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Self-monitoring of blood glucose in noninsulin-using type 2 diabetic patients: right answer, but wrong question: self-monitoring of blood glucose can be clinically valuable for noninsulin users.

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Self-Monitoring of Blood Glucose in Noninsulin-Using Type 2 Diabetic Patients

Right answer, but wrong question: self-monitoring of blood glucose can be clinically valuable for noninsulin users

Given the importance of glycemic control in the development of diabetes complications, the plethora of tools now available to monitor the day-to-day trends in glycemia is remarkable. In this regard, self-monitoring of blood glucose (SMBG) has been considered a key component of patient management. Arguably, there remains almost universal agreement that SMBG should be available to all diabetic patients regardless of current treatment strategy. However, recently there have been reports that have challenged the current paradigm that all patients should use SMBG and concluded that SMBG for type 2 diabetic patients not on insulin may not be beneficial on glycemic control and must be weighed against the expense and inconvenience. In the counterpoint narrative following the contribution by Malanda et al., Drs. Polonsky and Fisher provide a compelling argument suggesting that while it is evident that implementing SMBG in unstructured ways without training patients and clinicians is likely to be a waste of resources, there are effective and powerful ways to use structured SMBG in insulin-naïve type 2 diabetic patients.

—William T. Cefalu, md
Editor in Chief, *Diabetes Care*

In their recent review of 12 randomized clinical trials, Malanda et al. (1) concluded that self-monitoring of blood glucose (SMBG) for patients with type 2 diabetes not on insulin has only a minimal, though statistically significant, impact on improving glycemic control in the short term (a reduction in A1C of 0.3% after 6 months) and an even more minimal, and nonsignificant, impact on A1C in the long term (−0.1% at 12 months). Furthermore, they noted that there was no evidence that introducing SMBG affected changes in patient well-being, quality of life, or satisfaction. These findings are similar to those reported in previous reviews (2–5), which included many of the same studies. The implications of these conclusions are important: if SMBG for this population is clinically inefficacious, then there is little justification for directing sparse clinical and financial resources to support SMBG. In fact, in response to previous findings, health care systems in several countries, including Germany, Sweden, France, and Canada, have already curtailed reimbursement for SMBG among type 2 diabetic adults not on insulin.

The review by Malanda et al. is comprehensive and well designed, and the conclusions follow directly from the questions posed and the rigorous methods used. Unfortunately, we believe that the authors have addressed only one small aspect of the key question concerning the clinical efficacy of SMBG for this patient population. In essence, they have adopted a simplified pharmacological rationale to test the efficacy of a complex treatment: a single treatment is delivered to subjects and it either works or it does not work with respect to a well-defined outcome. The design of their meta-analysis follows accordingly. Studies were included that randomly assigned subjects to one of two groups, with administration of treatment (SMBG) to one group but not to the other; then the two groups were compared on a primary outcome (A1C). And, as in the pharmaceutical analogy, SMBG was considered a uniform, unvarying "medication" or treatment.

Unfortunately, unlike a medication, SMBG is not a uniform intervention administered in an identical manner across all patients and settings. It varies considerably by the clinical question it addresses, the recommended frequency and timing of tests, the expertise of patients regarding its use, and the involvement and knowledge of clinicians in interpreting and responding to SMBG data. Like any good tool, SMBG may be used well or poorly. What Malanda et al. and other reviewers (2–5) do not consider, and which should be included in the evaluation of any viable SMBG trial, is exactly how the SMBG "tool" was defined in the protocol of each study reviewed and how the resulting SMBG data were used clinically. Behavioral research has demonstrated that the effectiveness of health-related tools, such as SMBG, can be substantially magnified when there is comprehensive patient education, skills training, and—in the case of SMBG—structured data feedback, both in type 1 diabetes (6) and type 2 diabetes (7). In the opposite case, where education and support for SMBG are minimal or nonexistent, perhaps we should not be surprised that glycemic benefits are also nonexistent (8). Therefore, it is simply not enough to report the significance of generic SMBG "treatment" effects using a general omnibus test. The ways in which SMBG are used must also be given due consideration—especially when the conclusions of such investigations are likely to have major implications for health policy.

What are the crucial parameters of SMBG interventions for this population that should be included in SMBG efficacy studies (none of which were examined in the review by Malanda et al.)? We suggest the following (see Table 1).

Recommended frequency and timing of SMBG must be adequate—How many blood glucose tests are necessary and how should the frequency and timing of tests be structured? The answer varies depending on the clinical concern addressed. Is the goal to assure that clinicians have the data needed to propose timely medication adjustments and/or lifestyle recommendations? Or perhaps it is to alert patients that dietary or activity changes need to be made? For example, across many of the studies cited by Malanda et al., both pre- and postprandial tests were included in the protocol, but the recommended timing and frequency of testing varied greatly—often they were almost random (e.g., test after meals twice a week), and only in rare cases were they sufficient to obtain a reliable pattern of findings

Table 1—*Key parameters to be considered for SMBG in insulin-naïve type 2 diabetic patients*

Parameter	Rationale	Recommendation
SMBG frequency and timing	Sufficient SMBG frequency and appropriate timing of tests so that patients and clinicians can detect well-defined and reliable BG patterns and use them as the basis for corrective action.	Structured SMBG before and after selected meals, before and after exercise, and at other key moments, conducted regularly at set times over a period of days.
Patients' SMBG-related knowledge and skills	Patients must know when and why they should test, understand what BG data mean, and be able to make good use of SMBG data; otherwise, SMBG is of minimal value.	Practical and targeted SMBG-related education and skills training for patients is critical.
Clinicians' SMBG-related knowledge and skills and access to BG data	Clinician involvement in SMBG data interpretation and problem-solving with patients is critical. Clinicians need to be knowledgeable about SMBG, actually see the collected SMBG data, be able to detect reliable BG patterns, and have the skills and knowledge to make good use of SMBG data (e.g., timely and appropriate medication adjustments).	SMBG-related education and skills training for clinicians is key. Clinicians must have regular, easy access to patient SMBG data and must know how to interpret and respond to such data.
Display of SMBG data	SMBG data are more likely to be used by patients and clinicians when the data are collected and recorded in ways that allow BG patterns to be readily observable and easy to understand.	An easy-to-read SMBG profile sheet, web application, or online form that makes sense to both patients and clinicians and is tailored to address specific clinical questions and facilitate recognition of BG patterns.

BG, blood glucose.

that could be used for clinical decision making. We believe that highly structured SMBG before and after selected meals (and/or before and after bouts of physical activity), conducted at set times over several days is required if the purpose is to collect enough data that patients and their clinicians can detect well-defined blood glucose patterns and use them as the basis for corrective action (9).

Patients need to be knowledgeable about SMBG and have the necessary skills to use SMBG data—It is often assumed that SMBG functions similarly to an automated feedback device, where the patient unvaryingly takes the appropriate, corrective action after each measurement. But patients must know how to test, why they are testing, what the data mean, and what they can do. In none of the studies cited by Malanda et al. is it possible to tell how much patients knew and what they actually did with their data. In addition, the SMBG-related education and subsequent support that patients received varied widely across studies; in some cases, there was almost none at all (8). If patients do not understand or are not able to respond to SMBG data appropriately, the mere act of blood glucose monitoring will seem meaningless and the frequency of SMBG will likely decrease considerably over time as motivation to test declines (10,11).

Clinicians need to be knowledgeable about SMBG, actually see the SMBG data that patients collect, and have the necessary skills to use the SMBG data—A key value of SMBG is that it can provide clinicians with the information they need to make timely treatment adjustments. Clinician involvement in SMBG can also help patients see that their personal efforts to collect SMBG data are worthwhile, thus contributing to patients' motivation to continue SMBG over time. Unfortunately, we cannot assume that clinicians know how to use SMBG data effectively to adjust treatment. Appropriate training is critical in any evaluation of the clinical efficacy of SMBG for this population. Unfortunately, these issues are not addressed by Malanda et al. In several of the studies cited (5,8,12), physicians were not permitted to review SMBG data, whereas in others they were (13,14). Regular nurse and/or dietitian support occurred in many studies (5,12,13,15) but not all (8), and it was never clear what that support entailed or how, or if, nurses used SMBG data to adjust treatment directly. Nor were efforts made to ensure that the clinicians who saw SMBG data actually knew what to do with them. In sum, SMBG is more likely to be beneficial when clinicians actually review SMBG data with patients, know how to make good clinical use of the data, and work directly with patients around their SMBG findings in a close, collaborative manner.

SMBG data must be collected and recorded in a manner that permits blood glucose patterns to be readily observable and easily intelligible for clinicians and patients—A simple logbook or other unstructured list of blood glucose values is rarely helpful. It is frequently confusing to patients, and it requires far too much time for busy clinicians to review each page of results. We believe that a carefully constructed, easy-to-read, profile sheet, web application, or online form that makes sense to both patients and clinicians and is tailored to address specific clinical questions is necessary to facilitate recognition of trends in blood glucose values. None of the studies reviewed by Malanda et al. mentioned how SMBG data were actually recorded and how blood glucose trends were observed from the recorded data by both patients and clinicians; therefore, it remains unclear if blood glucose patterns were even observable or detected. If they were not, as we suspect, how could they be used effectively by clinicians to alter care?

We argue, therefore, that the key question in need of examination is, "Can a program of SMBG that makes good use of the four elements listed above

lead to improved glycemic control among insulin-naïve patients?" This question, however, is quite different from the question that Malanda et al. addressed, "Can simply obtaining and recording SMBG data, whether or not they are used to inform care, lead to improved glycemic control?" We believe that Malanda et al. and others have indeed reached the correct answer to their question. Simply obtaining and recording SMBG data is of minimal clinical value. But this is clearly the wrong question. Even a thermometer, blood pressure monitor, or electrocardiogram monitor may be clinically ineffective if the resulting data are never seen by educated clinicians or are used inappropriately by clinicians and/or patients. Therefore, if patients are given inadequate guidance regarding the interpretation and use of SMBG data, and if clinicians rarely see or make use of these data, why should we expect to see a positive glycemic impact? Nor should we be surprised that many patients then lose interest in SMBG and begin to see it as unimportant, viewing SMBG as a pointless, demotivating experience, where the results may lead to feelings of guilt, confusion, and helplessness, especially when it seems to them that blood glucose numbers are rising and falling for no apparent reason (10). Sadly, recent data suggest that such negative patient attitudes are far from uncommon (10,11).

Further concerns about study design—The studies included in the report by Malanda et al. and other recent reviews raise additional concerns about how SMBG efficacy studies of insulin-naïve type 2 diabetic patients have been designed and implemented. A report by the International Diabetes Federation (16), along with several other publications (9,17), suggests that many SMBG trials have serious design flaws that increase the probability of a type 1 error. For example, some studies included patients with baseline A1Cs far too low to benefit from the intervention (5); in other studies, only patients—not clinicians—were randomized, so that the same clinicians saw patients from both study arms (12). This can lead to the "bleeding" of SMBG benefits across study arms, thus reducing between-group differences. Furthermore, SMBG protocols are unlikely to be beneficial if patients do not follow them. Poor adherence to SMBG recommendations has been a perennial problem, noted to be as high as 48% among some studies (18), yet all but one (14) used only intention-to-treat analyses. No effort was made to determine the effectiveness of SMBG among patients who actually tested (per protocol analyses), nor were efforts devoted to determine why some patients tested and some did not. Thus, intention-to-treat analyses confounded the effectiveness of SMBG with patient motivation to test. And that motivation, we suggest, is directly tied to how SMBG is introduced, taught, and used by both patients and clinicians in a collaborative and clinically meaningful way.

Conclusions—Given the financial restrictions facing many health care systems and the potential positive clinical impact of SMBG on glycemic control, it is important to evaluate most carefully the clinical effectiveness of SMBG for the very large population of insulin-naïve type 2 diabetic patients. More comprehensive analyses of existing trials and the planning of more precise studies that include these factors are crucial for developing realistic health policy. We believe that the review by Malanda et al. drew the correct conclusions from their assessment of the available literature but that they posed the wrong question. Clearly, unstructured SMBG that is not directly tied to specific clinical questions in ways that direct and support care among educated patients and clinicians is of little value and is most likely wasteful of health care resources. This, however, does not mean that SMBG for this population should be eliminated from clinical use.

Of note, a number of studies that Malanda et al. explicitly excluded from their review have explored innovative ways of using structured and targeted SMBG testing for this patient population effectively, and have shown significantly reduced A1C, depression, and distress, and enhanced diabetes self-efficacy (7,19,20). Therefore, rephrasing the research question and retargeting studies to evaluate the specifics of effective use of structured SMBG are warranted. These might include identifying the optimum number and pattern of tests required to address specific clinical questions, how much and what forms of education for patients with different educational needs are most useful, how best to display such information for patients and clinicians, how clinicians can best be trained to maximize the use of SMBG data clinically, and how office systems can be developed to facilitate implementation of SMBG as a standard component of patient care.

In conclusion, we believe that there are effective and powerful ways to use structured SMBG in insulin-naïve type 2 diabetic patients. Although it is evident that implementing SMBG in unstructured ways without training patients and clinicians is likely to be a waste of resources, it is now time to move beyond this narrowly defined question, as posed by Malanda et al., and direct resources to discovering the best means for effectively using structured SMBG for this population.

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