CONSENSUS STATEMENT

A comprehensive examination by a panel of experts of a scientific or medical issue related to diabetes mellitus. A consensus conference is convened for the purpose of presenting expert opinion on an issue from which a consensus statement is developed. The statement represents the panel's collective analysis, evaluation, and opinion. The Consensus Statement is published in ADA journals and other scientific/medical journals, as appropriate. Once written by the panel, a Consensus Statement is not subject to subsequent review or approval and does not represent official association opinion.

Self-Monitoring of Blood Glucose

Self-monitoring of blood glucose (SMBG) has become a major adjunct to the care of individuals with diabetes mellitus in the past decade. It is an important technical advance that provides both the diabetic patient and the health-care team with vital clinical information that was previously unattainable. It is now possible for the diabetic patient and health-care personnel to measure and record blood glucose levels frequently with newly developed devices that are convenient to use and readily available. Individuals with diabetes mellitus as well as health-care professionals involved with their care must be trained to understand the purpose of SMBG, use the technique accurately, and record and make appropriate use of the results.

In view of the widespread use of SMBG, an examination and evaluation of medical and technical issues, training procedures, and general impact of SMBG was indicated. To address these issues, the American Diabetes Association, the Centers for Disease Control, the Food and Drug Administration, and the National Institute of Diabetes and Digestive and Kidney Disease convened a Consensus Development Conference on Self-Monitoring of Blood Glucose on 17–19 November 1986.

The conference consisted of invited presentations, panel discussions, 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, pediatrics, laboratory medicine, endocrinology, and diabetes education with backgrounds in clinical practice and academic medicine considered a broad spectrum of issues concerned with SMBG. The panel reached a consensus on the answers to these questions:

1. What is the intended and actual use of SMBG?
2. Is the design of SMBG devices adequate for their intended use?
3. To what degree are SMBG devices accurate and precise?
4. What is the reliability of these devices?
5. Is quality control in SMBG adequate?
6. Are patients adequately instructed on how to use the device, and in what manner is the instruction given?
7. How are the data generated by SMBG used in patient-care management?
8. How does SMBG influence medical outcome and day-to-day glucose control?
9. How is bedside glucose monitoring used in the hospital setting, and is this use appropriate?

WHAT IS THE INTENDED AND ACTUAL USE OF SMBG?—The primary intended use of SMBG is to assist in the management and evaluation of patients with diabetes. It has been estimated that 1,000,000 diabetic patients now use this technology.

The panel recommends SMBG for insulin-treated patients. It is especially important in *1*) pregnancy complicated by diabetes; 2) patients with unstable diabetes; 3) patients with a propensity to severe ketosis or hypoglycemia; 4) patients prone to hypoglycemia who may not experience the usual warning symptoms; 5) patients on intensive treatment programs, especially those using portable insulin-infusion devices and multiple daily insulin injections; and *6*) patients with abnormal renal glucose thresholds.

Although controversial, SMBG may be useful for patients not treated with insulin. SMBG must not be used to diagnose diabetes mellitus, and the role of SMBG systems in screening remains uncertain. Some insulin-treated patients may choose not to use SMBG routinely. Nevertheless, they should be trained in SMBG for use during emergencies. Patients who use SMBG should be properly trained and have a clear understanding of how the results of SMBG are to be incorporated into their individual treatment plans.

Monitoring systems involving visually or instrument-read strips are readily available from various sources. The panel recommends no change in this practice.

IS THE DESIGN OF SMBG DEVICES ADEQUATE FOR THEIR INTENDED USE?—Properly used, the available technologies for SMBG are sufficiently accurate for patient management. All systems depend on a glucose

THE CONFERENCE (17–19 NOVEMBER 1986) WAS SPONSORED BY THE AMERICAN DIABETES ASSOCIATION, THE CENTERS FOR DISEASE CONTROL, THE FOOD AND DRUG ADMINISTRATION, AND THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIH).

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oxidase colorimetric reaction that occurs when a drop of blood is placed on a reagent strip. The intensity of the color that develops is proportional to the amount of glucose present. Some strips are designed to be read by reflectance meters, some visually, and some by both methods. All meters are battery powered and use solid-state electronics. The effective concentration range depends on the system but generally covers the clinically relevant range. Size, shape, and calibration techniques vary by manufacturer, but in general the glucose monitors are lightweight, portable, and easily calibrated. However, all available systems are highly dependent on user skills.

The panel recommends that future glucose monitoring systems be simpler and less dependent on user skill. Because current systems cannot be used by individuals with poor vision, the panel also recommends development of a reliable system for the visually impaired.

Finally, the cost of blood glucose monitoring is a concern, particularly the cost of reagent strips. For example, if a patient is performing 4 tests/day, the cost would exceed $750/yr.

TO WHAT DEGREE ARE SMBG DEVICES ACCURATE AND PRECISE?

—The inherent accuracy (ability to obtain true values) and precision (ability to obtain reproducible results) of the SMBG devices are generally acceptable when evaluated under carefully controlled situations. In contrast, in actual patient-care situations the performance of these systems is not always adequate for making clinical decisions.

The following are factors affecting accuracy and precision.

User variability

The major source of variability in results obtained with SMBG devices is attributable to the user. In contrast to the satisfactory accuracy and precision of the systems under controlled laboratory conditions (coefficients of variation of 2–5%), up to 50% of the values may vary >20% from the reference values in general use. Some of these user variables are *1*) size and placement of the blood sample, *2*) timing of the test, and *3*) removal of blood from strip. Some systems are more dependent on user skills than others. In general, results obtained with instrument-read strips may be more accurate than those assessed visually. However, many patients develop satisfactory skills in reading strips. Patients whose vision is not adequate to distinguish the colors should not use strips requiring such assessment.

Hematocrit

With available systems, the values obtained for blood glucose may be markedly affected by anemia or polycythemia. Anemia falsely elevates and polycythemia falsely depresses SMBG values. The magnitude of this effect may vary 4–30% for every 10% change in hematocrit, depending on the system used.

Hypoglycemia and hyperglycemia

SMBG may be unreliable in the hypoglycemic or severe hyperglycemic ranges. Caution should be exercised in interpreting values in these ranges.

Instrument malfunction

Although potentially serious, instrument malfunction appears to be an infrequent problem.

Defective reagent strips

Use of reagent strips that are outdated or improperly stored may result in inaccurate results.

Because of these variables, the panel recommends the development and implementation of adequate quality-control programs. The panel further recommends the development of a system that requires the user to perform standard quality-control and calibration functions before accepting a sample. Also, systems should be developed to ensure accuracy in the hyperglycemic and hypoglycemic ranges that are not influenced by changes in hematocrit. The goal of all future SMBG systems should be to achieve a variability (system plus user) of <10% at glucose concentrations of 30–400 mg/dl 100% of the time. However, the panel is aware that the accuracy required for clinical management has not been rigorously defined. Further research should be undertaken in this area.

Although most of the marketed systems perform well, there are differences in performance. To make an informed choice, the panel suggests that users consult health-care professionals before selecting a system.

WHAT IS THE RELIABILITY OF THESE DEVICES?

—Blood glucose meters appear to be reliable. Users obtain acceptable customer service from the major manufacturers. According to one manufacturer, 60% of all inquiries are related to the function of the meter. Two-thirds of these problems can be solved via telephone, and most are related to user problems. These levels of reliability and customer service are commendable and are recommended for the entire industry. A desirable goal is that future instruments should be constructed so that after a malfunction they cannot be used without recalibration and verification that the system is operating correctly.

IS QUALITY CONTROL IN SMBG ADEQUATE?

—Quality control is required to evaluate the reliability of user-generated SMBG data. In general, quality-control practices are inadequate. Quality-control procedures should verify proper function of the meter, reagent strips, and user. The panel recommends that complete quality-control programs be implemented by all users and supported by manufacturers and health-care providers. The essential components of a quality-control program include *1*) cali-

bration checks to ensure that meter performance is adequate, 2) measurement of control solutions of known glucose concentration to evaluate the performance of reagent strips and meters, 3) comparison of results with a laboratory reference method, and 4) periodic review of user technique with correction of deficiencies by a qualified health-care professional.

The manufacturer's responsibilities include encouraging users to perform periodic quality-control procedures and providing control solutions of known glucose concentrations to verify monitor performance. With current systems, the frequency of calibration and the magnitude of permissible error may vary according to the goals of therapy, the purpose of SMBG, and the ability of the individual patient.

Quality-control solutions do not measure errors generated during collection and application of blood to the reagent strip. Therefore, the precision and accuracy of all facets of the SMBG technique should be evaluated at regular intervals by comparing the patient's SMBG results with a concurrently obtained measurement on the same blood sample by a reference method. The same blood sample should be used to avoid uncertainty introduced by differences among capillary, venous, whole blood, and plasma samples. In most instances this is readily accomplished at the time of follow-up visits with the health-care professional.

Quality control is essential for health-care professionals who use SMBG in either a hospital or outpatient setting. The panel endorses the position of the Joint Commission on Accreditation of Hospitals (JCAH) that SMBG by nonlaboratory personnel must meet the following minimum standards:

- Personnel performing the test must be qualified through training. Training must be documented.
- There should be written procedures and policies for test performance, quality control, standardization and calibration of instruments, and reagent acquisition and storage.
- Quality control must occur daily and be documented.
- A basic accession record to include patient name, test, and date should be maintained to correlate with documented quality control results.

With current systems, SMBG measurements should be within 15% of the results of the reference measurement. Individuals who do not consistently meet this criterion should undergo further training until this goal is met. Similar goals of quality control should be pursued if SMBG is to be used for patient management in another setting, such as camp, school, or nursing home.

The panel recommends that manufacturers develop simple, inexpensive and efficient methods for quality control.

ARE PATIENTS ADEQUATELY INSTRUCTED ON HOW TO USE THE DEVICE, AND IN WHAT MANNER IS THE INSTRUCTION GIVEN?

—The usefulness of SMBG depends on the accuracy of the results obtained. The accuracy of results depends on the use of proper technique, and the proper technique depends on the adequacy of training. Few data are available about the adequacy of the training of individuals to perform the test correctly. Training is offered in various settings, e.g., the hospital, clinic, pharmacy, and home.

Training is usually provided by health-care professionals, primarily nurses but also dietitians, pharmacists, manufacturer representatives, and physicians. In addition, many patients train themselves with manufacturer-provided training materials.

There are no standards for adequate training. However, the training procedure usually includes an explanation and demonstration of the proper procedure, a return demonstration by the learner, and a check of the learner's ability to accurately perform the testing procedure.

Approximately 50–70% of individuals who receive some sort of formal training are capable of obtaining a result within 20% of the reference method; however, performance may deteriorate over time. The most common reason for errors in SMBG is failure to follow instructions regarding proper application, timing, and removal of the blood sample.

The place of instruction is not a critical issue, but the quality of the instruction is critical. To be qualified, the trainer should 1) demonstrate adequate knowledge of the performance characteristics of the SMBG methods offered, 2) demonstrate accurate and precise blood glucose-testing technique with the system being used for training, and 3) participate in ongoing proficiency testing and monitoring programs.

The panel recommends that the following components be incorporated into training programs: 1) an assessment should be made by the health-care professional of the patient's abilities to properly use SMBG, 2) the person with diabetes should be trained by a qualified trainer, 3) trainers should assist the trainee in making the appropriate choice from the available systems, 4) the trainer should demonstrate proper procedures and techniques including visual interpretation whenever possible to verify meter results, 5) the trainee should demonstrate proficiency, 6) the trainee should practice until the procedure is correct, 7) the trainee should be instructed in the principles and importance of quality control, 8) the trainer should provide immediate assessment of the trainee's skills, 9) the trainer should provide periodic reassessment of the trainee's skills, 10) the trainee should be instructed with the system that will be used at home, and 11) documentation of the training outcome should be provided to the responsible physician.

HOW ARE THE DATA GENERATED BY SMBG USED IN PATIENT-CARE MANAGEMENT?—Blood glucose measurement is only one component of diabetes management and must be incorporated into the overall care plan of the person with diabetes mellitus. The SMBG component of the treatment plan should include a definition of blood glucose goals individualized for each patient, a schedule for blood glucose testing, a plan for data collection and use, and instructions for procedures to be followed during illness and emergencies (e.g., urine ketone determinations).

A recent American Diabetes Association survey indicates that many patients are not taught how to use SMBG data, and many health professionals do not review the data. The panel recommends that the proper uses of SMBG are:

- To develop a data base relating to the characteristics of the individual patient's blood glucose profile. This data base should be reviewed regularly by the health-care professional with the patient to evaluate and modify the overall treatment program.
- To allow the patient to make day-to-day decisions, based on immediately obtained data, regarding changes in various components of the treatment regimen (i.e., hypoglycemic medications, diet, and exercise), either alone (after an appropriate period of diabetes education) or in consultation with the health-care team. Patients can be taught to use algorithms for insulin, diet, and exercise to achieve the desired level of blood glucose control. The availability of these data to diabetic patients provides them with the opportunity of minimizing hyperglycemia and documenting and avoiding hypoglycemia.
- To recognize and respond to emergency situations, such as incipient diabetic ketoacidosis and hypoglycemia.
- As an educational or training tool to enhance understanding of diabetes by patients and their families.

The patient's report of blood glucose measurements must be viewed with caution in regard to accuracy. Accuracy may be compromised by errors in technique, equipment failure, or overt misrepresentation. The data obtained from self-monitoring of blood glucose should be evaluated in conjunction with other parameters of blood glucose control, such as glycosylated hemoglobin and periodic checks of blood glucose measurements with a reference laboratory method. Discrepancies between patient-generated blood glucose data and the results of the glycosylated hemoglobin test must be investigated.

The panel believes that further studies are needed to develop and evaluate programs to organize, display, and analyze patient-derived data.

HOW DOES SMBG INFLUENCE MEDICAL OUTCOME AND DAY-TO-DAY GLUCOSE CONTROL?—It has not yet been shown that attempts to achieve normoglycemia prevent or reverse chronic complications of diabetes. However, the prevailing opinion among health-care providers specializing in diabetes is that near normoglycemia may be a proper management goal. In pregnancy it is an essential goal. Without SMBG the goal of near normoglycemia is neither safe nor feasible in patients treated with insulin. Even with SMBG, extreme caution is necessary if this goal is to be pursued. Other treatment objectives that require SMBG include:

- Attempting to attain specific preset goals for blood glucose. To be effective, blood glucose goals must be reasonable and individualized.
- Providing for increased flexibility in the patient's lifestyle. SMBG can assist patients in minimizing the dangers of varying mealtimes, engaging in strenuous physical activity, and ascertaining the impact of changes in insulin dosage and/or the dietary program.
- Recognition and prevention of severe hypoglycemia.

SMBG is necessary (although not sufficient alone) to attain these treatment objectives.

SMBG may have other advantages. Many patients who use SMBG report considerable satisfaction from more active participation in their own treatment programs. Many also express a gratifying sense of enhanced control over their treatment, a feeling that has been conspicuously absent in previous treatment programs.

Regrettably, there is a paucity of evidence that SMBG has favorably impacted treatment outcomes, except in pregnancy. Carefully designed prospective studies are needed to investigate the impact of SMBG not only on blood glucose control but also on the quality of patient's lives and their sense of overall well-being.

HOW IS THIS BEDSIDE GLUCOSE MONITORING USED IN THE HOSPITAL SETTING, AND IS THIS USE APPROPRIATE?—During the last decade, the use of bedside blood glucose monitoring in hospitals has increased substantially. However, there has been serious concern regarding the accuracy and safety of bedside monitoring performed by nonlaboratory hospital personnel. The consensus of the panel is that the advantages of bedside monitoring can outweigh its potential hazards, as long as adequate measures are taken to ensure appropriate training and monitoring of all hospital personnel performing such testing. Appropriate applications of bedside monitoring include *1*) use as an education or training tool to enhance understanding of diabetes by patients and their families, 2) use in emergency rooms for the rapid evaluation of patients with suspected hypoglycemia or hyperglycemia, 3) assistance in determining appropriate insulin doses or infusion rates, 4) assessment of

the overall effectiveness of existing or new diabetes treatment regimens, 5) help in the diagnosis or prevention of symptomatic or asymptomatic hypoglycemia, 6) use in the perioperative management of surgical and obstetric diabetic patients, and 7) use in the management of patients given total parenteral nutrition or glucose infusions.

Hospital personnel performing bedside glucose monitoring must be trained in the use of this technique and must participate in rigorous quality-control programs. These programs should include criteria for establishing 1) the qualification of users, 2) standardized procedures for the calibration and maintenance of equipment, and 3) periodic verification of the competency of individual operators by comparing their results with those obtained by the hospital laboratory. These programs should be developed and implemented jointly by clinicians, nurses, and clinical laboratory personnel. In nursing services where bedside glucose monitoring is infrequent, it may be necessary for all glucose tests to be performed by laboratory personnel.

In any instance where the result of a bedside glucose measurement may make a critical difference in the management of a patient with a life-threatening illness, the result must be confirmed by a hospital laboratory glucose determination. Also, caution should be exercised in the interpretation of bedside monitoring results in patients with severe anemia or polycythemia.

CONCLUSIONS—Self-monitoring of blood glucose has proved to be an exciting addition to our armamentarium to ensure effective management of patients with diabetes. Notwithstanding the problems identified with implementation of this technique, we now have the capacity to rapidly obtain vital clinical information. Major problems needing resolution are to ensure quality control and to be certain that the data from SMBG are accurate and precise. We anticipate that with advances in technology, the implementation of quality-control programs, and the enhanced capacity for data analysis, remarkable progress will be made toward improving the care of diabetic patients in the future.

We make the following recommendations:

1. SMBG is recommended for insulin-treated diabetic patients.
2. No change should be made in the ready availability of SMBG systems from multiple sources.
3. Blood glucose monitors that are easier to use and less dependent on user skill should be developed.
4. A reliable glucose monitoring system for the visually impaired should be developed.
5. Complete quality-control programs should be implemented by all users and supported by manufacturers and health-care providers.
6. A glucose monitoring system should be developed that requires the user to complete quality control and calibration functions before accepting a sample.
7. Systems should be developed to ensure accuracy of SMBG in the hyperglycemic and hypoglycemic ranges and should not be influenced by changes in hematocrit.
8. The components of training as listed in the response to question 6 should be incorporated into training programs.
9. The proper uses of SMBG are 1) to develop a longitudinal data base related to the patient's blood glucose profile; 2) as an aid in making day-to-day decisions, based on immediately obtained data, regarding various components of the treatment regimen; 3) as an aid in the recognition and response to emergency situations; and 4) as an educational and training tool to enhance understanding of diabetes by patients and their families.

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