

Diagnostic Criteria for Diabetes Mellitus and Prediabetes

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Abstract :

Recent estimates indicate there were 171 million people in the world with diabetes in the year 2000 and this is projected to increase to 366 million by 2030 Diabetes is a condition primarily defined by the level of hyperglycaemia giving rise to risk of microvascular damage (retinopathy, nephropathy and neuropathy). It is associated with reduced life expectancy, significant morbidity due to specific diabetes related microvascular complications, increased risk of macrovascular complications (ischaemic heart disease, stroke and peripheral vascular disease), and diminished quality of life. The American Diabetes Association (ADA) estimated the national costs of diabetes in the USA for 2002 to be \$US 132 billion, increasing to \$US 192 billion in 2020.

Since 1965 the World Health Organization (WHO) has published guidelines for the diagnosis and classification of diabetes. These were last reviewed in 1998 and were published as the guidelines for the Definition, Diagnosis and Classification of Diabetes Mellitus³. Since then more information relevant to the diagnosis of diabetes has become available. In addition, in 2003, the ADA reviewed its diagnostic criteria⁴. While the criteria for the diagnosis of diabetes and Impaired Glucose Tolerance (IGT) remained unchanged, the ADA recommended lowering the threshold for Impaired Fasting Glucose (IFG) from 6.1mmol/l (110mg/dl) to 5.6mmol/l (100mg/dl)⁴. In view of these developments WHO and the International Diabetes Federation (IDF) decided that it was timely to review its existing guidelines for the definition and diagnosis of diabetes and intermediate hyperglycaemia.

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Key Words :

2hPG , 2-hour plasma glucose; A1C , glycated hemoglobin; FPG , fasting plasma glucose; IFG , impaired fasting glucose; IGT , impaired glucose tolerance; OGTT , oral glucose tolerance test; PG , plasma glucose.

Diabetes and Prediabetes

Diabetes mellitus is a metabolic disorder characterized by the presence of hyperglycemia due to defective insulin secretion, defective insulin action or both. The chronic hyperglycemia of diabetes is associated with relatively specific long-term microvascular complications affecting the eyes, kidneys and nerves, as well as an increased risk for cardiovascular disease (CVD). The diagnostic criteria for diabetes are based on thresholds of glycemia that are associated with microvascular disease, especially retinopathy.



“Prediabetes” is a practical and convenient term referring to impaired fasting glucose (IFG), impaired glucose tolerance (IGT) or a glycated hemoglobin (A1C) of 6.0% to 6.4%, each of which places individuals at high risk of developing diabetes and its complications.

Classification of Diabetes

The classification of type 1 diabetes, type 2 diabetes and gestational diabetes mellitus (GDM) is summarized in addresses the etiologic classification of diabetes. Distinguishing between type 1 and type 2 diabetes is important because management strategies differ, but it may be difficult at the time of diagnosis in certain situations. Physical signs of insulin resistance and autoimmune markers, such as anti-glutamic acid decarboxylase (GAD) or anti-islet cell antibody (ICA) antibodies, may be helpful, but have not been adequately studied as diagnostic tests in this setting. While very low C-peptide levels measured after months of clinical stabilization may favour type 1 diabetes, they are not helpful in acute hyperglycemia. Clinical judgement with safe management and ongoing follow-up is a prudent approach.

Types of tests :

1. Random plasma glucose test : A blood sample for a random plasma glucose test can be taken at any time. This doesn't require as much planning and is therefore used in the diagnosis of type 1 diabetes when time is of the essence.
2. Fasting plasma glucose test : A fasting plasma glucose test is taken after at least eight hours of fasting and is therefore usually taken in the morning.
3. Oral Glucose Tolerance Test (OGTT) : An oral glucose tolerance test involves taking a first taking a fasting sample of blood and then taking a very sweet drink containing 75g of glucose. After having this drink you need to stay at rest until a further blood sample is taken after 2 hours.
4. HbA1c test for diabetes diagnosis: An HbA1c test does not directly measure the level of blood glucose, however, the result of the test is influenced by how high or low your blood glucose levels have tended to be over a period of 2 to 3 months.

Indications of diabetes or prediabetes are given under the following conditions:

Normal: Below 42 mmol/mol (6.0%)

Prediabetes: 42 to 47 mmol/mol (6.0 to 6.4%)

Diabetes: 48 mmol/mol (6.5% or over)

Diagnostic Criteria of Diabetes

The diagnostic criteria for diabetes are summarized in Table 1 These criteria are based on venous samples and laboratory methods.



A fasting plasma glucose (FPG) level of 7.0 mmol/L correlates most closely with a 2-hour plasma glucose (2hPG) value of ≥ 11.1 mmol/L in a 75 g oral glucose tolerance test (OGTT), and each predicts the development of retinopathy.

The relationship between A1C and retinopathy is similar to that of FPG or 2hPG with a threshold at around 6.5%. Although the diagnosis of diabetes is based on an A1C threshold for developing microvascular disease, A1C is also a continuous cardiovascular (CV) risk factor and a better predictor of macro-vascular events than FPG or 2hPG. Although many people identified by A1C as having diabetes will not have diabetes by traditional glucose criteria and vice versa, there are several advantages to using A1C for diabetes diagnosis. A1C can be measured at any time of day and is more convenient than FPG or 2hPG in a 75 g OGTT. A1C testing also avoids the problem of day-to-day variability of glucose values as it reflects the average plasma glucose (PG) over the previous 2 to 3 months.

Diagnostic Criteria of Diabetes (Table 1)

1.	FPG ≥ 7.0 mmol/L	Fasting = no caloric intake for at least 8 hours
2.	A1C $\geq 6.5\%$ (in adults)	Using a standardized, validated assay in the absence of factors that affect the accuracy of the A1C and not for suspected type 1 diabetes
3.	2hPG in a 75 g OGTT ≥ 11.1 mmol/L or Random PG ≥ 11.1 mmol/L	Random = any time of the day, without regard to the interval since the last meal

Advantages and disadvantages of diagnostic tests for diabetes (Table 2)

Parameter	Advantage	Disadvantage
FPG	<ul style="list-style-type: none"> Established standard Fast and easy Single sample Predicts microvascular complications 	<ul style="list-style-type: none"> Sample not stable High day-to-day variability >Inconvenient (fasting) Reflects glucose homeostasis at a single point in time
2hPG in a 75 g OGTT	<ul style="list-style-type: none"> Established standard Predicts microvascular complications 	<ul style="list-style-type: none"> Sample not stable High day-to-day variability Inconvenient Unpalatable Cost
A1C	<ul style="list-style-type: none"> Convenient (measure any time of day) Single sample Predicts microvascular complications 	<ul style="list-style-type: none"> Cost Misleading in various medical conditions (e.g. hemoglobinopathies, iron deficiency, hemolytic)



	<ul style="list-style-type: none"> • Better predictor of macrovascular disease than FPG or 2hPG in a 75 g OGTT • Low day-to-day variability • Reflects long-ter 	<p>anaemia, severe hepatic or renal disease)</p> <ul style="list-style-type: none"> • Altered by ethnicity and aging • Standardized, validated assay required • Not for diagnostic use in children, adolescents, pregnant women or those with suspected type 1 diabetes
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Prediabetes : The term “prediabetes” refers to IFG, IGT or an A1C of 6.0% to 6.4% Table 3, each of which places individuals at high risk of developing diabetes and its complications. Not all individuals with prediabetes will necessarily progress to diabetes. Indeed, a significant proportion of people who are diagnosed with IFG or IGT will revert to normoglycemia. People with prediabetes, particularly in the context of the metabolic syndrome, would benefit from CV risk factor modification.

While people with prediabetes do not have the increased risk for microvascular disease as seen in diabetes, they are at risk for the development of diabetes and CVD . IGT is more strongly associated with CVD outcomes than is IFG. Individuals identified as having both IFG and IGT are at higher risk for diabetes as well as CVD. While there is no worldwide consensus on the definition of IFG . the Canadian Diabetes Association defines IFG as an FPG value of 6.1 to 6.9 mmol/L due to the higher risk of developing diabetes in these individuals compared to defining IFG as an FPG value of 5.6 to 6.9 mmol/L

Table 3 (Prediabetes)

2hPG, 2-hour plasma glucose; A1C, glycated hemoglobin; FPG, fasting plasma glucose; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; OGTT, oral glucose tolerance test.		
Test	Result	Prediabetes category
FPG (mmol/L)	6.1–6.9	IFG
2hPG in a 75 g OGTT (mmol/L)	7.8–11.0	IGT
A1C (%)	6.0–6.4	Prediabetes

Recommendations for diagnosis of diabetes and prediabetes .:

Diabetes should be diagnosed by any of the following criteria:

FPG \geq 7.0 mmol/L

A1C \geq 6.5% (for use in adults in the absence of factors that affect the accuracy of A1C and not for use in those with suspected type 1 diabetes)

2hPG in a 75 g OGTT \geq 11.1 mmol/L



Random PG ≥ 11.1 mmol/L [Grade D, Consensus]

In the absence of symptomatic hyperglycemia, if a single laboratory test result is in the diabetes range, a repeat confirmatory laboratory test (FPG, A1C, 2hPG in a 75 g OGTT) must be done on another day. It is preferable that the same test be repeated (in a timely fashion) for confirmation, but a random PG in the diabetes range in an asymptomatic individual should be confirmed with an alternate test. In the case of symptomatic hyperglycemia, the diagnosis has been made and a confirmatory test is not required before treatment is initiated. In individuals in whom type 1 diabetes is likely (younger or lean or symptomatic hyperglycemia, especially with ketonuria or ketonemia), confirmatory testing should not delay initiation of treatment to avoid rapid deterioration. If results of two different tests are available and both are above the diagnostic cutpoints, the diagnosis of diabetes is confirmed [Grade D, Consensus].

Prediabetes (defined as a state which places individuals at high risk of developing diabetes and its complications) is diagnosed by any of the following criteria:

IFG (FPG 6.1–6.9 mmol/L).

IGT (2hPG in a 75 g OGTT 7.8–11.0 mmol/L).

A1C 6.0%–6.4% (for use in adults in the absence of factors that affect the accuracy of A1C and not for use in suspected type 1 diabetes).

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