INTRODUCTION

Diabetes mellitus is a group of metabolic disorders of carbohydrate metabolism in which glucose is underutilized, producing hyperglycemia. The disease is classified into several categories. The revised classification, published in 1997 (1) is indicated in Table 1.

Table 1: Classification of Diabetes Mellitus*

I. Type 1 diabetes

- A. Immune mediated
- B. Idiopathic

II. Type 2 diabetes

III. Other specific types

- A. Genetic defects of b-cell function
- B. Genetic defects in insulin action
- C. Diseases of the exocrine pancreas
- D. Endocrinopathies
- E. Drug- or chemical-induced
- F. Infections
- G. Uncommon forms of immune-mediated diabetes
- H. Other genetic syndromes sometimes associated with diabetes

IV. Gestational diabetes mellitus

*From ADA (1)

Type 1 diabetes mellitus, formerly known as insulin-dependent diabetes mellitus (IDDM) or juvenile onset diabetes mellitus, is caused by autoimmune destruction of the b-cells of the pancreas, rendering the pancreas unable to synthesize and secrete insulin (2). Type 2 diabetes mellitus, formerly known as non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes, results from a combination of insulin resistance and inadequate insulin secretion (3, 4). Other types of diabetes are rare. Type 2 is the most common form, accounting for 90-95% of diabetes in developed countries.

In 1992 the costs of diabetes in the U.S. were estimated to be $98 billion (5). The mean annual per capita health care costs for an individual with diabetes are approximately 4-fold higher than those for individuals who do not have diabetes (5). Similarly, in the UK diabetes accounts for roughly 10% of the National Health Service budget (£49 billion).

The high costs of diabetes are attributable to care for both acute conditions (such as hypoglycemia and ketoacidosis) and debilitating complications (6). The latter include both microvascular complications – predominantly retinopathy, nephropathy and neuropathy – and macrovascular complications, particularly stroke and coronary artery disease. Together these result in diabetes being the seventh most common cause of death in the developed world (7).

The American Diabetes Association (ADA) publishes in January each year a supplement, titled Clinical Practice Recommendations, to Diabetes Care. This is a compilation of all ADA position statements related to clinical practice and is an important resource for health care professionals who care for people with diabetes. The National Academy of Clinical Biochemistry has developed evidence-based guidelines for the practice of laboratory medicine. The guidelines in this document are based on the best available published evidence. An assessment was made of virtually all analytes used in the diagnosis and management of individuals with diabetes. The resulting guidelines, intended for use

by laboratorians and providers of patient care, have been reviewed by the ADA Professional Practice Committee and found to be consistent in those areas where the ADA has also published Clinical Practice Recommendations. The guidelines in this document are not intended to supplant the ADA Recommendations. The objective is to supplement the ADA Recommendations, with an emphasis on the laboratory aspects of diabetes.

The ADA has developed a system to grade the quality of scientific evidence (Table 2). This scheme has been used in this paper to describe the quality of the evidence on which each recommendation is based. The ratings range from A to C, with A exhibiting the highest quality of evidence. Category E, expert opinion, is used for recommendations for which no evidence from clinical trials is available or where conflicting evidence has been published.

Table 2: ADA Evidence Grading System for Clinical Practice Recommendations

Level of evidence	Description
A	Clear evidence from well conducted, generalizable, randomized controlled trials that are adequately powered including: Evidence from a well-conducted multicenter trial Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling non-experimental evidence, i.e., "all or none" rule developed by Center for Evidence Based Medicine at Oxford*
	Supportive evidence from well-conducted randomized controlled trials that are adequately powered including: Evidence from a well-conducted trial at one or more institutions Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies Evidence from a well-conducted prospective cohort study or registry Evidence from a well-conducted prospective cohort study Evidence from a well-conducted meta-analysis of cohort studies
	Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls) Evidence from case series or case reports
	Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

*Either all patients died prior to therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

To facilitate comprehension and assist the reader, each analyte is divided into several headings and subheadings (listed in parentheses). These are use (diagnosis, screening, monitoring and prognosis), rationale (diagnosis and screening), analytical considerations [preanalytical (including reference values) and analytical (such as methods)], interpretation (including frequency of measurement and turnaround time) and, where applicable, emerging considerations, which alert the reader to ongoing studies and potential future aspects relevant to that analyte.