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The role of self-monitoring of blood glucose in the care of people with diabetes: report of a global consensus conference

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Self-monitoring of blood glucose (SMBG) is an underutilized but integral part of disease management for patients with both type 1 and type 2 diabetes. Guidelines on the recommended frequency and timing of SMBG vary among international diabetes associations, and patients are often unaware of actions they should take in response to SMBG results. In response to this, a global consensus conference of recognized diabetes experts convened to clarify the role of SMBG as a tool to help optimize glycemic control (e.g., complementing information provided by hemoglobin A1c, detecting postprandial excursions, identifying glucose patterns, and providing patients feedback on lifestyle and medications) while minimizing hypoglycemia and maintaining quality of life. The consensus panel also sought to reinforce the importance of appropriate and systematic patient and provider response to the collected SMBG data. A set of 16 consensus statements was approved by the panel. This article presents the 16 statements together with some brief rationale for their inclusion.

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KEYWORDS:
Consensus conference; Glycemic control; Glycosylated hemoglobin; Self-monitoring of blood glucose; Glucose monitoring; Glucose profile

Diabetes affects nearly 200 million people worldwide, and, without extensive global intervention, this number is expected to approach 350 million by 2030.1,2 Because of its broad impact, diabetes is estimated to account for nearly 10% of all healthcare expenditures.2 Numerous controlled clinical trials in patients with either type 1 or type 2 diabetes have demonstrated that improved control of blood glucose reduces the risk of diabetic complications.3–6 Nevertheless, data from the National Health and Nutrition Examination Surveys (NHANES) show that glycemic control in the United States did not improve between the assessment periods of 1988 to 1994 (NHANES III) and 1999 to 2000.7,8 Similar findings have also been reported in the Netherlands, United Kingdom, and Sweden.9–11 Clearly, different approaches or better implementation of existing approaches are needed to help patients understand and achieve the target glycemic control recommended by global diabetes organizations to reduce the serious complications associated with poor control.

Physicians and scientific societies that evaluate diabetes management agree that self-monitoring of blood glucose (SMBG) adds valuable information that complements the use of glycosylated hemoglobin (HbA1c).
testing to optimize glycemic control.\textsuperscript{12–17} HbA\textsubscript{1c} is often used as an index of long-term (2- to 3-month) glycemic control and serves as a reliable predictor of microvascular, neuropathic, and macrovascular complications of diabetes.\textsuperscript{12,18–22} Because the HbA\textsubscript{1c} value is a time-averaged result, it also has certain limitations as a marker for glycemic control. It does not provide “real-time” feedback to patients or physicians and thus, cannot reveal transient excursions in glycemic control, such as postprandial hyperglycemia or severe hypoglycemia, which may require short-term adjustments in treatment regimens.\textsuperscript{23} In contrast, SMBG allows for immediate patient feedback regarding glycemic control. It allows prompt determination of hypoglycemia or hyperglycemia that not only can improve patients’ safety but also can motivate them to make appropriate changes in diet, exercise, and insulin dosing.\textsuperscript{23–25} The effectiveness of oral antidiabetic agents can also be assessed by SMBG, thereby allowing for more timely adjustment of pharmacologic therapy than possible with HbA\textsubscript{1c} monitoring alone.

Substantial disparity exists between actual and recommended frequency of SMBG testing, especially by patients at highest risk for complications.\textsuperscript{26,27} One factor contributing to this disparity is the lack of a consensus on recommendations for self-monitoring regimens in defined patient groups, a problem driven by a paucity of well-designed clinical studies. Clear, detailed recommendations that describe how often, when, and under what conditions SMBG should be used would help physicians, diabetes educators, and patients establish comprehensive diabetes action plans for attaining and maintaining daily glycemic control.

A global consensus conference on SMBG, hosted by the International Diabetes Center (IDC), a World Health Organization (WHO) Collaborating Center for Diabetes Education and Translation, was convened in Minneapolis, Minnesota, on October 29–30, 2004 to develop just such a consensus. This international panel of recognized experts included representatives of the WHO, the IDC, the American Association of Diabetes Educators (AADE), and the Council for the Advancement of Diabetes Research and Education (CADRE), as well as diabetes specialists from various countries. In addition to their own clinical experience, the participants evaluated new and existing evidence regarding the role of SMBG in improving glycemic control. The panel was charged with the following 4 key tasks: (1) to reach consensus on the role of SMBG in identifying or avoiding glycemic excursions; (2) to provide guidance regarding the most effective method of glucose monitoring and supporting interventions to achieve optimal glycemic control; (3) to evaluate clinical evidence (including new studies) regarding the benefit of SMBG for patients with type 2 diabetes and to provide specific recommendations for testing in this population; and (4) to provide consensus recommendations for specialists, primary care physicians, diabetes educators, and patients with diabetes to guide the successful implementation of SMBG. The conference produced 16 consensus statements, which are summarized below. Brief explanations of how the panel supported these statements also are provided.

**Consensus statements**

**A call to action**

1. Failure to achieve metabolic goals—including glycemic control—is associated with serious consequences and substantial costs.
2. Control of blood glucose has been shown to improve clinical outcomes and quality of life in people with diabetes.
3. Worldwide, optimal glycemic control is not achieved in most people with diabetes; a re-evaluation of our approach to management is needed.

Substantial evidence from controlled clinical trials indicates that improved glycemic control reduces the risk of diabetic complications and attendant healthcare costs, and improves patient quality of life.\textsuperscript{4,21,28–32} The Diabetes Control and Complications Trial (DCCT) demonstrated the advantages of improved glycemic control in reducing microvascular complications.\textsuperscript{4} An emerging body of evidence supports the benefit of glycemic control in reducing macrovascular complications.\textsuperscript{21,22,33–35} Yet numerous studies, including NHANES 1999 to 2000, have shown that many patients with diabetes still do not achieve good glycemic control.\textsuperscript{7} In the NHANES study, for example, only 37% of patients with diabetes achieved glycemic control, as defined by an HbA\textsubscript{1c} <7%.\textsuperscript{7}

**Methods for monitoring glycemic control**

4. Both HbA\textsubscript{1c} and SMBG are essential for assessing glycemic control:
   - HbA\textsubscript{1c} assesses long-term glycemic control, has been shown to be a predictor of diabetes complications, and reflects the combination of preprandial and postprandial glucose.
   - SMBG is required to determine recent patterns of preprandial and postprandial glucose.
5. SMBG should be recommended to all patients with diabetes as an integral part of an overall diabetes management program because it provides:
   - Real-time, reliable blood glucose concentrations
   - Ability to assess pre- and postprandial hyperglycemia
   - Improved safety through detection of hypoglycemia
   - Possibility of timely therapeutic adjustments
6. SMBG is an essential component for insulin-treated patients with diabetes, both for safety reasons (detection of
hypoglycemia) and enhancement of effectiveness of insulin through dose adjustment.

7. Urine glucose testing is not recommended as a replacement for SMBG; its use should be restricted to those rare situations where there is no access to SMBG.

The HbA1c assay provides a value that is proportional to the average blood glucose concentration over the lifespan of the typical red cell (2 to 3 months). HbA1c provides an assessment of long-term blood glucose control while “averaging out” the short-term swings (highs and lows) of daily blood glucose fluctuations. SMBG, on the other hand, provides feedback on the effects of diet, exercise, and stress on the actual blood glucose levels at the time of testing, allowing a patient to determine immediately the pre- and postprandial blood glucose fluctuations on any given day. It allows a patient to confirm any suspected hypo- or hyperglycemia so that immediate action can be taken. Postprandial SMBG provides immediate feedback on diet and assists in the proper preprandial dosing of short-acting insulin analogs. SMBG improves a patient’s problem-solving skills for preventing, detecting, or treating out-of-range blood glucose concentrations, especially during illness. In these ways, SMBG facilitates patient self-management while guiding therapeutic decision-making by healthcare professionals. Because it adds significant safety information about daily glucose control, SMBG by all patients with insulin-treated diabetes is recommended by several professional groups.

The level of glucose in a urine sample is a measure of how much glucose was cleared by the kidneys during the interval since the previous urine voiding and is affected by the patient’s renal threshold for glucose. Results will be misleading whenever this threshold is decreased (e.g., pregnancy) or increased (e.g., aging). Urine glucose testing, while historically useful for indicating episodes of hyperglycemia, provides little information about real-time blood glucose concentrations, especially during illness. Furthermore, urine testing does not differentiate among hypoglycemia, euglycemia, or even mild-to-moderate hyperglycemia; it will give a negative (satisfactory) result in each of these instances. Urine testing cannot replace SMBG for the goal of achieving tight glycemic control to prevent diabetic complications, and it should only be used when blood glucose testing is not feasible.

Specific recommendations for SMBG frequency

8. Current guidelines for the use of SMBG testing in glycemic control should contain more specific recommendations regarding frequency, timing, and integration of SMBG into the management strategy of patients, especially those with type 2 diabetes.

9. Recommended frequency of SMBG testing will depend on:
   - Type of therapy
   - Degree of glycemic control

   • Risk of hypoglycemia
   • Need for short-term adjustment of treatment
   • Special situations (before and during pregnancy, intercurrent illness, hypoglycemia unawareness, etc.)

10. Recommended frequencies for SMBG in order to optimize or advance therapy are as follows:
   - For patients at or above target managed with oral agents plus once-daily insulin, once-daily insulin alone,* or oral agents alone: ≥2 times daily
   - For patients at target managed with once-daily insulin alone* or oral agents alone: ≥1 time per day, including a weekly profile
   - For patients at target managed nonpharmacologically: ≥1 weekly profile

11. Recommended frequencies should be varied for individual patients especially those not at glycemic target or in the setting of other special clinical circumstances.

Although the importance of frequent SMBG testing is well established for adjusting insulin doses, the value of SMBG among patients with type 2 diabetes not treated with insulin has been more controversial due, in part, to a paucity of well-designed, longitudinal studies. Recent data from randomized controlled trials and a meta-analysis of randomized controlled trials, together with preliminary results from a large, observational cohort study, support the use of SMBG in these patients. The most current recommendations from various diabetes organizations vary widely in their suggestions for method, technique, timing, and frequency of SMBG by patients with type 2 diabetes not using insulin. More detailed information is also needed for patients with diabetes treated with insulin; current asso-

*Once-daily insulin alone is generally less effective for achieving target blood glucose than oral agents plus once-daily insulin or multiple daily insulin injections with or without oral agents.
cation guidelines typically indicate only that SMBG practices should be determined by the needs of the individual patient. No single guideline would be appropriate for all patients. Patients and physicians must work together to set and adjust glycemic targets and self-monitoring practices to reflect the unique situation of each patient. Importantly, the value of SMBG is not only in evaluating glucose control but also in helping patients learn how various medications and/or lifestyle choices affect their glucose levels. Using SMBG values as a teaching tool maximizes their value.

Considerable variation exists in the testing regimens suggested by the various diabetes groups, but after surveying all the available data, the panel reached a consensus. Testing ≥3 to 4 times daily is appropriate for patients at or above glycemic target taking multiple daily injections of insulin or using insulin pumps. Testing ≥2 times daily is appropriate for patients above glycemic target managed with oral agents plus once-daily insulin, once-daily insulin alone, or oral agents alone. For patients at glycemic target and managed with once-daily insulin alone or oral agents alone, self-monitoring ≥1 time daily, including a weekly profile, is recommended to guide nutrition and physical activity, detect postprandial hyperglycemia, and prevent hypoglycemia. The same once-daily self-monitoring frequency is recommended for patients at glycemic target managed with oral agents plus once-daily insulin. However, more frequent profiles should be considered. Patients managed nonpharmacologically, whether at or above glycemic target, should perform ≥1 weekly profile in order to guide nutrition and physical activity and to trigger the addition of pharmacologic therapy if the patient is consistently above glycemic target. A blood glucose profile should include both pre- and postprandial measurements on ≥1 day of the week.

In special cases, such as preconception and during pregnancy, acute or intercurrent illness, or lack of good glycemic control, the frequency of SMBG should be increased. In other circumstances, such as an elderly patient controlled through lifestyle modifications, this frequent testing may be unnecessarily invasive.

**Specific recommendations for SMBG timing**

12. SMBG should be performed at various times of the day, including preprandially and 1 to 2 hours postprandially, to obtain glucose profiles.

13. If fasting and preprandial glucose levels are controlled, but HbA1c levels are above target, controlling postprandial glucose should be emphasized.

Profiling of blood glucose through self-monitoring at various times of the day has been recommended to provide an overall view of fasting, preprandial, and postprandial glycemic control. Fasting blood glucose has long been used to assess glycemic control, particularly in patients with type 2 diabetes not treated with insulin, but studies have shown the additional value of postprandial measurements. Although fasting hyperglycemia is more prominent in patients with poor control (HbA1c ≥8.4%), most individuals with HbA1c values between 6.0% and 7.0% have normal fasting glucose levels but abnormal 2-hour postprandial levels. Additional postprandial testing is necessary in these fairly well controlled patients in order to minimize the risk for cardiovascular disease associated with postprandial hyperglycemia. Preprandial measurements also provide valuable information about fluctuations in daily glucose control and can help assess risk of hypoglycemia.

**Successful implementation of SMBG**

14. In addition to its utility as a tool for evaluation of glycemic control, SMBG is an educational tool to inform patients and healthcare professionals about the effects of lifestyle (including both nutrition and exercise), behavioral, and/or medication changes.

15. Ongoing education and reinforcement regarding the use and interpretation of SMBG by patients and healthcare professionals are essential.

16. SMBG should be used by patients and healthcare professionals in conjunction with a diabetes management action plan.

The majority of evidence and most diabetes guidelines emphasize the importance of SMBG in the management of diabetes. SMBG is a self-care behavior, and patients benefit from ongoing education to help them understand the role that self-monitoring can play in helping attain optimal glycemic control. The AADE had identified monitoring as 1 of the 7 AADE self-care behaviors. Diabetes educators, where available, should be approached for ongoing education to maximize the benefit of self-monitoring. A critical step in achieving optimal blood glucose monitoring behavioral goals is identifying and resolving barriers to blood glucose monitoring. By demonstrating the effects that medications, diet, and exercise have on blood glucose levels, self-monitoring can motivate patients to become active participants in their own care. A comprehensive diabetes management plan is essential in achieving good glycemic control through SMBG. When diabetes self-management education is included as part of the action plan, the patient can learn accurate and reliable monitoring skills, proper interpretation of the results, and how to use the results to adjust medical nutrition therapy, exercise, or pharmacologic therapy to achieve specific glycemic goals. Furthermore, successful implementation of SMBG should include a return demonstration to assess patient technique.

**Summary**

By presenting these consensus statements, the conference participants hope to provide physicians with timely information to improve glycemic control in all patients with diabetes.
Appendix

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References


The importance of tight glycemic control

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KEYWORDS: Hypoglycemia; Macrovascular; Postprandial; Self-monitoring of blood glucose

Macrovascular complications of diabetes are the leading cause of morbidity and mortality in patients with diabetes and may begin well before diabetes is diagnosed. The precise mechanism of how postprandial hyperglycemia contributes to the pathogenesis of cardiovascular disease is not fully known but may be a result of direct effects on the vasculature. Several epidemiologic studies have suggested that increased glycemic exposure, especially postchallenge or postprandial hyperglycemia, is an independent risk factor for macrovascular disease with no apparent upper or lower threshold. Evidence is emerging that this association is also present in the prediabetic and nondiabetic states. In fact, therapies targeting postprandial hyperglycemia have shown reductions in cardiovascular events in patients with impaired glucose tolerance. Meal-related self-monitoring of blood glucose can inform patients and their healthcare providers about postprandial glycemic excursions so that diet, exercise, or medications can be adjusted.

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Control and complications

Controlled clinical trials in patients with type 1 and type 2 diabetes have conclusively demonstrated that improved glycemic control (as reflected by hemoglobin A1c [HbA1c] levels) reduces the onset of microvascular complications of diabetes, slows their progression, and may improve quality of life.1–5 The evidence of the importance of glycemic control for avoiding microvascular complications, based on interventional studies, is stronger than that for macrovascular complications. Nevertheless, numerous in vitro and in vivo studies have provided plausible molecular mechanisms through which hyperglycemia may cause cardiovascular disease.19–28 These include interactions between increased glucose fluxes through the polyol and glucosamine pathways, increases in nonenzymatic glycation products and glycosylation of certain proteins, activation of diacylglycerol and protein kinase C, decreased production of nitric oxide, and increases in the generation of free radicals (ox-
idative stress). Hyperglycemia itself may directly increase protein kinase C and diacylglycerol. Activation of protein kinase C and increased diacylglycerol promote expression, formation, and enhanced activity of transforming growth factor–β, type IV collagen, fibronectin, vascular endothelial growth factor, endothelin-1, caldesmon, plasminogen activator inhibitor–1, phospholipase A₂, prostaglandin E₂, and intercellular adhesion molecules. These have been identified as playing a role in basement membrane thickness, extracellular matrix formation, angiogenesis, increased vascular permeability, smooth muscle cell proliferation, increased inflammatory cell adhesion, and decreased fibrinolysis.

In addition, hyperglycemia will lead to glycosylation of extracellular proteins (such as low-density lipoprotein [LDL], which renders it more oxidizable and more atherogenic) and to the generation of free radicals and advanced-glycation end products. Binding of advanced-glycation end products to receptors on endothelial, smooth muscle, and fibroblast cells has been shown to lead to increased vascular permeability, increased coagulability, decreased thrombolysis, cell proliferation, and increased production of extracellular matrix proteins such as fibronectin, type IV collagen, laminin, and proteoglycans. Generation of free radicals by hyperglycemia may promote atherogenesis through peroxidation of LDL leading to a more atherogenic molecule, by oxidation of fibrinogen leading to products that enhance coagulation, by increasing platelet activation by collagen, and by decreasing production of nitric oxide.

Further, 2 independent meta-analyses and a large observational study have concluded that increases in glycemic exposure increase the risk for developing cardiovascular disease. These studies indicate that a 1% increase in HbA₁c values above 5% raises the risk for cardiovascular disease by about 20%. In the European Prospective Investigation of Cancer and Nutrition (EPIC)–Norfolk Study, individuals with an HbA₁c of 5.0% to 5.5% had a 2.5-fold increased risk of dying from cardiovascular disease, compared with individuals having HbA₁c levels ≤5.0%. It seems reasonable to conclude that glycemic exposure is an independent risk factor for macrovascular disease and that it is a continuous risk factor with no apparent threshold. The implication of the last conclusion is that glycemia—even in the nondiabetic range—can promote cardiovascular disease.

There is a lack of consensus with regard to the issues of (1) what should be the recommended targets for glycemic control, (2) how to achieve these targets without unacceptable adverse effects (e.g., hypoglycemia), and (3) the relative roles of fasting versus postprandial hyperglycemia.

**Therapeutic goals**

HbA₁c values are considered the “gold standard” for evaluating the long-term adequacy of glycemic control in people with diabetes. Recommended HbA₁c targets from a variety of diabetes professional associations are discussed in detail in the article by Renard in this supplement. Glycemic targets from selected organizations are presented in Table 1.

Attempts to achieve the lowest HbA₁c possible without unacceptable adverse effects, which is recommended by the Council for Advancement of Diabetes Research and Education (CADRE) and the Canadian Diabetes Association (CDA) may achieve the best cardiovascular outcomes. Data from the Third National Health and Nutrition Examination Survey (NHANES III) showed that the average HbA₁c level in people with normal glucose tolerance was 5.0%, whereas the EPIC-Norfolk Study demonstrated a substantial increase in cardiovascular mortality for individuals with HbA₁c values between 5.0% and 5.5% versus those with values <5.0%. These data suggest that earlier interventions than currently recommended would substantially reduce glycemie exposure in individuals at risk. Thus, unless there are compelling reasons to do otherwise, additional therapeutic steps should be taken if the HbA₁c is >6.0%. This recommendation is based on the premise that glycermia is a continuous risk factor for cardiovascular disease—the major cause of morbidity and mortality for patients with type 2 diabetes.

**Importance of fasting and postprandial hyperglycemia**

HbA₁c levels reflect total glycemic exposure during the previous 2 to 3 months and include both fasting and postprandial plasma glucose levels. For individuals with HbA₁c levels approximately <8.4%, daylong glycermia is largely determined by postprandial plasma glucose levels and contributes more to HbA₁c values than do fasting plasma glucose levels. As HbA₁c levels increase from 4% to 7%, postprandial glucose levels increase at a rate roughly 4 times faster than fasting plasma glucose levels. Individuals with HbA₁c levels of approximately 6.0% and approximately 7.0% have comparable fasting plasma glucose levels and differ only in their postprandial values. Most individuals who have hyperglycemia after meals (with normal fasting or premeal levels, or impaired fasting glucose) will, on average, have HbA₁c levels between 5.0% and 6.0%. Daylong glycermia in individuals with HbA₁c values of 5.0% averages approximately 100 mg/dL (5.55 mmol/L) but for individuals with HbA₁c values of approximately 7%, daylong glycermia levels are nearly twice as high (i.e., approximately 170 mg/dL [9.44 mmol/L]).

Considerable epidemiologic data indicate that isolated postprandial hyperglycemia increases the risk of cardiovascular disease. There are no data indicating the unique effects of postprandial hyperglycemia on the complications of diabetes. Its importance rests on the fact that it constitutes the bulk of glycemic exposure for most individuals who develop cardiovascular disease, and its control can be the rate-limiting factor for reducing glycemic risk for cardiovascular disease. Moreover, recent studies specifically targeting postprandial hyperglycemia have demonstrated that reducing postprandial hyperglycemia can reduce cardiovascular events in patients with impaired glucose tol-
Thus, in the vast majority of patients with type 2 diabetes, glycemic control can be treated to target without unacceptable side effects.

A major issue is whether optimal glycemic control can be achieved without unacceptable adverse effects. Weight gain and hypoglycemia are the major adverse effects observed with attempts to optimize glycemic control. Both the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that the beneficial effects of improved glycemic control outweigh the potentially deleterious effects of weight gain. It should be noted, however, that the effects of weight gain were limited to the length of the observation period in both studies and did not extend over the patient’s lifetime.

Hypoglycemia can be a major problem for people with type 1 diabetes. However, except for aged individuals and those with renal insufficiency, severe hypoglycemia is extremely uncommon in patients with type 2 diabetes who are treated intensively. For example, in the Kumamoto Study of patients with type 2 diabetes who were intensively treated with a basal bolus insulin regimen, no severe hypoglycemia was observed. Moreover, in the recent Treat-to-Target Trial, in which basal insulin was added to oral hypoglycemic agents, levels of <7.0% were achieved with only about 2% of patients having an episode of severe hypoglycemia. Finally, in the Veterans Affairs Affairs Cooperative Study in Type 2 Diabetes (VA-CSDM), levels <7.3% were achieved with no weight gain, and the incidence of severe hypoglycemia (i.e., coma or requiring the assistance of another person for recovery) was only 5% of that observed in the DCCT. Thus, in the vast majority of patients with type 2 diabetes, glycemic control can be treated to target without unacceptable adverse effects.

### Table 1: Targets for glycemic control from various professional diabetes associations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Target HbA1c (%)</th>
<th>Target FPG mg/dL (mmol/L)</th>
<th>Target PPG mg/dL (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADA</td>
<td>&lt;7.0</td>
<td>90–130 (5.0–7.2)</td>
<td>&lt;180 (&lt;10.0)</td>
</tr>
<tr>
<td>CDA</td>
<td>≤7.0</td>
<td>Most patients: 70–130 (4.0–7.0)</td>
<td>Most patients: 90–180 (5.0–10.0)</td>
</tr>
<tr>
<td>AACE/ACE</td>
<td>≤6.5</td>
<td>Normal range: 70–110 (4.0–6.0)</td>
<td>Normal range: 90–145 (5.0–8.0)</td>
</tr>
<tr>
<td>ANAES</td>
<td>≥6.5</td>
<td>&lt;110 (&lt;6.1)</td>
<td>&lt;140 (&lt;7.8)</td>
</tr>
</tbody>
</table>

**A new approach is needed**

During the past decade, clinical trials have demonstrated the importance of glycemic control in preventing and reducing the complications of diabetes, and several new therapeutic agents have become available to improve (metformin, thiazolidinediones, insulin analogs) and monitor (less painful and continuous monitoring devices) glycemic control in patients with type 2 diabetes. Furthermore, optimization of glycemic control has been shown to be cost-effective. Several likely explanations can be cited, including (1) lack of translation of evidence-based results into clinical practice; (2) lack of time and resources due to reimbursement considerations, for physicians to treat patients with diabetes; (3) misguided preconceptions (e.g., that insulin resistance is the primary cause of type 2 diabetes and that hyperinsulinemia causes cardiovascular disease); (4) suboptimal application of current therapeutic modalities; (5) patients’ economic, education, and adherence issues; and (6) lack of consensus on treatment goals and assessment methods.

Most clinicians are not aware of emerging data identifying glycemia as a continuous risk factor for cardiovascular disease. This is true for overall hyperglycemia as well as for postprandial glucose elevations. Patients with type 2 diabetes have numerous cardiovascular risk factors (e.g., obesity, hypertension, and hyperlipidemia) that require polypharmacy and counseling. These are time-consuming tasks, and optimal results require a team approach that may not be widely available. Many patients do not understand the relatively low risk of hypoglycemia in type 2 diabetes. Patients with diabetes have actually increased. Several likely explanations can be cited, including (1) lack of translation of evidence-based results into clinical practice; (2) lack of time and resources due to reimbursement considerations, for physicians to treat patients with diabetes; (3) misguided preconceptions (e.g., that insulin resistance is the primary cause of type 2 diabetes and that hyperinsulinemia causes cardiovascular disease); (4) suboptimal application of current therapeutic modalities; (5) patients’ economic, education, and adherence issues; and (6) lack of consensus on treatment goals and assessment methods.

A new approach is needed.
ical inactivity are largely responsible for the insulin resistance found in patients with type 2 diabetes, adherence and maintenance of recommendations for lifestyle changes are poor. Thus, after 3 to 6 months, when adequate glycemic control has not been achieved, a single oral agent is prescribed. After another 3 to 6 months when adequate glycemic control still is not achieved, a second oral agent is added. After another 3 to 6 months, a third oral agent or insulin may be added. Thus, ≥2 years may elapse before a patient is on an adequate regimen.

An alternative approach is to take into consideration the patient’s presenting HbA1c level and the effectiveness of therapeutic agents and diet, exercise, and monitoring. In general, oral agent monotherapy will lower HbA1c by 1.5% to 2.0%, and dual oral agent therapy will lower HbA1c by 2.5% to 3.0%. Assuming that the goal is an HbA1c of 6.0%, it therefore follows that a patient with an initial HbA1c of 8.0% may be successfully managed with monotherapy. Those patients with presenting HbA1c levels between 8.0% and 9.0% may require initial dual therapy; those with initial HbA1c levels >9% may require 2 oral agents plus a basal insulin. This new approach can reduce the time to optimize glycemic control and, thus, reduce glycemic exposure. In terms of glucose monitoring in patients with type 2 diabetes, if fasting plasma glucose levels are in range but HbA1c values are not, postprandial hyperglycemia is obviously the problem and needs to be monitored so that specific meal-related therapy can be introduced.

Summary

In patients with diabetes, failure to achieve metabolic goals—including glycemic control—is associated with serious consequences and substantial costs. Postprandial hyperglycemia is associated with complications in patients with diabetes; controlling postprandial hyperglycemia is particularly important as patients approach normal HbA1c levels. Tight control of blood glucose has been shown to improve clinical outcomes and quality of life in patients with diabetes. Timely attention to these issues is required. According to data from NHANES III, glycemic control in the United States has worsened over the last decade, necessitating a reevaluation of our approach to therapy.49,50

References

Monitoring glycemic control: the importance of self-monitoring of blood glucose

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Several methods, each with differing utility and limitations, exist for monitoring glycemic control. Hemoglobin A1c (HbA1c) is considered the standard measure of long-term glycemic control, and HbA1c levels are strongly associated with complications of diabetes. However, HbA1c does not provide “real-time” information about individual hyperglycemic or hypoglycemic excursions. Urine glucose testing is noninvasive and inexpensive, but it is dependent on the patient’s individual renal threshold and can only detect glucose concentrations above this threshold. As such, urine testing cannot be recommended for diabetes management that aims for near-normoglycemia. Self-monitoring of blood glucose (SMBG) complements HbA1c by providing real-time blood glucose data. It is an educational tool for both patients and their healthcare providers to understand the effects of diet, exercise, and medications on day-to-day glycemic control. However, guidelines from various international diabetes organizations vary in their level of specificity regarding the frequency and timing of self-monitoring. SMBG should be implemented for all patients as part of an overall diabetes management plan that includes specific instruction on how, when, and why to test.

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Glycemic control; Glycemic excursions; Hemoglobin A1c; Hypoglycemia; Self-monitoring of blood glucose; Urine glucose

Assessment of glycemic control is a crucial element of diabetes care. Reliable information about glycemic variations allows physicians and patients to evaluate the effect of treatment on restoration and maintenance of blood glucose to within the physiologic range. Monitoring of glycemic status allows adjustment in diet, exercise, and medications to achieve optimal blood glucose control, as well as an assessment of risks of hypoglycemia or hyperglycemia and of complications related to chronic hyperglycemia.1

A variety of modalities, with differing utility and limitations, exist for use by healthcare providers and patients to indicate and monitor glycemic status. The appropriate role, frequency, timing, and implementation of each in diabetes management have been addressed and reassessed in a variety of current guideline recommendations.

Hemoglobin A1c

Hemoglobin A1c (HbA1c) is a stable fraction of hemoglobin resulting from linkage of glucose to erythrocyte hemoglobin. Because the average erythrocyte lifespan is 120 days,2 the HbA1c level is proportional to ambient blood glucose levels during the previous 2 to 3 months. For this reason, HbA1c testing is usually performed quarterly or more frequently. Because lower HbA1c levels have been found to be strongly associated with decreased microvascular and neuropathic complications of diabetes, HbA1c levels have been
used as an index of long-term glycemic control. The current American Diabetes Association (ADA) goal for HbA1c is <7%, whereas the American Association of Diabetes Educators (AADE) has recently joined the American College of Endocrinology (ACE) and the French Agence Nationale d’Accréditation et d’Evaluation en Santé (ANAES; the French National Agency for Accreditation and Evaluation in Healthcare) in adopting a more stringent goal of ≤6.5%. 

Because the HbA1c level is a reliable predictor of future complications of diabetes, periodic monitoring allows healthcare providers and patients to be aware of overall glycemic status over the past few months and to adjust or intensify therapy, management, and treatment adherence accordingly. More frequent HbA1c monitoring (3 tests in the span of 8 months) has been associated with better glycemic control compared with less frequent monitoring.

Although the HbA1c value represents a global estimation of treatment success in diabetes control during the past few months, it indicates only a historical integrated measure of blood glucose; it does not reflect specific variations or wide excursions in blood glucose concentrations during that period. Because the HbA1c result is an average value rather than a “real-time” measurement, frequent blood glucose shifts that may characterize poor glycemic control in daily life are not detected and patients with apparently good control may have large glycemic excursions on a daily basis. Use of HbA1c as the sole means of measuring glycemic control does not provide patient feedback about the circumstances surrounding such changes that may necessitate modification of lifestyle. Furthermore, risk of hypoglycemia cannot be identified and appropriate alteration of treatment may be delayed. In the intensively treated arm of the Diabetes Control and Complications Trial (DCCT), a mean HbA1c of 7.3% was associated with a high frequency of severe hypoglycemia, indicating glucose control was far from physiologic. Another limitation of the HbA1c test, when used as the sole means for assessing blood glucose control, relates to the nature of the test and the temporal lag between a change in therapy and a noticeable change in HbA1c. The significance of this lag is highlighted in specific conditions such as pregnancy, where the effect of interventions should be evaluated as quickly as possible.

**Urine glucose**

Historically, urine glucose monitoring has been useful in indicating episodes of hyperglycemia during the corresponding urine excretion time. Urine glucose testing is noninvasive, inexpensive, and—for most patients—easy to perform. The renal threshold for glucose in healthy adults correlates with a plasma glucose concentration of approximately 180 mg/dL (10 mmol/L), but there is wide individual variation. Beyond patient-to-patient variations in the renal glucose threshold, conditions that decrease (e.g., pregnancy) or increase (e.g., aging) the renal threshold often render urine glucose test results over- or underestimated. Although glycosuria indicates that hyperglycemic spikes above the renal threshold occurred during the interval, hypoglycemic variations below the threshold are not identified. Similarly, a negative urine glucose test does not differentiate among hypoglycemia, euglycemia, and mild or even moderate hyperglycemia, thereby limiting the test’s value in prevention.

Furthermore, the urine glucose value does not represent a real-time measurement of glucose concentration at the time of the test, but rather the average level of blood glucose during the interval since the previous voiding. Although urine testing can be used in very poorly controlled patients (HbA1c >9.5%) where more sensitive methods may not add further information, gaining glycemic control requires more accurate technology. Because of its limited reliability and lack of precision, urine glucose testing cannot be recommended for intensive management of diabetes that aims for near-normoglycemia.

**Blood glucose and self-monitoring**

Self-monitoring of blood glucose (SMBG) provides patients with diabetes with real-time measurement of their blood glucose levels on a day-to-day basis. It improves patient safety by allowing immediate confirmation of hypoglycemia or hyperglycemia, suggested by symptoms, to permit behavioral adaptation (e.g., sugar intake or insulin supplementation) to correct the identified blood glucose deviation. Patients prone to asymptomatic hypoglycemic excursions can also use self-monitoring to prevent episodes that might be dangerous during such activities as driving. Intensification of blood glucose monitoring during intercurrent illness can prevent ketosis-prone hyperglycemic excursions by indicating the need for additional insulin.

SMBG is a crucial tool to inform and motivate patients regarding adjustment of medications. Preprandial glucose monitoring provides information regarding the efficacy of previously injected basal insulin or the corresponding insulin basal infusion rate for pump users. At the same time, it offers a reference value for the dose of fast-acting insulin or analog to be injected, or insulin bolus to be programmed on the pump, to meet insulin requirements related to mealtime carbohydrate intake. Postprandial self-monitoring allows an estimation of the effectiveness of insulin delivered preprandially and assists in appropriately adjusting doses of short-acting analogs. SMBG is recommended for patients treated with sulfonylureas or glinides to detect hypoglycemia and adjust treatment doses if necessary. Postprandial self-monitoring is recommended for patients who do not reach HbA1c levels despite fasting blood glucose levels within target ranges (90 to 130 mg/dL [5.0 to 7.2 mmol/L]).

Finally, patient empowerment is an important part of effective diabetes care; SMBG enables patients to self-
regulate their condition and its treatment. Because patient adherence to prescribed diet and regular physical exercise helps reach and maintain glycemic control, self-monitoring constitutes an educational and motivational instrument for illustrating the effects of these factors on blood glucose. Because patients using self-monitoring can see the impact of food choices and physical activity on glucose levels, potentially destabilizing foods or activities can be identified, enabling and fostering appropriate behavior modification. Consistent use of SMBG provides feedback to patients and healthcare providers regarding the effects of diet, exercise, and medication changes. Studies have found that, when properly integrated into an educational program for non–insulin-treated patients with type 2 diabetes, SMBG was statistically associated with better glycemic control than traditional management alone.

SMBG requires finger or alternative-site puncture to obtain capillary blood for testing, a necessity that may be painful or difficult for patients. This inconvenience can be ameliorated by careful patient education regarding less painful techniques (e.g., using the lateral side of the finger pad, avoiding puncturing thumbs and index fingers, and using shallower lancet depths). In addition, alternative sites such as the forearm may be used to give the fingers a rest. Alternative-site testing may be a useful option for routine self-monitoring at times when glucose levels are not rapidly changing. When a patient suspects hypoglycemia or has hypoglycemic unawareness, however, alternative-site testing should be restricted. Use of the fingertip, rather than alternative test sites, may allow more rapid detection of changes in blood glucose values within 2 hours after a meal. These restrictions on alternative-site testing may not extend to palm testing, which is indicated for some meter systems.

Although there is little question that SMBG is crucial for patients using insulin therapy, the cost-benefit ratio in non–insulin-treated patients with type 2 diabetes has been questioned in some studies. Other studies have found correlations between frequent testing and decreasing HbA1c levels.

<table>
<thead>
<tr>
<th>HbA1c (%)</th>
<th>Mean Plasma Glucose, mg/dL (mmol/L)</th>
<th>Whole Blood, Capillary, mg/dL (mmol/L)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>135 (7.5)</td>
<td>122 (6.8)</td>
</tr>
<tr>
<td>7.0</td>
<td>170 (9.4)</td>
<td>155 (8.6)</td>
</tr>
<tr>
<td>8.0</td>
<td>205 (11.4)</td>
<td>186 (10.5)</td>
</tr>
<tr>
<td>9.0</td>
<td>240 (13.3)</td>
<td>218 (12.1)</td>
</tr>
</tbody>
</table>

*Whole blood, capillary = mean plasma glucose/1.11.

Table 1 Correlation between hemoglobin A1c (HbA1c) level and mean plasma glucose levels

Fasting blood glucose and postprandial blood glucose

The respective contributions of fasting and postprandial blood glucose levels to the HbA1c level have been debated. Although fasting plasma glucose has been used widely for years to assess diabetes control in patients with type 2 diabetes who are not treated with insulin, as well as to alter treatment based on restoration of plasma glucose to the normal range, some data suggest that postprandial blood glucose values may be better correlated with HbA1c levels than fasting blood glucose values in non–insulin-treated patients with type 2 diabetes. Another study in patients with type 2 diabetes showed that fasting plasma glucose elevation is the main contributor to diurnal hyperglycemia in poorly controlled patients (HbA1c ≤8.4%) and increases its impact as diabetes worsens, whereas the contribution of postprandial plasma glucose excursions are predominant in moderately controlled patients (HbA1c ≤8.4%). These data indicate that monitoring of blood glucose preferably should be oriented toward fasting or postprandial values according to the level of glycemic control. Because repeated plasma glucose measurement is not generally feasible, use of capillary blood glucose monitoring by patients themselves is important in adjusting treatment to reach blood glucose targets.
Accuracy of capillary blood glucose monitoring versus plasma glucose

When properly performed, self-monitoring using blood glucose meters to measure glucose concentrations in capillary blood is accurate and precise with intra- and interassay coefficients of variation of ≤4% across a wide range of glucose concentrations. Currently used meters use reflectance or electrochemistry technology. Meter data are expressed either as plasma glucose equivalent values or whole-blood values. In the latter case, laboratory plasma glucose value must be divided by roughly 1.11 to allow direct comparison with meter value; fasting blood samples are preferred for this comparison.

Individual factors may impair the accuracy of capillary blood glucose monitoring. These include hematocrit values <25% or >55%, decreased water content of blood, excess or deficiency of oxygen pressure, drug interferences, and high blood levels of various substances. These parameters should be taken into account by healthcare providers when interpreting capillary blood glucose data.

The precision and accuracy of meters need to be assessed periodically to guarantee the quality of data. Reference laboratories can check meters in comparison with manufacturers’ claims. The patient and healthcare provider should check both the precision of meter measurements against control solutions at predefined levels of glucose concentration and the accuracy of the meter used versus laboratory-measured plasma glucose samples.

Ongoing education of patients regarding the proper use of blood glucose meters can substantially improve the accuracy of testing. Patients need to be aware of the importance of good hand washing before each blood glucose test, cleaning of the meter (when appropriate), and proper use of quality-control solutions.

Continuous blood glucose monitoring

Several continuous blood glucose monitoring devices, intended to measure glucose in subcutaneous interstitial fluid through sensors, are currently approved. Most are partially implantable and at least minimally invasive. They have been designed for short-term use extending from several hours to several days, mostly for “Holter-style” glucose monitoring with retrospective data analysis or trends in glucose alterations. Providing real-time data over a longer duration would require total implantation to allow closer access to blood glucose and a more stable environment at the measuring site. Repeated calibrations are necessary to minimize erroneous estimations due to discrepancies between actual levels of glucose in blood and in interstitial fluid related to insulin action and non–insulin-dependent clearance of glucose by tissues, such as during physical exercise. Nevertheless, some studies have found that at least some of the glucose values derived from continuous monitoring correlate with capillary blood glucose values.

Future developments in this technology may enable implantable versions of these devices, in combination with insulin pumps, to adjust insulin delivery rapidly and to signal hypoglycemic or hyperglycemic excursions. In a study by Hay and colleagues, 25 well-controlled patients (aged >65 years old) with type 2 diabetes on oral hypoglycemic therapy were included in a study to determine the prevalence of unrecognized hypoglycemia and the extent of postprandial hyperglycemia over a period of 288 hours. Due primarily to the inability of 40% of patients to manage the monitor, the mean observation period was 188 hours. Data derived from this small sampling indicate the potential for continuous monitoring of blood glucose to be a useful research tool; however, intensive patient education on management of the monitor is necessary. The clinical utility and benefit of continuous monitoring of blood glucose, therefore, needs to be ascertained through further research.

Consensus views on SMBG

General agreement

Measurement of blood glucose is preferable to urine glucose owing to its accuracy, its ability to guide diabetes management through real-time feedback, its ability to reflect postprandial excursions, its ability to provide real-time measurements as opposed to post hoc estimates, and its ability to improve safety for patients at risk of hypoglycemia.

Among scientific societies evaluating diabetes management, consensus has been reached that all insulin-treated patients with diabetes (type 1 and type 2) should use SMBG testing and that testing and HbA1c measurement complement each other. Both should be implemented as integral parts of comprehensive diabetes management. The combination of the results of the patient’s ongoing SMBG and the current, periodic HbA1c result provide the most complete picture of glycemic control.

SMBG testing enables patients with type 1 diabetes who self-titrate insulin to make appropriate adjustments of doses in real-time response to blood glucose values. Adherence to recommended testing frequency of ≥3 times daily in patients with type 1 diabetes and ≥1 time daily in insulin-treated patients with type 2 diabetes was associated with significant improvements in HbA1c of 1.0% and 0.6%, respectively, in the Northern California Kaiser Permanente Diabetes Registry.

In insulin-treated patients with type 2 diabetes, adherence to SMBG has been found to be associated with improvement of HbA1c levels, even when patients were not self-titrating their insulin doses. This suggests that patients may implement beneficial lifestyle changes as a result of the feedback provided by regular monitoring.

A meta-analysis of randomized controlled studies, presented at the 2004 ADA meeting, suggests a positive benefit of SMBG in non–insulin-treated patients with type 2 dia-
### Table 2 Summary of guideline recommendations for self-monitoring of blood glucose (SMBG)

<table>
<thead>
<tr>
<th></th>
<th>ADA(^7)</th>
<th>AACE/ACE(^8)</th>
<th>AAFP(^9)</th>
<th>CDA(^10)</th>
<th>ALFEDIAM(^11)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td>Dictated by needs and goals of patient</td>
<td>No specific frequency for SMBG recommended</td>
<td>SMBG is a tool for patients to gain control of their disease</td>
<td>—</td>
<td>Considered a tool for self-adaptation of diabetes therapy</td>
</tr>
<tr>
<td><strong>Type 1 diabetes</strong></td>
<td>≥3 times daily to monitor for and prevent hypoglycemia</td>
<td>Threat of hypoglycemia minimized with more frequent SMBG</td>
<td>≥3 times daily, more frequent in certain situations</td>
<td>≥3 times daily</td>
<td>≥4 times daily</td>
</tr>
<tr>
<td><strong>Type 2 diabetes</strong></td>
<td>Optimal frequency not known, sufficient to facilitate reaching glucose goals</td>
<td>Measuring blood glucose at various times of the day is useful to understand the effect of drugs in relation to meals, exercise, and stress</td>
<td>Patients not at goal may require SMBG multiple times a day (2–4 times/day)</td>
<td>Optimal frequency unclear, ≥1 time daily</td>
<td>SMBG useful:</td>
</tr>
<tr>
<td><strong>Type 2 diabetes + insulin</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• For educating patients about diet and exercise</td>
</tr>
<tr>
<td><strong>Type 2 diabetes + oral antidiabetic agent</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• In modifying dose of oral agents</td>
</tr>
<tr>
<td><strong>Type 2 diabetes + diet</strong></td>
<td>Role of SMBG not known in stable, diet-treated patients</td>
<td>Patients who adjust their food intake in response to SMBG achieve lower HbA(_1c) than controls</td>
<td>Patients may not need to perform daily SMBG</td>
<td>Optimal frequency unclear</td>
<td>SMBG useful:</td>
</tr>
<tr>
<td><strong>Modifying therapy or during illness</strong></td>
<td>More often than usual</td>
<td>SMBG should be done more often when traveling, meal or exercise plans change, or on sick days (every 3–4 hr)</td>
<td>More frequently during acute illness or medication adjustment</td>
<td>—</td>
<td>SMBG useful:</td>
</tr>
<tr>
<td><strong>Pregnancy or GDM</strong></td>
<td>≥3 times daily to monitor for and prevent hypoglycemia</td>
<td>MNT should be monitored with SMBG daily</td>
<td>SMBG, both preprandial and postprandial, is essential, often ≥4 times daily</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Other recommendations</strong></td>
<td>SMBG is an integral component of therapy</td>
<td>Patient must be taught to assume responsibility for self-monitoring and problem solving</td>
<td>Timing relates to when a patient is most likely to experience hypo- or hyperglycemia</td>
<td>—</td>
<td>Urine glucose testing and fructosamine are not recommended due to poor reliability</td>
</tr>
</tbody>
</table>

\(^{16}\) The American Journal of Medicine, Vol 118 (9A), September 2005
betes as well. Integrating self-monitoring into a comprehensive program including adequate patient education and provision for treatment adjustment based on the results of self-monitoring might also increase the proportion of patients with type 2 diabetes who benefit from self-monitoring.

General agreement has also been reached regarding the utility of daily SMBG in patients with gestational diabetes. Self-monitoring helps patients with gestational diabetes reach stringent goals of glycemic control by motivating adherence to and adjustments in diet and allowing more appropriate decision-making regarding insulin treatment and subsequent dose adjustment, which results in decreased incidence of fetal macrosomia and other fetal and maternal complications. Both fasting and postprandial blood glucose assessments are universally recommended in patients with gestational diabetes to help reach stringent targets for the best fetal outcome. Urine glucose monitoring is not useful in gestational diabetes.

Consensus has not been reached regarding the optimal frequency and timing of SMBG in non–insulin-treated patients with type 2 diabetes, particularly those who are stable on management with diet but not oral hypoglycemic agents. Most guidelines agree that SMBG can be useful for patients with type 2 diabetes using oral hypoglycemic agents and that some self-monitoring, even if not done daily, may be helpful for diet-treated patients with type 2 diabetes as well. Integration of self-monitoring into educational programs for patients with type 2 diabetes is likely to be useful in assisting patients in better implementation of dietary recommendations by providing immediate feedback on the effects of diet on blood glucose levels.

Review of current guideline recommendations regarding self-monitoring of blood glucose for glycemic control

The guidelines of 5 national and international societies recognize that SMBG is essential to the short- and long-term management of type 1 and type 2 diabetes and generally agree on overall management of patients with type 2 diabetes. However, there is some discrepancy between the organizations as to the recommended frequency of testing in each patient population. Association guidelines also are nonspecific regarding daily timing of self-monitored testing. Most indicate only that the frequency and timing of self-monitoring should be dictated by the individual needs and goals of each patient (Table 2).

For example, the ADA recognizes SMBG as part of a multifactorial intervention to be dictated by individual patient requirements. In patients with type 1 or gestational diabetes, SMBG should be performed ≥3 times a day. In patients with type 2 diabetes who are controlled by oral medications or diet and lifestyle alone, self-monitoring frequency should be sufficient to reach target goals, with no specificity as to the optimal daily frequency of testing.

Summary

Assessment of blood glucose control is a critical component of diabetes treatment and management. Although HbA1c levels are correlated with the incidence of complications of diabetes, they do not provide real-time measurement of glycemic status and cannot detect hypoglycemic excursions. Ideally, HbA1c measurement is most useful as part of a multifactorial strategy that also includes SMBG so that the 2 methods can complement each other. Urine glucose testing is not compatible with a strategy aimed at effective prevention of complications of diabetes.

SMBG is mandatory for accurate adjustment of insulin doses in all insulin-treated patients with diabetes. Recommendations are for ≥3 tests per day for patients with type 1 diabetes and ≥1 test per day for patients with type 2 diabetes, but testing should sometimes be more frequent depending on the insulin regimen used and level of glycemic control required. Self-monitored testing can help non–insulin-treated patients with diabetes reach blood glucose targets if specific information is provided for treatment adjustment based on the results of the testing. Postprandial blood glucose levels appear to contribute significantly to an increased risk of cardiovascular disease and death. Postprandial SMBG testing can help patients adjust doses of short-acting analogs or regular insulin and modify their diet; it also is recommended for patients who do not reach their HbA1c targets despite near-normal fasting blood glucose levels. Postprandial testing is mandatory for pregnant women with diabetes.

Current guidelines are unanimous in recognizing the need for tight glycemic control in patients with diabetes and in recommending SMBG for most forms of diabetes. However, the guidelines are less specific regarding recommended frequency and timing of self-testing as well as about its use in non–insulin-treated patients with type 2 diabetes. Detailed assessment of these issues in the development of future guidelines would be most valuable to clarify the utility of SMBG in effective diabetes management.

The following statements summarize these concepts: Assessment of blood glucose control is a crucial component of diabetes treatment. Regular HbA1c measurement, quarterly for most patients, represents one component of monitoring glycemic control. SMBG is an essential complement for insulin-treated patients with diabetes, for both safety reasons (detection of hypoglycemia) and enhancement of effectiveness of insulin through dose adjustments. Urine glucose testing is an inadequate replacement for SMBG for daily assessment of blood glucose control due to its poor reliability, lack of precision, and inability to detect hypoglycemia. Urine glucose testing is not compatible with a
strategy directed at effective prevention of complications of diabetes. SMBG is an effective tool (when combined with an education program) for monitoring glycemic status and offers several advantages, including real-time, reliable blood glucose concentration, ability to reflect postprandial excursions, and improved safety through detection of hypoglycemia. Current guideline recommendations for the use of SMBG in glycemic control should be more specific about frequency, timing, and integration of self-monitoring in the management strategy of patients, especially for those individuals with type 2 diabetes.

References


Current evidence regarding the value of self-monitored blood glucose testing

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Diabetes can be called an emerging epidemic. In the United States, >18 million people have diabetes, including an estimated 5.2 million who are as yet undiagnosed.1 On a global scale, diabetes affects nearly 200 million people; without extensive intervention, this number is expected to exceed 300 million by 2025.2,3 A recent study estimated that of people born in 2000, 33% of all men, 39% of all women, and 53% of Hispanic women will develop diabetes during their lifetime.4 The United Kingdom Prospective Diabetes Study (UKPDS), as well as other research, has demonstrated that improved glycemic control will reduce the development and progression of diabetic complications.5 Yet, most people with diabetes do not come close to attaining or maintaining glycemic goals.6–8 Increased use of self-monitoring of blood glucose (SMBG) is among the many proposed strategies to help address this problem.

While glycosylated hemoglobin A1c (HbA1c) provides an overall or long-term assessment of glycemia and correlates with end-organ impact, SMBG test results provide day-to-day data on glycemic patterns that can be used to further optimize glycemic control and minimize diabetic complications. Blood glucose monitoring provides feedback on the impact of nutrition, physical activity, therapy with oral antidiabetic agents, and insulin, and allows design, implementation, and adjustment of physiologic insulin replacement programs. This article reviews and evaluates the existing and emerging evidence relating performance of SMBG to improvement in glycemic control.

Evaluating the evidence

An increasing number of published reports have focused on whether a management strategy that includes SMBG can improve glycemic control. Evaluating the evidence for self-
monitoring is complicated by several factors, including the existence of relatively few large, randomized, controlled trials and various shortcomings in design for the studies that are available. The following are some factors to consider when evaluating the evidence:

- Was the study designed to demonstrate a change in glycemic control over time, resulting from a clearly defined management strategy that included SMBG?
- Was the patient instructed about how to properly perform SMBG, how to interpret the results, and what actions to take based on the results?
- Was sufficient time allocated for patients to incorporate the SMBG practice into their daily routine?
- Were the data analyzed for any potential confounding factors or interactions?
- Was the study design experimental (i.e., a prospective study design) or observational (e.g., cross-sectional or longitudinal/cohort)? Cross-sectional studies examine the association between SMBG and glycemic control at a single time point, whereas longitudinal studies (a methodologically stronger form of observational design) assess changes in patients over time. Studies of natural experiments examine the impact of large-scale interventions (e.g., policy-mandated changes in coverage for testing supplies).

**Self-monitoring of blood glucose in patients treated with insulin**

Several studies have demonstrated the effectiveness of SMBG for patients with type 1 diabetes and those with type 2 diabetes treated with insulin.9–13

One of the early studies that demonstrated the relation between SMBG and glycemic control was performed >20 years ago. Schiffrin and Belmonte13 studied 21 adolescents with type 1 diabetes on insulin pump or multiple daily injection therapy and showed that as self-monitoring frequency increased (to 5 to 7 times per day), glycemic control improved; when monitoring frequency decreased (to twice daily), control deteriorated. When testing frequency was again increased in the same group, control once again improved. This was the first longitudinal observation demonstrating improvement in glucose control with increased testing frequency.

Evans and colleagues10 undertook an observational, cross-sectional study to determine the effect of SMBG in real-life conditions among patients with type 1 diabetes and in those with type 2 diabetes treated with insulin. In patients with type 1 diabetes, there was a direct relation between the number of glucose monitoring reagent strips dispensed and glycemic control that corresponded to a decrease in HbA1c of 0.7% for every 180 strips dispensed over a 6-month period. A similar relation for patients with type 2 diabetes was not seen.

Recently, Davidson and associates14 performed a cross-sectional study to model the relation between blood glucose monitoring frequency and HbA1c levels in 378 subjects with C-peptide levels <1 ng/dL, using insulin pumps with blood glucose targeted to 100 mg/dL (5.55 mmol/L). They determined that the relation between monitoring frequency and HbA1c level was best fit by a nonlinear curve with the following equation:

\[
    \text{HbA1c} = 5.99 + \frac{5.32}{(\text{tests per day} + 1.39)}. 
\]

Thus, little additional benefit in glycemic control is achieved by monitoring >10 times per day. Similar findings were also observed in people with type 2 diabetes managed with oral agents or diet.15

Murata and colleagues16 undertook a longitudinal survey of veterans (94% men) with insulin-treated type 2 diabetes and found that SMBG (4 times daily) benefited patients whose testing adherence was >75% or whose baseline HbA1c was >8.0%. For patients whose adherence was >75%, HbA1c decreased 0.56% (P <0.001), while patients with an entry HbA1c >8.0% experienced an HbA1c decrease of 0.67% (P <0.001).

Nyomba and coworkers17 performed a randomized controlled trial in 62 insulin-treated patients with type 1 or type 2 diabetes. Patients were randomized into 2 groups that were matched for age, sex, education, income, type and duration of diabetes, years of insulin treatment, number of daily insulin injections, and HbA1c. All patients were given a glucose meter, but 1 group was provided with glucose meter test strips free of charge (NC) while subjects in the second group (control C) purchased strips as necessary. During the first 4 months, SMBG frequency was significantly higher in the group that received test strips for free compared with the control group (2.0 ± 0.2 tests per day vs. 1.4 ± 0.1 tests per day; P <0.025). Mean HbA1c remained stable over the 12 months in the group that received free testing strips, whereas HbA1c increased with time in the control group. The HbA1c difference between the 2 groups was significant (P <0.002) after 6 months. Random blood glucose levels measured at each visit and average glucose meter readings also were lower in the group that received free testing strips versus the control group (P <0.005).

There was a negative correlation between HbA1c and SMBG testing frequency, with HbA1c in patients testing ≥2 times daily lower than in those testing <2 times daily (8.8 ± 0.2% vs. 9.6 ± 0.2%; P <0.001). Thus, access to glucose meter strips, provided free of charge to patients, increased blood glucose testing frequency, which in turn was associated with improved glycemic control. However, due to the relatively small number of patients included, outcomes data did not allow for subgroup analysis by type of diabetes.

Kibriya and colleagues18 conducted a prospective controlled trial of SMBG in 64 patients with type 2 diabetes treated with insulin or oral agents in the developing country of Bangladesh. All patients received similar health education that included urine sugar monitoring and how to adjust the dose of oral agents or insulin. In addition, the interven-
tion group received a glucose meter, test strips, and specialized instruction on their use. Patients in the intervention group were asked to monitor blood glucose 2 to 3 times per day (fasting, 2 hours after breakfast, 2 hours after lunch) every 2 weeks. If SMBG results were above target levels, the patient was instructed to adjust medication dose and recheck blood glucose at the appropriate time after several days. For patients in the intervention group, HbA1c decreased significantly from baseline by 3 months and remained significantly decreased over each 3-month period for the remainder of the study, achieving a reduction of 1.37% at 18 months. Patients in the control group were not significantly improved from baseline at 3, 6, 12, or 18 months. This study demonstrates the value of periodic multipoint profiles together with medication adjustment based on the results.

**Self-monitoring of blood glucose data for patients not treated with insulin**

The data evaluating whether SMBG is advantageous for glycemic control in patients with type 2 diabetes who are not receiving insulin therapy but who are treated with oral agents or controlled with diet and exercise are still emerging. Much of the existing information for the efficacy of SMBG in these subjects comes from cross-sectional studies rather than prospective longitudinal studies. For example, Northern California Kaiser Permanente researchers performed a cross-sectional survey of SMBG use, stratified by type of diabetes and treatment, controlled for a wide variety of potential confounders, and evaluated these results for possible selection bias.9 This study demonstrated that SMBG at recommended frequencies was associated with significantly lower HbA1c levels than less frequent (nonadherent) monitoring. Adherent monitoring (relative to nonadherent) was associated with 1.0% lower HbA1c levels for patients with type 1 diabetes who tested ≥3 times daily (P = 0.0001), 0.6% lower HbA1c levels for patients with type 2 diabetes treated with insulin who tested ≥1 time daily (P = 0.0001), and 0.6% lower HbA1c levels for patients with type 2 diabetes treated with oral agents who tested ≥1 time daily (P = 0.0001). Among patients with type 2 diabetes treated nonpharmacologically, use of SMBG at any frequency was associated with a 0.4% lower HbA1c level compared with no self-monitoring (P <0.0001).

Preliminary results from the Division of Research of Kaiser Permanente Northern California, which performed a longitudinal study of approximately 31,000 patients followed over a 3-year period, support these cross-sectional findings.19 This study found a dose-responsive benefit associated with long-term SMBG among pharmacologically treated patients with diabetes, irrespective of therapeutic modality (oral agents, insulin, or combination). However, there was an even larger benefit observed in patients with diabetes who newly initiated SMBG. The gain in self-awareness of glycemic responses afforded by initiating self-monitoring may account for this effect. The author speculates that the educational benefit might be simulated by asking patients to periodically perform intensive monitoring (e.g., before and after each meal) for 1 day to refresh their understanding of diurnal glucose patterns and glycemic response to diet, exercise, and therapy.

Meier and associates20 conducted a retrospective study in a Veterans Affairs population of patients with type 2 diabetes treated with lifestyle measures or oral therapy. Stable patients were restricted to the use of 50 glucose test strips for every 90 days. Patients who performed SMBG testing had a lower HbA1c than patients who did not (mean difference, 0.43%; 95% confidence interval, 0.346% to 0.434%); however, a decrease in self-monitoring frequency of 46% for patients treated with oral agents and 35% for patients treated with diet alone showed no significant impact on HbA1c levels.

Soumerai and colleagues21 performed a retrospective longitudinal study that evaluated whether a new managed care coverage policy requiring full insurance coverage of blood glucose meters increased SMBG in patients who had either type 1 or type 2 diabetes and whether initiating SMBG testing was associated with improved glycemic control. They assessed changes in HbA1c that were associated with blood glucose testing by using interrupted time-series analysis. Data on mean HbA1c levels by 60-day periods compared blood glucose testing initiators with noninitiators. At baseline, HbA1c levels in both arms were nearly identical. Among those with poor baseline glycemic control (HbA1c >10%), initiation of SMBG testing was associated with a reduction in mean HbA1c level of 0.63% compared with noninitiators of blood glucose testing (P = 0.03). A statistically significant decrease was not observed for patients with good or adequate baseline glycemic control. Interestingly, compared with noninitiators, initiators of blood glucose testing showed significant improvements in medication adherence.

Coster and coworkers22 performed a meta-analysis of 4 randomized controlled trials that compared blood or urine glucose self-monitoring with no self-monitoring in patients with type 2 diabetes. One of the studies included patients treated with insulin while the other 3 studies were restricted to patients managed with oral antidiabetic agents or diet. In all, 3 of the 4 studies included in the analysis could not detect a reduction in HbA1c of <1%. Although the component studies were described as “generally poorly reported and lacking in statistical power,” the pooled effect was a 0.25% reduction in HbA1c. This difference was not statistically significant. Other well-designed longitudinal studies provided important additional data and almost uniformly demonstrated the ability of SMBG testing to help improve glycemia.16–18,21,23–29

Schwedes and colleagues24 focused on the impact of meal-related SMBG on glycemic control and well-being in non–insulin-treated patients with type 2 diabetes. These
investigators conducted a 6-month prospective, multicenter, randomized, controlled comparison of a group of patients who performed SMBG testing, kept a blood glucose/eating diary, and received standardized counseling versus a control group that received nonstandardized counseling on diet and lifestyle. Although an intention-to-treat analysis was not performed, the use of SMBG testing significantly reduced HbA1c levels by (mean ± SE) 1.0 ± 1.08% compared with 0.54 ± 1.41% for the control group (P = 0.0086). Self-testing was associated with a marked improvement in general well-being, with significant improvements in depression (P = 0.032) and well-being (P = 0.02). The study supports the benefits of teaching patients how to perform self-testing and emphasizes the importance of (1) enhancing self-perception by keeping an eating/self-monitoring/well-being diary; (2) promoting self-reflection about experiences with self-monitoring; and (3) enhancing self-management using the testing results and a diary to improve glycemic control. Teaching patients how to use testing values to implement and adjust lifestyle and other therapies is critical to the successful implementation of an SMBG program.

Guerci and coworkers25 conducted an open-label randomized prospective study designed to compare changes in metabolic control over 6 months in patients managed with usual recommendations alone (conventional assessment group) or combined with SMBG. The control group received standard care. Those randomized to SMBG also received standard care and were instructed to perform a minimum of 6 capillary glucose assays per week. This study demonstrated a significant improvement in HbA1c in the self-testing group compared with the control group (8.1% vs. 8.4%; P = 0.012). Significantly more patients in the self-monitoring group than in the conventionally treated group had a ≥0.5% decrease in HbA1c (57.1% vs. 46.8%; P = 0.007). Unfortunately, patients were not analyzed by treatment modality.

The most recent randomized controlled trial of SMBG was published by Davidson and colleagues.30 This 6-month study, involving patients with type 2 diabetes treated with oral agents, randomized 43 patients to the self-monitoring arm and 45 patients to the control arm. Self-monitoring was recommended before and 1 to 2 hours after a single meal for 6 days of the week (2 breakfasts, 2 lunches, and 2 dinners). Actual adherence to recommended self-monitoring frequency was only 44% (average of 0.75 test per day). Patients met with a dietitian (weeks 0, 2, 4, 8, and 12) and received nutritional counseling based on glucose values and meal descriptions. A nurse, blinded to treatment group, followed detailed algorithms to make therapeutic adjustments with the aim of achieving glycemic targets. HbA1c levels decreased significantly in both groups (~0.8% for self-monitoring, −0.6% for control), but the decrease was not significantly different between the 2 groups. The beneficial impact of the high frequency of clinic visits and blinded medication adjustments (every 2 weeks until fasting glucose concentration reached <130 mg/dL [7.22 mmol/L]) on glycemic control may have diluted the glycemic benefits of SMBG and attenuated the difference between the groups. Furthermore, the wide 95% confidence interval seen in the change in HbA1c levels (−1.1% to +0.6%) suggests that this study may have been insufficiently powered, and the authors noted that a significant effect may have been missed as a result. A final point raised by the authors was that the predominantly poorly educated population examined in this study may have had difficulty interpreting the information provided by nutritional counseling and self-monitoring values.

Fontbonne and colleagues31 assigned non–insulin-treated poorly controlled patients with type 2 diabetes to 1 of the following 3 study groups: HbA1c determined every 2 months; self urine-glucose monitoring twice every other day; and self-monitoring of fasting and postprandial plasma glucose twice every other day. Similar to the Guerci group’s investigation,25 the data were not analyzed by type of treatment. Although the study found no significant differences between the 3 study groups, there was significant correlation between the number of reagent strips used and decrease in HbA1c over 6 months in the group assigned to SMBG (r = 0.36, P <0.02).

A recent meta-analysis of 8 randomized controlled trials of SMBG involving 1307 non–insulin-treated adult patients with type 2 diabetes was recently published by Sarol and associates.32 This analysis included studies authored by Schwedes, Guerci, Jaber, Estey, Muchmore, Fontbonne, Davidson, and Kwon that were identified by literature review.24,25,27–29,31,33,34 Studies were included if they were randomized controlled trials comparing non–insulin-treated adult patients with type 2 diabetes who performed SMBG testing with those who did not and if they provided measurements of any HbA1c changes for both groups. The included studies also used interventions with education and/or treatment adjustment based on the results of self-monitoring, representing the optimal use of SMBG data. Data analysis using a random-effects model (most appropriate for clinically heterogeneous studies) yielded a mean HbA1c reduction of 0.42% for therapies that included SMBG testing as part of a multicomponent management strategy compared with therapies that did not use self-testing and monitoring.32

Welschen and coworkers35 recently published a meta-analysis that reported results similar to those of the Sarol group’s32 meta-analysis. These investigators analyzed data from 5 studies, including 1,159 non–insulin-treated patients, and concluded that self-monitoring was associated with a statistically significant decrease in HbA1c of 0.39% (random-effects model) compared with control groups. This meta-analysis used similar eligibility criteria and included 4 studies that overlapped with Sarol and colleagues,32 but eliminated the studies headed by Jaber,27 Estey,28 and Kwon.34 Additionally, Welschen and coworkers used the recently published 2005 study by Davidson and colleagues30 rather than the smaller study (n = 89) by the same
investigators in 2004,33 which was included by Sarol and colleagues32 in their meta-analysis. Welschen’s group noted that only the 2 largest studies (headed by Schwedes24 and Guerci25) showed statistically significant results in favor of self-monitoring. Ipp and associates46 have commented that the remaining studies were not large enough to detect a 0.75% difference in HbA1c with >80% power.

Thus, for non–insulin-treated patients with type 2 diabetes, several newer observational and experimental studies provide evidence suggesting that more frequent SMBG testing is associated with better glycemic control. Most other studies that have failed to show a statistically significant improvement in HbA1c for patients performing SMBG have been limited by small study sizes or the failure to educate and encourage patients to take action based on their self-monitoring results.36 Whereas some individual randomized controlled trials have not been sufficiently powered, combining studies in meta-analyses have demonstrated that SMBG can lead to statistically significant improvements in glycemic control. Although individual studies have their limitations, taken as a whole, these study findings support clinical recommendations for increased use of self-testing.

**Self-monitoring of blood glucose in children**

Studies performed in children with diabetes who are treated with insulin, although generally small and limited in scope, demonstrate that frequent SMBG testing is correlated with lower HbA1c levels.11–13 In a study by Levine and colleagues,12 glycemic control improved significantly as the frequency of self-monitoring increased, achieving the best result when monitoring was done ≥5 times per day. The crossover study design used by Schiffrin and Belmonte13 showed that optimized glucose control cannot be maintained in insulin-dependent patients without frequent SMBG testing. In this study, a decrease in self-monitoring frequency (to 2 times daily) resulted in deterioration of glycemic control, whereas a return to frequent monitoring (4 times daily) resulted in improved control.13 Clearly, the ability to adjust insulin doses according to the results of frequent blood glucose determinations is essential to maintaining optimal glycemic control, although the paucity of existing data suggests that more research is needed to establish the role of SMBG in children.

**Self-monitoring of blood glucose in gestational diabetes**

A review of SMBG in gestational diabetes concluded that SMBG testing improves neonatal outcome in pregnancies complicated by diabetes and provides important information for guiding dietary and insulin therapy.37 A study of 153 pregnant women with gestational diabetes concluded that a program of self-monitoring combined with intensive dietary therapy with selective use of insulin kept the incidence of fetal macrosomia equal to that of the general population.38 Another study comprising 2,461 patients with gestational diabetes concluded that intensified management including SMBG testing 7 times daily using memory reflectance meters and adherence to an established criterion for insulin initiation was associated with superior perinatal outcomes compared with conventional management using weekly venous glucose measurements and SMBG testing 4 times daily with visual strips.39 SMBG enhances patient education, facilitates lifestyle modifications, and encourages patients to actively participate in their own care.

**Frequency and timing**

The frequency of SMBG testing specified in clinical trials varied widely. This was not unexpected given the inconsistency in existing guidelines and the clinical differences across study populations. For example, Hoffman and associates40 found that twice-daily strategies were sufficient to assess glycemic control in adults with stable insulin-treated type 2 diabetes. Controlled studies by Guerci and colleagues25 in patients with type 2 diabetes not using insulin (self-testing ≥6 times weekly on 3 different days) and Schwedes and coworkers24 (self-testing 6 times daily on 2 days per week) both demonstrated significant reductions in HbA1c.

Monnier and associates41 recommended monitoring from 8 times daily (for those with poorly controlled type 1 diabetes) to once or twice per week for patients with type 2 diabetes demonstrating good control. However, Fontbonne and colleagues41 found a significant correlation between the number of blood glucose strips used and the decrease noted in HbA1c in non–insulin-treated patients with type 2 diabetes. Patients who achieved a decrease in HbA1c of 1% or better used significantly more blood glucose strips over 6 months than patients who did not achieve this decrease. Wing and colleagues42 concluded that SMBG was not helpful in obese patients with type 2 diabetes, but the study required only 9 measurements per week for the first 12 weeks of the study and 5 determinations per week after that. Even with this limited self-testing regimen, they noted an improvement in glycemic control (fasting blood glucose, HbA1c) during the initial weeks of the program. These values returned to pre-study levels by the 1-year follow-up evaluation. During the 9 months before this evaluation, only 5 SMBG determinations were required per week.42 Thus, there is likely a threshold below which testing may not provide benefit.

Therefore, although additional studies regarding frequency and timing for SMBG would be beneficial, existing evidence demonstrates the benefits of frequent self-monitoring as a tool to educate patients about the effects of diet and exercise, to facilitate self-adjustment of therapy, and to help physicians implement and modify treatment.
Summary

Existing data are supportive of SMBG in certain patient populations (type 1 diabetes, gestational diabetes, type 2 diabetes on insulin), and newer evidence supporting the value of SMBG in non–insulin-using type 2 diabetes is now emerging. Data from more recent observational studies and clinical trials using appropriate study designs and meta-analysis of SMBG testing in non–insulin-using patients with type 2 diabetes suggest that self-testing is associated with improvements in HbA1c. Although more work is needed to establish optimal testing frequencies, existing studies can be used to craft appropriate conservative recommendations that can guide patients with diabetes as well as their healthcare providers.

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Strategies for improving glycemic control: effective use of glucose monitoring

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Despite the increasing prevalence of diabetes, improved understanding of the disease, and a variety of new medications, glycemic control does not appear to be improving. Self-monitoring of blood glucose (SMBG) is one strategy for improving glycemic control; however, patient adherence is suboptimal and proper education and follow-up are crucial. Patients need to understand why they are being asked to self-test, what their glycemic targets are, and what they should do based on the results of self-monitoring. Patients also must be taught proper technique and must be given specific recommendations regarding frequency and timing for self-monitoring. Situations in which SMBG is essential or should be more frequent include self-adjustment of insulin doses, changes in medications, lack of awareness of hypoglycemia, gestational diabetes, illness, or when hemoglobin A1c (HbA1c) values are above target. SMBG should include postprandial monitoring to identify glycemic excursions after meals, to indicate the need for lifestyle adjustments, and to provide patient feedback on dietary choices.

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KEYWORDS:
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Over the past 2 decades, evidence has accumulated regarding the critical importance of tight control of blood glucose levels in individuals with diabetes. A variety of practice guidelines for achieving such control has been developed and widely publicized. Nevertheless, data from the Third National Health and Nutrition Examination Survey (NHANES III), 1988 to 1994, and NHANES 1999 to 2000 indicated that overall glycemic control did not improve—and actually worsened among individuals with type 2 diabetes—between the 2 survey periods.1,2 This has also been observed in the United Kingdom, Sweden, and the Netherlands.3-5

Facilitating diabetes treatment success

Among the recommendations for improving glycemic control to emerge from NHANES are ongoing monitoring and measurement of the quality of care; empowerment of healthcare providers with medical-decision support tools; provision of patient information to improve the quantity and quality of self-participation both in disease management and in care received; and incorporation of economic incentives in the healthcare system (such as incremental payments for improved clinical performance) for providing comprehensive care.1,6 Early, aggressive management of diabetes, including type 2 diabetes, is crucial to increasing glycemic control.2 In addition to lowering blood glucose levels in patients with diabetes, attention should be paid to cardiovascular risk factors (i.e., serum triglyceride levels, low-density lipoprotein and high-density lipoprotein cholesterol, blood pressure, and body weight) that can also contribute to complications.7 Clearly, to avoid devastating complications of diabetes, greater efforts must be made to increase patient adherence.
awareness of the importance of glycemic control and enhance implementation of effective management strategies by patients and healthcare providers.

Self-monitoring of blood glucose (SMBG) is considered a tool for guiding patient and healthcare provider actions regarding dietary changes, physical activity, and pharmacologic therapy. Healthcare providers can help patients understand that diets lower in fat can help control cholesterol, that body weight control through diet and exercise can affect lipid levels and blood pressure, and that all of these interventions can facilitate glycemic control. Guidance and interactive training regarding appropriate choices of diet and exercise plans, combined with encouragement and monitoring of progress, can empower patients to make beneficial lifestyle modifications.

SMBG is considered a tool for guiding patient and healthcare provider actions regarding dietary changes, physical activity, and pharmacologic therapy. Once a patient is diagnosed with diabetes, SMBG should be considered essential in all individuals, even though specific frequency and timing may vary due to degree of glycemic control. This recommendation is based on the fact that self-monitoring is an excellent educational tool to help inform patients about their disease and the effects of diet, exercise, and medications on glucose levels. Changes in diabetes management in response to glycemic fluctuations are the joint responsibility of patients and healthcare providers. A team approach involving healthcare providers, patients, and family members is useful in managing diabetes effectively.

Using self-monitoring of blood glucose as part of an overall strategy to improve glycemic control

Barriers to self-monitoring

The majority of the evidence—and almost all guidelines for diabetes management—support the integral role of SMBG in overall treatment programs. Use of self-monitoring is recognized as valuable in assisting patients and healthcare providers in evaluating therapeutic effectiveness, adjust medication dosages, and detect or prevent hypoglycemia. However, adherence to SMBG regimens and frequency of testing remain below recommended levels; 60% of patients with type 1 diabetes and 67% of those with type 2 diabetes fail to self-monitor at the frequencies recommended by the American Diabetes Association (ADA). Furthermore, the patients at greatest risk for poor health outcomes—and who might reap the greatest benefit from this testing—are the least likely to self-monitor.

A longitudinal 12-month study found that easier availability (free of charge) of self-monitoring supplies increased frequency of use and improved glycemic control compared with more limited access (necessity to purchase). Financial, linguistic, and educational factors—as well as patient inability to interpret results of SMBG or act on them—have also been identified as barriers to more adherent self-monitoring and thus to more effective glycemic control. Facilitating access to SMBG, along with training and education about its use and value, can increase adherence and improve glycemic control, helping to avoid complications of diabetes. Patients need to know and understand the ranges of test results and what steps to take, such as modifying diet, exercise, and/or medication, in response to a high or low reading.

Effective implementation of SMBG

Effective implementation of SMBG requires that healthcare providers familiarize themselves with the value, techniques, and objectives of self-monitoring and provide this information to their patients with diabetes. Because a substantial number of patients with diabetes use their glucose meters incorrectly, healthcare providers should provide periodic evaluation of testing technique and reinforcement or retraining if necessary. Close follow-up by healthcare providers has also been shown to enhance adherence and to increase glycemic control. Similarly, diabetes educators can be very helpful in properly preparing patients to self-monitor their blood glucose appropriately. It is important for patients to understand what they are trying to accomplish by using self-monitoring and to be aware that adherence to this element of self-care can allow them to respond appropriately in “real time” to help maintain control of their blood glucose. Patients are more likely to self-monitor properly and at the recommended frequency if they understand that their proactive participation is a critical component of effective diabetes management.

Patients should know their target blood glucose goals in order to recognize out-of-range values requiring attention. Although such goals must be individualized, the American College of Endocrinology (ACE) recommends that, for adults with diabetes, fasting plasma glucose levels should target a value of <110 mg/dL (6.11 mmol/L); treatment-targeted 2-hour postprandial blood glucose levels should be <140 mg/dL (7.77 mmol/L). Each patient needs to understand, for example, what specific postprandial glucose value he or she is aiming for and that large glycemic excursions should be avoided. Patients should be taught exactly how to interpret and use the data gained from SMBG to adjust medication dosage, food intake, and/or physical activity, as well as to make other lifestyle modifications to achieve specific glycemic goals.

Specific recommendations for self-monitoring of blood glucose

Situations in which self-monitoring is essential

Self-testing is an essential part of management for patients who self-adjust their insulin doses based on glucose mea-
surement. Some patients are unaware of hypoglycemic symptoms or are known to experience asymptomatic periods of hypoglycemia. In these patients, self-monitoring can prevent glycemic deviations that might be hazardous during certain types of employment (e.g., shift work, night work), driving, or exercise. When a medication regimen is altered, SMBG provides detailed feedback on the effectiveness of the change, allowing prompt adjustments if necessary. Similarly, in patients with diabetes who also have an intercurrent illness, self-monitoring can help provide the specific information necessary to maintain stringent glycemic control. Regular blood glucose self-testing is essential in pregnant women with diabetes to optimize fetal and maternal outcomes.

**Situations requiring frequent SMBG**

When diabetes treatment regimens involve intensive insulin therapies, such as multiple daily injections or insulin pumps, the regular feedback provided by multiple daily self-monitored tests is essential for proper self-adjustment of insulin dose. In people with suspected or confirmed impaired awareness of hypoglycemia, self-monitoring is crucial to identify excursions and enhance safety. In addition, patients whose hemoglobin A1c (HbA1c) levels are out of target range require more frequent self-monitoring to help identify the daily glucose fluctuations and the patterns of glucose readings over several days that periodic HbA1c testing cannot capture.

**Recommendations for frequency and timing of self-monitoring in individual populations**

The ADA recommends that the frequency and timing of SMBG be determined by the needs and objectives of individual patients. General recommendations for the frequency and timing of self-monitoring cover a wide range in practice guidelines and in research studies. Within this range, it appears reasonable to provide more specific guidance that can be tailored to the requirements of each individual with diabetes within predefined patient groups (e.g., according to pharmacologic management strategies).

**Type 1 diabetes and intensively treated type 2 diabetes**

In intensively insulin-treated patients, i.e., patients with either type 1 or type 2 diabetes receiving multiple daily injections or using an insulin pump, an optimal course of action would be to self-test blood glucose levels 3 to 4 times daily. Many patients, including those above glycemic target or experiencing frequent hypoglycemia, will require more frequent monitoring. The timing for self-monitoring should include both preprandial and postprandial tests with occasional values obtained at 2:00 AM to 3:00 AM to coincide with meals, exercise, and the peak action of the insulin used. At least twice-daily monitoring should be performed for patients receiving a single daily injection to monitor for and prevent hypoglycemia and to facilitate reaching glycemic goals. Under certain conditions—such as changes in medication and acute or intercurrent illness—self-monitoring should be performed more frequently.

**Type 2 diabetes treated with oral antidiabetic agents or once-daily insulin**

Studies in patients with non–insulin-treated type 2 diabetes have found that SMBG is statistically associated with better glycemic control than traditional management alone. Self-testing can demonstrate the hypoglycemic effectiveness of oral antidiabetic agents and provide feedback to patients and healthcare providers regarding the effects of diet, exercise, and medication changes. Meal-related blood glucose self-monitoring may be especially useful for improving patient adherence to diet or other treatment interventions. A study of non–insulin-using patients with type 2 diabetes measured diurnal plasma glucose at 8:00 AM, 11:00 AM, 2:00 PM, and 5:00 PM. This study concluded that glucose excursions during morning periods seem to be a permanent condition in these patients regardless of level of glycemic control, degree of residual β-cell function, or type of medication, and that mid-morning self-monitoring should be recommended for detecting these excursions. A more recent study by the same group demonstrated that glucose monitoring during the extended post-lunch period (5:00 PM) was optimal for detecting patients at risk of hypoglycemia and for assessing short-term control of diabetes. Long-acting sulfonylureas or gliptins (gliburide, repaglinide) have been found to increase hypoglycemic rates more than thiazolidinediones or biguanides. The lowest blood glucose values have been found to occur more frequently in the evening rather than in the morning. Therefore, in addition to mid-morning glucose monitoring, inclusion of routine evening self-testing can be advantageous in patients taking oral agents. Considering these factors, it seems reasonable to suggest that in patients above glycemic target, managed with oral agents plus once-daily insulin, once-daily insulin alone, or oral agents plus once-daily insulin, SMBG should be performed ≥2 times daily. For patients who have achieved glycemic target and are managed with once-daily insulin alone or oral agents alone, self-monitoring is recommended ≥1 time daily. Daily testing should be accompanied by ≥1 weekly profile to guide nutrition and physical activity, detect postprandial hyperglycemia, and prevent hypoglycemia. A weekly profile should include both preprandial and postprandial blood glucose measurements. For patients treated with once-daily insulin plus oral agent(s) who have achieved glycemic target, the recommended frequency for self-monitoring is ≥1 time daily with
Type 2 diabetes treated nonpharmacologically

Patients with type 2 diabetes not using insulin or oral hypoglycemic agents have also been shown to benefit from SMBG.37 Self-monitoring can provide awareness of the effects of diet and exercise on blood glucose levels and can motivate individuals to adjust their diet or physical activity to achieve glucose goals.11,24,36,42 A properly implemented program of self-monitoring that incorporates patient education improves patient motivation and self-care behaviors. Pairing blood glucose testing with a meal or event may be a particularly effective strategy to explore the effects of food, exercise, or stress.11,27 Meal-related testing has been shown to improve overall glycemic control and lead to significant improvements in general well-being.35 Several clinical studies of self-monitoring in patients managed by diet and exercise have used multiple-point profile days on ≥1 day each week.11,27,35,36,43 The study by Jaber and colleagues11 used SMBG 4 times per day (relative to meal consumption) for 2 days per week. A study of patients with type 2 diabetes treated with oral agents or diet used a self-monitoring frequency of 6 times per day for the first month of the 44-week study.27 Schwedes and associates35 used meal-related self-monitoring 6 times per day on 2 days of the week. Each of these studies examining different profiling strategies showed significant decreases in HbA1c for the group using SMBG. Based on these and other studies, it is reasonable to recommend that patients with type 2 diabetes who are nonpharmacologically managed can benefit from self-monitoring by performing ≥1 weekly profile whether they are at or above glycemic target. In addition to its ability to guide nutrition and physical activity, the results of frequent SMBG testing can be used to trigger the addition of pharmacologic therapy for patients who are consistently above glycemic target.

Pregnancy and gestational diabetes

Women with diabetes who become pregnant are at increased risk for congenital malformations, stillbirths, and other pregnancy-related complications. Glycemic targets are more stringent for women with diabetes who are pregnant than for nonpregnant women. Due to the ability of oral glucose–lowering drugs to cross the placenta, women with type 2 diabetes who become pregnant are commonly switched to insulin when medical nutrition therapy fails to achieve these lower targets (preprandial capillary whole-blood glucose ≤105 mg/dL (5.83 mmol/L), 2-hour postprandial levels ≤130 mg/dL (7.22 mmol/L)29 Increased self-testing is especially important in these patients, with the ADA recommending a frequency of ≥3 times daily and the American Academy of Family Physicians (AAFP) recommending ≥4 times a day.13,30 In gestational diabetes, medical nutrition therapy is the first approach to management and should be monitored by self-testing of blood glucose. The ADA recommendations state that daily self-monitoring appears to be superior to intermittent (i.e., medical office) monitoring of blood glucose.29 As in women with diabetes who become pregnant, self-monitoring is recommended ≥3 times daily in women with gestational diabetes who are treated with insulin.30

Postprandial testing for all patients with diabetes

Postprandial glucose has been found to be a significant contributor to overall glycemic control and to correlate better with HbA1c levels than fasting plasma glucose.44–48 Postprandial glucose excursions have been found to be greater contributors to overall hyperglycemia in fairly well-controlled patients (HbA1c ≤8.4%) than in poorly controlled patients (HbA1c >8.4%), in whom the contribution of fasting hyperglycemia is predominant.46 A recent study showed that meal-related self-testing in patients with non–insulin-treated type 2 diabetes both improved overall glycemic control and significantly improved patients’ general well-being.35 Other studies in patients with type 1 and type 2 diabetes who were poorly controlled with insulin or oral antihyperglycemic agents, respectively,36,49,50 showed decreases in HbA1c when postprandial self-monitoring was performed regularly, leading other researchers to suggest that postprandial glucose is a stronger reflection of the pathophysiologic process than fasting hyperglycemia.45 In addition to the contribution of postprandial glucose to HbA1c levels, data from other clinical trials reviewed earlier demonstrate a correlation between postprandial hyperglycemia and increased risk of cardiovascular events, even when glucose levels are at or below target levels.51,52 Therefore, postprandial SMBG should be performed by all patients to detect postprandial excursions and to indicate the need for lifestyle adjustments in order to minimize cardiovascular morbidity.

Avoiding hypoglycemic episodes

The development of hypoglycemia can increase many serious risks for patients with diabetes, including immediate and long-term complications. Therefore, avoidance of hypoglycemic episodes is critical to effective diabetes management. Hypoglycemia awareness training and education are important for patients to attain and maintain glycemic control. Episodes of severe hypoglycemia have been found to be preceded and followed by blood glucose disturbances, which—if identified—could be used to warn of imminent severe hypoglycemia.53 Frequent self-testing expands awareness of the correlation of symptoms with decreases in
blood glucose, enabling patients to take early action to reverse hypoglycemic excursions.\textsuperscript{34,40} In all patients with diabetes, certain situations (e.g., acute illness or change in medication type or dosage) should prompt more frequent self-monitoring.

**Recommendations for additional studies of self-monitoring of blood glucose**

As the availability of well-designed, high-quality clinical studies of SMBG has grown, the clinical effectiveness of self-monitoring has become more apparent. Additional randomized controlled trials would be beneficial, especially if focused on determining optimal frequency and timing. Future studies should consider measures to minimize patient dropout and quantify adherence with the prescribed intervention. Data should be adjusted to control for potential confounding factors. Inclusion criteria should delineate diabetes type, baseline HbA\textsubscript{1c} ranges, and prescribed treatments, as results may be applicable only to select patient strata. Additional data are also needed to determine the economic impact and cost-effectiveness of SMBG, especially in patients with non–insulin-treated type 2 diabetes. Health-economic modeling may be able to link improvements in clinical parameters with healthcare savings related to avoiding or delaying complications of diabetes. The long-term healthcare savings achieved by preventing diabetic complications would likely outweigh the short-term costs of increased use of self-monitoring.\textsuperscript{19}

**Summary**

Controlling blood glucose levels is important to preventing serious complications of diabetes, yet evidence suggests that glycemic control is not improving. When properly implemented, SMBG is an important tool for achieving glycemic control. Barriers to effective use of self-monitoring include poor patient adherence, limited access to supplies, incomplete patient education (how to perform self-monitoring, understanding glycemic targets, actions to take based on results), and lack of specific recommendations for timing and frequency. Healthcare professionals and patients must work together to overcome these barriers.

The following statements relate to the implementation of SMBG: (1) SMBG should be initiated in all patients with diabetes as an integral part of an overall diabetes management program. (2) Recommended frequencies for SMBG are $\geq 3$ to 4 times daily for patients treated with multiple daily insulin injections or using an insulin pump; $\geq 2$ times daily for patients above glycemic target managed with oral agents and/or once-daily insulin; $\geq 1$ time per day with a weekly profile for patients at glycemic target managed with either once-daily insulin or oral agents alone; $\geq 1$ time per day with more frequent weekly profiles for patient at glycemic target managed with oral agents plus once-daily insulin; and $\geq 1$ weekly profile for patients managed nonpharmacologically whether at or above target. (3) Additional self-monitoring should be performed in certain situations, such as acute illness, intercurrent illness, changes in medication, patients with impaired awareness of hypoglycemia, and during pregnancy. (4) Postprandial SMBG testing should be used by all patients with diabetes to minimize postprandial excursions and to guide lifestyle changes. (5) In addition to its utility as a tool for evaluation of glycemic control, SMBG should be viewed as an educational tool to inform patients about the effects of lifestyle and behavioral changes.

**References**


