



## Diagnosis and Classification of Diabetes Mellitus

### 1. Who developed the new guidelines for the diagnosis and classification of diabetes, and what was CDC's role?

An international Expert Committee on the Diagnosis and Classification of Diabetes Mellitus working under the sponsorship of the American Diabetes Association (ADA) developed the new guidelines. The committee published its report in *Diabetes Care* 1997; 20(7):1183-97, which was updated in [Diabetes Care 2004;27:S5-S10](#).

The committee had 17 members including clinicians and researchers from academia, the private sector, the National Institutes of Health (NIH), and the ADA. Open collaboration in the World Health Organization (WHO) occurred.

No Centers for Disease Control and Prevention (CDC) experts were on the committee, but they were consulted during the process. They reviewed and commented on preliminary drafts of the report, and provided some epidemiologic data to the committee. Among other sources of information, CDC's data were used to study the diagnostic criteria.

### 2. What are the major recommendations in the report for the diagnosis and classification of diabetes?

The major recommendations in the report include the following:

For classification

- Eliminate using the confusing terms insulin-dependent diabetes mellitus (IDDM) and non-insulin-dependent diabetes mellitus (NIDDM).
- Replace IDDM or juvenile-onset diabetes with "type 1 diabetes" to describe diabetes characterized primarily by an absolute deficiency of insulin.
- Replace NIDDM or adult-onset diabetes with "type 2 diabetes" to describe diabetes characterized primarily by insulin resistance (that is, insulin ineffective in target tissue) and inadequate compensatory insulin secretory response.
- Use a category called "other specific types" in cases where specific genetic defects, surgery, drugs, or other things, have caused hyperglycemia.
- The committee retained the term gestational diabetes mellitus (GDM) as a fourth category to describe diabetes that develops during pregnancy.
- Impaired glucose tolerance or IGT (2-hour post-meal glucose between 140 and 199 milligrams/deciliter or mg/dl) and impaired fasting glucose (IFG) between 110 mg/dl and 125 mg/dl) are now risk categories for diabetes mellitus.



#### 4. What scientific research supports these recommendations?

##### For classification

- In proposing the new classification system, the committee considered the data and rationale for the current classification system that was adopted in 1979, along with research findings of the last 18 years. The present classification is based on etiologic pathophysiology, rather than on treatments used.

##### For diagnosis

- Data from several population-based studies were used as the basis of the recommendations for the new fasting diagnostic values; studies included the U.S. National Health and Nutritional Examination Survey III (NHANES III), the Pima Indians, and data from surveillance investigations in Egypt.

##### For testing

- As mentioned previously, limited data support testing people aged 45 years and older every 3 years. However, the committee members concurred that this approach was logical and reasonable on the basis of the Diabetes Control and Complications Trial (DCCT), the pilot phase of the Veterans Administration study on type 2 diabetes, the United Kingdom Prospective Diabetes Study, and Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) data.

#### 5. What is the rationale for screening people aged 45 years and over every 3 years?

The committee cited the following reasons:

- the steep rise in the incidence of diabetes after age 45
- the negligible likelihood of developing significant and serious complications from diabetes within 3 years of an initial negative test, for example, if diabetes developed the "day after" the initial negative tests, but before retesting in 3 years.

At present, CDC does not recommend broad-based, population screening programs.

#### 6. What are the public health implications and challenges?

Data from the NHANES III survey (a U.S. population-based survey) were used to develop the new diagnostic criteria (that is, using the new fasting measurement alone with no OGTT). These criteria lower the estimated total (diagnosed and undiagnosed) diabetes prevalence in people 40 to 74 years of age to 12.3%, compared with 14.3% found by applying the WHO's current diagnostic criteria, which uses both a fasting value of 140 mg/dl and the OGTT measurement. The impact of the new FPG criteria on total prevalence will vary by clinic and state.

However, the new fasting diagnostic criteria will help find asymptomatic people with undiagnosed diabetes because of the utility and ease of obtaining fasting measurements compared with the difficulty of using OGTTs. The number of people who shift from undiagnosed to diagnosed diabetes may potentially increase the total by 2 million; that is, from 8 million to 10 million people diagnosed with diabetes. Thus, the new criteria should begin to address the "missing 8 million."



Public health challenges include addressing issues for newly diagnosed people, and issues for the health care system. Patient anxiety, personal economic impact, insurability, and employability will need attention. However, these concerns possibly will be overshadowed by the benefit to the individual in terms of the potential of a healthier life and of living fewer years with disabling diabetic complications.

Issues for the health care system include the following concerns:

- possible provider work overload with the number of newly identified cases
- that this opportunity is used to make sure that newly diagnosed people with diabetes get appropriate treatment to prevent microvascular and macrovascular complications.

Ensuring that evidence-based, cost-effective interventions are used to maximize the nation's investment value is critical.

## **7. What are the economic implications?**

The use of the new fasting criteria will identify a higher proportion of those with diabetes who are currently undiagnosed. As noted, about 2 million people with diabetes may be diagnosed. This may initially result in an increase in diabetes expenditures. However, over a lifetime, the cost may decrease to care for people with diabetes diagnosed using the new criteria, because disease will be diagnosed at an earlier stage and complications may be easier to prevent.

No scientific study, to date, has been carried out to support or refute these conjectures. However, CDC is presently engaged in a cost-effectiveness analysis of more active screening programs.

## **8. What impact will these recommendations have on CDC's state diabetes control programs?**

The new recommendations will probably result in people with early, undiagnosed diabetes being found more frequently. Most of these new cases will have few diabetic complications, if any. Identifying cases earlier provides an opportunity and greater "potential" to prevent microvascular and macrovascular complications. State diabetes control programs will need to emphasize using the fasting criteria to diagnose cases to aggressively prevent complications in newly diagnosed people, along with those with diabetes of longer duration.

## **9. What impact will these recommendations have on the National Diabetes Education Program?**

These issues may require that National Diabetes Education Program representatives develop initiatives that focus on adopting, communicating, and implementing the new recommendations, which include the classification system, the diagnostic criteria, and the testing algorithm. Emphasizing quality care of patients with newly diagnosed diabetes and considering the role of diet and physical activity as an aggressive initial treatment option will also be important.



## 10. What CDC activities will further understanding of the committee's recommendations?

Currently, most of CDC's focus is on important public health research issues. Activities include the following:

- CDC's Division of Diabetes Translation (DDT) dedicated a Translation Advisory Committee meeting to reviewing the public health issues related to screening and early detection of diabetes. Participants explored in detail public health screening issues related to research, programs, and policies. This effort has been supportive of CDC's current research agenda.
- CDC will perform an epidemiologic study to examine the effect that screening and early detection have on development and progression of diabetic complications. This critical question has not been studied directly.
- CDC will conduct studies to characterize the performance of various screening tests to detect undiagnosed diabetes. This information is critical for cost-effectiveness studies.
- CDC will collaborate with state diabetes control programs to develop and characterize the performance of various population-based diabetes screening strategies.
- CDC will use statistical models to conduct cost-effectiveness studies of screening for undiagnosed diabetes and the benefit it may have compared to typical clinical diagnosis.

The findings of this research agenda should enhance CDC's ability to support an effective, efficient, and appropriate public health response to the impact of diabetes in the United States.