

## Randomized Studies Are Needed to Assess the True Role of Self-Monitoring of Blood Glucose in Noninsulin-Treated Type 2 Diabetes

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### Abstract

Numerous trials have been conducted to assess the utility of self-monitoring of blood glucose (SMBG) in noninsulin-treated type 2 diabetic (T2DM) patients. Although recent meta-analyses support the benefits of SMBG, the clinical utility of SMBG in this population remains controversial due to a lack of large, randomized controlled trials. Much of the skepticism regarding SMBG in noninsulin-treated T2DM may stem from a misapplication or misunderstanding of the true role of SMBG. The benefits of SMBG are realized only when both the patient and the health care provider (HCP) know how and are willing to monitor, interpret, and respond appropriately to acute glucose excursions and patterns of glycemia identified through SMBG. Optimal utilization of SMBG requires that patients be trained and motivated to accurately perform SMBG at the time and frequency prescribed, accurately interpret the data they obtain, act upon the information when appropriate, and consistently document results for later review with their HCP. HCPs must be willing and able to routinely monitor SMBG data and make appropriate adjustments in therapy. Numerous studies are needed to evaluate the true value and utility of SMBG within the diverse T2DM population to ensure that resources for diabetes management can be used efficiently. This article identifies and discusses key factors to consider for the design of randomized studies that can provide a foundation upon which HCPs and health care systems may reevaluate their current strategies/protocols and incorporate the learnings into more effective approaches to patient care.

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### Introduction

Large prospective and observational trials have demonstrated the value of self-monitoring of blood glucose (SMBG) in type 1 diabetes (T1DM)<sup>1,2</sup> and insulin-treated type 2 diabetes (T2DM)<sup>3</sup>; however, the clinical utility of SMBG in noninsulin-treated T2DM remains controversial. While some studies<sup>4-7</sup> have reported that SMBG has little or no value in

noninsulin-treated patients, more recent studies<sup>8-11</sup> have demonstrated that therapeutic management programs that include structured SMBG result in greater hemoglobin A<sub>1c</sub> (A1C) reduction compared to programs without SMBG. Moreover, large, retrospective studies have shown an association between frequency of SMBG and A1C levels<sup>12,13</sup> regardless of treatment modality.

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**Abbreviations:** (A1C) hemoglobin A1c, (HCP) health care provider, (NSM) no self-monitoring, (SMBG) self-monitoring of blood glucose, (SMUG) self-monitoring of urine glucose, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

**Keywords:** blood glucose, blood glucose self-monitoring, clinical trials, diabetes mellitus, glucose, randomized controlled trials, self-care, study design, urine glucose monitoring

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However, whether and/or to what degree there is a causal relationship between SMBG frequency and clinical outcomes has yet to be determined through prospective trials.

Given the significant and increasing prevalence of diabetes worldwide, there is a clear need to evaluate the true value and utility of SMBG to ensure that resources for diabetes management can be used efficiently. This article discusses key issues and findings from recent meta-analyses that may explain some of the discrepancies in the literature and then presents a list of factors to consider for the design of the various randomized studies needed to accurately describe the potential roles and benefits of SMBG in noninsulin-treated T2DM patients.

## Review of Recent Meta-analyses

Numerous trials have been conducted to assess the utility of SMBG in noninsulin-treated T2DM patients; however, there have been no large, randomized trials to provide conclusive evidence to support SMBG. Therefore, we must rely on meta-analyses to provide guidance in this area. **Table 1** presents a summary of the four more recent meta-analyses regarding SMBG.

The National Health System health technology assessment by Coster and colleagues<sup>4</sup> summarized the results of randomized trials in SMBG until 1999. The authors reported that they found no clear evidence of SMBG benefit in noninsulin-treated T2DM subjects.

**Table 1.**  
Recent Meta-analyses<sup>a</sup>

Meta-analysis	Studies included	Results	Conclusions
Coster <i>et al.</i> (2000) <sup>4</sup>	Allen <i>et al.</i> <sup>7</sup> Estey <i>et al.</i> <sup>20</sup> Fontbonne <i>et al.</i> <sup>6</sup> Muchmore <i>et al.</i> <sup>34</sup> Rutten <i>et al.</i> <sup>35</sup>	<ul style="list-style-type: none"> <li>The estimated reduction in A1C from SMBG was -0.25% (95% CrI: -0.61–0.10%). According to the authors, no study had significant power to detect differences in A1C of less than 0.5%</li> </ul>	<ul style="list-style-type: none"> <li>Results from the analysis provide no clear evidence that SMBG is beneficial in noninsulin-treated T2DM patients</li> </ul>
Sarol <i>et al.</i> (2005) <sup>11</sup>	Davidson <i>et al.</i> <sup>5</sup> Estey <i>et al.</i> <sup>20</sup> Fontbonne <i>et al.</i> <sup>6</sup> Guerci <i>et al.</i> <sup>36</sup> Jaber <i>et al.</i> <sup>37</sup> Kwon <i>et al.</i> <sup>21</sup> Muchmore <i>et al.</i> <sup>34</sup> Schweddes <i>et al.</i> <sup>8</sup>	<ul style="list-style-type: none"> <li>Regimens that included SMBG as part of a multicomponent management strategy showed an additional A1C reduction of 0.39% (95% CI: -54–0.23%) under the “fixed-effects” model and an additional A1C reduction of 0.42% (95% CrI: -63–0.21%) compared to regimens that did not include SMBG</li> </ul>	<ul style="list-style-type: none"> <li>Multicomponent diabetes management programs with self-monitoring of blood glucose result in better glycemic control among noninsulin-using type 2 diabetic patients</li> </ul>
Welschen <i>et al.</i> (2005) <sup>14</sup>	Allen <i>et al.</i> <sup>7</sup> Davidson <i>et al.</i> <sup>5</sup> Fontbonne <i>et al.</i> <sup>6</sup> Guerci <i>et al.</i> <sup>36</sup> Muchmore <i>et al.</i> <sup>34</sup> Schweddes <i>et al.</i> <sup>8</sup>	<ul style="list-style-type: none"> <li>The overall effect of SMBG was a statistically significant 0.39% reduction in A1C compared with control groups (95% CrI: -0.56–0.21%)</li> <li>The comparison between SMBG and SMUG showed a nonsignificant decrease of 0.17% (-0.96–0.61) in A1C in favor of SMBG</li> </ul>	<ul style="list-style-type: none"> <li>SMBG in noninsulin-treated patients has a positive effect on A1C levels; however, no significant difference was seen between SMBG and SMUG</li> <li>Results should be interpreted cautiously because of the limited methodological quality of the studies analyzed</li> </ul>
Jansen (2006) <sup>10</sup>	Allen <i>et al.</i> <sup>7</sup> Brown <i>et al.</i> <sup>38</sup> Davidson <i>et al.</i> <sup>5</sup> Estey <i>et al.</i> <sup>20</sup> Fontbonne <i>et al.</i> <sup>6</sup> Guerci <i>et al.</i> <sup>36</sup> Jaber <i>et al.</i> <sup>37</sup> Kwon <i>et al.</i> <sup>21</sup> Miles <i>et al.</i> <sup>19</sup> Muchmore <i>et al.</i> <sup>34</sup> Schweddes <i>et al.</i> <sup>8</sup> Wing <i>et al.</i> <sup>31</sup>	<ul style="list-style-type: none"> <li>Adjusted for baseline A1C level and internal validity, regimens that included SMBG showed a reduction in A1C of 0.4% (95% CrI: 0.07–0.70%) compared to interventions without SMBG</li> <li>Reductions in A1C more than doubled when regular medical feedback was provided to patients</li> <li>SMUG showed comparable results to interventions that did not include SMBG</li> <li>There is an 88% probability that interventions with SMBG are more effective than regimens that use SMUG; the relative reduction in A1C is 0.38% (95% CrI: 0.30–1.00%)</li> </ul>	<ul style="list-style-type: none"> <li>Interventions with SMBG positively impact the effectiveness of treatment regimens in T2DM patients</li> <li>Interventions with SMBG that include regular medical feedback produce an additive effect versus SMBG alone</li> <li>Regimens that include SMBG are more likely to be effective in lowering A1C than those that utilize SMUG</li> </ul>

<sup>a</sup> SMBG, self-monitoring of blood glucose; SMUG, self-monitoring of urine glucose; CrI, credible interval.

Sarol and colleagues<sup>11</sup> published their meta-analysis in 2005, which included trials from 1966 through 2004, many of which were analyzed previously in the Coster report. Although Coster and colleagues<sup>4</sup> found no evidence for clinical effectiveness for SMBG in the studies analyzed, with the addition of more recent data, Sarol and colleagues<sup>11</sup> concluded that utilization of SMBG as part of a “multicomponent diabetes management program” results in better glycemic control than regimens that do not use SMBG.

An analysis by Welschen and colleagues,<sup>14</sup> which included many of the same studies used by Sarol, also showed a beneficial effect of SMBG. However, the authors cautioned that their findings may have been influenced by the limited methodological quality of the studies analyzed. It is important to note that in three of the six studies reviewed by Welschen, no standard instructions were provided to the patients to adjust their behavior or medication(s) to modify their glucose values.

The most recent meta-analysis was conducted by Jansen,<sup>10</sup> who concluded that interventions with SMBG positively impact the effectiveness of treatment regimens in T2DM patients compared to regimens with no self-monitoring (NSM) and that the effect is more than doubled when medical feedback is included in the intervention. The authors also reported an 88% probability that regimens including SMBG are more likely to be effective in lowering A1C than those that utilize self-monitoring of urine glucose (SMUG).

Unlike previous systematic reviews, which focused on pair-wise, direct comparisons of interventions, Jansen used a mixed treatment comparison meta-analysis within a Bayesian framework to obtain a generalization of standard meta-analysis for pair-wise trials to the simultaneous analysis of SMBG versus NSM, SMBG versus SMUG, and SMUG versus NSM trials. The author stated that this approach has an advantage over standard meta-analysis in that it strengthens inference concerning the relative effectiveness of treatments by including both “direct” and “indirect” comparisons.<sup>10</sup> As noted elsewhere, this approach has been shown to facilitate calculation of the probability of the best treatment.<sup>15-17</sup>

### Role and Utility of SMBG

Despite the growing body of evidence supporting the use of SMBG in noninsulin-treated T2DM, the designs of many of the studies cited have been criticized due to the utilization of more intensive counseling and/or treatment in the intervention groups.<sup>18</sup> However, much

of the criticism may stem from a misapplication or misunderstanding of the true role of SMBG. While it is possible to measure what we do not manage, which is often the case, we cannot manage what we do not measure. It is important to accurately define the role of SMBG within the context of the overall diabetes management regimen. **Table 2** presents proposed criteria for effective use of SMBG.

**Table 2.**  
**Proposed Criteria for Effective Utilization of SMBG**

	Utilization of SMBG may improve glycemic control in noninsulin-treated T2DM subjects when the following criteria are met:
Subjects	<ul style="list-style-type: none"> <li>• Possess the knowledge and ability to accurately perform SMBG and accurately interpret their testing data</li> <li>• Consistently use SMBG according to a prescribed regimen that facilitates detection of patterns of glycemia control</li> <li>• Possess the knowledge and ability to make appropriate adjustments in their therapy</li> <li>• Consistently make appropriate adjustments as needed</li> <li>• Consistently and accurately record their test results and related events (manually or electronically). If recorded electronically, the patient must ensure that the meter is accurately programmed (time and date) and that accurate and complete event data are entered</li> </ul>
Health Care Providers	<ul style="list-style-type: none"> <li>• Utilize therapies that adequately address all parameters of glycemic control (fasting/preprandial and postprandial glucose)</li> <li>• Possess the knowledge and ability to accurately interpret SMBG data</li> <li>• Possess the knowledge and ability to make timely and appropriate adjustments in patient therapy</li> <li>• Consistently monitor patient SMBG results and make appropriate adjustments as needed, based on SMBG data</li> </ul>

### Patient Utilization

SMBG allows individuals with diabetes to obtain and utilize information about current glucose levels, which, in turn, facilitates timely changes in their regimen to achieve and maintain near-normal glycemia; it is a tool, not an intervention. Thus, benefits of SMBG are realized only when there is action, such as modification of lifestyle or medication, based on the glucose results. This requires both the patient and health care provider (HCP) to know how to monitor, interpret, and respond appropriately to acute glucose excursions and patterns of glycemia identified through SMBG. Optimal utilization of this tool requires that patients be trained and motivated to accurately perform SMBG at the time and frequency prescribed, accurately interpret data they obtain, appropriately respond to data, and consistently document results for later review with their HCP. Thus,



patients must understand their glucose goals and receive comprehensive instructions regarding glucose appropriate adjustments in their therapy.

Although recent meta-analyses provide strong evidence for the benefits of SMBG in noninsulin-treated T2DM subjects,<sup>10,11,14</sup> many of the trials included in these meta-analyses have been widely used to refute the value of SMBG in this patient population.<sup>5-7,19</sup> For example, the study by Fontbonne and colleagues,<sup>6</sup> which is included in all four of the meta-analyses presented here, showed SMBG to have a neutral effect when compared to SMUG and NSM. A likely reason for this, however, is that the study protocol provided no instructions to the patients for adjusting behavior based on SMBG data. Conversely, studies that emphasized the role of factors that supported compliance with therapy (i.e., education, reminders to monitor) showed SMBG to have a clear benefit in improving metabolic control.<sup>8,20,21</sup>

Another issue that must be considered is the appropriateness of the therapeutic intervention. An example of this is the randomized crossover study by Miles and colleagues,<sup>19</sup> which has become a key element in the reimbursement debate regarding the value of SMBG versus SMUG. One must question why better glucose control was not achieved. Was it a consequence of the inappropriateness of treatment, inadequate testing regimens, or both? Subjects using SMUG were asked to test once daily for glycosuria, alternating before or 2 hours after different meals or at bedtime, with aglycosuria as the target glucose. Subjects using SMBG were asked to test once daily before a different meal or at bedtime with a target glucose of <8 mmol/liter (144 mg/dl).

Given that the renal threshold for spilling glucose into the urine is plasma blood glucose of 10 mmol/liter (180 mg/dl) in most individuals,<sup>22</sup> it is unlikely that subjects using SMUG would take any action until blood glucose levels were >10 mmol/liter (180 mg/dl). Further, because subjects had no pharmacologic agent to address postprandial excursions, their only option for addressing premeal glycosuria was to skip the meal or decrease the meal carbohydrate load. Moreover, given the lack of correlation between semiquantitative measures of glycosuria and prevailing blood glucose levels of <200 mg/dl,<sup>23</sup> detection of glucose in the urine 2 hours following a meal presents virtually no reliable information about the occurrence or degree of glucose excursion resulting from the meal. In subjects using SMBG, the absence of postmeal glucose data precluded their ability to monitor the glycemic impact of their meals. Thus, a more accurate conclusion from this study is that neither testing regimen provided

adequate information to effectively adjust therapy and control glycemia. This may partially explain the high dropout rate in both study groups at 3 months.

### *Health Care Provider Utilization*

Just as important in demonstrating the utility of SMBG in noninsulin-treated patients is the role of the HCP in supporting SMBG with their patients and utilizing data to reinforce behaviors and make necessary adjustments in medications. While an early study by Harris<sup>24</sup> concluded that SMBG has no role in the management of T2DM management, Blonde and colleagues<sup>25</sup> observed that SMBG has a substantial affect on diabetes care when the role of the HCP is considered. In essence, their position is that rather than simply collecting blood glucose data, it is the effective use of blood glucose information for making clinical decisions that leads to improvements in diabetes control.

The study by Davidson and colleagues<sup>5</sup> provides an example of how underutilized SMBG data can negatively impact glucose control. In that study, investigators looked at the effects of SMBG on A1C levels in noninsulin-treated patients who were asked to test their blood glucose before and after six meals per week. A dietitian reviewed SMBG data and provided counseling to patients regarding the effects of various foods and portion sizes on postprandial glucose excursions, yet medication changes were made by a nurse according to algorithms based on laboratory analysis; SMBG data were not used to monitor and titrate medication. Although baseline A1C levels were approximately 8.5% in both groups, no medications that specifically target postprandial glucose were used in the study. Compliance with SMBG and with study visits was poor. It is therefore not surprising that neither patient group achieved the study A1C target of 7.5% despite intensive (twice monthly) titration of therapy. Although the authors concluded that SMBG provides no statistically significant benefit in glycemic control compared to NSM, a more reasonable conclusion may be that failure to utilize SMBG data and rely solely on A1C could perpetuate inappropriate selection and utilization of therapeutic agents, resulting in suboptimal glycemic control.

The recently completed DiGEM trial<sup>26</sup> presents a similar potential vulnerability. Although the study findings have not yet been published, the protocol states that the two experimental groups were to be followed primarily by nurses who would “manage” patient care based on blood glucose data; however, medication changes would be made by a general practitioner based on quarterly

A1C levels in all treatment arms. SMBG data are largely used for lifestyle counseling. According to the protocol, the practitioner would review SMBG data only when test results were consistently  $>15$  mmol/liter (270 mg/dl). Thus, it is conceivable that no therapeutic changes would be made until blood glucose levels were well above the glycemic targets established by recognized diabetes organizations.<sup>22</sup> The reliance on A1C for all therapy decisions may negate any glycemic advantage obtained by subjects performing SMBG.

## Study Considerations

Discrepancies in the literature regarding the clinical utility of SMBG are not surprising given the wide differences in the trials conducted in terms of study design, subject characteristics, end points, and other factors. While discussion of the various methodologies for statistical analysis is beyond the scope of this review, we have identified other key factors to be considered when designing studies that accurately assess the utility of SMBG in diabetes management regimens in noninsulin-treated T2DM individuals.

### Structure

Because effective utilization of SMBG requires specialized training for both subjects and HCPs in the experimental group, a randomized, unblinded, parallel design is probably an appropriate structure for the study, whereas a crossover design would clearly impact results obtained from the post-crossover period. Further, although blinding of subjects or HCPs would not be an option, it may be advantageous to blind HCPs to A1C data for subjects performing self-monitoring. In a pay-for-performance or guideline-driven environment, medication titration may stop once the target A1C is reached, even if glucose data reveal ongoing hyperglycemia.

### Outcomes Measures

#### A1C

A common end point for interventional studies in diabetes is improvement in A1C because it is linked directly to the development and/or progression of microvascular and macrovascular complications.<sup>1,27,28</sup> However, in order to address potentially confounding factors, such as the Hawthorne effect and the timing/efficacy of the pharmacologic agents used (glitazones may take months to be effective), it may be necessary to extend the study duration to 12 months or longer.

Another factor to consider is the influence of baseline A1C on the degree of glycemic improvement; pharmaceutical

studies have shown the greatest reduction in A1C levels when baseline A1C is high. However, in studies using SMBG, those patients with the highest A1Cs may be challenged to modify lifestyle and obtain benefit from SMBG. Also, baseline A1C may determine the selection of pharmacologic therapies to be utilized. Utilization of therapies that specifically address postprandial glucose levels may become progressively more relevant at A1C levels of  $<8.4$ .

### Other End Points

In addition to changes in A1C, it may be valuable to examine the impact of SMBG data utilization by HCPs on frequency (or adequacy) of therapeutic adjustments. This is particularly important in light of a study by Brown and Nichols,<sup>29</sup> which showed that physicians in a large managed care organization often made no therapeutic changes in patient regimens until A1C levels reached 9% or higher. Would frequent and appropriate utilization of SMBG data prompt more timely adjustments in therapy?

Another end point would be changes in glycemic variability, which is emerging as an important aspect of glucose control, independent of A1C levels.<sup>30</sup> This end point could be assessed easily using the data management features included in many of the current blood glucose monitoring systems.

A third end point could be a reduction in hypoglycemia, which can be important in individuals treated with sulfonylureas. Ironically, ethical considerations regarding the safety of not using SMBG in sulfonylurea-treated subjects prohibit the implementation of studies designed to assess the utility of SMBG in these patients; the risk of hypoglycemia associated with insulin secretagogues may limit titration, particularly in nontesters.

Regardless of the end point(s) used, investigators must also consider the level at which differences between experimental and control groups become clinically significant. This, in turn, will help determine how the study must be powered.

## Protocol

### Patient populations

A significant factor in the design of any study is defining the patient population adequately. This is particularly important in T2DM, which may involve a widely diverse group of subjects in terms of duration of diabetes, current medications, metabolic status, prevalence and degree of complications, overall health status, ethnic/cultural

differences, language barriers, literacy, numeracy, and other factors. Subject characteristics must be factored into the study design because they can impact study outcomes significantly.

### *Health care provider populations*

Another aspect of the study design is defining the HCP population. Is there a bias for or against SMBG? Who will make the therapeutic decisions? Are HCPs able and willing to accurately interpret and appropriately act upon the results? Will learnings from the SMBG arm influence treatment in the control arm? All of these factors must be considered in the study design.

### *Education and counseling*

A distinction must be made between basic diabetes education and more advanced self-management training. Basic education would generally include information about treatment goals and instruction in meal planning, medications, prevention/treatment of acute complications, and prevention/detection of chronic complications. More advanced training would include all of these elements, along with focused training in use of SMBG utilization, including SMBG procedures (testing, documentation of results, quality control, maintenance, troubleshooting), timing of SMBG, interpretation of test results, and therapy adjustment (lifestyle and pharmacologic) based on test results.

The Schwedes *et al.* study<sup>8</sup> has been critiqued because different education and counseling were provided to the SMBG and control groups. However, in this study, the standardized counseling was a series of simple questions designed to get patients to self-reflect and then self-regulate on the testing experience and glucose data. This “counseling” would not have been possible in the nontesting group, which group received usual care, including nonstandardized dietary and exercise “counseling” without knowledge of specific effects they exert on glycemia.

### *Frequency of visits*

The frequency of patient contact with HCPs can influence outcomes in a number of ways. For example, when subjects in both groups have more frequent contact with the HCP, there is a potential for bias; differences in outcomes between the groups may be minimized due to the Hawthorne effect. This may have been an issue in the study examining whether SMBG can facilitate weight loss by Wing *et al.*,<sup>31</sup> where subjects had weekly and then monthly visits during much of the study. Conversely, inadequacy of visit frequency may also bias results in

that subjects may not receive needed therapy adjustments or behavioral reinforcement. Investigators are challenged to determine whether the frequency of visits is both adequate and realistic for the populations being studied.

### *Medications/medication adjustments*

As discussed earlier, the value of SMBG is directly linked to the consistent and appropriate use of monitoring data. Thus, the method used to adjust therapy is a key issue in the study design. The protocol should clearly define the glucose goals for each study group. Will the HCP follow a formalized treatment algorithm to adjust therapy or will dose titrations and therapeutic changes be made at the discretion of the HCP? Will patients be responsible for self-titration of oral agents based on SMBG data? The protocol must also address methods by which compliance with testing and medication use is assessed and the statistical plan will need to consider noncompliance issues.

### *Testing issues*

Frequency of testing and overall SMBG regimen must be determined and defined in the protocol. Will timing and frequency of testing be based on a defined algorithm or at the discretion of the HCP? Testing must be of sufficient frequency to reinforce behavioral change. Note that the observational study by Karter *et al.*<sup>13</sup> suggested progressive benefits of SMBG up to three tests a day. The specific testing regimen may also be critical in demonstrating glycemic improvement. Testing only fasting glucoses in the morning may not provide actionable information to patients. Postprandial testing may help educate patients about food and may play a critical role in helping patients reach A1C goals, as postmeal hyperglycemia becomes a major determinant of glycemic control as A1C levels decrease below 8.4%.<sup>32</sup> However, if premeal glucoses are high, postprandial glucose goals may be impossible to reach. The most important, usable information for a patient may be the meal excursion. Paired meal testing around different meals could be part of a glucose profile that could be used to educate and motivate patients and help HCPs direct therapy.<sup>33</sup>

How will documentation of test results be handled, by logbook or computer download? Although the minority of HCPs routinely download data, most SMBG systems offer data management capabilities that calculate means, variance, and trends by time of day or over weeks and months. Software programs facilitate downloading data to personal computers to generate graphs. Utilization of these data management features can facilitate data analysis and interpretation (by the subject and/or the



HCP) and allow the HCP to monitor compliance with the testing regimen. It is important, however, that the correct time and date are entered into the blood glucose meter.

## Discussion

SMBG must be viewed as an integral component of comprehensive diabetes treatment, not as an independent intervention; patients and HCPs must be willing and able to act on data with appropriate changes in behaviors and pharmacologic therapies. Although recent meta-analyses have demonstrated that SMBG may be of benefit in the management of noninsulin-treated T2DM, the findings have been deemed inconclusive by some clinicians because of the small study size and potential flaws in study design. However, as described in an editorial by Davidson,<sup>18</sup> utilization of SMBG in noninsulin-treated individuals has several potential benefits, including enhanced patient education and motivation; detection and documentation of hyperglycemia and hypoglycemia; and utilization by HCPs to adjust therapy. Nevertheless, large, randomized trials are needed to definitively assess the utility of SMBG in various noninsulin-treated diabetic populations. Further, rather than limiting investigations to the "effect" of SMBG, studies are needed to determine the extent to which patients and HCPs can be trained to optimize SMBG utilization.

While the concepts and approaches to designing these studies presented here may not reflect "real world" clinical scenarios, it is our view that a key role of research is to guide clinicians in developing and implementing treatment strategies that improve patient care. Given the financial costs and other resource expenditures associated with SMBG, it is prudent that the value of SMBG be definitively assessed within specific noninsulin-treated T2DM populations through well-designed clinical trials. These studies can provide a foundation upon which HCPs and health care systems may reevaluate their current strategies/protocols and incorporate the learnings into more effective approaches to patient care.

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