Current Medicare guidelines allow patients with diabetes mellitus to SMBG at varying frequencies, depending upon their treatment regimen. Patients who utilize insulin injections are allowed 100 test strips and lancets every month while patients treated with oral agents or diet alone can receive 100 test strips and lancets every three months. These amounts of testing supplies result in a testing capability of 1x/day for non-insulin treated and 3x/day for insulin treated patients, respectively. Additional quantities of testing supplies are allowed, with no maximum number specified, with additional justification from the treating physician.

Optimal testing frequency has been the subject of much debate, especially for patients who are not managed with insulin injections or insulin pumps. The American Diabetes Association recommends that for most patients utilizing multiple daily injections of insulin or insulin pumps, patients should test three or more times daily. This is given an evidence rating of “A” representing clear clinical evidence in support of this position. For patients using less frequent insulin injections, non-insulin therapies or medical nutrition therapy (MNT), the ADA guidelines do not recommend a testing frequency but state “SMBG may be useful as a guide to the success of therapy.” The evidence rating for the less frequent insulin injection patients, non-insulin treated patients or those on MNT is “E” reflecting only a consensus recommendation, the lowest evidence rating.

The lack of a testing frequency recommendation for non-insulin treated patients from the ADA is not unique and reflects the state of the medical literature with respect to testing efficacy. In fact, the Canadian Agency for Drugs and Technologies in Health recommends against routine testing of blood sugar for most adults with type 2 diabetes on oral hypoglycemic medications. This uncertainty in recommendations was confirmed by Burgers et.al. in their analysis of 15 clinical guidelines on type 2 diabetes from 13 countries. Burgers’ work determined that despite a high degree of international consensus on recommendations for care, there was no consensus on SMBG in patients on diet alone or on oral medication. This guideline analysis takes on greater significance when one considers the medical literature examined in support of each guideline had little overlap from guideline to guideline.

In the absence of consensus for optimal testing frequency in non-insulin treated patients, researchers have resorted to meta-analysis of existing studies to discern the answer to this question. Faas et.al. in 1997 identified six randomized prospective controlled trials that addressed optimal testing frequency; however, only one study demonstrated improvement in glycolated hemoglobin A1C (HbA1) and this study was plagued by methodologic criticism. The remaining studies were predominantly negative. This meta-analysis exercise was repeated again in 2005 by Welschen et.al. This review identified five published randomized controlled trials (interestingly, only one overlapping with the Faas review) and one article in press. The authors concluded that the overall effect of SMBG was a statistically significant decrease of 0.39% in HbA1C compared to control groups. However, the analysis did not evaluate the optimal frequency of testing and the studies included in the meta-analysis varied in both testing frequency, patient education and other interventional factors. A contrasting meta-analysis by Coster et.al. found no evidence of benefit from self-monitoring.

Most recently Towfigh and colleagues published a meta-analysis in the American Journal of Managed Care and concluded that “At most, SMBG produces a statistically significant but clinically modest effect in controlling blood glucose levels in patients with diabetes mellitus not taking insulin. It is of questionable value in helping meet target values of glucose control.” This conclusion was based on a review of nine trials - five of 6 month’s duration and four trials reporting outcomes of one year or longer. For the six month trials, SMBG resulted in a pooled estimated effect of -0.21% decrease in HbA1C (95% confidence interval, -0.38% to -0.04%) whereas the pooled estimate of effect for the longer trials resulted in a mean decrease in HbA1C of -0.16% (95% CI, -0.38% - 0.05%).
While the meta-analysis are suggestive that testing at some frequency improves glycemic control in type 2 diabetes mellitus patient, it is more illustrative of the dilemma on optimal frequency to achieve this outcome to delve into the studies themselves. Two studies are often quoted as supporting SMBG in non-insulin treated patients - Schwedes and Guerci. Schwedes and colleagues conducted a 6 month study which included 6 months of follow-up on 223 patients in a randomized prospective controlled multicenter study. This study did not access the impact of testing frequency on the primary endpoint HbA1C; however, patients did test an average of almost 25x/week (3-4x/day) which was twice as much as recommended. The authors concluded that this increased frequency of testing was the result of experimenting with their favorite meals. Consequently, from the standpoint of assessing optimal testing frequency, no conclusion can be drawn from this study.

Guerci et.al. examined the impact of SMBG on 689 patients with a primary criterion of lowering HbA1C. Patients in the study arm were asked to perform SMBG at least 6x/week. At endpoint, the HbA1C was lower in the SMBG group (8.1± 1.6%) than in the control group (8.4±1.6%) with the most benefit demonstrated in persons with higher initial HbA1C. No information was provided by the authors on compliance with the recommended testing of at least 6x/week or the testing frequency in the control group. This lack of information on how often the patients actually tested to achieve a reduction in HbA1C represents a significant limitation of this study for the purposes of determining optimal frequency.

Karter et.al. is also an often quoted source for support of SMBG and improved glycemic control. This cohort design examined the treatment and pharmacy records for 24,312 adult health maintenance organization (HMO) members with diabetes in 1996. Frequency of testing was based on monitoring of strip utilization as documented by number of glucometer strips redeemed at Kaiser pharmacies. Amounts utilized were expressed as average strips per day and patients with non-insulin treated diabetes (oral agents) were categorized as monitoring daily if they used an average of at least 0.75 strips per day; less than daily but at least occasionally for lesser levels of utilization; or not practicing self monitoring. At the time this study was conducted, the ADA clinical guidelines did not include a recommendation for SMBG in type 2 patients managed with diet alone, a goal of “at least occasionally” was used.

In all patient groups (insulin using, pharmacological and diet) glycemic control improved as monitoring frequency increased. In patients treated with insulin or oral agents, the largest improvements were seen in patients performing SMBG at the recommended frequencies (i.e., at least three times daily in patients using insulin, at least daily in patients using oral agents). The authors go on to conclude that less frequent monitoring conferred little benefit. Interestingly in this study, adherence to monitoring reflected the experience in the third National Health and Nutrition Examination Survey (NHANES III). The Kaiser cohort demonstrated that patients utilizing insulin were adherent to testing at least three times per day 34% and 54% of the time (Type I insulin treated, Type 2 insulin treated, respectively). Adherence declined to 20% with oral agent only-treated patients. In NHANES III, 29% of insulin treated patients, 65% of oral agent patients and 80% of diet managed patients had never monitored their blood glucose or monitored it less than once per month. More revealing with NHANES III was the fact that self monitoring at least once per day was practiced by 39% of those taking insulin and only 5-6% of those treated with oral agents or diet alone.

In contrast to Karter’s conclusion that testing less often than once per day conferred little benefit, Meier and colleagues examined this same issue and reached a different conclusion. This study examined the impact of reducing the allowance of test strips per month at a Veteran’s Affairs (VA) medical center in a retrospective noncrossover trial.

At baseline, patients on oral hypoglycemic therapy had HbA1C results of 7.83% with a testing frequency of 1.36 strips per day. After implementation of a new policy allowing 50 strips per 90 days, the frequency of testing decreased by 46% to 0.74 strips per patient per day with a resulting HbA1C of 7.86% (p=0.63 vs. baseline). While this is not a randomized controlled trial and was conducted in a closed system with ready access to supplies and medical care, it is additional evidence regarding the optimal frequency of testing in non-insulin treated patients.

Finally, two recently published studies not included in any of the above meta-analyses reached different conclusions regarding the utility of SMBG. Barnett and colleagues published a large, multi-center, prospective, randomized trial evaluating the efficacy of SMBG in type 2 patients treated with a modified release oral hypoglycemic agent. The DINAMIC 1 study randomized 610 patients at multiple international locations (none in the United States) and according to the
authors was designed to overcome some of the biases present in previous investigations of SMBG efficacy (e.g., nutrition, educational counseling, and behavior adjustments). For patients in the SMBG arm, blood glucose levels were assessed on two days per week - 5 readings on each of those days (before each meal, 2 hrs. after the main meal, before bedtime). Once per month SMBG patients were asked to increase the frequency of their post-prandial testing to after each of the three main meals. All patients were placed on modified release gliclazide and SMBG patients were asked to adjust their dosage based on monitor results. Exclusion criteria included current management with SMBG.

At the end of the 6 month follow-up, there was a 0.25% difference in the mean HbA1C level between the SMBG and non-SMBG groups. HbA1C levels decreased from 8.12% to 6.95% compared with 8.12% to 7.20%, respectively. This was statistically significant. The study investigators concluded that the reduction in each group and between groups was significant and clinically relevant if sustained in the long term. They noted that their results contrasted with those of the Diabetes Glycaemic Education and Monitoring (DiGEM) study (see below) which found no significant improvement in glycemic control after 12 months. The authors hypothesized that the divergent results may be the result of patients in the DINAMIC 1 study titrating their oral hypoglycemic medication based on SMBG results. In addition, the monitoring frequency in the DiGEM study was less intensive than the schedule in DINAMIC 1 (5-7 x/day on two days/week in DINAMIC vs. 3x/day on two days/week in DiGEM).

The Diabetes Glycaemic Education and Monitoring Trial Group (DiGEM) was a three arm, open, parallel group randomized trial published in 2007 in the *British Medical Journal*. Patients were randomized to usual care (control group), less intensive SMBG (instructions to call healthcare provider for interpretation of results) and more intensive SMBG (additional training in interpretation and application of results). While the more intensive group received additional education, they were not instructed in how to make medication changes as with DINAMIC 1 but rather make exercise and diet modifications. Self-monitoring was performed three times per day on two days per week. At 12 months the differences in HbA1C between the three groups were not statistically significant.

The DiGEM study had several weaknesses that potentially confound the comparison to other studies of SMBG. First, patient included in the study were reasonably well controlled at enrollment. Second, there were a moderately high percentage of patients in both the less intensive and more intensive groups that did not persist in monitoring their blood glucose. Of the 150 and 151 patients randomized to those two groups, 51 (33%) and 72 (48%) respectively did not persist in monitoring. In published responses to this article, several commenters noted that if patients are not encouraged or educated to use their results to make medication changes or other interventions, their interest or compliance with SMBG wanes with time. Furthermore, the study reinforces the often cited conclusion that monitoring has the greatest impact and is most beneficial to patients who are poorly controlled. Stated another way by Simon Heller in his editorial comments on DiGEM, “[T]he DigiEM trial has shown that in patients with established diabetes relatively well controlled by oral drugs who monitor their blood glucose infrequently, little is gained in promoting blood glucose testing even in conjunction with an education programme.”

Finally in 2010, Dr. Mayer Davidson, a leading researcher in the field of diabetes and SMBG, attempted to analyze the evidence from multiple clinical trials to determine if the current literature supports improvement of HbA1C through SMBG. The author notes “Of the 14 published bona fide RCTs [randomized controlled trials], nine show no benefit in lowering HbA1C levels. In four of the five positive ones, the SMBG group received more intensive education and/or treatment than the control group. In the one in which patients in both groups were followed similarly, over 500 patients were required to produce a statistically significant difference of 0.2% favoring SMBG, the clinical significance of which is debatable.”

**Summary**

Although not an exhaustive review of the scientific literature, the major studies and results are represented above. What do we know about the optimal testing frequency in patients with diabetes? The only certain conclusion is that the literature is uncertain, at least with respect to non-insulin treated patients. The ADA guidelines support testing in insulin treated patients at least 3x/day and further state that testing at this frequency may not be adequate to achieve glycemic goals without hypoglycemia. Other guidelines and consensus statements support this conclusion.
For diabetic patients who do not utilize insulin therapy, there is emerging support that testing at some frequency will result in improved glycemic control; however, unfortunately, there is scant evidence for the optimal frequency of testing in this population. Furthermore, studies also demonstrate that this population of patients is less likely to perform SMBG on a regular basis.

Viewing Medicare’s policy on home blood glucose monitoring in light of this medical literature, it is clear that the usual allowance of testing 3x/day in insulin treated patient is supported in by the current clinical literature; however, the sum of evidence for testing in non-insulin treated patients, insulin injections less than multiple times per day and medical nutrition managed (i.e., diet-controlled) suggests that Medicare’s current allowance of testing 1x/day is generous. There is little or no evidence in the medical literature that routine testing at frequencies higher than these limits improves glycemic control or confers any medical benefit for either population.

References

1 American Diabetes Association: Standards of Medical Care in Diabetes - 2011 (Position Statement). Diabetes Care 2011;34 (Suppl. 1):S4-S10.
2 Ibid
15 Davidson, MB. Evaluation of Self Monitoring of Blood Glucose in Non-Insulin Treated Diabetic Patients by Randomized Controlled Trials: Little Bang for the Buck. Reviews on Recent Clinical Trials 2010; 5