

Table 2. Rating scale for the quality of the evidence.

High: Further research is very unlikely to change our confidence in the estimate of effect. The body of evidence comes from high-level individual studies which are sufficiently powered; provide precise, consistent, and directly applicable results in a relevant population. Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate and the recommendation. The body of evidence comes from high/moderate-level individual studies which are sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the included studies; generalizability of results to routine practice; or indirect nature of the evidence. Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate and the recommendation. The body of evidence is of low level and comes from studies with serious design flaws, or evidence is indirect. Very low: Any estimate of effect is very uncertain. Recommendation may change when higher quality evidence becomes available. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.
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manufacturers. Although recommendations were developed for national and international use and are intended to be generic, certain recommendations may not reflect views that are universally held or may have limited applicability in healthcare settings with differing organizational, cultural, and economic backgrounds. The guideline committee therefore advises users to adapt recommendations to local settings.

To facilitate comprehension and assist the reader, each analyte is divided into several headings and, where pertinent, subheadings (listed in parentheses). These are description/introduction/terminology, use and rationale (diagnosis, screening, monitoring, and prognosis), preanalytical (including sample types, frequency of measurement), analytical considerations (including methods), interpretation (including reference intervals, decision limits, therapeutic targets, and turnaround time) and, where applicable, emerging considerations, which alert the reader to ongoing studies and potential future aspects relevant to that analyte.

Glucose

DESCRIPTION/INTRODUCTION/TERMINOLOGY

The disordered carbohydrate metabolism that underlies diabetes manifests as hyperglycemia. Therefore, measurement of blood glucose was for many years the sole diagnostic criterion. This strategy is indirect as hyperglycemia reflects the consequence of the metabolic derangement, not the cause. Nevertheless, until the underlying molecular pathophysiology of the disease is identified, measurement of glycemia is likely to remain an essential diagnostic modality.

USE/RATIONALE

Diagnosis.

Recommendation: *Fasting glucose should be measured in venous plasma when used to establish the diagnosis of diabetes, with a value ≥ 7.0 mmol/L (≥ 126 mg/dL) diagnostic of diabetes. A (high)*

The diagnosis of diabetes is established by identifying the presence of hyperglycemia. For many years the only method recommended for diagnosis was a direct demonstration of hyperglycemia by measuring increased glucose concentrations in the plasma (16, 17). In 1979, a set of criteria based on the distribution of glucose concentrations in high-risk populations was established to standardize the diagnosis (16). These recommendations were endorsed by the World Health Organization (WHO) (17). In 1997, the diagnostic criteria were modified (18) to better identify subjects at risk of retinopathy and nephropathy (19, 20). The revised criteria comprised: (a) fasting plasma glucose (FPG) ≥ 7.0 mmol/L (126 mg/dL), (b) 2-h post load glucose >11.1 mmol/L (200 mg/dL) during an oral glucose tolerance test (OGTT), or (c) symptoms of diabetes and a casual (i.e., regardless of the time of the preceding meal) plasma glucose ≥ 11.1 mmol/L (200 mg/dL) (Table 4) (18). The WHO and International Diabetes Federation (IDF) recommend either FPG or 2-h post load glucose using the same cutoffs as the ADA (21) (Table 5). In 2009 an International Expert Committee (22), with members appointed by the ADA, European Association for the Study of Diabetes (EASD) and IDF, recommended that diabetes could also be diagnosed by measurement of