

REVIEW

## Self-Monitoring of Blood Glucose in Diabetes: From Evidence to Clinical Reality in Central and Eastern Europe—Recommendations from the International Central-Eastern European Expert Group

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### Abstract

Self-monitoring of blood glucose (SMBG) is universally considered to be an integral part of type 1 diabetes management and crucial for optimizing the safety and efficacy of complex insulin regimens. This extends to type 2 diabetes patients on intensive insulin therapy, and there is also a growing body of evidence suggesting that structured SMBG is beneficial for all type 2 diabetes patients, regardless of therapy. However, access to SMBG can be limited in many countries in Central and Eastern Europe. A consensus group of diabetes experts from 10 countries in this region (with overlapping historical, political, and social environments)—Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia, Slovenia, and Ukraine—was formed to discuss the role of SMBG across the spectrum of patients with diabetes. The group considered SMBG to be an essential tool that should be accessible to all patients with diabetes, including those with non-insulin-treated type 2 diabetes. The current article summarizes the evidence put forward by the consensus group and provides their recommendations for the appropriate use of SMBG as part of individualized patient management. The ultimate goal of these evidence-based recommendations is to help patients and providers in Central and Eastern Europe to make optimal use of SMBG in order to maximize the efficacy and safety of glucose-lowering therapies, to prevent complications, and to empower the patient to play a more active role in the management of their diabetes.

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## Self-Monitoring of Blood Glucose in Diabetes— The Evidence

### Introduction to self-monitoring of blood glucose

**S**ELF-MONITORING OF BLOOD GLUCOSE (SMBG) is the collection by the patients of detailed information about their blood glucose levels at many time points during the day on a day-to-day basis in order to aid adjustments in therapy and lifestyle activities and ultimately improve glycemic control and prevent diabetes-related complications.<sup>1</sup> This is typically achieved using conventional personal blood glucose meters to measure finger prick blood samples several times per day. Unlike glycated hemoglobin (HbA1c) testing, this allows real-time measurement of blood glucose levels. Continuous glucose monitoring systems, which rely on a subcutaneously implanted sensor (noninvasive systems are also in development), take measurements automatically every 4–10 min but still require regular (usually every 6 h) finger prick testing for calibration. This article focuses on the use of conventional personal blood glucose meters, as this represents the most commonly used approach to SMBG.

The recent position statement from the American Diabetes Association and the European Association for the Study of Diabetes emphasized that individualized treatment goals and therapeutic strategies are the cornerstone of success in type 2 diabetes.<sup>2</sup> Knowledge of prevailing glucose trends through the use of SMBG, especially in those on insulin therapy, provides a means to tailor therapy and empower the patients to play a more active role in the control of their disease. This should involve appropriate patient SMBG skills training that is reinforced on a regular basis (e.g., yearly). Furthermore, it requires the availability of accurate, reliable SMBG devices, and there is currently scope for health authorities to improve the regulation and monitoring of such devices and to standardize the approval process.<sup>3</sup>

Current SMBG devices are ultraportable, with some requiring measurement times of only 5 s and many allowing small sample sizes of less than 2  $\mu$ L,<sup>4,5</sup> are able to calculate means, discern between premeal and postmeal glucose measurements, and store up to 500 results in their memory. The most recent development in glucose meters technology is embedding an automated bolus calculator with the goal to propose recommendations about insulin dosage to patients, and there is increasing evidence that these new smart devices make patients' decision-making safer.<sup>6</sup> At present, SMBG is widely used and widely reimbursed and is considered an integral part of treatment for people with type 1 diabetes and those with insulin-treated type 2 diabetes.<sup>7,8</sup> In one study, SMBG usage between 1993 and 2009 increased from 67% to 90% in insulin-treated type 2 diabetes patients and from 9% to 27% in type 2 diabetes patients on oral antihyperglycemic agent therapy.<sup>9</sup> However, there has been considerable controversy regarding the value of SMBG in non-insulin-treated type 2 diabetes patients, especially as the data (at least until recently) have been largely inconsistent<sup>10–13</sup>—as such, this patient group is the major focus of the current article. Specific goals for performing SMBG by patients with type 1 and type 2 diabetes are summarized in Table 1.

Also, SMBG use and reimbursement policies vary from country to country and from region to region. The differences are particularly visible in Europe, where countries belonging to one political and economic entity (i.e., the European

TABLE 1. SPECIFIC GOALS FOR PERFORMING SELF-MONITORING OF BLOOD GLUCOSE BY PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES

Specific goals for SMBG	Type 1 diabetes	Type 2 diabetes
Assessment of fasting, preprandial, and postprandial blood glucose control	Yes	Yes
Insulin dose adjustment	Yes	Yes, in patients treated with insulin
Prevention of hypoglycemia	Yes	Yes, in patients treated with insulin or sulfonylureas
Intensified blood glucose control during physical activity, acute illness, etc.	Yes	Yes
Detecting clinically silent hypoglycemia	Yes, in subjects with hypoglycemia unawareness	No
Blood glucose control at any occasion suspected of being or might have been caused by a sudden swing in glycemia	Yes	Yes

SMBG, self-monitoring of blood glucose.

Union) follow discrepant regimens in regard to recommending access to and usage of SMBG. As authors of this consensus article, we have analyzed the current evidence for SMBG and set it against the situation in 10 countries in Central and Eastern Europe. We represent the countries that have accessed the European Union in the last 10 years (Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Slovakia, and Slovenia) and those that aspire to be in the—even if unforeseen—future (Serbia and Ukraine). In all, we cover a large part of the territory between Germany and Russia, with a population of just over 100 million. The aim of this article is to help improve blood glucose control, prevent complications, and empower type 2 diabetes patients living in these populations via recommending evidence-based SMBG use.

### What do the guidelines say on SMBG in diabetes?

Clinical practice guidelines universally recommend regular individualized SMBG as an essential tool for the optimal management of all patients with type 1 diabetes.<sup>14–18</sup> The underlying rationale is based on consideration of several factors, including safety (detection and prevention of hypoglycemia), efficacy (enhancement of effectiveness of insulin through dose adjustment), and flexibility for the patient (e.g.,

regarding dietary choices and physical activity). The guidelines generally recommend that SMBG be performed at least three times per day in patients with type 1 diabetes and that it should include both fasting and postprandial glucose measurements.<sup>14–18</sup> Guidelines from the International Diabetes Federation also recommend that SMBG should be performed frequently during pregnancy in diabetes, and in those with preexisting diabetes this will relate to any previous pattern of testing and insulin regimen.<sup>7</sup> The guidelines also recommend that women with gestational diabetes are instructed in SMBG and perform testing four times daily (fasting and 1 h after each meal).<sup>7</sup>

Clinical practice guidelines that incorporate recommendations on the use of SMBG in type 2 diabetes have been issued by several national and international healthcare bodies.<sup>7,8,14–16,18–20</sup> Key recommendations from the International Diabetes Federation, the American Diabetes Association, and the National Institute for Health and Care Excellence in the United Kingdom are summarized in Table 2. The available guidelines recommend the use of SMBG in insulin-treated type 2 diabetes and generally suggest that SMBG may be beneficial in non-insulin-treated type 2 diabetes, especially when incorporated into a comprehensive education and management program, and this is supported by recommendations from expert consensus groups.<sup>10,21–24</sup> The International Diabetes Federation guidelines, in particular, recommend that SMBG protocols (intensity and frequency) should be individualized to address the individual needs of each patient, as well as the requirements of the healthcare provider. The guidelines also recommend that healthcare providers should discuss the purpose of SMBG with patients and get agreement on how it should be interpreted and that patient skills and the impact of SMBG should be monitored. However, the evidence-based nature of these guidelines remains questionable. A recent review of current guidelines on SMBG in non-insulin-treated type 2 diabetes concluded that clinical practice guidelines were generally more in favor of SMBG use than the systematic reviews that were cited.<sup>25</sup> The authors also concluded that the citation practice in the guidelines was nonsystematic.

#### *The evidence supporting SMBG use in type 1 and type 2 diabetes*

Type 1 diabetes and insulin-treated type 2 diabetes. In spite of the strong rationale supporting the use of SMBG in conjunction with intensive insulin therapy in type 1 diabetes, the formal evidence base is relatively limited.<sup>12</sup> In the Diabetes Control and Complications Trial, intensive insulin therapy guided by frequent SMBG delayed the onset and slowed the progression of microvascular complications compared with conventional therapy in patients with type 1 diabetes.<sup>26</sup> However, rigorous studies comparing SMBG versus no SMBG are not available and would not be considered ethical in this patient group.<sup>12</sup> Nevertheless, a meta-analysis of four early studies comparing SMBG with urinary glucose testing found that SMBG was associated with 0.6% greater reduction in HbA1c.<sup>27</sup> Further support comes from observational analyses in type 1 diabetes, and several studies have found a strong association between higher SMBG frequency and lower HbA1c levels.<sup>28–31</sup> Evidence also suggests that more structured, focused SMBG intervention in suboptimally controlled patients with type 1 diabetes can provide

significant improvements in HbA1c compared with regular guideline-based care.<sup>32</sup>

Like in type 1 diabetes, the rationale for the use of SMBG in insulin-treated type 2 diabetes is compelling and is supported by data from large prospective and observational trials.<sup>30,33,34</sup> Similar to the Diabetes Control and Complications Trial, the Kumamoto study showed that intensive insulin therapy guided by SMBG can reduce the risk of microvascular complications compared with conventional therapy in type 2 diabetes.<sup>33</sup> In the Diabetes Outcomes in Veterans Study (DOVES), intensified SMBG improved glycemic control (0.3% reduction in HbA1c over 1 year) in a large cohort of stable, insulin-treated veterans with type 2 diabetes.<sup>34</sup> Benefits were only seen in patients whose SMBG compliance exceeded 75% or those with baseline HbA1c > 8% (64 mmol/mol).

Non-insulin-treated type 2 diabetes. Prior to 2001, data supporting the use of SMBG in non-insulin-treated type 2 diabetes were limited, in spite of increasing SMBG use, leading to repeated calls for more studies in this patient group.<sup>35,36</sup> However, until recently, the majority of randomized controlled trials (nine out of 14 performed up to the year 2010) failed to show any significant benefit on metabolic control<sup>37–39</sup> (for reviews, see Davidson<sup>11</sup> and Kolb et al.<sup>12</sup>). The inconsistent findings have been attributed to differences in study designs, populations, and the interventions, and the SMBG protocols and structures may not have allowed adequate SMBG-guided management.<sup>7,12,13</sup> However, several subsequent meta-analyses of SMBG studies in non-insulin-treated people with type 2 diabetes have suggested that SMBG is associated with modest, but nonetheless statistically significant, reductions in HbA1c of between 0.2% and 0.4%.<sup>40–47</sup> It is notable that SMBG appeared to be useful only when SMBG results were used to adjust therapeutic regimens and was more effective in patients with higher baseline HbA1c levels.<sup>42</sup> However, no associations with general health-related quality of life, general well-being, or patient satisfaction were reported.<sup>44,45,47</sup>

Individual studies also suggest that more intensive SMBG in non-insulin-treated type 2 diabetes patients may not necessarily lead to changes in self-reported health behaviors.<sup>48</sup> A recent cross-sectional study found that SMBG was not associated with improved metabolic control in type 2 diabetes.<sup>49</sup> Indeed, patients with worse glucose control tended to perform SMBG more often. However, only half of patients modified their behavior because of abnormally high results of SMBG, highlighting the need for better education to make effective use of SMBG.

In terms of other outcomes, a recent randomized controlled trial suggests that the use of SMBG for 6 months can provide significant improvement in calculated coronary heart disease risk scores.<sup>50</sup> The retrospective observational ROSSO study found that SMBG was associated with reduced incidence of micro- and macrovascular events and all-cause mortality, irrespective of insulin use.<sup>51–53</sup> On the other hand, longitudinal observational data from the Fremantle Diabetes Study found that SMBG was not independently associated with improved survival, and there were inconsistent findings relating to the association of SMBG with cardiac death and retinopathy.<sup>54</sup> A recent cross-sectional study in Turkey suggested that regular use of SMBG was not superior to irregular/never use of SMBG on glycemic control, but it seemed to be good intervention for prevention of diabetic nephropathy.<sup>55</sup> It is notable that recent

TABLE 2. KEY CLINICAL GUIDELINES WITH RECOMMENDATIONS FOR SELF-MONITORING OF BLOOD GLUCOSE IN TYPE 2 DIABETES

Guideline	Key recommendations
International Diabetes Federation <sup>8,97</sup>	<p>Standard care:</p> <ul style="list-style-type: none"> <li>• SMBG on an ongoing basis should be available to people with diabetes using insulin.</li> <li>• SMBG should be considered for people using oral glucose-lowering medications as an optional component of self-management, and in association with HbA1c testing: <ul style="list-style-type: none"> <li>◦ to provide information on, and help avoid, hypoglycemia</li> <li>◦ to assess changes in blood glucose control due to medications and lifestyle changes</li> <li>◦ to monitor the effects of foods on postprandial glycemia</li> <li>◦ to monitor changes in blood glucose levels during intercurrent illness</li> </ul> </li> <li>• Regular SMBG should not be considered part of routine care where diabetes is well controlled by lifestyle or oral medications alone.</li> <li>• SMBG protocols (intensity and frequency) should be individualized to address specific educational/behavioral/clinical requirements and provider requirements for data on glycemic patterns to monitor therapeutic decision-making.</li> </ul> <p>Comprehensive care:</p> <ul style="list-style-type: none"> <li>• SMBG could be offered to all people with type 2 diabetes, irrespective of treatment, as part of a comprehensive and ongoing education and therapeutic program.</li> </ul>
American Diabetes Association <sup>18</sup>	<ul style="list-style-type: none"> <li>• Patients on MDI or insulin pump therapy should do SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.</li> <li>• SMBG results may be helpful to guide treatment decisions and/or patient self-management for patients using less frequent insulin injections or non-insulin therapies.</li> </ul>
National Institute for Health and Care Excellence <sup>14,15</sup>	<ul style="list-style-type: none"> <li>• SMBG should be available: <ul style="list-style-type: none"> <li>◦ to those on insulin treatment</li> <li>◦ to those on oral glucose-lowering medications to provide information on hypoglycemia</li> <li>◦ to assess changes in glucose control resulting from medications and lifestyle changes</li> <li>◦ to monitor changes during intercurrent illness</li> <li>◦ to ensure safety during activities, including driving</li> </ul> </li> <li>• SMBG should be offered to a person newly diagnosed with type 2 diabetes only as an integral part of self-management education.</li> <li>• If HbA1c levels remain above target but premeal SMBG levels remain well controlled (&lt;7.0 mmol/L), SMBG should be considered to detect postprandial hyperglycemia (&gt;8.5 mmol/L) and manage to below this level, if detected.</li> </ul>

HbA1c, glycated hemoglobin; MDI, multiple-dose insulin; SMBG, self-monitoring of blood glucose.

economic analyses from the United States and Europe suggest that the SMBG can be cost-effective in non-insulin-treated type 2 diabetes and that its costs can be partly offset by a reduction in complications.<sup>56–58</sup>

#### Structured SMBG in non-insulin-treated type 2 diabetes.

Structured SMBG is an approach in which blood glucose data are gathered according to a defined regimen, interpreted, and then utilized to make appropriate pharmacologic and/or lifestyle adjustments.<sup>13</sup> An early prospective, randomized controlled study looking specifically at structured meal-related SMBG in non-insulin-treated type 2 diabetes found that SMBG provided a significant improvement in HbA1c over 6 months compared with non-SMBG control (–1.0% vs. –0.5%, respectively;  $P < 0.01$ )<sup>37</sup> (Table 3). Recently, large numbers of

studies (at least 10 since 2010) have specifically investigated the use of structured SMBG in non-insulin-treated type 2 diabetes, and most of these have not yet been included in meta-analyses (Table 3).<sup>59–67</sup> Other studies on structured SMBG in this patient population are underway.<sup>68</sup> It is notable that all but one of these structured SMBG studies in non-insulin-treated type 2 diabetes found a significant benefit.<sup>13,61</sup> These results thus demonstrate a vast improvement in consistency.

In the St Carlos Study—a prospective, randomized clinic-based interventional study with parallel groups involving well controlled newly diagnosed type 2 diabetes patients—SMBG used as part of a structured educational program was associated with significantly greater reductions in median HbA1c (from 6.6% to 6.1%;  $P < 0.05$ ) and body mass index (from 29.6 kg/m<sup>2</sup> to 27.9 kg/m<sup>2</sup>;  $P < 0.001$ ) over 1 year



TABLE 3. SUMMARY OF STUDIES OF STRUCTURED SELF-MONITORING OF BLOOD GLUCOSE IN DIABETES (ADAPTED FROM PARKIN ET AL.<sup>13</sup>)

Study	Study design	Intervention	Key results
Schwedes et al. <sup>57</sup>	<ul style="list-style-type: none"> <li>Randomized</li> <li>Standardized lifestyle program including SMBG versus nonstandardized program without SMBG</li> <li>Non-insulin-treated T2DM (<math>n=250</math>)</li> <li>Baseline HbA1c 8.4–8.5% (68–69 mmol/mol)</li> <li>6-month duration (+6 months follow-up)</li> </ul>	<p>Experimental arm:</p> <ul style="list-style-type: none"> <li>Blood glucose/eating diary, standardized counseling, provided with SMBG device</li> <li>6-point glucose profiles 2 times per week</li> </ul> <p>Control arm:</p> <ul style="list-style-type: none"> <li>Nonstandardized counseling on diet and lifestyle</li> </ul>	<ul style="list-style-type: none"> <li>Significantly greater reduction in HbA1c (<math>-1.0</math> vs. <math>-0.5\%</math> [<math>-11</math> vs. <math>-6</math> mmol/mol]; <math>P&lt;0.01</math>)</li> <li>Marked improvement of general well-being, with significant improvements in the subitems Depression (<math>P=0.032</math>) and Lack of well-being (<math>P=0.02</math>)</li> </ul>
Bonomo et al. <sup>59</sup>	<ul style="list-style-type: none"> <li>Randomized</li> <li>Simple SMBG program versus more intensive SMBG</li> <li>Non-insulin-treated T2DM (<math>n=273</math>)</li> <li>Baseline HbA1c 8.0–8.1% (64–65 mmol/mol)</li> <li>6-month duration</li> </ul>	<p>All subjects encouraged to increase diet/exercise compliance when fasting and/or postprandial glucose targets not reached</p> <p>Treatment adjustments based on SMBG</p> <p>Experimental arm:</p> <ul style="list-style-type: none"> <li>4-point glucose profiles every 2 weeks</li> </ul> <p>Control arm:</p> <ul style="list-style-type: none"> <li>4-point glucose profiles monthly</li> </ul>	<ul style="list-style-type: none"> <li>Significant HbA1c reductions in compliant experimental subjects</li> <li>Compliance significantly less in the experimental group (44% vs. 73%)</li> </ul>
Durán et al. <sup>60</sup>	<ul style="list-style-type: none"> <li>Randomized</li> <li>SMBG-based educational/pharmacological intervention versus HbA1c-based treatment algorithm</li> <li>Newly diagnosed T2DM (<math>n=161</math>)</li> <li>Baseline HbA1c 6.6% (49 mmol/mol)</li> <li>12-month duration</li> </ul>	<p>All patients instructed in lifestyle interventions</p> <p>Experimental arm:</p> <ul style="list-style-type: none"> <li>6-point glucose profiles every 3 days</li> <li>Treatment adjustments based on SMBG</li> </ul> <p>Control arm:</p> <ul style="list-style-type: none"> <li>SMBG started when deemed appropriate—always with insulin treatment</li> <li>Treatment adjustments based on HbA1c</li> </ul>	<ul style="list-style-type: none"> <li>Significantly higher rates of regression and remission in experimental subjects</li> <li>Significantly greater reductions in median HbA1c and BMI in experimental subjects</li> <li>Significantly more experimental subjects achieved lifestyle score of <math>&gt;12</math></li> <li>Treatment changes occurred earlier and more frequently in experimental subjects.</li> </ul>
Kleefstra et al. <sup>61</sup>	<ul style="list-style-type: none"> <li>Randomized</li> <li>Structured SMBG added to usual care versus usual care alone</li> <li>Non-insulin-treated T2DM (<math>n=41</math>)</li> <li>Baseline HbA1c 7.5–7.6% (59–60 mmol/mol)</li> <li>12-month duration</li> </ul>	<p>Experimental arm:</p> <ul style="list-style-type: none"> <li>4-point glucose profiles 2 times per week</li> <li>Blood glucose diary</li> <li>Extra measurement in cases of high/low glucose, with action if abnormal measures persist</li> </ul> <p>Control arm:</p> <ul style="list-style-type: none"> <li>No SMBG</li> </ul>	<ul style="list-style-type: none"> <li>No significant differences in HbA1c, HRQoL, or treatment satisfaction</li> <li>Significant worsening of health perception (SF-36 dimension "health change") in SMBG arm</li> </ul>
Kempf et al. <sup>62</sup>	<ul style="list-style-type: none"> <li>Interventional</li> <li>Evaluated impact of SMBG-structured intervention on glucometabolic and health parameters</li> <li>Non-insulin-treated T2DM (<math>n=405</math>)</li> <li>Baseline HbA1c 6.7% (50 mmol/mol)</li> <li>12-week duration</li> </ul>	<p>7-point glucose profiles every 4 weeks</p> <p>Patients received tape measure, step counter, and manual that provides guidance for diet and exercise adjustments based on SMBG</p>	<ul style="list-style-type: none"> <li>Significant reductions in HbA1c, weight, BMI, systolic BP, diastolic BP, and LDL-cholesterol</li> </ul>
Mohan et al. <sup>98</sup>	<ul style="list-style-type: none"> <li>Randomized</li> <li>Determined effect of treatment based on preprandial and postprandial SMBG on progression of CIMT and HbA1c change</li> <li>Non-insulin-treated T2DM (<math>n=200</math>)</li> <li>Baseline HbA1c 7.2–7.3% (55–56 mmol/mol)</li> <li>18-month duration</li> </ul>	<p>All patients instructed in meal planning, but no specific instructions for addressing elevated fasting or postprandial glucose</p> <p>Study Arm 1 (FP):</p> <ul style="list-style-type: none"> <li>3 fasting glucose measurements per week</li> <li>Instructions for adjusting medication based on SMBG</li> </ul> <p>Study Arm 2 (PP):</p> <ul style="list-style-type: none"> <li>3 postprandial glucose measurements per week</li> <li>Instructions for adjusting medication based on SMBG</li> </ul>	<ul style="list-style-type: none"> <li>Significant reductions in CIMT and HbA1c in PP but not FP subjects</li> <li>Significant improvements in BMI, waist circumference, systolic BP, and serum cholesterol in PP subjects but not FP subjects</li> </ul>

(continued)

TABLE 3. (CONTINUED)

Study	Study design	Intervention	Key results
Shiraiwa et al. <sup>63</sup>	<ul style="list-style-type: none"> <li>• Randomized</li> <li>• Determined effect of occasional postprandial SMBG on glycemic control</li> <li>• Non-insulin-treated T2DM (<math>n = 71</math>)</li> <li>• Baseline HbA1c 6.7% (50 mmol/mol)</li> <li>• 4-month duration</li> </ul>	<p>Experimental arm:</p> <ul style="list-style-type: none"> <li>• 10 postprandial glucose measurements per month</li> <li>• Recorded eating and exercise habits</li> </ul> <p>Control:</p> <ul style="list-style-type: none"> <li>• No SMBG</li> </ul>	<ul style="list-style-type: none"> <li>• Significant reductions in HbA1c (<math>P = 0.028</math>) and body weight (<math>P &lt; 0.01</math>) in experimental subjects versus control subjects</li> <li>• 94% of experimental subjects reported making lifestyle changes</li> <li>• No medication changes made in either study group</li> </ul>
Franciosi et al. <sup>64</sup>	<ul style="list-style-type: none"> <li>• Randomized</li> <li>• Assessed the efficacy of SMBG-based disease management strategy</li> <li>• T2DM treated with OAs (<math>n = 62</math>)</li> <li>• Baseline HbA1c 7.9% (63 mmol/mol)</li> <li>• 6-month duration</li> </ul>	<p>Experimental:</p> <ul style="list-style-type: none"> <li>• “Staggered” SMBG regimen</li> <li>• Instructed in lifestyle interventions based on SMBG</li> <li>• Treatment adjustments based on SMBG</li> </ul> <p>Control:</p> <ul style="list-style-type: none"> <li>• Standard instruction in diet/exercise</li> <li>• No SMBG</li> <li>• Treatment adjustments based on HbA1c</li> </ul>	<ul style="list-style-type: none"> <li>• Significantly greater reduction in HbA1c (<math>-1.2\%</math> vs. <math>-0.7\%</math> [<math>-13</math> vs. <math>-8</math> mmol/mol]; <math>P = 0.04</math>)</li> </ul>
Khamseh et al. <sup>65</sup>	<ul style="list-style-type: none"> <li>• Interventional</li> <li>• Evaluate the effect of structured SMBG on patient self-management behavior and metabolic outcomes</li> <li>• T2DM (<math>n = 30</math>)</li> <li>• Baseline HbA1c 8.4% (68 mmol/mol)</li> <li>• 3-month duration</li> </ul>	<ul style="list-style-type: none"> <li>• 7-point glucose profiles over 3 consecutive days per month</li> <li>• Education on device use and data collection using a paper tool</li> <li>• Basic core education to use SMBG to alter diet and physical activity</li> </ul>	<ul style="list-style-type: none"> <li>• Significant reductions in HbA1c and mean, fasting, and postprandial glucose (all subjects combined)</li> <li>• Significant reductions in HbA1c and mean and postprandial glucose in poorly controlled subjects (HbA1c <math>\geq 8\%</math> [64 mmol/mol] at baseline)</li> <li>• No significant metabolic improvements in subjects with relatively good control at baseline (HbA1c <math>&lt; 8\%</math>)</li> </ul>
Kato and Kato <sup>66</sup>	<ul style="list-style-type: none"> <li>• Randomized</li> <li>• Determined effect of structured SMBG versus routine SMBG</li> <li>• T1DM and insulin-treated T2DM (<math>n = 86</math>)</li> <li>• Baseline HbA1c 7.9% (63 mmol/mol)</li> <li>• 6-month duration</li> </ul>	<p>Experimental arm:</p> <ul style="list-style-type: none"> <li>• 7-point glucose profiles over 3 consecutive days per month</li> <li>• Treatment adjustments made by clinicians based on SMBG</li> </ul> <p>Control arm:</p> <ul style="list-style-type: none"> <li>• Usual “random” SMBG</li> <li>• Treatment adjustments made by clinicians based on SMBG</li> </ul>	<ul style="list-style-type: none"> <li>• Significant reductions in HbA1c in experimental subjects versus control subjects</li> </ul>
Polonsky et al. <sup>67</sup>	<ul style="list-style-type: none"> <li>• Randomized</li> <li>• Assessed impact of structured SMBG intervention on glycemic control</li> <li>• Non-insulin-treated T2DM (<math>n = 483</math>)</li> <li>• Baseline HbA1c 8.9% (74 mmol/mol)</li> <li>• 12-month duration</li> </ul>	<p>Experimental arm:</p> <ul style="list-style-type: none"> <li>• 7-point glucose profiles over 3 consecutive days, every 3 months</li> <li>• Instructed in lifestyle interventions based on SMBG</li> <li>• Treatment adjustments based on SMBG and/or HbA1c</li> </ul> <p>Control arm:</p> <ul style="list-style-type: none"> <li>• Usual care</li> </ul>	<ul style="list-style-type: none"> <li>• Significantly greater improvement in mean HbA1c, glucose levels at all preprandial and postprandial time points, and MAGE in experimental subjects</li> <li>• Treatment changes occurred earlier and more frequently in experimental subjects.</li> </ul>

BMI, body mass index; BP, blood pressure; CIMT, carotid intimal-medial thickness; HRQoL, health-related quality of life; LDL, low-density lipoprotein; MAGE, mean amplitude of glycemic excursions; OA, oral (glucose-lowering) agent; SF-36, 36-item Short Form; SMBG, self-monitoring of blood glucose; T1DM/T2DM, (type 1/type 2) diabetes mellitus.

compared with a HbA1c-based control group.<sup>60</sup> Furthermore, the percentage of patients achieving a lifestyle score of >12 was significantly greater in the SMBG compared with the control group (38.4% vs. 9.7% respectively;  $P < 0.001$ ). In addition, pharmacological treatment changes occurred earlier and more frequently in the SMBG group.

One key recent trial was the Structured Testing Program (STeP) study—a cluster randomized trial in poorly controlled insulin-naive type 2 diabetes patients.<sup>67</sup> Primary care practices were randomized to the active control group or the structured testing group, the latter of which included quarterly review of structured SMBG results. The structured testing group patients used a paper tool that graphs seven-point glucose profiles over 3 consecutive days, and physicians received a treatment algorithm based on SMBG patterns. Among those who received at least one treatment modification recommendation, structured testing group patients demonstrated a greater reduction in HbA1c at 12 months compared with active control group patients ( $-1.2\%$  vs.  $-0.8\%$  [ $-13.1$  vs.  $-8.7$  mmol/mol];  $P < 0.03$ ). The results suggest that collaborative use of structured SMBG data leads to earlier, more frequent, and more effective treatment modification recommendations for poorly controlled patients. Further analyses from this study found that structured SMBG led to significant increases in self-confidence and autonomous motivation associated with diabetes self-management.<sup>69</sup>

The ROSSO-in-praxi study was an uncontrolled trial that evaluated the impact of a relatively inexpensive 12-week structured SMBG-based lifestyle intervention on metabolic and other outcomes.<sup>62</sup> Participants were advised to perform a seven-point SMBG diurnal profile every 4 weeks and were also urged to perform event-driven SMBG measurements. Participants significantly reduced weight, body mass index, waist circumference, blood glucose, blood pressure, low-density lipoprotein cholesterol, and HbA1c by 0.3% (3.3 mmol/mol) (all  $P < 0.001$ ), alongside increased physical and mental health and reduced depression measurements. After long-term follow-up of 2 years, the reduction in HbA1c was only maintained in those who continued with daily SMBG.<sup>70</sup> The Rosso-in-praxi-international study used the same intervention but randomly assigned patients to either SMBG or a non-SMBG control group.<sup>70</sup> After 12 weeks, the SMBG group had significantly improved HbA1c levels (from 7.4% to 6.9% [from 57 to 52 mmol/mol];  $P < 0.001$ ) and weight ( $-0.9$  to  $-1.9$  kg;  $P < 0.05$ ), whereas changes were not significant in the control group. After 1.5 years of follow-up, HbA1c remained stable in the SMBG group but increased in the control group. It is notable that those who measured their blood glucose more than three times per week demonstrated an overall reduction in HbA1c of 1.0% (11 mmol/mol) ( $P = 0.006$  vs. three times or fewer per week) after 1.5 years. Another recent study also suggests that intensification of relatively simple structured SMBG policy (one profile every 2 weeks with pre- and postprandial values vs. one profile every month with fasting and postprandial values) can provide HbA1c improvements, as long as compliance is sufficient.<sup>59</sup>

**SMBG and hypoglycemia.** Although the evidence for an association between SMBG and glycemic control is now extensive, the data remain more limited for hypoglycemia in non-insulin-treated type 2 diabetes. The few studies with hypoglycemia data have reported inconsistent findings, which likely reflect the inconsistent criteria used to define

hypoglycemia, the low frequency of events in non-insulin-treated patients, and the relevance of the control groups when looking at this outcome.<sup>38,72–74</sup> The study by O’Kane et al.<sup>74</sup> found no significant difference in hypoglycemia between SMBG and non-SMBG groups, whereas Farmer et al.<sup>73</sup> reported a statistically significant increase in the frequency of grade 2 hypoglycemic episodes with SMBG versus control. In the study by Guerri et al.,<sup>72</sup> hypoglycemia (symptomatic or asymptomatic) was reported by 10.4% of subjects in the SMBG group and 5.2% in the non-SMBG group ( $P = 0.003$ ), but the difference was solely due to a significant difference in asymptomatic events. In the DINAMIC 1 study, symptoms suggestive of mild to moderate hypoglycemia were reported by 27 subjects (8.7%) in the SMBG group, which included 51 events in total (27 symptomatic, 11 asymptomatic, 11 SMBG-confirmed hypoglycemia, and two non-graded).<sup>38</sup> In the non-SMBG group, mild-to-moderate hypoglycemia was reported by 7.0% of subjects (66 events in total), with 64 symptomatic and two non-graded events. Thus, there was a decrease in symptomatic events with SMBG. This is to be expected, as patients in the SMBG groups are able to use their device to both detect asymptomatic episodes (that might otherwise go unreported) and also to confirm symptomatic episodes.<sup>47</sup> Evidence for severe hypoglycemic episodes is limited, but some evidence suggests that over half of severe hypoglycemic events in type 1 or type 2 diabetes can be predicted by specific glucose fluctuation patterns (based on at least three SMBG readings) in the 24 h before an episode.<sup>75</sup>

**SMBG and current controversies.** Recently, two major debates around SMBG are thriving. One concerns accuracy of SMBG devices, as glucose meters are increasingly expected to deliver most accurate results. Independently conducted studies show that over 80% of marketed devices in Europe meet the high system accuracy requirements of DIN EN ISO 15197:2003, and all of them show acceptable measurement reproducibility.<sup>76</sup>

A second debate, even more heated, evolves around cost-effectiveness of SMBG, particularly in patients not treated with insulin. However, more and more studies show that having considered long-term impact of increased risk of developing vascular complications SMBG is cost-effective across the whole spectrum of diabetes patients.<sup>57,77,78</sup>

### Conclusion on SMBG evidence

In spite of the recent increase in the number of studies consistently showing a benefit of structured SMBG in non-insulin-treated type 2 diabetes, the relative merits of improved glycemic control versus expense and inconvenience continue to be debated.<sup>79–81</sup> The data suggest that SMBG may benefit both well-controlled and poorly controlled patients not on insulin therapy. Recent consensus statements have acknowledged the increase in high-quality efficacy data, but also highlight the need for further well-defined studies with end points beyond HbA1c.<sup>21,24</sup> Guidelines of SMBG may require updating in light of the large number of recent studies showing benefits on metabolic and other outcomes. Data on the impact of SMBG on hypoglycemia remain scant, and this is an area that warrants further study. However, the available evidence suggests that SMBG can help patients to detect asymptomatic episodes and also to confirm symptoms

suggestive of hypoglycemia, which may be particularly appropriate in those with impaired hypoglycemia awareness. Indeed, hypoglycemia unawareness is one of the utmost important indications for frequent SMBG. The importance of hypoglycemia avoidance is exemplified by growing evidence for an association between a history of severe hypoglycemic episodes and serious adverse outcomes over the long term, including death, major vascular events, and dementia.<sup>82,82</sup>

It has been suggested that the utility of SMBG can be improved through attention to several key factors, including (1) sufficient SMBG frequency and appropriate timing (and the use of a more structured approach), (2) education and skills training for patients, (3) education and skills training for physicians and nurses or educators, and (4) the use of easy-to-read ways of displaying SMBG profile data that make sense to patients, physicians and nurses, or educators.<sup>81</sup> Such strategies should aid motivation and adherence to SMBG and remove barriers to optimal SMBG implementation.<sup>84</sup> Furthermore, appropriate education and regular patient monitoring may also help to avoid inappropriate overuse of SMBG, which has cost implications and may adversely affect patient quality of life.<sup>85</sup> Other factors, such as use of the palm rather than finger testing, may be beneficial in some patients.<sup>86</sup> It is interesting that some evidence suggests that SMBG values appear to predict HbA1c better in patients on oral therapy compared with patients on insulin therapy.<sup>87</sup>

Practice nurses and other nurses working in the community are well situated to support people with diabetes to make effective use of SMBG.<sup>88</sup> They can play a key role first in identifying those patients who are most likely to benefit from SMBG and second in providing suitable education and problem-solving skills.<sup>88</sup> The latter role should involve education on the purpose of SMBG and the techniques required to use specific glucose meters and strips effectively.<sup>88</sup> Furthermore, patients should be taught how to interpret and use SMBG test results to adjust treatment, diet, and other lifestyle factors, thus empowering them to manage their diabetes more optimally and, it is hoped, avoiding hypoglycemic episodes and improving glycemic control.<sup>88</sup> Actually, having practice nurses—or even better, diabetes nurse specialists or educators—is a prerequisite of successful diabetes care as they are the best suited to provide essential and advanced diabetes education. At present, with doctors often unable to devote sufficient time for individual visits, a patient may obtain the necessary knowledge of how to manage her or his disease either from a professionally trained diabetes nurse or from no one. It is regrettable that in all countries from Central and Eastern Europe, nursing in diabetes is still in its infancy, with educational infrastructure and human resources being slowly built.

Unfortunately, it appears that no general agreement exists at present between healthcare professionals regarding the advice on various aspects concerning SMBG (e.g., on frequency, timing, and practical considerations) highlighting the need for education and more uniform guidelines.<sup>89,90</sup> A recent European expert panel has provided recommendations regarding frequency and timing of SMBG also for various clinical scenarios and suggested a less intensive and an intensive scheme for SMBG across the type 2 diabetes continuum, depending on clinical circumstances and the quality of glycemic control.<sup>21</sup> The expert panel also recommended further evaluation of various schemes for SMBG in type 2 diabetes in

clinical studies.<sup>21</sup> However, as noted by the International Diabetes Federation, SMBG should only be used when individuals with diabetes and/or their healthcare providers have the knowledge, skills, and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan.<sup>7,8</sup> The key word that should always accompany “SMBG” in non-insulin-treated diabetes patients is “structured,” and as long as patients and their care providers do not learn to use these two together, SMBG will never develop to its full potential in diabetes control. There is a sufficient body of evidence to show that structured SMBG is beneficial for all type 2 diabetes patients, regardless of the therapy they are using.

### SMBG in Central and Eastern Europe—The Reality

The Central and Eastern European countries represented in this statement make up a group with relatively limited financial resources by the standards of many Western European nations (Table 4). In terms of gross domestic product (purchasing power parity) per capita, they have a relatively broad range, from \$7,374 (Ukraine) to \$28,195 (Slovenia).<sup>91</sup> Thus, they overlap with the poorest Western European nations (approximately \$23,000–27,000 for Portugal, Greece, Malta, and Cyprus) but are all well below the levels of the major Western European economies (approximately \$35,000–40,000 for France, the United Kingdom, and Germany) and are all below the European Union average (\$32,021). In spite of this financial disadvantage, the available evidence suggests that, in general, patients with diabetes in Central and Eastern Europe receive a quality of care (e.g., in terms of control of both glycemic levels and cardiovascular risk factors) comparable to patients in Western Europe, although there are many potential areas for development.<sup>92</sup> Any disparities with Western European countries are related mainly to limited economic resources.<sup>93</sup> Cost-effective improvements in care are therefore highly relevant to the countries represented in this statement, some of which (e.g., Poland and Slovenia) have a particularly high burden of diabetes, in terms of both prevalence and healthcare spending, and many people with diabetes remain undiagnosed (Table 4). As in Western Europe, both glycemic control and cardiovascular risk factor control remain unsatisfactory in many patients, and there is a continuing need for improvements in education and management guidelines, as well as access to cost-effective drug therapies and devices, such as those required for SMBG.<sup>92,93</sup>

In most countries in the region, diabetes care is provided by both general practitioners and diabetologists/endocrinologists, with patients typically managed by general practitioners, in the first instance, with subsequent referral to specialists if insulin treatment is required or where there is deterioration of glycemic control. However, in some countries (the Czech Republic, Romania, Slovakia), the majority of patients are managed by specialists. Diabetes education is typically provided by doctors, nurses, or dietitians, although access to structured education may be limited in some countries.

Reimbursement for glucose meters and testing strips varies widely across the region (Table 4). Depending on the country, glucose meters may be fully reimbursed (typically for children/adolescents, patients on insulin, and during pregnancy), partially reimbursed, or not reimbursed at all. However, glucose meters may also be distributed free of charge by the manufacturers in some instances. Similarly, there is wide variation in the levels of reimbursement for glucose test



TABLE 4. SELF-MONITORING OF BLOOD GLUCOSE AND DIABETES BURDEN IN CENTRAL AND EASTERN EUROPE

Country	Population and GDP per capita (PPP) (2012 estimate) <sup>a,b</sup>	Number of patients with DM (IDF 2012 estimate) <sup>c</sup>	Adult DM prevalence (2012 estimate) <sup>c,d</sup>	Cost of DM <sup>e</sup>	Local SMBG reimbursement	Local SMBG guidelines
Bulgaria	7,254,000 (total) 5,703,000 (adult) \$14,312 GDP per capita	530,500 DM (adult), including 190,000 undiagnosed DM Local estimate: 420,000 T2DM (including 55,000 on insulin)	9.3% (national) 6.7% (comparative)	10.2% of total health budget (2011); \$532 per person with DM per year (2012)	Glucose meters fully reimbursed for all insulin-treated patients Children/adolescents/during pregnancy: 1,100 test strips/year fully reimbursed Insulin-treated (> 18 years of age): 150 test strips/year fully reimbursed	No special guidelines on SMBG Some SMBG recommendations included in the National Guidelines on Good Clinical Practice in Diabetes, developed by the Bulgarian Society of Endocrinology Croatian National Guidelines for treatment of DM regulate SMBG use
Croatia	4,402,000 (total) 3,307,000 (adult) \$17,810 GDP per capita (PPP)	225,400 DM (adult), including 93,700 undiagnosed DM Local estimate: 230,084 registered DM, including 90% with T2DM (26% on insulin alone, 19% on OAs+ insulin; 53% on OAs alone)	7.9% (national) 5.3% (comparative)	7.8% of total health budget (2011); \$1,441 per person with DM per year (2012)	Glucose meters fully reimbursed for all insulin-treated patients OA-treated: 100 test strips/year fully reimbursed Insulin-treated (once daily): 360 strips/year fully reimbursed Insulin-treated (twice daily): 720 strips/year fully reimbursed Insulin-treated (3 times daily): 1,100 strips/year fully reimbursed Insulin-treated (> 3 times daily): maximum 1,500/year fully reimbursed	
Czech Republic	10,553,000 (total) 8,083,000 (adult) \$27,191 GDP per capita (PPP)	605,900 DM (adult), including 251,900 undiagnosed DM Local estimate (2011): 825,382 registered DM, including 55,542 T1DM, 758,719 T2DM, 205,049 on insulin	7.5% (national) 5.6% (comparative)	8.0% of total health budget (2011); \$1,677 per person with DM per year (2012)	Glucose meters fully reimbursed for all insulin-treated patients; frequently distributed by manufacturers free of charge Lifestyle intervention only: 50 strips/year fully reimbursed OA-treated: 100 strips/year fully reimbursed Insulin-treated ( $\geq 3$ times daily): 400 strips/year fully reimbursed (with up to extra 600 upon request by diabetologist [up to extra 1,400 for children under 18 years of age]). There are no limits for strips during pregnancy.	No specific local SMBG guidelines are available, but general recommendations are $\geq 3$ daily measurements for T1DM and T2DM treated with 3 or more insulin injection per day or with insulin pump.
Hungary	9,962,000 (total) 7,519,000 (adult) \$19,638 GDP per capita (PPP)	578,100 DM (adult), including 240,300 undiagnosed DM Local estimate: 850,000 T2DM, 15% on insulin	7.7% (national) 6.1% (comparative)	8.6% of total health budget (2011); \$1,272 per person with DM per year (2012)	Glucose meters 50% reimbursed for patients on insulin $\geq 2$ times daily; frequently distributed by manufacturers free of charge Children/adolescents: 1,800 test strips/year 80% reimbursed Insulin-treated (twice daily): 400 strips/year 80% reimbursed Insulin-treated (3 times daily): 1,200 strips/year 80% reimbursed Insulin-treated ( $\geq 4$ times daily): 1,800 strips/year 80% reimbursed	Local guidelines for SMBG use have been formulated by the Hungarian Diabetes Association, most recently in 2011.
Poland	38,896,000 (total) 28,997,000 (adult) \$20,592 GDP per capita (PPP)	3,082,800 DM (adult), including 1,105,900 undiagnosed DM Local estimate (2011): 2,500,000 DM (90% T2DM) Data (2011) from National Health Fund (universal public payer): 1,996,996 treated pharmacologically (including 627,971 on insulin)	10.6% (national) 9.0% (comparative)	12.4% of total health budget (2011); \$1,145 per person with DM per year (2012)	Glucose meters are not reimbursed; distributed by manufacturers free of charge OA-treated: strips 70% reimbursed Insulin-treated ( $\leq 2$ times daily): strips 70% reimbursed Insulin-treated ( $\geq 3$ times daily): small flat fee (< 1€) for 50 strips In all cases, the number of strips provided is up to the prescribing physician. Up until 2011, test strips were virtually free and unlimited.	Well-defined local SBMG guidelines are published and updated yearly by Diabetes Poland.

(continued)

TABLE 4. (CONTINUED)

Country	Population and GDP per capita (PPP) (2012 estimate) <sup>a,b</sup>	Number of patients with DM (IDF 2012 estimate) <sup>c</sup>	Adult DM prevalence (2012 estimate) <sup>d,e</sup>	Cost of DM <sup>f</sup>	Local SMBG reimbursement	Local SMBG guidelines
Romania	21,347,000 (total) 16,312,000 (adult) \$12,808 GDP per capita (PPP)	Local estimate: ●10,134 DM ●674,383 on OA ●135,751 insulin-treated	9.3% (national) 7.7% (comparative)	10.8% of total health budget (2011); \$607 per person with DM per year (2012)	Glucose meters fully reimbursed for all insulin-treated patients Insulin-treated (<18 years of age): 600 strips/year fully reimbursed Insulin-treated (≥18 years of age): 400 strips/year fully reimbursed	No specific local SMBG guidelines are available, but general recommendations are ≥3 daily measurements for T12DM and 1–3 daily measurements for insulin-treated T2DM.
Serbia	7,566,000 (total) 7,183,000 (adult) \$10,405 GDP per capita (PPP)	673,800 DM (adult), including 241,700 undiagnosed DM 70,000–80,000 patients on insulin	9.4% (national) 7.7% (comparative)	11.0% of total health budget (2011); \$586 per person with DM per year (2012)	Glucose meters and test strips fully reimbursed for patients <18 years of age, those on multiple daily insulin injections/insulin pump therapy, and during pregnancy Patients on intensive insulin therapy are reimbursed: 50 strips/month Pregnant patients and children reimbursed for 150 strips/month	Local guidelines for SMBG have been in place since 2002 as part of the National Guidelines on Diabetes (updated in 2012).
Slovakia	5,439,000 (total) 4,170,000 (adult) \$24,249 GDP per capita (PPP)	279,500 DM (adult), including 116,200 undiagnosed DM Local estimate (2010): 336,552 registered DM patients; 87,983 on insulin	6.7% (national) 5.7% (comparative)	8.4% of total health budget (2011); \$1,744 per person with DM per year (2012)	Glucose meters fully reimbursed for all insulin-treated patients T1DM/insulin-treated T2DM (≥3 times daily): 900 strips/year (adults), 1,200 strips/year (children/students <25 years of age) fully reimbursed During pregnancy: 1,200 strips/year fully reimbursed Insulin-treated T2DM (≤2 times daily): 300 strips/year fully reimbursed OA-treated/lifestyle intervention only: 150 strips/year fully reimbursed	SMBG recommendations are included in the National Guidelines on Diabetes and in the official textbook on diabetes, developed by the Slovakian Diabetes Society.
Slovenia	2,055,000 (total) 1,565,000 (adult) \$28,195 GDP per capita (PPP)	174,800 DM (adult), including 72,700 undiagnosed DM Local estimate (2012): 135,000 DM; 16,000 on insulin only, 10,500 on OAs+ insulin, 53,000 on OAs only	11.2% (national) 8.1% (comparative)	11.3% of total health budget (2011); \$2,436 per person with DM per year (2012)	Glucose meters fully reimbursed for all insulin-treated patients Insulin-treated, once, twice, three times, and (>3 times daily: 200, 250, 550, and maximum of 700, respectively/3 months fully reimbursed During pregnancy and insulin pump therapy: 900 strips/3 months fully reimbursed	Slovenian National Guidelines for treatment of T2DM includes also SMBG, last updated 2011
Ukraine	45,453,000 (total) 34,432,000 (adult) \$7,374 GDP per capita (PPP)	1,311,335 DM (officially registered), estimated undiagnosed DM 1,099,201 No figures for number of patients on insulin	3.5% (national) 2.9% (comparative)	4.3% of total health budget (2011); \$332 per person with DM per year (2012)	Glucose meters fully reimbursed for children/adolescents and during pregnancy Children/adolescents/during pregnancy: 200 strips/year fully reimbursed	In 2012, leading specialists in endocrinology and health authorities developed a standardized clinical protocol of medical care for patients with T2DM, but this is not yet fully approved; however, it does include some SMBG recommendations.

Adult data are for the 20–79 year age range.

<sup>a</sup>Source for total population and GDP data was the IMF World Economic and Financial Surveys.<sup>91</sup> Source for adult population data was the IDF Diabetes Atlas, 5<sup>th</sup> ed.<sup>99</sup>

<sup>b</sup>Gross domestic product (GDP) based on purchasing-power-parity (PPP) per capita GDP (PPP takes into account differences in the cost of living between countries).

<sup>c</sup>Source for IDF estimates was IDF Diabetes Atlas, 5<sup>th</sup> ed.<sup>99</sup>

<sup>d</sup>National prevalence provides a measure of actual DM burden with a country. Comparative prevalence adjusts for age and allows between country comparisons independently of population age distribution.

<sup>e</sup>Sources were Diabetes. The Policy Puzzle: Is Europe Making Progress?, 3rd ed.<sup>100</sup> and IDF Diabetes Atlas, 5<sup>th</sup> ed.<sup>99</sup>

<sup>f</sup>DM, diabetes mellitus; IDF, International Diabetes Federation; OA, oral (glucose-lowering) agent; SMBG, self-monitoring of blood glucose; T1DM/T2DM, type 1/type 2 diabetes mellitus.

strips, in terms of both patient eligibility and the number of strips provided. In most countries, strips are reimbursed for patients on insulin therapy, but the number of strips may depend on the number of daily injections and other factors such as age (see Table 4). Some countries in the region still have no specific clinical guidelines on the use of SMBG.

## Recommendations

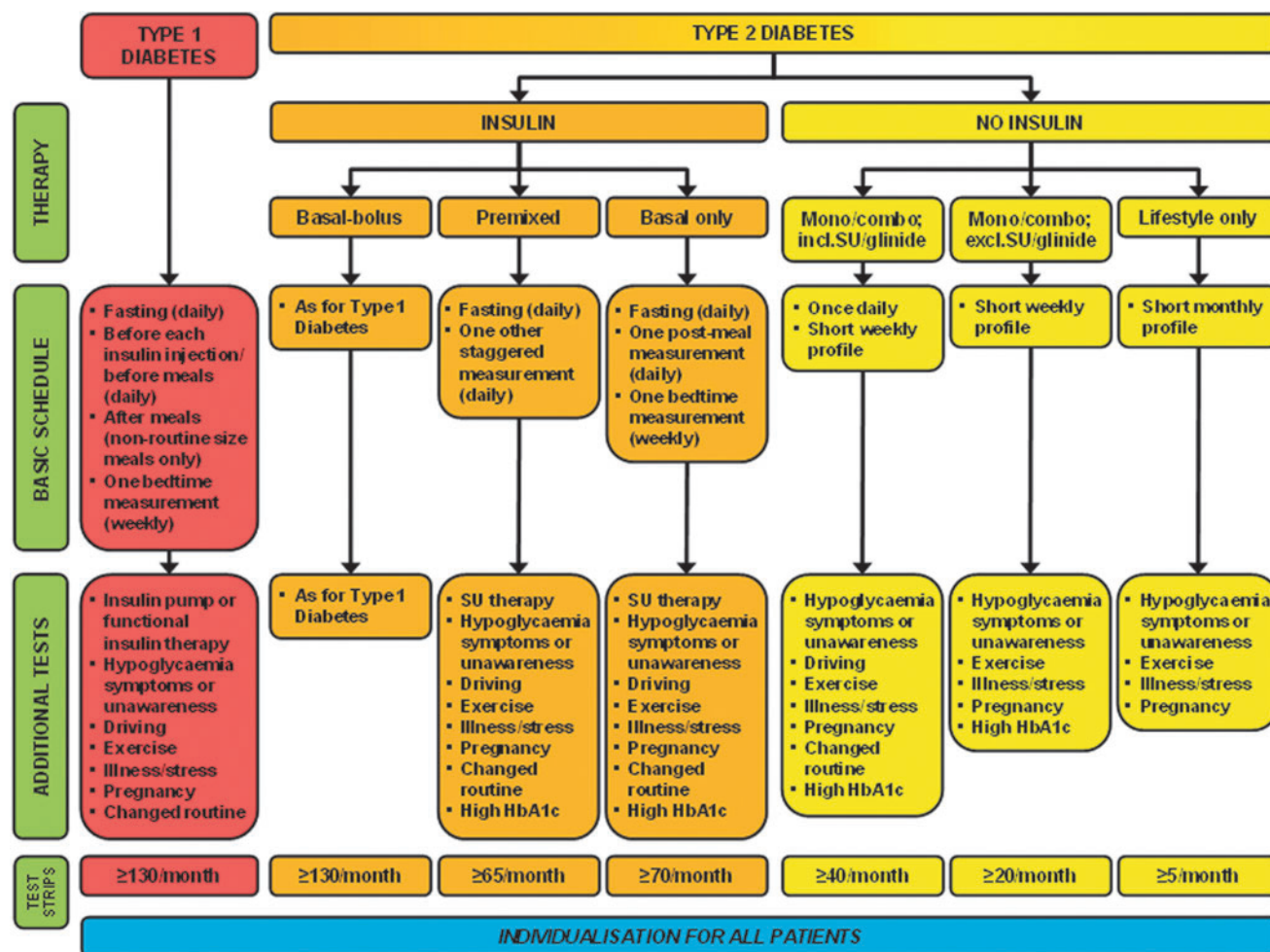
SMBG is an essential tool that should, as a minimum, be accessible to all patients with diabetes, including those with non-insulin-treated type 2 diabetes. Like other treatments, SMBG needs to be individualized by the physician in partnership with the patient, and guidelines can play an important role when deciding on an appropriate level of intervention. The ultimate goal of any SMBG strategy is to maximize the efficacy and safety of glucose-lowering therapies and to empower the patients to play a more active role in the management of their diabetes. Unfortunately, access to SMBG can be limited in many countries in our region of Central and Eastern Europe. To some extent, this may reflect the lack of local SMBG guidelines, which is in stark contrast to the extensive guidelines available for glucose-lowering drug therapy. As we come from similar historical, political, and social

environments, it seems appropriate for us to make some recommendations for SMBG in diabetes that would be applicable to the region as a whole (summarized in Figure 1). It should, however, also be stated that it would take major changes in several countries (most notably Bulgaria, Romania, and Ukraine) to introduce the following recommendations into routine practice. Nevertheless, we are convinced that these changes are necessary for the patients' well-being and that it is only a matter of time until clinical practice in our region changes in the directions outlined below.

The grading of the recommendations has been conducted according to the adopted system proposed by the U.S. Agency for Health Care Policy and Research as shown in Table 5.<sup>94</sup>

### Type 1 diabetes

It is impossible to treat type 1 diabetes safely without SMBG. Patients with type 1 diabetes are at risk of both severe hypoglycemic episodes and acute hyperglycemic crises, as well as the long-term microvascular risk associated with poor overall glycemic control. As such, SMBG is an integral part of type 1 diabetes management and crucial for optimizing the safety and efficacy of the complex insulin regimens required in these patients (Grade A). The minimum requirements for



**FIG. 1.** Consensus recommendations for self-monitoring of blood glucose in diabetes. HbA1c, glycated hemoglobin; SU, sulfonylurea.

TABLE 5. GRADING SYSTEM ADOPTED FROM THE PROPOSAL BY THE U.S. AGENCY FOR HEALTHCARE POLICY AND RESEARCH<sup>93</sup>

	<i>Description</i>
Level of evidence	
Ia	Evidence from a meta-analysis of randomized controlled trials
Ib	Evidence from at least one randomized controlled trial
IIa	Evidence from at least one controlled study without randomization
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from observational studies
IV	Evidence from expert committee reports or experts
Grade of recommendation	
A	Directly based on Category I evidence
B	Directly based on Category II evidence or extrapolated from Category I evidence
C	Directly based on Category III evidence or extrapolated from Category I or II evidence
D	Directly based on Category IV evidence or extrapolated from Category I, II, or III evidence

SMBG in patients with type 1 diabetes are (1) daily testing of fasting glucose, (2) premeal testing before every insulin injection, (3) postmeal testing after non-routine-size meals, and (4) at least one bedtime measurement per week (Grade C). This should be sufficient to obtain a full SMBG profile under normal conditions and to allow patients to identify periods of hyper- or hypoglycemia and to adjust insulin doses and diet accordingly. The bedtime measurement should help patients make adjustments to avoid nocturnal hypoglycemia. Postmeal testing addresses the potential risk of vascular complications, which is well documented in type 2 diabetes, but obviously cannot be excluded in patients with type 1 diabetes either.<sup>95</sup> However, additional testing should be implemented as often as required in patients experiencing symptoms of hypoglycemia or those with impaired hypoglycemia awareness, and therefore no limit should be imposed, in justifiable cases, on the number of test strips that a patient can access. Patients using insulin pump therapy and more intensive “functional” insulin regimens also usually require more frequent testing. Furthermore, additional testing should also be performed before driving, during pregnancy, during periods of illness, stress, or disruption of normal routine, and before, during, and after exercise, as well as more generally in any patient deemed to be at increased risk of hypoglycemia (Grade A).

#### *Insulin-treated type 2 diabetes*

Patients with type 2 diabetes on insulin therapy represent a heterogeneous group, as insulin regimens can vary widely from a single daily injection of long-acting insulin (typically added to existing oral glucose-lowering therapy) to the complex basal-bolus regimens used in type 1 diabetes. Furthermore, the progressive nature of type 2 diabetes and the frequent need for intensification of therapy mean that SMBG requirements may evolve over time. As well as an increase in the need for insulin therapy with more advanced disease, patients may become more prone to hypoglycemia due to impaired glucose counterregulation (associated with declining insulin production, increasing glucagon release, and attenuated increase in adrenaline) and the development of hypoglycemia unawareness (the result of attenuated increase in sympathoadrenal activity).<sup>96</sup> As such, it is difficult to make general SMBG recommendations for this patient group, and the pattern and frequency will depend on the particular insulin regi-

men and use of other specific glucose-lowering drugs, as well as the intrinsic risk of hypoglycemia. For patients on a single injection of long-acting insulin, the minimum SMBG requirement should be two measurements per day (a fasting measurement and one postmeal measurement), plus one bedtime measurement per week (Grade C). Morning fasting measurements are important for adjusting insulin doses to achieve target fasting blood glucose, and a single postmeal measurement should help to determine if postmeal glucose control is adequate (Grade C). For patients on premixed insulins, the minimum should be a fasting measurement plus one postmeal measure each day (using a staggered pattern by testing after different meals on different days). Patients on insulin who are also receiving sulfonylurea or glinide oral agent therapy will require additional testing owing to the increased risk of hypoglycemia with this combination. For patients on basal-bolus insulin regimens, the recommendations should mirror those for type 1 diabetes. Everyday circumstances and other factors contributing to an increased risk of hypoglycemia (e.g., illness, exercise, etc.) should also be taken into consideration. Furthermore, if the HbA1c level remains elevated in spite of good fasting glucose control, more postmeal SMBG measurements may be required to determine the extent of postmeal glucose control.

#### *Non-insulin-treated type 2 diabetes*

For patients receiving glucose-lowering drugs other than insulin, the pattern of SMBG testing should be dictated by the risk of hypoglycemia associated with specific agents, as well as the other factors contributing to hypoglycemia risk. For patients receiving agents known to have a low propensity to cause hypoglycemia (e.g., metformin, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, glucagon-like peptide-1 receptor agonists), either as monotherapy or in combination with each other, a short weekly SMBG profile (consisting of four or five measurements) is usually adequate (Grade C). However, if therapy includes higher-risk agents (i.e., sulfonylureas or glinides), an additional single daily test is recommended in order to detect episodes of hypoglycemia (Grade C). For patients being treated with lifestyle intervention alone (i.e., not receiving any glucose-lowering drug therapy), a short SMBG profile performed once per month is usually sufficient (Grade D). In all patients with non-insulin-treated type 2 diabetes, additional testing may be required



during illness or other unusual circumstances or if glycemic control is poor (Grade B).

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