

## CME Review Paper

# Self-Monitoring of Blood Glucose (SMBG) in Insulin- and Non-Insulin-Using Adults with Diabetes: Consensus Recommendations for Improving SMBG Accuracy, Utilization, and Research

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CNA/ANCC 1.3 contact hours provided

### CME AND CNE ACCREDITATION

- Self-Monitoring of Blood Glucose (SMBG) in Insulin- and Non-Insulin-Using Adults with Diabetes: Consensus Recommendations for Improving SMBG Accuracy, Utilization, and Research
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This activity is supported by an educational grant from Bayer Diabetes Care.

**Target Audience:** Endocrinologists, registered nurses, primary care physicians treating diabetes

#### Statement of Need/Program Overview

Current clinical guidelines for diabetes care encourage self-monitoring of blood glucose (SMBG) to improve glycemic control. Specific protocols remain variable, however, particularly among non-insulin-using patients. This is due in part to efficacy studies that neglect to consider (1) the performance of monitoring equipment under real-world conditions (2) whether or how patients have been taught to take action on test results, and (3) the physiological, behavioral, and social circumstances in which SMBG is carried out. As such, a multidisciplinary group of specialists, including several endocrinologists, a health psychologist, a diabetes nurse practitioner, and a patient advocate (the Panel), discuss within this review article how the potential of SMBG might be fully realized in today's healthcare environment. The resulting recommendations cover technological, clinical, behavioral, and research considerations

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with the aim of achieving short- and long-term benefits of SMBG. The panel also made suggestions for designing future studies that increase the ability to discern optimal models of SMBG utilization for individuals with diabetes who may, or may not, use insulin.

### Educational Objectives

*After completing this activity, the participant should be better able to:*

- Recount the technological and user factors that affect meter accuracy and ensuing clinical care
- Review reasonable expectations of SMBG as a tool for improving diabetes management among insulin-using and non-insulin-using patients
- Outline specific strategies of glucose pattern management and behavioral intervention for sustained glyce-mic control
- Cite the limitations of current research models with respect to determining SMBG effectiveness among different patient groups

### Faculty

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### Physician Continuing Medical Education

#### Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and The Diabetes Education Group. PIM is accredited by the ACCME to provide continuing medical education for physicians.

#### Credit Designation

Postgraduate Institute for Medicine designates this educational activity for a maximum of 1.25 *AMA PRA Category 1 Credit(s)*<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

### Nursing Continuing Education

#### Purpose

Although clinical guidelines for controlling diabetes encourage self-monitoring of blood glucose (SMBG), specific protocols remain variable, particularly among non-

insulin-using patients. This continuing education program discusses how coordinating the components of diabetes care, with emphasis on nurse-driven patient education and follow-up, can enhance the therapeutic benefits of SMBG for patients who may, or may not, use insulin.

### Accreditation Statements

#### CNA/ANCC

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PIM is an approved provider of continuing nursing education by the Colorado Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

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## **Abstract**

Current clinical guidelines for diabetes care encourage self-monitoring of blood glucose (SMBG) to improve glycemic control. Specific protocols remain variable, however, particularly among non-insulin-using patients. This is due in part to efficacy studies that neglect to consider (1) the performance of monitoring equipment under real-world conditions, (2) whether or how patients have been taught to take action on test results, and (3) the physiological, behavioral, and social circumstances in which SMBG is carried out. As such, a multidisciplinary group of specialists, including several endocrinologists, a health psychologist, a diabetes nurse practitioner, and a patient advocate (the Panel), discuss within this review article how the potential of SMBG might be fully realized in today's healthcare environment. The resulting recommendations cover technological, clinical, behavioral, and research considerations with the aim of achieving short- and long-term benefits, ranging from fewer hypoglycemic episodes to lower complication-related costs. The panel also made suggestions for designing future studies that increase the ability to discern optimal models of SMBG utilization for individuals with diabetes who may, or may not, use insulin.

## **Introduction**

**E**XPERIENCES WITH SELF-MONITORING of blood glucose (SMBG) and physiologically based insulin therapy were first published 30 years ago (in 1978) in the premier issue of *Diabetes Care*.<sup>1</sup> Subsequent landmark trials showed that careful management of blood glucose levels delayed or even prevented complications of diabetes.<sup>2-5</sup> These studies also codified the use of SMBG as a tool for preventing hypoglycemia and adjusting medications, dietary regimens, and physical activity to achieve glycemic goals.<sup>6,7</sup>

Although current clinical guidelines encourage SMBG for fine-tuning diabetes management, specific protocols remain variable, especially among non-insulin-using patients with

type 2 diabetes.<sup>8-13</sup> This ambiguity is due in part to efficacy studies that focus narrowly on the improvement of overall glycemic control, as measured by glycosylated hemoglobin (A1C), without systematically examining the broader context of SMBG implementation.<sup>14,15</sup> Since both short- and long-term outcomes of SMBG are governed largely by the day-to-day actions of individual patients, evaluations of efficacy should ideally allow for numerous interrelated factors impacting multiple healthcare priorities.<sup>14</sup> These include the analytical performance of blood glucose monitors under varying circumstances, whether or how patients have been taught to take action on blood glucose results, and the physiological, behavioral, and social milieu in which SMBG is carried out.<sup>16-18</sup>

Without a consistent methodology for determining which factors contribute to which effects in which patients, dis-

secting the costs and benefits of SMBG has been difficult, with most health policies considering A1C the primary criterion of appropriate care.<sup>15,19–22</sup> Yet the shortcomings of this conventional view are perhaps most clearly demonstrated by the scourge of diabetes worldwide.<sup>23</sup> In the United States alone, nearly 18 million adults are currently diagnosed with the disease, another 6 million have it but do not know it, and approximately 57 million show evidence of its precursor, impaired glucose tolerance or “prediabetes.” Thus, over 25% of the population is at risk for the potentially devastating, but preventable, micro- and macrovascular complications stemming from poorly controlled glycemia.<sup>24</sup> Moreover, the soaring cost (direct and indirect) of diabetes, approximately \$174 billion in 2007, corroborates reports that 40% of American adults with diabetes still do not meet the American Diabetes Association (ADA) A1C target of <7%.<sup>25–27</sup>

Regarding SMBG specifically, a gradual increase in the percentage of adults self-testing has kindled cautious optimism. Most notably, the Centers for Disease Control and Prevention reported that 63.4% of patients with diabetes now monitor blood glucose at least once daily, exceeding the goal of 61% established by the government’s *Healthy People 2010* initiative.<sup>28</sup> While this ostensible success is attributed in part to the Balanced Budget Act of 1997, which expanded Medicare coverage of monitoring supplies to non-insulin users,<sup>29</sup> the potential for extrapolating optimal models of care or distinguishing causal relationships from this information remains limited.

As such, a multidisciplinary group of specialists, including several endocrinologists, a health psychologist, a diabetes nurse practitioner, and a patient advocate (the Panel), discuss in this article how the potential of SMBG might be fully realized in today’s complex healthcare environment.<sup>30</sup> The resulting consensus recommendations, which appear below, address the complementary influences of (1) glucose monitor accuracy, (2) ways in which clinicians and patients use glucose data to inform diabetes care, (3) individual volition surrounding SMBG, and (4) healthcare policies affecting device development and utilization. The panel also made suggestions for developing research methodologies aimed at establishing systematic SMBG-driven protocols across the continuum of diabetes care.

### 1. What Technological and Patient Factors Should Be Addressed to Improve SMBG Accuracy?

Over 30 different handheld blood glucose meters are listed in the ADA 2008 *Resource Guide*.<sup>31</sup> The commonly used electrochemical technology involves a biosensor employing enzyme mechanisms—typically glucose oxidase or glucose dehydrogenase and electrochemical mediators—on a disposable strip.<sup>32</sup> The enzymes provide specificity, and the mediators are oxidized or reduced (redox reaction) during the biochemical reaction, generating a charge that is measured and translated as a blood glucose concentration on the meter display screen.<sup>33</sup>

Many issues have emerged regarding standards of practice for evaluating the accuracy of home blood glucose testing. Meter accuracy studies are often conducted by commercial companies that submit clinical trial data to regulatory organizations such as the U.S. Food and Drug Administration. From the manufacturing standpoint, accuracy

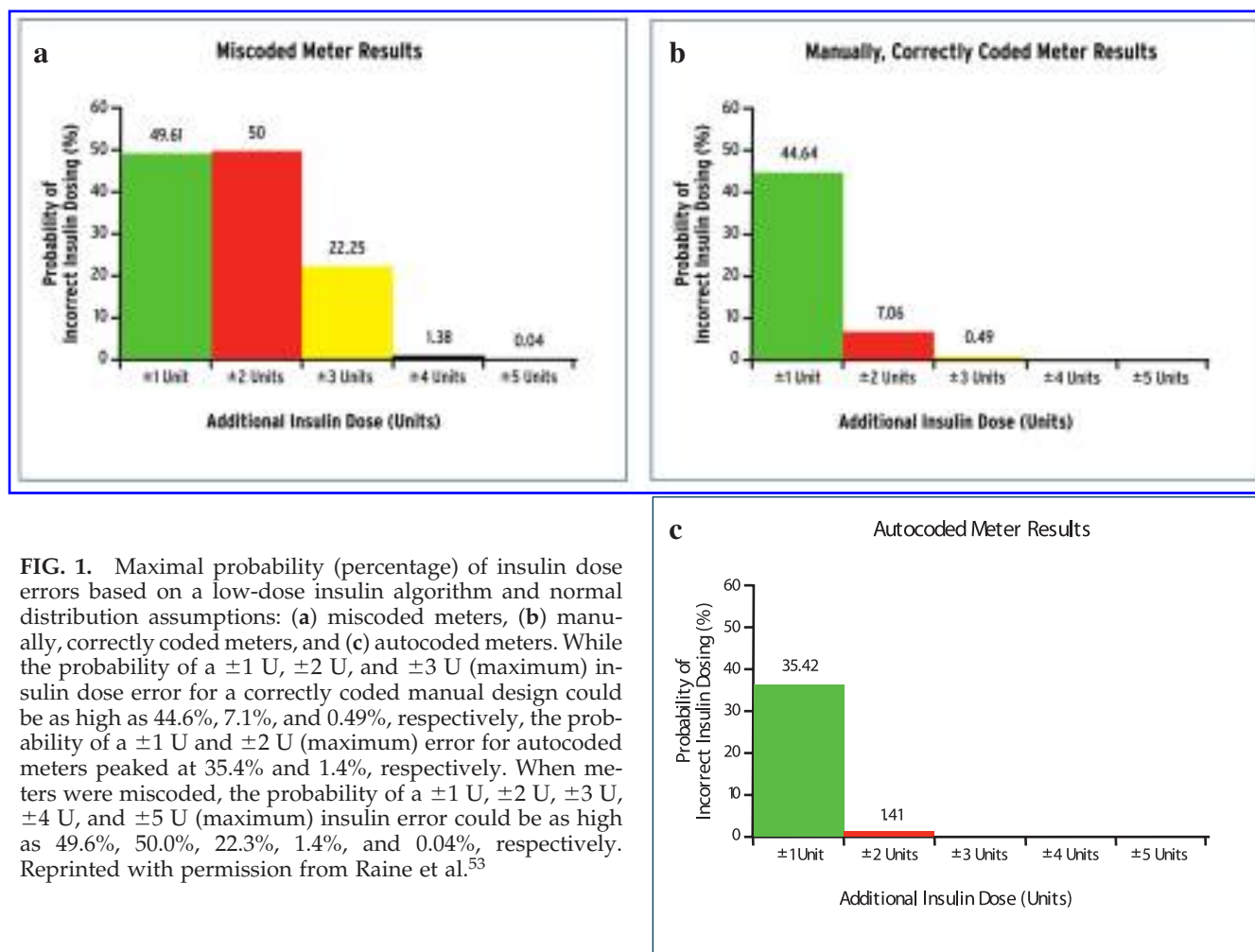
must be carefully checked to ensure that data are free of protocol-bias or patient-specific interferences.<sup>34,35</sup> User-dependent factors, such as the accuracy of calibration coding, can also affect data quality and, by extension, treatment outcomes.<sup>35–37</sup> Given the centrality of SMBG to guiding daily diabetes regimens, particularly the timing and dosing of insulin in patients with type 1 diabetes and insulin-requiring type 2 diabetes, the panel called for greater emphasis on quality-control protocols to achieve clinically reliable levels of accuracy in the course of everyday use.

#### *Standards and practices affecting meter accuracy*

Standardizing analytical goals for the performance of blood glucose meters remains a work in progress. In 1987, the ADA recommended a goal for total error (user plus analytical) of <10%, which was subsequently revised to <5%.<sup>38</sup> To date, there are no reports of glucose meters that meet this goal. The goal established by the International Organization for Standardization ([www.iso.org](http://www.iso.org)) is less stringent: 95% of the measurements should be within  $\pm 20\%$  for glucose concentrations  $\geq 75$  mg/dL and within  $\pm 15$  mg/dL for levels <75 mg/dL.<sup>39</sup> The U.S. Food and Drug Administration requires all meters to have an error rate of <20% of the reference value when glucose is >100 mg/dL and within 20 mg/dL when glucose is <100 mg/dL.<sup>40</sup>

Efforts to relate quality measures more directly to medical practice have been undertaken, most notably by Clarke et al.,<sup>41</sup> who developed an accuracy grid for evaluating clinical significance. Additionally, Boyd and Bruns<sup>37</sup> used simulation modeling to determine the effects of analytical imprecision and analytical bias (a systematic error causing a consistent high or low deviation) on insulin dose. Although today’s meters are capable of producing results that meet established standards of accuracy under controlled conditions, clinical studies demonstrating consistently comparable performance in the hands of patients are lacking. Moreover, observed error limits exceeding  $\pm 20\%$  for patients in real-world settings suggest a widening gap between actual performance and the evolving needs of contemporary clinical care (e.g., accurate dosing of insulin analogues and/or calibration of adjunctive continuous glucose monitoring [CGM] devices).<sup>35,42–45</sup> Manufacturers can help close this gap by reexamining labeling information, and clinicians by reinforcing the following technical and clinical considerations affecting meter performance.

**Strip factors.** Blood glucose meter test strips are complex biochemical devices subject to numerous pre-analytic (e.g., enzymes denature, mediators oxidize), physical, and patient variables.<sup>46</sup> No single strip formulation has been identified as the calibration standard, and many clinicians and patients remain unaware that test strips exposed to humidity, excessive temperature, or high altitude may give falsely elevated results.<sup>47,48</sup> Individually wrapped test strips containing a desiccant may reduce these problems,<sup>49</sup> yet verifying quality control remains largely the responsibility of patients, who must be instructed to use commercial control solutions with each new pack of test strips opened. Given numerous reports that patients often neglect this procedure because of the time, inconvenience, and cost involved, manufacturers should examine less



**FIG. 1.** Maximal probability (percentage) of insulin dose errors based on a low-dose insulin algorithm and normal distribution assumptions: (a) miscoded meters, (b) manually, correctly coded meters, and (c) autocoded meters. While the probability of a  $\pm 1$  U,  $\pm 2$  U, and  $\pm 3$  U (maximum) insulin dose error for a correctly coded manual design could be as high as 44.6%, 7.1%, and 0.49%, respectively, the probability of a  $\pm 1$  U and  $\pm 2$  U (maximum) error for autocoded meters peaked at 35.4% and 1.4%, respectively. When meters were miscoded, the probability of a  $\pm 1$  U,  $\pm 2$  U,  $\pm 3$  U,  $\pm 4$  U, and  $\pm 5$  U (maximum) insulin error could be as high as 49.6%, 50.0%, 22.3%, 1.4%, and 0.04%, respectively. Reprinted with permission from Raine et al.<sup>53</sup>

onerous safeguards to reduce the opportunity for error. Additionally, clinicians should always verify that a prescription for a control solution is included with each prescription for strips and actively impress upon patients the importance of confirming meter and strip accuracy with fresh supplies.<sup>36,42,45,47,49–51</sup>

**Calibration factors (coding).** A key step in ensuring compatibility between blood glucose meters and test strips is properly calibrating the meter based on the calibration code for a given set of strips. A study by Raine<sup>52</sup> examining coding errors showed that 32 of 201 patients (16%) had mismatched glucose meter and glucose strip codes; moreover, three out of 26 patients with type 1 diabetes (12%) and 10 out of 82 (12%) insulin-treated patients with type 2 diabetes had nonmatching codes.

Additionally, Raine et al.,<sup>53</sup> using simulation models for quantifying the risk of insulin dosing errors resulting from miscoding, demonstrated a significantly lower probability of inappropriate insulin dosing with properly used manually coded meters or autocoded meters versus miscoded meters; however, the autocoded meters performed better than manually coded meters, even when the latter were correctly coded (Fig. 1). Moreover, when meters were miscoded, the probability of an insulin dosing error of  $\pm 2$  U could be as

high as 50%. Such potential magnitude of error highlights the importance of instructing patients—preferably in a formal program conducted by a diabetes nurse educator or pharmacist—to either correctly code their meters or use autocoded meters for more reliable implementation of SMBG-guided therapy.

**Procedural factors.** The accuracy of SMBG results depends largely on user technique. Basics such as meter cleanliness and careless hand washing remain common sources of error.<sup>54</sup> Factors such as the size and placement of the blood sample, timing of the test, and removal of blood from the strip can also distort results. To minimize these and other operator errors, newly trained patients should have their testing technique evaluated at 1 and 6 months. Subsequent annual evaluations are also necessary to reinforce skills that may lapse over time or to introduce new skills in response to changing needs.<sup>8,36</sup>

**Hematocrit.** Hematocrit may affect results of glucose testing because erythrocytes in the whole-blood sample can alter the ratio of blood glucose to plasma glucose, as well as the flow of plasma and delivery of oxygen into the test strip.<sup>55</sup> Higher-than-normal hematocrit concentrations will underestimate blood glucose levels, while lower-than-normal

mal concentrations will overestimate levels. Other factors, such as microclot formations in the samples or on the test strips, hemolysis, protein deposition, and fibrin aggregation, may add to hematocrit error. It is particularly important to consider hematocrit when treating patients with diabetes who smoke, live at high altitude, or present with dehydration, sickle-cell disease, anemia, polycythemia vera, or end-stage renal failure. Clinicians should also be aware of normal hematocrit ranges for different patient populations.

Because individual meter systems respond differently to glucose changes at fixed hematocrit levels, checking the hematocrit range specified by the manufacturer is a key safety measure, especially in the hospital setting. Particular care is required with respect to meter selection and interpretation of results when hematocrit and glucose changes occur rapidly and concurrently (e.g., in situations of acute blood loss or transfusion). Tools that simultaneously measure the patient's hematocrit with algorithmic adjustment of glucose results, warning of potential errors, or results lockout could help reduce hematocrit effects in such circumstances.

**Other factors.** Analyses of meters, strips, and control solutions subjected to temperature variations indicate that temperature and, to a lesser extent, humidity often correlate significantly with glucose value.<sup>35,48</sup> Altitude, when combined with the effects of temperature and humidity, may also affect meter results. For example, in a field study of mountain climbers with diabetes using a glucose oxidase meter by Fink et al.,<sup>56</sup> elevation underestimated blood glucose by approximately 1–2% (unadjusted) for each 1,000 ft gained. Alternatively, glucose dehydrogenase-based meters tested in a hypobaric chamber had a tendency to overestimate glucose readings, but generally performed better when compared with a glucose oxidase-based meter.<sup>47</sup> High altitudes combined with lower temperatures produced a similar magnitude of discrepancy in both meter types. Such findings reinforce the need to alert patients with diabetes who engage in high-altitude activities of the potential for false low or high readings, particularly at lower temperatures, irrespective of the meter used.

Finally, a wide variety of medications interfere with the accuracy of blood glucose readings. Acetaminophen and ascorbic acid are commonly used drugs that affect glucose oxidase-based meters (<25% error), while maltose and icodextrin, present in peritoneal dialysis solution, affect glucose dehydrogenase-based meters employing the dehydrogenase pyrroloquinolinequinone test method (25–100% and >100% error, respectively).<sup>46,57</sup> Given the potential for polypharmacy over the course of diabetes treatment, clinicians must review patients' drug regimens and meter type regularly and adjust data interpretation accordingly, keeping in mind that package inserts may not provide adequate warning information for drugs used in critical care settings or at relatively high doses without medical supervision.

## 2. How Should SMBG Data Be Used to Inform Care in Individual Patients?

In contrast to periodic A1C testing, which indicates the mean value of blood glucose over the preceding 2–3 months,

SMBG provides immediate feedback to patients regarding glucose levels throughout the day. Both tests are essential for assessing glycemic control, with A1C considered the preferred standard for predicting long-term micro- and macrovascular complications.<sup>58</sup>

Most published trials of SMBG focus on A1C as a surrogate marker for overall glycemic control and complication risk—often without detailing the specific features (e.g., SMBG frequency, education, and follow-up) of the intervention being studied or the relationship between the intervention and relevant clinical outcomes.<sup>13–15,21</sup> As a consequence, much of the evidence to date, especially regarding type 2 diabetes, is neither generalizable nor conclusive.<sup>11</sup>

Even carefully designed and adequately powered trials may overlook the subtle physiological and behavioral interplays governing SMBG-guided disease management. A recent example is the DiGEM study randomizing 453 non-insulin-requiring patients (mean baseline A1C, 7.5%) to one of three arms: (1) “standardized usual care” where therapy was based only on A1C results received every 3 months prior to the office visit; (2) a “less intensive” intervention directing patients to monitor blood glucose three times per day, twice weekly, and to consult their doctor if readings were consistently high; and (3) a “more intensive” protocol that required patients to monitor glucose levels at the same frequency but also gave them the skills and encouragement to interpret and act on the data themselves.<sup>59</sup> Although the more intensive arm showed a 0.17% reduction in A1C after 1 year, the between-group differences did not reach statistical significance, prompting the authors to conclude that SMBG, with or without patient education, had no benefit in non-insulin-treated patients with reasonably well-controlled glycemia.

Yet the panel cited several significant caveats to this conclusion, typifying those noted in recent meta-analyses.<sup>14,15,21,60</sup> First, the relatively low mean baseline A1C may have inhibited motivation to improve self-care in response to SMBG. Second, the ability to preemptively adjust therapy—a main benefit of effective SMBG utilization—was virtually precluded given that patients were instructed to report only persistently high ( $\geq 269$  mg/dL) readings to their physicians. Third, subjects were given the choice of monitoring either before or after meals, with no provision for controlling postprandial hyperglycemia, even though postprandial glucose has been shown to contribute disproportionately to overall glycemia when A1C levels are <8.4%.<sup>61</sup> Finally, and most significantly, this study provided scant opportunity for developing a feedback system capable of cuing proactive, patient-centered self-management. As such, the proposed alternative conclusion, stated by the panel, is that SMBG, with or without instruction, is no substitute for effective, aggressive management of glycemia—*it simply makes it possible*.

This view of glucose monitoring as a primary tool of optimal diabetes control, potentially enhanced or inhibited by the manner in which it is carried out, constitutes the basis of the following guidelines regarding how, when, and for whom SMBG can be maximized—ideally, within an integrated system of physiological and behavioral management (see below, How Do Behavioral Factors and Health Policy Affect Implementation of SMBG?).

### Goals and frequency of SMBG

SMBG can lead to improved glycemia by revealing the immediate effect of patient behavior on blood glucose levels. When the data are viewed systematically, preferably in a computerized format, the numerical, narrative, and/or graphic profiles can be used to inform therapeutic decision-making and raise awareness of physiologic responses to eating, medication administration, and physical activity. This, in turn, can minimize the risk for both hyper- and hypoglycemic excursions, while engendering more educated, empowered, and actively involved patients.<sup>11</sup>

Although SMBG is indicated in the daily management of type 1 diabetes and insulin-requiring type 2 diabetes, worldwide healthcare guidelines do not require SMBG for non-insulin-using patients. This is attributable to the high cost of frequent SMBG, the research tradition of evaluating SMBG use/frequency in terms of A1C levels regardless of whether patients have received consistent guidance as to when and how to monitor or interpret and act on results, and the inherent limitations of cross-sectional research in showing direct causality between testing frequency and A1C.<sup>13,62,63</sup>

It is also worth noting that "A1C-centric" research may fail to capture the significance of acute fluctuations of blood glucose resulting in cell-damaging oxidative stress and superoxide formation.<sup>64</sup> Such glycemic variability, commonly manifesting as postprandial "spikes," has been implicated in the development of complications of diabetes, independent of A1C.<sup>65–67</sup> In a study using CGM to compare the respective contributions of acute glucose fluctuations and chronic hyperglycemia to oxidative stress (measured by urinary excretion of 8-iso-prostaglandin F<sub>2α</sub>), Monnier et al.<sup>68</sup> found that the acute fluctuations had a more specific triggering effect on oxidative stress in non-insulin-using subjects with poorly controlled type 2 diabetes versus normoglycemic controls. Thus, it has been suggested that all patients with diabetes perform SMBG to monitor glycemic variability.<sup>64,65,69,70</sup> Further, because A1C measures the amount of glucose bound to red blood cells over the 120-day lifespan of erythrocytes, clinicians must remain alert to processes or conditions affecting erythrocyte turnover—e.g., liver disease, kidney disease, hemolytic anemia, blood loss, hemoglobinopathies, aplastic anemia, and iron-deficiency anemia—and confirm A1C results with attendant SMBG data.<sup>12</sup>

Besides revealing specific patterns of hyperglycemia, SMBG is vital for detecting or preventing asymptomatic hypoglycemia and for enhancing safety in cases of suspected or confirmed hypoglycemia unawareness. Moreover, a recent

analysis of SMBG data from Diabetes Control and Complications Trial (DCCT) subjects indicated that mean blood glucose and glucose variability (measured by standard deviation [SD]) independently predict severe hypoglycemia.<sup>71</sup> The risk for an initial hypoglycemic episode increased 1.05-fold for each 18 mg/dL decrease in mean blood glucose and increased 1.07-fold for each 18 mg/dL increase in SD. Thus, the SD calculation, provided by most glucose meter software programs, affords ready identification of situations or time periods in which there is considerable risk for clinically significant hypo- or hyperglycemia. A simple target is  $SD \times 2 < \text{mean glucose}$  (see below, Pattern management and downloading data).<sup>72</sup>

**Glycemic goals.** Worldwide glycemic targets for non-pregnant adults with type 1 or type 2 diabetes are shown in Table 1.<sup>6,7,73,74</sup> While the benefit of lowering overall glycemia is continuous for most patients with diabetes, the recent Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, which found 20% higher mortality in patients with type 2 diabetes and cardiovascular disease receiving therapy to reduce A1C to <6.5%, has raised the as yet unresolved question of whether glycemic goals should be individualized in this subgroup.<sup>75</sup> Also, as glycemic targets are tightened, the risk for increased frequency and severity of hypoglycemic events rises, especially for individuals with type 1 diabetes, thereby necessitating more vigilant SMBG.

Before beginning SMBG, patients must have a thorough understanding of their individualized glucose targets and the relationship between monitoring and glycemic control. Those for whom SMBG may not translate directly to an acute intervention involving insulin administration (i.e., individuals treated with diet and/or non-insulin therapies) might benefit from a written schedule of glycemic goals corresponding to stepwise interventions that are reviewed and adjusted at regular intervals. For example, a patient might be instructed to start a sulfonylurea at the lowest dose and, depending on his or her blood glucose average over the following 2 weeks, self-titrate upward until the glycemic goal is met or the maximal dose reached. Such an approach can enhance prompt and appropriate escalation of therapy while fostering the cycle of monitoring, assessment, reassessment, problem solving, and decision-making essential to sustained and effective self-care.<sup>8</sup>

**Frequency recommendations.** Frequency and timing of SMBG should be governed by the particular circumstances, needs, and goals of the patient. Considerations include type

TABLE 1. GLYCEMIC GOALS FOR NONPREGNANT ADULTS WITH DIABETES RECOMMENDED BY VARIOUS PROFESSIONAL ORGANIZATIONS

Organization	A1C (%)	FPG (mg/dL)	PPG (mg/dL)
ADA <sup>6</sup>	<7	70–130 (3.9–7.2 mmol/L)	<180 (<10 mmol/L)
AAACE <sup>7</sup>	≤6.5	<110 (6 mmol/L)	<140 (<7.8 mmol/L)
IDF <sup>73</sup>	≤6.5	<110 (6 mmol/L)	<145 (<8 mmol/L)
ESC/EASD <sup>74</sup>			
Type 1 diabetes	≤6.5	<108 (6 mmol/L)	135–160 (7.5–9 mmol/L)
Type 2 diabetes	≤6.5	<108 (6 mmol/L)	<135 (<7.5 mmol/L)

AAACE, American Association of Clinical Endocrinologists; ECS/EASD, European Society of Cardiology/European Association for the Study of Diabetes; FPG, fasting plasma glucose; IDF, International Diabetes Federation; PPG, postprandial glucose.

of therapy, degree of glycemic control, risk for hypoglycemia, and the need for short-term adjustment of treatment.<sup>11</sup> The link between frequent SMBG and improved glycemic control is most conclusive for insulin-using patients who can apply monitoring data directly to the implementation of a treatment plan.<sup>76,77</sup> The correlation is less clear for non-insulin-using patients, although a recent meta-analysis of randomized trials by Poolsup et al.,<sup>60</sup> pooling data from seven studies of SMBG in non-insulin-requiring type 2 diabetes ( $n = 1,625$ ), revealed that self-monitoring versus no monitoring significantly reduced A1C (pooled mean difference  $-0.24\%$ ; 95% confidence interval,  $-0.37\%$  to  $-0.12\%$ ;  $P = 0.0002$ ). Additionally, a comparable review of eight studies by Sarol et al.<sup>78</sup> ( $n = 1,307$ ) demonstrated a more than twofold reduction in mean A1C among non-insulin-using patients testing approximately five to seven times weekly versus non-testers. Patient education was a component of each of these studies, and, in contrast to the DiGEM study described previously,<sup>59</sup> one study by Jaber et al.<sup>79</sup> attributed glycemic improvement more to the optimized therapy regimen and attendant understanding of diabetes enabled by SMBG than to SMBG per se.

In a notably large managed care study ( $n = 24,312$ ), Karter et al.<sup>80</sup> observed an association between frequent monitoring of blood glucose and clinically and statistically better glycemic control regardless of diabetes type or therapy. Interestingly, subsequent longitudinal analyses of this population revealed marked A1C improvement among new users of SMBG, whether treated with or without medication, compared with ongoing users who changed their frequency of SMBG.<sup>81</sup> Among ongoing users, those treated pharmacologically showed a less marked, but significant, association between changes in SMBG frequency and A1C, whereas those treated nonpharmacologically showed no significant correlation. Taken together, these findings reinforce the potentially empowering effect of biological feedback during the transition to diabetes self-care, when viewable data render an “imperceptible illness visible” and, in so doing, heighten health awareness independent of the need for therapy adjustment.<sup>82</sup>

Finally, a study by Martin et al.<sup>83</sup> focusing on long-term clinical end points revealed that regular SMBG correlated with decreased morbidity and all-cause mortality among both insulin-using and non-insulin-using patients. Although the reasons behind this association require further study, the authors noted that patients in the SMBG cohort visited their physicians more frequently, possibly signifying more active participation in their own disease management.

Given the difficulty of deducing conclusive, evidence-based frequency recommendations from studies such as those mentioned above, the guidelines issued by the International Diabetes Center (IDC) Global Consensus Conference on Glucose Monitoring Panel in 2005 remain the most practical tool for clinicians and patients.<sup>11,54</sup> They are summarized as follows:

- For all patients on an intensive multiple daily injection (MDI) insulin regimen, including basal, mealtime, and correction-dose insulin, or using an insulin pump: *monitor at least three or four times daily*
- For patients who are *above target* and managed pharma-

cologically, but who are not on an MDI regimen or insulin pump: *monitor at least two times daily*

- For patients *at target* and managed pharmacologically, but who are not on an MDI regimen or using a pump: *monitor at least one time per day, including at least one weekly profile ranging from one or more pre-/postprandial readings to a full 7-point profile*
- For all patients managed nonpharmacologically: *obtain at least one weekly profile ranging from one or more pre-/postprandial readings to a full 7-point analysis*

In general, patients with type 1 diabetes and those with a history of severe hypoglycemia, no matter what their A1C or insulin regimen, should monitor *at least* three times per day—preferably more if on an intensive basal-bolus insulin regimen aimed at achieving near-normal glycemia—while those with type 2 diabetes should base frequency on the extent of diabetes progression and insulin deficiency. Although testing  $>10$  times per day has been shown to provide no added benefit with respect to A1C lowering,<sup>84</sup> testing above recommended frequency levels is advised in special situations, such as the presence of hypo- or hyperglycemic symptoms, hypoglycemic unawareness, intercurrent illness, gastroparesis, and pregnancy, as well as circumstances involving self-adjustment of insulin dosage, evaluation of the effects of other medication therapies (e.g., steroids), initiation or change of therapy, rigorous physical activity, and preconception planning.<sup>8,11</sup> Conversely, testing less often than recommended is acceptable for certain patient groups, such as the frail elderly whose glucose is adequately controlled through lifestyle measures. Although empirical evidence suggests that the use of CGM may reduce the number of fingerstick tests necessary per day in some patients, further study is needed to confirm this observation.

**Preprandial versus postprandial measurements.** Given that glycemic status is the sum of the fasting, postprandial, and postabsorptive states, at least one test per day from each of these periods would be ideal. In reality, though, over 65% of patients with pharmacologically treated type 2 diabetes practice SMBG less than once daily, due in part to long-standing barriers of cost, inadequate patient education, and/or poor patient motivation.<sup>63</sup> While these obstacles call for long-term solutions, a feasible interim step toward more regular testing is to target either fasting or postprandial glucose, depending on A1C level. Monnier et al.<sup>61</sup> enhanced the practicality of this approach by showing that, in patients with non-insulin-requiring type 2 diabetes, postprandial glucose contributes  $\sim 70\%$  to overall glycemia when A1C levels are  $<7.3\%$ , whereas fasting glucose contributes  $\sim 70\%$  when levels are  $>10.2\%$ . Given that the contribution of fasting blood glucose decreases as A1C levels decrease, the authors were able to specify an A1C of  $\leq 8.4\%$  as the point where treatment might be better focused on postprandial glucose control.

In another study of non-insulin-using patients, Schwedes et al.<sup>85</sup> showed improvement in overall glycemic control and well-being when blood glucose was measured before and 1 h after main meals 2 days per week. The timing of peak postprandial excursions is variable, however, depending on the composition and quantity of the meal, as well as factors such as carbohydrate absorption and endogenous insulin

production. Although the ADA recommends measuring postprandial glucose 1–2 h after the start of a meal, further study is needed to refine postprandial analyses according to eating patterns and the types of food consumed.<sup>6</sup>

The prevalence of postprandial hyperglycemia may be higher than previously assumed: In a nationally representative sample of non-insulin using adults with diabetes, Erlinger and Brancati<sup>86</sup> found that postprandial hyperglycemia (>200 mg/dL) occurred in nearly 40% of cases where A1C was <7.0% and in approximately 10% where fasting plasma glucose was <126 mg/dL. Until the implications and extent of postprandial hyperglycemia are more fully understood, approaches to postprandial testing should be guided by individual need.<sup>54</sup> At minimum, postprandial monitoring can be useful for patients who (1) have suspected postprandial hyperglycemia manifesting as within-range pre-meal glucose values but a high A1C, (2) receive medical treatment targeted at lowering postprandial glucose values, or (3) report postprandial hypoglycemia, usually in response to rapid-acting insulin analogues or exercise.<sup>87</sup> The panel also observed that postprandial SMBG can be a powerful motivating tool for dietary interventions to manage blood glucose.

Finally, postprandial glucose monitoring is unequivocally recommended for pregnant women with preexisting or gestational diabetes.<sup>88</sup> In a study of insulin-using pregnant women conducted by de Veciana et al.,<sup>89</sup> postprandial monitoring and glucose control decreased the risk of neonatal hypoglycemia, macrosomia, and cesarean delivery. Another study by Manderson et al.,<sup>90</sup> which randomized two groups of pregnant women with type 1 diabetes to either preprandial or postprandial glucose monitoring, found that postprandial monitoring significantly reduced the incidence of pre-eclampsia and neonatal triceps skinfold thickness. ADA preprandial, 1-h, and 2-h postprandial plasma glucose targets for pregnant women are  $\leq 105$ ,  $\leq 155$ , and  $\leq 130$  mg/dL, respectively.<sup>6</sup> Alternatively, Jovanovic-Peterson et al.<sup>91</sup> have proposed the following acceptable levels: preprandial blood glucose, <90 mg/dL; 1-h postprandial blood glucose, <120/mg/dL.

#### *Pattern management and downloading data*

Pattern management is the systematic interpretation of SMBG data over time to determine whether changes are needed to optimize glucose control. Specifically, a pattern of high readings at the same testing time each day, lasting at least 3 days in a row, or a pattern of low readings, lasting 2 days in a row, warrants further examination to determine the source of the problem and a defensive strategy to improve control.<sup>92</sup> For patients using a written logbook, the mechanics of this process entail entering daily readings in a single row so that the readings at the same time each day line up in a column, together with notes on medications, insulin doses, exercise, hypoglycemic episodes, and food consumption. Although such diaries are considered an essential component of diabetes management, the high incidence of recording errors and/or information gaps, combined with the sheer complexity and volume of information, makes computerized data management ideal for assessing the relationships among blood glucose, medication, meals, and activity.<sup>72</sup>

Meter data can be downloaded in the office setting, in pa-

tients' homes, or in some cases on the Internet. Many clinicians prefer the latter two options because the time and responsibility of downloading are borne by the patient, allowing more time for data interpretation during appointments. Between-visit reviews, if deemed appropriate by the clinician, are also easier when data can be printed out and faxed or accessed online. Importantly, the time and date of the glucose meter must be set correctly to ensure smooth and accurate downloads. This fundamental step is often overlooked even in clinics where downloading is routinely implemented.<sup>93</sup>

Most meter software programs employ a number of versatile formats (e.g., pie charts, bar graphs, and electronic logbooks) to show the average frequency of meter readings and their mean value over a certain number of days and during set time periods within each day, as well as the percentage of readings above, below, and within established target ranges. SD values are also provided so patients and clinicians can readily determine the consistency of readings within these periods (see above, Goals and frequency of SMBG). In general, a mean blood glucose less than twice the SD suggests severe insulin deficiency and signals the presence of problems such as poor matching of caloric intake and insulin, noncompliance with insulin doses, missed meals, gastroparesis, or erratic insulin absorption.<sup>72</sup>

According to one anecdotal report (I.B.H., unpublished data), quantitative relationships among the SD, mean, and median values serve as fairly reliable cues for glucose variability: that is, when all three of these values (SD, mean, and median) are high, overall variability is usually high; when the SD is low but the mean and/or median are high, blood glucose may be generally stable with the exception of one or two outlying events, such as a pump occlusion or missed insulin dose; and, finally, when SD is low and both the mean and median values are low, blood glucose is generally stable. Taking time to review SD, mean glucose, and median values with patients during the office visit, along with the glucose diary, can help track patterns in glycemic control, pinpoint components of the self-management regimen in need of change, and encourage regular assessments between appointments.

Although approaches to applying computerized data will depend on the information made available by the particular software, the following precepts should be kept in mind for optimal utility of data downloading programs:

- The data must be reviewed.
- The data formats must allow quick and simple interpretation by the clinicians and patients who use them.
- Interpretation must be relevant to the health objectives of both the patient and the clinician.
- The time and date must be properly entered into the meter to ensure accurate downloads.

An example of a data download appears in Figure 2. The narrative, tabular, and graphic formats provide several perspectives on the glucose patterns of this patient, a triathlete with type 1 diabetes who eats high quantities of carbohydrates to ward off hypoglycemia associated with strenuous activity. The ensuing swings in blood glucose are first signaled by the fact that the SD (80 mg/dL) does not meet the goal of less than half the mean blood glucose (160 mg/dL) (Fig. 2a). Figure 2b provides a visual representation of the

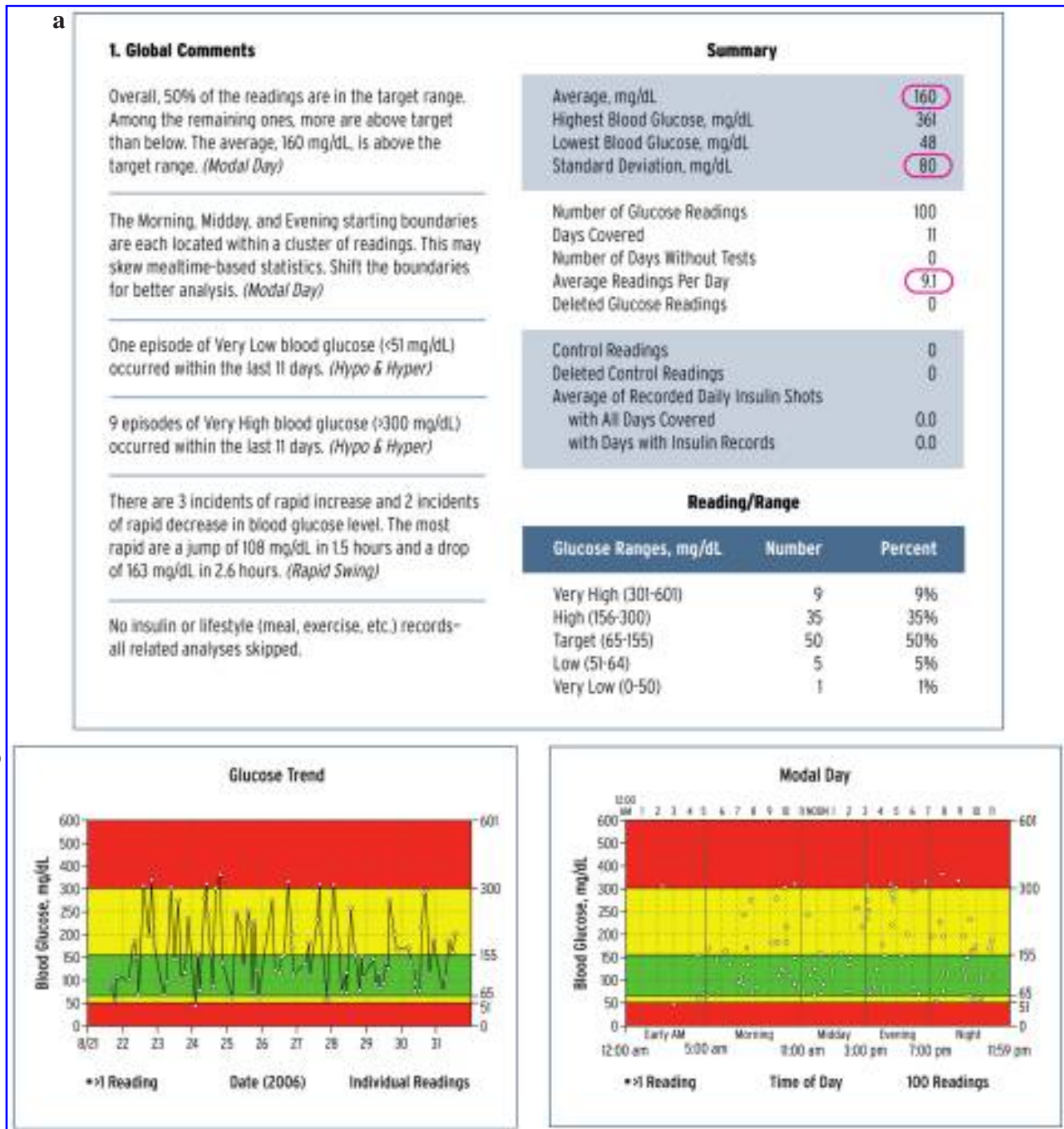


FIG. 2a-c. (see legend on page 429, under Fig. 2d)

variability over 10 days, whereas Figure 2c graphically depicts the clustering of within-target, low, and high readings at different times of day over the 10-day span, with the greatest density of high readings during the evening hours. The electronic logbook shown in Figure 2d allows closer inspection of specific values for the purpose of problem solving. In this case, the clinician prescribed adjunctive CGM so that the patient could obtain more immediate feedback on upward or downward glucose trends and thus break the habit of “carb loading” and reactive insulin administration.

Important unmet needs with respect to software development, as observed by the panel, include (1) universal standardization of data formats and access venues (e.g., home-based, office-based, and/or online) for seamless and reciprocal use of programs by patients and clinicians, (2) automatic integration of accurate time and date within and between meters and management software, and (3) creation of axiomatic algorithms for “automatic” pattern management, including the appropriateness of insulin dose adjustments based on glucose readings at different times of day.

d

Date	Early AM 12:00 am-4:59 am	Morning 5:00 am- 10:59 am	Midday 11:00 am-2:59 pm	Evening 3:00 pm-6:59 pm	Night 7:00 pm-11:59 pm
08/21/06 Mon				3:15 pm 85 4:09 pm 86 6:01 pm 87	7:28 pm 55 9:16 pm 104 10:03 pm 108
08/22/06 Tue		5:01 am 99 7:35 am 171 9:31 am 184 10:36 am 149	11:49 am 67	3:08 pm 311	7:12 pm 196 8:50 pm 336 10:51 pm 169
08/23/06 Wed		5:02 am 67 7:07 am 96 9:59 am 305	12:34 pm 145	3:09 pm 273 5:14 pm 103	7:52 pm 117 9:36 pm 234
08/24/06 Thu	3:01 am 48 4:33 am 156	5:54 am 76 9:27 am 278 10:36 am 320	11:25 am 242 1:29 pm 157	3:16 pm 74 3:36 pm 86 4:56 pm 303	7:53 pm 361 9:31 pm 137
08/25/06 Fri	4:35 am 61	7:26 am 244 10:02 am 215	11:50 am 128	3:14 pm 251 4:41 pm 220 6:21 pm 72	7:42 pm 226 9:06 pm 121 10:18 pm 63
08/26/06 Sat		7:51 am 275 9:59 am 122	12:53 pm 117 2:05 pm 150	4:15 pm 155 6:47 pm 327	9:10 pm 199 9:53 pm 173 10:37 pm 113
08/27/06 Sun		6:34 am 135 9:11 am 182 10:15 am 109		3:08 pm 223 4:37 pm 319 5:39 pm 200	9:29 pm 66 9:48 pm 55 10:11 pm 63
08/28/06 Mon	2:18 am 316	6:17 am 165 7:55 am 74	11:33 am 114 12:11 pm 70 2:29 pm 257	4:05 pm 177 5:17 pm 153	7:52 pm 78 9:24 pm 152 10:16 pm 105

**FIG. 2.** Example of a data download from the meter of a triathlete with type 1 diabetes. The narrative, graphic, and tabular formats reveal different aspects of the glucose patterns of this patient, a triathlete with type 1 diabetes on a continuous subcutaneous insulin infusion who eats high quantities of carbohydrates to ward off hypoglycemia related to strenuous activity: (a) glycemic instability is initially signaled by the fact that the SD (80 mg/dL) does not meet the goal of less than half the mean blood glucose (160 mg/dL); (b) the variability over 10 days is apparent from the glucose trend graph; (c) the modal day graphically depicts the clustering of within-target, low, and high readings at different times of day over the 10-day span, with the greatest density of high readings during the evening hours; and (d) the electronic logbook allows closer inspection of specific values for the purpose of problem solving. In this case, the clinician prescribed adjunctive CGM so that the patient could obtain more immediate feedback on upward or downward glucose trends and thus break the habit of “carb loading” and reactive insulin administration. Courtesy of Bruce W. Bode.

### 3. How Do Behavioral Factors and Health Policy Affect Implementation of SMBG?

While breakthroughs in genetics, bioengineering, and biotechnology have advanced diabetes-related pharmacotherapy and technology in recent decades, successful strategies for SMBG depend largely on human behavior. When optimally utilized, monitoring poses complex behavioral demands, requiring patients to balance the exigencies

of daily life against the disciplined protocols of diabetes self-management. At minimum, patients must learn how to cue themselves to test at appropriate times and act prudently when a reading is high or low. They must also develop the skills for communicating effectively with busy clinicians, who are often under-reimbursed for patient education and counsel.<sup>94</sup>

People with limited resources, mental illness, or difficult home lives may be especially daunted by the responsibilities

of SMBG.<sup>95</sup> In one large survey conducted by Kaiser Permanente, 60% of patients with type 1 diabetes and 77% of pharmacologically treated patients with type 2 diabetes reported checking blood glucose less frequently than ADA recommendations (three times daily for patients with type 1 diabetes; twice daily for patients with type 2 diabetes).<sup>63</sup> Factors affecting adherence included language barriers, socioeconomic status, longer time since diagnosis, less intensive therapy, ethnicity, male sex, age, education level, smoking, and excessive alcohol consumption. Many psychological obstacles to SMBG adherence have been cited as well, including depression, low self-esteem, low self-efficacy, low overall competence, high anxiety, and perceived painfulness of the sampling procedure.<sup>96–100</sup>

In the area of healthcare delivery, the Diabetes Attitudes, Wishes, and Needs (DAWN) study, a qualitative, cross-sectional survey of 5,000 patients with type 1 or type 2 diabetes from 13 countries, showed that suboptimal patient–clinician relationships and limited access to coordinated care correlated with poor self-management and control.<sup>101</sup> Conversely, high-quality patient–clinician collaboration was associated with better regimen adherence in all domains, whereas access was not, corroborating the view that depth and continuity of care, including diabetes education and psychosocial assessment, may be more relevant to successful outcomes than frequent superficial contact.<sup>30,94</sup> Routine inclusion of behavioral science principles in research aimed at understanding SMBG effectiveness would further clarify these issues.<sup>18,102</sup>

In the absence of such studies, and given that <50% of all patients with diabetes participate in education/behavioral programs, clinicians should employ simple behavioral interventions during routine office visits, imparting information about SMBG, the self-care skills needed to act on test results, and the motivation needed to maintain SMBG as part of an optimal pattern of care.<sup>18,103</sup> Nurses and diabetes educators, accustomed to patient-centered care, are particularly well suited to take up the mantle of behavior change by focusing on psychological determinants of adherence (e.g., self-efficacy, problem solving, and coping skills) to improve patient outcomes and overall health.<sup>104,105</sup>

Finally, it has been observed that successful utilization of SMBG is a joint function of patient factors and biomedical technology; if patient knowledge, motivation, and self-care skills fall below a threshold level, biomedical technology will be rendered futile. Thus, recognition of the integral role of behavioral science by professional organizations, payer groups, policymakers, and investigators—coupled with research committed to increasing the practicality, cost-effectiveness, and availability of behavioral interventions—could allow more systematic application of the existing evidence base during routine clinical care.

### *Rethinking adherence*

Adherence has been described as the “active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result.”<sup>106</sup> Non–insulin-using patients are generally less adherent to SMBG, presumably because the value of blood glucose monitoring for reasons other than guiding insulin

therapy has not been definitively established and there has not been emphasis on using SMBG to determine if current therapy is working. Apart from the direct objective of adjusting pharmacological therapy to achieve near-term glucose goals, the concept of “a mutually acceptable course of behavior to produce a therapeutic result” may be subject to widely varying interpretation by both patients and clinicians (see above, Goals and frequency of SMBG).<sup>100</sup>

Indeed, in interviews of newly diagnosed patients with type 2 diabetes conducted by Peel et al.<sup>107</sup> over a 4-year period, an explicit and unified message about whether, when, and how to test was conspicuously absent in every case. Additionally, over time, patients developed the impression that clinicians based their treatment decisions primarily on A1C. Since they had only limited understanding of the connection between A1C and SMBG, the impetus to use blood glucose data as a prompt for behavior change gradually waned. Although controversial, an international movement to translate A1C values into estimated average glucose values that more closely resemble day-to-day SMBG results may help to address this problem.<sup>108,109</sup>

A related study by Vincze et al.<sup>100</sup> measured SMBG adherence as the extent to which patients’ self-reported SMBG frequency met clinician recommendations, as opposed to an absolute measure (e.g., the number of times patients actually monitor during a given period of time). Despite this relatively flexible standard, only one-third of the study population ( $n = 213$ ) could be characterized as adherent (cut point, 80%). Twenty-five participants (11.7%) reported that they received no recommendations from their clinician regarding SMBG, while 22 (10.3%) reported not being able to remember them. Notably, subjects with type 2 diabetes exhibited significantly lower adherence than their type 1 counterparts, and one-fifth of the study population did not test at all—corresponding to the number of patients failing to receive or to remember recommendations from their clinician.

An important implication of these and similar studies is that the assumption of a direct relationship between glyce-mic control and SMBG frequency may be misguided unless the quality of clinician–patient communication is verifiably high enough to assure a reasonable expectation of optimal adherence and appropriate patient response to test results.<sup>15,18,30</sup> Hence, the panel recommended that all clinicians treating patients with diabetes ask themselves the following questions:

- Are frequency targets sufficient to achieve desired levels of glycemic control with the minimum amount of testing and hypoglycemia?
- Are they individually justifiable?
- Have they been communicated to and understood by the patient?
- Do patients understand the actions to be taken in response to their meter data and possess the skills for self-cuing SMBG to sustain glycemic control?

Clinicians should be mindful that population-based guidelines for SMBG adherence, while useful for establishing a practical frame of reference, must be weighed against the tenets of individualized therapy.<sup>110</sup> Further, people with optimal glycemic control may monitor frequently as a conse-

quence of successful outcomes, and those with poor control may monitor just as frequently in “chase” of better outcomes. These two plausible routes to frequent SMBG can further confound efforts to demonstrate causality between “adherence” and A1C levels.

### *Behavioral interventions*

As mentioned previously, fostering the cycle of monitoring, assessment, reassessment, problem solving, and decision-making is essential to sustained and effective diabetes self-management. Clinicians can promote this cycle by helping patients incorporate SMBG into their voluntary self-regulatory behavior. From the outset, patients should be reassured that objective readings are valid indicators of blood glucose status and that out-of-target results are a signal for adjusting treatment, *not* a sign of failure. Encouraging patients to express their personal healthcare priorities in their own words can provide meaningful criteria for selecting among the many interventions available.<sup>18,30,111</sup>

Interventions to change behavior must enable (1) the choice of a goal or objective, preferably by the patient, (2) acquisition of the necessary skills to meet that goal, and (3) opportunities for the behavior to be performed in a manner that informs and rewards the patient so that the desired behavior becomes self-propagating.<sup>30</sup> A meta-analysis of self-management training by Norris et al.<sup>105</sup> showed that interventions with regular reinforcement are more effective than one-time or short-term education.

In general, interactive educational activities produce more favorable effects on glycemic control and other health parameters than didactic approaches.<sup>105</sup> Diabetes educators, nurse practitioners, and registered nurses are often ideally suited to collaborative interventions, including goal setting, psychosocial assessment, and care coordination, because of their focus on patient-centered care.<sup>104</sup> However, all members of the healthcare team can facilitate an SMBG-propelled feedback loop by incorporating the following practices into routine office visits:

- Pay attention to the behavioral requirements of each clinical recommendation and address them directly with patients
- Engage in active listening, using the tools of reflection (paraphrasing what the patient has said in the tone of question) and summarization (restating general ideas for confirmation of understanding)
- Ask open-ended questions that allow patients to articulate goals, ambivalent feelings, and priorities in their own words
- Break down sweeping long-term goals into achievable and measurable short-term objectives
- Confirm that recommendations regarding SMBG are patient-tailored and clear in terms of how, why, and when to test, and that they are consistently reinforced

**Motivational interviewing.** Many of the abovementioned strategies are involved in motivational interviewing, an evidence-based behavioral intervention to promote health behavior performance that works in part by exploring patients' perceptions regarding the importance of a particu-

lar health behavior and their confidence in carrying it out.<sup>112</sup> Through a series of reflective, open-ended questions, clinicians prompt patients to examine the costs and benefits of change from their own perspective, work through ambivalent feelings regarding their readiness for change, and formulate a realistic plan of action (Fig. 3). The clinic visit might ideally end with a *written* “prescription for prevention” that, for some patients, could be as basic as “think about monitoring blood glucose.” The prescription can be intensified upward during subsequent visits to achieve mutually agreed-upon and feasible steps toward optimal SMBG.

**Technological interventions.** The development of memory meters that collect, store, and display SMBG data has created opportunities for more efficient, effective, and collaborative patient-provider interaction.<sup>72,113,114</sup> Viewing data on a computer screen or printout during the office visit is an ideal way for patients and clinicians to work side-by-side in identifying problems with the diabetes management regimen (see above, Pattern management and downloading data). Patients may access the data at home to chart their own progress or, if the situation allows, transmit data to the clinician between office visits for comparison and additional consult. Other technologies specifically designed to promote behavior change include touch-screen computer counseling programs that provide behavioral assessments in the office waiting room, Internet-based self-management support programs, and Internet “chat” and e-mail to enhance patient peer support.<sup>113</sup> The panel called for increasing focus on the development of “smart software” that incorporates voice-recognition and response algorithms, enabling users to engage in dialogue and receive advice specific to their own SMBG data.

### *Follow-through, not breakthrough*

Traditional healthcare systems modeled on symptom-driven treatment of acute illnesses are frequently ill-equipped to support long-term diabetes self-management.<sup>18</sup> In cases where age or disease progression may alter optimal approaches to glucose monitoring, for example, re-education and enhanced psychosocial support may be poorly reimbursed by coverage programs that stress procedures over prevention.<sup>115</sup> Although recognition of the value of preventive services is increasing, persistent issues of health quality and value present formidable quandaries without clear-cut solutions. As such, consistent application of time-tested and low-cost behavioral interventions, as opposed to waiting for the definitive evidence-based practice, may be the most effective near-term approach to sustaining SMBG adherence.<sup>116</sup>

Recently, the American Association of Diabetes Educators endorsed the Chronic Care Model, a framework designed to provide greater support for individuals with chronic illness by enlisting the health system and community in ongoing comprehensive care.<sup>94,117</sup> Although educators' expertise in self-care behaviors places them at the forefront of the Chronic Care movement, many self-management education programs struggle for lack of resources.<sup>104</sup> The panel urged greater leveraging of educators' expertise to answer the following questions:

**Motivational Interviewing:  
Sample Dialogue for Stimulating SMBG Adherence**

**Determining Importance [0 = not at all important; 10 = extremely important]:**

"How important is it for you to test your blood glucose level at the recommended frequency?"

Why do you say "7" and not less important?

What would it take or what would have to happen to make testing your blood glucose at the recommended frequency a "10" in importance?

**Determining Confidence [0 = not at all confident; 10 = extremely confident]:**

"How confident are you that you could test your blood glucose at the recommended frequency?"

Why do you say "6" and not less confident?

What would it take or what would have to happen to raise your level of confidence in being able to test your blood glucose at the recommended frequency to a "10"?

**FIG. 3.** Motivational interviewing for stimulating SMBG adherence. Through a series of reflective, open-ended questions, clinicians cue patients to examine the costs and benefits of behavior change from their own perspective, work through ambivalent feelings regarding their readiness for change, and formulate a realistic plan of action, which may then be written as a "prescription for prevention" at the end of the clinic visit.

- What behavioral interventions can be practically and economically introduced into the current care environment to promote more ambitious application of SMBG?
- What incentive systems work best among clinicians and patients to encourage consistent follow-up and support of glucose monitoring?
- What challenges do compensation and reimbursement issues pose, and are there ways to mobilize community- and peer-based resources to address them?

The panel also advocated that clinicians, payers, and policymakers join forces to create a practice architecture, supported in part by behavioral science principles, that transcends traditional silos of care to focus on factors that influence SMBG effectiveness. Greater advocacy for and professional development of skills such as goal setting, group facilitation, and cognitive-behavioral techniques will be needed to further this effort.

#### 4. Is There a Business Case for SMBG?

Ten percent of healthcare spending in the United States is attributable to diabetes, and, if trends continue, one in three

Americans born after 2000 will likely develop the disease.<sup>25,118</sup> Longitudinal data show an association between glucose levels in middle age and future Medicare charges.<sup>119</sup> This finding, if confirmed, portends a crushing economic burden since >10% of adults age 40–59 years currently have glucose levels warranting a diagnosis of diabetes, and nearly 20% of all adults (58 million) have prediabetes.<sup>24</sup>

Of the \$116 billion spent on diabetes-related medical care in 2007, complications leading to or prolonging hospitalization accounted for approximately half.<sup>25</sup> Twelve percent of expenditures covered diabetes medications and supplies, including SMBG meters and strips. Estimates indicate that 2 million people with diabetes have no medical insurance, and approximately 50% are insured through Medicare or other government programs.<sup>25</sup>

Considered together, these statistics validate the concept that preempting the onset or progression of diabetes is more cost-effective than treating its complications. Yet, healthcare resources in the United States have been largely concentrated on late-stage disease, with 25% of Medicare expenditures devoted to the last year of life (see above, Follow-through, not breakthrough).<sup>120</sup> Although healthcare decision-makers are beginning to appreciate that interventions such as SMBG

might curb long-term spending, only 1–3% of healthcare dollars are currently devoted to disease prevention, and, consistent with this level of investment, the criteria for reimbursement remain ill-defined.<sup>121,122</sup>

Pervasive skepticism about the ability to change behavior further undermines the business case for SMBG.<sup>123</sup> Therefore, future studies of SMBG should strive to document its value in a well-described multicomponent system of volitional control whereby patients<sup>14</sup>:

- Know how to test their blood glucose and can feel assured that their meters, strips, and testing techniques meet official standards of quality (see above, Standards and practices affecting meter accuracy)
- Understand the connection between SMBG and A1C
- Establish individualized glycemic goals with their diabetes care team and appreciate the implications of readings that are above or below target
- Discern the relationships between out-of-target readings and prior behavior (e.g., exercise, under- or overuse of medication, and eating)
- Understand the steps that may be taken to address out-of-target SMBG readings
- Have and implement a realistic mutually agreed-upon action plan to regulate glucose levels prospectively

Rational reimbursement policies will also require that future studies<sup>124</sup>:

- Focus on factors influencing effectiveness (versus efficacy)
- Select clinically relevant interventions to compare
- Include a diverse population of participants from a variety of practice environments
- Collect data on a broad range of health outcomes, including symptom severity, patient satisfaction, and costs

To better substantiate the role of diabetes education in containing diabetes-related costs, program directors should initiate systems to collect data prospectively, ideally through the use of electronic health records that can track intervention-related costs, health status, and economic benefits.<sup>125</sup> Investment in an infrastructure linking general practitioners with local skilled professionals equipped to provide intensive counseling on diabetes self-management issues, including SMBG, offers another promising and economical route to sustaining healthy behavior change.

#### *Causality, outcomes, and cost-effectiveness: a new research agenda*

By far, the greatest obstacle to demonstrating the cost-effectiveness of SMBG remains the dearth of adequately powered studies establishing direct causality between frequent testing and glycemic control, especially among non-insulin-using patients.<sup>126</sup> Cross-sectional studies are inherently inconclusive because a “snapshot” cannot reveal whether good (or suboptimal) control resulted from optimal (or suboptimal) SMBG or simply coincided with it.<sup>14</sup> Randomized controlled trials have often fallen short because they offer no way of knowing whether SMBG was itself responsible for the outcome as opposed to one or more aspects surrounding its implementation.<sup>127</sup>

In addition, a number of variables may influence interpretation of A1C outcomes, which continue to serve as the surrogate measure by which the health risks and costs of diabetes are assessed.<sup>121,128</sup> For example,

- Exceedingly high or low baseline A1C values may signal clinical situations that could have implications for study design.
- Inclusion of a large number of subjects with near-target baseline A1C levels (~7%) may not result in appreciable change between intervention and control groups.
- Patients with high A1C on maximum doses of glucose-lowering oral agents or glucagon-like peptide-1 receptor agonists may not show any benefit of SMBG without initiation of insulin therapy.
- A 7% A1C value obtained from a routine clinical laboratory could actually represent a broader value range (e.g., 6.5–7.5%) because of total error.
- A1C values are partially under the control of health systems and clinicians who, because of clinical inertia or reimbursement issues, may resist altering therapy despite clear indications for change.

Recognizing these caveats, one cost-effectiveness calculation by Neeser et al.,<sup>129</sup> based on A1C reduction among non-insulin-using patients practicing SMBG, concluded that glucose monitoring seven times per week would account for ~6% of the total direct diabetes-related costs covered by health insurance, considering savings from reduced complications over 10 years. However, since only two out of the six studies comprising the pooled data met accepted standards of methodological quality, this analysis should be viewed as a starting point only.<sup>15</sup> Other less specific cost-effectiveness analyses of categories such as “medical equipment” or “disposable supplies” also suggest that SMBG may provide a sustainable cost benefit, even in patients with type 2 diabetes.<sup>126</sup>

Outcomes other than A1C cited by the panel as independently worthy of cost/benefit analysis were:

- Frequency and severity of hypoglycemia
- Psychological stress
- Hyperglycemia illness management
- Preventing emergency room visits
- Patients’ understanding of their disease and the value of motivational feedback on behavior change
- Relief from anxiety and/or depression
- The usefulness of SMBG in guiding therapy titration, timely transition to insulin, or intermittent insulin administration in patients with non-insulin-requiring diabetes

The panel also advocated large, long-term qualitative and quantitative studies, planned jointly by those who pay for, regulate, provide, and receive care, to (1) identify the active components of SMBG-driven interventions relative to glycemic control, (2) improve understanding of what optimal SMBG interventions may entail for different patient subgroups, and (3) determine what magnitude of effect—encompassing adherence, quality of life, well-being, patient satisfaction, and metabolic issues such as hypoglycemia and glycemic variability—should inform policy. In the interim, local pilot studies examining short-term costs and benefits of SMBG can help clarify the translatability of research find-

TABLE 2. CONSIDERATIONS FOR OPTIMIZING SMBG UTILIZATION

**Technological considerations**

Given the centrality of SMBG in guiding therapy, clinicians and manufacturers should focus on quality-control protocols to ensure clinically reliable meter accuracy during everyday use:

- Recommendations for clinicians
  - Verify that a prescription for control solution materials is included with each prescription for strips and actively impress upon patients the importance of confirming meter accuracy with fresh supplies
  - Alert all patients to the importance of meter coding and instruct them to correctly code their meters or use an autocoded meter for more reliable implementation of SMBG-guided therapy
  - Remind patients to clean their meters as directed and to wash their hands before testing
  - Verify proper testing technique at 1 and 6 months for new patients, then annually to either reinforce skills that may lapse over time or introduce new skills in response to changing needs
  - Become familiar with normal hematocrit ranges for different patient populations to ensure that they fall within the range of the specific meters being used
  - Alert patients engaging in high-altitude activities, particularly at low temperatures, of the potential for false high or low readings
  - Regularly review patients' drug regimens and meter type to determine the necessity of adjusting data interpretation resulting from drug effects; note that package inserts for meters may not provide adequate warning information about drugs used in critical care settings or at high doses without medical supervision
- Recommendations for manufacturers
  - Reexamine labeling information regarding factors (e.g., drug effects, hematocrit, temperature, altitude, and testing technique) that could potentially affect meter performance in real-world situations
  - Pursue measures (e.g., adding desiccants to strip packaging, automatic coding) that ease the burden of quality control currently borne by patients
  - Develop a feature for measuring hematocrit levels—with algorithmic adjustment of glucose results, warning mechanisms, or results lockout—to reduce the risk for potential error, particularly when hematocrit and glucose changes are occurring rapidly and concurrently

**Clinical considerations**

SMBG, with or without instruction, is no substitute for effective, aggressive management of glycemia—it simply makes it possible.

- Recommendations for clinicians
  - Ensure that, before beginning SMBG, patients have a thorough understanding of their individualized glucose targets and the relationship among monitoring, glycemic control, and A1C
  - For patients not using SMBG for acute intervention (i.e., those treated with diet and/or non-insulin therapies), provide a written schedule of glycemic goals corresponding to stepwise interventions; this schedule should be reviewed and adjusted at regular intervals to facilitate prompt and appropriate escalation of therapy and an understanding of factors affecting glycemia
  - Consider the particular circumstances, needs, and goals of the patient in determining the ideal frequency and timing of SMBG
  - Use the 2005 IDC Global Consensus Conference on Glucose Monitoring Panel guidelines as a practical tool for determining appropriate SMBG frequency and timing (see p. 426)
  - In general, patients with type 1 diabetes and those with a history of severe hypoglycemia should monitor at least three times per day, preferably more if on an intensive basal-bolus insulin regimen; patients with type 2 diabetes should base frequency on the extent of diabetes progression and insulin deficiency
  - In patients with type 2 diabetes, focus on lowering postprandial glucose when A1C is  $\leq 8.4\%$ ; note that further study is needed to refine postprandial analyses according to eating patterns and food choice
  - Consider postprandial monitoring when patients meet SMBG goals but have high A1C, are receiving medical treatment targeted at lowering postprandial glycemia, report postprandial hypoglycemia, or require motivation for dietary interventions to manage blood glucose
  - Postprandial monitoring is imperative in the setting of gestational diabetes mellitus or preexisting diabetes in pregnancy
  - Pursue "pattern management," preferably with computerized downloading of blood glucose data, if high glucose readings at the same testing time each day persist for at least 3 days in a row or low readings persist for 2 days in a row
  - Make sure that the time and date of the patients' glucose meters are set correctly and reinforce the importance of this measure to obtain accurate data interpretation
  - As a rule of thumb, if the mean blood glucose is less than twice the SD, look for severe insulin deficiency and/or the presence of problems such as poor matching of caloric intake and insulin, noncompliance with insulin doses, missed meals, gastroparesis, or erratic insulin absorption
  - When downloading glucose data, take time with patients to review SD, mean glucose, and median values against the glucose diary, so that patterns of glycemic control and components of the current regimen in need of change can be identified and addressed
  - The data must be reviewed!
- Recommendations for manufacturers
  - Develop diabetes management software that includes (1) universal standardization of data formats and access venues, (2) automatic integration of accurate time and date, and (3) axiomatic algorithms for "automatic" pattern management

TABLE 2. CONSIDERATIONS FOR OPTIMIZING SMBG UTILIZATION (CONT'D)

**Behavioral considerations**

In order to be optimally utilized, SMBG poses complex information, motivation, and behavioral skill demands on patients. At minimum, patients must learn how to cue themselves to test at appropriate times, act prudently when a reading is out of target, communicate effectively with busy clinicians, and maintain motivation to practice SMBG over time.

- Recommendations for clinicians
  - Remain alert to factors affecting SMBG adherence (e.g., language barriers, socioeconomic status, less intensive therapy, depression)
  - Employ simple behavioral interventions (e.g., motivational interviewing techniques, *written* “prescriptions for prevention”) during routine office visits to better impart information about SMBG, as well as the skills and confidence to act on the information
  - Foster adherence by considering the following questions: (1) Are frequency targets sufficient to achieve desired glycemic control with the minimum amount of testing and hypoglycemia? (2) Are they individually justifiable? (3) Have they been communicated and understood by the patient?
  - Consider the tenets of individualized therapy in tandem with population-based guidelines
  - Remember that SMBG frequency is not an end itself; people with optimal glycemic control may monitor frequently as a consequence of successful outcomes, and those with poor control may monitor just as frequently in “chase” of better outcomes
  - Help patients incorporate SMBG into their voluntary self-regulatory behavior by reassuring them that objective readings, when obtained properly, are valid indicators of blood glucose status and that out-of-target readings are a cue for adjusting treatment, *not* a sign of failure; establish a self-propagating SMBG-driven feedback loop
  - Pose open-ended questions in a process of active listening that allows patients to articulate their goals, ambivalent feelings, and priorities in their own words
  - Break down sweeping long-term goals into achievable and measurable short-term objectives
  - Confirm that SMBG recommendations are patient-tailored and clear in terms of how, why, and when to test and that they are consistently reinforced
  - Use technology (e.g., diabetes management software, touch-screen computer counseling) for more efficient and collaborative decision making during and between office visits
  - Start now; investigate feasibility of time-tested, low-cost behavioral interventions, currently used by many nurses and diabetes educators, rather than waiting for definitive evidence-based practices
  - Pay attention to the information, motivation, and behavioral demands posed by every clinical recommendation
- Recommendations for manufacturers
  - Consider the behavioral aspects of real-world testing in both hardware and software design
  - Develop “smart software” that incorporates voice recognition and response algorithms enabling users to chart their own progress, remotely receive information from clinicians in response to personalized SMBG data, and engage in Internet “chat” or other forms of online peer support

**Policy and research considerations**

Only 1–3% of healthcare dollars are currently devoted to disease prevention; the criteria for reimbursing preventive practices such as SMBG remain inconsistent. Future research should be directed at helping policymakers evaluate the business case for SMBG in different patient subgroups.

- Recommendations for clinicians
  - Substantiate the role of diabetes education in containing diabetes-related costs by initiating systems to collect data prospectively, ideally through the use of electronic health records that can track intervention-related costs and economic outcomes
  - Advocate for investment in an infrastructure linking general practitioners with local skilled professionals equipped to provide intensive counseling on diabetes self-management, including SMBG
- Recommendations for researchers
  - Address skepticism about interventions requiring behavior change by ensuring that future studies of SMBG document its effectiveness and value in a clearly described multicomponent system of volitional control
  - Focus on factors of SMBG utilization influencing effectiveness (versus efficacy)
  - Select clinically relevant interventions to compare
  - Include a diverse population of participants from a variety of practice environments
  - Collect data on a broad range of health outcomes beyond A1C, e.g., hypoglycemia, stress, preventing emergency room visits, improved disease understanding, motivation for behavior change, relief from anxiety/depression, and timely escalation of therapy
  - Conduct large-scale studies to identify the active components of SMBG-driven interventions, improve understanding of what optimal SMBG entails in different patient subgroups, and determine what magnitude of effect in which domain (e.g., adherence, quality of life, well-being, patient satisfaction, A1C, and/or glycemic variability) should inform policy
  - Conduct local pilot studies of SMBG examining short-term cost and benefits, as well as translatability of findings to communities where people live and receive healthcare
  - Develop protocols for standardizing the accuracy of monitoring practices and procedures in real-world settings
- Recommendations for policymakers
  - Support development of a practice architecture that transcends traditional silos of expertise to achieve optimal SMBG effectiveness and, by extension, more efficient, economical, and appropriate diabetes care

ings to communities where people live and receive their health care.

Finally, from the technological standpoint, agendas for standardizing the accuracy of monitoring practices and procedures, particularly when performed by patients in real-world settings, should be formulated by an independent consortium of stakeholders representing multiple perspectives on SMBG utilization.

### Summary and Conclusions

SMBG remains the mainstay of diabetes self-management for the majority of patients with type 1 or type 2 diabetes. Yet, the current healthcare model of fragmented, underfinanced programs dependent on overburdened clinicians operating in separate silos of care is antithetical to the optimal utility of SMBG.

As this article describes, successful glucose monitoring depends on the continuity of individualized care and a flow of prior processes informing subsequent processes that, in turn, promote escalating levels of appropriate self-management behaviors. Recommendations for facilitating this feedback loop, as agreed upon by the panel, are summarized in Table 2. Conceivably, these technological, clinical, behavioral, and research initiatives, if coordinated across the continuum of care, can produce a ripple effect of desired outcomes—radiating out from the achievement of personal goals, such as fewer hypoglycemic episodes, to more distal societal benefits, including lower hospitalization rates and complication-related costs.

Further, issues of implementation, such as organizational resistance to change, as well as infrastructure and resource limitations, must be addressed through the development of research methodologies that allow for systematized decision-support processes within the varying context of personalized care. An academic International SMBG Working Group was recently established to explore these challenges worldwide, with the aim of prioritizing research questions and formulating trial designs useful to regulatory authorities and policymakers.<sup>130</sup> Such efforts will expand the focus of SMBG research from strict numerical benchmarks to more practical dimensions of human experience and behavior and, in doing so, advance the commonsense idea that efforts to improve outcomes must be preceded by a greater understanding of the “self” on whom success depends.

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