AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY 2016 OUTPATIENT GLUCOSE MONITORING CONSENSUS STATEMENT

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This document represents the official position of the American Association of Clinical Endocrinologists and American College of Endocrinology. Where there were no randomized controlled trials or specific U.S. FDA labeling for issues in clinical practice, the participating clinical experts utilized their judgment and experience. Every effort was made to achieve consensus among the committee members. Position statements are meant to provide guidance, but they are not to be considered prescriptive for any individual patient and cannot replace the judgment of a clinician.

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(Appendixes are available online at http://aace.journals.aace.com)

Abbreviations:
A1C = glycated hemoglobin; **AGP** = ambulatory glucose profile; **ARD** = absolute relative difference; **BGM** = blood glucose monitoring; **CGM** = continuous glucose monitoring; **CMS** = Centers for Medicare and Medicaid Services; **CSII** = continuous subcutaneous insulin infusion; **CV** = coefficient of variation; **DCCT** = Diabetes Control and Complications Trial; **DirecNet** = Diabetes Research in Children Network; **FDA** = US Food & Drug Administration; **GDM** = gestational diabetes mellitus; **GM** = glucose monitoring; **IDF** = International Diabetes Federation; **ISO** = International Organization for Standardization; **MARD** = mean absolute relative difference; **MDI** = multiple daily injections; **MedARD** = median absolute relative difference; **MNT** = medical nutrition therapy; **SAP** = sensor-augmented pump; **T1DM** = type 1 diabetes mellitus; **T2DM** = type 2 diabetes mellitus.

INTRODUCTION

The measurement of glycemic status is a key element in the care of all persons with diabetes (1,2). Glucose monitoring (GM) enables clinicians to evaluate the efficacy of current therapy, make insulin and medication dose adjustments, ensure patients' glucose levels are within therapeutic goal ranges, and monitor treatment safety. Both capillary blood glucose monitoring (BGM) and continuous glucose monitoring (CGM) with interstitial fluid sensors enable patients to better understand the impact of diet, exercise, illness, stress, and medications on glucose levels and to recognize and treat hypoglycemic and hyperglycemic episodes. Likewise, both BGM and CGM have been shown to improve the efficacy and safety of diabetes therapy (3-12).

This document provides recommendations to clinicians regarding the type and frequency of GM technology that should be employed in the management of patients with type 1 diabetes mellitus (T1DM: pediatric or adult), type 2 diabetes mellitus (T2DM), and pregnancy complicated by pre-existing diabetes or gestational diabetes mellitus (GDM). In this document, we refer to GM technology that improves the lives of people with diabetes as "meaningful monitoring." "The scope" of this document does not extend to the complexities of insulin adjustments based on the GM data obtained. Other pivotal reference documents can be consulted for this information (13,14). **(Endocr Pract. 2016;22:231-261)**

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Additional aims of the document are to:

1. Provide a primer on GM accuracy
   a. Describe various ways to characterize accuracy, such as mean absolute relative difference (MARD)
   b. Review GM accuracy guidelines from the International Organization for Standardization (ISO) and the US Food and Drug Administration (FDA)
   c. Discuss how device accuracy has the potential to affect glucose control
2. Review measures of glycemic control (glucometrics) such as the glycated hemoglobin (A1C) laboratory measurement, change in average glucose with time, percentage of time in target, hypoglycemic and hyperglycemic ranges, and glucose frequency distribution. Graphical methods to display glycemic data will also be presented.

History of GM in Diabetes

For several decades, urine glucose testing was the mainstay of diabetes monitoring (15). While patients could perform measurements at home and potentially adjust their therapy, the shortcomings of urine glucose testing were well recognized. Urine glucose correlated very poorly with blood glucose levels, provided no information about hypoglycemia, and gave negative results until the renal threshold for glucose excretion was exceeded. Therefore, urine glucose testing is presently of historical interest only.

The colorimetric Dextrostix® glucose test strip was developed in 1965. It was used for the first blood glucose meter in 1970 (15). Starting in the late 1970s, daily BGM gained wider acceptance as research data began to support the correlation and causation between poor glycemic control and diabetic complications (15-23). The "glucose hypothesis" was confirmed in the landmark Diabetes Control and Complications Trial (DCCT), the first long-term randomized prospective study to compare intensive (≥4x/day) self-GM coupled with an insulin titration algorithm versus standard therapy using once-daily GM and 1 to 2 daily insulin injections (24). Intensive therapy delayed the onset and slowed the progression of microvascular complications in patients with T1DM. Following the publication of the DCCT results in 1993, the value of BGM in T1DM management became widely accepted, and its use gradually increased. It was clear that intensive insulin therapy and self-adjustment of insulin dosage in T1DM required frequent BGM (9,13,25-27). Subsequently, the effectiveness of BGM in GDM was demonstrated.

The value of BGM in T2DM has been controversial. As shown in Table 1, studies of BGM in T2DM have presented mixed conclusions. Several have shown a clear benefit from frequent BGM (11,12,28-30). This has been particularly evident for patients with T2DM who are receiving insulin therapy, especially involving multiple daily injections (MDI), "basal-bolus" therapy, or insulin pump (continuous subcutaneous insulin infusion) (31). Newer studies using a more structured testing approach have suggested benefit even for persons with diabetes not receiving insulin (9); these data support the need for patient education to ensure that each measured glucose leads to an action plan.

There is a common misperception that BGM is an expensive, complex undertaking with limited benefit, leading some to assert that BGM is not warranted in patients with T2DM (32-35). The studies that appear to give negative results in patients with T2DM have been criticized for serious experimental design flaws (28). Several studies included rapid intensification of medication regimens following diagnosis, which may have obscured the effect of BGM. Additionally, many studies failed to couple GM to therapy adjustment, thus attenuating the benefit of the monitoring (28).

While BGM is a widely used and important component of T1DM therapy, it has drawbacks: patients' monitoring may be infrequent or intermittent, their reports may be inaccurate, and overnight glucose levels are seldom measured. Given these limitations, episodes of hypo- and hyperglycemia may be missed and not factored into treatment decisions (26,36). CGM offers the potential to revolutionize patient treatment by providing more frequent information that may allow a greater proportion

Table 1
Key Studies of BGM in T2DM (7,9-12,29,30,32-34,183-185)

T2DM: Evaluation of the role of BGM	
Pro: Use of BGM significantly improves glycemic control and/or reduces risk of hypoglycemia	**Con: Use of BGM does *not* significantly improve glycemic control and/or reduce risk of hypoglycemia**
Observational studies	
ROSSO (12) Karter, et al (Kaiser Permanente) (29)	Freemantle Diabetes Study (183) QuED (184)
Randomized controlled trials	
German-Austrian (30) DINAMIC (111) ASIA (185) SteP (9) ROSES (7) St. Carlos (10)	King-Drew Medical Center (34) ESMON (32) DiGEM (33)

Abbreviations: ASIA = Auto-Surveillance Intervention Active Study; BGM = blood glucose monitoring; DiGEM = Diabetes Glycaemic Education and Monitoring Study; DINAMIC 1 = Diamicron MR in NIDDM: Assessing Management and Improving Control; ESMON = Efficacy of Self Monitoring of Blood Glucose in Patients with Newly Diagnosed Type 2 Diabetes Study; QuED = Quality of Care and Outcomes in Type 2 Diabetes Study; ROSES = Role of Self-Monitoring of Blood Glucose and Intensive Education in Patients with Type 2 Diabetes Not Receiving Insulin Study; ROSSO = Retrolective Study "Self-monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes"; SteP = Structured Testing Protocol Study; T2DM = type 2 diabetes mellitus.

of patients to achieve target glucose and A1C levels with greater safety.

The first CGM device was approved in the United States in 1999. The MiniMed CGM System sampled glucose through a subcutaneously implanted sensor, recording glucose levels every 5 minutes over a period of 3 days. Initial versions of this technology did not provide glucose values in real time; data were downloaded and retrospectively evaluated by clinicians and used to make treatment adjustments (26). The first real-time CGM for prospective patient use was approved in 2001 (Glucowatch Biographer; Cygnus Inc, San Francisco, CA). The device used reverse iontophoresis to sample blood glucose, providing approximately 36 measurements directly to patients over the 12-hour life of the sensor (37). It was withdrawn from the market due to skin site reactions, discomfort, limited accuracy, and difficult setup and calibration procedures (38). Since then, CGM technology has improved dramatically in terms of accuracy, usability, and duration of use. The landmark Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study Group trial (6) established the role of CGM in T1DM, demonstrating significant A1C reductions in adults. The magnitude of benefit correlated positively with both wearing and interacting with the technology (4). In patients with lower baseline A1C, there were smaller reductions in A1C, but a reduction in hypoglycemia (39). These benefits persisted for up to 12 months (40). Other unmasked parallel-group studies have confirmed significant reductions in A1C and a trend for reductions in severe hypoglycemia (3,4,41,42). A summary of trial results for A1C and hypoglycemia reduction with CGM is shown in Figure 1.

CGM has the ability to provide alerts to actual or predicted episodes of hypo- and hyperglycemia. Further, all modern-day sensor devices display arrows reflecting the current slope of glucose versus time, which can assist clinical decision-making by the patient. However, CGM technology has drawbacks including expense; a need to frequently calibrate most devices; and some issues related to accuracy, comfort, convenience, and patient acceptance.

Current Status of GM

Previous publications from the American Association of Clinical Endocrinologists (AACE), Endocrine Society, and American Diabetes Association (ADA), provide sound general recommendations to guide diabetes therapy based on personal glucose records and laboratory values (1,2,28,43,44). No clinician caring for patients with diabetes would dispute the value of employing some form of GM.

The Effective Health Care Program of the US Agency for Healthcare Research and Quality conducted comparative effectiveness research assessing GM methods and intensive insulin therapy methods. This included effectiveness studies comparing real-time CGM to BGM in adults, adolescents, and children with T1DM (45). While methods of GM did not affect patient quality of life, A1C was lowered by 0.3% in patients who used CGM compared with

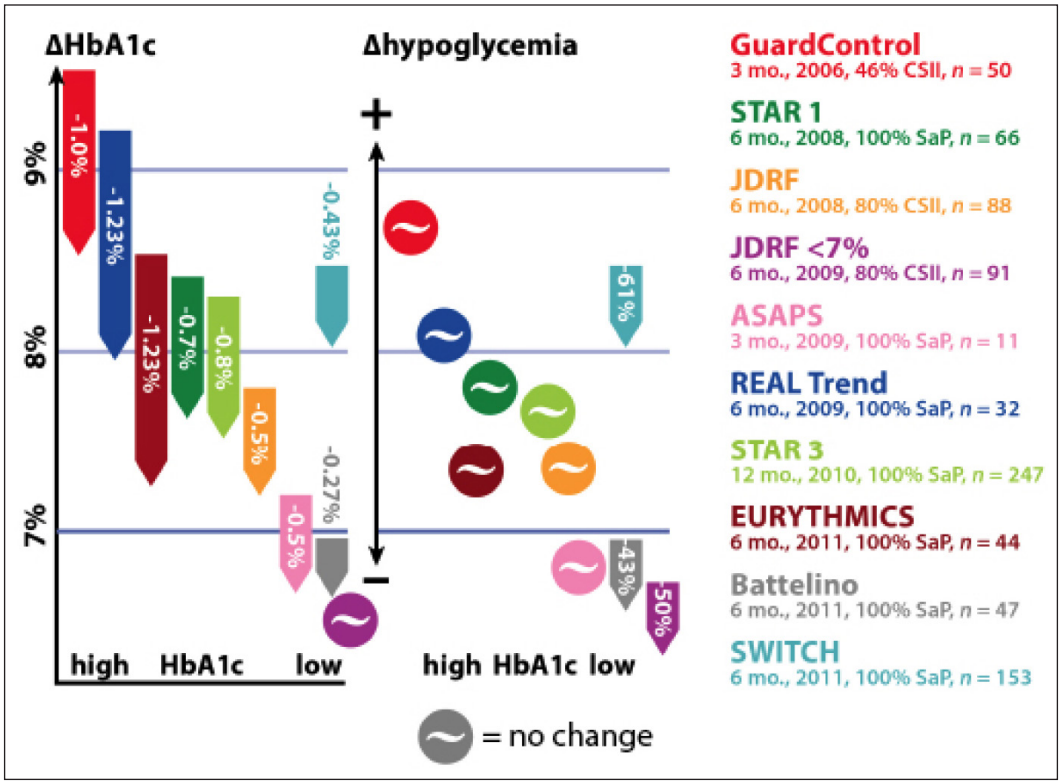


Fig. 1. Glycated hemoglobin and hypoglycemia reductions in continuous glucose monitoring studies (189).

patients who used BGM. This positive outcome for CGM was consistent for patients <18 years of age, supporting its use in adolescent patients and children. Unfortunately, because GM is a substantial cost driver in the management of patients with diabetes (28,46,47), governments and insurance companies have restricted coverage, payments, and reimbursement. However, improvements in A1C and accompanying reductions in hypoglycemia have been used to justify the cost of newer diabetes medications. To the extent that GM can also enable patients to achieve lower A1C values with less hypoglycemia, a similar and stronger case can be made for increasing access to GM (48), particularly as costs come down and evidence continues to show benefit for both T1DM and T2DM. For patients who use insulin, CGM offers the distinct advantage of being able to securely maintain a more normal glucose range with less risk of hypoglycemia. As of the writing of this document, there remains no CGM coverage for elderly patients with T1DM, a population with frequent and severe hypoglycemia (49).

Over the last 30 years, the FDA has approved many monitor models for use in GM. Since 2003, the FDA has required the accuracy of BGM devices to be within 20% of the true value at least 95% of the time (50). Certain monitors have shown substantially greater variability than allowed by FDA standards, leading to the recall of several brands of glucose meters and test strips in 2013 (51-54). The importance of GM accuracy and the emergence of stricter accuracy standards are discussed in greater detail in the "GM Accuracy and Precision" section later in this manuscript.

In 2013, the US Centers for Medicare and Medicaid Services (CMS) implemented the controversial process of competitive bidding for BGM meters and test strips, with the intended goal of cost savings (55). This was one factor that led to a surge in the number and types of "generic" BGM meters. In some cases, when meters sourced from retail distribution channels were tested, the generic testing systems meters demonstrated dramatically inferior accuracy and precision compared to systems from major branded manufacturers (56-59). These generic meters showed sufficient performance data to obtain initial FDA clearance; however, they may not have maintained adequate performance over time, in part due to poor quality control leading to large between-lot variability in test strips. One proposed response has been to require postmarket surveillance of BGM products (60-62). The CMS competitive bidding process may have had other unintended consequences. A recent analysis of CMS data by the National Minority Quality Forum (NMQF) found that test areas in which competitive bidding was initially implemented had substantial disruptions in BGM supply acquisition compared to nontest markets (23% increase in partial acquisition vs. 1.7% in nontest markets) (63). Within the test markets, decreases in full acquisition (14.4%) and increases in migration from full to partial acquisition (58.1%) were

significant ($P<.0001$ for both) (64). Patients in these markets had increased mortality and hospitalization rates and increased medical costs (63,64). Based on these results, the NMQF has called for the CMS to suspend competitive bidding until proper safety review and monitoring can be implemented (65).

The purpose of the next section of this document, "GM Strategy and Rationale by Patient Profile," is to provide concise and specific recommendations for clinicians on the type, frequency, and intensity of GM within the framework of specific patient profiles. The intent is to help clinicians counsel their patients to meaningfully monitor their glucose levels to optimize their diabetes care.

GM STRATEGY AND RATIONALE BY PATIENT PROFILE T1DM

T1DM currently constitutes 5 to 10% of all people with diabetes globally (66,67). GM is one of the essential elements of effective T1DM management (68,69). The Type 1 Diabetes Exchange Clinic Registry (2013) found a systematic, statistically significant decrease in A1C levels in relation to increased frequency of daily BGM in children, adolescents, and adults (Fig. 2) (70).

Adult Patients With T1DM

People with T1DM experience much greater glycemic variability than those with T2DM (71). This variability is associated with a higher risk of hypoglycemia (72). GM has a role in the early detection of hypoglycemia prior to overt symptoms.

BGM provides patients with important information regarding treatment efficacy (68,69). BGM can also facilitate appropriate modifications to the therapeutic regimen, providing critical information that clinicians need to adjust dosage and/or timing of basal and bolus insulins, as well as reflecting the impact of food intake and physical activity (2,68,73). Use of BGM is supported by clinical data: the DCCT, Epidemiology of Diabetes Interventions and Complications (EDIC), and many other clinical trials have clearly established the usefulness of BGM toward achieving the goals of improved glycemic control and decreasing the risk of diabetes-related complications in T1DM (2,74).

In all patients with T1DM, a rational and effective insulin regimen requires frequent GM. Frequent BGM is endorsed in all major clinical practice guidelines, including AACE, the ADA, the American Association of Diabetes Educators, the Joslin Diabetes Center, and the International Diabetes Federation (IDF) (2,28,68,73,75). Table 2 lists major organizations' general recommendations for BGM timing and glucose goals in patients with T1DM. Current guidelines advise patients to check their blood glucose frequently; recommendations range from at least 4 to 6 to 10 or more times per day. All guidelines emphasize the need for individualization for each patient, with more or less frequent monitoring before meals, postprandially, at bedtime, before exercise, and when undertaking potentially hazardous tasks (e.g., driving) (2,68,69). Patients with T1DM should also monitor their blood glucose before driving and should not drive if their glucose level is <90 mg/dL (5.0 mmol/L).

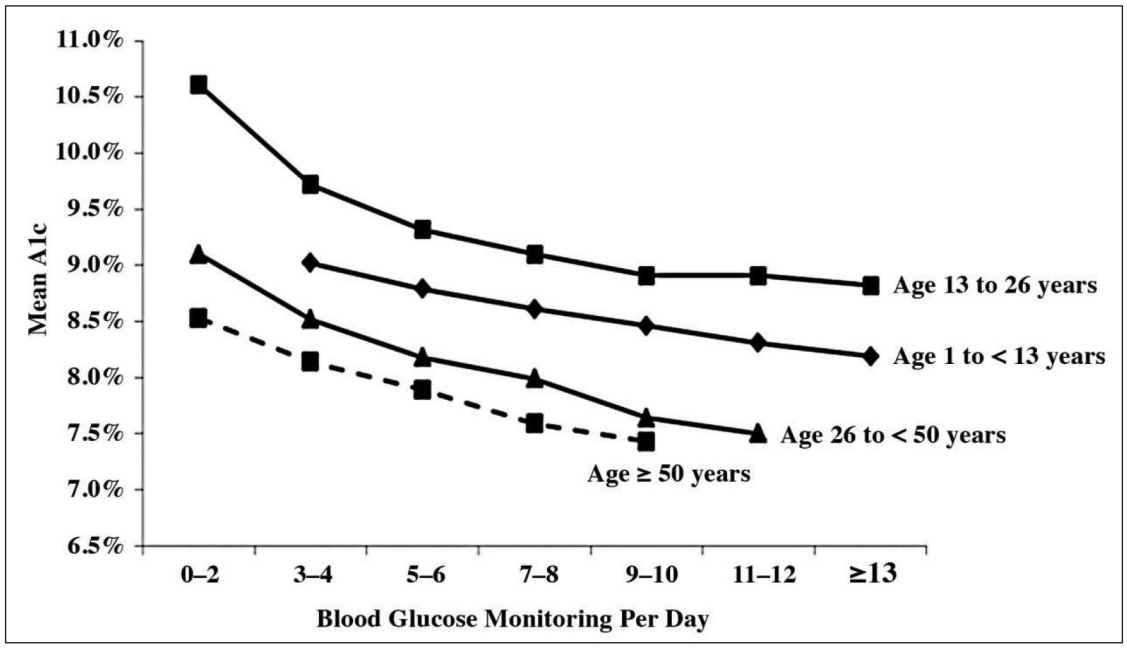


Fig. 2. Association between blood glucose monitoring frequency and A1C in patients with T1DM (70). *A1C* = glycated hemoglobin; *T1DM* = type 1 diabetes mellitus.

Table 2
Recommendations for Daily Blood Glucose Testing in Patients with Type 1 Diabetes (2,68,69)

	Timing	Goal	
		mg/dL	mmol/L
Fasting plasma glucose	Test on awakening and before meals	80-130 (ADA) 70-130 (Joslin) <110 (AACE)	4.2-7.2 (ADA) 3.9-7.2 (Joslin) <6.1 (AACE)
Postprandial	2 hours after meal 1-2 hours after meal	<180 (ADA) <180 (Joslin) <140 (AACE)	<10.0 (ADA) <10.0 (Joslin) <7.8 (AACE)
Bedtime glucose	At bedtime	90-150 (Joslin)	5.0-8.3 (Joslin)
These goals must be individualized to personal patient needs regarding pregnancy, hypoglycemia unawareness, patients who live alone, or occupational hazards that require further reduction of risk of hypoglycemia (2,68).			
Abbreviations: AACE = American Association of Clinical Endocrinologists; ADA = American Diabetes Association; Joslin = Joslin Diabetes Center.			

These guidelines also recommend the use of CGM, particularly for patients with a history of severe hypoglycemia or hypoglycemia unawareness (1,2,44,68). Once again, the timing and frequency of monitoring must be individualized to meet specific patient needs (2,28). Table A1 in Appendix A of this document summarizes pivotal trials of CGM in adult and pediatric patients with T1DM.

Pediatric Patients With T1DM

BGM remains a cornerstone for achieving optimal metabolic control in children, adolescents, and adults with T1DM (70). Frequent BGM, with a minimum of 4 blood glucose tests per day (premeal and at bedtime), should be the goal. In addition to these traditional 4 tests, many patients can gain a more robust picture of daily glucose trends by strategically adding additional tests, such as 2 hours after meals, overnight, and before and after exercise (76).

Optimal glycemic control of T1DM is particularly difficult to achieve in pediatric patients. Food intake and activity are unpredictable in very young patients, complicating parents' efforts to regulate glucose levels. Additionally, many parents experience a "Scylla and Charybdis" situation, where their fear that severe hypoglycemia will cause irreparable brain damage may lead to allowing a child's glucose to "run high." Data from the Type 1 Diabetes Exchange Clinic Registry indicate that children with elevated blood glucose and A1C levels are not protected against severe hypoglycemic events (77). Moreover, recent evidence from the Diabetes Research in Children Network (DirecNet) indicates that hyperglycemia is at least as detrimental to normal brain development as hypoglycemia (78). In adolescents, the emotional fatigue of managing their diabetes often leads to a reduced frequency of BGM, missed insulin doses, and markedly elevated A1C levels. In older children and adolescents, the adverse effects of prolonged hyperglycemia on the cardiovascular system outweigh the potential harm from hypoglycemia (79), particularly as treatment modalities and hypoglycemia management strategies have improved (2).

Another special challenge of managing T1DM during childhood and adolescence is that insulin requirements change frequently. Simply measuring blood glucose and giving immediate correction doses are insufficient for long-term glycemic control in pediatric patients. Physicians, parents, and patients need to be instructed on how to recognize trends that indicate the patient has outgrown their insulin dose(s) and learn to make longer-term regimen adjustments (80). Such pattern recognition requires maintaining and periodically reviewing an electronic or written log of blood glucose levels. Unfortunately, only a small proportion of physicians, patients, and families are downloading data from glucose meters to appropriate computer programs; reviewing glucose meter data (including multiple graphs and statistics); and carefully making thoughtful, appropriate insulin dosage self-adjustments on a systematic, periodic basis (81,82).

As in the case of BGM, CGM is only as beneficial as the patient's desire and ability to use it. It is essential that all CGM users know the basics of sensor insertion, calibration, and real-time data interpretation. To maintain a high frequency of use, patients and their parents require in-depth training with reinforcement, including periodic follow-up with clinicians and diabetes educators. The results of the JDRF CGM Study Group, using all the first-generation CGM devices available at that time (2007), showed that

children, adolescents, and young adults (aged 8-24 years) who used the sensor almost every day benefitted clinically. Unfortunately, a much lower percentage of children and adolescents (34%) than adults (59%) performed daily CGM (83).

DirecNet studied the efficacy and safety of CGM in children <10 years of age. In a randomized clinical trial of 146 patients aged 4 to 9 years, CGM did not improve metabolic control. Despite a high degree of parental satisfaction with CGM, at the end of the 6-month study, only 41% of families reported daily CGM use (42). Similar results were reported by DirecNet in a nonrandomized, 6-month pilot study of 23 children <4 years of age (84). These studies were performed with older devices; the improved accuracy and ease of use of current devices might be better accepted. However, in a recent update of the state of the art of treatment of T1DM in the US, the T1D Exchange reported that <5% of youth <18 years old were currently utilizing a CGM device (85).

Combination of continuous subcutaneous insulin infusion and CGM (sensor-augmented pump)

The Sensor-Augmented Pump Therapy for A1C Reduction (STAR 3) Study (2012) examined a system that combines the use of a continuous subcutaneous insulin infusion (CSII) pump and a CGM system, termed sensor-augmented pump (SAP) therapy. In this 1-year study, children (aged 7-12) and adolescents (ages 13-18) with T1DM and baseline A1C ranging from 7.4 to 9.5% were randomized to either SAP or MDI therapy. Overall, patients in the SAP group had significantly improved ($P<.05$) A1C values compared with the MDI group at all postbaseline visits (86). Furthermore, children and adolescents in the SAP group were consistently more likely to meet age-specific A1C targets (88% and 57%, respectively) compared with those in the MDI group (51% and 13%, respectively) (86). Children and adolescents in the SAP group had lower area under the curve values than the MDI group, without increased risk of hypoglycemia, as well as improved glucose variability (86). STAR 3 was the first study to examine the efficacy and safety of switching from conventional injections and BGM to 2 advanced technologies (CGM + CSII) nearly simultaneously; prior studies had only evaluated the impact of a single technology.

A SAP system with threshold suspend functionality was approved by the FDA in 2013 following considerable experience in Europe. This device can suspend insulin delivery for up to 2 hours when the sensor glucose value reaches a predetermined lower threshold (87). The improved accuracy of CGM sensors and this threshold suspend (called "low glucose suspend" in Europe) may increase the performance and frequency of CGM use in pediatric patients. More recent studies have indicated the effectiveness of the predictive low glucose suspend system in children (88).

An international group of leading pediatric diabetologists issued a 2012 consensus statement regarding the use of CGM in children (89). They recommended that CGM be considered for regular daily use in children and adolescents with T1DM who:

- Are performing frequent BGM
- Have experienced severe hypoglycemic episodes
- Have hypoglycemic unawareness, especially in young children
- Have nocturnal hypoglycemia
- Have wide glucose excursions, regardless of A1C
- Have suboptimal glycemic control, with A1C exceeding the target range
- Have A1C levels <7% and wish to maintain target glycemic control while limiting hypoglycemia risk

Accordingly, CGM is potentially applicable and desirable in most children with diabetes. Recent enhancements have made it possible for parents and others to monitor glucose levels continuously via smartphones, wristwatches, and computers. In 2015, the FDA approved marketing of 3 such systems: Dexcom Share (90), Dexcom G5 with Bluetooth (91), and MiniMed Connect (92). An open-source system (not FDA approved) called Nightscout was created (hacked together) by a group of people with diabetes and their families to allow remote monitoring by parents of children with diabetes (93). Other companies are likely to follow, as anecdotal reports suggest that parents and other caregivers find the technology invaluable when their children are away from home or participating in sports. Randomized controlled trial results evaluating these technologies are not available.

T2DM

Adult Patients with T2DM

BGM is an essential tool that should be accessible to all patients with T2DM, regardless of whether or not they are receiving insulin treatment (28). BGM is clearly beneficial for adult patients with T2DM because it provides immediate feedback regarding glycemic control (rather than requiring waiting, possibly months, for the next A1C measurement), and it assists with patient education, understanding, and behaviors. Table A2 in Appendix A of this document summarizes pivotal trials of GM in adult patients with T2DM.

To ensure meaningful monitoring, use of BGM in patients with T2DM must be individualized by the physician and healthcare team in partnership with the patient. The patient should be given specific guidelines including frequency and timing of testing and taught how to communicate these results to the healthcare team. Methods for communication of glucose data are shown in Table 3. Two

of the goals for any BGM strategy are to empower patients to play a more active role in their diabetes management and to maximize the efficacy and safety of glucose-lowering therapies, including lifestyle management (94). GM results are also a vital component of the data that should be presented to the diabetes care clinician at each medical appointment, and potentially between visits, to assist in therapy titration.

Several randomized trials and literature reviews have called into question the clinical utility and cost-effectiveness of routine BGM in patients with T2DM who are not receiving insulin therapy (32,33,35,95,96). A key consideration is that BGM, used alone, does not lower blood glucose levels. To be useful, the information must be *communicated* to the healthcare team in an effective and timely manner and integrated into self-management plans. Several recent trials of structured BGM included specific instructions on testing frequency and timing, interpreting and communicating these results, and integrating results into self-management plans. These studies have shown improved glycemic control in patients with T2DM who do not receive insulin therapy (8,9,97,98).

General guidelines on the frequency and timing of testing based on specific patients' diabetes therapy are presented below and are outlined in Table 4.

GM in patients with T2DM on insulin therapy

If the patient is on intensive insulin therapy using prandial insulin combined with basal insulin, BGM should be performed when fasting, premeal, at bedtime, and periodically in the middle of the night. Such monitoring allows for appropriate adjustment of doses of premeal insulin, correction boluses, and basal insulin.

If the patient is receiving only basal insulin, with or without other diabetes medications, BGM should be performed at minimum when fasting and also at bedtime to evaluate the impact of basal insulin on lowering overnight glycemic levels. If the decline in Bedtime to AM (morning) glucose (known as the BeAM factor) is >55 mg/dL (3.1 mmol/L), this suggests an excessive basal insulin dose (99), just as an overnight rise in glucose levels may indicate a need to increase basal insulin. Before titrating basal insulin to higher doses, consider improving the bedtime glucose by other means (e.g., with prandial insulin administered before dinner). This may prevent nocturnal hypoglycemia caused by excessive basal insulin and lead to improved overall glycemic control (31). If the patient is receiving basal insulin combined with 1 daily prandial or premixed insulin injection, BGM should be performed at minimum when fasting and before the prandial or premixed insulin and periodically at other times (i.e., premeal, bedtime, 3 AM, and possibly 2 hours postprandially). Insulin adjustments should be made to achieve acceptable glycemic targets.

GM in patients with T2DM on noninsulin therapies

The IDF published a 2009 guideline specific to BGM in noninsulin-treated patients with T2DM (28). The IDF recommends that:

1. BGM should only be used when patients and/or caregivers have the knowledge, skills, and willingness to incorporate both BGM monitoring and accompanying therapeutic adjustments into their diabetes care plan.
2. BGM is only appropriate if protocols are individualized to meet their patients' educational/behavioral/clinical requirements and have been mutually agreed upon by the patient and clinician.
3. BGM should be considered both at the time of diagnosis, to enhance patient education and facilitate treatment initiation, and as part of ongoing diabetes self-management education. The goal is to help patients actively and effectively participate in their treatment.

GM in patients with T2DM on noninsulin therapies associated with frequent or severe clinical problems related to hypoglycemia

Patients with T2DM receiving noninsulin agents associated with elevated hypoglycemia risk (specifically, sulfonylureas, and glinides) should perform BGM at least once daily (fasting) and periodically at other times to confirm the effectiveness of therapy and detect possible hypoglycemia. Appropriate therapeutic adjustments should be made

Table 3
Methods for Communication of Glucose Data

1. Logbook at time of office visit
2. Computer outputs (graphs, statistics, interpretation) generated by patient or clinic staff, immediately before or at time of office visit
3. Periodic phone calls, faxes, or emails to office
4. Automated transfer from meter or sensor to Internet for review
5. Automated interpretation by the glucose monitoring device displayed on its screen (e.g., "Your before-lunch glucose has been running high")

Table 4
Use of Glucose Monitoring Technology by Diabetes Type (1,2,44,48,68,76,80,101,107,115-120,186)

Diabetes type	BGM recommendations	CGM recommendations
Type 1 – Adult	At least twice per day to 6-10 times per day, including before meals, occasionally postprandially, before exercise or critical tasks (e.g., driving), and at bedtime.	CGM recommended, particularly for patients with history of severe hypoglycemia, hypoglycemia unawareness and to assist in the correction of hyperglycemia in patients not at goal. CGM users must know basics of sensor insertion, calibration, and real-time data interpretation.
Type 1 – Pediatric	At least 4 times per day, including before eating and at bedtime. A more accurate picture of daily glucose trends may be gained with additional testing, including 1-2 hours after meals, overnight, and before/after exercise. Insulin requirements for pediatric patients change frequently. Physicians, patients, and caregivers should learn to recognize glucose trends that indicate that the insulin regimen requires adjustment. This requires maintaining and periodically reviewing electronic or written logs of BG levels.	Same as Adult Type 1. Both prevalence and persistent use of CGM is lower in children than adults. More in-depth training as well as more frequent follow-up is recommended to enable children to adopt the technology more successfully.
Type 2 – Receiving insulin/ sulfonylureas, glinides	Structured BGM is recommended. BGM in patients on intensive insulin: fasting, premeal, bedtime, and periodically in the middle of the night. BGM in patients on insulin ± other diabetes medication: at minimum, when fasting and at bedtime. BGM in patients on basal insulin + 1 daily prandial or premixed insulin injection: at minimum when fasting and before the prandial or premixed insulin, and periodically at other times (i.e., premeal, bedtime, 3 AM). Additional testing before exercise or critical tasks (e.g., driving) as needed.	Data on CGM in T2DM are limited at this time. Trials assessing the use of CGM in T2DM patients are ongoing.
Type 2 – Low risk of hypoglycemia	Daily BGM not recommended. Initial periodic structured BGM (e.g., at meals and bedtime) may be useful in helping patients understand effectiveness of MNT/ lifestyle therapy. Once at A1C goal, less frequent monitoring is acceptable.	No recommendation.
Gestational	Patients not receiving insulin: fasting and 1 hour postprandial. Patients receiving insulin: fasting, preprandial, and 1 hour postprandial.	Benefits of CGM in pregnant females with pre-existing diabetes are unclear based on current data; additional studies are ongoing. CGM during pregnancy can be used as a teaching tool, to evaluate glucose patterns, and to fine-tune insulin dosing. CGM in pregnancy can supplement BGM, in particular for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

Abbreviations: A1C = glycated hemoglobin; BG = blood glucose; BGM = blood glucose monitoring; CGM = continuous glucose monitoring; MNT = medical nutrition therapy; T2DM = type 2 diabetes mellitus.

if patients are not at goal. Consideration should be given to altering therapy to employ 1 or more of the multiple classes that are not associated (or minimally associated) with increased risk of hypoglycemia (e.g., metformin, dipeptidyl peptidase-4 [DPP-4] inhibitors, sodium-glucose cotransporter-2 [SGLT-2] inhibitors, thiazolidinediones [TZDs], or glucagon-like peptide-1 [GLP-1] receptor agonists).

GM in patients with T2DM on noninsulin therapies not associated with hypoglycemia

Patients with T2DM receiving treatment regimens not typically associated with increased risk of hypoglycemia and who are not at goal should be instructed to perform structured testing (e.g., systematically before meals and at bedtime) at least weekly to adjust and confirm therapeutic effectiveness (9). Patients should be educated about when and how frequently to monitor glucose and should record the data in an organized logbook for subsequent review by a diabetes professional. Guidance for communication of glucose data is outlined in Table 3. After the A1C goal has been reached, and in the absence of evidence of hypoglycemia, then less frequent monitoring may be necessary.

GM in patients with T2DM on diet/lifestyle therapy only

Daily BGM has not been shown to be effective in patients on diet/lifestyle therapy who are at low risk for hypoglycemia (28,33,35,94). However, structured testing may help patients improve their understanding of the effectiveness of medical nutrition therapy (MNT) and lifestyle management. Initial periodic testing at meals and bedtime provides feedback to the patient regarding the impact of various foods and physical activity on glycemic levels. After the goal A1C has been achieved, less frequent monitoring may be needed.

Use of CGM in patients with T2DM

There are limited data on the use of real-time CGM in patients with T2DM, either masked for retrospective analysis or unmasked for real-time use. Several studies have evaluated masked CGM, in which patients cannot see glucose values in real time, to help understand the progression from nondiabetes to prediabetes and T2DM (100). Other trials are ongoing to evaluate the potential use of masked CGM to guide both patients and clinicians regarding appropriate medication and lifestyle changes to improve glycemic control. Real-time CGM trials in T2DM patients are also ongoing, with several randomized controlled trials completed in recent years.

Vigersky et al compared real-time CGM (used for 8 of the initial 12 weeks of the study) to BGM 4 times a day in 100 patients with T2DM who were being treated with diet and exercise alone or with glucose-lowering therapies other than prandial insulin. At 12, 24, 38, and 52 weeks, respectively, this study found mean, unadjusted A1C decreases of 1.0%, 1.2%, 0.8%, and 0.8% in the CGM group compared with 0.5%, 0.5%, 0.5%, and 0.2% in the BGM group (P = .04). The reduction in A1C over the study period remained significantly greater in the CGM versus BGM group after adjusting for covariates (P<.0001). Patients who used CGM for at least 48 days showed the most improvement (P<.0001) (48).

A multicenter trial randomized 57 insulin-treated patients with T2DM to real-time CGM versus Internet-based BGM monitoring; results showed a greater reduction in A1C in the CGM group (1.31%) compared to the BGM group (0.83%), although the difference was not statistically significant (101). Additional randomized trials of CGM will be helpful in the evaluation of the benefits of CGM in T2DM.

Pregnancy Complicated by Diabetes

Approximately 8% of US pregnancies are complicated by either GDM or pre-existing T1DM or T2DM (102-104). In the early weeks of pregnancy, the excessively high maternal glucose levels of patients with poorly controlled or undiagnosed T1DM and T2DM are associated with an increased risk of miscarriage and congenital malformations (103,105). Hyperglycemia during the second and third trimesters results in fetal hyperinsulinemia that increases the risk of macrosomia and neonatal hypoglycemia (106,107). Maintenance of maternal glycemia as close to normal as possible through a program of BGM (or CGM), MNT, and insulin therapy offers the most effective protection against these complications (108).

The feasibility and efficacy of BGM in pregnancy complicated by diabetes were demonstrated in a seminal 1980 clinical trial that used BGM (8 measurements per day), MNT, and basal (neutral protamine Hagedorn) plus regular insulin in pregnant patients with T1DM (n = 10). All patients achieved normal mean plasma glucose and A1C levels, and the infants showed no signs of diabetes-related complications (109). Today, BGM is integral to the management of diabetes in pregnancy (104). Real-time results enable individuals to make informed daily self-care decisions regarding diet, exercise, and insulin. Retrospective analysis of BGM data enables clinicians to develop individualized care plans (110), informing decisions related to insulin initiation and adjustment and the possible needs for interventions or hospitalization to improve inadequate self-monitoring (111).

CGM generates a detailed profile of glucose excursions that can be helpful when making decisions regarding self-care and treatment planning. Currently available CGM devices do not measure blood glucose levels <70 mg/dL (3.9 mmol/L) very accurately (112-114). Nevertheless, CGM can identify many episodes of hypo- and hyperglycemia that would go undetected by BGM (108,115). CGM appears superior to BGM in this regard, but it remains to be seen whether CGM improves pregnancy outcomes. A 2013

trial comparing BGM alone to BGM combined with several 6-day periods of unmasked CGM in pregnant women with T1DM or T2DM (n = 154) found no differences in maternal A1C at term or in neonatal morbidity. Only 64% of the patients in that study were fully compliant with the CGM protocol, so potential benefits may have been missed. The most common reasons for noncompliance were device discomfort, sleep disturbances caused by alarms, and sensor inaccuracy (116).

The potential benefit of CGM for pregnant women with pre-existing diabetes is unclear based on currently available data. A prospective, randomized controlled trial performed in the United Kingdom assigned 71 pregnant females with T1DM or T2DM to prenatal care with or without CGM (117). While no maternal A1C differences were observed at baseline or throughout the first 2 trimesters, patients in the CGM group began to experience lower A1C levels between weeks 28 and 32, a difference that became statistically significant by weeks 32 to 36 (5.8% vs. 6.4%, P = .007). In contrast, a Danish trial that randomized 123 pregnant females with T1DM or T2DM to routine prenatal care alone or similar care plus CGM did not find any differences in outcomes between the 2 groups (118). Another randomized controlled trial of 340 Chinese females with GDM found that the use of CGM combined with standard care led to decreased A1C levels and less severe glycemic excursions compared to standard care alone (P<.001). Additionally, the use of CGM decreased the risk of pre-eclampsia and cesarean birth (P = .019 and P = .028, respectively) (119).

An ongoing study, the Continuous Glucose Monitoring in Women with Type 1 Diabetes in Pregnancy Trial (CONCEPTT, expected completion in late 2015), will attempt to determine if real-time CGM can safely improve glycemic control in patients with T1DM who are pregnant or planning pregnancy; this study will also assess infant outcomes (120).

CGM during pregnancy should be regarded as a teaching tool to evaluate peak postprandial blood glucose, fine-tune insulin dosing, and identify foods associated with blood glucose spikes (116). CGM can also be used as an adjunct to BGM to monitor nocturnal hypoglycemia and hyperglycemia, as well as the peak and duration of postprandial hyperglycemia. A 2007 clinical trial of CGM in pregnancy reported that the additional information provided by CGM altered clinical management decisions in 62% of cases (this trial did not evaluate patient outcomes) (121).

Table A3 in Appendix A of this document summarizes pivotal trials of BGM and CGM in patients with pregnancy complicated by diabetes. Blood glucose goals and recommended BGM patterns during and prior to pregnancy are summarized in Table 5.

Before attempting to become pregnant, females with pre-existing diabetes should maintain glycemic control as close to normal as possible for 3 to 6 months. Preprandial and fasting blood glucose should be maintained in the 60 to 90 mg/dL range, and postprandial glucose tested at 1-hour postmeal should be between 100 and 120 mg/dL (107).

The typical target fasting plasma glucose range during pregnancy complicated by diabetes is 55 to 90 mg/dL (3.1 to 5.0 mmol/L). This implies a heightened risk of hypoglycemia. Accordingly, meter accuracy in the low blood glucose ranges is critically important in patients with pregnancy complicated by diabetes. Hypoglycemia, in particular asymptomatic hypoglycemia, is a key safety concern during pregnancy. Pregnant females with diabetes should monitor their blood glucose before driving and should not drive if their glucose level is <90 mg/dL (5.0 mmol/L). Likewise, they should always keep appropriate carbohydrate snacks with them in the car in case they become hypoglycemic.

GM ACCURACY, PRECISION, AND DATA DISPLAY METRICS

Accuracy (the ability to obtain a true value without systemic bias) and precision (the ability to obtain highly reproducible results) have been steadily improving since the introduction of BGM in the 1970s. A 1986 ADA consensus conference, convened at a time when an estimated 1 million people with diabetes were using BGM, concluded that more than 50% of glucose meter measurements deviated by more than 20% from a reference method. This was

Table 5
Recommendations for Daily Blood Glucose Testing in Pregnancy Complicated by Diabetes (103)

	Timing	Goal	
		mg/dL	mmol/L
Fasting	On awakening	60-90	3.3-5.0
Preprandial	Before every meal	60-90	3.3-5.0
1-hour postprandial	1 hour after every meal	100-120	5.6-6.7

attributed to both system and human factors. The ADA stated an aspirational goal in 1987 that 100% of BGM readings be within 10% of reference values (122). In 1993, a similar panel was convened and recommended that the analytic error not exceed 5% (123). Since it is only recently that any devices have even approached such performance, regulatory criteria for device approval have been more pragmatic, focusing on the hazards of incorrect readings (e.g., suboptimal treatment decisions, including improper adjustments in medication dosage, potentially increasing the frequency of both hypoglycemia and hyperglycemia) (58).

Accuracy, ergonomics, and ease of use of blood glucose meters have improved dramatically over time (124-126), and the accuracy of CGM is beginning to approach that of BGM devices (113,114,127-130). However, a clinically significant variation in accuracy and precision persists among currently marketed GM devices. Clinicians must be familiar with the clinical and laboratory standards used to characterize the accuracy and precision of the devices that they recommend in order to work safely and most effectively with patients using BGM or CGM systems.

Measures of BGM and CGM Accuracy

There is a logical progression as to how one should interpret performance data with the objective of choosing the appropriate GM device for a particular patient. The following presents such an approach.

(*1*) Bias. This refers to any systematic error in the measurements provided by the meter or sensor. This may be due to improper calibration, lack of calibration, or calibration with an inaccurate BGM. Bias may vary depending on the glucose levels being measured.

(*2*) Precision: Precision refers to the reproducibility of measurements, irrespective of whether they accurately measure the true value they are supposed to be measuring. Measurements may be highly reproducible but may be clustered around an erroneous value. We can measure the precision of a BGM or CGM by repeating measurements on the same blood sample or repeatedly measuring glucose using 2 or more CGM sensors simultaneously on the same subject. Even if the true value is not known, comparing the results for the multiple readings, we can derive a measure of precision.

For example, if 100 measurements gave a mean of 110 mg/dL with an SD of 5, the values would be very reproducible with a percentage error of about 5%. However, if the true value were actually 100 mg/dL, then these measurements would be biased and would be significantly inaccurate.

(*3*) Arithmetic deviation: If the true value is 100 mg/dL and the measured value is 110 mg/dL, then there is an arithmetic deviation of +10; similarly a value of 90 mg/dL would have an arithmetic deviation of −10.

For example, if the result of the meter or CGM being evaluated is 85 mg/dL, and the true value is 100 mg/dL (as provided by a very precise and accurate laboratory method or by some other reference method), then the arithmetic deviation is −15. These values can be calculated for each pair of true value and test-method value, and then averaged. The average should be extremely close to 0. One can then plot the arithmetic deviation versus the true value, to see if the average magnitude of the deviations varies systematically with the true value (Fig. 3) Bias is defined as a systematic (built-in) error, which makes all measured values wrong by a certain amount. As an overall estimate of bias, one can use the mean arithmetic deviation divided by the mean or average glucose level, expressed as a percentage (131,132).

(*4*) Absolute deviation: The absolute deviation is the absolute value of the arithmetic deviation. In the cases above, the absolute deviations of the arithmetic deviations +10 and −15 would be 10 and 15, respectively.

One should next examine the relationship of the absolute deviation and its average magnitude for various glucose ranges. There is almost always a systematic relationship between the absolute deviations and the true glucose level. If the true glucose level is not known, one can use the average value of multiple replicated measurements (Fig. 4).

(*5*) Absolute Relative Difference (ARD): Since an absolute deviation of 15 has a very different implication for a true value of 45 mg/dL compared with a true value of 400 mg/dL, it is common practice to express the absolute difference as a percentage of the true glucose. One can also plot ARD versus the true glucose levels as a continuous function (Fig. 5).

a. Mean Absolute Relative Difference (MARD): When we calculate an absolute relative deviation based on individual measurements using the meter

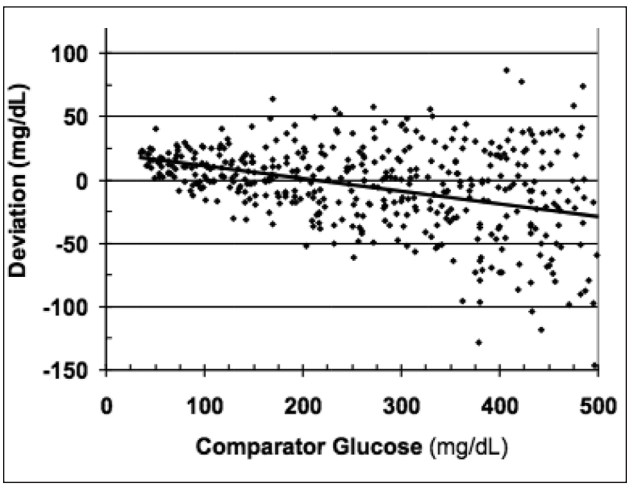


Fig. 3. Arithmetic deviations versus true glucose values (134). Relationship of deviations versus comparator glucose. The arithmetic (signed) deviations can vary in magnitude (bias) and in terms of their own variability depending on glucose level.

or CGM being evaluated (test method) as compared with a "true" laboratory-based method, there is a very large random sampling error. The mean absolute relative difference (MARD) is calculated as the average (mean) value of individual ARDs (133). To reduce the random sampling error in the measurement of ARD, it is desirable to calculate a MARD using a large number of paired test-comparator values for each specified narrow ranges of glucose (to achieve a 10% relative error in the MARD, it is necessary to have at least 500 data pairs).

MARD values have frequently been reported in the literature for the entire range of observed glucose levels (e.g., from 40 to 400 mg/dL). Since the ARD values differ systematically in the hypoglycemic, normoglycemic, and hyperglycemic ranges based on a specific GM device's performance, providing ARD data for narrow glucose ranges gives important and useful performance information (134). MARD values for CGM can vary systematically by day of wear (e.g., day 1 vs. day 3 vs. day 7) (Fig. 6) (135,136). MARD also depends on rate-of-change of glucose.

b. Median ARD: Rather than using MARD, some authors prefer to present results in terms of the median ARD.

One advantage of median ARD is that it is less influenced by outliers. However, it may be biased due to exclusion of the effects of outliers. Many studies have reported values for both MARD and the median ARD (frequently abbreviated as MedARD). MedARD is generally numerically smaller than MARD. The ratio of the MedARD to MARD has been found to be approximately 0.8 empirically for a variety of data in the literature. This is due to reduction in the influence of outliers, and the fact that the median is smaller than the mean for asymmetrical distributions such as ARD. It can be shown both empirically, using simulations, and theoretically, that the MedARD is approximately 0.8 MARD.

Table 6 summarizes the most commonly used terms that describe performance of glucose meters and sensors.

Understanding Clinical Standards for Accuracy of Current BGMs and CGMs

Error grids were the most popular early efforts to characterize the clinical significance of BGM device measurement errors. Regions of the grid are identified by letter designation, each reflecting the potential risk severity of incorrect treatment triggered by the measurement error (e.g., the device indicating hyperglycemia when someone is actually hypoglycemic). Clarke et al introduced the first error grid in 1987 (137). A variation of this grid was presented by Parkes et al in 2000 (Fig. 7) to smooth the boundaries of the grid regions. It incorporated the opinions of a greater number of expert clinicians (138). More recently, in 2014, a surveillance error grid with finer gradations in the categories for clinical error was introduced (139,140).

Device performance is typically reported as a percentage of glucose values in zone A or zones A + B (higher percentages in zone A or zones A + B indicate better performance). However, there are no generally accepted targets for clinical accuracy metrics such as percentage of observations within the various zones. These percentages may also depend on the range of blood glucose levels obtained. Error grids were a good tool to identify the frequency of egregious errors, but as meters have become more accurate, they are less useful for comparing device accuracy.

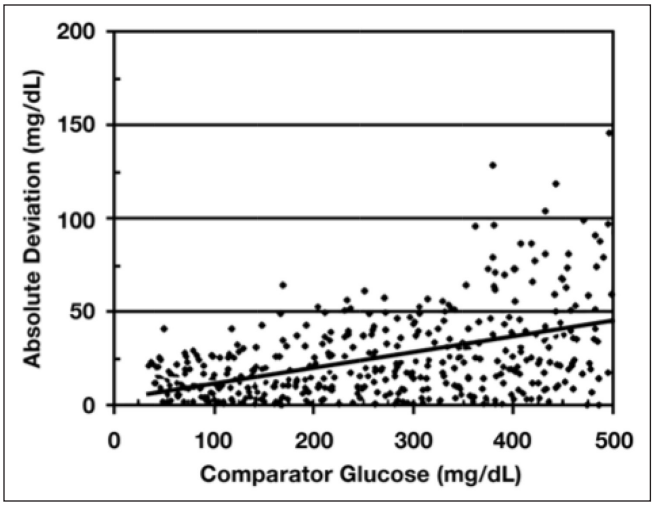


Fig. 4. Absolute difference: average magnitude of absolute deviations for various glucose levels (134). The absolute deviation of the test method from the comparator shows large random sampling variability. The magnitude of the absolute deviation and its own variability depend on glucose level. The least-squares regression line is shown.

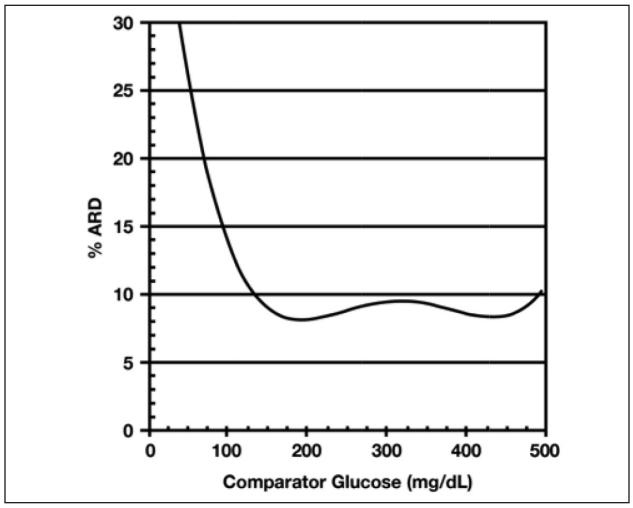


Fig. 5. Absolute relative deviation as a continuous function of true glucose (134).

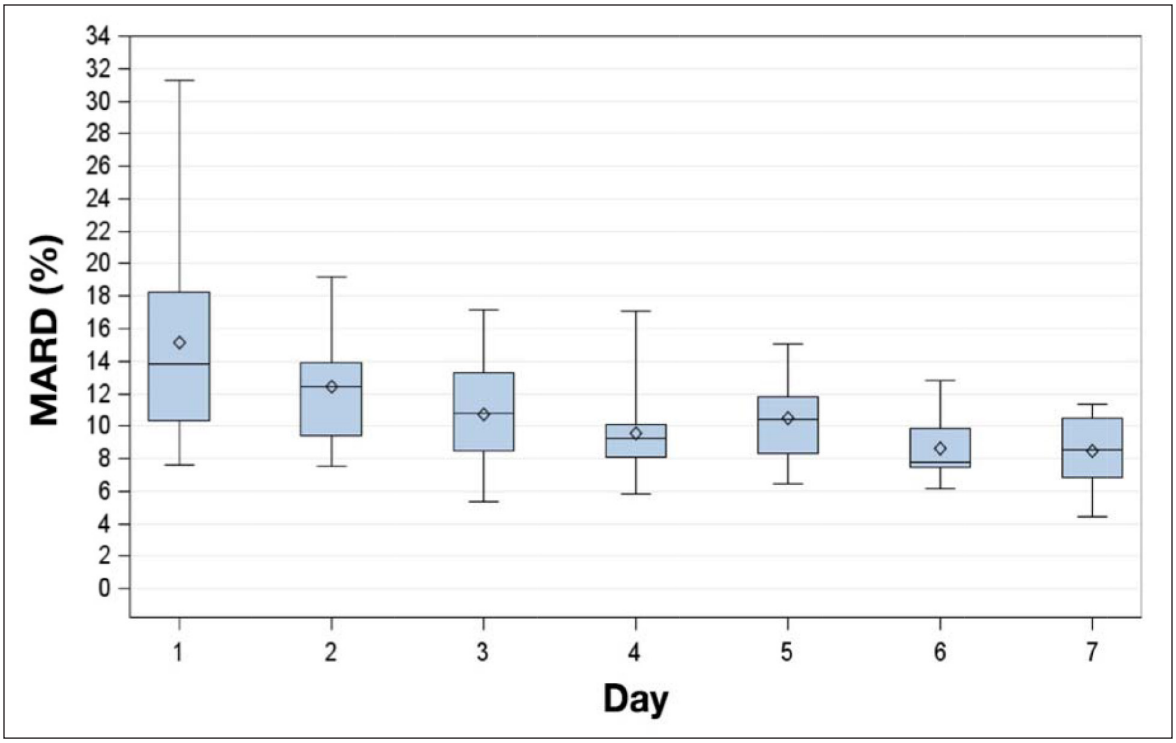


Fig. 6. CGM MARD values displayed by day of wear (135). Box plots for MARD on successive study days. Displayed are mean (diamonds), median (horizontal lines within boxes), 25th and 75th percentiles (lower and upper edge of the boxes), and minimum and maximum values (antennae). *CGM* = continuous glucose monitoring; *MARD* = mean absolute relative difference.

Linear regression and correlation is another common way of expressing device accuracy (Fig. 8). Bland-Altman plots are used to illustrate the magnitude of errors depending on the glucose level (Fig. 3) (134); these plots have been presented in a variety of formats. The vertical axis may show either arithmetic or relative error. The glucose levels shown on the horizontal scale may be the result of the comparator method or the average value of glucose measured by 2 methods subject to roughly comparable magnitude of error.

ISO Standards

In 2003 the ISO criteria for glucose meters were introduced; the FDA adopted these the following year. Official meter approval standards from 2003 to 2014 are summarized in Table 7 (122,123,131,141-143). The 2003 ISO 15197 standard requires that 95% of the values be accurate within ±15 mg/dL (0.83 mmol/L) for glucose values <75 mg/dL (4.2 mmol/L) and within ±20% for glucose values ≥75 mg/dL (4.2 mmol/L). These were updated in 2013 (ISO 15197-2013) to require 95% of values to be accurate within ±15 mg/dL (0.83 mmol/L) for glucose values <100 mg/dL (5.55 mmol/L) and within ±15% for glucose values ≥100 mg/dL (5.55 mmol/L) (131,142).

On January 7, 2014, the FDA released draft guidance for BGM accuracy that would require far more accuracy and precision from BGMs (143). The draft proposes that there be smaller errors in the hypoglycemic range and fewer outliers, allowing only 5% of measurements to have an error larger than ±15% and 1% of measurements to have an error greater ±20% above or below the reference value, rather than the 5% permitted under the 2003 ISO Guidelines. Further, the FDA was considering requesting that the experiment test be repeated 3 times, and the device would need to pass all 3 tests. This would make the testing more rigorous and conservative. If devices are tested by trained technicians, one would expect greater accuracy than if they were tested by untrained lay-persons such as patients and family caregivers. There is a suggestion that testing performed by nontrained people under "real-world" conditions might become required (144).

Not all BGMs that receive FDA approval provide the same degree of accuracy. Several published studies have compared BGM brands and models by name during head-to-head testing (56,57,136,145-148). For clinicians and consumers, MARD provides an excellent measure of accuracy and precision when evaluating a BGM (134). It has also been recommended that bias and coefficient of variation (%CV) should be reported (one can show mathematically and by simulations that there is a direct relationship between MARD and %CV: MARD is approximately 0.8 %CV) (132). The degree of BGM accuracy that is desired and required is likely to depend on the clinical needs of individual patients. There is a growing consensus among

Table 6
Common Terminology Related to GM Accuracy

Accuracy is defined as the closeness of agreement between a glucose test result and an accepted reference value. Accuracy improves when it has minimal bias and relative error (%CV, MARD, and minimal absolute error). Point accuracy refers to blood glucose values and sensor readings at single points in time (142,187).
Bias is an average of systematic error. It is measured as the difference or percentage difference of glucose values above (+) or below (–) reference values. The level of bias may differ systematically depending on the glucose level. The ideal bias is 0.0% (132,142).
Calibration for CGM refers to using periodic BGM measurements or a more accurate reference level from the laboratory, YSI device, or other measurement with higher accuracy to ensure accuracy. Devices and sensors vary in their requirements for frequency of calibration. Calibration of devices at the factory may eliminate the need for this step.
Percent coefficient of variation (%CV), defined as 100 × SD/(mean BG), expresses variability as the SD as a percentage of the mean glucose. This is a measure of the percentage error of repeated measurements of the same sample. The %CV usually varies systematically depending on glucose level.
Device stability is determined by the amount of change (also called drift) in accuracy over time (usually between the first and last measurement or between the first and second measurement). A commonly used stability standard is ≤4 mg/dL difference between measurements at BG concentrations ≤100 mg/dL or ≤4% at BG concentrations >100 mg/dL. Most current CGM devices require periodic recalibration to ensure accuracy over the life of the device (56,57,142,158).
Lag time refers to the difference in time between features (apices, nadirs) observed using capillary blood glucose as reflected in BGM or reference measurements and the time when the feature is observed using CGM (188).
Mean absolute relative deviation (MARD) is the most common measure used to characterize the accuracy of CGM but may also be used with BGM. MARD includes the effects of all outlier values.
Median absolute relative deviation (MedARD) is the median value of the absolute percentage deviation from reference glucose values. MedARD is less affected by outlier values than MARD. The MedARD is typically about 0.8 times the MARD.
Precision shows how closely a series of meter values agree with each other, regardless of how close they come to reference values. A GM that always reads 20% lower (or higher) than the true reference values may still have excellent precision. The precision of a device's readings is often measured as the %CV. High precision (repeatability) does not indicate accuracy.
Trend accuracy is a CGM device's ability to correctly measure the rate and direction of BG change over time (187).

Abbreviations: BG = blood glucose; BGM = blood glucose monitoring; CGM = continuous glucose monitoring; CV = coefficient of variation; GM = glucose monitoring; MARD = mean absolute relative deviation; SD = standard deviation; YSI = Yellow Springs Instruments.

endocrinologists and other clinicians that the accuracy and precision performance characteristics of each BGM and CGM device should be made available both to the patient and physician, to properly match a BGM device to the appropriate individual or clinical setting (149).

How Much Accuracy Is Needed?

Research on the impact of GM inaccuracy on health outcomes is limited; however, computer modeling can separate the impact of GM errors on glucose outcomes from those due to other factors. Modeling studies indicate that patients receiving bolus insulin therapy face increased risk of hypoglycemia even when using GM devices that achieve current standards (140,150-153).

One study used 100 simulated adults with T1DM to run 16,000 virtual trials applying varying levels of simulated BGM error (5%, 10%, 15%, and 20% deviation from true blood glucose values). Results showed that glycemic control deteriorated with each increase in BGM error. Failure to detect hypoglycemic episodes, hypoglycemia risk, glycemic variability, and A1C increased as BGM error level increased (150). In another study, Schnell and colleagues reported that improvements in BGM accuracy (reducing error from ±20 to ±5%) would be expected to result in a 10% reduction in severe hypoglycemia, a 0.4% reduction in A1C levels, and a 0.5% relative reduction in myocardial infarction. This study (2012 data) estimated an annual cost savings from this kind of improvement in BGM accuracy of €9.4 million for patients with T1DM and €55.5 million for insulin-treated patients with T2DM for Germany alone (151).

Another study of 100 simulated cases being treated with intravenous insulin therapy in an intensive care setting found that increases in either BGM imprecision

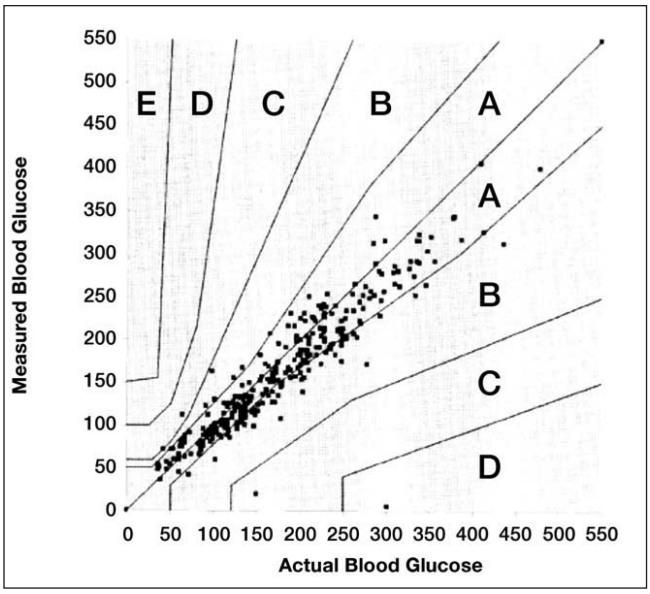


Fig. 7. Parkes error grid (138).

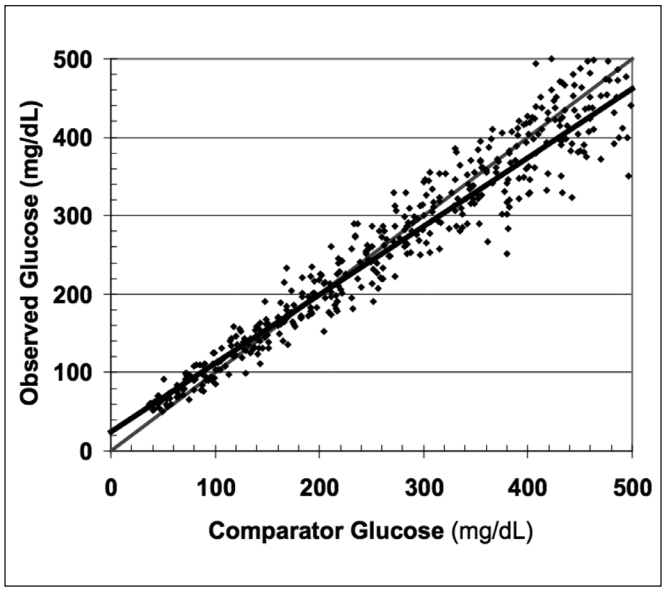


Fig. 8. Linear regression relationship between observed and comparator glucose (134).

(measured as %CV) or bias, tested separately (with 1 or the other variable set to 0), increased glucose variability and the frequency of hypoglycemia and hyperglycemia (154). BGMs with a %CV ≤6.5% and bias ≤5% rarely lead to major (2-step or greater) errors in insulin dosing. This degree of accuracy would ensure that the rate of any insulin dosing errors would be <5% (155). Table 8 summarizes clinical situations where increased accuracy may be of particular benefit.

What Impacts Accuracy?

Manufacturing defects and test-strip lot-to-lot variations directly impact accuracy and introduce bias (156,157). Bias is typically measured in the hypoglycemic range, target range, and hyperglycemic range. One study of test-strip accuracy compared 7 meters and tested 3 test-strip lots for each range and found that lot-to-lot variations were as high as 11% using the same meter (158). Another study found that the difference in bias between widely used BGM devices was as high as 4.8% (159). Underfilling the test strip can introduce errors >20% in some BGMs. In another study, only 5 of 31 glucose meters were able to maintain 100% accuracy (either giving the correct reading or rejecting the reading appropriately) when test strips were deliberately underfilled (160).

Although many meters have been approved for alternate site testing (e.g., sampling from the palm, upper arm, forearm, thigh or calf, rather than the fingertip), this practice can generate inaccurate results, particularly when glucose levels are changing rapidly such as after meals or after exercise, when the patient is ill or under stress, or shortly after insulin administration (68).

BGM testing methods are predominately based on the glucose oxidase or glucose-1-dehydrogenase enzyme. Any factor that interferes or impacts these enzymes or the BGM itself can degrade overall accuracy. Variation can be due to issues such as competing blood substrates (e.g., maltose, vitamin C) (161,162), environmental issues (e.g., cold temperature, high altitude with reduced oxygen pressure), and factors related to individual patients. Reduced accuracy and precision have been observed in tests performed by patients and other lay users compared with highly trained, experienced health professionals (163). GM accuracy is just one of many factors influencing the quality of subsequent glycemic control achieved. Contaminants on the skin from food sources (fruits, juices, sodas, milk) and even hand lotions can artificially raise capillary blood glucose levels and potentially lead to an overdose of insulin with subsequent hypoglycemia. Acetaminophen is well-known to result in spurious values in CGM systems (15,44,56,164,165). Physical compression of the CGM sensor during sleep can result in seriously low glucose readings.

How to Communicate Device Accuracy Data

It would be highly desirable to be able to label each GM device and its test strips or sensors with their performance characteristics, and methods for labeling have been contemplated for several years (166,167). In a recent guidance document (143), the FDA suggests a simple system that shows the percentage of a BGM glucose values expected to fall within 5%, 10%, 15%, and 20% of the reference values (Fig. 9) (143). This allows clinicians and patients more insight into the accuracy of a particular GM device so they can make an informed choice.

Table 7
Prior, Current, and Proposed Glucose Meter Performance Recommendations and Standards (131,142,143)

Meter approval standards			
ISO 15197 2003 (adopted by FDA 2004)	<75 mg/dL (<4.2 mmol/L)	±15 mg/dL (±0.83 mmol/L)	95%[a]
	≥75 mg/dL (≥4.2 mmol/L)	±20%	
ISO 15197 2013	<100 mg/dL (<5.55 mmol/L)	±15 mg/dL (±0.83 mmol/L)	95%[a,b]
	≥100 mg/dL (≥5.55 mmol/L)	±15%	
FDA 2014	50-400 mg/dL (2.8-22.2 mmol/L)	±15%	95%
	AND		
	50-400 mg/dL (2.8-22.2 mmol/l)	±20%	99%

Abbreviations: ADA = American Diabetes Association; FDA = US Food and Drug Administration; ISO = International Organization for Standardization.
[a] Both FDA and ISO standards allow 5% of meter values to be outside these limits. There was no limitation on the clinical severity of these outliers prior to 2013.
[b] 99% of values must be within Consensus Error Grid (138) zones A or B.

BGM Accuracy Is Necessary but not Sufficient to Improve Quality of Glycemic Control

As measurement tools, BGMs and CGMs generate data used to make treatment decisions and adjust diabetes medication doses. The aptitude of patients and clinicians with regard to data analysis and interpretation varies widely. Accordingly, the methods of data display and reporting are critically important. Older BGMs displayed a single value without context. In contrast, many current BGMs report weekly or monthly averages for glucose and may also highlight patterns in glycemic variability (e.g., consistently high or low values at a particular time of day or in relationship to a specified meal). Similarly, current CGM devices have on-screen analysis capabilities that display glucose trend lines over time, with arrows reflecting the magnitude of the current rate-of-change of glucose. These features provide additional information and help give context to raw glucose numbers. However, many users will require guidance to effectively use these informative features.

Clinicians should also consider the ease and speed of BGM downloading to ensure that the end user will be able to identify glucose patterns and that clinical interventions will be properly implemented. Currently, each device has proprietary software that displays data in widely differing formats, making clinical interpretation difficult. To accommodate their patients, clinicians need to master multiple software products. Although no current software downloads every device, several companies and organizations are attempting to develop standardized methods to download and display data from nearly every type of BGM, CGM, insulin pump, and other health devices (e.g., activity monitors).

To correctly gauge the timing of hypoglycemic and hyperglycemic events, the clock setting in the BGM must be accurate (168). BGM clock settings should be clearly visible and easy to adjust and should remain accurate when a battery is changed or temporarily removed. Clocks in the meter, CGM, and insulin pump (if utilized) should be synchronized (automatically if possible), with accommodation for travel across time zones. Ideally, all glucose and related data should be integrated with an electronic health record.

It has been proposed that the ongoing routine quality assurance verification currently being performed by manufacturers to ensure the accuracy and precision of subsequent lots of test strips should be confirmed by independent laboratories using a standardized methodology (146). In support of this concept, Freckmann and colleagues reviewed the accuracy of 27 meters previously approved in Europe under the 2003 ISO 15197 standard (±20% for glucose levels >75 mg/dL and ±15 mg/dL for glucose levels ≤75 mg/dL). In postapproval testing, more than 40% of the meters failed to meet the standard by which they had previously received approval (58). When people with diabetes

Table 8
Clinical Situations That May Require Greater Glucose Monitoring Accuracy

Patients requiring the highest possible accuracy in glucose monitoring
• History of severe hypoglycemia
• Hypoglycemia unawareness
• Pregnancy
• Infants and children receiving insulin therapy
• Patients at risk for hypoglycemia, including:
o Patients receiving basal insulin
o Patients receiving basal bolus inulin therapy with multiple injections per day
o Patients receiving sulfonylureas or glinides (insulin secretagogues)
o Patients with irregular schedules, skipped or small meals, vigorous exercise, travel between time zones, disrupted sleep schedules, shift work
• People with occupational risks that enhance possible risks from hypoglycemia (for example, involving driving or operating hazardous machinery)

Your ABC meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the testing technology.

The chart below shows the results of a study where 350 typical users used the ABC meter to test their blood glucose levels. For example, in this study, the ABC meter gave results within 15% of their true blood glucose level 340 out of 350 times.

Difference in range between the true blood glucose level and the ABC meter result	Within 5%	Within 10%	Within 15%	Within 20%
The percent (and number) of meter results that match true blood glucose level with x%	57% (200/350)	94% (330/350)	97% (340/350)	100% (350/350)

Accuracy Levels	**Meter Results Meeting Standard**	**Percentage of meter values compared to laboratory values**
Accurate	350 out of 350	±15%
More Accurate	262 out of 350	±10%
Most Accurate	175 out of 350	±5%

Fig. 9. Sample label information for meter and test-strip boxes (From the US Food and Drug Administration Guidance Document) (143).

performed the testing, fully one-third of meters failed to meet the 2003 ISO 15197 standards (169). A recent study showed that only 12 (44.4%) of 27 available BGMs met the most recent 2013 ISO 15197 standard. Only 13 of 27 (48.1%) BGMs gave adequately accurate results in the hypoglycemic range, while 19 (70.3%) had sufficient accuracy for glucose levels >250 mg/dL (13.9 mmol/L) (170). Unfortunately, one cannot assume that FDA approval implies that a BGM will continue to meet FDA accuracy requirements for subsequent batches of test strips.

Glucometrics, Downloading, and Interpretation of GM Data

The analysis and display of glucose data is termed "glucometrics" (171). It can describe the average value, distribution of glucose, glucose variability, patterns during the day and night, effects of days of the week, and long-term trends. The availability of GM devices with electronic memory and the ability to download these data has fueled the rapidly growing science of glucometrics. Retrospective analysis of glucose levels, both overall and at specific times (e.g., after major meals or on selected days of the week), can provide insights into how factors such as medications, diet, stress, and activity contribute to diabetes control and how those factors should be addressed or adjusted (82,172). Communication of glucometric data to the healthcare team is key; communication methods between patient and clinician are presented in Table 3.

Which glucometrics parameters are best? Approaches vary in complexity but usually generate similar types of information (171,173). With enough information, it becomes possible to evaluate whether the A1C level, still the gold standard, is consistent with the patient's average blood glucose (174).

Table 9 summarizes high-level, clinically relevant information that can be obtained from BGM or CGM data. Either the mean or median can be used to characterize the average glucose level. Since the SD of glucose is fairly highly correlated with the mean glucose, %CV is usually the best single simple method to characterize variability (26,37,175-178). As an approximation, SD tends to be higher in patients with higher mean glucose values. While mean, median, and %CV metrics describe overall glycemia, several additional methods have been developed to describe actionable patterns to help clinicians optimize diabetes therapy. In a graphical presentation, the "standard day," "modal day," (179,180) or ambulatory glucose profile (AGP) displays individual glucose measurements (pooled over multiple days) by time of day on a single 24-hour scale (Table 9; image 1*A*; image 1*B*.; image 2*A*.). This graph indicates both the glucose values and the times of day when people have been monitoring their glucose levels, facilitating the detection of any consistent patterns in glucose excursions and providing an assessment of the adequacy of GM. The "Standard Day" is simple in principle but can be difficult to interpret in view of the large amount of scatter observed in glucose data obtained over several days.

AGP

The AGP was introduced by Mazze et al (1987) for BGM and subsequently applied with further enhancements (display of the smoothed curves for the 10th and 90th percentiles) to CGM data by Mazze (2008) and Bergenstal and colleagues (2013). The AGP provides an excellent starting point for a standardized computerized display of BGM and/or CGM data by time of day (173,178,179). To generate the AGP, an individual's blood glucose levels are measured via CGM or BGM with all glucose data pooled and analyzed as if it had been collected during a single 24-hour period. The result is a standardized software report that can be displayed graphically. Examples of graphic AGP displays for patients with normal glucose tolerance, T1DM, and T2DM are shown in Table 9 (images 2*A*-*C*) (173,181). AGP has been proposed as a standardized method for glucose reporting and analysis (173,178,181). One can also examine these 24-hour patterns in glucose by day of the week (180). It is customary to report a number of statistics to accompany the graphical display of the AGP (173).

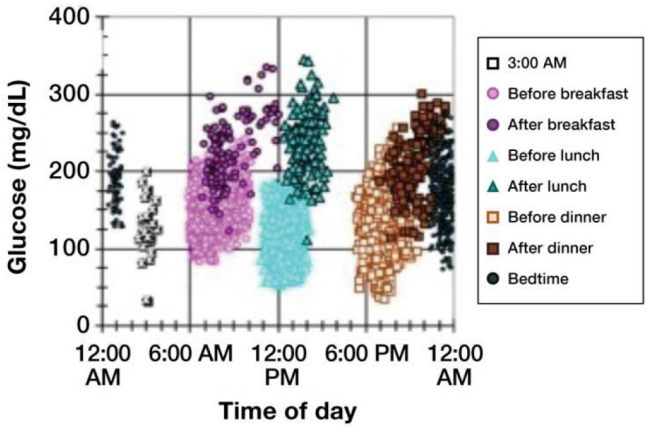
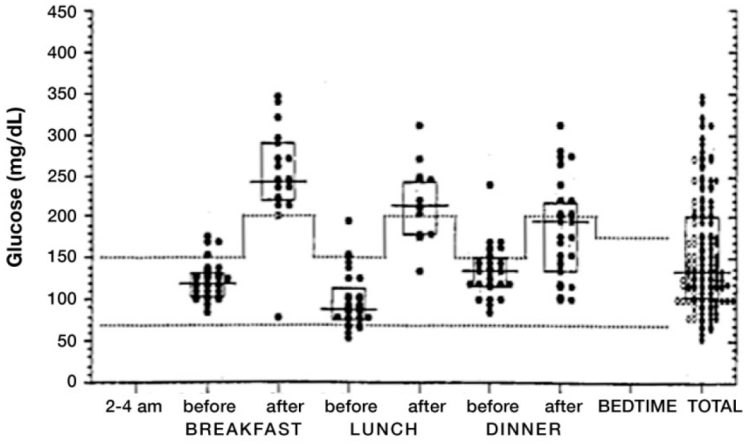
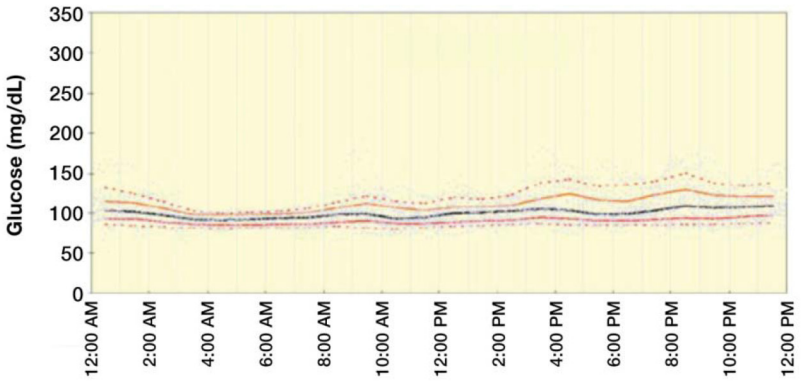
Several additional graphic displays of data related to changes in glucose over time, time within different glucose ranges, glucose profile, etc. are shown in Table 9. Some are simplistic (e.g., pie graphs or simple bar charts displaying percentages of glucose values above, below, and within the target range). Others are slightly more complex (e.g., box plots [a methodology introduced by Tukey as part of his approach to Exploratory Data Analysis that makes no assumptions about the nature of the underlying distribution of glucose values and was introduced into glucometrics by Rodbard (180,182)], scattergrams, stacked bar charts, and histograms). Their purpose is to help the clinician identify and prioritize clinical problems and then educate and motivate the patient to achieve improved glycemic control.

Recommendations

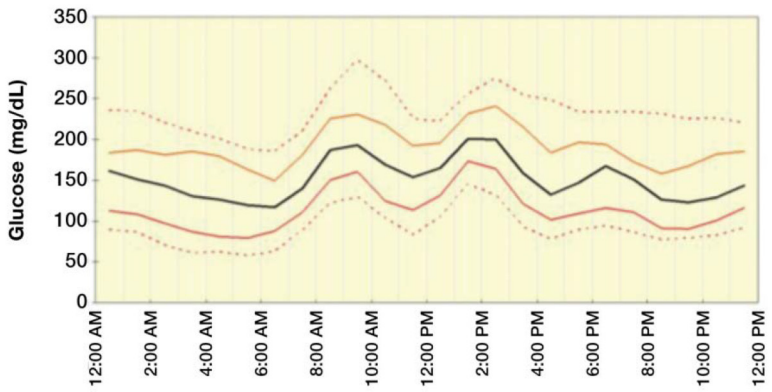
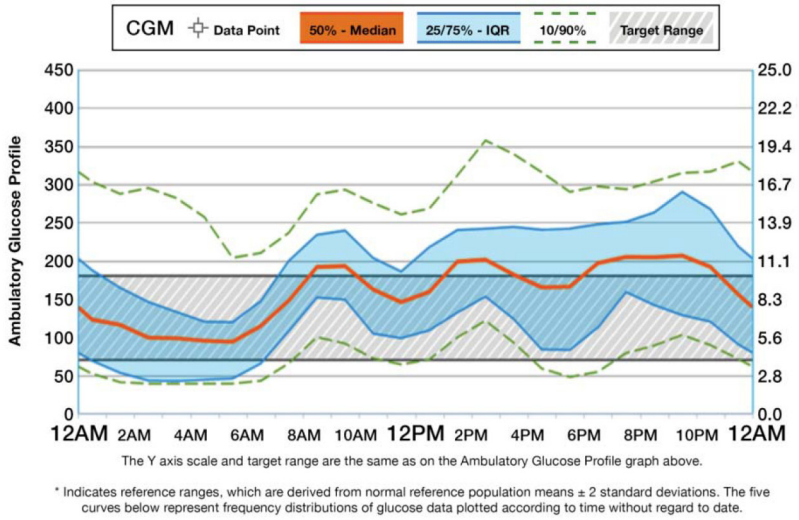
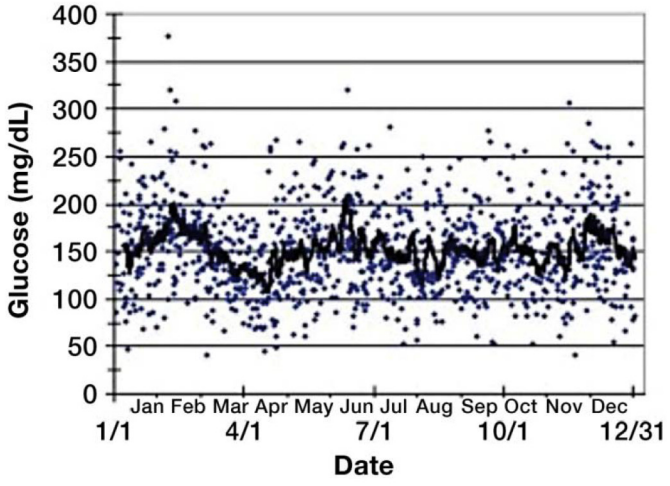
Health professionals should educate patients regarding the interpretation and use of GM data to help modify patient behaviors, enhance their ability to self-adjust therapy, and help them decide when to seek medical assistance.

To assess glucometrics, first examine the overall statistics (mean, SD, %CV); distribution of glucose values (e.g., stacked bar charts); and glucose by date, time of day, in relationship to meals, and by day of the week. This document provides several examples for each of these types of analyses. Usually, the most helpful are graphs of glucose by date, the AGP by time of day, stacked bar charts in relationship to time of day, and stacked bar charts and "box plots" for glucose in relation to meals and by day of the week.

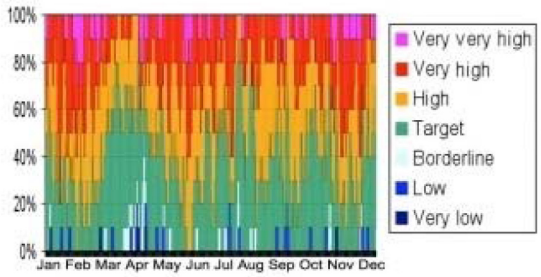
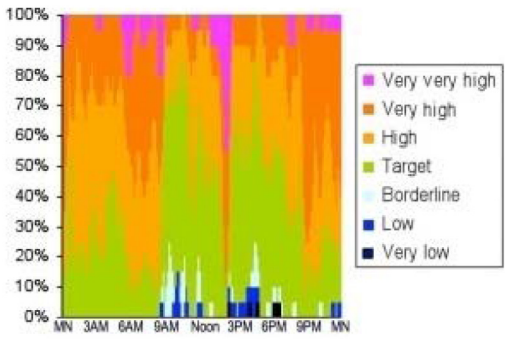
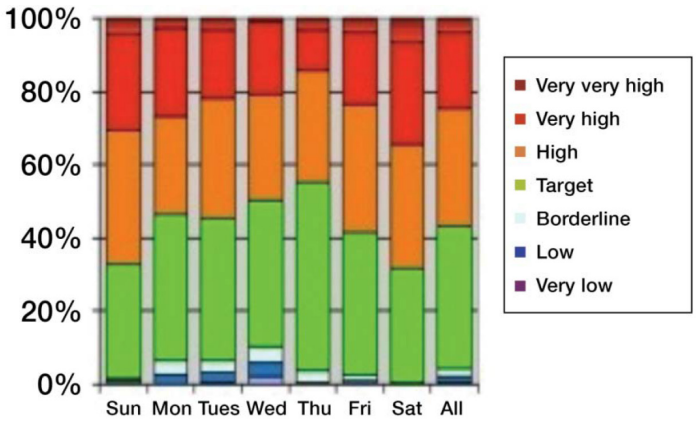
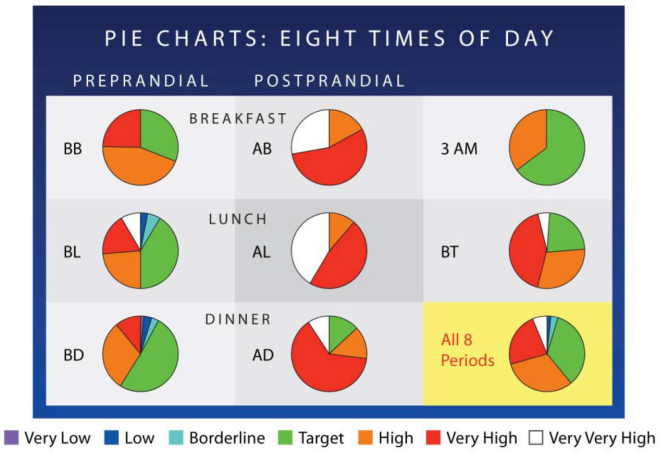
Table 9
Glucometrics: Key Characteristics of BGM and CGM Glucose Data (171,173,174,179,181,182, 190)

Average glucose	
Mean, median Calculated value of A1C corresponding to the observed average glucose	
Glucose variability	
SD, %CV, IQR, maximum, minimum, range	
Standard/modal day	
1*A*. Glucose profile by time of day	
1*B*. Glucose values shown in relation to meals (solid circles) superimposed on target ranges for preprandial and postprandial glucose. Horizontal lines: median. The rectangles show the 25th and 75th percentiles.	
AGP	
2*A*. Patient with normal glucose tolerance (example) Ambulatory glucose profile (AGP) for CGM data (typically using data from 14 days), with smoothed estimates of 10th, 25th, 50th, 75th, and 90th percentiles	

(Continued next page)

2*B*. Patient with T1DM (example)	
2*C*. Patient with T2DM The solid curve in the middle represents the smoothed median glucose (50th percentile) values for a 24-hour period. The blue shaded area around the median reflects the range between the 25th and 75th percentiles, which includes 50% of the patient's glucose readings for any specified time of day. The average vertical distance between the shaded curves is the overall IQR. The dashed lines show smoothed 10th and 90th percentiles. The striped, shaded area shows the presumptive target range (70-180 mg/dL or 3.9-10 mmol/L).	
Change in glucose over time	
3. Glucose by *date* for all glucose values. May also be used for: • Mean glucose • Fasting glucose • Glucose values at any selected time of day	

(Continued next page)

4. Percentage of time in 7 categories, by date, for 1 year	
Glucose distribution	
Quality of glycemic control	
5. Percentage of values in multiple categories of glycemic quality by time of day • Percentage in target range (green) • Percentage hyperglycemia (orange, dark orange, or pink, representing different degrees of severity) • Percentage hypoglycemia (light blue, dark blue, blue-black)	
6. Categories of glycemic quality by day of the week (using stacked bar charts with 7 glucose level categories)	
7. Proportion of glucose values within the hypoglycemic, target, and hyperglycemic ranges in relationship to meals 7*A*. Pie charts showing before and after meals, at bedtime, and overnight (3 AM)	

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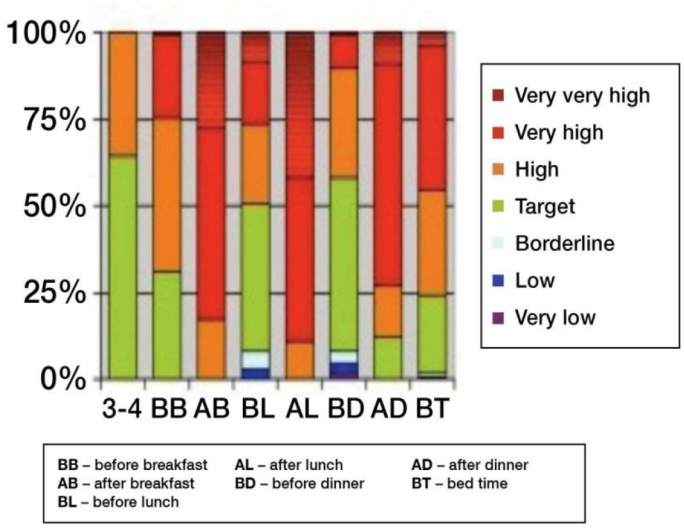
7*B*. Proportion of glucose values within the hypoglycemic, target, and hyperglycemic ranges in relationship to meals (stacked bar charts)



Integration with other relevant "logbook" data

8. Medications, insulin doses, diet, physical activity/exercise, illness, stress, travel

8.9 Enhanced Logbook		Breakfast		Lunch		Dinner		Night	
		Before	After	Before	After	Before	After	Bedtime	2 a.m.
Sun ___/___/___ Notes:	BG								
	Time								
	Carbs								
	Bolus								
Mon ___/___/___	BG								
	Time								
	Carbs								
	Bolus								
Tue ___/___/___	BG								
	Time								
	Carbs								
	Bolus								

Abbreviations: AB = after breakfast; AD = after dinner; AGP = ambulatory glucose profile; A1C = glycated hemoglobin; AL = after lunch; BB = before breakfast; BD = before dinner; BG = blood glucose; BGM = blood glucose monitoring; BL = before lunch; BT = bedtime; CGM = continuous glucose monitoring; CV = coefficient of variation; IQR = interquartile range; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus.

Image citations: 1A, 3, 4, 5, 6, 7A, 7B: Rodbard D, et al. J Diabetes Sci Technol. 2009;3:1388-1394.; 1B.: Pernick N and Rodbard D. Diabetes Care. 1986;9:61-69.; 2. A., 2. B.: Mazze RS, et al. Diabetes Technol Ther. 2008;10:149-159.; 2C.: Bergenstal R, et al. J Diabetes Sci Technol. 2013;7:562-578.; 8: Walsh J, et al. Using Insulin: Everything You Need for Success with Insulin. San Diego, CA: Torrey Pines Press. 2003.

Persons with diabetes who use an insulin pump have a rich data set of additional information to supplement glucose values that includes the time and amount of all insulin administered whether for a meal or for a correction, as well as all recorded carbohydrate intake. Nonpump users must track insulin use manually. A review of reports that include medication history can greatly improve one's ability to make therapeutic decisions and advise the patient.

CONCLUSION

GM is an essential component of care for all patients with diabetes. Over the years, BGM meters and CGM sensors have improved dramatically in terms of accuracy, data usefulness, and the availability of automated analyses and interpretation. This document seeks to encourage "meaningful monitoring," a term that signifies an approach that

is intended to empower patients to manage glucose levels and reduce the risk of hypoglycemia. Meaningful monitoring will likely be different for each individual. Clinical practice guidelines from all major diabetes organizations recommend routine BGM for patients with T1DM. Most of these guidelines also recommend CGM for patients with a history of severe hypoglycemia or hypoglycemia unawareness, as well as for patients not at goal based on A1C. Many pediatric patients with T1DM are candidates for CGM, especially if they and their family caregivers have the appropriate training to use the information effectively.

Meaningful monitoring in patients with T2DM should also be individualized depending on the risk of hypoglycemia estimated based on prior history, presence of hypoglycemia unawareness, and the nature of the current therapy (e.g., whether the patient is receiving medications with relatively high hypoglycemia risk, such as insulin, sulfonylureas, or glinides). There have been some studies of CGM in T2DM, but more trials are needed to identify the settings in which it can be most beneficial and cost-effective. In T2DM as in T1DM, CGM can be useful in patients with unappreciated hyperglycemia, as well as in patients who are at high risk for hypoglycemia, those who have hypoglycemia unawareness, and those using intensive insulin therapy (44).

Patients and clinicians should be educated to understand and use GM data. Glucometric data analysis can help both patients and clinicians assess the quality of glycemic control, identify glucose patterns and responses to therapy, and evaluate glucose variability. Glucometric analysis can also be used as an educational tool. Education is essential to making apparent the relationship of specific glucose data with medication and other therapeutic interventions.

Looking forward, one can expect increased BGM accuracy and the continuing rapid evolution of CGM devices. Many improvements are in progress, including data sharing via the Internet (e.g., as implemented by Nightscout, Dexcom Share, Medtronic), use of additional displays (e.g., Apple Watch™), increased duration of use, and improved usability (size, weight, form factor, ease of insertion, ease of interface with other devices, options for placement site). Several mobile-health applications have been developed for mobile phones, enabling patients to monitor and adjust their lifestyle and therapy on a continuing real-time basis. As the technology advances, there is a vital need to integrate the multiple data inputs from insulin pumps, glucose sensors, glucose meters, and carbohydrate intake in a comprehensive and standardized way so clinicians and patients can make sense of it all.

Additionally, CGM devices are now available with a longer duration of use (2 weeks); others in development may be implanted and last 6 months or longer. Some devices are factory calibrated and do not require additional calibrations by the end user. Devices will become smaller, lighter, and simpler to use. Some will have fewer features (e.g., no alarms), while others may have additional features and will integrate with insulin delivery (e.g., "artificial pancreas") systems. These are examples of device innovations that may broaden the appeal and applicability of CGM both in T1DM and T2DM. New clinical trials will be needed to better understand how to optimally utilize this technology for various patient populations with T2DM.

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Correction

In the 2016 Outpatient Glucose Monitoring Consensus Statement published in the February issue of *Endocrine Practice* (Volume 22, pgs. 231-261), there were omissions in Tables 2 (p. 236) and 6 (p. 245) of the print version. In Table 2, fasting plasma glucose was tested before meals in addition to on awakening. In Table 6, "%C" should read "%CV." We apologize for the errors.

Table 2
Recommendations for Daily Blood Glucose Testing in Patients with Type 1 Diabetes (2,68,69)

	Timing	Goal	
		mg/dL	mmol/L
Fasting plasma glucose	Test on awakening and before meals	80-130 (ADA) 70-130 (Joslin) <110 (AACE)	4.2-7.2 (ADA) 3.9-7.2 (Joslin) <6.1 (AACE)
Postprandial	2 hours after meal 1-2 hours after meal	<180 (ADA) <180 (Joslin) <140 (AACE)	<10.0 (ADA) <10.0 (Joslin) <7.8 (AACE)
Bedtime glucose	At bedtime	90-150 (Joslin)	5.0-8.3 (Joslin)
These goals must be individualized to personal patient needs regarding pregnancy, hypoglycemia unawareness, patients who live alone, or occupational hazards that require further reduction of risk of hypoglycemia (2,68).			
Abbreviations: AACE = American Association of Clinical Endocrinologists; ADA = American Diabetes Association; Joslin = Joslin Diabetes Center.			

Table 6
Common Terminology Related to GM Accuracy

Accuracy is defined as the closeness of agreement between a glucose test result and an accepted reference value. Accuracy improves when it has minimal bias and relative error (%CV, MARD, and minimal absolute error). Point accuracy refers to blood glucose values and sensor readings at single points in time (142,187).
Bias is an average of systematic error. It is measured as the difference or percentage difference of glucose values above (+) or below (–) reference values. The level of bias may differ systematically depending on the glucose level. The ideal bias is 0.0% (132,142).
Calibration for CGM refers to using periodic BGM measurements or a more accurate reference level from the laboratory, YSI device, or other measurement with higher accuracy to ensure accuracy. Devices and sensors vary in their requirements for frequency of calibration. Calibration of devices at the factory may eliminate the need for this step.
Percent coefficient of variation (%CV), defined as 100 × SD/(mean BG), expresses variability as the SD as a percentage of the mean glucose. This is a measure of the percentage error of repeated measurements of the same sample. The %CV usually varies systematically depending on glucose level.
Device stability is determined by the amount of change (also called drift) in accuracy over time (usually between the first and last measurement or between the first and second measurement). A commonly used stability standard is ≤4 mg/dL difference between measurements at BG concentrations ≤100 mg/dL or ≤4% at BG concentrations >100 mg/dL. Most current CGM devices require periodic recalibration to ensure accuracy over the life of the device (56,57,142,158).
Lag time refers to the difference in time between features (apices, nadirs) observed using capillary blood glucose as reflected in BGM or reference measurements and the time when the feature is observed using CGM (188).
Mean absolute relative deviation (MARD) is the most common measure used to characterize the accuracy of CGM but may also be used with BGM. MARD includes the effects of all outlier values.
Median absolute relative deviation (MedARD) is the median value of the absolute percentage deviation from reference glucose values. MedARD is less affected by outlier values than MARD. The MedARD is typically about 0.8 times the MARD.
Precision shows how closely a series of meter values agree with each other, regardless of how close they come to reference values. A GM that always reads 20% lower (or higher) than the true reference values may still have excellent precision. The precision of a device's readings is often measured as the %CV. High precision (repeatability) does not indicate accuracy.
Trend accuracy is a CGM device's ability to correctly measure the rate and direction of BG change over time (187).
Abbreviations: BG = blood glucose; BGM = blood glucose monitoring; CGM = continuous glucose monitoring; CV = coefficient of variation; GM = glucose monitoring; MARD = mean absolute relative deviation; SD = standard deviation; YSI = Yellow Springs Instruments.