Self-Monitoring of Blood Glucose

AMERICAN DIABETES ASSOCIATION

Self-monitoring of blood glucose (SMBG) is an important component of the treatment plan of patients with diabetes mellitus. Its use was the subject of an American Diabetes Association Consensus Conference in 1986 that dealt with issues regarding the intended and actual use of SMBG, the design, accuracy, and reliability of SMBG devices, how well patients were instructed in SMBG, and how patients and health care providers used the information generated to influence metabolic control. Over the ensuing 7 years, these devices have improved in portability and ease of use. Diabetes educators are teaching an ever-increasing number of people with diabetes to use SMBG. In addition, the recent publication of the results of the Diabetes Control and Complications Trial has given validity to the concept that better metabolic control can significantly reduce the onset and progression of the microvascular and neuropathic complications of insulin-dependent diabetes (IDDM).

Despite these advances, questions remain as to which type(s) of patients might best use SMBG, whether the procedure is accurate, and how the information generated by SMBG should be used. The economics of SMBG also needs to be considered in the context of a changing health-care system. To answer these questions, the American Diabetes Association convened a second Consensus Development Conference on Self-Monitoring of Blood Glucose on 27–29 September 1993.

The conference consisted of 24 invited presentations and contributions from a large audience of health-care professionals and representatives from industry. A consensus panel with expertise in the areas of internal medicine, laboratory medicine, nursing, nutrition, pharmacy, endocrinology, and diabetes education, with backgrounds in clinical practice and academic medicine, considered a broad spectrum of issues related to SMBG. The panel reached a consensus on the answers to these questions: *1)* What is the epidemiology of SMBG? *2)* Who should self-monitor? *3)* What is the current technology? *4)* How should the data obtained from self-monitoring be used? *5)* What is the future of self-monitoring?

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WHAT IS THE EPIDEMIOLOGY OF SMBG?

Diabetes affects more than 13 million people in the U.S. About 300,000 have IDDM; the remainder have non-insulin-dependent diabetes mellitus (NIDDM). It is estimated that approximately 3 million diabetic patients are being treated with insulin.

A 1989 national sample of nearly 2,500 individuals with diabetes who were over 18 years of age showed that the frequency of self-monitoring varied considerably. Overall, 33% of the diabetic patients self-monitored their blood glucose. Of the IDDM population, 40% monitored once or more a day, 39% monitored less than once a day, and 21% never performed SMBG. Within the NIDDM population using insulin, 26% monitored at least once a day, 27% monitored less than once a day, and 47% never self-monitored. In both of these groups, the proportion of people who self-monitored was found to be directly related to the number of insulin injections per day. For patients with NIDDM not using insulin, only 5% monitored one or more times a day, 19% less than once a day, and 76% never self-monitored.

This survey also showed that the proportion of individuals who self-monitored at least once a day declined with age; the probability of testing decreased 18% with each decade of life in adults. African Americans were 60% less likely than non-Hispanic whites and Hispanics to self-monitor one or more times per day. Factors related to a higher proportion of testing (i.e., 1 or more times a day) included the use of insulin, the frequency of insulin injections, a higher educational level, frequency of physician office visits, and participation in a diabetes education class. This survey did not indicate that health insurance coverage is a determinant of self-monitoring; however, the sampled population was not asked if their insurance covered blood glucose testing equipment, supplies, or education in the use of SMBG.

Community-based intervention programs have increased the proportion of people with diabetes who self-monitor. For example, from 1981 to 1991, in selected communities in Michigan that implemented such programs, the use of SMBG increased from 29 to 85% in the IDDM population, from 6 to 82% in the NIDDM insulin-using population, and from 2 to 31% in the non-insulin-using NIDDM population.

The attitude of physicians regarding the appropriateness of SMBG varies

according to the medical specialty. In a recent study, internists and pediatricians expressed a stronger belief in the value of SMBG compared with general practitioners. Younger physicians were found to be more likely to believe that SMBG was useful in achieving glycemic goals.

While self-management is a goal of diabetes care, little information is available concerning how patients use SMBG results. In one study, approximately 70% of IDDM patients thought that SMBG was "very important" in helping them control their diabetes by allowing them to adjust their insulin dosage. Although 60% of insulin-using NIDDM patients thought that monitoring was "very important," only 21% altered their insulin dose based on SMBG results. Further information is needed to determine *1)* what frequency of monitoring is optimal for the care of people with IDDM and NIDDM and *2)* whether the actions taken in response to SMBG are appropriate.

Future research is also needed to identify and reduce barriers that impede the appropriate use of SMBG and to determine ways to increase the proportion of individuals who initiate a change in self-management in response to SMBG.

WHO SHOULD SELF-MONITOR?

SMBG is a means of achieving a goal rather than a goal in itself. When properly performed, SMBG permits people with diabetes to determine their blood glucose level. However, the value of SMBG is limited unless it is used as part of an integrated treatment program. The health professional supervising the care of the patient must clearly define the goals of treatment and therefore the reason for performing SMBG. Patients (or designated care providers) must be capable of learning the proper use of SMBG, must be motivated and willing to expend the effort necessary to ensure that the measurements are accurate, and must be committed to constructively modifying their treatment plans in response to the feedback provided by SMBG.

The indications and frequency for monitoring will vary considerably depending on the clinical situation of each patient and the purpose for which SMBG is being used. Potential indications for SMBG include but are not limited to the following areas.

Achievement and maintenance of a specific level of glycemic control

Recent clinical trials have demonstrated that when IDDM patients maintain glucose levels in the near-normal range, they both delay the onset and slow the rate of progression of diabetic retinopathy, nephropathy, and neuropathy. These studies also suggest that if normoglycemia cannot be achieved, any improvement in chronic glycemic control likely will be associated with a decrease in microvascular complications. People with NIDDM were not included in these trials. However, since hyperglycemia is associated with the presence or progression of complications in NIDDM, it is likely that lowering blood glucose levels will also decrease microvascular complications in these people. In addition, in women with diabetes, maintenance of blood glucose levels in the near-normoglycemic range before conception and during pregnancy has been shown to decrease rates of fetal malformation, morbidity, and mortality.

Thus SMBG is an essential component of any intensive insulin program directed toward achieving near-normoglycemia. Virtually all intensive therapy programs in insulin-deficient patients depend on the measurement of glucose levels at least four times a day. Knowledge of preprandial, bedtime, and nocturnal blood glucose concentrations is required to determine the appropriate basal and preprandial insulin doses. A decrease in the frequency of monitoring to less than four times a day has been shown to result in a worsening of glycemic control.

A lesser frequency of SMBG may suffice if the patient is still able to secrete substantial amounts of insulin (e.g., recent onset of IDDM, most cases of NIDDM). In these patients glycemic goals often can be met using less complex insulin regimens, oral hypoglycemic agents, and diet. SMBG may be used in these patients to assess temporal patterns (i.e. does glucose concentration rise/fall during the day vs. during the night) so that the morning or evening doses of insulin and/or oral agents can be appropriately increased or decreased. Once therapy is optimized and glycemic control has stabilized, the frequency of monitoring often can be decreased substantially, particularly in people with NIDDM. If the patient's social situation, medical condition, or motivation would discourage or preclude efforts at achieving near-normoglycemia, then the frequency of SMBG or the use of other monitoring systems, e.g. urine glucose measurements, should be utilized in relation to the patient's willingness or ability to obtain the needed information.

Prevention and detection of hypoglycemia

Hypoglycemia is a major complication in the treatment of diabetes. The risk of hypoglycemia increases when pharmacological treatments are used to maintain glucose levels in the near-normal range. Hypoglycemia can be a particular problem in people who are unable to recognize the early warning signs of hypoglycemia. People with NIDDM on either insulin or oral agents also are at risk for hypoglycemia. Hypoglycemia, produced by oral agents, may occur more frequently in people with considerable insulin secretory reserve (i.e. hypoglycemia is rare in people in whom oral agents have minimal therapeutic effect) and in the elderly. Appropriately timed SMBG is the only practical means of detecting asymptomatic hypoglycemia in the outpatient setting. By detecting temporal patterns of change in glucose levels, SMBG permits therapy to be modified so as to prevent hypoglycemia. This may be particularly important in individuals in

whom hypoglycemia may have serious health consequences (e.g. people with underlying atherosclerotic vascular disease). Glucose levels also should be closely monitored whenever a medication that may decrease recognition of hypoglycemia or impair glucose counterregulation (e.g., β-blockers) is added to the patient's existing regimen. Hypoglycemia may be particularly dangerous in situations in which impaired mental function may lead to serious bodily harm (e.g. driving). Insulin-taking patients should be instructed to always measure their glucose level before engaging in such activities.

Avoidance of severe hyperglycemia
Illness or drugs that alter insulin secretion (e.g., phenytoin, thiazide diuretics) or insulin action (e.g., prednisone) may worsen glycemic control. The risk of severe hyperglycemia and/or ketoacidosis may be increased in individuals with limited insulin secretory reserve (IDDM), limited access to fluids (elderly people with either IDDM or NIDDM), or increased fluid loss due to diarrhea, vomiting, or fever. People with diabetes should be instructed to initiate SMBG or increase the frequency of monitoring in all of these situations, as well as to consult their health-care provider. People using insulin should be provided with guidelines as to how to use SMBG data to appropriately increase their insulin dosage to avoid severe hyperglycemia.

Adjusting care in response to changes in life-style in individuals requiring pharmacological therapy
Changes in activity and diet can have major effects on blood glucose levels. Regular exercise can increase insulin action, thereby decreasing the dose of either insulin or oral agents required to achieve a given level of glycemia. Exercise can result in an increase, decrease, or no change in glucose levels both during and after exercise, depending on the prevailing insulin concentration. Exercise can alter subcutaneous blood flow and therefore alter the rate of insulin absorption. SMBG can be useful in determining patterns of response to planned or unplanned exercise, permitting pharmacological therapy or diet to be appropriately modified. SMBG may be particularly important in children and adolescents who have wide day-to-day variations in activity.

A reduction in caloric consumption can decrease insulin or oral agent needs. An increase in caloric consumption can have the opposite effect. Regular SMBG may be of assistance in modifying pharmacological therapy during periods of increased or decreased caloric consumption. It also provides the necessary information to determine whether pharmacological therapy should be modified when meal size is altered.

Determining the need for initiating insulin therapy in gestational diabetes mellitus (GDM)
Elevation in blood glucose levels in pregnant women influences fetal development. Because of the decrease in insulin action associated with pregnancy, some women not known to have diabetes are found to have abnormal blood glucose concentrations during pregnancy and are therefore diagnosed as having GDM. Untreated, GDM may result in an increased incidence of macrosomia, respiratory distress syndrome, and other abnormalities of fetal metabolism. Women with GDM who have elevated fasting plasma glucose levels are often treated with insulin and perform SMBG frequently each day to achieve near-normoglycemia. (These individuals are included in Goal #1.) However, evolving evidence suggests that SMBG may help identify a subset of women with GDM whose fetal outcome may benefit by earlier initiation of insulin therapy.

SMBG has occasionally been used to document hypoglycemia in nondiabetic individuals. Screening methods must be confirmed by laboratory testing before establishing any medical diagnosis. In some circumstances such as children with hypopituitarism, SMBG may be useful in screening and management of hypoglycemia.

SMBG is only one component of an overall program of diabetes care. Additional studies are needed to determine whether SMBG, as part of a treatment regimen, improves adherence to treatment or quality of life and to determine the associated costs. Until such evidence exists, using SMBG to simply enhance compliance or improve quality of life is of questionable value.

WHAT IS THE CURRENT TECHNOLOGY?

Measurement principles and limitations of SMBG systems
The operating principles of most self-monitoring systems are the same. Glucose is oxidized enzymatically, followed by a coupled reaction to develop a chromogenic product; the color intensity is proportional to the amount of glucose present, which is quantified by reflectance spectrometry. In other systems, the electrical current generated by glucose oxidation is measured. There is generally good agreement between the glucose concentration measured in whole blood by SMBG systems and that measured in serum or plasma by clinical laboratory procedures. The strength of the correlation varies according to the glucose concentration; a decrease in accuracy is seen at both extremes of glucose concentration. Factors that may influence the results of SMBG include variations in hematocrit, altitude, environmental temperature and humidity, hypotension, hypoxia, and triglyceride concentrations. Drugs taken in pharmacologic dosage do not appear to affect the accuracy of the measurements.

Performance of SMBG systems
The overall performance of SMBG systems is a combination of the analytical performance of the instrument, profi-

ciency of the operator(s), and the quality of the test strips. The previous American Diabetes Association Consensus Statement recommended that the performance goal of all SMBG systems should be to achieve a total error (analytical plus user) of less than 10% at glucose concentrations ranging from 30 to 400 mg/dl. Unfortunately, this goal has not been achieved for most SMBG systems. In an assessment of the analytical variability of SMBG systems, the College of American Pathologists recently found that the coefficient of variation ranged within systems from 4 to 33%. Some of this variability may be due to matrix effects, and uniform standards for the determination of the accuracy of SMBG systems are needed. In view of the proven benefits of good metabolic control, it is even more important now than it was in 1986 for SMBG systems to measure glucose accurately. The goal of SMBG device manufacturers should be to make future SMBG systems with an analytic error of +5%.

Operator performance is influenced by the characteristics of the system and the extent and quality of user training. Although some of the commercially available meters have been made less dependent on operator skill, further efforts in this direction are needed. The extent and quality of user training continues to be seriously hampered by current reimbursement policies for diabetes education.

Users are largely dependent on the system manufacturer to ensure the quality of each test strip. There is no way that a user can both verify that a single test strip is satisfactory and at the same time use it to test a blood specimen. In addition, there is significant within-lot and lot-to-lot variation in strips, and their use can be adversely affected by environmental factors. Because of the complexity of the calibration of strips to meters, the use of generic strips should be carefully studied before patients are encouraged to use them. Finally, since control solutions are used in teaching patients SMBG, and to check the functioning of the system, efforts should be made to narrow the acceptable range specified for the solutions.

Assessment of clinically significant error

The reduction of analytic and user errors will result in more accurate glucose measurements. However, it is important to point out that not all errors are clinically significant such that they will result in change in management, e.g., a change in insulin dose. Although the *Error Grid* developed by Clark and associates is a useful attempt at defining such clinically important errors by defining relatively broad "target ranges," with intensive insulin therapy designed to adjust insulin doses for narrow target ranges, even relatively small errors may cause a change in insulin dosage. Thus, depending upon the therapeutic goals of treatment, outlined above, clinically significant error may in some cases approach analytic plus user error. Efforts should be made to refine the *Error Grid* target ranges to account for intensive treatment goals. Also, further efforts are needed to link technical error with clinically significant error in future work.

Quality assurance

All manufacturers define proper quality-assurance practices to be used with their SMBG systems. A quality-assurance program necessitates periodic monitoring of control specimens at both high and low concentrations. If such quality-assurance measurements were performed at frequent intervals it would increase the cost of SMBG, thereby potentially creating a barrier to performance of quality assurance by patients in the home setting. In addition, testing of the instrument with control specimens does not monitor the quality of the collection procedure or the proper application of blood to the test strip. A complete quality-assurance program would address the entire self-monitoring process, from collection of the sample to measurement of the glucose value to application of the result. The development of such a program is recommended by the Panel.

Application of SMBG in hospital practice

It is debatable whether patients should perform glucose measurements on their own blood within a hospital, except for training purposes. If this practice is adopted, acceptable conditions under which this is done should be established by each hospital.

Further recommendations

The Panel recommends the following. *1)* Efforts should be made to develop fail-safe SMBG systems. The meter should identify faulty operation and specify the nature of the problem. Also, systems should be less dependent on user skill. *2)* Manufacturers should establish a uniform standard for calibration and the determination of the accuracy of SMBG systems. *3)* Periodic comparisons should be made between results obtained by the patient with his/her SMBG system and a fasting sample simultaneously obtained and measured by a referenced laboratory.

HOW SHOULD THE DATA OBTAINED FROM SELF-MONITORING BE USED?

SMBG is a tool used by both health-care providers and patients to monitor therapy. It is important that qualified health-care providers and trained patients have access to this technology. However, it can be of little value without a comprehensive package of diabetes education, counseling, and management. Health-care providers should use SMBG data to *1)* set glycemic goals, *2)* develop recommendations for pharmacological therapy, *3)* evaluate the effectiveness of pharmacological therapy, *4)* instruct patients to interpret and respond to blood glucose patterns, *5)* evaluate the impact of dietary factors on glycemic control, *6)* modify therapy during acute/intercurrent

illness or when patients receive medications that affect glycemic control, 7) modify the management plan in response to changes in activity, and 8) identify hypoglycemic unawareness and strategies for treatment.

This information should be conveyed by the health-care provider in a non-pejorative manner that encourages open and honest communication.

People with diabetes should use SMBG data to 1) self-adjust diet, exercise, or pharmacological therapy, 2) identify and properly treat hyper- and hypoglycemia, and 3) improve decision making and problem solving.

The effective use of SMBG encourages the patient to assume a greater responsibility for control, thereby improving confidence and self-management.

Appropriate use of SMBG is dependent on proper processing and interpretation of the data. Manual recording of data in log books has advantages and disadvantages. The advantages include simplicity, familiarity, opportunity to review a written record, and low cost. Disadvantages include difficulty in detecting trends and the integration of large volumes of data. Manual recording is subject to errors in entry and transcription and to falsification of data.

Newer systems, which include a memory meter and a computer with data management software, can potentially avoid many of the problems associated with traditional log books. In addition, these systems provide a variety of methods of data analysis and display. Disadvantages of data management systems include increased expense and complexity. Also, patients may fail to keep personal written log-book records and such decreased direct patient involvement in data analysis may lead to a decrease in self-management and a delay in the implementation of appropriate modifications of therapy. The utility of manual and computer-based systems is likely to vary depending on the expertise and interest of patients and health-care providers.

The Panel recommends that further research be directed toward identifying characteristics of patient/health-care provider relationships that influence interactions and improve glycemic control and health outcomes.

WHAT IS THE FUTURE OF SELF-MONITORING?

Ideally, SMBG should be a reliable, convenient, safe, closed-loop system easily used by patients. Its cost must be reasonable, and it must show clear benefits when integrated into a comprehensive treatment program. It should be easy to use by children and by people with decreased vision, impaired manual dexterity, or other special needs.

There are a number of areas in which existing SMBG systems should be improved. The systems should be made less dependent on user skill and should decrease the pain associated with monitoring. Also, better methods are needed to detect and prevent analytic, user, and sample collection errors. The cost of monitoring should be reduced. The accuracy and precision of SMBG systems should be increased. Access to and effectiveness of patient and professional education should be a high priority. Appropriate reimbursement for such education and testing supplies must be widely available. Optimal methods of data storage, telecommunication, presentation, and analysis need to be developed further.

Technology now on the horizon has the potential to monitor blood glucose levels on an almost continuous basis. Near-infrared and implantable continuous monitoring systems may decrease or eliminate the pain and inconvenience of testing and thereby facilitate more frequent monitoring. Such increased monitoring is likely to improve glucose control while at the same time decreasing hypoglycemic risk. These new glucose-sensing devices may ultimately allow the development of a closed-loop system. With both of these methods, however, difficulties in miniaturization, mass production, and reliability must be overcome.

The future of SMBG in diabetes care also will be affected by changes in the health-care system. Whatever changes occur, SMBG must be accessible and affordable. Government, third-party payers, manufacturers of diabetes care products, nonprofit organizations, health-care providers, and people with diabetes must work closely together to carry out the activities and research that have been identified at this conference. SMBG is integral to the management of diabetes, and coverage of SMBG should be an important component of any benefits package. The waivered status of SMBG devices under CLIA-88 is an important step in assuring access to this technology, and is endorsed by the Panel.

Advances in computer data analysis for handling the large amounts of data generated by such systems are also forthcoming, including the evolution of "expert" systems, which may aid in the development of individualized, instantly modifiable insulin treatment algorithms.

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SUGGESTED READING

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