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Screening for Diabetes Mellitus in High-Risk Patients: Cost, Yield, and Acceptability

CONTEXT. Although universal screening for diabetes mellitus is generally not recommended, recent reports suggest that screening individuals with multiple diabetes risk factors may be worthwhile. Little is known about the cost, yield, or acceptability of this kind of screening.

PRACTICE PATTERN EXAMINED. Screening of high-risk patients for diabetes mellitus using a two-step, glucose-based screening protocol: Patients were initially screened with a random glucose test; those with abnormal results received a follow-up fasting, 2-hour, 75-gram oral glucose tolerance test.

CLINIC SELECTION. Three volunteer clinics from a large medical group in Minnesota.

PATIENT SELECTION. Of 38,989 adults receiving care at the three clinics, we identified 1548 high-risk patients with evidence of both dyslipidemia and hypertension in laboratory and administrative databases. Many of these 1548 patients were not eligible for screening: Twenty-five percent already had diagnosed diabetes; 41% had been screened for diabetes in the past year; and 3% had died, disenrolled, or changed clinics before screening commenced. The remaining 30% ($n = 469$) were invited for diabetes screening.

RESULTS. Of the 469 high-risk patients invited, 206 (44%) initiated screening; 176 (38%) completed diabetes screening. Five new patients with diabetes were identified in this high-risk group (one from the random glucose test and four from the glucose tolerance test). One new patient with diabetes was identified for every 40 high-risk patients screened. The program cost \$4064 per new case of diabetes identified (screening costs alone).

CONCLUSION. In this high-risk managed care population, the yield and acceptability of systematic diabetes screening were low, and the costs were relatively high. The acceptability of office-based diabetes screening may be improved by using a one-step screening test, such as glycosylated hemoglobin, during routine visits.

The practice of screening for diabetes mellitus remains controversial.¹⁻⁵ While it is generally agreed that available data do not support universal diabetes screening,⁶ some recent reports suggest that screening programs targeting individuals with multiple diabetes risk factors may be worthwhile.⁷⁻¹¹ In fact, the American Diabetes Association calls for office-based screening of patients with a variety of risk factors, including advanced age, central obesity, physical inactivity, family history of diabetes, or a personal history of gestational diabetes.⁷

The argument for screening high-risk adults for diabetes is based on two considerations. First, undetected diabetes is common. Approximately 3% to 4% of the U.S. adult population has occult diabetes.¹² The prevalence is, of course, likely to be

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substantially higher among people with diabetes risk factors. Second, there is some evidence that early detection of diabetes may not only improve glycemic control, but blood pressure and lipid control as well.¹³ These benefits are especially important given the strong association between diabetes and cardiovascular disease.

The success of a screening program targeting individuals at high risk for diabetes will depend on how well this “high-risk” population can be identified. The proportion of cases likely to be detected in a real-world office practice is unknown. Unfortunately, obtaining risk-factor data directly from patients is time-consuming and often yields incomplete data.^{2, 12, 14}

In this paper, we explore an alternative approach. We used automated clinical data to identify adults with dyslipidemia and hypertension—conditions associated with an increased risk for diabetes—and we ascertained the cost, yield, and acceptability of diabetes screening in these high-risk patients.

Methods

Clinic Selection

Three of the 19 clinics in the HealthPartners Medical Group, a multispecialty medical group, volunteered to participate in this study (Figure 1). These three clinics had a total of 38,989 adult members, 14% of whom were 65 years of age or older. Diabetes education nurses at each clinic were informed of this research project and asked to recruit patients. Improvement activities related to diabetes in this medical group were not yet under way in the three study clinics at the time of this study.^{15, 16} The study protocol and patient informed consent procedures were reviewed in advance, approved, and monitored by the HealthPartners Institutional Review Board.

Identification of High-Risk Patients

Patients with established diagnoses of both dyslipidemia and hypertension were considered to be at high

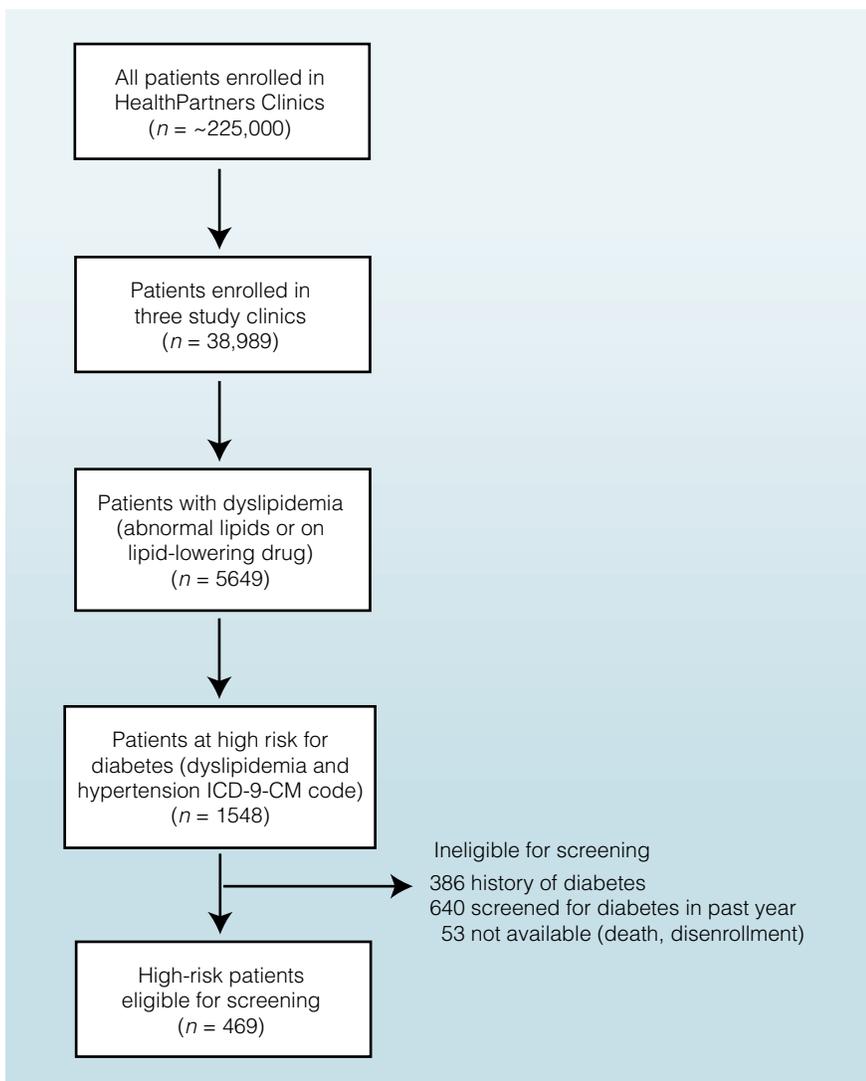


FIGURE 1. Selection of patients at high risk for diabetes (dyslipidemia and hypertension) eligible for screening.

risk. A diagnosis of dyslipidemia was assigned if any patient had 1) filled a prescription for a dyslipidemia-specific drug from October 1, 1994, to September 30, 1995, at a HealthPartner's pharmacy or 2) had a total cholesterol value of 240 mg/dL or more, a high-density lipoprotein (HDL) cholesterol value of 35 or less, a fasting low-density lipoprotein (LDL) cholesterol value over 190 mg/dL, or a fasting triglyceride level of 300 mg/dL or more from October 1, 1994, to September 30, 1995. Fasting values required a minimum 12-hour fast for inclusion in the analysis. All lipid assays were conducted at one centralized, accredited clinical chemistry laboratory that used standard assays for all tests,¹⁷ with LDL cholesterol values calculated by a standard equation. Lipid-specific drugs included HMG-CoA reductase inhibitors, gemfibrozil, cholestyramine, prescription niacin formulations, or probucol. Patients taking nonprescription niacin formulations who had either no lipid tests or normal lipid tests would not be identified. A previous study showed that most patients taking niacin did not reach normal lipid levels¹⁸ and thus would be identified for this study.

A diagnosis of hypertension was assigned if any patient had been given International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) codes 401, 401.1, or 401.9 at two or more outpatient clinic visits from October 1, 1994, to September 30, 1995. Previous studies in the health plan show that over 90% of such patients are receiving one or more antihypertensive medications.¹⁹

Patients Eligible for Screening

No History of Diabetes

The diabetes status of each participant was defined before the initiation of formal diabetes screening activity. A diagnosis of diabetes mellitus was assigned if the patient either filled a prescription for a diabetes-specific drug at a HealthPartner's pharmacy from October 1, 1994, to September 30, 1995, or had been assigned two or more outpatient ICD-9-CM codes for diabetes mellitus (code 250.0) from October 1, 1994, to September 30, 1995. Diabetes-specific drugs included insulin, sulfonylureas, biguanides, and α -glucosidase inhibitors. This method of identifying diabetes mellitus has been previously validated at HealthPartners and has an estimated sensitivity of 0.91 and a positive predictive value of 0.94.¹⁵

No Previous Screening

Some adults who were dyslipidemic and hypertensive and who did not have a diagnosis of diabetes had already been screened for diabetes as part of routine clinical care. This group included those with dyslipidemia and hypertension

who had received a random or a fasting plasma glucose test from October 1, 1994, to September 30, 1995, ascertained from a search of laboratory databases. In these clinics, all glucose tests must be specifically and individually circled on laboratory order sheets and were not available as part of panels of laboratory tests.

Screening Protocol

Each screen-eligible, high-risk patient was targeted for diabetes screening as part of this project. Patients were sent a letter on clinic stationery signed by the adult care, primary care physicians at their clinic inviting them to come to the laboratory for a free diabetes screening test. Patients were told that the test did not require an appointment and that they did not need to fast beforehand. To maximize attendance, we sent a postcard 1 week after the letter and a second letter 3 weeks later (to those who had not yet come in for screening).

The initial diabetes screening test was a random plasma glucose test. The results were evaluated using published Centers for Disease Control and Prevention (CDC) nomograms based on age and hours fasting before the test.²⁰ The cut-points for defining normal were set at the lowest value of the normal ranges used by CDC to maximize sensitivity for new patients. All patients who were screened were sent a letter informing them of the test results. If results were normal, patients were given written advice on physical activity and weight management to reduce future risks for diabetes. If results were not normal, patients were invited back to their primary care clinic for a fasting, 2-hour, 75-gram oral glucose tolerance test (GTT) and were given instructions on proper preparation for this test.

We telephoned patients found to have diabetes (fasting plasma glucose [FPG]>140 mg/dL or 2-hour GTT plasma glucose \geq 200 mg/dL)²¹ to inform them of the result and of the physician visit that was scheduled for them. Physicians were also informed of these new diagnoses. For patients with a fasting or 2-hour glucose value over 300 mg/dL, clinic visits with a physician were scheduled urgently. All other patients received their results by mail. Those with impaired glucose tolerance were informed and advised to schedule a physician visit, and the physician was also informed of test results.

Results

Patients Eligible for Screening

Figure 1 shows that 1548 high-risk patients with both dyslipidemia and hypertension were identified at the three study clinics. Many of these patients were ineligible for screening: Twenty-five percent ($n = 386$) already had known diabetes; 41% ($n = 640$) had been screened

within 1 year; and 3% ($n = 53$) had died, disenrolled, or changed clinics before screening commenced for diabetes. This left a total of 469 (30%) high-risk patients who were targeted for diabetes screening.

Yield

After receiving one or more mailed invitations to participate in the study, 206 (44%) of the 469 eligible study patients came to their clinic and had a random plasma glucose test (Figure 2). Among the 206 who completed screening, 102 (50%) had glucose values at or below the age-adjusted and hours postprandial-adjusted lower limit of normal values defined in CDC nomograms; 104 (50%) were above the lower limit of normal. Of these 104 patients with abnormal random glucose, one had a random plasma glucose value over 200 mg/dL with symptoms of diabetes. This patient was categorized as having diabetes mellitus and referred for clinical care. The remaining 103 participants with abnormal screening values were invited by mail to have a 2-hour, 75-gram oral GTT.

Seventy-three (71%) of the 103 patients with abnormal random glucose tests completed the GTT. Applying the World Health Organization (WHO) diagnostic criteria²² for diabetes, 58 had a normal GTT; 11 met criteria for impaired glucose tolerance on the GTT; and 4 had a new diagnosis of diabetes mellitus based on the GTT, with a 2-hour plasma glucose value of 200 mg/dL or higher. As stated before, the fifth patient with diabetes mellitus was diagnosed by high values on a random plasma glucose test and therefore never needed or had a GTT. The four participants with new diabetes on the basis of the GTT had FPG values of 101, 112, 134, and 140 mg/dL. The two with the lowest FPG values met WHO²² but not National Diabetes Data Group (NDDG)¹² GTT criteria for diabetes. Three of the five total, newly diagnosed patients had a glycosylated hemoglobin A test (HbA_{1c}) within 3 months of diagnosis and before glucose-lowering drug therapy, with values of 6.7%, 6.9%, and 7.2% (normal range, 4.5% to 6.1%).²² All screening-related diagnoses were verified as new by chart review.

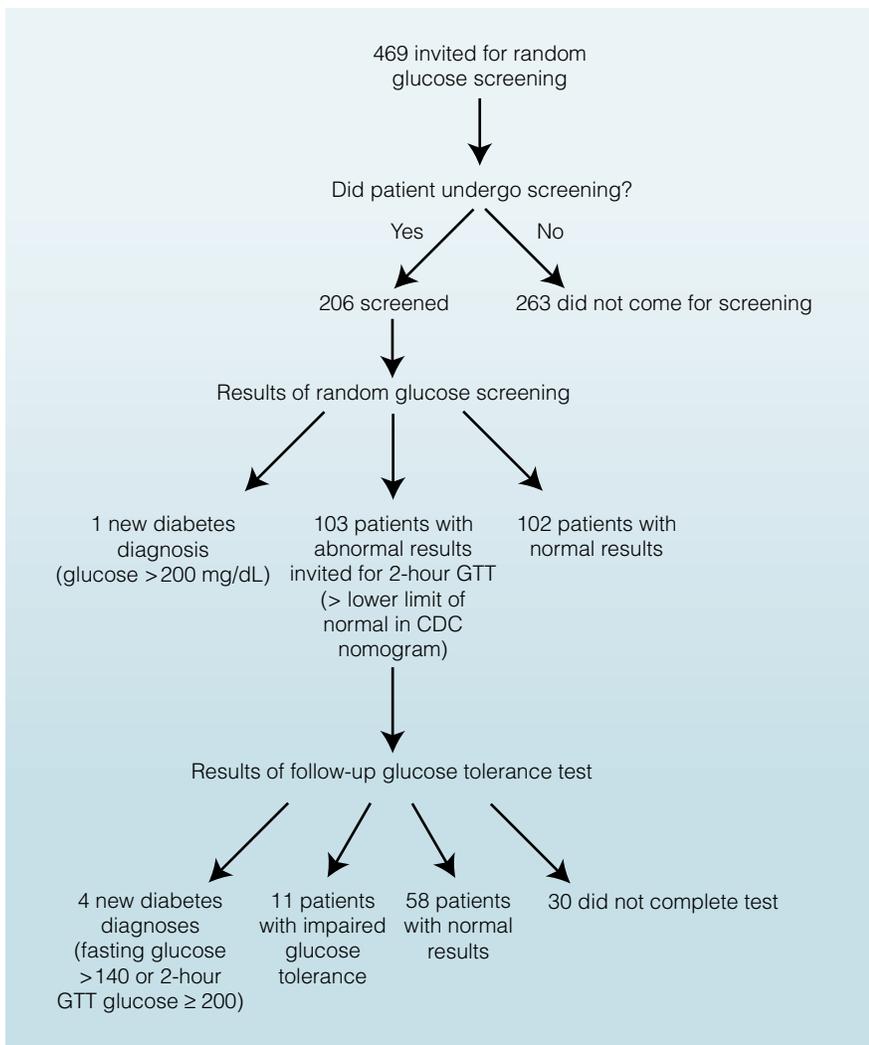


FIGURE 2. Yield and acceptability of two-step, glucose-based screening strategy among high-risk patients.
 CDC = Centers for Disease Control and Prevention; GTT = glucose tolerance test.

Acceptability

The first screening invitation (initial mailing and follow-up postcard mailed 7 days later) resulted in no complaints. However, six written or telephone call complaints were received (about one complaint per 50 patients) after the second mailing to nonrespondents. Typical responses included, "Stop bothering me" and "Leave me alone, please." Because of these complaints, plans for subsequent telephone follow-up were abandoned.

Costs

Table 1 shows the actual costs (in 1995 U.S. dollars) of screening these 469 patients for diabetes. Overall, the program cost \$4064 per each new case of diabetes detected (total costs divided by five new patients). This estimate is conservative because it excludes both research costs (developing the study design, analyzing, and reporting the results) and more important, the costs of additional care for newly diagnosed patients with diabetes (additional visits, pharmacotherapy, and patient education).

Discussion

In this managed care population, the acceptability and yield of systematic diabetes screening of high-risk patients were low, and the costs were relatively high.¹² Among high-risk patients targeted for screening, only 44% initiated the two-step screening process, and 38% completed the screening protocol. Targeting 469 high-risk adults with dyslipidemia and hypertension for

screening yielded five newly diagnosed patients with diabetes by WHO criteria,²² only three of whom met the more stringent NDDG criteria.¹² Thus, one new diabetes patient was found for every 34 patients who completed screening, for every 40 patients who initiated screening, and for every 94 high-risk patients invited to screening.

Is it worth screening 94 high-risk patients and spending \$4064 to detect each new case of type 2 diabetes? The answer to this question depends heavily on whether earlier diagnosis confers significant clinical benefits.¹³ In another study population, we found that patients who were newly diagnosed with diabetes in advance of hyperglycemic symptoms had a mean HBA_{1c} of 8.0% at diagnosis, whereas those diagnosed in the presence of hyperglycemic symptoms had a mean HBA_{1c} of 9.9% at diagnosis. One year later, HBA_{1c} in both groups improved to 7.1%, with concurrent improvements in blood pressure, LDL cholesterol, and weight.¹³ These clinical changes, if maintained, are sufficient to reduce the risk for subsequent cardiovascular and microvascular complications.^{21, 23–26} In our opinion, diabetes screening is better justified on the basis on macrovascular risk reduction than on microvascular risk reduction. Macrovascular events are much more common than end-stage microvascular complications, and they are the principal drivers of both the excess mortality and excess costs associated with type 2 diabetes in adults.^{16, 27–32}

Even if clinical benefit is assumed, the cost of screening relative to its yield must be considered. Other

TABLE 1
Assumptions for Estimating the Cost To Screen 469 Participants to Detect 5 New Cases of Diabetes*

ITEM	COST PER UNIT	NUMBER OF UNITS	TOTAL COSTS
Programming to identify high-risk patients	\$50/hr	40 hours	\$2000
Average cost of up to three mailings per patient (recruit and results)	\$6/patient	469 patients	\$2814
Coordinator to track responses to mailings and screening results	\$20/hr	100 hours	\$2000
Plasma glucose tests	\$28/test	206 tests	\$5768
Oral glucose tolerance tests	\$106/test	73 tests	\$7738
Costs			
Total			\$20,320
Per new patient diagnosed			\$4064

*Cost in 1995 U.S. dollars.

studies have suggested that diabetes screening is not cost-effective, but these studies have not considered the effects of early diagnosis on macrovascular complications mediated through blood pressure control, lipid control, weight management, and use of aspirin.⁵ Patients with diabetes have health care costs about 250% higher than age- and gender-matched patients without diabetes.³¹ Diabetes patients with heart disease have costs about 400% higher than age- and gender-matched patients without heart disease.²⁸ It is likely that some of the excess costs related to heart disease in those with diagnosed diabetes may be partially averted by earlier diagnosis and aggressive management of glucose, lipids, blood pressure, and aspirin use.^{3, 32-34} It is in this clinical economic context that the cost of earlier diabetes diagnosis must be considered.

This study suggests two strategies that might substantially increase the acceptability of diabetes screening to targeted patients. First, conducting diabetes screening of high-risk patients at the time of a routinely scheduled office visit would be more convenient for patients and could likely achieve a higher rate of screening than the systematic screening strategy we tested. Patients with hypertension average five to six primary care visits a year; each visit is an opportunity to screen for diabetes.¹⁹ In many office settings, automated databases are capable of identifying high-risk patients in advance of the visit or during the visit and can prompt physicians to screen.

Second, use of a one-step, nonfasting screening test, such as HBA_{1c}, would have increased screening completion rates by about 15% in this study. The use of HBA_{1c} to screen for diabetes makes good clinical sense, since HBA_{1c} is a strong and valid predictor of both macrovascular and microvascular events even in the 5%-to-7% range.³⁵⁻³⁷ Thus, lack of perfect agreement between the HBA_{1c} and other diagnostic tests that convey less prognostic information is no longer a plausible argument against using HBA_{1c} as a diagnostic test for diabetes. However, standardization of HBA_{1c} assay methods across laboratories is needed.

Several factors limit the interpretation of our findings. First, it is clear that high-risk patients in this practice were receiving rather high baseline surveillance for diabetes. The yield from screening patients in other practices with less surveillance may be greater than what was observed here. Second, it is likely that patients at lower risk for diabetes would have even higher costs and lower yield of screening than what we observed here. Third, only about 10% of patients were nonwhite; screening in populations of color may be more productive.

Historically poor control of glycemia, blood pressure, and lipids does not constitute a strong argument against the identification of yet more patients with

chronic diseases by screening. Recent data provide strong evidence of improvement in control of glycemia, lipids, and blood pressure in primary care settings.^{16, 19, 38-40} Our common goal should be to identify and effectively manage all chronic diseases and health-risk factors^{29, 30, 41, 42} that exist in our patients. However, the high cost, low yield, and low acceptability of the systematic screening strategy we tested suggest the need for a more effective strategy than was used here.

Take-Home Points

- **Disagreement exists about the value of screening adults for type 2 diabetes.**
- **We studied the cost, yield, and acceptability of diabetes screening in high-risk patients (those with both dyslipidemia and hypertension) identified in three large primary care clinics.**
- **Of 469 patients invited to participate, only 38% completed the two-step screening program.**
- **Only five new patients with diabetes (1%) were identified, at a cost of over \$4000 per patient.**
- **The acceptability of office-based diabetes screening may be improved by using a one-step screening test, such as glycosylated hemoglobin.**

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