

Diabetes Diagnostic Criteria and Impaired Glycemic States: Evolving Evidence Base

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In 1979 and 1980, two groups, the National Diabetes Data Group in the United States and the World Health Organization (WHO), published reports addressing diabetes diagnostic criteria.^{1,2} The two groups reached the same conclusions, and the criteria were eventually adopted throughout the world (Table 1). Before that time, criteria were variable and established by research groups and clinicians using their individual clinical experiences and limited data.

By the late 1970s, research on the natural history of diabetes had accumulated such that the criteria put forth by these two reports considered the entire world's literature and were evidence-based. Impaired glucose tolerance (IGT) was also established and defined as a 2-hour 75-g oral glucose tolerance test (OGTT) result of 140–199 mg/dl. IGT is an abnormal metabolic state that falls short of diabetes but is associated with an elevated risk of developing diabetes. These criteria provided a means to uniformly track secular trends of diabetes as the epidemic was unfolding

and to make valid comparisons across research studies. Both groups acknowledged that, as diabetes research progressed, future assessments of the performance of these criteria would be important.

Subsequently, in 1997 and 1999, two new reports on diabetes diagnostic criteria were published. The first was sponsored by the American Diabetes Association (ADA) and was the report of its Expert Committee on the Diagnosis and Classification of Diabetes Mellitus.³ The second was from WHO.⁴ Comprehensive reviews of the world's research findings by each group led to a lowering of the fasting glucose diagnostic criteria from ≥ 140 mg/dl to ≥ 126 mg/dl (Table 1). The 2-hour criterion (≥ 200 mg/dl) was unchanged. In addition, a new category, impaired fasting glucose (IFG), was established and defined as 110–125 mg/dl. IFG, a metabolic state akin to IGT, is considered abnormal but not yet diagnostic of diabetes. The only major difference between the two reports was that the ADA-sponsored report favored using fasting glu-

cose as the preferred test for diagnosis, whereas the WHO-sponsored report noted that some cases detected by 2-hour glucose levels were not detected by fasting measurements. It did not identify a preference for fasting glucose measurement for diagnosis.

In 2003, the Expert Committee published a follow-up report in which it carefully considered new data since its 1997 report.⁵ This follow-up report, reprinted in this issue of *Clinical Diabetes* on page 71, retained the previous fasting and 2-hour diagnostic criteria and the IGT criteria. However, the committee changed the IFG criteria to 100–125 mg/dl, lowering the previous lower threshold of 110 mg/dl (Table 1). The evidence that supported this change came from four large U.S. and international population-based observational studies finding that IFG defined as 100–125 mg/dl predicted future diabetes (by either fasting or 2-hour criteria) better than IFG defined as 110–125 mg/dl. This change in IFG criteria has been estimated to increase the proportion of the population affected by two- to five-

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Table 1. Summary of Diagnostic Criteria for Diabetes and Impaired Glycemic States

Criteria	Year of Reports		
	1979 and 1980	1997 and 1999	2003
Fasting plasma glucose			
Diabetes	≥ 140 mg/dl	≥ 126 mg/dl	≥ 126 mg/dl
IFG	**	110–125 mg/dl	100–125 mg/dl
2-hour plasma glucose *			
Diabetes	≥ 200 mg/dl	≥ 200 mg/dl	≥ 200 mg/dl
IFG	140–199 mg/dl	140–199 mg/dl	140–199 mg/dl
*2-hour 75-g OGTT			
**Not considered			

fold, depending on demographic subgroup.⁶

Concerns regarding the new IFG criteria include:

- There is scant evidence that interventions among this group are effective in preventing diabetes, whereas the recently completed prevention trials were effective in people with IGT.
- We currently lack a strong association of IFG glucose levels with cardiovascular events, whereas IGT is associated with cardiovascular events.
- “Labeling” individuals using the new criteria may result in their having difficulty securing employment or obtaining life insurance or health care insurance.⁶

Other notable conclusions from the follow-up report include that the hemoglobin A1C test should not be used as a criterion for the diagnosis of diabetes and is best used to monitor the effectiveness of glycemic therapy.

Diagnostic and impaired glycemia criteria are major assets for addressing today’s diabetes pandemic. These evidence-based criteria are evolving as newly available data are carefully exam-

ined. Recommendations to modify the IFG criteria dramatically increase the number of people defined as having this metabolic state. Because these criteria do have major implications for individuals, providers, health care systems, and society, we will need to carefully consider the implications of any changes. Revisiting these criteria as we further our understanding of diabetes will be essential.

The presence of diabetes in a patient requires the addition of efforts to address glycemic control, to screen for diabetes-related complications, and to intensify cardiovascular risk reduction. Detecting IGT or IFG in the clinic leads to considering efforts to prevent their progression to diabetes.⁷ Thus, it is important for primary care practitioners to be vigilant and familiar with the diagnostic and impaired status criteria.

REFERENCES

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