemia or hyperglycemia; and calculating correction doses based on an individualized ISF or a predetermined insulin algorithm. All these actions must be performed every day to achieve and maintain euglycemia and avoid short- and long-term complications. These tasks can be especially challenging for PWD with low literacy or numeracy levels (91).

Insulin dose calculators are incorporated into insulin pumps, but many PWD who use an MDI insulin regimen instead of a pump can also benefit from such a tool to improve their dosing accuracy. Dose calculators are preprogrammed with a user’s ISF, individualized I:C ratio, and target glucose range. When users enter a blood glucose reading and the amount of carbohydrate they intend to eat, the calculator will provide a recommended insulin dose.

Numerous insulin calculator apps are available, but the accuracy and reliability of some are poor. An evaluation of 46 such apps found that two-thirds posed a risk for inappropriate dosing (92,93). Therefore, clinicians must proceed with great caution when recommending an insulin dose calculator to limit exposure of PWD to incorrect calculations that could result in erroneous insulin dosing recommendations with potentially catastrophic results.

Eiland et al. (94) identified 20 diabetes self-management apps that were cleared by the FDA or bore a CE (European Conformity) mark and had evidence of efficacy, safety, or feasibility reported in peer-reviewed literature. Of these 20 apps, fewer than half contained insulin dose calculators. Since 2019, insulin dose calculator apps have been considered medical devices and are regulated by the FDA (86,94). Those available in the United States are described in Table 11.

**TABLE 11** Insulin Dose Calculators Available in the United States

<table>
<thead>
<tr>
<th>Brand</th>
<th>Platform</th>
<th>Regulatory Clearance/Marking</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accu-Chek Connect (Roche Diabetes Care)</td>
<td>Meter, phone app</td>
<td>FDA</td>
<td>• Prescription only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Insulin calculator provides bolus recommendations taking into account multiple variables</td>
</tr>
<tr>
<td>Glooko Mobile Insulin Dosing System (Glooko)</td>
<td>Phone app</td>
<td>FDA</td>
<td>• Prescription only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Long-acting insulin dose recommendations according to the parameters set by the clinician</td>
</tr>
<tr>
<td>InPen (Companion Medical)</td>
<td>Phone app</td>
<td>FDA</td>
<td>• Prescription only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Bolus calculator tracks insulin doses</td>
</tr>
<tr>
<td>Insulia (Voluntis)</td>
<td>Phone app</td>
<td>FDA/CE</td>
<td>• Prescription only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Long-acting insulin dose calculator with treatment algorithm entered by the clinician</td>
</tr>
<tr>
<td>iSageRx (Amalgam Rx)</td>
<td>Phone app</td>
<td>FDA</td>
<td>• Prescription only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Long-acting insulin dose calculator with treatment algorithm entered by the clinician or from a validated algorithm from research studies</td>
</tr>
<tr>
<td>My Dose Coach (Sanofi)</td>
<td>Phone app</td>
<td>FDA</td>
<td>• Long-acting insulin dose calculator based on the algorithm recommended in American Association of Clinical Endocrinologists guidelines</td>
</tr>
</tbody>
</table>
**Connected Care**

The term “connected diabetes care” (95) refers to diabetes management systems that use smartphone apps, connected devices, and remote human and automated coaching. The goal of such systems is to provide PWD with remote education, coaching, and communication to augment their usual care and improve self-management and outcomes.

Most such systems use connected BGM. Some programs use a business-to-business-to-consumer model, providing the program to an employer or insurer, which in turn offers it to PWD, and some offer peer support and an interactive curriculum. All connected diabetes care companies with remote human coaches employ teams of diabetes care and education specialists, nurses, dietitians, and exercise scientists. Presently, Virta Health (https://virtahealth.com) and Onduo Health (https://onduo.com) consider themselves to be virtual medical clinics and employ physicians who can prescribe and titrate medications (96,97). The most salient features of selected connected care companies and their key published data are summarized in Table 12 (98–113).

**Artificial Intelligence**

Artificial intelligence (AI) decision-support systems are becoming commercially available and have the potential to improve diabetes management by providing tools to automate insulin titration and dose adjustment recommendations for PWD on insulin therapy. One such system is the DreaMed Advisor Pro (https://dreamed-diabetes.com, DreaMed), which received FDA clearance in 2018.

With this system, data from CGM or BGM and insulin pumps are uploaded to a data management system such as Tidepool or Glooko. After uploading and analyzing the data, the Advisor searches for hyperglycemic or hypoglycemic patterns and produces an insulin titration recommendation for optimization of insulin pump settings. Future versions are expected to incorporate smart insulin pens for patients using an MDI insulin regimen. Clinicians can review the automated recommendations, edit them, and share them with PWD either during a visit or electronically. In the future, availability of additional AI systems is anticipated.

To summarize, diabetes self-management is often limited by the absence of real-time BGM data needed

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**TABLE 12 Major Connected Diabetes Care Companies and Published Evidence of Their Impact**

<table>
<thead>
<tr>
<th>Company</th>
<th>Peer Support?</th>
<th>Prescribing HCPs on Team?</th>
<th>Published Research, Study Type, Year, n, Reference</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canary Health</td>
<td>Yes</td>
<td>No</td>
<td>• Non-RCT, 2018, 558 (98)</td>
<td>• Cost savings</td>
</tr>
<tr>
<td>Cecelia Health</td>
<td>No</td>
<td>No</td>
<td>• Non-RCT, 2017, 181 (99)</td>
<td>• 2.4% A1C reduction at 6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-RCT 2020, 34, (100)</td>
<td>• 1.1% A1C reduction at 3 months</td>
</tr>
<tr>
<td>Livongo Health</td>
<td>Yes</td>
<td>No</td>
<td>• Non-RCT, 2017, 4,544 (101)</td>
<td>• Fewer hypoglycemia and hyperglycemia events</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-RCT, 2018 330 (102)</td>
<td>• 1% A1C reduction at 34 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non RCT, 2019, 86 (103)</td>
<td>• 0.66% A1C reduction at 1 year</td>
</tr>
<tr>
<td>mySugr Bundle (mySugr/Roche)</td>
<td>Yes</td>
<td>No</td>
<td>• Non-RCT, 2019, 52 (104)</td>
<td>• Increase in glucose testing frequency</td>
</tr>
<tr>
<td>Onduo</td>
<td>No</td>
<td>Yes</td>
<td>• Non-RCT, 2018, 44 (105)</td>
<td>• 1.3% A1C reduction at 6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-RCT, 2020, 612 (106)</td>
<td></td>
</tr>
<tr>
<td>One Drop</td>
<td>Yes</td>
<td>No</td>
<td>• Non-RCT, 2017, 1,288 (107)</td>
<td>• 1.27% A1C reduction at 4 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-RCT, 2017, 256 (108)</td>
<td>• 1.36% interval A1C reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-RCT, 2018, 127 (109)</td>
<td>• 0.86% A1C reduction at 12 weeks</td>
</tr>
<tr>
<td>Virta Health</td>
<td>Yes</td>
<td>Yes</td>
<td>• Non RCT, 2017, 329 (110)</td>
<td>• 0.9% A1C reduction at 2 years</td>
</tr>
<tr>
<td>BlueStar (Welldoc/Lifescan)</td>
<td>No</td>
<td>No</td>
<td>• RCT, 2008, 30 (111)</td>
<td>• 2.03% A1C reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• RCT, 2011, 163 (112)</td>
<td>• 1.9% A1C reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• RCT, 2019, 223 (113)</td>
<td>• No A1C difference</td>
</tr>
</tbody>
</table>

RCT, randomized controlled trial.
to make informed decisions to help PWD achieve and maintain their glycemic targets. The advent of mobile health apps allows PWD to use their glucose meters in a partner-based model, through which app-based BGM becomes a “health companion,” providing reminders for performing BGM and taking medications and offering immediate feedback and graphic depictions of current glycemic status. Device-agnostic software platforms can enable clinicians’ easy review and assessment of BGM data as displayed in standardized reports, facilitating treatment optimization. For PWD using MDI insulin therapy, insulin dose calculators, as stand-alone tools or integrated into insulin pens, can ease the burden of complex dose calculations.

However, challenges remain. Regulatory agencies must ensure that available apps are safe (i.e., accurate), and HCPs need improved access to FDA-cleared apps and the knowledge and confidence to use them in clinical practice. Apps should be affordable and available in multiple languages, and access to smartphones and Internet services must be expanded.

CONCLUSION

Throughout the past several decades, BGM has been fundamental for optimal diabetes self-management, and it will remain an important tool for PWD for years to come. BGM devices have become smaller and more accurate and now require less blood and include more features such as Cloud-based data management systems and connectivity to other devices. The accuracy of BGM is crucial because its results are used to direct therapy.

Accuracy can vary among devices. Errors can be caused by use of expired, improperly stored, or damaged strips; poor technique, including inadequate site cleansing; conditions such as hypoxemia and anemia; and the use of high-dose vitamin C and acetaminophen. Over the years, the standards required to gain FDA clearance have become more stringent (9), and more accurate glucose meters are now available in the marketplace. However, there is no formal re-evaluation of meters after clearance to ensure continued device accuracy.

BGM is only helpful if PWD know how to view, interpret, and act on their results. Education is essential in this regard. PWD need to learn proper technique, overcome barriers to use, and receive training in understanding and using their results to optimize glycemic management.

The recommended frequency of BGM should be individualized. People with type 1 diabetes will generally need to perform BGM 4–10 times/day, whereas those with type 2 diabetes who are at or near their glycemic targets and not taking medications that can cause hypoglycemia may use BGM less frequently or not at all (Table 3).

Pattern recognition, including identifying glycemic excursions related to eating, physical activity, stress, and illness, is important and should be used to help direct treatment. The use of structured BGM profiles such checking before and after meals, before and after exercise, and at bedtime and fasting, can assist in adjusting food, physical activity, treatment regimens, and medication dosing. BGM also is needed when hypoglycemia is suspected and, for PWD using insulin, before driving or performing other crucial tasks (29). Adopting a counseling strategy that focuses on the information, motivation, and behavioral skills PWD need to succeed and incorporates the use of negotiated, incremental, achievable goals that are elicited, if possible, from PWD rather than HCPs, will facilitate efficient and effective use of BGM.

Differences abound in the ability of various glucose meters to communicate with other glycemic management systems. Integration of meters with Cloud-based data management systems facilitates remote monitoring. The use of additional innovations such as insulin dosing calculators, smartphone apps, remote coaching, and artificial intelligence systems is on the rise, and their availability and accessibility are expected to expand.

Glucose monitoring can now be accomplished via CGM as well as BGM. The ADA recommends that PWD who use CGM have the ability to perform BGM to verify readings when symptomatic, if they are concerned that their CGM transmitter or sensor is not working properly, and to calibrate certain CGM devices per manufacturers’ instructions (29). In general, the use of CGM is costlier than BGM and is not necessary for people with type 2 diabetes who are not treated with insulin and are maintaining their glycemic goals. For those who have not achieved their glycemic goals, directed BGM based on glucose patterns observed through the intermittent use of CGM can help PWD make needed lifestyle and medication adjustments.

As countries worldwide struggle with health care costs, it is important for all HCPs to recommend glucose monitoring approaches that are cost-effective. BGM is less expensive than CGM and sufficient for
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many people with type 2 diabetes. BGM also needs to be available for people using CGM. The ability to download, examine, interpret, and transmit stored glucose data facilitates communication with HCPs and empowers PWD to make health decisions to manage their condition. When used as part of a diabetes management plan and with appropriate support, BGM can help PWD better reach their glycemic goals.

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Dualities of Interest

R.S.W. has received research support through her institution from Boehringer Ingelheim, Diasome, Eli Lilly, Insulet, Kowa, Medtronic, and Tolerion and receives royalty payments from Wolters Kluwer Health (Up-to-Date). She has also received honoraria for presentations from the American Diabetes Association.

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R.M.B. has received research support from, consulted for, or been on a scientific advisory board of Abbott Diabetes Care, Ascensia, DexCom, Hygieia, Johnson & Johnson, Lilly, Medtronic, Novo Nordisk, Onduo, Roche, Sanofi, and United Healthcare. His technology research is funded by the National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases and the Leona M. and Harry B. Helmsley Charitable Trust. R.M.B.’s employer, the nonprofit HealthPartners Institute, contracts for his services, and no personal income goes to him for these services.

W.A.F. has received research support and has been a consultant to and speaker for Ascensia and Roche.

D.A.G. is a consultant for Lifescan and Lifescan Diabetes Institute; serves on an advisory board for Novo Nordisk; in addition to her consulting work and prior to the publication of this compendium, she was hired as an employee of Dexcom.

L.A.Y. has received research support from the American Diabetes Association, Bayer, Boehringer Ingelheim, Dexcom, Johnson & Johnson, Lexicon, Novo Nordisk, Sanofi, and vTv Therapeutics.

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Author Contributions

Lead author R.S.W. reviewed all content and wrote the introduction and conclusion. G.A. wrote the section titled “Innovations in BGM.” T.S.B. wrote the section titled “BGM Accuracy.” R.M.B. wrote section titled “Use of BGM in CGM Users.” W.A.F. wrote the section titled “Overcoming Barriers to BGM.” D.A.G. wrote the section titled “Using BGM Data to Achieve Treatment Goals.” L.A.Y. wrote the section titled “Recommendations for BGM Use.” All authors reviewed and edited the manuscript and approved the final version for publication. R.S.W. is the guarantor of this work.

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