Effective Use of Structured Self-Management of Blood Glucose in Type 2 Diabetes: Lessons From the STeP Study

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According to the latest estimates, more than 25 million Americans > 20 years of age have diabetes.[1] Approximately 35% of all U.S. adults have prediabetes, a condition characterized by glucose levels that are elevated but below the glycemic cut points for clinical diabetes.[1]

Uncontrolled diabetes is linked to severe microvascular and macrovascular disease. However, studies have shown that optimal management of glycemia and other risk factors reduces the development and progression of the microvascular and macrovascular complications associated with diabetes.[2–4] Despite advances in medications and medical device technology, however, most patients with diabetes are not at their recommended glucose treatment goals.[5]

Because most diabetes patients in the United States are managed in community settings, it is important that primary care clinicians develop strategies to more effectively utilize all available tools and therapies in their practices to improve the clinical, social, and financial outcomes of diabetes. One such tool is structured self-monitoring of blood glucose (SMBG), a systematic approach to glucose monitoring that reveals significant patterns of glycemia occurring throughout the day.

In the Structured Testing Program (STeP) study, a large, 12-month, cluster-randomized, multicenter clinical trial, use of structured SMBG as a component of a comprehensive and collaborative intervention demonstrated significant clinical, behavioral, and quality-of-life benefits.[6] This article discusses some of the key lessons learned from the STeP study and presents a practical approach to incorporating and utilizing structured SMBG in primary care.

Obstacles to Effective Diabetes Care

Clinician-related obstacles

Clinical inertia is a key contributor to suboptimal diabetes control. Studies have shown that many health care providers often do not initiate or intensify diabetes therapy in patients who are above their recommended glycemic goals,[7–11] which can lead to suboptimal glycemic control and poor subsequent outcomes. One recent study[12] showed that most insulin treatment was initiated only after A1C levels were ≥ 9.6% for an extended period of time.

IN BRIEF

The Structured Testing Program (STeP) study used structured self-monitoring of blood glucose (SMBG) as a component of a collaborative intervention. Study results showed significant clinical, behavioral, and quality-of-life benefits from the intervention. This article discusses some of the key lessons learned from the STeP study and presents a practical approach to incorporating and utilizing structured SMBG in primary care.

Because patients often develop type 2 diabetes 9–12 years before the disease is diagnosed,[13] early intervention is essential to stem the progression of diabetes complications that may already be present. In the U.K. Prospective Diabetes Study, patients on average had already lost 50% of their β-cell function by the time type 2 diabetes was diagnosed.[14] However, early intervention is not enough; type 2 diabetes is a chronic, progressive disease that requires persistent treatment modification as needed to address the relentless worsening of β-cell function.

Competing clinical demands during time-limited office visits has been identified as a major obstacle to medication intensification in diabetes management.[15] However, a recent study by Grant et al.[16] also found that physicians who did not intensify therapy more often indicated that they needed more clinical information.

Another obstacle to effective clinical management of diabetes is finding the time and resources to develop and implement efficient workflow protocols into practice operations. Most primary care settings are structured to provide acute care, involving episodic interactions with patients. Such care does not address the needs of patients with chronic conditions.[17] Lack of

organizational support and computerized tracking systems limits clinicians' ability to achieve and sustain improvements in diabetes care using traditional physician-targeted approaches.[18] Given the current climate of financial constraints and limited resources, primary care clinicians are challenged by the task of modifying their practice operations to meet the complex, chronic needs of their diabetic patients.

Patient-related obstacles

Unlike acute illnesses, diabetes requires patients to actively manage their disease throughout each day. They must employ several complex cognitive and physical tasks to carefully balance their food intake, medications, and physical activity to maintain target glucose levels. For many patients, diabetes self-management can become overwhelming. Approximately 18–35% of patients with type 2 diabetes experience significantly high levels of diabetes-related distress,[19] which is linked to poor self-care and poor glycemic control.[20,21]

The burden of self-management is an important contributor to distress. However, fears about acute and future complications and guilt and anxiety when patients get "off track" with their diabetes self-care are also major factors associated with diabetes-related distress in both insulin-treated and non–insulin-treated diabetes.[22] These concerns can cause patients to become discouraged, significantly affecting adherence to their self-management regimens. However, even patients who are not significantly distressed can become discouraged if their treatment plan does not make sense or seem effective to them or if they feel they lack the ability to succeed with their diabetes management.

Overcoming the Challenges

Role of structured SMBG

Virtually all aspects of diabetes management—use of medications, nutrition, and physical activity—revolve around glycemic control. Although managing lipids and blood pressure is clearly an important component of diabetes care, the primary focus should be on maintaining normal or at least near-normal glucose throughout the day.

Although A1C is commonly used to assess long-term glycemic control, it does not provide information about intraday glucose excursions. You cannot problem-solve with an A1C value. Structured SMBG fills this information deficit by identifying significant glycemic excursions throughout the day and night.

Structured SMBG can be performed as daily glucose profiles (e.g., a 5- or 7-point profile) that are representative of daily glucose excursions, or as paired testing, which allows clinicians and patients to determine the effects of medications or health behaviors (e.g., food intake or physical activity) at specific time points. For example, an individual may want to learn how physical exercise (e.g., a 30-minute walk immediately after breakfast) affects his or her postprandial glucose levels. To obtain this information, he or she might test pre- and postprandial blood glucose at breakfast for 2 or 3 days before initiating exercise to document current glucose control, then incorporate the postbreakfast exercise into the daily regimen, and finally repeat the testing to see the effects of the exercise.

New guidelines from the International Diabetes Federation specify that the timing and frequency of SMBG regimens should be individualized to address each patient's specific educational, behavioral, and clinical requirements and to meet clinicians' needs for data on glycemic patterns and to monitor the impact of therapeutic decision-making.[23] Whatever the defined testing regimen may be, it should be designed to meet each patient's individual needs with a specific information goal in mind. However, the actual glucose testing is only a part of the process; structured SMBG is useful only when patients and clinicians possess the ability and willingness to accurately assess the significance of the blood glucose data generated and then use that information to make appropriate, effective treatment changes (medication or behavioral) that lead to positive outcomes.[23]

Structured SMBG provides crucial information that allows clinicians to identify and address specific patterns of hyperglycemia and hypoglycemia when they are evident, evaluate the effects and efficacy of therapy changes, and monitor glycemic control on an ongoing basis to address emerging issues as diabetes progresses. Also, the availability of structured SMBG data seems to facilitate more timely diabetes treatment and persistent therapeutic adjustments.[24]

Improved clinical decision-making is clearly a benefit of structured SMBG; reviewing glucose data with patients also creates opportunities for more meaningful discussions about their concerns and daily challenges. Clinicians and patients can begin to work collaboratively to address these issues without the "blame and shame" that patients often feel when interacting with their health care providers. Working within this collaborative relationship, clinicians and patients can mutually agree on treatment goals and strategies, which more fully engages patients in their self-management. Patients understand the problem, they have played a role in

devising a solution, and they leave the office visit knowing what to do, why to do it, how to assess the results of their efforts, and what they need to do if they do not get the desired results.

Structured SMBG also provides patients with significant educational and emotional benefits, yielding immediate feedback regarding the effects of nutrition, medications, physical activity, stress, and illness on their daily glucose control. This feedback allows patients to visualize their daily glycemic control and to start making the connection between their actions and their blood glucose levels. In essence, it helps patients make sense of their diabetes management, demonstrating the effects of the various components of their treatment regimen. Through this process, patients see that they do have control over their diabetes, which promotes a sense of self-efficacy. When patients see that adherence to their medication and lifestyle regimen positively affects glycemic control, they feel more confident and empowered to manage their diabetes.

An evidence-based approach to diabetes management

Although some well-publicized studies have questioned the value of SMBG in non–insulin-treated type 2 diabetes,[25–27] the validity of the findings has been challenged.[23,28] Were the testing regimens sufficient to reveal meaningful patterns of glycemic excursions? Were the SMBG data actually used to make clinical decisions?

More recent studies that have included both insulin-treated[29] and non–insulin-treated[24,30–33] patients with type 2 diabetes have shown that structured SMBG is beneficial in improving glycemic control and facilitating adoption of healthier behaviors when it is incorporated into a comprehensive intervention that encourages strong collaboration between patients and clinicians.

ROSSO-in-praxi trial. Kempf et al.[30] assessed the impact of a 12-week structured SMBG-based lifestyle intervention on glycemic control and general health parameters, including weight, quality of diet, and level of physical activity in 405 patients with type 2 diabetes. Patients were instructed to measure their weight and waist circumference, document the number of steps they walked per day, and generate a 7-point blood glucose profile every 4 weeks. At the end of 12 weeks, 81% of patients had completed the program, showing significant improvement in A1C, quality of diet, and level of physical activity, as well as weight reduction ($P < 0.0001$). Patients also experienced significant ($P < 0.001$) improvements in physical and mental health measurements. Surprisingly, the cost of the intervention was relatively inexpensive, ~ $200 per patient, which included training materials, SMBG test strips, and telephone consultations (~ 53 minutes per patient).

ROSES trial. In a recent open-label, randomized pilot study, Franciosi et al.[31] utilized a "staggered testing" regimen to assess the efficacy of a structured SMBG-based intervention in patients with type 2 diabetes treated with oral agents. The regimen involved preprandial and postprandial testing at breakfast on day 1, at lunch on day 3, and at supper on day 5. Patients were asked to complete two weekly profiles per month during the 6-month study period. At 6 months, patients in the structured SMBG group showed significant A1C reductions compared to a control group (–1.2 vs. –0.7%; $P = 0.04$). Similar to the ROSSO-in-praxi trial described above,[30] the intervention was both resource-efficient (an average of 20 minutes of telephone contact per patient each month) and readily adopted by patients. More than 92% of patients performed > 80% of the required number of SMBG measurements.

STeP study. The STeP study,[24] a large, 12-month, cluster-randomized, multicenter clinical trial in primary care, evaluated the impact of a structured SMBG regimen in poorly controlled, insulin-naive patients with type 2 diabetes. Utilizing a structured data collection form (ACCU-CHEK 360° View tool; Roche Diagnostics, Indianapolis, Ind.) that enabled patients to record and plot a 7-point SMBG profile on three consecutive days, intervention physicians and patients participated in a collaborative program to gather, interpret, and act on the structured SMBG data at quarterly intervals to make treatment modifications. By 12 months, patients in the structured SMBG group showed significantly greater improvements in overall glycemia (as measured by A1C) than those in the control group. Significant reductions in postprandial glucose excursions and overall glycemic variability were also seen. These improvements were driven largely by more timely and persistent therapy adjustments (medication and lifestyle) by clinicians. Almost three times more patients in the structured testing group received a treatment change recommendation at the month 1 visit compared to patients in the control group (179 [75.5%] vs. 61 [28.0%]; $P < 0.0001$), and patients in the structured SMBG group continued to receive significantly more therapy adjustments throughout the 12-month study period ($P < 0.0001$).

Study results also showed improvement in quality-of-life measures and reductions in diabetes-related distress, all of which positively affect patients' adherence to their treatment regimens. In exit interviews with study subjects, many patients in the structured SMBG group stated that the intervention

helped them better understand their diabetes and the effects of their medications and behaviors on their glucose control. Moreover, they felt that use of the data collection tool provided a focal point for more meaningful discussions with their physicians.

A Practical Approach to Integrating Structured SMBG Into Clinical Practice

An important aspect of the STeP study is that it was conducted in primary care practices, which demonstrates the efficacy and feasibility of the intervention in real-world settings. Findings from the STeP study provide valuable guidance to primary care clinicians who would like to make more effective use of SMBG data in managing their patients with diabetes. This section presents a description of the key components of the STeP intervention and recommendations for implementing structured SMBG in clinical practice.

SMBG data collection tool

SMBG data were collected using the ACCU-CHEK 360° View tool, a validated instrument[34] that allows patients to record and plot a 7-point SMBG profile (before and after meals and at bedtime) on three consecutive days (Figure 1). The rows highlighted in yellow indicate a general target range for glucose. The tool also collects information about relative meal size and energy level associated with the blood glucose values. Space is provided for patients to record their experiences and lessons derived from using the tool. As patients test, they can start connecting the Xs to create a graph of their blood glucose levels throughout the day.

Using pattern management to interpret and act on SMBG data

Pattern management is a systematic, four-step approach to identifying glycemic patterns within SMBG data and then taking appropriate action based on those results. The process involves *1*) identifying the primary glycemic abnormality, *2*) determining the timing and frequency of the occurrence, *3*) investigating the potential causes, and then *4*) taking action.

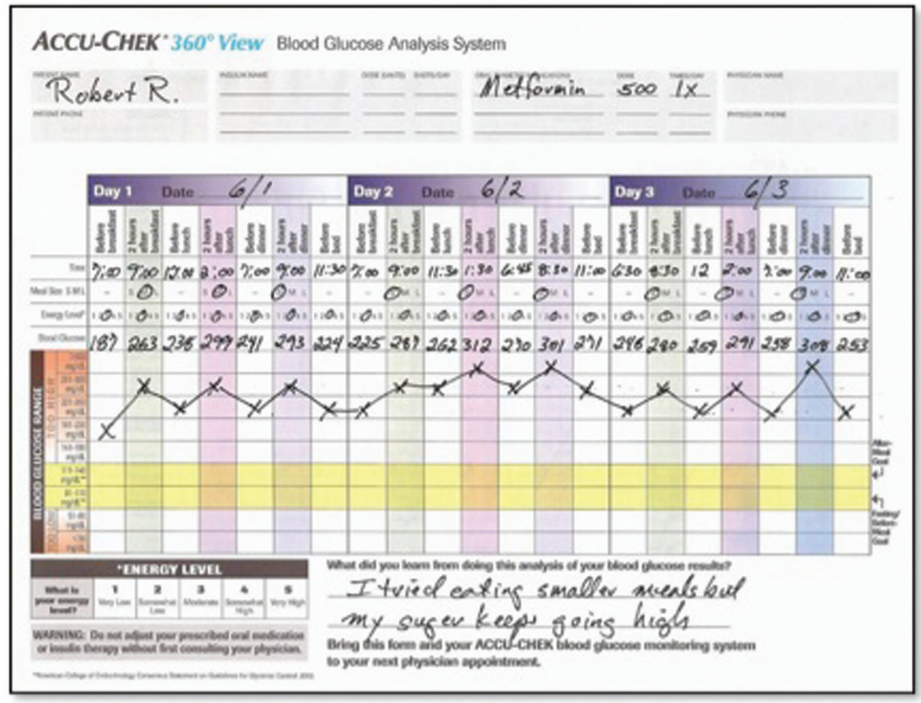

Figure 1. STeP study data collection tool.

Within the context of pattern management, there are three main abnormalities that should be addressed in order of priority as presented here: *1*) hypoglycemia, *2*) fasting hyperglycemia, and *3*) 2-hour postprandial hyperglycemia, which is defined as glucose excursions > 50 mg/dl above the fasting or preprandial glucose value. Figure 2 presents examples of each of these abnormalities. An abnormality that occurs frequently (2 out of 3 days) at the same time of day indicates a problem that needs to be addressed.

When reviewing SMBG data, clinicians should start by looking for hypoglycemia, which is the first priority. Although hypoglycemia is usually defined as a blood glucose level < 70 mg/dl, the data collection tool uses a range of 51–80 mg/dl as a way of identifying hypoglycemia risk as well as clinical hypoglycemia. When hypoglycemia occurs frequently or at specific times of the day, review patients' medications and ask them about their behaviors to determine the cause. The potential cause may be medication-related, behavior-related, or (in many cases) both (Figure 2). Once the cause or causes have been identified, the next step is to collaborate with patients to develop workable strategies to address the problem. After the hypoglycemia has been resolved, clinicians can then move on to addressing any fasting or postprandial hyperglycemia that may be present. The key is to address each abnormality in order of priority before moving on to the next.

Matching medications to specific abnormalities

A key component of the STeP study intervention was emphasizing the

need to match pharmacological therapy to the abnormalities identified in the SMBG data. For example, insulin and sulfonylureas can cause hypoglycemia and would need to be reduced if low blood glucose was an issue. Conversely, other medications would need to be initiated or increased to address hyperglycemia—metformin and pioglitazone for fasting hyperglycemia; and glinides, glucagon-like peptide-1 (GLP-1) agonists, and dipeptidyl peptidase-4 (DPP-4) inhibitors for postprandial hyperglycemia.

Although some medications such as the sulfonylureas have a moderate effect on both fasting and postprandial glucose, selection of medications should be based on their primary action. Table 1 presents a list of medications according to primary glycemic effect. The list is based on recommendations from the American Association of Clinical Endocrinologists[35] and was used by the STeP study clinicians as part of the intervention.

Workflow recommendations for pattern management utilization

Each clinical practice is unique in its available resources and time and staff restrictions. However, there are some basic steps that most practices can take to initiate and utilize the STeP study structured SMBG protocol with minimal disruption of current workflow procedures.

1. Initiate the process. In preparation for a patient's next visit, use the ACCU-CHEK 360° View tool to introduce structured SMBG, explaining the benefits and diagnostic value of the approach. It is helpful to assist patients in completing the medication section to ensure that the information is correct and that they understand what medications they are currently taking. Ask patients to identify the three consecutive days when they will be able to complete the tool before their next visit; obtain their commitment to perform the testing. Remind patients to complete the form before their upcoming visit, and encourage them to bring it to the visit.

2. Remind before the next visit. Send patients a blank tool along with a letter, e-mail, or phone call reminding them of their upcoming visit. Remind them to complete the tool and bring it with them to the visit.

3. Discuss at the clinic visit. Ask to see patients' completed tool and congratulate them for completing it. This helps reinforce the importance of structured SMBG. Then ask patients to explain what they learned from their structured testing experience. Carefully review all the data and discuss findings with patients. If no

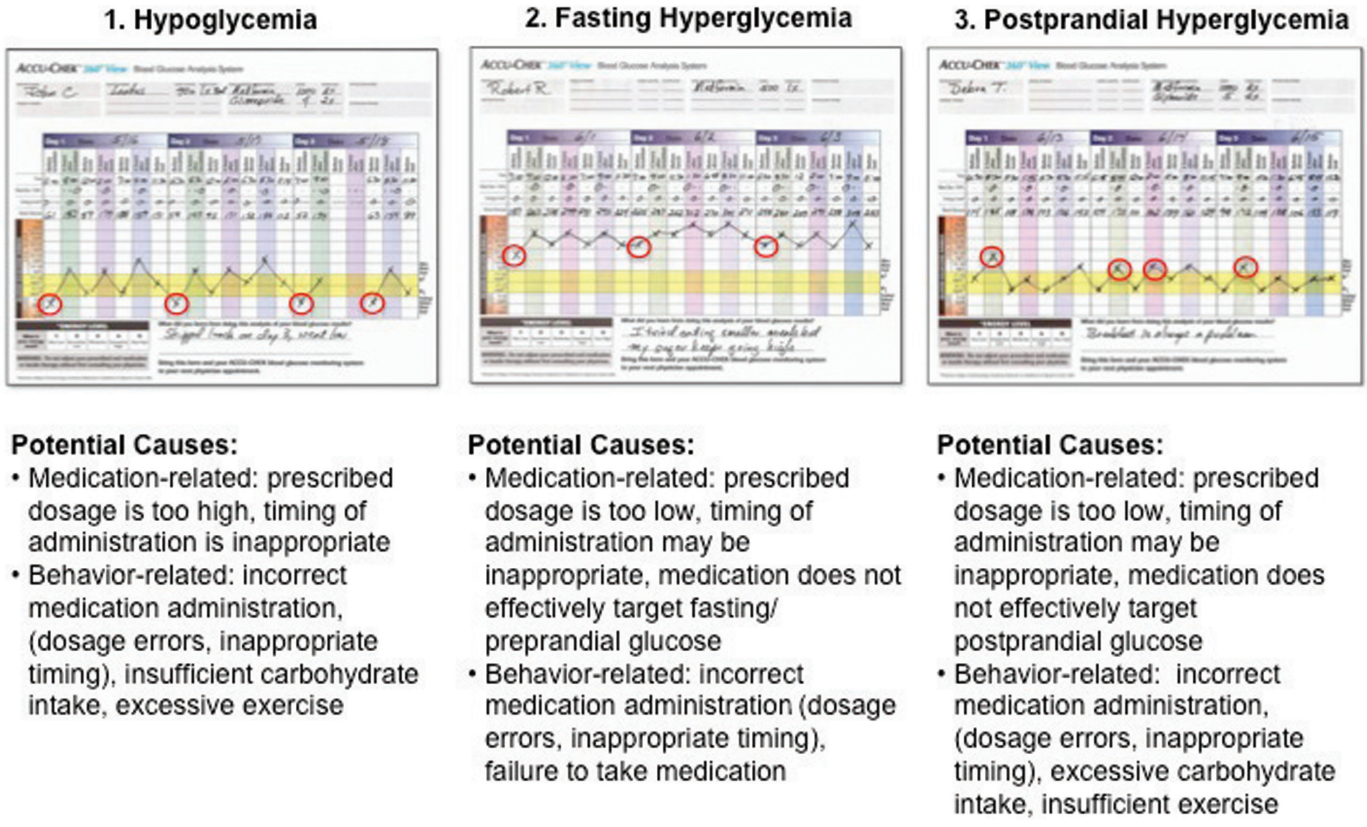

Figure 2. Patterns of significant glycemic abnormalities and potential causes.

Table 1. Medications by Primary Glycemic Abnormality Targeted[35]

Fasting and Preprandial Blood Glucose Medications *Moderate to marked fasting/preprandial glucose-lowering effect*	**Postprandial Blood Glucose Medications** *Moderate to marked postprandial glucose-lowering effect*
Biguanides Metformin **Thiazolidinediones** Pioglitazone **Sulfonylureas**** Glyburide, glipizide, glimepiride **Intermediate- or Long-Acting Insulins** NPH*, glargine*, detemir* **Fixed-Dose Combinations** Glyburide/metformin, glipizide/metformin, pioglitazone/metformin	**Glinides** Repaglinide, nateglinide **α-Glucosidase Inhibitors** Acarbose, miglitol **Rapid- and Short-Acting Insulins** Aspart*, lispro*, glulisine*, human regular* **GLP-1 Agonists** Exenatide*, liraglutide* **DPP-4 Inhibitors** Sitagliptin, saxagliptin, linagliptin **Neuroendocrine Hormone** Pramlintide* **Fixed-Dose Combinations** Sitagliptin/metformin, lispro mix (75/25)*, lispro mix (50/50)*, aspart mix (70/30)*, human regular mix (70/30)*

** Moderate to marked effect; all other medications have only a moderate effect on their associated glycemic abnormality.*
*** Moderate effect on fasting/preprandial and postprandial glucose.*

treatment adjustments are needed, ask patients to complete another tool before the next visit.

If any glycemic abnormalities are apparent, involve patients in the problem-solving process. Listen thoughtfully to patients' perspectives and concerns, correct any misunderstandings, and discuss appropriate recommendations for adjusting therapy, medications, and behaviors. Make sure that patients are willing to try the recommendations and that they understand what they need to do and have the necessary skills and resources to follow the recommendations.

Ask patients to complete another tool within a few weeks and monitor the effects of the recommended changes. Agree on a follow-up plan with patients (e.g., fax, phone, e-mail, or face-to-face appointment) and a date for review.

4. Carry out patient follow-up. When patients return their completed tools, promptly follow-up with them to discuss findings and any recommendations for additional therapy adjustments. If patients have not returned their completed tool within 2 weeks of the scheduled testing dates, send a reminder (letter, e-mail, or phone call) if possible to reinforce the importance of structured SMBG as a key part of their diabetes self-management plan.

Fostering a collaborative relationship with patients

Establishing a relationship of openness and close collaboration with patients is an essential part of implementing structured SMBG. This creates opportunities to reassure patients that they can, in fact, avoid or prevent the progression of diabetes complications through effective self-management. Moreover, it allows clinicians to help patients accept that life sometimes gets in the way of good management and that there should be no shame (or blame) when they become discouraged, frustrated, or overwhelmed with their self-management and take a break from their regimens.

Conclusions

Structured SMBG is recognized as an important tool that guides glycemic management strategies and has the potential to improve problem-solving and decision-making skills for both patients and clinicians.[23] However, many clinicians underutilize SMBG in managing their patients with diabetes because of uncertainty about how to integrate it into their practices or misperceptions regarding its value.

Although some studies have questioned the value and utility of SMBG, specifically in non–insulin-treated patients,[25–27] more recent studies have shown that appropriate use of structured SMBG, within the framework of a collaborative relationship between patients and their clinicians, facilitates and reinforces adoption of healthy behaviors and promotes timely and persistent therapy adjustments, resulting in improved clinical and behavioral outcomes.[24,29–33] Moreover, the interventions used in these studies are practical in real-world clinical settings and can be integrated into most community practices with minimal resources or modifications to current workflow. STeP study tools and resources are available at www.behavioraldiabetes.org/studies/STeP-Study.html.

Because patients with diabetes are responsible for most of their diabetes care, they require immediate and ongoing feedback regarding

their glycemic control. They must be able to assess the significance of the data generated by their glucose monitoring and then use that information to make appropriate, effective changes in their health behaviors.[23] Through mastery of these skills, patients can develop a sense of self-efficacy in their ability to manage their diabetes as they become more engaged in their self-management. Appropriate use of structured SMBG facilitates this vital behavioral and emotional process that eventually leads to empowerment.

ACKNOWLEDGMENTS

Funding for development of this article was provided as an unrestricted grant by Roche Diagnostics in Indianapolis, Ind. The authors are solely responsible for the content.

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Notes of Disclosure: *Mr. Parkin has received consulting fees, and Ms. Hinnen and Dr. Tetrick have received consulting fees and honoraria from Roche Diagnostics.*