Screening Healthy People for Diabetes: Is It Worthwhile?

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Background. The objectives of this study were (1) to estimate the prevalence of previously unknown diabetes mellitus in an apparently healthy population aged 40 years and older, (2) to estimate the ratio of known to unknown diabetics, and (3) from this information, to estimate the true prevalence of diabetes.

Methods. A one in five random sample of healthy patients aged 40 years and older attending six rural family physician offices had their fasting plasma glucose (FPG) level tested with a reflectance glucometer. If the FPG was \geq 7.8 mmol/L (140.5 mg/dL), a second FPG test was done on a later day.

Results. The sample of 1264 patients contained 139 known patients with diabetes. Of the remaining 1125 patients, 936 (83%) were tested. Twenty-three

Long-term population studies^{1–6} have shown that persons with diabetes mellitus have increased morbidity and mortality, mostly because of the cardiovascular effects of the disease.^{1,4,5,7}

The true prevalence of diabetes mellitus in Canada, the United States, and Great Britain is not known. In Great Britain, the estimated prevalence of diagnosed diabetes mellitus obtained from general practice surveys ranges from 1% to 2%.8-11 Prevalence estimates in the United States are higher, usually in the 5% to 6% range, 12-17 but these figures are for the total prevalence rate, that is, they include an estimate of "undiagnosed" diabetes assumed to be present in the population in those persons who have not yet been tested by a physician. The current estimated total population prevalence of diabetes In Canada is 5%, 18 although earlier estimates were 2% to 2.7%. 19-20 The Atlantic Heart Health Survey21 found a prevalence of diagnosed diabetes of 5%, which compares with the estimates of 1.54% in Prince Edward Island²² and 3.55% in Newfoundland and Labrador.23

It is known that isolated and racially homogeneous

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From the Department of Community Medicine, Memorial University of Newfoundland, Gloverton, Newfoundland. Requests for reprints should be addressed to Graham Worall, MD, Medical Clinic, Glovertown, Newfoundland, Canada AOG 2LO. patients had an elevated FPG level on the first test, but only nine of them had an elevated FPG level on the second test. One new patient with diabetes was found for each 15 patients already diagnosed; thus, the prevalence of unknown diabetes in the study population was 0.7%. As a result of this survey, the estimated prevalence of diabetes in the population age 40 years and older rose from 11.0% to 11.7%, and the estimated prevalence for the entire population rose from 4.4% to 4.6%.

Conclusions. Routine screening for diabetes mellitus in otherwise healthy patients aged 40 years and older is not worthwhile. Such screening should be restricted to high-risk groups.

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groups of people may have a high prevalence of diabetes.^{24–29} The prevalence of diabetes is higher among Afro-Americans³⁰ and in people from the Indian subcontinent.²

Until quite recently, the population of Newfoundland and Labrador was relatively isolated; there was little travel to and from the province, and within the province the communities were small, coastal, and remote. The inhabitants are mostly of southern Irish and western English heritage. Their diet produces an above-average level of obesity due to a higher than average median intake of calories at all ages.¹⁹ Between 40% and 60% of the elderly population is moderately obese.²⁰

Physicians often quote the "Rule of Halves" for chronic diseases: for any chronic disease, probably only half of patients who have it are known, and of those, only half are being treated properly. This idea was supported by the National Health and Nutrition Examination Survey¹⁶; 15,327 adults aged 20 to 74 years were tested, and the prevalence of known diabetes in the white population was 3%, with an additional 3.2% who were diagnosed as having diabetes by blood testing using the National Diabetes Group diagnostic criteria. The present study was conceived to test whether this situation (ie, approximately half of the patients with diabetes remaining undiagnosed) was true for the population in rural Newfoundland.

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The increasing prevalence of diabetes in the aging population was well shown by a total population survey of diagnosed diabetes done in 1988 in Newfoundland and Labrador.²³ Most people with diabetes are in the non-insulin-dependent diabetes mellitus (NIDDM) category, and most of them are over 40 years of age. People who have diabetes have a greater longevity than they used to. Increasing public awareness of the disease and increasing availability of inexpensive portable reflectance glucose instruments are making it more likely that diabetes will be detected before it becomes symptomatic. The population of Canada is demographically younger than that of western Europe, but by 2021 the projected proportion of the population over 65 years will be from 16.4% to 21%.31 The population of Newfoundland is younger still,³² with two thirds who are younger than 40 vears old.

The primary objective of the study was to estimate the prevalence of previously unknown diabetes in the apparently healthy population aged 40 years and older. Other objectives were to estimate the ratio of known to previously unknown diabetes in this population and, hence, to estimate the true prevalence of diabetes in the population of the province.

Methods

During the period from July 1, 1989, to January 1, 1990, family physicians in six clinics in the Gander and District Hospital Board area of rural Newfoundland tested a random sample of their patients aged 40 years and older. Ethical approval for this study was given by the Human Investigations Committee of Memorial University of Newfoundland.

Patients younger than 40 years old were excluded from the study, as were those who were mentally incompetent, legally incompetent, pregnant, institutionalized, housebound, or suffering from an intercurrent illness; those taking thiazide diuretics, beta blockers, systemic corticosteroids, thyroxine or antithyroid drugs; those who were nonfasting; and those with other endocrine or bleeding disorders.

The exclusion of institutionalized patients and those patients on long-term treatment for hypertension, heart disease, and endocrine disorders was adopted because it was believed that such patients were likely to have been screened for diabetes already as part of the medical examination done before institutionalization or as part of the management of their disease.

Sampling Procedure

A one in five random sample was selected from active patient files using random number tables. Files were deemed active if the patient has attended the clinic in the 3 years before the start of the study. A research assistant selected the sample from the physician's charts. All eligible patients were called for testing. Patients were approached directly if they happened to attend the clinic during the study period; otherwise, they were contacted by telephone. When patients came to the clinics for testing, they were questioned by the physician to confirm that they were not ineligible because of illness or medication. Patients who refused to participate or who did not attend after two contacts were not asked again.

All patients who had fasting plasma glucose levels that were \geq 7.8 mmol/L (140.5 mg/dL) on two occasions were told of the possible diagnosis of diabetes; they were asked to see their personal physician with the results for further advice and treatment. Participating physicians were informed that it might be necessary to do a glucose tolerance test to measure the level of glycosylated hemoglobin, or to obtain a 2-hour postload glucose level to confirm the diagnosis of diabetes.

Patients who were known to have diabetes were not tested in this study, but their diagnosis, together with the treatment they were receiving, was recorded.

Procedure for Obtaining Fasting Plasma Glucose

Patients were instructed to fast from midnight the day before testing and to drink only water. A fingerprid whole blood sample was taken between 8:30 AM and 10:30 AM the next day. A research assistant taught the physicians and their office staff how to use the Ames Glucometer II (Miles Canada Inc., Etobicoke, Ontario, Canada), using Glucostix and Program 5. The instruments were controlled against standard solutions in the office of the project coordinator (G.W.).

When a patient had an initial fasting plasma glucose level $\geq 7.8 \text{ mmol/L}$ (140.5 mg/dL), he or she was asked to return for a second test and reminded of the procedure for fasting, and the patient's records were screened for possible pharmacological or metabolic causes of elevated blood glucose. If the fasting plasma glucose level on the second visit was also $\geq 7.8 \text{ mmol/L}$ (140.5 mg/dL), the patient was advised that he or she may have diabetes and w discuss further testing with his or her family physician. A fasting plasma glucose that is $\geq 7.8 \text{ mmol/l}$ (140.5 mg/dL) on two separate occasions is one of the National Diabetes Data Group's criteria for the diagnosis of diabetes.³³

Table 1. Number of Cases of D	iabetes Mellitus in Men and
Women Over 40 Years of Age i	in a Newfoundland
Population $(N = 1264)$	

Diabetes Mellitus	Men	Women	Total
Previously diagnosed			
Insulin dependent	6	14	20
Noninsulin dependent	46	73	119
Newly diagnosed			
Insulin dependent	0	0	0
Noninsulin dependent	3	6	9

Statistical Methods

All survey data were manually recorded and visually inspected. The data were analyzed using Epi Info Version 5 software (Centers for Disease Control, Stone Mountain, Georgia).³⁴

Results

The number of active patient files in the six clinics was 18990, of whom 6331 were born before July 1, 1949 (that is, they were at least 40 years old at the start of the study). A one in five random sample yielded 1264 eligible study patients, of whom 139 were known to have diabetes. The remaining 1125 were called for testing.

Of the 1125 study sample, it was possible to test 936 (83.2%). Of the remaining 189 patients, 40 had moved, 37 refused to be tested, 40 were ineligible because of their medical state or because they were taking medication, 63 did not present for testing, and 9 patients were unaccounted for in the final data.

There were 139 known patients with diabetes, and of the 23 patients who were found to have a whole blood glucose level that was high at the time of the first test, only 9 had a persistently high blood glucose level when tested a second time.

There were 55 men and 93 women with diabetes. Of these, 20 had insulin-dependent diabetes and 128 had non-insulin-dependent diabetes. These ratios are shown in Table 1, and they confirm the results of previous studies.^{5,6,11-13,15,16,18}

The increasing prevalence of diabetes (known and newly diagnosed) among both sexes as the study population increases in age is shown in Figure 1. This pattern follows that of previous work in a province-wide survey in 1988²³; Figure 2 shows the results from this survey and the previous one.

The study sample contained 139 known patients with diabetes, which gives a prevalence of diabetes of 10.99% (95% confidence interval [CI] from 9.27 to 12.71) in this population of 40 years and older. Using

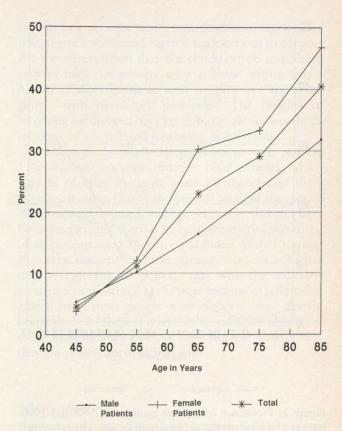


Figure 1. Prevalence of diabetes mellitus in a 1990 survey of a Newfoundland population of male and female patients over 40 years of age. The prevalence rates were calculated by decade and plotted at mid-decade.

the figure obtained in the 1988 total population survey of the province,²³ 84% of all persons with diabetes are aged 40 years or older, the prevalence estimate for the total population is 4.36% (95% CI, from 3.23 to 5.49) for patients known to have diabetes.

The number of newly diagnosed patients with diabetes was nine, all of them non-insulin-dependent. When added to the 139 previously known persons with diabetes, a prevalence of 11.71% (95% CI, from 9.94 to 13.48) for the population aged 40 years and older is obtained. This yields an estimate of 4.64% (95% CI from 3.48 to 5.80) for the total population. In Newfoundland, almost one third of the population (33.2%) was aged 40 years or older at the time of the 1986 census.³²

There were 15 known patients with diabetes for each new one (139/9) diagnosed by this screening program.

Discussion

The number of patients who were newly diagnosed for diabetes during the study was much smaller than ex-

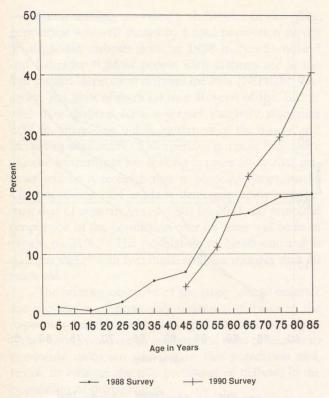


Figure 2. Prevalence of diabetes mellitus in 1988 and 1990 surveys of a Newfoundland population by age. The prevalence rates were calculated by decade and plotted at mid-decade. Smaller numbers in the 1988 survey result in wider confidence intervals than in the 1990 survey.

pected. The total was much smaller than the number that the Canadian Diabetes Association maintains (perhaps based on earlier work in the United States) are undetected in the population. Undetected diabetes is the major motivation for public screening campaigns. In the rural area that was included in this study, there is little chance that any health professional other than the family physician will be responsible for checking plasma glucose levels and making a diagnosis of diabetes.

The results of this study agree with some previous studies that have found a low prevalence (between 0.48% and 1.18%) of new cases of diabetes when populations are screened.^{35–37}

Although only 83.2% of the study sample was tested, this is a high figure for a screening survey offered to a population that is not taking medication, not seeing a physician regularly, and, in general, thinks itself healthy. Some clinics did even better; one tested 92% of its study sample.

Nonetheless, some will argue that the untested 16.8% of the study sample might contain some persons with diabetes. The evidence from surveys of healthy populations of people who never or rarely attend their physician is different^{36,37}; however, such people ar found to be either no different or slightly healthier than average. Their inclusion in the study might have lowered the prevalence figures slightly. An inspection of the age and sex distribution of the nonparticipants in this study indicated that they were no different from the participants.

Although 23 patients were found to have an elevated fasting plasma glucose level at the time of the first test, only 9 were found to have a high level on the second test. This finding can be explained by the statistical phenomenon of regression to the mean, and having been alerted to the possibility that there might be something wrong, patients may have been more scrupulous about fasting before their second test.

The study confirmed the well-known tendency for diabetes prevalence to rise with the increasing age of a given population (Figure 1) for both men and women, with a slightly higher prevalence in women than in men. Figure 2 compares the 1988 Newfoundland study with this study; the prevalence figures are much the same, except for the highest age groups. This can be explained by the relatively small numbers of very old persons tested and the consequent imprecision of the estimates for these age groups; in these age groups, the 95% confidence limits from both studies overlap.

Some authors have suggested that the psychological effects of screening may sometimes be bad enough to undermine the benefits of screening.⁴⁰ A positive result of any screening test (in this case, telling previously "healthy" patients that they now have diabetes) may be received with negative feelings,⁴¹ but support at the time of diagnosis usually helps. There is also the danger of obtaining a false-positive test result. A study of people falsely told that they had hypertension⁴² found that these people reported more symptoms of depression and a lower state of general health than a matched normotensive group.

It is possible that some patients newly diagnosed with diabetes may subsequently be found to be normal, but previous work suggests that the risk for false-negative results may be greater than for false-positive results. The use of determining fasting plasma glucose levels to establish a diagnosis of diabetes has been found to be highly specific (in the range of 98.1% to 99.7%) but to have only moderate sensitivity (in the range of 46.2% to 79.0%, depending on the population studied).^{43,44} Fasting plasma glucose levels have a good predictive value (in the range of 94%–98%) for a negative diagnosis of diabetes. In this population of patients 40 years of age and older with a diabetes prevalence of greater than 10%, the positive predictive value is about 90%.⁴³ In the total population of Newfoundland, where the expected prevalence of diabetes is 4% to 5%, the positive predictive value is lower. The diagnosis of diabetes is not easily made; even the classic glucose tolerance test (GTT) produces variable results over time in the same patient.^{6,13} Conversely, a negative result of a test is usually reassuring.^{45–48} In Newfoundland, where diabetes is common and many families have at least one member with the disease, it was possible to reassure the 927 people who tested negative that they did not have the disease at the time of testing. The participating physicians reported that their screening was well received by their patients.

Concern has been expressed that the use of capillary whole blood by the fingerprick method may not be as accurate as using venous blood for blood glucose determinations. A recent British study found good correlation between venous blood glucose levels and reagent strips read with a reflectance meter at the time of sampling.⁴⁹ Even if there were some false-positive results, with only 9 positive results in 1264 tests, the effect on the total prevalence rate would be low. The same study found that home testing with fingerprick blood samples and reflectance meters was the most acceptable method to patients with diabetes.⁴⁹

It can be argued that the criterion of two fasting whole blood glucose levels \geq 7.8 mmol/L (140.5 mg/dL) used in this study is not sufficient to make a diagnosis of diabetes, and that in addition to a high fasting blood glucose level, a blood glucose level greater than 11.0 mmol/L (198 mg/dL) 2 hours after an oral glucose load is necessary, as suggested by the World Health Organization.50 The instructions to the family physicians who took part in this study cautioned them that, even in the presence of high fasting blood glucose levels on two occasions, further testing might be needed to confirm that diabetes was present. Even if a GTT was not done, some studies have suggested that determining the patient's glycosylated hemoglobin level as well an FPG level as additional criteria on which to base the diagnosis of diabetes.51

It could be argued that the results of our study, which was restricted to one small rural area of Canada, are not generalizable to other settings. Although there is a high prevalence of diabetes in Newfoundland, it is likely that physicians in other areas of the developed world are equally aware of the disease and, like us, may well have identified most of their patients who have the disease.

Our study has confirmed the recommendations of the Canadian Task Force on the Periodic Health Examination⁵² and the US Preventive Services Task Force⁵³ that there is "fair evidence to support the recommendation that screening for diabetes be excluded from consideration in a periodic health examination of the healthy nonpregnant adult, and there is fair evidence to support the recommendation that the condition be considered only in high risk groups, such as those with a family history of diabetes, those who are pregnant and those people with circulatory problems." The benefits of screening for diabetes have yet to be clearly demonstrated in terms of any reduced morbidity or mortality.

Although the study has provided us with baseline FPG readings on approximately 1000 patients, which may be of value in future years for the care of these patients, it seems that at the present time, in the part of Newfoundland studied, most patients with diabetes have been detected and there is no need for routine screening of all patients aged 40 years and older. Such screening should be reserved for those patients who are at higher than average risk. It is likely that with the increased awareness of diabetes and the increased use of reflectance glucometers, most people with diabetes have already been detected. There is therefore no need for physicians to do additional screening of their patients, above what they are already apparently doing.

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