EXECUTIVE SUMMARY

The following guidelines provide recommendations based on the best available evidence derived from published data or expert consensus.

1. Glucose

A. Accredited laboratory

Glucose should be measured in an accredited laboratory to establish the diagnosis of diabetes and to screen high-risk individuals. Analysis in an accredited laboratory is not recommended as the primary means for routine monitoring or evaluating therapy in individuals with diabetes. Blood should be drawn after the subject has fasted overnight. If plasma cannot be separated from the cells within 60 min, a tube containing a glycolytic inhibitor should be used. Glucose should be measured in plasma.

Although methods for glucose analysis exhibit low imprecision at the diagnostic decision limits of 7.0 mmol/L [(126 mg/dL), fasting] and 11.1 mmol/L [(200 mg/dL), post glucose load], the relatively large intraindividual biological variability (CVs of ~5-7%) may result in classification errors. Based on biological variation, glucose analysis should have analytical imprecision ≤ 3.3%, bias ≤ 2.5% and total error ≤ 7.9%.

B. Portable meters

Portable meters are used by health care workers in acute and chronic care facilities, in physicians' offices and by patients. Due to the imprecision and variability among meters, they should not be used to diagnose diabetes and have limited value in screening.

Self-monitoring of blood glucose (SMBG) is recommended for all insulin-treated patients. It should be performed at least three times a day for patients with type 1 diabetes. The efficacy of SMBG in patients with type 2 diabetes has not been established.

Multiple performance goals for portable glucose meters have been proposed. These targets vary widely and lack consensus. Clinical studies are needed to determine these analytical goals. We recommend meters that measure and report plasma glucose concentrations.

C. Oral glucose tolerance test (OGTT)

We do not recommend the OGTT for the routine diagnosis of type 1 or 2 diabetes. This issue is controversial and the World Health Organization supports its use. The key limitation of the OGTT is its poor reproducibility. Proponents, however, argue that it has slightly higher sensitivity than fasting glucose for diagnosing diabetes.

D. Non- or minimally-invasive glucose analyses

Non-invasive glucose analyses cannot be recommended at present as replacements for SMBG or glucose measurements by an accredited laboratory. Although promising, clinical studies remain limited. Several methodologies are available, but no analytical performance goals have been established.

2. Ketones

Ketones should be measured in urine or blood by patients with diabetes at home and in hospitals or clinics as an adjunct to the diagnosis of diabetic ketoacidosis (DKA). Methods based on the nitroprusside reaction should not be used to monitor treatment of DKA. Although specific measurement of b-hydroxybutyrate is available, further studies are needed to ascertain whether this offers clinical advantage.

3. Glycated hemoglobin (GHb)

GHb should be measured at least biannually in all patients with diabetes to document their glycemic control. Treatment goals should be based on the results of prospective randomized clinical trials (such as the Diabetes Control and Complications Trial, DCCT) that documented the relationship between glycemic control (quantified by GHb analysis) and the risks for the development and progression of chronic complications of diabetes.

US laboratories should use GHb assays certified by the National Glycohemoglobin Standardization Program (NGSP) as traceable to the DCCT reference. GHb concentrations should be maintained <7% and the treatment regimen should be reevaluated if GHb >8% as measured by NGSP-certified methods. Laboratories should participate in proficiency testing. Efforts to achieve global harmonization of GHb testing, an important goal, are underway.

4. Genetic markers

Routine measurement of genetic markers is not recommended at this time for the diagnosis or management of patients with diabetes.

5. Autoimmune markers

Several autoantibodies have been detected in individuals with type 1 diabetes. However, these lack specificity and are not recommended for routine diagnosis or screening of diabetes. Until type 1 diabetes can be prevented, islet cell autoantibody measurement should be essentially confined to research protocols.

6. Microalbuminuria

Diabetes is the leading cause of end-stage renal disease. Annual microalbuminuria testing should be performed in patients without clinical proteinuria. To be useful, semi-quantitative or qualitative screening tests must be shown to be positive in >95% of patients with microalbuminuria. Positive results of such tests must be confirmed by quantitative testing in an accredited laboratory.

7. Miscellaneous potentially important analytes

Several other analytes are measured in patients with diabetes. All adults with diabetes should receive annual lipid profiles. There is no role for routine testing for insulin, C-peptide or proinsulin in most patients with diabetes. These assays are useful primarily for research purposes. Similarly, measurement of amylin or leptin is not of value at this time in the management of patients with diabetes.