

## REVIEW ARTICLE

## HOME BLOOD GLUCOSE MONITORING

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## KEYWORDS

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Diabetes affects more than 37 million Americans. More than one-third of American adults (96 million) have prediabetes, so it is anticipated that the prevalence of diabetes will continue to climb in the generation to come. There have been major advances in the options for home glucose monitoring. Home glucose monitoring provides critical information and feedback for patients with diabetes to help them understand how daily activities affect their glucose levels and timely data to assist in behavior reinforcement and modification. Self-monitoring of blood glucose (SMBG) is of great value to those with type 1 diabetes and those with type 2 diabetes on insulin as it reduces HbA1c and rates of hypoglycemia. Currently, there is less support for long-term benefit of SMBG in those with type 2 diabetes not on insulin or insulin secretagogues. Continuous glucose monitoring (CGM) is becoming increasingly available to help manage diabetes. This form of monitoring provides benefits in terms of HbA1c, reduced time and rates of hypoglycemia, and increased time in range for those on insulin. CGM reports now include standardized reporting and target goals that will make widespread use easier to implement. This article will review the current data on home glucose monitoring for those with diabetes.

## HOME SELF-MONITORING OF BLOOD GLUCOSE

Diabetes affects more than 37 million Americans.<sup>1</sup> More than one-third of American adults (96 million) have prediabetes, so it is anticipated that the prevalence of diabetes will continue to climb in the generation to come and will eventually affect more than one-third of the US population.<sup>2</sup> Blood glucose monitoring can offer important information when tailoring a diabetes treatment plan. Recommendations on when to test, how often to test, and how to interpret the results are variable and need to be individualized to the patient and the treatment regimen. When used as a tool to gather information for both the physician and patient, blood glucose monitoring can make a significant impact on achieving glycemic goals and patient engagement and satisfaction.

Home blood glucose monitoring, also called self-monitoring of blood glucose (SMBG) utilizes a lancet to obtain capillary blood from a fingerstick that is then measured in a glucometer. Glucometers are available over the counter and by prescription and vary in insurance coverage. The US Food and Drug Administration (FDA) and the International Organization for Standardization have guided regulatory standards for glucometers. In 2020, the criteria became more strict, stating that for over-the-counter

glucometers, 95% of all blood glucose readings should be  $\pm 15\%$  of comparator results across the entire measuring range of the device.<sup>3</sup> Additionally, glucometers that require a prescription should show 95% of all readings, including those  $\leq 75$  mg/dL, and should be within  $\pm 12\%$  of comparators.<sup>4</sup> These standards ensure both accuracy and precision when urgent treatment depends on a blood glucose reading. A full range of glucometers, as well as continuous glucose monitors are available for review in an annual issue of *Diabetes Forecast*, a journal published by the American Diabetes Association (ADA).<sup>5</sup>

**Clinical case:**

*Sixty-two-year-old male with a 12-year history of type 2 diabetes. He used to check every morning, but says he can “feel” what his glucose is, so he stopped checking. He is taking metformin 1000 mg bid, glipizide 5 mg bid, and insulin glargine 48 units per day. He is surprised as his HbA1c is consistently between 8.5%–8.9% but when he occasionally checks his glucose in the morning, it typically runs between 58 mg/dL–162 mg/dL.*

For many patients with diabetes, multiple daily SMBG was the standard of care. But as treatment options evolve, so has the need for monitoring. Several groups of individuals may benefit from continuing multiple daily SMBG checks. Those with type 1 and type 2 diabetes on insulin need SMBG to direct insulin therapy. Many of those patients choose to use continuous glucose monitors, but some prefer to continue SMBG by fingerstick. Even those with continuous glucose monitors should have a fingerstick glucometer as a backup means of checking blood glucose in the event the monitor malfunctions.

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However, many patients with type 2 diabetes may not require multiple fingerstick glucose checks. Treatment algorithms now rely less on insulin and other medications that have a high risk of hypoglycemia. For example, the ADA now recommends considering glucagon-like peptide-1 receptor agonists (GLP-1 RA) as first-line agents when initiating an injectable medication instead of insulin.<sup>6</sup> The therapeutic effect of GLP-1 RAs involves glucose-dependent insulin secretion, so the risk of hypoglycemia is very low.<sup>6</sup> Other medications for the treatment of type 2 diabetes that have a low incidence of hypoglycemia include metformin, pioglitazone, dipeptidyl-peptidase IV (DPP-4) inhibitors, and sodium-glucose cotransporter-2 (SGLT-2) inhibitors. In patients with type 2 diabetes on treatments with low risk of hypoglycemia, routine SMBG may not be necessary. The drawbacks of home SMBG include cost, time, and inconvenience. Although glucometers are usually inexpensive (\$9–\$60), glucose testing strips can sometimes be expensive (\$15–\$100 per month) depending on insurance coverage and availability.<sup>5</sup> Another study looked at the cost-effectiveness of SMBG in those without insulin. In this modeling study, costs were estimated in patients completing SMBG >7 times a week. This testing was associated with a 0.25% reduction in HbA1c at the incremental cost per quality-adjusted life year of \$113,643 (based on current commercial pricing).<sup>7</sup>

Carrying the glucometer everywhere and the time needed to test can be inconvenient and there is some pain associated with multiple daily fingerstick glucose readings. That is why it is important to use shared decision-making to identify when SMBG will benefit the patient.

Self-monitoring of blood glucose does not improve outcomes in patients with type 2 diabetes who are not at risk for hypoglycemia. A large study found that in patients with an HbA1c of 6.5%–9.5% who are not on insulin, there was no significant change in HbA1c, hypoglycemia frequency, healthcare utilization, or insulin initiation between groups with or without SMBG.<sup>8</sup> A meta-analysis showed those using SMBG had improvements in HbA1c at 12 and 24 weeks but no difference at one year of follow-up.<sup>9,10</sup> Another study explored patient perspectives on the role of SMBG in diabetes management. Patients reported that when there was no actionable plan for their glucose readings and when doctors focused on HbA1c and showed a lack of interest in the SMBG readings, the practice was not worth continuing and readings became associated with “good and bad” behavior and a reminder of not achieving success.<sup>11</sup>

A Cochrane review was completed on the benefit of SMBG in patients with type 2 diabetes who are not on insulin. The findings revealed that when diabetes duration is more than 1 year, the overall effect of self-monitoring of blood glucose on glycemic control in patients with type 2 diabetes is small up to 6 months after initiation and subsides after 12 months.<sup>12</sup> However, the authors recommended that further study be completed “to explore the psychological impact of SMBG and its impact on diabetes-specific quality of life and well-being, as well as the impact of SMBG on hypoglycemia and diabetic complications.”<sup>12</sup>

The International Diabetes Federation states, “SMBG should be used only when individuals with diabetes and/or their

healthcare providers have the knowledge, skills, and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals.”<sup>13</sup> When structured SMBG has been utilized and treatment changes have been made based on the results, studies have shown improvement in glycemic control in noninsulin-using type 2 diabetes, improvements in postprandial glucose management, reduced cardiovascular risk, and improvements in other health parameters, such as body weight, quality of diet, level of physical activity, and mental health.<sup>10</sup> The goal of SMBG is to provide data for both the patient and physician. This data can then be utilized to change health behaviors and pharmacologic therapies only if the patient and the physician know how to interpret the data (table 1).<sup>14</sup>

When glycemic goals are not being met, evaluating glucose patterns is essential and can facilitate treatment changes and improve HbA1c.<sup>15,16</sup> Patients can gain insight into the effect food choices, physical activity, stress, and medications have on their blood glucose. This empowers the patient to take an active role in decision-making. Physicians can recognize the need for increased treatment of fasting glucose or postprandial glucose and employ targeted medication changes. Utilizing tools such as glucose logbooks or tracking apps can make it easier to identify patterns. Data can be collected at the same time for as little as 3–4 days, then analyzed.<sup>17</sup>

Another important time to utilize structured SMBG is at the onset of type 2 diabetes. One study looked at newly diagnosed patients with type 2 diabetes and divided them into two groups: SMBG intervention or monitored by HbA1c alone. Higher rates of regression (HbA1c < 6% on metformin alone) or remission (HbA1c 6%–6.4%) were achieved in the group with SMBG, as well as greater reductions in HbA1c and decreased body mass index (BMI).<sup>18</sup> It is also important to teach the skill of checking SMBG to those newly diagnosed before they need the skill, such as if they develop symptomatic hypoglycemia or develop an acute illness and have hyperglycemia. The American Diabetes Association suggests that SMBG should be prescribed as part of a diabetes self-management education and support program for all patients receiving insulin and may be helpful for patients on noninsulin therapies when altering diet, physical activity, or medications.<sup>19</sup>

**TABLE 1:**

ADA recommendations for self-monitoring blood glucose<sup>17</sup>

<b>Type 1 diabetes</b>	4–10 times daily or CGM
<b>Gestational diabetes mellitus</b>	4 times daily until controlled; then 1–2 times daily
<b>Type 2 diabetes on insulin</b>	Before every insulin injection
<b>Type 2 diabetes on insulin secretagogues</b>	As needed to identify and prevent hypoglycemia or as part of an acute illness
<b>Type 2 diabetes: no insulin, no insulin secretagogues</b>	FSG monitoring may not be needed. Best used when treatment is being adjusted, acute illness is present, or symptoms of hyperglycemia are present

**The role of HbA1c alone in glycemic assessment:**

HbA1c has become a powerful measure of glucose control. It is a validated reference marker for assessing glycemic control and predicting the risk of developing long-term complications in both type 1 and type 2 diabetes.<sup>16,17</sup> The assay has been rigorously standardized, can be drawn in the fasting or nonfasting state, and is widely available in labs and as a point-of-care test in the office. The HbA1c provides an estimate of mean glucose over the last 2–3 months, but it is more heavily weighted to more recent control.<sup>18</sup>

However, the weaknesses of HbA1c are many, including measurements that are affected and become less accurate in patients who have anemia, a hemoglobinopathy, iron deficiency, recent blood loss or transfusion, or pregnancy.<sup>19,20</sup> HbA1c also does not shed light on the lived experience of glucose control over time. This includes daily glucose excursions, glucose variability, or time in range. It also is weighed toward more recent events, and it does not predict rates of hypoglycemia.<sup>19</sup>

Hypoglycemia is a particular concern not well addressed by HbA1c. In type 1 diabetes, HbA1c was a poor predictor of rates of severe hypoglycemia, whereas 13.2% of the patients with an HbA1c <7.0% had severe hypoglycemia. Those with an A1c of 8%–9% had a 13.7% incidence, and even those with an HbA1c >10.0% had a 12.1% incidence.<sup>21</sup> In type 2 diabetes, rates were high across all HbA1c levels (14.4%–29.8%) but lowest in the 8%–8.9% group (14.4%) and highest in those who take insulin (39.4%), insulin secretagogues (48.3%), those who had diabetes lasting more than 10 years (57.4%), and those on 4 or more medications (71%).<sup>22</sup> In another outpatient study of 108 patients with type 2 diabetes treated at a specialty center (64 of whom were on insulin), a blinded CGM was placed for 5 days. Surprisingly 53 participants (49%) had at least one episode of hypoglycemia with a mean of 1.74 episodes over the 5-day period and equal rates of hypoglycemia in the daytime and at night. The great majority of the participants were asymptomatic and not aware of these episodes (75%). Twenty-one percent reported hypoglycemic symptoms when there was no SMBG or CGM evidence of hypoglycemia.<sup>23</sup> These results underscore the need for data to support glycemic excursions as patient symptoms are unreliable in identifying hypoglycemia and hyperglycemia.

Recent attention has focused on glucose variability caused by both hyperglycemia and hypoglycemia as a contributor to increased complications. Glucose variability and hypoglycemia have been linked to microvascular and macrovascular complications.<sup>24,25</sup> It is important to not only achieve an HbA1c, which is linked to complications, but also to look at how a person gets to that HbA1c based on glucose variability along the way. This is often hard to capture with SMBG and is now best captured with CGM.

**CONTINUOUS BLOOD GLUCOSE MONITORING IN 2022**

Continuous glucose monitoring systems use measurement of subcutaneous interstitial fluid to provide glucose measurements at 1- to 5-minute intervals. These correlate well with blood glucose measurements but provide a more comprehensive

view of glucose excursions, including glucose trends and rate of change of glucose. When taken in summary, a more complete picture of glycemic patterns is seen, including variations during the day and overnight. Variability of glucose levels also provides important information about the timing, frequency, and duration of hypoglycemia, which can be central to prevention. The first 10 years has seen a dramatic expansion and improvement in the precision and ease of use of CGM systems. Originally CGMs were not more precise than blood glucose monitors and they required multiple daily calibration (table 2). Currently, two CGM systems require no blood glucose monitoring calibrations and can be used independently to guide medication, including insulin dosing.

**TABLE 2:**  
ADA recommendations for continuous glucose monitoring (CGM)

1. When prescribing CGM, robust diabetes education, training, and support are required for optimal device implementation and ongoing use. (Expert opinion)
2. When used properly, CGM, in conjunction with insulin therapy, is a useful tool to lower HbA1c levels and reduce hypoglycemia in adults with type 1 diabetes. (A-level evidence)
3. When used properly, CGM, in conjunction with insulin therapy, is a useful tool to lower HbA1c levels and reduce hypoglycemia in adults with type 2 diabetes. (B-level evidence)
4. Real-time CGM devices should be used as close to daily as possible for maximal benefit. (A-level evidence)
5. Blinded CGM data, when coupled with diabetes self-management education and support, can be helpful in identifying and correcting patterns of hyper- and hypoglycemia in patients with type 1 and type 2 diabetes. (Expert opinion)

Outcomes indicate that CGM can provide benefits, including increased time in range, reduced hypoglycemia, and improved HbA1c levels. This has been shown both in type 1 diabetes<sup>20,21</sup> and type 2 diabetes.<sup>22,23</sup> A recent study looked at the real-world impact of universal coverage for intermittently scanned CGM for type 1 diabetes and found that unrestricted reimbursement of CGM in patients with type 1 diabetes resulted in less severe hypoglycemia and less work absenteeism while maintaining quality of life and HbA1c.<sup>24</sup> Recently, a 3-year follow-up to this study found HbA1c reductions of –0.96% in multiple daily insulin dosing individuals and an HbA1c reduction of –0.71% in those on insulin pump therapy. Further, those on CGM had a 68% reduction in hypoglycemia and 100% reduction in diabetic ketoacidosis rates over the 3-year observational period. These changes resulted in per-person savings of \$3,555–\$6,747 over the course of 3 years.<sup>25</sup>

Another study in adults with poorly controlled type 2 diabetes utilized CGM as a motivational tool for behavior change. Over a 3-month period, the CGM group saw an HbA1c reduction from 9.1% to 8.0%, versus SMBG 8.7% to 8.3%, *P* = 0.004. Further, the CGM group saw an improvement in self-care behaviors, including a significant reduction in total daily calorie intake, weight, and BMI and a significant increase in total exercise time per week.<sup>26</sup>

While CGM systems are widely available, healthcare professionals will need to learn how to access and interpret the data to provide the biggest impact. In 2019, an international committee met to develop standards and targets for CGM data (table 3). These were developed to maximize the benefit of CGM use in patients with diabetes and provide a structure for interpretation of the data.<sup>27</sup> Key metrics to consider from a CGM report (ambulatory glucose profile) include target range, below target, above target, glucose variability and time range, and glucose management indicator—an HbA1c estimate based on readings obtained from CGM.<sup>27</sup> This will require substantial physician education about how to incorporate systems into the practice and how to share results with patients.

**TABLE 3:**

Goals for time in range on an ambulatory glucose profile from a continuous glucose monitor

DIABETES TYPE	GLUCOSE GOAL RANGE	GOAL TIME IN THIS RANGE
<b>T1 and T2</b>	Overall target range 70 mg/dL–180 mg/dL	>70%
	Hypoglycemia: below target <70 mg/dL (low) <54 mg/dL (very low)	<4% <1%
	Hyperglycemia: above target >180 mg/dL (high) <54 mg/dL (very low)	<25% <5%
<b>Older high-risk adults T1/T2</b>	Hypoglycemia: target range <70 mg/dL Hyperglycemia: >250 mg/dL	>50% <1% <30%

For glucose monitoring to have the greatest effect, there must be goals to help address specific issues. More recently, continuous glucose sensors have become available. These sensors provide ongoing feedback that provides even more information about glucose responses to eating, exercise, and other activities. This has served as the ultimate feedback tool for some. However, when these technologies are applied to the 34 million Americans with diabetes, this can prove costly to the healthcare system and may not provide equal benefit to all users.

Self-monitoring of blood glucose is of greatest value in patients with type 1 and type 2 diabetes who are taking insulin or medications that can cause hypoglycemia. There is little evidence of long-term benefits of SMBG in patients not using insulin who are on secretagogues to manage their diabetes. Optimal use of SMBG relies on “targeted testing” that identifies specific glycemic challenges to address with the patient. Continuous glucose monitoring use has become much more widespread since the last review on this topic. These systems benefit patients on insulin the most but can be used as a powerful educational tool when part of a comprehensive diabetes self-management education plan. Physicians can have an impact on the utility of SMBG. A well-informed physician able to download and interpret the data can provide more meaningful feedback to the patient completing SMBG. Useful reviews are available for a physician hoping to utilize CGM in their practice.<sup>17,28,29</sup>

### **Clinical case follow-up:**

*As a reminder, our patient was on metformin, glipizide, and insulin. He was frustrated that his glucose monitoring did not match his HbA1c levels and he stopped checking regularly. The patient was placed on a 14-day glucose monitoring system and asked to return to review his results. To his surprise, his glucose dropped low pretty regularly, followed by long periods of time when he became hyperglycemic afterward. He was not feeling these hypoglycemic events (known as hypoglycemic unawareness). The treatment team first stopped his glipizide and his hypoglycemic episodes went away. He initially focused on his fasting glucose. With minor changes in his basal insulin, his morning glucose was at the target range of 100 mg/dL–150 mg/dL set for him. The treatment team then asked him to stop the morning SMBG and move to checking 90 minutes after one meal per day. He found that these readings were higher at 150 mg/dL–250 mg/dL. The team discussed that he would need some treatment to help better cover his meals. He agreed to reduce carbohydrates at meals and to start an SGLT-2 inhibitor. He continued on metformin and insulin glargine 54 units daily. He was happy to report that his glucose readings improved and his next HbA1c was 7.2%. He was looking forward to checking his glucose as the results now made sense and he could respond to them.*

### **CONCLUSION**

Glucose monitoring without patient education or advisement may have limited value. However, recent research has supported the value of targeted glucose monitoring and even continuing glucose monitoring in patients with diabetes—even those who are not taking insulin.

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