

Diabetes Screening in Canada (DIASCAN) Study

Prevalence of undiagnosed diabetes and glucose intolerance in family physician offices

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OBJECTIVE — To assess the prevalence of undiagnosed diabetes and glucose intolerance in individuals ≥ 40 years of age who contacted their family physician for routine care.

RESEARCH DESIGN AND METHODS — The study used a stratified randomized selection of family physicians across Canada that was proportional to provincial and urban/rural populations based on Statistics Canada Census data (1996). Consecutive patients ≥ 40 years of age were screened for diabetes. If a casual fingerprick blood glucose was > 5.5 mmol/L, the patient returned for a fasting venous blood glucose test. If the fasting blood glucose was 6.1–6.9 mmol/L, a 2-h 75-g post-glucose load venous blood glucose was obtained. Results of these tests were used to classify patients in diagnostic categories.

RESULTS — Data were available for 9,042 patients. Previously undiagnosed diabetes was discovered in 2.2% of the patients, and new glucose intolerance was found in an additional 3.5% of patients. Overall, 16.4% of patients had previously known diabetes. The decrease in fasting plasma glucose criterion from 7.8 to 7.0 mmol/L resulted in a 2.2% versus a 1.6% prevalence of new diabetes. Several risk factors were reported in a significantly greater proportion of patients with new glucose intolerance and either new and known diabetes compared with the normal glucose tolerance group of patients.

CONCLUSIONS — Routine screening for diabetes by family physicians is justified in patients ≥ 40 years of age, given the finding of previously undiagnosed diabetes in 2.2% of these patients and newly diagnosed glucose intolerance in an additional 3.5% of these patients. Another 16.4% of primary care patients ≥ 40 years of age have known diabetes. This has important implications regarding health resources and physician education.

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It is estimated that ~1.5 million Canadians (5% of the population) have been diagnosed with diabetes and that 3–5% of the general adult population is thought to have undiagnosed type 2 diabetes (1,2). Type 2 diabetes is the most preva-

lent form of the disease, and because it is often asymptomatic in its early stages, it frequently goes undiagnosed for many years. Hyperglycemia develops gradually, and a degree of hyperglycemia sufficient to cause pathological and functional

changes in various target tissues may not be severe enough for the patient to notice any of the classic symptoms of diabetes (3). Type 2 diabetes is usually only recognized 5–12 years after hyperglycemia develops (4).

Many of these asymptomatic patients will have or will be at risk for preventable diabetes complications (5). Epidemiological evidence shows that retinopathy begins to develop at least 7 years before the clinical diagnosis of type 2 diabetes (6). Individuals with type 2 diabetes are at a significantly higher risk for coronary heart disease, stroke, and peripheral vascular disease than nondiabetic individuals (7). They also have a greater likelihood of having dyslipidemia, hypertension, and obesity (8). Tests for hyperglycemia can identify these asymptomatic patients (9).

Studies have clearly demonstrated that lowering blood glucose delayed the onset and slowed the progression of microvascular complications in patients with type 1 diabetes (10,11). There is now evidence that lowering blood glucose also reduces the incidence of microvascular complications in type 2 diabetes (12). The U.K. Prospective Diabetes Study (13–16), the largest and longest study with type 2 diabetic patients ever conducted, reported that the overall microvascular complication rate was decreased by 25% by lowering blood glucose levels with intensive therapy.

As a result of the increasing burden of the disease, its complications, and, most importantly, the potential to prevent these complications with earlier diagnosis and more aggressive treatment of hyperglycemia, efforts are underway to aid the earlier diagnosis of diabetes. In an attempt to better detect these undiagnosed cases of type 2 diabetes, the Canadian Diabetes Association (CDA) has recommended routine screening for the presence of diabetes in individuals ≥ 45 years of age, as well as in other individuals at increased risk (9). Family physician offices provide an excellent opportunity for screening.

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Abbreviations: ADA, American Diabetes Association; CDA, Canadian Diabetes Association; FPG, fasting plasma glucose; IGT, impaired glucose tolerance; PG, post-glucose load.

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

Most Canadians see their family physician on a regular basis (17), and the family physician can obtain appropriate consent and can follow up on any abnormal results.

The purpose of this study was to evaluate the prevalence of undiagnosed diabetes and glucose intolerance in the Canadian population. The study also assessed the feasibility of screening patients ≥ 40 years of age in primary care physician offices when patients present for routine care. Diagnostic categories for patients who were not known to have diabetes were defined based on results from up to three glucose tests. An initial casual capillary blood glucose test (with a cutoff of >5.5 mmol/l for further testing) was performed in the office to easily rule out most patients, so they would not have to go to a laboratory for a fasting plasma glucose (FPG) test. Only individuals with values above the cutoff were sent for an FPG test, and the results of the FPG test determined whether patients required an 2-h 75-g post-glucose load (PG) test for final diagnosis.

RESEARCH DESIGN AND METHODS

The study was designed to test the assumption that the prevalence of new diabetes cases in Canada could be as high as 5%. The sample size was calculated so that even a very small prevalence (0.02%) would be detected with a type 1 error of 0.05 and a power of 80%. A total of 20,000 patients were to be enrolled by 400 primary care physicians. The physicians were selected using a stratified randomized sampling method to ensure accurate representation of the population across Canada (18). The proportion of the 400 physicians randomly selected from each province matched the proportion of the Canadian population in that province, relative to the total Canadian population (based on 1996 Statistics Canada Census data). Postal codes were used to stratify further physician selection to match the mix of urban versus rural practices reported within each province.

Each physician was to enroll 25 consecutive men and 25 consecutive women who presented for routine care. Patients had to be at least 40 years of age and free from an intercurrent illness that might affect glucose tolerance. It was at each physician's discretion to determine intercurrent illnesses that might affect glucose tolerance: the protocol provided

Table 1—Definition of diagnostic categories for diabetes

| Previously diagnosed | Casual capillary blood glucose (mmol/l) | FPG (mmol/l) | 2-h Blood glucose (mmol/l) | Diagnostic category |
|----------------------|---|--------------|----------------------------|--------------------------|
| No | >5.5 | ≥ 7.0 | — | New diabetes |
| No | >5.5 | 6.1–6.9 | ≥ 11.1 | New diabetes |
| No | >5.5 | 6.1–6.9 | 7.8–11.0 | IGT |
| No | >5.5 | 6.1–6.9 | <7.8 | Impaired fasting glucose |
| No | ≥ 11.1 | — | — | Probable diabetes |
| Yes | — | — | — | Known diabetes |
| No | >5.5 | ≤ 6.0 | — | Normal glucose tolerance |
| No | ≤ 5.5 | — | — | Normal glucose tolerance |

an example of acute infection. Patients receiving glucocorticoids were also excluded. All patients provided written informed consent to participate in the study. Ethics committee review was conducted by Phoenix International Life Sciences Institutional Review Board, and approval was granted on 17 March 1998. Patient enrollment began on 1 April 1998 and finished on 17 September 1998.

A diabetes screening questionnaire was completed for each participant before blood glucose levels were measured to avoid recall bias. The nurse or receptionist inserted basic demographic data including each patient's date of birth, sex, and initials.

The patient was asked to complete a portion of the questionnaire collecting data concerning past diagnosis of diabetes and risk groups for diabetes. The past diagnosis of diabetes section queried whether patients had ever been told that they had diabetes or high glucose levels and if so, what year were they diagnosed and what treatment(s) were they following (insulin injections, diabetic pills, increased physical activity, diet, or no treatment). In the section addressing risk groups for diabetes, the patient indicated whether any of the following was applicable to him/her: >40 years of age; has a parent, sibling, or child with diabetes; has high-risk ethnicity (Hispanic, aboriginal Canadian, Asian, African-Canadian, or Pacific Islander); had gestational diabetes; or has given birth to a baby weighing >10 lb.

Before the capillary blood glucose measurement, the family physician completed the rest of the questionnaire, including data concerning the presence or absence of the following risk factors for diabetes: high blood pressure; low HDL level; elevated triglyceride level; previ-

ously identified impaired glucose tolerance (IGT); and coronary heart disease, angina, or previous heart attack. The doctor indicated "yes," "no," or "unknown" for each risk factor based on knowledge of the patient, as his/her family physician. Specific criteria for high blood pressure, etc., were not defined and were based on the individual doctor's judgement. The physician also recorded patient height and weight and the date, time, and results of the capillary blood glucose test, as well as the FPG and 2-h PG, if performed.

Patients with known diabetes completed the questionnaire but did not proceed with the blood tests. Each patient who did not have known diabetes had a casual fingerprick capillary blood glucose level determined by the physician or his/her trained designate using a Precision QID Blood Glucose Testing System (Abbott Laboratories, MediSense Products, Bedford, MA). The Precision QID system is a biosensor based on electron-mediated glucose oxidase reaction. The system gives results within 20 s and is calibrated to provide blood glucose results to agree with plasma-referenced laboratory analyzers. The glucose measurement range is 1.1–33.3 mmol/l.

If the capillary blood glucose was >5.5 mmol/l, the patient returned for a FPG test on a different day. A low screening threshold of >5.5 mmol/l was chosen based on results of an Australian diabetes screening study reporting a maximized case-finding rate using this cutoff as the basis for further testing (19). If the FPG was 6.1–6.9 mmol/l, the patient returned for a 75-g 2-h PG. In 1997, the American Diabetes Association (ADA) lowered the fasting glucose criterion for the diagnosis of diabetes from 7.8 to 7.0 mmol/l to increase the sensitivity of the diagnostic test

and to reduce the number of missed diagnoses (20). The CDA also incorporated this change in their 1998 guidelines (9). The lowered value of ≥ 7.0 mmol/l was incorporated into the diagnostic criteria for diabetes used in this study.

Diagnostic categories were defined according to the criteria summarized in Table 1, including blood glucose test results. The four major diagnostic categories were normal glucose tolerance, known diabetes, new diabetes, and new glucose intolerance. The category of new glucose intolerance included patients who were defined as having impaired fasting glucose, impaired glucose tolerance, or probable diabetes.

Data were summarized by percentage and analyzed with χ^2 statistics. A preliminary analysis of 7,991 patients, performed to observe trends in the data, was presented at the CDA Meeting in Calgary, October 1998. The observed prevalence rates from the survey data were sufficiently high to justify a smaller sample size (~10,000) for well-powered analyses. The study was completed when 9,564 patients had been enrolled. Because of the relatively small percentage of patients recruited from the Atlantic Provinces (Nova Scotia, New Brunswick, Prince Edward Island, and Newfoundland), data from these provinces were combined. Adjusted prevalence rates were calculated for the diagnostic categories of new diabetes and new glucose intolerance to account for provincial and urban/rural survey response imbalances for planned versus actual enrollment (see APPENDIX).

Risk factor frequency calculations included all patients for whom the absence or presence of the risk factor was known by the physician; this ranged from 7,536 (83%) to 7,744 (86%) patients for the five physician-recorded risk factors for diabetes. The total number of patients included in each diagnostic category for each risk factor is indicated in the applicable table. Height and weight data are not reported because of the inability to distinguish between imperial versus metric units in the recorded data.

RESULTS — A total of 9,564 patients were enrolled in the study by 241 family physicians across Canada. Initial data cleaning removed nine duplicate entries. Capillary blood glucose values were missing for 513 patients who had not been previously diagnosed with diabetes. Of

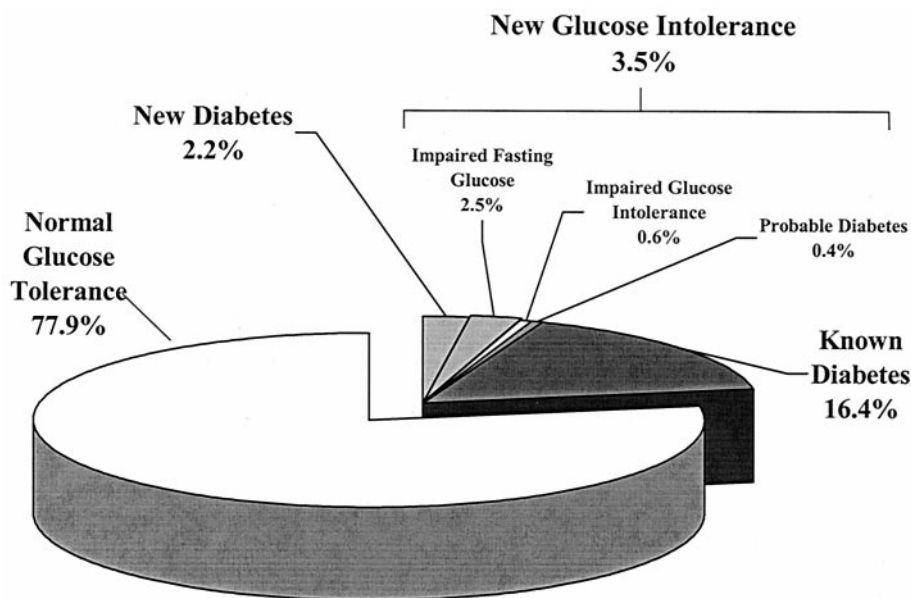


Figure 1—The proportion of 9,042 patients defined in each diagnostic category of diabetes for Canada-wide data.

the remaining 9,042 patients available for data analysis, 2 had not recorded the name of the center and therefore could not be included in any analysis by province or urban versus rural location. In addition, 162 patients had missing or unreliable information regarding date of birth, and 179 patients had missing information regarding sex and were therefore excluded from analysis by age or sex. In accordance with the protocol, 3,684 of 4,803 patients (76.7%) with capillary blood glucose >5.5 mmol/l returned for an FPG test, and 321 of 766 patients (41.9%) with an FPG ≥ 6.1 mmol/l had a 2-h PG performed.

Overall, 71.5% of the patients were from urban practices, and 28.5% were from rural practices. Of the 8,863 patients for whom sex was recorded, 51.9% of patients were female and 48.1% male. Of the 8,880 patients for whom the date of birth was recorded, 25% were 40–49 years of age, 25.9% were 50–59 years of age, 22.6% were 60–69 years of age, and 26.5% were >70 years of age.

Prevalence of diabetes/glucose intolerance

The proportion of patients classified in each diagnostic category is presented in Fig. 1 for all of Canada. The screening process identified previously undiagnosed diabetes in 2.2% of patients and newly diagnosed glucose intolerance

(consisting of impaired fasting glucose, IGT, and probable diabetes) in an additional 3.5% of patients. After statistical adjustment for unbalance in patient enrollment for province and urban versus rural setting, the estimated prevalence of new diabetes in Canada is at least 2.3% and the estimated prevalence of new glucose intolerance is at least another 3.4%.

The decrease in FPG criterion from 7.8 to 7.0 mmol/l recommended by the ADA in 1997 and the CDA in 1998 for the diagnosis of diabetes resulted in a 2.2 vs. 1.6% prevalence of new diabetes.

The use of a >5.5 mmol/l cutoff for further testing after the casual capillary blood glucose rather than a >7.5 mmol/l cutoff resulted in a prevalence of newly diagnosed diabetes of 2.2% instead of 1.4%. The prevalence of previously undiagnosed glucose intolerance was 3.5% compared with 1.4%. A cutoff of >7.5 mmol/l rather than the >5.5 mmol/l value that was previously used would have overlooked 72 cases of new diabetes and 188 cases of new glucose intolerance in the 9,042 patients included in the study.

Overall, 16.4% of patients >40 years of age who made a routine visit to their primary care physician had previously known diabetes. Reported treatments included insulin injections for 12.2%, increased physical activity for 20.0%, diet and tablets for 29.3%, diet only for

Table 2—Proportion of patients with risk factors for diabetes by diagnostic category

| Risk factor/group | New glucose intolerance | New diabetes | Known diabetes | Normal glucose tolerance |
|----------------------------------|-------------------------|----------------|-------------------|--------------------------|
| High blood pressure | 138/263 (52.5)* | 86/178 (48.3)* | 602/1,070 (56.3)* | 2,117/6,233 (34.0) |
| Elevated triglycerides | 66/260 (25.4)* | 42/173 (24.3)* | 341/1,043 (32.7)* | 906/6,117 (14.8) |
| Heart disease | 53/260 (20.4)* | 36/174 (20.7)† | 253/1,020 (24.8)* | 752/6,082 (12.4) |
| Low HDL | 40/258 (15.5)† | 24/175 (13.7) | 209/1,039 (20.1)* | 598/6,103 (9.8) |
| Previously identified IGT | 21/261 (8.0)* | 29/172 (16.9)* | 611/992 (61.6)* | 92/6,123 (1.5) |
| Family history | 135/318 (42.5)* | 75/203 (36.9) | 641/1,485 (43.2)* | 2,161/7,036 (30.7) |
| Member of high-risk ethnic group | 26/318 (8.2) | 15/203 (7.4) | 149/1,485 (10.0)‡ | 573/7,036 (8.1) |
| History of gestational diabetes | 3/318 (0.9) | 8/203 (3.9)† | 64/1,485 (4.3)* | 94/7,036 (1.3) |
| Delivered baby >10 lbs | 6/318 (1.9) | 9/203 (4.4) | 58/1,485 (3.9)‡ | 191/7,036 (2.7) |

Data are n (%). New glucose intolerance = impaired fasting glucose + impaired glucose tolerance + probable diabetes. * $P < 0.001$, † $P < 0.01$, and ‡ $P < 0.05$ all compared with normal glucose tolerance.

22.0%, tablets only for 14.5%, and no treatment for 13.5%.

Previously undiagnosed diabetes was found in 2.0% of women versus 2.4% of men enrolled in the study. Similarly, a new diagnosis of glucose intolerance was found in 3.0% of females versus 4.0% of males. The normal glucose tolerance group was 46.9% male, whereas the new diabetes group was 52.6% male, and the new glucose intolerance group was 54.6% male ($P = 0.009$ compared with the normal glucose tolerance group).

The proportion of patients in the diagnostic categories was calculated by 5-year age-groups. The prevalence of new diabetes tended to increase with age, with a minimum of 1.4% in the 40–44 and 45–49 years age ranges and a maximum of 3.4% in the 65–69 years age range. The prevalence of new glucose intolerance ranged from 1.7% in the 40–44 years age range to 5.3% in the 75–79 years age range.

When the data were assessed by urban versus rural practice setting, new diabetes was discovered in 2.0% of urban patients versus 2.9% of rural patients. New glucose intolerance occurred in 3.0% of urban patients and in 4.9% of rural patients. There was a significantly greater proportion of rural patients in the new diabetes group (36.5%, $P = 0.004$) and in the new glucose intolerance group (39.6%, $P = 0.001$) compared with the normal glucose tolerance group (27.3%). Data were also assessed according to province. The prevalence of new diabetes ranged from 1.5 to 4.2%, and the prevalence of new glucose intolerance ranged from 2.5 to 9.9% in the different provinces (Manitoba had the highest prevalence).

Risk factors in patients with diabetes/glucose intolerance

Questions regarding the presence of nine possible risk factors for type 2 diabetes were included in the survey. The proportion of patients with these risk factors is presented for each of the four main diagnostic categories in Table 2. There was a significantly higher prevalence of all nine risk factors in the patients with known diabetes versus the patients with normal glucose tolerance ($P < 0.001$; except ethnic group and having delivered a baby >10 lbs, $P < 0.05$). There was a significantly higher prevalence of high blood pressure ($P < 0.001$), elevated triglyceride levels ($P < 0.001$), heart disease ($P < 0.01$), and previously identified IGT ($P < 0.001$) in both the new diabetes group and the new glucose intolerance group compared with the normal glucose tolerance group. In addition, significantly more patients in the new glucose intolerance group had a family history of diabetes ($P < 0.001$) and low HDL ($P < 0.01$). A significantly greater proportion of the new diabetes group had a history of gestational diabetes ($P < 0.01$) compared with the normal glucose tolerance group.

CONCLUSIONS—Hyperglycemia in type 2 diabetes causes microvascular disease and may cause or contribute to macrovascular disease, making undiagnosed diabetes a serious condition. The results of this study indicate at least a 2.2% prevalence of undiagnosed diabetes and at least a 3.5% prevalence of undiagnosed glucose intolerance. These values are similar to the 2.0% of new cases of diabetes and the 3.4% of new cases of impaired glucose tolerance reported in a similar Australian general practice diabetes screening study in addition to the 2.7% prevalence of undiagnosed diabetes reported from the Third National Health and Nutrition Examination Survey in the U.S. (19,21).

The Canadian values likely represent underestimates of the true prevalences because almost a quarter of the individuals with casual capillary blood levels >5.5 mmol/l did not return for the required FPG test, and just less than half of patients with an FPG of 6.1–6.9 mmol/l had a 2-h PG performed. Any differences between individuals who returned for the FPG test and those who did not return is unknown. According to the diagnostic criteria, all those with an FPG of 6.1–6.9 mmol/l who did not return for a 2-h PG (445 patients, 4.9%) had abnormal glucose tolerance and would have been classified as having either new diabetes or new glucose intolerance.

The testing and diagnostic categories defined in the study did not detect individuals with an isolated 2-h PG ≥ 11.1 mmol/l but a normal fasting glucose (< 6.1 mmol/l). Results of the Diabetes Epidemiology Collaborative Analysis of Diagnostic Criteria in Europe Study indicated that these individuals with “isolated postchallenge hyperglycemia” have a risk of premature death of the same order as other patients with diabetes (22).

In addition, this study could not obtain data for the population of individuals who did not visit their family physician for routine care. Canada has a publicly funded health care system for physician services with no user fees acting as financial obstacles to access primary care physicians. A total of 86% of Canadians report that they have a regular medical doctor, and 78% consulted their family

physician or general practitioner at least once over a 1-year period (17). It is unclear whether this population would be at a higher risk for diabetes because they avoid doctors or are deniers and are in fact less healthy or whether they would be at less risk because the reason that they do not routinely visit their family physician is because they are healthier. Authors of a recent Canadian study assessing visits by adults to family physicians for the common cold reported that they found few determining characteristics of the adults themselves that explained whether a visit would be made (23).

The study revealed that the prevalence of undiagnosed diabetes tended to increase with patient age. In addition, a significantly greater proportion of new diabetes and new glucose intolerance was found in rural versus urban areas. This was somewhat unexpected, as urban areas tend to include a greater proportion of individuals from ethnic groups at a higher risk for diabetes, and one would therefore expect to find more undiagnosed diabetes and glucose intolerance in urban rather than rural areas. The 1997 ADA and 1998 CDA recommended decrease in FPG criterion for the diagnosis of diabetes (from 7.8 to 7.0 mmol/l) (9,20) resulted in a 2.2% versus a 1.6% prevalence of new diabetes.

There was a significantly higher prevalence of several risk factors in patients with new diabetes or new glucose intolerance compared with patients with normal glucose tolerance. Risk-factor data were not systematically collected for all individuals and were unknown by the family physicians for 14–17% of the patients. This may have affected the statistical associations between risk factors and diabetes.

The study also found that 16.4% of patient visits to family physicians are by patients with known diabetes. This is notably higher than the 5.1% overall prevalence of self-reported diabetes in Canadian adults (1), suggesting that diabetic patients are using a high proportion of family physician services. The higher values in the study may be partially explained by the fact that the study included older individuals (≥ 40 years of age), whereas the national prevalence values included adults 18–74 years of age and reported that the prevalence rates increased with age (1).

The recommendation of the CDA to

routinely screen people >45 years of age for diabetes has created controversy. Marshall (24) argued that there is no evidence that such screening will decrease morbidity or mortality. Gerstein and Meltzer (25) support the CDA recommendation and cite preventive therapies that have proven effective in diabetes. They argue that good diabetes care is good preventive medicine. Similarly, Mahon (26) noted that the knowledge of treatments that prevent the progression of some complications of diabetes justifies the recommendation for screening. The results of this study demonstrate that a substantial proportion of Canadians with type 2 diabetes remain undiagnosed. Both diagnosed and undiagnosed diabetes are strong risk factors for chronic disease and significant morbidity and mortality (25). Screening for type 2 diabetes was easily performed in primary care physician offices when patients presented for routine care. The screening process yielded a clinically significant number of cases of new diabetes and new glucose intolerance, and the data support the current CDA and ADA recommendations to screen high-risk individuals.

APPENDIX

Adjustment for survey design unbalance

The following method was used to adjust the unbalance between provinces:

Let $w(i)$ be the assigned weight for the province i .

Let $o(i)$ be the observed weight for province i .

Let $p(i)$ be the observed frequency of diabetes for province i .

Let $p^*(i)$ be the adjusted frequency by province that is calculated as follows:

$$p^*(i) = p(i) \times w(i)/o(i).$$

The Canada-wide adjusted frequency is $P(\text{Canada}) = \text{sum}\{[p(i) \times w(i)/o(i)]w[i]\}$, summation over all provinces.

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A preliminary analysis of data was presented as a poster at the Professional Conference and Annual Meetings of the CDA in Calgary, 17 October 1998. The final data were presented as a poster at the CDA meeting in

Ottawa and at the ADA meeting in San Diego, CA, in 1999.

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