

# Self Blood Glucose Measuring in the Non-insulin-requiring Diabetic Patient— To Test or Not to Test

a report by

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## History

The initial patent for a practical glucose meter was issued in Elkhart, Indiana, in 1971, and the device has now evolved into a frequently used tool. The utility of finger-stick blood glucose testing using such meters has been solidly demonstrated in patients requiring insulin therapy; however, data are conflicting in non-insulin-requiring type 2 patients.<sup>1</sup> A systematic review of self blood glucose monitoring (SMBG) in type 2 patients not taking insulin concluded: "The overall effect of SMBG was a statistically significant decrease of 0.39% in glycated hemoglobin (HbA<sub>1c</sub>) compared with the control groups. This is considered clinically relevant. Based on the UK Prospective Diabetes Study, a decrease of 0.39% in HbA<sub>1c</sub> is expected to reduce risk of microvascular complications by 14%."<sup>2</sup> Davidson, on the other hand, in a counterpoint to this study, reviewed several trials and concluded that SMBG fails to reduce HbA<sub>1c</sub> in type 2 patients not taking insulin and is therefore a waste of money.<sup>3</sup>

## Frequent Self Blood Glucose Measuring Is Expensive

The total Medicare/Medicaid expenditure for reagent strips, lancets, lancing devices, meters, batteries, and calibration solutions, etc., in 2006 was over \$1 billion.<sup>4</sup> It makes little sense to spend this amount of money if there are no tangible positive results. A single finger-stick blood glucose measurement can cost as much as \$1 retail; four tests a day can add up to nearly \$1,500 per patient per year. So, where's the beef? There are studies and there are studies. In the clinic or the practitioner's office, what do we request of our patients and those paying for supplies? There are several criticisms of some studies included in reviews not showing efficacy, including:

- the 'study patient' effect—subjects in a control group are likely to have better outcomes than 'real-world' patients because of the attention of the study itself, so differential effects may be blunted;
- interventions in studies were heterogeneous;
- there was no use of SMBG data to effect change; and
- study and control groups had outcome-altering interventions.

The only randomized controlled trial to meet the *British Medical Journal's* clinical evidence criteria found an insignificant HbA<sub>1c</sub> reduction of 0.8% in SMBG subjects compared with 0.6% in non-SMBG controls.<sup>5</sup> Subjects in both arms of this trial had five meetings with a dietician over the six-month study.<sup>6</sup> In the real world, such intensive educational efforts are likely impractical and may be more expensive than frequent SMBG.

## Self Blood Glucose Measuring Is Not Therapy

SMBG is a tool that can provide information to direct therapy or provide insight into behavior modification and medication adherence.<sup>7</sup> If the information is not

used, it is worthless. Patients frequently indicate that meters and strips are sent by mail order with no instructions on meter use (outside of a manufacturer's instruction booklet) and no indication of when to test or what to do with the results. Worse yet, there are indications that some healthcare providers (HCPs) never look at meters or logs during clinic or office visits. Such practices might be metaphorically compared to recording the number of deaths from drunk drivers speeding on a stretch of highway, but doing nothing to alter it. To have a patient repeatedly test blood glucose and change nothing to correct poor control conforms to one definition of idiocy: continuing to do the same thing over and over while expecting a different outcome.

## Rationale for Testing

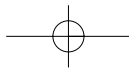
SMBG as a means to improve glycemic control in type 1 patients and in pregnancy is well established and will not be discussed here. The rationale for patients with type 2 diabetes who have a change in therapy or who have started insulin therapy also receives little objection. It is in the group not requiring insulin therapy that the rationale for SMBG is questioned. American Diabetes Association 2005 standards indicate: "The optimal frequency and timing of SMBG for patients with type 2 diabetes on oral agent therapy is not known, but should be sufficient to facilitate reaching glucose goals. Patients with type 2 diabetes on insulin typically need to perform SMBG more frequently than those not using insulin."<sup>8</sup> Recommendations for 2007 indicate: "SMBG should be carried out three or more times daily for patients using multiple insulin injections. (Grade-A recommendation, i.e. based on clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered...). For patients receiving less frequent insulin injections or oral agents or medical nutrition therapy (MNT) alone, SMBG is useful in achieving glycemic goals (Grade-E recommendation, i.e. based on expert consensus or clinical experience)."<sup>1</sup>

We must therefore revert to the truism brought to any clinical teaching situation: patients are different and there are different approaches to the therapy of the disease state. It therefore becomes the clinician's



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## Blood Glucose Monitoring

responsibility in diabetes to use whatever tools are available at whatever frequency necessary to achieve the best possible control of glycemia with the least risk of acute complications and at an economically feasible cost.

With the risks of retinopathy, cardiovascular disease, neuropathy, and possible amputation associated with uncontrolled glycemic levels, where is the line drawn in terms of healthcare expenditure? Perhaps the cost of long-term SMBG versus short-term usage has to be assessed from an alternate viewpoint. Although it is arguably expensive to fund SMBG, the value gained from monitoring and controlling blood glucose cannot be denied. After all, is it not more cost-effective, if not logical, to pay for the blood-testing apparatus than to pay for heart surgery and leg amputations?

### Common Errors

A tool such as SMBG can contribute substantially to improved glycemic control if reasonably accurate and used appropriately. What if, however, the information is incorrect either because of technical inaccuracies or user error? Confounding issues related to blood glucose testing in the inpatient setting have been well elucidated.<sup>9</sup> In the outpatient setting, common errors in SMBG have been documented in observational studies.<sup>10,11</sup> SMBG data can be rendered inaccurate by several user errors, including:

- failure to store glucose strips properly;
- failure to set glucose meter codes to match strip codes;
- failure to apply sufficient blood on the meter's strip;
- failure to use control solutions;
- use of date-expired control solutions;
- use of date-expired strips; and
- failure to wash hands properly.

The frequency of user error relating to meter codes has been reported at approximately 16%.<sup>10,11</sup> In one study, exactly half of the patients were of Medicare age. As these patients are often challenged by cognitive and dexterity limitations and frequently have long-standing diabetes requiring insulin, therapeutic interventions based on such erroneous data can be destructive.

### Recommendations

#### The Meter

The glucose meter should be accurate, easy to use, small, and convenient. Meters that do not require coding, are rapid and accurate, and require a very small amount of blood are preferred. The choice of meter should be a joint effort between the patient and the HCP based on the cognitive and physical limitations of the patient and the facility of the HCP to harvest the data, e.g. download capability. The choice should not be that of the mail order company or insurer. The number of meters

available, some of which are downloadable (each having different software) and some of which are not, can be time-consuming and a daunting deterrent to HCP evaluation of the data.

#### The Patient

The diabetes patient should be thoroughly instructed in the proper operation of the meter. Meters requiring fewer steps facilitate ease of teaching and learning and may lead to increased accuracy of test results. In addition, those instructions should be periodically reviewed and competency demonstrated. Information obtained from SMBG should be reviewed by the HCP, preferably using downloaded meter data. Downloaded blood glucose data are very useful in detecting glucose trends to effect therapeutic changes. As patients are infrequently evaluated in the clinic/office, the patient must be instructed how to act on the blood glucose information. Specific instructions are needed relating to frequency of testing and timing, e.g. post-prandial testing. Type 1 patients, pregnant patients, those starting insulin therapy, and those with changing therapy require multiple tests daily. Stable type 2 patients who are at glycemic goal will likely require less frequent testing. Post-prandial tests in this setting are especially useful for patient education. It is also important to spot trends of progressive  $\beta$ -cell deterioration and the need for accelerated therapy.

#### The Healthcare Provider

Regardless of how well a patient performs SMBG, the results are useless if the HCP overlooks the data. If the HCP shows little to no interest in the information, patients will feel less inclined to adhere to SMBG. Conversely, HCPs who take the time to look over the data and log books and educate patients about the importance of SMBG readings will not only benefit the patient, but will also positively reinforce their SMBG performance and adherence.

#### Summary

The worldwide epidemic of diabetes is producing unacceptable human suffering. This in turn produces economic losses from direct costs and lost production. Therapeutic endeavors must be directed to attenuation of this effect. A cure is not on the horizon; the best tools available to HCPs are those that reduce risks and delay or prevent disease progression. In type 2 patients, therapeutic approaches must be progressive, reflecting the gradual loss of  $\beta$ -cell function. SMBG is the singular, immediate, accurate measure available to the patient allowing therapy adjustment. With appropriate education, the patient and healthcare team can adjust therapy to approach glycemic goals. The value of testing, not simply the cost, must be appreciated by patients, HCPs, and the healthcare system. Prevention or delay of complications and improvement in daily symptoms and quality of life are priceless. As with all tools employed to alter disease states, the use of SMBG must be individualized. The frequency of testing must be geared to outcome goals set by the healthcare team and the patient. ■

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