Projected Impact of Implementing the Results of the Diabetes Prevention Program in the U.S. Population

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OBJECTIVE — To determine the feasibility of using either fasting plasma glucose or HbA_{1c} to identify individuals in the U.S. population who meet the Diabetes Prevention Program (DPP) criteria for intervention, defined as BMI ≥24 kg/m^2, fasting plasma glucose level 96–125 mg/dl, and 2-h glucose level 140–199 mg/dl in an oral glucose tolerance test (OGTT).

RESEARCH DESIGN AND METHODS — Analysis of a representative sample of U.S. adults aged 40–74 years with no medical history of diabetes for whom data on height, weight, fasting plasma glucose, HbA_{1c}, and 2-h plasma glucose during an OGTT were obtained. Sensitivity, specificity, positive predictive value (PPV), and receiver operator characteristic (ROC) curves for fasting glucose and HbA_{1c} were determined.

RESULTS — Using BMI <24 kg/m^2 as an initial criterion eliminated 27.2% of U.S. adults from further testing. Of the remaining group, 41.1% did not have to be considered for an OGTT because their fasting glucose level was below or above 96–125 mg/dl. Overall, 10.6% of adults aged 40–74 years without medical history of diabetes met the DPP eligibility criteria for intervention. Among individuals with BMI ≥24 kg/m^2 and fasting glucose level 96–125 mg/dl, applying a fasting plasma glucose cutoff of ≥105 mg/dl excluded 62.5% of this group and resulted in 56.0% of those with 2-h glucose level 140–199 mg/dl in this group being identified, with a specificity of 72.0% and a PPV of 17.1%. Similar values were obtained for an HbA_{1c} cutoff value of ≥5.5%.

CONCLUSIONS — Using data on BMI and setting cutoff values for fasting glucose and HbA_{1c} would greatly reduce the number of individuals who would need to undergo an OGTT while achieving adequate sensitivity, specificity, and PPV.

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The U.S. Diabetes Prevention Program (DPP) and the Diabetes Prevention Study in Finland were the first major randomized, controlled clinical trials to investigate whether type 2 diabetes could be prevented; both studies were completed in 2001. Before these studies, it was unknown whether type 2 diabetes could be prevented by lifestyle or pharmaceutical intervention. The studies indicate that metformin or lifestyle interventions can have dramatic effects in preventing type 2 diabetes. In both trials, individuals at high risk for diabetes based on BMI, fasting plasma glucose, and response to an oral glucose tolerance test (OGTT) reduced their risk of diabetes by 58% by participating in a structured physical activity and weight loss program (1,2). The risk was reduced by 31% in participants taking metformin in the DPP. The DPP intervention was applied to individuals at high risk for diabetes based on BMI ≥24 kg/m^2, fasting plasma glucose level 96–125 mg/dl, and 2-h plasma glucose level 140–199 mg/dl at 2 h after an oral glucose challenge (3). It was estimated that 10 million people in the U.S. would meet these criteria and that a substantial reduction in diabetes incidence would occur if the DPP interventions were implemented in these people (1).

Diabetes presents a significant public health burden associated with increased morbidity, mortality, and economic costs. Diabetes leads to increased rates of microvascular disease (retinopathy, neuropathy, renal disease, and lower extremity amputations), coronary heart disease and peripheral vascular disease, stroke, and disability and a reduced life expectancy of 7–8 years (4). It is estimated that $44 billion in direct costs, including inpatient care and nursing homes, was spent on diabetes in 1997 and $54 million was incurred in indirect costs, including disability and premature mortality (5). Furthermore, the prevalence of diabetes in the U.S. has increased fivefold in the past 30 years, and it is projected that 21.4 million people will have diabetes in the U.S. by 2025 (6).

Because of the success of the DPP interventions and the significant public health burden presented by diabetes, a program to identify individuals at high risk for diabetes and meeting the DPP criteria would offer a method to implement a program to markedly reduce diabetes in the U.S. One barrier to identifying these individuals is the need to administer an OGTT. Currently, few physicians and patients are willing to undergo an OGTT due to the time, inconvenience, and expense of the test. Indeed, the American Diabetes Association (ADA) recommended abandonment of the OGTT as a screening and diagnostic test for diabetes

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Abbreviations: DPP, Diabetes Prevention Program; NHANES III, third National Health and Nutrition Examination Survey; OGTT, oral glucose tolerance test; PPV, positive predictive value; ROC, receiver operator characteristic.

The opinions expressed in this paper are those of the authors and do not necessarily represent the position of the National Institute of Diabetes and Digestive and Kidney Diseases.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

See accompanying editorial on p. 2098.

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(7). An alternative is to use fasting glucose or HbA_{1c} levels to identify individuals who meet the DPP criteria.

To investigate this issue, we analyzed data from a representative sample of U.S. adults to determine the sensitivity, specificity, and positive predictive value (PPV) of using fasting glucose or HbA_{1c} or a combination of both to identify individuals who meet the DPP criteria for intervention.

RESEARCH DESIGN AND METHODS

Design, setting, and participants

The third National Health and Nutrition Examination Survey (NHANES III) was conducted from 1988 to 1994 and included a stratified probability sample of the U.S. population (8). Participants were interviewed in their homes and underwent a standardized set of physical examinations and laboratory measurements in an examination center. After an overnight fast of ≥9 h, a venous blood sample was obtained and a 2-h 75-g OGTT was administered to the subset of subjects who were aged 40–74 years and did not report a prior diagnosis of diabetes (n = 2,844) (9). The OGTT was only administered to NHANES III participants aged 40–74 years, whereas the eligibility for DPP was ≥25 years of age. Consequently, we do not have information for the U.S. population aged 25–39 years or for those aged ≥75 years.

Statistical analysis

We determined the sensitivity, specificity, PPV, and likelihood ratio of fasting glucose and HbA_{1c} to accurately identify individuals with 2-h glucose level 140–199 mg/dl and specifically those who met the DPP eligibility criteria. Sensitivity, specificity, and PPV were determined for a series of 5-mg/dl cut points for fasting glucose and 0.5% cut points for HbA_{1c}. Receiver operator characteristic (ROC) curves were plotted for fasting glucose and HbA_{1c} and the area under the curve was calculated. Comparisons between fasting glucose and HbA_{1c} and between groups were performed using the χ^2 test statistic. Analyses were performed using SUDAAN version 7.5 software (Research Triangle Institute, Research Triangle Park, NC) with appropriate sampling weights to account for the complex survey design and to provide nationally representative estimates. ROC curves were plotted using STATA version 7.0 software (Stata, College Station, TX).

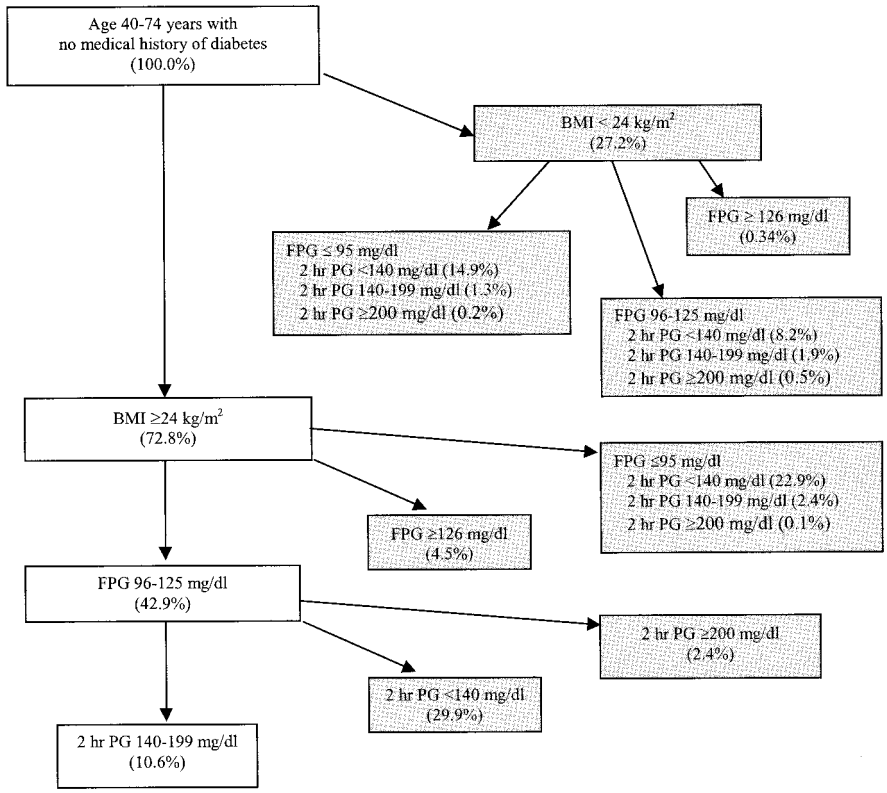

Figure 1—*Distribution of the U.S. adults aged 40–74 years according to DPP eligibility criteria. Shaded boxes indicate individuals who do not meet DPP eligibility criteria at each stage. All percentages are calculated relative to the entire group aged 40–74 years, with no medical history of diabetes as the denominator. Percentages are weighted to adjust for the complex sampling scheme of the survey to reflect percentages in the U.S. population. FPG, fasting plasma glucose; 2 hr PG, plasma glucose at 2 h during an OGTT.*

RESULTS — The DPP determined eligibility for the study by administering an OGTT only to individuals with BMI ≥24 kg/m^2 and fasting plasma glucose level 96–125 mg/dl; those with 2-h glucose level 140–199 mg/dl were eligible for the study (3,10). Based on NHANES III, 27.2% of the U.S. population aged 40–74 years with no medical history of diabetes had BMI <24 kg/m^2 and 72.8% had BMI ≥24 kg/m^2 (Fig. 1). Of those with BMI ≥24 kg/m^2, 6.2% had a fasting plasma glucose level ≥126 mg/dl and would be classified as having newly diagnosed diabetes. These individuals would be recommended for confirmatory testing for diabetes in accordance with ADA recommendations (7). Of those with BMI ≥24 kg/m^2, 34.9% had fasting plasma glucose level <96 mg/dl and would not meet the DPP eligibility criteria for intervention and are considered to be at low risk for diabetes. The remainder (58.9%) of those with BMI ≥24 kg/m^2 had fasting plasma glucose level 96–125 mg/dl. Among those with BMI ≥24 kg/m^2 and fasting glucose level 96–125 mg/dl, 69.6% had 2-h plasma glucose level <140 mg/dl (normal glucose tolerance), 24.8% had 2-h glucose level 140–199 mg/dl (impaired glucose tolerance), and 5.6% had 2-h glucose level ≥200 mg/dl (newly diagnosed diabetes). Those with newly diagnosed diabetes, classified by 2-h glucose level ≥200 mg/dl, were recommended for further testing and treatment. In summary, among those aged 40–74 years with no medical history of diabetes in the U.S. population, 10.6% would meet the DPP eligibility criteria for intervention (100% × 0.728 × 0.589 × 0.248).

Based on the ROC curve for subjects with BMI ≥24 kg/m^2 and fasting plasma glucose level 96–125 mg/dl, the area under the curve, to predict 2-h glucose level 140–199 mg/dl, for fasting plasma glu-

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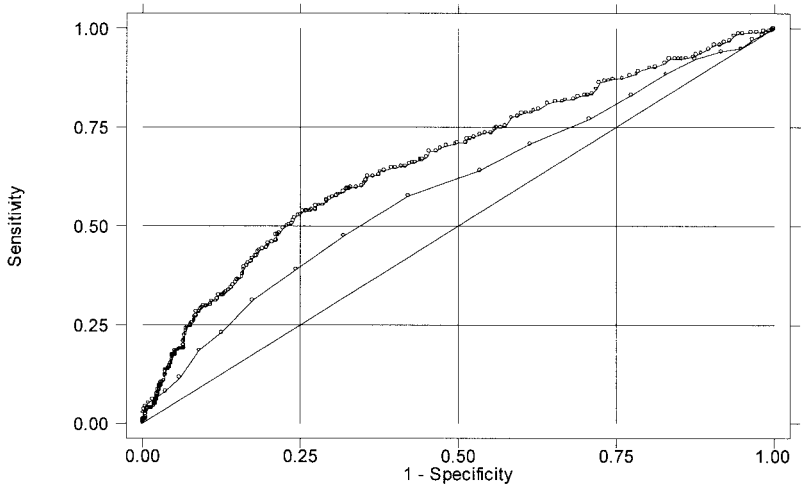

Figure 2—*ROC curve for fasting plasma glucose and HbA_{1c} for adults aged 40–74 years with no medical history of diabetes and with BMI ≥24 kg/m² and fasting plasma glucose 96–125 mg/dl. The line with the closely spaced circles is the ROC curve for fasting plasma glucose (area under the curve 0.6653). The line with the widely spaced circles is the ROC curve for HbA_{1c} (area under the curve 0.5927). The solid line represents an area under the curve of 0.500.*

cose level and HbA_{1c} was 0.665 (95% CI 0.630–0.700) and 0.593 (0.557–0.629), respectively, and differed significantly ($P = 0.002$) (Fig. 2). We stratified further to determine whether including other factors known to be associated with elevated 2-h glucose level improved the accuracy of fasting plasma glucose or HbA_{1c}. The ROC curves after stratification by age (40–59 vs. 60–74 years), race (non-Hispanic white versus all others) and family history (having a first-degree relative with diabetes versus no first-degree relative) did not differ significantly. Stratifying by age, the area under the curve for fasting glucose for those aged 40–59 years was 0.569 (0.517–0.620) and for those aged 60–74 years was 0.596 (0.546–0.647; $P = 0.452$). Stratifying by race, the area under the curve for fasting glucose for non-Hispanic whites was 0.633 (0.584–0.682) and for all others was 0.655 (0.611–0.697; $P = 0.522$). Stratifying by family history, the area under the curve for fasting glucose for those with no family history was 0.627 (0.587–0.667) and for those with a family history was 0.689 (0.634–0.742; $P = 0.075$).

Among those with BMI ≥24 kg/m² and fasting plasma glucose level 96–125 mg/dl (i.e., those eligible for the OGTT in DPP), as fasting glucose values increased, the sensitivity of fasting glucose to identify individuals with 2-h glucose level 140–199 mg/dl decreased, the specificity increased, and the PPV increased (Table 1). The likelihood ratio for the odds that a given cut point of fasting glucose would be expected in an individual with 2-h glucose level 140–199 mg/dl was highest at fasting glucose level ≥115 mg/dl. At fasting glucose level ≥105 mg/dl, which included 37.5% of participants, the sensitivity of fasting glucose to identify the individuals with 2-h glucose of 140–199 mg/dl was 56.0%, the specificity was 72.0%, and the PPV was 17.1%. Similarly, at HbA_{1c} ≥5.5%, which included 38.3% of participants, the sensitivity of HbA_{1c} to identify the individuals with 2-h glucose level 140–199 mg/dl was 60.0%, the specificity was 55.0%, and the PPV was 21.4% (Table 1). Requiring both fasting glucose level ≥105 mg/dl and HbA_{1c} ≥5.5% decreased the sensitivity to 33.4% but increased the specificity to 84.8% and PPV to 37.9%. Requiring either fasting glucose level ≥105 mg/dl or HbA_{1c} ≥5.5% increased the sensitivity to 82.6% but decreased the specificity to 42.3% and did not substantially change the PPV (31.3%). Using a higher fasting glucose cut point of ≥110 mg/dl decreased the sensitivity further, increased the specificity, and did not substantially change the PPV. Similarly, using a higher HbA_{1c} cut point of ≥6.0% also decreased the sensitivity, increased the specificity, and did not substantially change the PPV (Table 2).

Increasing BMI from ≥24 to ≥27 or

Table 1—*Sensitivity, specificity, PPV, and likelihood ratio for identifying individuals who have a 2-h glucose of 140–199 mg/dl among U.S. adults aged 40–74 years with BMI ≥24 kg/m² and a fasting glucose of 96–125 mg/dl, according to fasting plasma glucose and HbA_{1c} cut points*

Glycemic measure	Cut points	Percent distribution	Sensitivity (%)	Specificity (%)	PPV (%)	Likelihood ratio
Fasting glucose (mg/dl)						
	≥100	66.2	76.5 ± 3.5	37.9 ± 2.8	17.9 ± 2.9	1.23
	≥105	37.5	56.0 ± 5.1	72.0 ± 1.9	17.1 ± 2.9	2.00
	≥110	20.7	34.9 ± 4.5	86.9 ± 1.5	31.4 ± 4.7	2.66
	≥115	10.2	19.9 ± 3.6	95.4 ± 1.0	33.9 ± 6.5	4.33
	≥120	4.5	7.5 ± 2.7	97.4 ± 0.9	54.3 ± 7.6	2.88
HbA_{1c} (%)	≥4.5	97.7	98.0 ± 1.2	1.8 ± 0.9	24.2 ± 18.9	1.00
	≥5.0	80.2	90.2 ± 2.3	17.2 ± 2.4	14.9 ± 4.5	1.09
	≥5.5	38.3	60.0 ± 3.4	55.0 ± 4.3	21.4 ± 2.2	1.33
	≥6.0	8.2	16.7 ± 2.4	92.9 ± 1.3	27.6 ± 4.4	2.35
	≥6.5	0.9	1.6 ± 0.5	99.3 ± 0.4	39.8 ± 5.3	2.29

Data are means ± SD unless otherwise indicated.

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Table 2—*Sensitivity, specificity, and PPV for identifying individuals who have a 2-h glucose of 140–199 mg/dl among U.S. adults aged 40–74 years with BMI ≥24 kg/m² and a fasting glucose 96–125 mg/dl using combinations of fasting glucose or HbA_{1c} cut points*

	Sensitivity (%)	Specificity (%)	PPV (%)*
Fasting glucose ≥105 mg/dl			
and HbA_{1c} ≥5.5%	33.4	84.8	37.9
or HbA_{1c} ≥5.5%	82.6	42.3	31.2
and HbA_{1c} ≥6.0%	11.2	97.5	45.1
or HbA_{1c} ≥6.0%	61.5	67.5	36.1
Fasting glucose ≥110 mg/dl			
and HbA_{1c} ≥5.5%	21.1	93.5	42.3
or HbA_{1c} ≥5.5%	73.8	48.7	31.4
and HbA_{1c} ≥6.0%	6.2	98.7	42.3
or HbA_{1c} ≥6.0%	45.5	81.3	40.4

≥30 kg/m² resulted in an increase in sensitivity and PPV for both fasting glucose and HbA_{1c} (Table 3). For those aged 60–74 years, sensitivity, specificity, and PPV for fasting glucose and HbA_{1c} were somewhat better than for those aged 40–59 years, but the differences were not substantial. The effect of race was minor for fasting plasma glucose but, for HbA_{1c}, non-Hispanic whites had lower sensitivity and higher specificity than all others.

CONCLUSIONS — Identification of individuals who would meet the criteria for a DPP intervention is both a public health and a clinical issue. It could also be an enormous undertaking, given the fact that there are ~95 million people aged 40–74 years without a medical history of diagnosed diabetes in the U.S. (11,12). The DPP recruited participants at high risk for developing diabetes based on BMI, fasting plasma glucose level, and response to an OGTT. To determine those who might be eligible for a DPP intervention in the general U.S. population to reduce their risk of developing diabetes, measurement of height and weight could immediately eliminate from further testing the 27.2% of individuals with BMI <24 kg/m². Measurement of fasting plasma glucose in those with BMI ≥24 kg/m² would eliminate 41.1% of this group who are below or above the DPP fasting plasma glucose criteria. For the remaining 41 million individuals with BMI ≥24 kg/m² and fasting plasma glucose level 96–125 mg/dl, setting the fasting glucose cutoff value at ≥105 mg/dl would eliminate 62.5% from further testing by the OGTT while including fully 56.0% of those with 2-h glucose level 140–199 mg/dl. Thus, for the 95 million people aged 40–74 years without diagnosed diabetes, 15 million would have to undergo an OGTT by this scheme. A similar procedure could be followed using HbA_{1c} ≥5.5%, which does not require an individual to be fasting and can be measured in a blood sample collected without regard to time of the prior meal. If HbA_{1c} is used, the method for measuring HbA_{1c} would have to be standardized to the Diabetes Control and Complications (DCCT) method (13) to use the same cutoff values as in Table 1.

Although the results are representative of the U.S. population, we only have data on individuals aged 40–74 years. Therefore, we cannot draw specific conclusions for those aged >74 years or <40 years. In addition, the data in NHANES III were collected from 1988 to 1994. The prevalence of being overweight or obese (BMI ≥25 kg/m²) in the U.S. was ~5% higher in 1999 than during NHANES III (14). This increase likely corresponds to an increase in the prevalence of those with elevated fasting and 2-h glucose values. Therefore, the overall prevalence of individuals who would meet the DPP criteria for intervention likely has increased. The increase in prevalence would not affect the sensitivity or specificity of the meth-

Table 3—*Sensitivity, specificity, and PPV for identifying individuals who have a 2-h glucose of 140–199 mg/dl among U.S. adults aged 40–74 years with BMI ≥24 kg/m² and fasting glucose 96–125 mg/dl, according to BMI, age, and race/ethnicity*

	Sensitivity (%)	Specificity (%)	PPV (%)
Fasting plasma glucose ≥105 mg/dl			
BMI ≥24 kg/m²	56.0 ± 5.1	72.0 ± 1.9	17.1 ± 2.9
BMI ≥27 kg/m²	62.9 ± 5.5	69.8 ± 2.6	39.0 ± 4.7
BMI ≥30 kg/m²	65.4 ± 6.9	72.1 ± 3.4	42.5 ± 5.4
Age 40–59 years	49.1 ± 7.3	73.2 ± 2.4	15.8 ± 4.2
Age 60–74 years	58.7 ± 4.7	69.7 ± 2.9	22.4 ± 3.0
Non-Hispanic whites	53.4 ± 5.3	72.7 ± 2.0	18.7 ± 3.3
All others	51.9 ± 7.4	70.2 ± 3.2	15.7 ± 4.0
HbA_{1c} ≥5.5%			
BMI ≥24 kg/m²	60.0 ± 3.4	55.0 ± 4.3	21.4 ± 2.2
BMI ≥27 kg/m²	67.5 ± 3.7	52.1 ± 4.6	32.7 ± 3.7
BMI ≥30 kg/m²	71.8 ± 4.7	55.5 ± 4.7	37.4 ± 4.0
Age 40–59 years	52.7 ± 5.4	59.8 ± 4.7	16.9 ± 2.6
Age 60–74 years	61.5 ± 4.2	46.6 ± 3.1	28.2 ± 4.3
Non-Hispanic whites	56.7 ± 3.8	60.3 ± 4.2	21.5 ± 2.3
All others	74.7 ± 5.1	40.0 ± 4.1	16.3 ± 3.5

Data are means ± SD.

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ods proposed but would increase the PPV slightly. The prevalence of diabetes and abnormal glucose tolerance increases with increasing age and BMI and is higher in those of minority race/ethnicity (9). The DPP lifestyle intervention for reducing the incidence of diabetes was almost equally effective in each gender, BMI, and race/ethnicity group and showed the greatest reduction in incidence of diabetes for individuals aged ≥60 years (1). For metformin, the risk reduction relative to the placebo group was greater for younger individuals and overweight individuals than for older and less overweight individuals.

Ideally, a screening test should have high sensitivity and high specificity; it is desirable to miss very few people who have the disease and to not misclassify a large number of people who do not have the disease. In the identification of people meeting the DPP criteria, these requirements may not be necessary. By using a fasting plasma glucose cutoff value of ≥105 mg/dl, 44.0% of DPP-eligible individuals will be missed. However, an annual measurement of fasting glucose would address this issue. In the DPP control group, 11.0% progressed to diabetes per year (1). Therefore, only 4.8% (11.0% × 0.44) of DPP-eligible individuals who were not entered into a DPP type of intervention program would progress to diabetes between annual measurements of fasting plasma glucose, and 9.6% of DPP-eligible individuals would progress to diabetes if fasting glucose was measured every other year. If it were desired to increase the number of people found to have 2-h glucose levels of 140–199 mg/dl, sensitivity could be increased by setting the fasting glucose cutoff level at ≥100 mg/dl. This would markedly decrease specificity (and increase the number of OGTTs that need to be performed), but because 2-h glucose values of 140–199 mg/dl do not constitute disease, identifying more individuals needing an OGTT to confirm whether they have elevated postchallenge glucose carries far less stigma and social burden than having a low specificity on a test for diagnosing a disease. However, identifying too many people for an OGTT would also place a greater burden, in terms of time and cost, on both the individual patient and the health care system and physician. Another option would be to increase the fasting glucose cutoff level to ≥110 mg/dl, which corresponds to the ADA definition for impaired fasting glucose. Increasing the cutoff increases the specificity, resulting in fewer false positives, but decreases the sensitivity and results in a greater number of false negatives. Overall, the fasting glucose cutoff level proposed seems to be a balance between sensitivity and specificity with 2:1 odds of identifying an individual with 2-h glucose between 140 and 199 mg/dl. Neither fasting plasma glucose nor HbA_{1c} alone are ideal screening tests. Based on the ROC curve analysis, neither includes an area under the curve significantly greater than the 0.50 that is expected by chance alone. In other words, once individuals are identified as having a BMI ≥24 kg/m^2 and fasting glucose between 96 and 125 mg/dl, specific cut points of fasting glucose within that range do not improve the chances of identifying an individual as having 2-h glucose between 140 and 199 mg/dl without performing an OGTT. The same can be said for various cut points of HbA_{1c}. Therefore, to find individuals eligible for the DPP intervention, clinicians can eliminate a large proportion of individuals from further testing based on BMI ≥24 kg/m^2 and fasting glucose 96–125 mg/dl. Using either fasting glucose ≥105 mg/dl or HbA_{1c} ≥5.5% would further reduce the number of individuals who would undergo further testing with the understanding that a portion of eligible individuals may be missed.

Even though individuals with BMI <24 kg/m^2 would not meet the DPP criteria for intervention, there are still a number of people in this group who have elevated 2-h glucose levels and who presumably would be at increased risk for diabetes. However, because such individuals were not included in DPP, we have no information regarding whether the intervention would be effective. Furthermore, in these individuals, BMI is considered normal and a structured weight loss program may not be advisable.

Few studies have examined the ability to identify individuals with abnormal glucose tolerance without administering an OGTT. Overall, these studies found that the sensitivity of fasting glucose to identify individuals with impaired glucose tolerance was fairly low (15,16) and that HbA_{1c} was fairly specific but not very sensitive (17–19). However, only one of these studies focused specifically on screening for impaired glucose tolerance (15) and none were representative of the general U.S. population.

For a screening program to be effective, it must have a number of attributes: *1*) the disease should represent a sizable burden to the population; *2*) it should have a preclinical phase during which it can be diagnosed; and *3*) it should have improved prognosis after diagnosis. Based on the promising results from DPP and the Finnish Diabetes Prevention Study, diabetes now meets all three of these attributes. Data from NHANES III provide physicians and public health officials a clearer idea of the number of OGTTs and the scope of the screening that would need to be undertaken to implement DPP. It was estimated that 10 million people in the U.S. meet the DPP criteria for eligibility for intervention and that 11.0% of these will develop diabetes in 1 year (1). Reducing the risk of diabetes by 58% within this group would significantly reduce the burden of diabetes in the U.S. and potentially prevent many complications and premature deaths.

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