The BRAID Study Design: Believing We can Reduce the Aboriginal Incidence of Diabetes

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Background

> The fact that Sandy Lake holds a record, of sorts, as having the third highest prevalence of diabetes in the world is more a tragedy than a source of prestige … it is imperative that we salvage the next generation from the ravages that are plaguing this generation. The preventable nature of this complex combination of physical and social calamity demands action. Harry Meekis, Sandy Lake First Nation (Elliott 1997).

Type 2 diabetes incidence, prevalence, complications, and costs are increasing worldwide (Rubin et al. 1994, Simpson et al. 2003, Venkat Narayan et al. 2000, Zimmet 2000). By 2025 it is estimated that 333 million people will have diabetes, most of whom will inhabit China, India, and the United States (King et al. 1998). Ethnicity appears to be an important predictor of the disease, as the prevalence rates are higher in virtually all ethnic groups in contrast to the Caucasian population (Kenny et al. 1995). Disease prevalence has been rising since the early 1960s; however, over the past couple of decades there has been an explosion in the incidence of diabetes. While type 2 diabetes was once a disease of the elderly, it has recently become increasingly prevalent in youth. The factors that are thought to predispose people to type 2 diabetes are: heredity, age, ethnicity, socioeconomic status, obesity, and lack of physical activity (Zimmet et al. 2001). Individuals with diabetes are at high risk of cardiovascular disease because the majority have hypertension, dyslipidemia, and are obese (Haffner 1998). It is estimated that, on average, people have had type 2 diabetes for up to 12 years before they are diagnosed (Harris and Eastman 1996, Harris 1993a). Research also suggests that retinopathy (eye damage) can be present as early as 7 years prior to diagnosis with diabetes and hyperglycemia (high blood sugar) (Harris 1993b).

The BRAID (Believing we can Reduce the Aboriginal Incidence of Diabetes) study analyzed data on 1220 Aboriginal people in Alberta who were screened for diabetes, prediabetes, the metabolic syndrome, and other cardiovascular risk factors with portable technology. Data was collected from 2001 to 2005 from 43 Aboriginal communities including Metis settlements and First Nations reserves.

Hypothesis

1. Portable technology used in screening for type 2 diabetes, prediabetes, the metabolic syndrome, and risk factors in a rural setting are comparable to laboratory standards used in major urban centres.

2. The prevalence of type 2 diabetes, prediabetes, the metabolic syndrome, and other risk factors will be significantly higher in an opportunistic screening project as compared to a population based screening project.

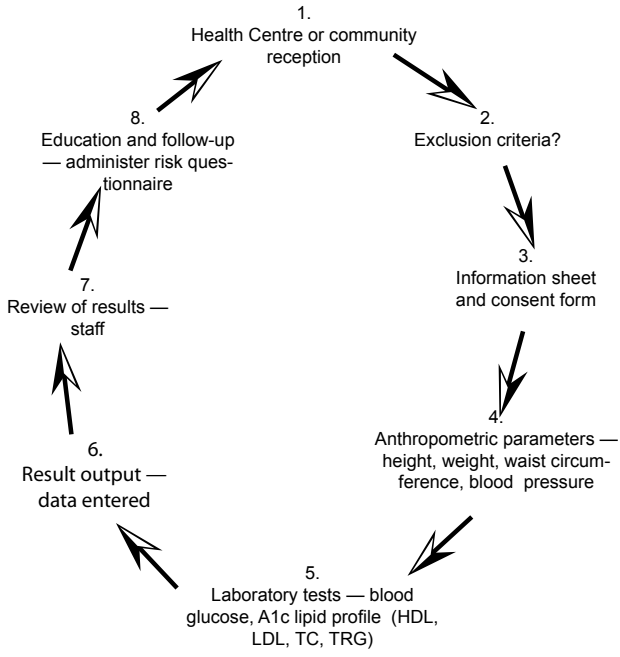
The SLICK, MDSi, and BRAID Projects

Three projects were analyzed in this research. All projects are concerned with Aboriginal peoples in Alberta: First Nation people on First Nation reserves; Metis people living on Metis settlements; in remote areas of Alberta. The three projects are named SLICK, MDSi, and BRAID.

The SLICK project — Screening for Limbs, I-eyes, Cardiac, and Kidneys

The SLICK Project is an Alberta First Nations–University of Alberta–First Nations and Inuit Health branch of Health Canada initiative. It aims to reduce the burden of diabetes among First Nations communities in Alberta by providing access to a comprehensive, coordinated, and integrated screening program for limb, I-eyes, cardiac, and kidney complications of diabetes. The SLICK project, commenced in 2001, provides two mobile vans equipped with screening staff and portable testing equipment to all 44 Alberta First Nations communities. Screening of clients with known diabetes includes retinal photography, and lab testing for glucose, A1c, lipids and microalbumin (see Figure 1). The program provides relevant education and counselling in conjunction with screening activities. Results for each individual are printed and delivered on site to the client, the nurse or health centre, and/or the doctor(s). The SLICK program is designed to increase awareness of diabetes complications and their management, as well as to increase services. Intermediate goals include client empowerment, and increased identification of complications. It is hoped that the achievement of these short-term and intermediate goals will eventually lead to the long-term outcome of decreasing the burden of diabetes among First Nations populations. Current funding and operation is through Health Canada. Although initially conceived as a program to screen for complications of diabetes, consenting individuals wishing to be screened for diabetes are assessed with a pre-specified protocol. Thus the SLICK project is an opportunistic screening project that screens volunteers wishing to be screened for diabetes. The exclusion criteria used in this project are shown in Table 1.

Figure 1. The SLICK, MDSi, and BRAID projects



The MDSi project — The Mobile Diabetes Screening Initiative

The ten-year Alberta Diabetes Strategy comprises four components of which one is to provide resources for "screening for diabetes and its complications" in Aboriginal "off reserve" and remote Alberta communities. A specialized team travels to Metis Settlements and other remote communities in a van transporting portable testing equipment. The MDSi project is similar to the SLICK project in respect to screening for diabetes complications. It is also a screening program for volunteers who are interested in being tested. Screening protocols and exclusion criteria are identical to SLICK. Individual counselling is provided to all clients by a diabetes educator. The majority (~70%) of individuals who visited the MDSi van have not been previously diagnosed with diabetes.

The BRAID project — Believing we can Reduce the Aboriginal Incidence of Diabetes

The BRAID project is exclusively carried out in a single First Nation community in Northern Alberta. This project's main focus is to screen all members of the community over the age of six who have not been previously

diagnosed with diabetes. This project is different from the SLICK and MDSi project in that it is a population-based screening project. This project actively encourages all the members of the community to come and be screened. The project utilizes health care centre staff (in the community) to recruit individuals to the screening project. The exclusion criteria are similar to the SLICK project and the MDSi project (see Table 1). The BRAID project screens clients for diabetes using the same portable technology and protocols as SLICK and MDSi. The BRAID and MDSi projects also administer the seven question "American Diabetes Association Risk Questionnaire" (ADA Score). The questions asked relate to the individuals BMI, age, physical activity, mothers with high-birth-weight offspring, and genetic precursors to diabetes. Each question is given a score, and then, once the questionnaire has been administered, the scores are summed. A score of 10 or greater places an individual at higher risk for having undiagnosed diabetes. Three additional "yes or no" questions are asked, to determine any influence of heredity, medications, or history of gestational diabetes in women on the frequency of diabetes. These values were not scored. All individuals with significant abnormal findings are referred and encouraged to see their doctors. The BRAID project is one of a few community diabetes screening initiatives in Canada's First Nations. This project is partially funded by the Aboriginal Diabetes Initiative (ADI) and the University of Alberta.

Table 1. Exclusion criteria for the SLICK, MDSi and BRAID projects when screening clients previously undiagnosed with diabetes

Exclusion Criteria
Under Age 6
Inability to give consent
Documentation of Diabetes (FPG > 7.0mmol/L or Random >11.1mmol/L)
Prediabetes (IFG: FPG > 6.1mmol/L, or Random > 7.8mmol/L)
Medications for Diabetes
Pregnancy or < 6 weeks post partum
Foreshortened Life Expectancy (<12 months)
Hospitalization, or any stress (<1 month ago)
Use of Corticosteroids (< two weeks ago)

Note: Individuals who were > 6 weeks post partum and had gestational diabetes were screened.

Ethics

Before obtaining appropriate permission from individuals and organizations, the BRAID study underwent ethics review with the Health Research Ethics Board (HREB) at the University of Alberta. The SLICK, MDSi, and BRAID projects have their own separate ethics approval to work with their respective communities. Approval was obtained simultaneously and in discussion with Health Directors and/or Chief and Council in First Nations communities, and appropriate persons or committees in Metis settlements who were contacted and asked to verbally and/or in writing provide approval and cooperation with the research. Once the respective community approval was received, and the projects implemented, each individual was asked to read an information sheet and consent to the SLICK, MDSi, or BRAID projects. The main aspects of the individual consents pertaining to research are the permission to enter the results in a database (computer), and the permission to send relevant clinical results to caregivers (nurses or physicians). Permission for aggregate analysis is also important. Individuals can, upon request, receive "health services" screening for diabetes, and withhold consent for research.

Data Collection

After informed consent is discussed, each individual was assessed against the exclusion criteria (Table 1). In a small number of cases, where exclusion criteria applied, "health services" were carried out if clinically reasonable. These individuals will not be included for the analysis of this study. Individuals that were not excluded then had anthropometric measurements taken. Body mass index (BMI) was calculated by dividing the weight in kilograms by the height squared (kg/m^2). All three projects used the Cholestech LDX® analyzer for measurement of blood glucose (fasting or random), high density lipoprotein (HDL cholesterol), low density lipoprotein (LDL cholesterol), total cholesterol (TC), and triglycerides (TG). If a random blood test was done (individual being tested had any food or drink within the previous 8 hours) triglyceride and low density lipoprotein values were disregarded, since these tests are not reliable in a random state. The DCA 2000® analyzer was used for measurement of hemoglobin A1c (A1c), which is not affected by the random state.

Quality Assurance

Prior to blood collection, a strict quality assurance (QA) procedure was completed on the Cholestech LDX®, and the DCA 2000® analyzers. This QA

procedure was completed in cooperation with Canadian External Quality Assurance Laboratories (CEQAL, Vancouver BC). The analyzers were tested before being used in the field to ensure accurate functioning. Each project had separate analyzers. The analyzers were handled with utmost care because of their delicate instrumentation.

The DCA 2000® and Cholestech LDX® performance characteristics are similar to those achieved at major testing centres in urban communities, as assessed by the CEQAL. Thus, in our analysis, we plan to use the Cholestech LDX® determined fasting glucose as the "standard." In the BRAID project we also utilize the OneTouch® Ultra® blood glucometer as an additional measure of glycemia. Each glucometer is coded to the correct test strip lot number,

Table 2. Project, study, and community statistics

	The BRAID Study			
Project	*BRAID (population based)*	*MDSI (opportunistic)*	*SLICK (opportunistic)*	*Total*
Number screened (unique)	309	562	357	1220
Communities visited (unique)	1	8	34	43
Potential population available for screening	450	3694	43144	47288
Percent screened	68.7	15.2	0.8	2.6

Table 3. Breakdown of gender and age in the three projects

	The BRAID Study		
	BRAID	*MDSI*	*SLICK*
Gender			
Female	57.0%	62.6%	65.3%
Male	43.0%	37.4%	34.7%
Age (Mean years)	29.8	38.4	41.9
5-19	37.2%	19%	5.3%
20-39	30.8%	31.9%	42%
40-59	26%	35.8%	39.2%
60-79	6%	12.3%	12.4%
>80	0%	1%	1.1%

Table 4. Summary of the Analyses

Hypothesis	*Data Fields Required*	*Data Source*	*Analyses*
Diagnostic Accuracy	1. Fasting Cholestech LDX® Glucose 2. Fasting OneTouch® Ultra® Glucometer Glucose 3. A1c (DCA 2000®)	1. BRAID, MDSi, SLICK 2. BRAID 3. BRAID, MDSi, SLICK	1. A1c ROC 2. Glucometer ROC
Prevalence of: Undiagnosed DM IFG Metabolic Syndrome Risk Factors	1. Fasting Cholestech LDX® Glucose 2. Blood Pressure 3. Lipid Panel 4. Waist Circumference 5. BMI 6. Age 7. Gender 8. Gestational Diabetes 9. Parental Diabetes 10. Siblings with Diabetes 11. Grandparents with Diabetes	1. BRAID, MDSi, SLICK 2. BRAID, MDSi, SLICK 3. BRAID, MDSi, SLICK 4. BRAID, MDSi, SLICK 5. BRAID, MDSi, SLICK 6. BRAID, MDSi, SLICK 7. BRAID, MDSi, SLICK 8. BRAID, MDSi 9. BRAID, MDSi 10. BRAID, MDSi 11. BRAID, MDSi	1 – 11: Frequency distribution on data 1-6: Linear regression analysis for the continuous variables and logistic regression for the categorical variables. 1-6: Analysis of Covariance - for test comparison between groups (opportunistic vs. population based). 8-11: Chi-Square comparisons for determination of association.

and is then verified to be working properly using the quality assurance method that is provided with each machine.

Limitations

The BRAID project has not succeeded in recruiting the entire population of its community. However, it is likely that those declining to participate fall into one of 2 categories: "deniers," who likely know they have risk factors;

and "healthy," simply not interested, or too busy. Seventy percent of community participation is still very high.

It is not known how representative this community is of all Aboriginal communities in Alberta. Preliminary data from Alberta Health and Wellness using analysis of administrative databases for estimating incidence and prevalence of diabetes in First Nations populations indicates this community to be near the higher end. The prevalence of diabetes is 4.2 percent for all communities in Alberta including non-Aboriginal communities. The range of the prevalence of diabetes in Alberta in 2003 was between 2–15 percent, and the BRAID community was ~12 percent. There is not a well documented average for only Aboriginal communities, although it is assumed and initially appears to be higher than 4.2 percent.

Summary

The BRAID study will analyze data on 1220 Aboriginal individuals participating voluntarily in 3 projects that screened for diabetes and its risk factors in Aboriginal communities, where there is heightened awareness of an epidemic of diabetes. Understanding the diagnostic accuracy of the instruments being used in mobile programs will aid in better planning of projects, expansion of testing strategies, and analysis of cost-effectiveness. Understanding the frequencies of abnormalities found in "opportunistic screening" vs. "population-based screening" will assist communities in planning testing protocols for their members.

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