# Does Patient Blood Glucose Monitoring Improve Diabetes Control?

## A Systematic Review of the Literature

## Objective

The purpose of this systematic review was 2-fold: first, to perform a comprehensive review of relevant studies on the impact of self-monitoring of blood glucose (SMBG) on HbA1c levels for patients with type 2 diabetes mellitus and, second, to explore mediators and moderators within a self-regulation framework.

## Data Sources

Five databases—Medline, PsychInfo, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Cumulative Index to Nursing & Allied Health Literature (CINAHL)— were searched.

## Study Selection

Cross-sectional, longitudinal, and randomized control trials from 1990 to 2006, which included patients with type 2 diabetes not on insulin, were reviewed. In total, 6769 studies were screened for inclusion, 89 were retrieved for detailed analysis, and 29 met criteria for inclusion in the review.

## Data Extraction

Data on the impact of SMBG on HbA1c, potential mediators and moderators, study design and participants, and limitations of each study were retrieved.

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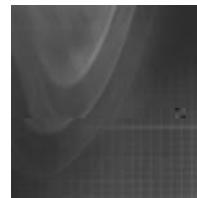
## Data Synthesis

Twenty-nine studies were included in this review: 9 cross-sectional studies, 9 longitudinal studies, and 11 randomized controlled trials. Evidence from the cross-sectional and longitudinal studies was inconclusive. Evidence from randomized controlled trials suggests that SMBG may lead to improvements in glucose control. Very few studies examined potential mediators or moderators of SMBG on HbA1c levels.

## Conclusions

SMBG may be effective in controlling blood glucose for patients with type 2 diabetes. There is a need for studies that implement all the components of the process for self-regulation of SMBG to assess whether patient use of SMBG will improve HbA1c levels.

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This review summarizes current studies on the relationship between patient self-monitoring of blood glucose (SMBG) and the control of type 2 diabetes. Although there is some evidence to suggest that SMBG is effective in improving blood glucose levels among patients with type 2 diabetes not on insulin, the evidence is still unclear and contested. In this article, assessment of these studies focuses on the overall efficacy of monitoring on glucose control and, more important, examines what the studies do and do not tell us as to how, and for whom, SMBG may be effectively incorporated into patients' voluntary, self-regulatory behavior to achieve effective blood glucose control. The authors use the commonsense model of self-regulation[1,2] as the theoretical framework for appraising whether the studies address the "for whom" and "how" questions. The use of the model is consistent with calls to make theory more explicit in research on diabetes education[3] and to state hypotheses a priori.[4]

The current debate is focused on whether SMBG is efficacious among patients with type 2 diabetes who are not on insulin.[5,6] The American Diabetes Association (ADA), in its Clinical Practice Recommendations 2007, has found sufficient evidence to recommend SMBG for patients prescribed multiple daily insulin injections (ADA level of evidence = A); the recommendation for the use of SMBG among patients not on insulin, in addition to recommendations for when and how patients should use SMBG, is based on less sufficient evidence (ADA level of evidence = E).[7] The ambiguity regarding the use of SMBG for patients not on insulin arises as prior studies and reviews have focused on the overall impact of SMBG on HbA1c and have not assessed whether the implementation was sufficiently comprehensive to address each of the factors needed to create a complete feedback system for effective, patient-centered self-management.[6,8-11] The central issue for both theory and practice is to identify the conditions under which self-monitoring, a patient-centered "executive control process," can control the biomarkers that are ordinarily regulated by complex, automatic, involuntary processes in patients without diabetes. Teaching volitional management to patients with type 2 diabetes involves more than instructing them in the use of a meter. SMBG can only be effective if patients recognize when a reading is high or low; make changes in oral medication, diet, or exercise in response to the reading; and evaluate the efficacy of these self-management behaviors with a subsequent reading. The patients also must learn that these objective readings and not their subjective feelings (fatigue, dizziness, etc) are valid indicators of elevated blood glucose and the basis for guiding self-management. Learning to use objective readings rather than subjective feelings as the target for self-regulation means that patients must ignore the commonsense knowledge of their personal histories and culture that define symptoms and dysfunction as valid signs of illness.[12,13]

The logic underlying this study's view of patient-centered self-management (ie, the commonsense model of self-regulation[1-3]) led to the expectation that the efficacy of SMBG would depend on whether the interventions created a patient-centered behavioral control system that would address the patient's skills in (1) taking a blood glucose reading; (2) interpreting the reading as a target for action; (3) perceiving linkages between specific behaviors (diet, exercise) and the reading (ie, which behaviors lower an above-target reading and which raise a below-target reading); (4) implementing action plans (ie, behavioral and treatment adjustments) in response to SMBG; (5) giving less weight to subjective symptoms that are the basis for commonsense decisions that one is sick or well, as these cues are invalid guides for the regulation of blood glucose levels; (6) incorporating the behavioral system into the patient's ongoing daily behavioral patterns to

eventually become automatic; and (7) viewing difficulties in achieving control as issues of adjusting the behavioral treatment, not deficits in personal motivation or competence for self-management. The goals of this systematic review are (1) to report on the overall impact of SMBG on HbA1c for patients with type 2 diabetes and (2) to examine whether existent studies have identified and assessed the mediators and moderators comprising the processes underlying the relationship of SMBG to HbA1c.

## Method

### Searching

Five databases were searched: Medline, PsychInfo, Cochrane Database of Systematic Reviews (first quarter 2006), Cochrane Central Register of Controlled Trials (first quarter 2006), and Cumulative Index to Nursing & Allied Health Literature (CINAHL). Search terms included words for (1) diabetes mellitus/diabetes, (2) monitoring/self-monitoring, and (3) glucose/blood glucose/blood glucose in each database.

### Selection

All citations were entered into endnotes and duplicates removed. Reviewer LD screened the remaining entries' titles and abstracts for articles that met the inclusion and exclusion criteria. The articles were then retrieved and read for final inclusion.

The inclusion criteria were empirical studies published since 1990 that included patients with type 2 diabetes who were not using insulin and that examined the effect of SMBG on HbA1c levels, the primary outcome measure, and the currently accepted standard for monitoring long-term glucose control.[14-18] Because a major objective of this review is to identify conditions that mediate the efficacy of SMBG, this study retained cross-sectional, longitudinal, and randomized control trials (RCTs), as well as studies that included both patients who were on and not on insulin and studies with patients with both type 2 and type 1 diabetes.

Studies that focused on special subsets of patients, such as adolescents with type 2 diabetes and patients with gestational diabetes and patients dealing with blindness or renal failure, were excluded, as these patients are not representative of the broader population of patients

with type 2 diabetes. It is unclear how findings in specialized populations would illuminate the efficacy of monitoring in the larger population. Studies were also excluded if monitoring was performed by someone other than the patient (eg, a health professional) or used fructosamine monitoring. Although this discussion is informed by findings from relevant qualitative studies, a comprehensive review of these studies was not conducted as they do not provide quantitative results of the effect of SMBG on HbA1c. Studies in which SMBG was embedded in complex interventions that used multiple factors unrelated to SMBG monitoring were also excluded. The decision to exclude studies published before 1990 was based on substantial improvements in ease and accuracy of monitoring from that time to the present. As the efficacy of monitoring for patients on insulin is accepted,[7] studies assessing efficacy of monitoring only for patients on insulin were excluded. Finally, only studies available in English were reviewed.

### Validity Assessment

Studies were reviewed for the ADA evidence grading criteria by LD, and questions regarding grading were referred to and resolved by the medical members of the team (SHS, EB). Only studies that met ADA evidence grading criteria A, B, or C were included in the review.

### Data Abstraction

The data were collected and organized by LD, and a trained research assistant reviewed the data for accuracy. Both the results of the data abstraction and questions about the data were then reviewed and discussed in detail with all authors.

### Study Characteristics

Data were collected on the primary outcome (HbA1c), study population (number of participants, gender, ethnicity, current medication used by patients, and type of diabetes), study design, mediators and moderators, and limitations.

### Data Synthesis

Data are summarized in Table 1. Missing data were marked "not reported" (NR) within the table.

Table 1

Study Characteristics

| Study | Sample | Design | Results-HbA1c | Moderators and Mediators |
|---|---|---|---|---|
| Chan et al (2000)[20] | N = 562, type 2, no medication limits reported, male = 43%, ethnicity = NR, mean age = 53, study completed in China. | Cross-sectional. Recruited consecutive patients at teaching hospital. | SMBG was associated with lower HbA1c (SMBG = 7.9% vs not SMBG = 8.6%). This relationship was not significant in linear regression analysis, which looked at many predictors. | NR |
| Franciosi et al (2001)[21] | N = 2855, type 2, no medication limits, ethnicity = NR, mean age = 63, study completed in Italy. | Cross-sectional. Patients with type 2 diabetes were recruited from diabetes clinics and GPs in Italy. | SMBG was associated with higher HbA1c. | For patients not on insulin, SMBG was associated with higher HbA1c. For patients on insulin, SMBG was not associated with HbA1c. Ability to adjust insulin was associated lower HbA1c among patients who had SMBG >1 a day. |
| Hanninen et al (2001)[22] | N = 260, type 2, no medication limits, males = 54%, ethnicity = NR, mean age = 56 (patients' descriptions were reported in a previous study), study completed in Finland. | Cross-sectional. Approached 381 patients to participate; 68% (N = 260) participated. | SMBG was associated with higher HbA1c (SMBG = 9% vs not SMBG = 8.5%). | NR |
| Harris et al (2001)[23] | N = 1480, type 2, no medication limits reported, male = 44%, ethnicity = 27% identified as minority, mean age = 63. | Cross-sectional. Analysis from NHANES III. | SMBG was associated with higher HbA1c. | Within each treatment (insulin vs oral medication vs. diet), there was little association between SMBG and HbA1c. Patients on insulin had higher HbA1c and were more likely to monitor. |

| Study | Population | Study design | Result | Detail |
|---|---|---|---|---|
| Jaworska et al (2004)[26] | N = 218, type 2, no medication limits reported, males = 31%, ethnicity = NR, mean age = 62%, study completed in Poland. | Cross-sectional. Recruited patients who presented for outpatient care. | SMBG was not associated with HbA1c. | Within each treatment group (insulin vs oral medication), SMBG was not related to HbA1c. Among patients who reported the ability to change insulin dose based on SMBG, SMBG was not related to HbA1c. |
| Mitchell et al (2004)[25] | N = 434, type 2, no insulin, male = 52%, ethnicity = NR, mean age = 64, study completed in Canada. | Cross-sectional. This study reported baseline data from a randomized control trial. Patients were given a questionnaire and sent to have HbA1c tested. | SMBG was not associated with HbA1c. | NR |
| Oki et al (1997)[24] | N = 98, type 2, no medication limits, male = 29%, ethnicity: AA = 69%, C=27%, H=2%, O = 2%, mean age = 56. | Cross-sectional. A total of 98 consecutive patients who presented for routine care. | SMBG was not associated with HbA1c. | No difference in HbA1c between patients who had SMBG <7/wk and patients who had SMBG >7/wk. SMBG not associated with HbA1c when analyzed based on treatment group (insulin vs diet/oral). |
| Patrick et al (1994)[27] | N = 200, type 2, no insulin, male = 52%, ethnicity = NR, mean age = 65. | Cross-sectional. Compared patients who monitored (blood, urine, or both) to those who did not monitor. | SMBG was not associated with HbA1c. | No difference between patients who reported that they would act on monitoring results and those who reported that they would not act. |
| Rost et al (1990)[19] | N = 84, type 2, no medication limitations, mean age = 56, 32% = male, ethnicity = NR. | Cross-sectional. Surveyed patients with type 2 diabetes hospitalized for elective admission. | SMBG was associated with lower HbA1c. | Not tested directly, but the relationship of SMBG to HbA1c was independent of other self-care behaviors. |

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Table 1 (continued)

| Study | Sample | Design | Results-HbA1c | Moderators and Mediators |
|---|---|---|---|---|
| Blonde et al (2002)[34] | N = 228, type 2, no medication limits reported, male = NR, ethnicity = NR, mean age = NR (age range, 35-65). | Longitudinal. Chart review compared consistent reporting of SMBG vs inconsistent reporting of SMBG vs no reporting of SMBG. | Seventy percent of patients with consistent reporting of SMBG had 95% of reported HbA1c below 8% vs 18% of patients with inconsistent reporting of SMBG vs 22% of patients with no reporting of SMBG. | NR |
| Karter et al (2001)[33] | N = 23 412, types 1 & 2, no medication limits, male = 52%, ethnicity: C = 60%, AA = 11%, H = 8%, A/PI = 12%, NA = 1%, O = <1%, M = 7%, mean age = 60. | Longitudinal. Reviewed HMO database for adherence to general SMBG recommendations. | Following ADA recommendations for SMBG, based on patient diabetes type and medication, was associated with lower HbA1c. | Greater frequency of SMBG associated with lower HbA1c. |
| Klein et al (1993)[35] | N = 229, type 2, no medication limits, male = 97%, ethnicity: AA = 11%, C = 68%, H = 20%, mean age = 62, recruited from VA. | Longitudinal. Reviewed charts at VA medical center for patients with type 2 diabetes who received blood or urine monitoring supplies. | There were no significant differences between SMBG and urine monitoring. | HbA1c did not differ based on length of time monitored or number of strips dispensed. Seven patients reported making insulin changes in response to monitoring; this was not associated with HbA1c. |
| Meier et al (2002)[32] | N = 1467, type 2, no insulin, male = 98%, ethnicity = NR, mean age = 64, patients recruited from VA. | Longitudinal. Chart review of patients who filled script for monitoring strips. Initiated a VA policy change that reduced the number of dispensed strips for patients with type 2 diabetes not on insulin to 50 per 90 days. | SMBG was associated with lower HbA1c. Changes in frequency of SMBG had no effect on HbA1c. | NR |

| Study | Sample | Finding | Moderator/Mediator |
|---|---|---|---|
| Newman et al (1990)[31] | N = 38, types 1 & 2, no medication limits, male = NR, ethnicity = NR, mean age = 60, recruited from VA. | Longitudinal. Randomly reviewed charts from patients who monitored and patients who did not (3 patients who monitored urine were considered nonmonitors). All patients had 2 HbA1c recorded a year for 3 years. | SMBG was not associated with HbA1c. | NR |
| Rindone et al (1997)[28] | N = 115, type 2, on oral medications only, male = NR, ethnicity = NR, mean age = 68, patients recruited from VA. | Longitudinal. Compared patients who were prescribed monitoring strips to patients who were not. Data were collected over 2 years. If multiple data points were recorded, means were used. | Receiving a script for SMBG strips was not associated with HbA1c. | Receiving more bottles of SMBG strips was not associated with HbA1c. |
| Soumerai et al (2004)[36] | N = 3219, on insulin or oral diabetes medication, type 1 or 2, mean age = 54, male = 54%, ethnicity: C = 46%, AA = 19%, O = 3%, M = 32%. | Longitudinal. Interrupted time-series analysis of a database of an HMO that began offering free SMBG monitors to patients with diabetes. Previous year's data were controlled for. | Starting SMBG was not associated with improved HbA1c for patients with "good or adequate control" but was associated with improved HbA1c among those with poor control. | Effect of SMBG was moderated by initial HbA1c and potentially mediated by medication adherence. |
| Wen et al (2004)[30] | N = 976, male = 97%, prescribed oral medication, mean age = 63, ethnicity: AA = 8%, C = 38%, H=48%, O = 6%, recruited from VA. | Longitudinal. Reviewed 3 years of medical charts for patients prescribed oral medication for diabetes. Compared HbA1c of patients who did not SMBG vs SMBG year 3 vs SMBG years 2-3 vs SMBG years 1-3. | SMBG was not associated with HbA1c. | NR |
| Wieland et al (1997)[29] | N = 216, type 2, prescribed glyburide, male = 100%, ethnicity = NR, mean age = NR (age range, 39-89), recruited from VA. | Longitudinal. SMBG was operationalized as refill of SMBG strips. Compared HbA1c of patients who did not monitor, SMBG once a day, and SMBG 2 or more times a day. | Frequency of SMBG was not associated with HbA1c. | NR |

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Table 1 (continued)

| Study | Sample | Design | Results-HbA1c | Moderators and Mediators |
|---|---|---|---|---|
| Allen et al (1990)[46] | N = 54, type 2, no insulin, male = 100%, ethnicity: C = 63%, mean age = 58, recruited from VA. | RCT. Compared urine monitoring to SMBG. SMBG: SMBG 36/month. Urine: Monitored urine 36/month. Both: Received diet counseling and monthly visits with treatment team, which used treatment algorithm (including medication changes) in response to monitoring. | SMBG: Baseline = 12.4%, 6 months = 10.4% (P < .001). Urine: baseline = 11.7%, 6 months = 9.7% (P < .001). No significant between-group differences. | Trend toward younger and better educated improving more. Baseline HbA1c, baseline weight, baseline fasting plasma glucose, use of oral medications, duration of diabetes, and race did not predict improved glucose control. |
| Davidson et al (2005)[43] | N = 88, type 2, no insulin, mean age = 50, ethnicity: AA = 22%, H = 75%, O = 3%. | RCT SMBG = instructed to monitor BG before and 1/2 hours after meals 6 times a week. C = not instructed to SMBG. Both = meet with dietitian 5 times; nurses blinded to treatment used a treatment algorithm that included medication changes. | SMBG = a significant reduction of 0.8% in HbA1c. C = a significant reduction of 0.6%. No significant between-group differences. | NR |
| Guerci et al (2003)[37] | N = 689, type 2, oral medication only, males = 55%, ethnicity = NR, mean age = 62, study completed in France. | RCT SMBG = SMBG trained by GP; patients instructed to monitor 6/week. Both = Followed every 6 weeks for 24 weeks, given general dietary and diabetes recommendations, HbA1c | SMBG = a significant reduction of 0.88% in HbA1c. Control = a significant reduction of 0.60%. SMBG showed a statistically significant improvement as compared to control. | Patients who did SMBG were more likely to report following dietary advice. Predictors of improvement included SMBG group, higher initial HbA1c, lower duration of diabetes, and lower body mass index. |

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|---|---|---|---|
| Kibriya et al (1999)[38] | N = 64, type 2, on oral medication or insulin, male = 55%, mean age = 50, ethnicity = NR, study completed in Bangladesh. | taken every 3 months, and GP allowed to change treatment based on HbA1c at 3-month visit.<br><br>RCT<br>SMBG = 2-day class on SMBG, instructed to monitor fasting and 2 hours after breakfast and/or 2 hours after lunch and to adjust medications. Taught to make treatment changes in response to SMBG. Visited doctor every 3 months.<br>Control = Monthly visits; doctor could make med changes.<br>Both: Received education. | SMBG = HbA1c decreased 1.37% (P = .022).<br>Control = HbA1c decreased 0.38% (P = .29).<br>Did not report if there was a statistically significant difference between the 2 groups. | NR |
| Kwon et al (2004)[39] | N = 110, type 2, no medication limits reported, male = 61%, ethnicity = NR, mean age = 54, study completed in Korea. | RCT<br>Internet SMBG = 12-week Internet recording of SMBG; patient received recommendations via the Internet, including some medication changes, no outpatient visit, SMBG pre- and postmeals.<br>Control = regular monthly outpatient visits.<br>Both = recommended to SMBG 3 or more days per week 1 to 3 times a day, including after meals. | Internet SMBG = HbA1c reduced 0.54% (P < .001).<br>Control = HbA1c increased 0.33% (NS).<br>There was a statistically significant difference in the 2 groups. | The differences between the 2 groups were more pronounced among patients with an initial HbA1c of 7 or higher. |

Table 1 (continued)

| Study | Sample | Design | Results–HbA1c | Moderators and Mediators |
|---|---|---|---|---|
| Miles et al (1997)[47] | N = 150, type 2, no medication limits reported, male = 60%, mean age = 65, ethnicity = NR, study completed in United Kingdom. | RCT. Patients asked to either SMBG or urine monitor. Both = Patients asked to monitor either before, 2 hours after meals, or bedtime once daily and to attend 4 education sessions. At 3 months, patients switched to an alternative monitoring method. At 6 months, patients were able to choose preferred method for monitoring. | HbA1c significantly declined in both groups at 12 months (10.3% to 7.5% in both groups). There were no between-group differences. | NR |
| Moreland et al (2006)[45] | N = 199, types 1 & 2, no medication limits, male = 58%, ethnicity = NR, mean age = 49. | RCT Control = diabetes education. "MT" (attentional control) = monitoring education session, support from educator. "BGT" (intervention) = blood glucose monitoring booklet, monitoring education session, support from educator. | No significance, improvement in HbA1c in any group. When individuals who improved were compared to individuals who did not improve, a greater percentage of improvers were in the "BGT" group. | NR |
| Muchmore et al (1994)[44] | N = 23, type 2, no insulin, male = 39%, ethnicity = NR, mean age = 59, all patients overweight. | RCT SMBG = education on carb counting and SMBG, given monitor and strips to monitor 6 times a day (before and 2 hours after meals) for 4 weeks, then reduced to twice a day for 4 months, results charted. | SMBG = HbA1c reduced 1.54% (P < .05). Control = HbA1c reduced 0.84% (P > .3). No significant differences between groups at study end. | Duration of diabetes, initial HbA1c, and number of SMBG were not related to HbA1c. |

Control = general diabetes education.
Both = 28-week behavioral weight control program, followed by GP who could make medication changes.

| Study | Sample | Methods | Results | Notes |
|---|---|---|---|---|
| Rutten et al (1990)[44] | N = 149, type 2, no insulin, male = 35%, ethnicity = NR, mean age = 63. | RCT. Eight practices matched and randomized. Intervention = 33 patients received 2 to 5 education sessions on SMBG, and patients contacted diabetes nurse monthly to report fasting blood glucose. If BG high, made appointment and also met with GP after 6 months. Thirty-three patients did not SMBG and met with GP at least 4 times a year. All used medication algorithm to treat patients. Control = patients not instructed in SMBG, did not use fixed appointments. | Intervention = mean group HbA1c decreased 0.5% (P < .05). Control = mean group HbA1c increased in 0.5% (P < .001). | Patients with initial HbA1c >10 in the intervention condition were more likely to improve than those with initial HbA1c >1 in the control condition. |
| Schwedes et al (2002)[41] | N = 223, type 2, no insulin, male = 52%, ethnicity = NR, mean age = 60. | RCT. SMBG = SMBG before and 1 hour after 3 meals, twice a week, and record the monitoring; patients were seen every 4 weeks by a nurse who used a SMBG counseling algorithm. Control = nonstandardized counseling every 4 weeks. | SMBG = reduction of 1%. Control = reduction of 0.54%. There was a statistically significant difference between the groups. | In the SMBG group, not making behavioral changes in response to SMBG led to failure. Longer diabetes duration and higher baseline HbA1c predicted a delay in response. |

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Table 1 (continued)

| Study | Sample | Design | Results-HbA1c | Moderators and Mediators |
|-------|--------|--------|---------------|--------------------------|
| Seaton (1996)[42] | N = 10, type 2, only on oral medications, mean age = NR, male = NR, ethnicity = NR. | RCT. Reported in abstract. Both = standardized treatment algorithm. SMBG = SMBG. Control = no SMBG. | SMBG = statistically significant reduction of 0.8% in HbA1c. Control = no change. Did not report if there was a statistically significant difference between the 2 groups. | NR |

RCT, randomized control trial; SMBG, self-monitoring of blood glucose; NR, not reported; GP, general practitioner; AA, African American; H, Hispanic; C, Caucasian; O, other; A/PI, Asian/Pacific Islander; NA, Native American; M, mixed race or ethnicity; ADA, American Diabetes Association; HMO, health maintenance organization; VA, Veterans Administration; BG, blood glucose; NHANES III, Third National Health and Nutrition Examination Survey.
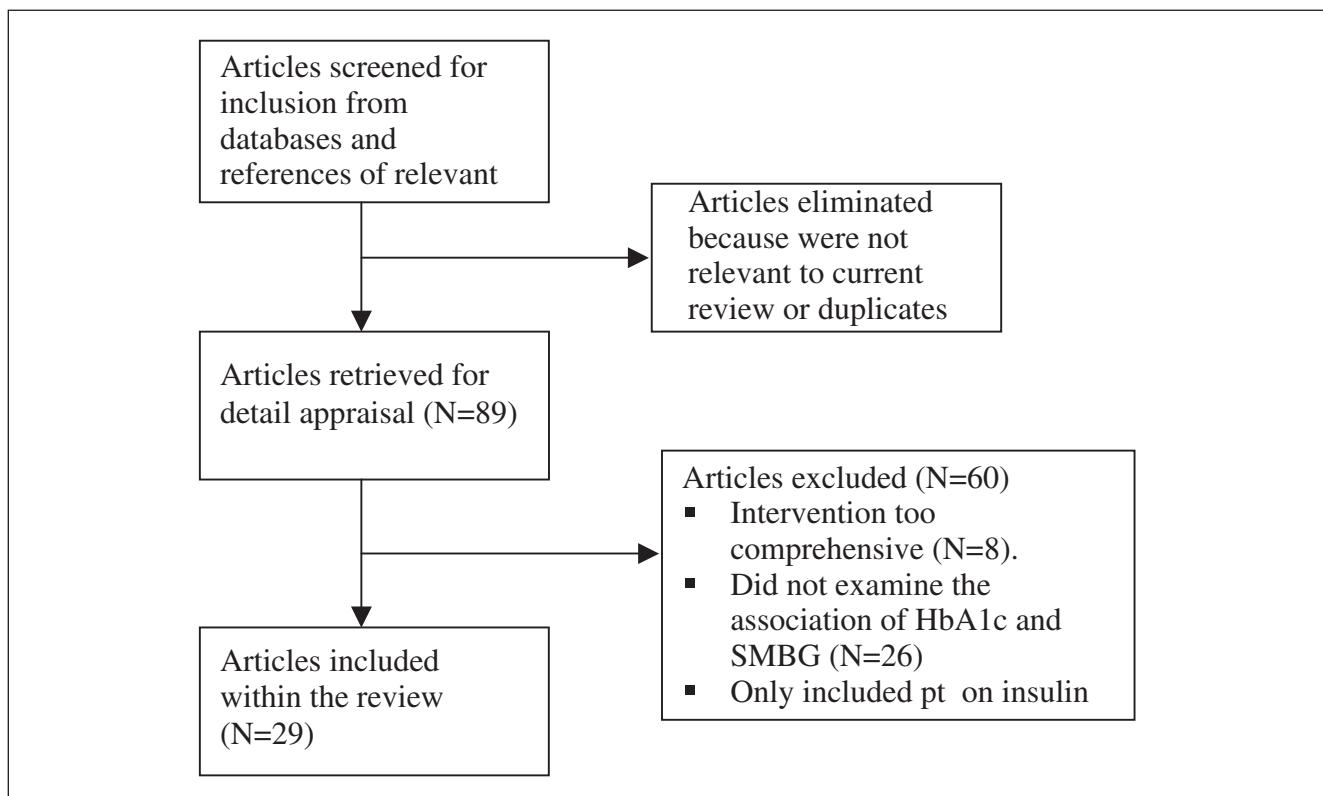
**Figure 1.** Trial flow diagram.

## Results

### Trial Flow and Study Characteristics

Twenty-nine studies met criteria for review: 9 cross-sectional studies, 9 longitudinal studies, and 11 RCTs (see Figure 1 for trial flow). Study details are shown in Table 1.

### Data Synthesis

Data are presented by the 3 types of study design: cross-sectional, longitudinal, and RCT. Each section first describes the results of SMBG on HbA1c, reports next on study limitations, and then describes factors that mediate or moderate the relationship between SMBG and HbA1c levels.

*Cross-sectional studies.* Results of the 9 cross-sectional studies were inconclusive. Two showed that monitoring of glucose was correlated with lower HbA1c levels,[19,20] and 3 found that glucose monitoring correlated with higher HbA1c levels.[21-23] Among the latter 3 studies,

that by Franciosi and colleagues[21] found monitoring associated with worse control only for patients not on insulin; there was no association of SMBG with HbA1c for patients on insulin. The remaining 4 studies reported no significant association between self-monitoring and HbA1c[24-27]; 1 of the 4 compared "home glucose monitoring" of urine (74 patients) and blood glucose (19 patients) to patients not monitoring (103) and found no significant differences in HbA1c among the groups.[27]

As monitoring and glucose control are assessed at the same time point in cross-sectional studies, it is impossible to tell whether monitoring affected glucose control or, conversely, whether patients in poor control were motivated to monitor. As it is unlikely that monitoring would worsen control, it seems likely that the 3 studies reporting a negative relationship of monitoring to HbA1c reflect high levels of self-monitoring among patients with elevated HbA1c. This interpretation is consistent with Harris's[23] finding that patients with higher levels of HbA1c were both more likely to monitor and more likely to be on insulin.

With respect to mediators and moderators of SMBG, only 3 cross-sectional studies assessed if and how

monitoring affected patient behavior. For example, Franciosi and colleagues[21] reported better control among patients prescribed insulin who self-administered in response to SMBG readings in comparison to patients who did not use insulin in response to these readings. Self-management procedures were not assessed for non-insulin users. In a study by Patrick and colleagues,[27] only 38% (37 of 97) of patients with type 2 diabetes not treated with insulin reported they would change a treatment in response to self-monitoring feedback. Glucose control for these patients was not significantly better than that of the 62% of patients who did not report making changes; however, it is unclear how often these patients actually changed their management practices in response to monitoring information. Finally, Jaworska and colleagues[26] found that patients who reported being able to make insulin changes in response to readings did not have lower HbA1c levels. In summary, the cross-sectional studies are inconclusive as to the result of the effect of SMBG on glucose control. Most important, the directionality of any of the reported effects is indeterminate.

*Longitudinal studies.* Nine studies examined the effect of SMBG on HbA1c using longitudinal data. Four[28-31] of the 9 found no association of SMBG with HbA1c. Two other studies found lower HbA1c levels among patients who did SMBG in comparison to those who did not monitor[32] and to those who did not monitor at a recommended frequency.[33] A brief commentary in a seventh study stated that patients whose medical charts documented that they were doing SMBG were significantly more likely to have HbA1c levels below 8%.[34] An eighth study by Klein and colleagues[35] compared those who monitored urine to those who did SMBG. There was no control group that did not monitor, and there was no difference in HbA1c between the 2 groups that did.

The ninth study by Soumerai and colleagues[36] examined the effects of providing free monitors to patients in a New England health maintenance organization (only monitoring strips had been previously provided). Monitoring behavior, defined as test strip distribution, was examined for 19 months prior to the policy change, 5 months during the transition, and 17 months after the policy change. An interrupted time-series analysis of trend line for monitoring behavior, pre- and postintroduction of free monitors, showed an increase in the initiation of SMBG and in the use of test strips among patients with type 2 diabetes on oral medication. Patients who previously had been inconsistent in refilling their oral medication and now increased their use of test strips also increased medication adherence, and patients who were previously in poor control and began monitoring showed a reduction in HbA1c levels. The analyses by Soumerai and colleagues[36] suggest that the initial level of HbA1c may moderate one's ability to detect the efficacy of monitoring and that the effects of monitoring on HbA1c may be mediated by increases in medication adherence.

The Methods sections of these studies point to limitations in the implementation and assessment of mediators and moderators similar to those found in the cross-sectional studies. It is unclear if patients were instructed to monitor because they were in poor control or if self-monitoring did not lead to control. It was also unclear whether the intervention addressed the components of self-regulation essential for mediating the benefits of monitoring. The specific instructions patients were given about the procedure and the validity of self-monitoring (ie, when to monitor and what to do in response to readings) were rarely described, and most studies did not assess these mediators. One study[31] reported that when clinicians became aware "that SMBG level may be unreliable, these levels were rarely used alone as criteria for insulin change or life-style adjustment suggestions." If this was explicitly or implicitly communicated to patients, it would likely undermine motivation to self-monitor and the use of SMBG to guide behavior.

Five of the 9 studies reported mixed results on the relationship between frequency of monitoring and HbA1c levels. Karter and colleagues[33] found that more frequent monitoring was correlated with better control among patients with type 2 diabetes. Although Meier and colleagues[32] found that SMBG was associated with better control, they also found no change in glucose control from a policy change that reduced the availability of test strips and lowered the average frequency of monitoring from 1.37 to 0.74 times a day had. Finally, 3 of the 9 that assessed frequency of monitoring[28,29,35] found no evidence of a relationship of frequency of SMBG to HbA1c, and 2 reported no relationship between length of time monitoring and HbA1c levels.[30,35] In summary, the evidence is suggestive at best that monitoring might help patients better manage blood glucose levels and lower HbA1c levels.

*Randomized control trials.* Eleven RCTs tested the effects of monitoring on HbA1c levels. Six of the 11 trials

comparing monitoring to a control condition reported improved glucose control in the monitoring condition.[37-42] One[38] of the 6 reported a significant decrease of HbA1c (1.37%) in the intervention arm and a nonsignificant reduction (0.38%) in the control arm but did not, however, report whether the magnitude of HbA1c reduction in the monitoring arm was statistically superior to that in the control.

Two of the 5 remaining trials failed to detect an advantage of a monitoring intervention on glucose control. That by Davidson and colleagues[43] reported a reduction of HbA1c in the monitoring condition (0.8%) not significantly different from the control (0.6%), and Muchmore and colleagues[44] reported that the comparison between the 12 patients in the monitoring group (HbA1c lowered by 1.54%) was not significantly greater than that for the 11 patients in the control condition (HbA1c reduced 0.84%); the study was likely underpowered. The third of the 5 studies by Moreland and colleagues[45] used a 3-arm design that compared an intervention, which combined monitoring with a booklet designed to help patients form more reasonable "expectations and responses" to monitoring, to monitoring alone and a control arm. Although there were no significant differences in the magnitude of the change in HbA1c across the 3 conditions, Moreland and colleagues[45] found that the number of patients who showed an improvement in HbA1c was significantly greater in the monitoring intervention with a booklet.

The final 2[46,47] of the 5 nonsignificant RCTs are less relevant to the main objective of this review (ie, does patient monitoring lead to improvements in HbA1c?) as they compared SMBG to urine monitoring and did not use a nonmonitoring control. Both studies[46,47] reported significant reductions in HbA1c in both trial arms and no differences in HbA1c between patients who monitored urine levels and those monitoring blood glucose.

A number of methodological factors complicate the interpretation of the results of these trials. In 3 trials,[39,41,42] patients in the monitoring arm received additional resources (ie, education, medication, or support) not given control patients. Additions that told patients how to respond to high or low SMBG readings would define a key mediator for the formation of a coherent self-regulatory system. Additions that facilitated reductions in HbA1c but were unrelated to the behavioral monitoring system (eg, additional social support) would be defined as independent influences or trial confounds. Studies also combined data from patients with type 1 and type 2 diabetes, as well as data from patients on insulin, with patients controlled by oral medication or diet alone.[38,39] Perhaps less problematic, patients were randomized by group rather than by person, and new patients were added to replace dropouts.[38,44,46] Davidson and colleagues[43] conducted the only trial that blinded clinicians to the patients' treatment group. Finally, the trial by Seaton[42] should be given little weight as only 10 patients were randomized, the author did not report if the between-group difference was statistically significant, and the results were reported only in an abstract.[42]

In examining potential moderators of response, 3 studies[37,39,40] found that patients in poor control were more likely to benefit from SMBG. This supports the prior suggestion[36] that the initial level of glucose control will moderate the effects of SMBG on HbA1c. Guerci and colleagues[37] found that lower duration of diabetes predicted improved HbA1c, whereas Schwedes and colleagues[41] found that longer duration of diabetes may lead to a delayed response. Muchmore and colleagues[44] and Allen and colleagues,[46] however, did not find that either initial HbA1c or duration of illness was related to the effect of SMBG on HbA1c. Finally, Allen and colleagues reported a trend for greater improvement in HbA1c from SMBG among younger and more educated patients.

The RCTs differed on the instruction given to patients concerning monitoring. Supplemental findings from 2 studies[37,41] are consistent with the view that SMBG should be viewed as a component of a larger behavioral system. Schwedes and colleagues[41] instructed patients to monitor 12 times a week before and after meals and to change their regulatory behaviors (diet, exercise, medication) in response to their SMBG readings; patients who changed behaviors in response to SMBG readings had significantly lower HbA1c levels than those who did not. Although Guerci and colleagues[37] did not give explicit instruction to patients concerning changing behaviors in response to monitoring, they reported that patients who monitored were more likely to follow dietary recommendations and had better controlled HbA1c.

## Discussion

### Effect of SMBG on HbA1c

Neither the cross-sectional nor longitudinal studies support the hypothesis that SMBG can be effective for improving the control of blood glucose levels among

patients with type 2 diabetes not using insulin. Six studies found that monitoring was related to lower levels of HbA1c (2 cross-sectional[19,20] and 4 longitudinal[33-36]), 8 found no association between monitoring and HbA1c (4 cross-sectional[24-27] and 4 longitudinal[28-31]), and 3 cross-sectional studies[21-23] reported that SMBG was associated with worse control. Regardless of their findings, the cross-sectional studies are basically uninterpretable as one cannot conclude that SMBG preceded or was accidentally correlated with good control, or was initiated by patients who were in poor control. The longitudinal studies fail to clarify the picture as they are evenly divided between positive effects and null effects.

A more favorable image of SMGB for controlling blood glucose levels emerges from the results of the RCTs and Soumerai and colleagues'[36] well-designed interrupted time-series analyses. Of the 9 RCTs[37-45] that compared a monitoring intervention to a control, 6[37-42] reported lower levels of HbA1c for patients in the monitoring condition. In no trial did the monitoring condition lead to worsening of HbA1c, although for 3[43-45] of the 9, improvements in the monitoring condition were not statistically greater than the control condition. Soumerai and colleagues'[36] time-series analysis finding of lower HbA1c levels following the initiation of monitoring than during the nonmonitoring time period is consistent with the results of the RCTs.

This study's positive view of the benefit of SMBG in controlling HbA1c for patients with type 2 diabetes is consistent with previous reviews by Welschen and colleagues in *Diabetes Care*[6] and the *Cochrane Database*.[10] Sarol and colleagues[11] also concluded that SMBG improved glucose control for patients with type 2 diabetes. All 3 reviews examined only RCTs whose participants were not on insulin. Less favorable judgments were offered by Coster and colleagues[9] and Faas and colleagues,[8] both of whom stated that the evidence is insufficient to support the hypothesis that self-monitoring is effective in improving glycemic control, although both called for further studies. Coster and colleagues[9] and Faas and colleagues[8] also included a study in which some participants were on insulin.

This study broadened the criteria for inclusion and reviewed cross-sectional studies, longitudinal studies, and RCTs using a variety of treatment strategies, including studies with some patients on insulin, to obtain as much evidence as possible respecting the effects of SMBG on HbA1c and the moderators and mediators of treatment outcomes.[48-50] This study balanced the broader inclusiveness in the type of studies reviewed by narrowing the focus to studies of patients with type 2 diabetes, some of whom were not on insulin and others who were. By excluding studies of patients with type 1 diabetes and studies that only included patients on insulin, this study avoided duplicating prior recommendations that have led to acceptance of SMBG for patients using multiple insulin injections a day (ADA level of evidence = A).[7] This allowed the authors to conduct a thorough review of studies for which the ADA recommendations have the least evidence (ADA level of evidence = E).[7] It is important to note, however, that the favorable evidence for SMBG for patients using insulin is consistent with this study's theoretical model. Insulin is relatively fast acting, and SMBG provides a direct indication of its effects. The combination of insulin and SMBG provides patients with clear evidence of the utility of the combination for controlling blood sugar levels and facilitates the acquisition of the volitional patient-centered feedback loop essential for effective self-management.

## Mediators and Moderators

The optimistic message that monitoring can be an effective tool in patient-centered care for patients with type 2 diabetes (ie, for self-regulation of blood glucose and lower levels of HbA1c over time) assumes that SMBG is embedded in a multicomponent system for effective, volitional control. This study suggests that conscious or voluntary management requires the implementation of a complete control system in which the patient must (1) know how to take a reading; (2) understand when the reading is above (or below) target values; (3) see the connection between deviant readings and prior behavior (eating, exercise, and under- or overuse of medication); (4) have and implement an action plan to control glucose levels; (5) rely more heavily on SMBG readings and give less weight to subjective feelings of well-being and possibly false signs of hyperglycemic distress (eg, feeling dizzy or shaky); (6) create simple action plans that will allow the patient to integrate them into his or her ongoing life patterns, the use of SMBG, and the behaviors needed for effective blood glucose management; and (7) evaluate glucose readings in a nonjudgmental framework. Meeting blood glucose targets needs to be viewed as an ongoing problem-solving process and target misses as problems with the intensity

or timing of specific control behaviors and not as failures of the self.

Of these 6 hypotheses, only 1 hypothesis was examined by the studies reviewed. The RCT conducted by Schwedes and colleagues[41] found that patients who changed self-management behaviors in response to SMBG showed improvement in HbA1c, and this finding is consistent with this study's hypothesis that SMBG is effective when it is used by the patient to make treatment adjustments. Similarly, Guerci and colleagues[37] found that patients who monitored were more likely to follow dietary advice and had better glucose control. Of the 3 cross-sectional studies[21,26,27] and 1 longitudinal study[35] that examined the impact of treatment adjustment in response to SMBG on HbA1c, only 1 found that patients who made treatment changes in response to SMBG were in better control.[21] The quality of these studies, however, prevents interpretation (all used self-report, 2 studies asked only about the ability[26] or if the patient "would ever"[27] adjust therapy, and in 1 study, only 7 patients reported making changes[35]). Although this study had no specific hypotheses regarding moderators, evidence from the review of RCTs suggested that greater initial HbA1c[37,39,40] and shorter duration of diabetes[37,41] may be associated with improved response and lower HbA1c. Other RCTs, however, found no association of initial HbA1c[44,46] or duration of diabetes[44,46] with improved response.

This study's finding of an inadequate assessment of moderators and mediators by the studies reviewed may reflect a particular bias in the way medical investigators view the RCTs. Randomized controlled trials testing SMBG and lifestyle changes are not experiments in which the independent variable is a single factor, as seen in classical behavioral studies of perception and learning. The RCT for glucose monitoring implements a multi-component system; SMBG is not equivalent to a medical RCT comparing an active pill to a placebo (with biases such as differences in adherence, etc, removed). Interventions that introduce monitoring without creating the perceived linkages between specific behaviors and meaningful and valid blood glucose readings do little more than provide the patient a number, which may be differ from target but be of little utility for control. The call for the assessment of moderators and mediators is not new: it has been advocated by clinical trial investigators.[51] Assessment of the specific components of an intervention allows statistical analyses to identify those that are active.[52]

## Implications

This systematic review suggests that SMBG may lead to improvements in HbA1c for patients with type 2 diabetes not on insulin. Few studies, however, implemented and/or examined the components of the behavioral monitoring system that self-regulation and behavior theory would suggest as critical for patients to manage diabetes on their own. Thus, this study found little data to support or refute hypotheses regarding mediators. For example, the studies reviewed did not report on the specifics of what patients were instructed to do in response to their monitoring results. Some instructed patients to use fixed time monitoring schedules, which does little to help patients see how self-management by medication, diet, and exercise relates to glucose levels. And in 1 instance,[46] patients were instructed to monitor blood glucose levels before meals. It is not clear that patients would learn how specific meals affected blood glucose levels by premeal and/or fasting blood glucose monitoring. When SMBG is embedded in a volitional control system, it provides feedback as to how specific behaviors increase or decrease blood glucose.

In addition to using monitoring within a system that connects behaviors to blood glucose levels, interventions need to ensure that the objective data provided by SMBG are used in place of the commonsense subjective cues that are highly available and easy for patients to use to manage diabetes. Patients and clinicians believe that fluctuations in blood glucose produce subjective changes. Seventy-seven percent of patients have answered yes to the question "Can you tell, just by how you feel, when your glucose is too high?"[53] The subjective cues that common sense selects as indicators of blood glucose may be ambiguous, confounded by affective experiences unrelated to variation in blood glucose and therefore poorly correlated with actual blood glucose levels. Not surprising, patients generally underestimate their blood glucose levels.[53] Moving patients from commonsense cues to objective blood glucose monitoring may be an important step for improving monitoring interventions and is consistent with Peel and colleagues'[54] conclusion from their detailed qualitative findings that SMBG helped patients make "their otherwise invisible and imperceptible illness visible." None of the studies reviewed assessed or discussed the transition from subjective cues and feelings to objective monitoring as patients shaped their self-regulatory behaviors to control blood glucose.

Finally, success in self-regulation requires that patients create and implement action plans that fit within their daily lives. Studies of patients with type 1 diabetes have taught strategies and specific skills that allow patients to adjust insulin in response to glucose levels and diet and develop a high level of autonomy for effective management that allows them the "life they would live without diabetes."[55,56] There is no indication that the interventions reviewed here considered the issues involved in incorporating SMBG into the daily life of patients with type 2 diabetes. This is not a trivial issue as time for self-management has been reported to take an average of 2 hours a day.[57] Measures of quality of life are a potential source of evidence for effective and autonomous self-management processes that fit within a patient's life pattern; quality of life was assessed in only 4[21,22,41,44] of the studies reviewed. Only 1 study found that SMBG was associated with higher depression,[21] whereas the remaining 3[22,41,44] found that SMBG was not associated with impaired quality of life. Of these, 1 RCT found that SMBG led to improved quality of life for patients in the monitoring arm. Both qualitative[54] and quantitative[58] research on quality of life and SMBG is consistent with the assumption that quality of life will be positively associated with SMBG when it is implemented effectively (ie, the patient views the information nonjudgmentally and takes responsibility for his or her management).

Given the scarcity of the empirical evidence, caution is needed respecting the conclusions that have been drawn about specific mediators and moderators of the effectiveness of SMBG. Caution does not, however, preclude emphasizing the importance of a theoretical analysis of the behavioral processes that underlie a volitional action such as SMBG. Effective blood glucose control through blood glucose monitoring, either in a RCT or in clinical practice, requires careful and thorough implementation. Medication and lifestyle changes that are unused or used inappropriately will not improve the function of a complex, in vivo physiological system; this is true for the control of blood glucose, blood pressure, and other biological markers for risk. Successful treatment, whether it be medication, diet, or exercise in combination with SMBG, requires that practitioners address both the physiological and the behavioral control systems regulating blood glucose levels. Failure of blood glucose control in personalized medicine represents a failure of the medical care system, not a failure of the patient.

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## Addendum

Since the completion of this systematic review of self-monitoring of blood glucose (SMBG) for patients with type 2 diabetes, one of the largest randomized control trials of SMBG was published in the *British Medical Journal*.[1] This study provides an important contribution to the literature in that it is a well-designed trial that addresses many of the limitations of previous SMBG interventions, including sufficient power to detect clinically meaningful differences in HbA1c levels. In addition, it examined not only SMBG but also SMBG within a behavioral framework using psychological theory. Farmer and colleagues[1] randomized 453 patients to 1 of 3 arms: a control where patients and their doctors received HbA1c readings prior to an appointment; an SMBG intervention that asked patients to monitor blood glucose 3 times a day, twice a week and talk to their doctor for interpretation; and an intense SMBG intervention that asked patients to monitor their glucose levels at the same rate and taught them skills for personal interpretation. All patients received a behavioral goal-setting intervention based on Leventhal's commonsense model of self-regulation. Although the intense self-monitoring group showed a 0.17% reduction in HbA1c, the between-group difference for HbA1c did not reach statistical significance.

Although Farmer and colleagues[1] should be commended for their well-thought-out and timely study, of concern is the discrepancy between HbA1c improvement found in this trial and the HbA1c improvement found in other trials. Of the 11 randomized control trials (RCTs) examined in this systematic review, only 1 found less improvement in HbA1c levels for the SMBG arm,[2] with the majority showing at least 3 times the level of improvement. The results presented here suggest that patients who are in poor control are the ones who may benefit the most from SMBG. The mean baseline HbA1c level of 7.5% of the patients recruited by Farmer and colleagues[1] may have limited the ability to detect improvement from monitoring. Consistent with this possibility, Farmer and colleagues' reporting of subgroups suggests that patients in their study who were in poorer control benefited the most from the SMBG intervention, as patients on oral medication had a greater reduction in HbA1c levels than those treated with diet alone (this effect was not statistically tested).

Further analysis of mediating and moderating variables may provide clues as to why intensive intervention patients did not show significant improvements in HbA1c levels. Specifically, patients need to substitute objective readings (SMBG) for subjective cues to assess blood sugar levels. Participants in Farmer and colleagues' intensive intervention, however, were reporting significantly more subjective symptoms used to identify hypoglycemia episodes.[1] As patients concerned about hypoglycemia have elevated glucose, intensive participants may have experienced conflict between subjective cues and objective indicators, accepted higher readings, and had the greatest difficulty with self-management based on objective readings. This is consistent with their less frequent use of meters. In addition, patients appear more likely to succeed in using SMBG to regulate diet and exercise if they monitor both before and 2 hours after a meal.[3] In the paper by Farmer and colleagues, patients were described as monitoring either before or after a meal.[4] It is unclear how patients could develop a behavioral regulatory system without specific feedback about their diet and exercise activities.

Although the conclusion that SMBG may be effective in controlling HbA1c for patients with type 2 diabetes not treated with insulin is maintained here, the well-designed and adequately powered study by Farmer and colleagues[1] highlights the difficulties both for conducting trials and for clinical practice. Attention to how (pre- and postaction), when (initially diagnosed), and for whom (poorly controlled) can maximize the possibility that SMBG can help the patients achieve effective blood sugar control. As patients develop a steady state of good diabetes control, they may use SMBG only as an occasional check. But as the patient's physiology changes, causing a deterioration of control, the individual should use SMBG to readjust his or her self-regulation. Recommendations to not use self-monitoring may have

small ramifications in the short term, but as patients continue in maladaptive regulatory behaviors, the effects may be magnified. As such, trials should continue to examine the effect of SMBG on patients with type 2 diabetes not on insulin.

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