

The BRAID Study

Believing we can Reduce the Aboriginal Incidence of Diabetes

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Master's Thesis

[excerpts]

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ABSTRACT

The BRAID (Believing we can Reduce the Aboriginal Incidence of Diabetes) study assessed 1170 Aboriginal people in Alberta from three unique projects. Individuals were screened for diabetes, prediabetes, the metabolic syndrome, and other cardiovascular risk factors. 43 unique Aboriginal communities including Metis settlements and First Nations reserves were visited. Portable technology was utilized in the screening of all individuals, and was assessed for diagnostic accuracy compared to a laboratory standard. Individuals were screened with one of two strategies; opportunistic or population based. 3.18% of individuals screened had undiagnosed diabetes, 28.3% had prediabetes, 50.4% had the metabolic syndrome, and 51.7% were obese. Age and family history of diabetes were the most significant predictors of diabetes. Regarding diabetes, prediabetes, and the metabolic syndrome, no significant differences in prevalence was found between the opportunistic or population based screening paradigms. Portable technology was shown to be accurate for the determination of diabetes, however it cannot yet be recommended for prediabetes. The BRAID study documented the highest prevalence of prediabetes and the metabolic syndrome in North America.

Chapter 2

Hypothesis

Hypothesis 1

Portable technology will be comparable to standard laboratory methods for determination of diabetes and prediabetes (IFG).

Hypothesis 2

The prevalence of diabetes, prediabetes, diabetes and cardiovascular disease risk factors, and the metabolic syndrome will be higher in an opportunistic screening program (SLICK and MDSI) as compared to a population based screening program (BRAID).

Chapter 3

Methods

3.1 – The projects explained – The SLICK, MDSI, and BRAID projects

Three projects will be utilized for the analysis in this research. All projects are concerned with Aboriginal peoples in Alberta, either with First Nation people on First Nation reserves, or Metis people living on Metis settlements or in remote areas of Alberta. The three projects are named SLICK, MDSI, and BRAID. This section will attempt to briefly describe each of these projects. The three projects have travelled to numerous communities in Alberta.

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

The SLICK Project is a University of Alberta - Alberta First Nations initiative that 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, retinal, cardiovascular, and renal complications of diabetes. The SLICK project commenced in 2001 and involves the deployment of 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. Although initially conceived as a program to screen for complications of diabetes, consenting individuals wishing to be screened for diabetes are pre-screened with portable technology and a pre-specified protocol (see Figure 3.1.2). Thus the SLICK project is an opportunistic screening project that screens volunteers wishing to be screened for diabetes. A specialized team travels to First Nation communities transporting portable testing equipment. The exclusion criteria used in this project are shown in Table 3.1.1. The program provides relevant education and counselling in

conjunction with screening activities. The Alberta Aboriginal Diabetes Initiative is being deployed simultaneously, and both programs are coordinated by the Implementation Committee of the Aboriginal Diabetes Initiative (ICADI). The SLICK program is designed to increase awareness of diabetes complications and their management, as well as 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. The SLICK project is currently funded by Health Canada. Dr. Ellen Toth is the principal investigator from the University of Alberta.

3.1.2 – The MDSI project – The Mobile Diabetes Screening Initiative

In May 2003 Health Minister Gary Mar (Alberta) announced the 10 year Alberta Diabetes Strategy, comprising four components of which one was to provide resources for “screening for diabetes and it’s complications” in Aboriginal ‘off reserve’ and remote Alberta communities. The MDSI project is similar to the SLICK project in respect to screening for diabetes. It is also an opportunistic screening program, screening volunteers who are interested in being screened. A specialized team travels to Metis Settlements and other remote communities in a van transporting portable testing equipment. Screening of clients with known diabetes includes retinal photography, and lab testing for glucose, A1c, lipids and microalbumin. Consenting individuals wishing to be screened for diabetes are pre-screened with portable technology and a pre-specified protocol (see Figure 3.1.2). The exclusion criteria used in this project are shown in Table 3.1.1. Individual counselling is provided to all clients by a diabetes educator. The majority (~70%) of individuals who visit

the MDSI van have not been previously diagnosed for diabetes. Dr. Ellen Toth is also the principal investigator of this project.

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

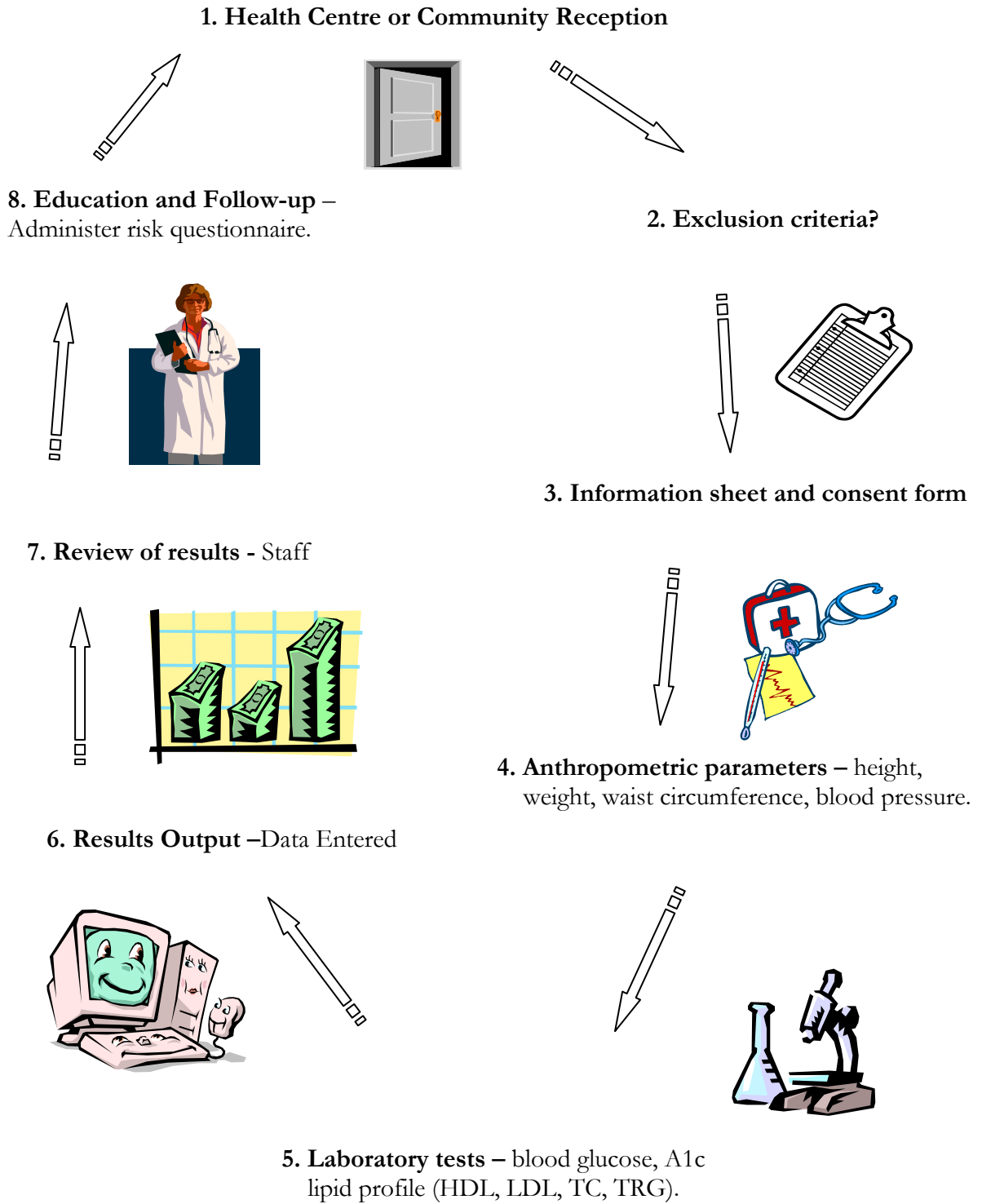
The BRAID project is a unique project that is exclusively carried out in a single First Nation community in northern Alberta. This project's main focus is to screen the entire community over the age of 6 that have not been previously diagnosed with diabetes. This project is different from the SLICK and 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 to try and get an accurate representation of the population. 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 3.1.1). The BRAID project screens clients for diabetes using portable technology which will be discussed later in this chapter. Individuals who consent to being screened go through a series of stations, as shown in Figure 3.1.2, where testing of blood glucose, A1c, lipids, and anthropometric measurements are done. All individuals who are screened received counselling on their results. Each individual then has documentation sent to either (and or all): A. themselves, B. their nurse or health centre, and C. their doctor. The BRAID project is one of only a handful of community diabetes screening initiatives in Canada's First Nations. Dr. Ellen Toth is also the principal investigator of this project. This project is partially funded by the Aboriginal Diabetes Initiative (ADI) and the University of Alberta.

Table 3.1.1 – Exclusion criteria for the SLICK, MDSI and BRAID projects

Exclusion Criteria
Under Age 6
Inability to give consent
Documentation of Diabetes (FPG > 7.0mmol/L or Random >11.1mmol/L)
Prediabetes (IFG > 6.1mmol/L, or Random > 7.8mmol/L)
Medications for Diabetes
Insulin for Diabetes
Pregnancy
< 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.

Figure 3.1.2 – The SLICK, MDSI, and BRAID projects



3.2 – Ethics

Before obtaining appropriate permission from individuals and organizations the BRAID study underwent an extensive 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. Ethics 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 is asked to read an information sheet and consent to the SLICK, MDSI, or BRAID projects (attached in Appendix 3). 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.

3.3 – Collection of data

After informed consent is discussed, each individual is assessed with respect to whether they meet the exclusion criteria (see Table 3.1.1). In a small number of cases, where exclusion criteria applied, “health services” were carried out if clinically reasonable. These individuals were not included in the analysis of this study. Individuals that were not excluded were then passed on to another station where they had anthropometric measurements taken. The results were recorded on a report sheet that was created once the

individual had consented (see Figure 3.3.1), (the SLICK and MDSI projects had similar report sheets). Height was measured in meters using a standard height scale (Road Rod 214 from Seca); weights were recorded in kilograms by a standard dial weigh scale (Health o meter[®]) already present in the health centers. Body mass index (BMI) was calculated (automatically by the database) by dividing the weight in kilograms by the height squared (kg/m^2). Waist circumference was measured, in centimeters, using a standard measuring tape (Prym-Dritz Corporation) at the iliac crest. Blood pressure was taken using a standard professional adult sphygmomanometer (A.M.G. Medical) always in a supine position. For children or other individuals with smaller upper arm circumference, a childrens blood pressure cuff was used. Once these measurements were taken individuals were asked to proceed for blood testing. All three projects used the Cholestech LDX[®] analyzer (Cholestech Corporation) for measurement of blood glucose (fasting or random), high density lipoprotein (HDL cholesterol), low density lipoprotein (LDL cholesterol), total cholesterol (TC), and finally triglycerides (TG). If a random blood test was done (individual being tested had any food or drink within the previous 8 hours) their triglyceride and low density lipoprotein values were disregarded, since these tests are not reliable in a random state. The DCA 2000[®] analyzer (Bayer diagnostics) was used for measurement of hemoglobin A1c (A1c), which is not affected by the random state.

Figure 3.3.1 – Patient report sheet for the BRAID Project

The BRAID Project

Believing we can Reduce Aboriginal Incidence of Diabetes

Collaboration between (removed for privacy) First Nation, Aboriginal Diabetes Initiative,
and University of Alberta

Visit #

RESULTS FORMS (1)

Male/ Female

Date: _____

Name (last, first, middle)	
Date of Birth (month/day/year)	

CLINICAL ASSESSEMENT	
Height (cm)	
Weight (kg)	
Waist Circumference (cm)	
Blood pressure	
Time last ate	
BMI (see chart in index)	

American Diabetes Association Risk Assessment Score*

BLOOD WORK	Results		Target
Triglycerides (fat that you eat)			Less than 2.3
Total cholesterol			Less than 5.2
Blood glucose	Meter	Cholestec	Less than 6.1 for fasting Less than 7.0 if after meal
HDL (good cholesterol)			Over 0.9
LDL (bad cholesterol)			Less than 3.4
Hemoglobin A1c (diabetes control)			Less than 6.1 %

RESULTS FORM (2) -- Please refer to the Results Interpretation Guide section for guidance

1. Clinical Interpretation:
 Obese (BMI over 30) Overweight (BMI 25-30) Hypertensive

Notes

2. Lipid Interpretation:
 High LDL High TG + Low HDL
 presumed normal uninterpretable

Notes

3. Glycemia Interpretation:
 Presumed diabetes possible IGT / IFG
 presumed normal uninterpretable

Notes

3.4 – Quality Assurance

Prior to blood collection, a strict quality assurance (QA) procedure is completed on the Cholestech LDX[®], and the DCA 2000[®] analyzers. This QA procedure is completed in cooperation with Canadian External Quality Assurance Laboratories (CEQAL, Vancouver B.C). Figure 3.4.1 and Figure 3.4.2 shows the process for the QA. The analyzers are tested before they are used in the field (by CEQAL) to make sure all instrumentation is functioning. Once the analyzers were initially sent to Edmonton, a workshop was established for all those working with the technology. All staff had two full days of education along with hands on use with the technology. The procedure was explained and all the machines were distributed accordingly. Each project has separate analyzers. The instruments are handled with utmost care because of the delicate instrumentation present in the analyzers. The analyzers do not have an expiry date associated with them, but the reagent cartridges that are used to test the blood expire within three months. Once the reagents are obtained (from a local warehouse that orders and stores the reagents), they are transported on ice (Cholestech LDX[®] reagents), and at room temperature (DCA 2000[®] reagents). The Cholestech LDX[®] reagents must be stored at 2-8°C, until they are ready to use. Once they are removed from refrigeration and placed at room temperature the reagents are only valid for 30 days. The DCA 2000[®] reagents can be stored at 2-8°C for 1 year, but once placed at room temperature are only valid for 3 months. Both reagents are only used when they have reached room temperature (17-25°C), as recommended by the manufacturers.

In addition CEQAL provides controls. These are samples of blood taken from a venous puncture in the laboratory, and analyzed by CEQAL in Vancouver. CEQAL then

compares their results to an external laboratory in Minnesota, which once completed, establishes the criteria for the QA. Once CEQAL tests and analyzes the results they establish reference values or a “valid range” for the analyzers. Each analyzer has a “valid range” that the QA must satisfy. QA is performed before screening any individual, and at the end of the day it is repeated. Criteria for the QA have reference values for 5 variables (A1c, glucose, total cholesterol, HDL cholesterol, and triglycerides). For each variable there is an “orange” value referring to the lower scale criteria, and “pink” referring to the higher scale criteria. After the control sample is run and the output has been obtained, the results for the DCA 2000[®] are recorded in a QA binder. For the Cholestech LDX[®] a further step is necessary. The Cholestech LDX[®] needs a correction spreadsheet called the “Cholestech Regression spreadsheet”. Each analyzer has its own specific regression spreadsheet (provided by CEQAL). Results that are obtained are corrected by entering in the raw data output from the analyzer into the regression spreadsheet. The spreadsheet automatically corrects the raw data, and labels it “corrected data”. This corrected data is then used to assure that the machines are working within the “valid range”. If the results for the QA are not valid the first time, they are to be repeated once more. If the results are not valid a second time, a technician is phoned and a problem report and trouble shooting procedure is completed. If the results are in the “valid range”, screening commences. This process is then repeated after the last individual is screened for that day. Again if there are any problems they are to be handled in a similar manner as mentioned previously. If the QA results do not fall in the appropriate reference range at the end of the day, the results for that day are to be discarded (however this did not occur in any instances). The Cholestech LDX[®] correction process is completed for every individual screened in the three projects using the same regression spreadsheet used in the QA.

Figure 3.4.1 – QA procedure background before analyzers are utilized

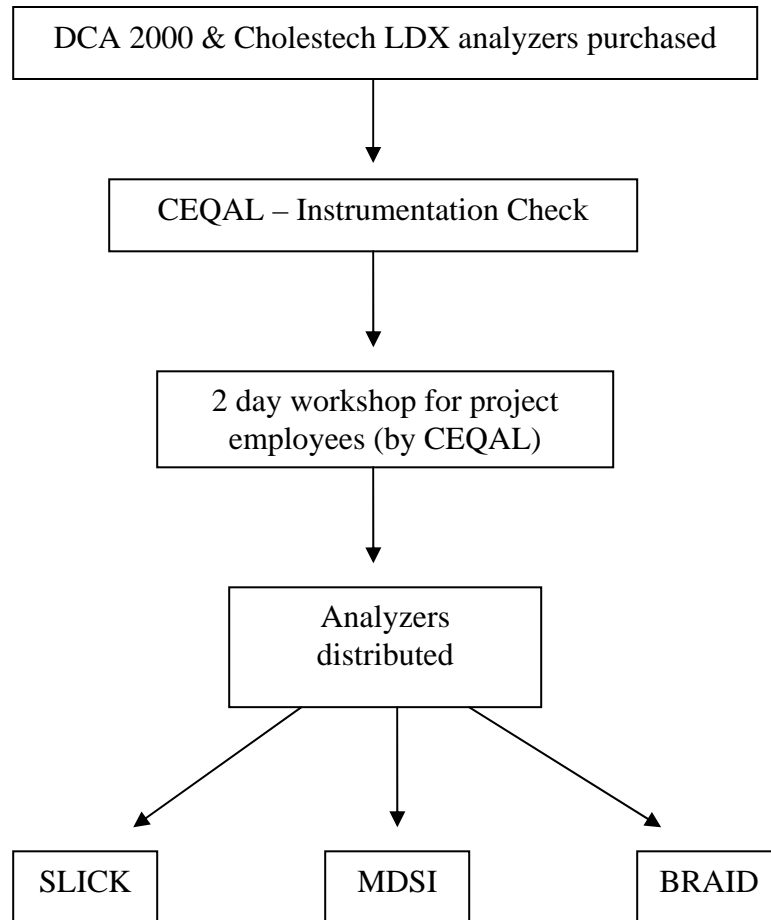
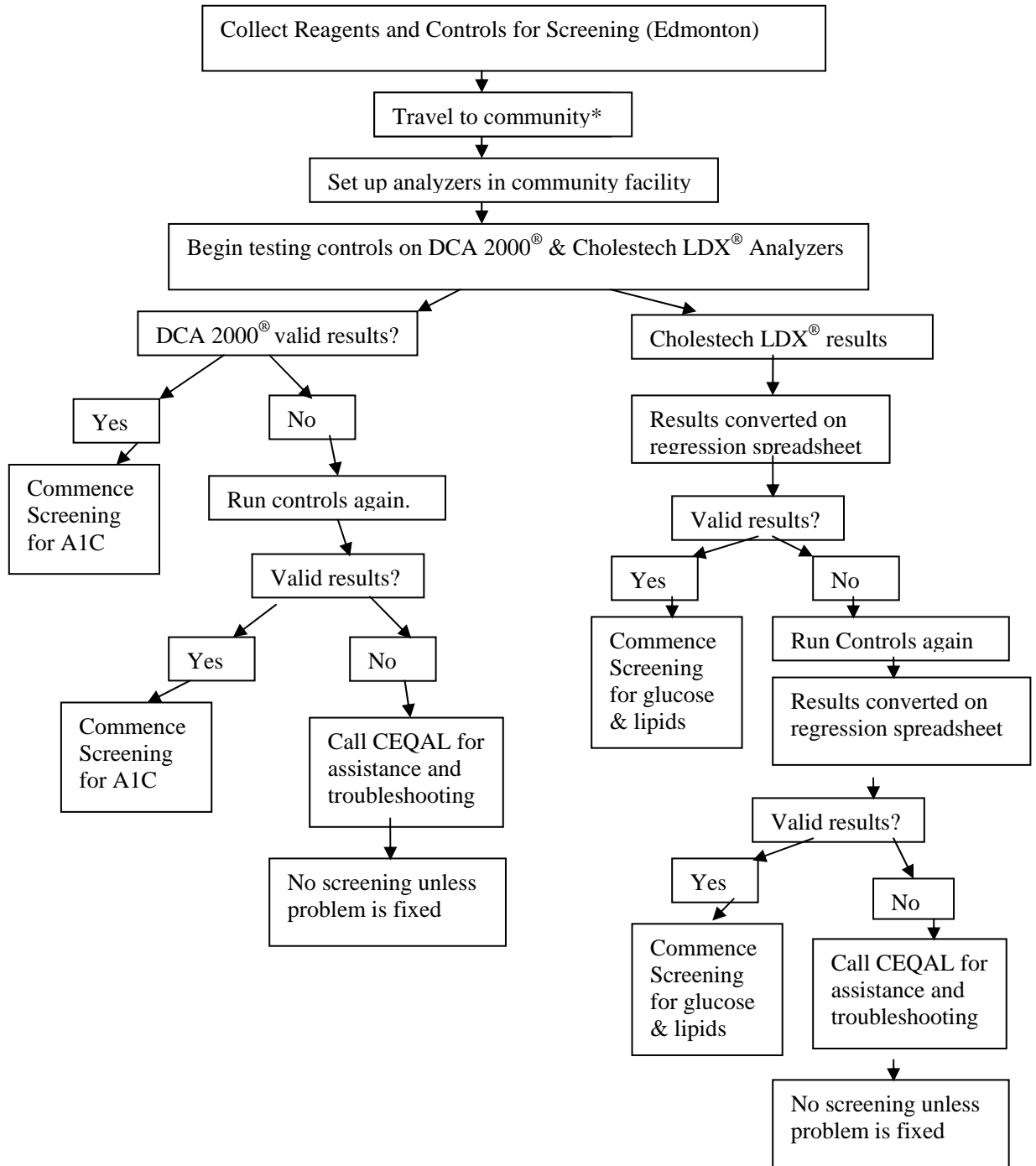


Figure 3.4.2 – QA procedures from community to the individual.



* Analysers are transported with the SLICK and MDSI projects (in vans), whereas they are kept in the Community in the BRAID project.

The controls that were used in the three projects were shipped (frozen, and on ice) to a warehouse in Edmonton. Controls were obtained by staff from the projects before every

trip, or screening visit was planned. These controls were kept frozen (<-10°C) while transported to communities, and while stored in community health centres. Once the controls were thawed, they could not be frozen again, and they were to be used within 3 days of thawing.

Once screening is completed in a community, the QA results are entered into various spreadsheets (created by CEQAL) and emailed to CEQAL. CEQAL provides detailed feedback on the function of the analyzers. If any problems are occurring CEQAL provides feedback as to what actions need to be taken. The DCA 2000[®] analyzer operates with a CV of 2.5% and an average bias of 6.19% for a total error of 12.1%. Total cholesterol, HDL cholesterol, triglycerides, calculated LDL and glucose are all measured using a single testing cassette on the Cholestech LDX[®] analyzer. The performance characteristics for these tests on this analyzer are shown in Table 3.4.1:

Table 3.4.1 – Performance Characteristics for the Cholestech LDX[®] Analyzer

Analyte	CV (%)	Average Bias (%)	Total Error (%)
Total cholesterol	2.68	0.86	6.1
HDL cholesterol	1.95	- 0.06	3.9
Triglycerides	2.38	- 0.66	5.3
Glucose	1.97	- 2.75	6.6

These performance characteristics are similar to those that are currently being achieved at major testing centers 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”

3.5 – Biochemical Measurements

When blood collection is to begin, the individual is asked if they have washed their hands; additionally a health care professional sanitizes the finger that will be utilized for the puncture with a Webcol[®] isopropyl alcohol sterile swab (Kendall). Only one capillary puncture is done for the testing (in some instances where more volume of blood is required another puncture is done). We utilize the Accu-Chek Safe-T-Pro (Roche Diagnostics) lancet for all blood testing. The depth of the puncture can be adjusted on these pen-shaped tools for the various skin thickness of the individual being tested. Once the puncture has been administered the first blood droplet is discarded using a sterile cotton swab. The subsequent blood is collected for the DCA 2000[®]. This is done by using the capillary holder (Figure 3.5.1). This holder uses capillary action to collect 1uL of blood. Then the Cholestech LDX[®] analyzer sterile capillary tubes (see Figure 3.5.2) are used to collect blood for this test. These capillary tubes collect between 45-60uL of capillary whole blood (although venous whole blood could be used).

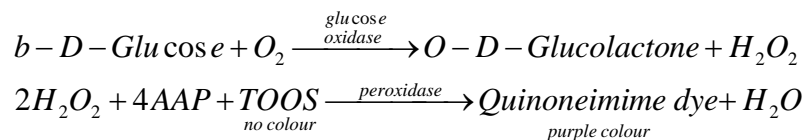
A1C

The DCA 2000[®] Analyzer utilizes an immunochemical technique for measuring HbA_{1C}. The blood is then loaded onto the reagent cartridge shown in Figure 3.5.2. A monoclonal antibody reacts specifically with an amino acid sequence on the A_{1C} molecule. A_{1C} is formed by the non-enzymatic glycation of the N-terminus of the beta-chain of H-A₀. The concentration of HbA_{1C} and total Hb are measured and the ratio is reported as percent HbA_{1C}.

Glucose

For measurement of glucose the Cholestech LDX[®] utilizes the glucose oxidase method. Glucose oxidase catalyzes the oxidation of (beta)-D-glucose to D-gluconic acid and hydrogen peroxide. The quantity of hydrogen peroxide is measured by a colour change when reacted with a chromogenic oxygen receptor. The glucose concentration in the blood is derived from this colour change. This reaction is shown in Equation 3.5.1.

Equation 3.5.1 – Measurement of Glucose using the Cholestech LDX



Total Cholesterol and Triglyceride

These two predictors of cardiovascular disease are measured enzymatically using a Trinders indicator system with N-ethyl-N-sulfohydroxylpropyl-m-toluidine sodium salt (Trinder, 1969).

HDL Cholesterol

HDL needs to be separated from other lipoproteins prior to analysis. The cholesterol is isolated using dextran sulphate/magnesium acetate (Warnick *et al.*, 1982). The remaining filtrate, which contains the HDL cholesterol, is moved to the HDL cholesterol reaction pad where it is measured enzymatically as above.

LDL Cholesterol

LDL Cholesterol is calculated using the formula shown in Equations 3.5.2. This is known as the Friedewald formula, and it provides an adequate estimate of the LDL cholesterol (Friedewald *et al.*, 1972). It is important to note that triglyceride concentrations must be under 4.5 mmol/L. This is one of the reasons why fasting measurements are preferred during lipid screening.

Equation 3.5.2 – The Friedewald formula for LDL cholesterol

$$LDL\ Cholesterol = Total\ Cholesterol - HDL\ Cholesterol - \frac{Triglyceride}{2.2}$$

The Cholestech can analyze concentrations within the following ranges: total cholesterol 2.6 to 12.9 mmol/L, triglyceride 0.5 to 7.3mmol/L, and HDL cholesterol 0.4 to 2.6 mmol/L.

For the SLICK and MDSI projects, the blood collection phase is now completed. Every individual is then asked to proceed to the next station to wait for their results to be printed, interpreted, and then finally discussed.

In the BRAID project we have a unique addition to the assortment of tools that have been mentioned previously. We utilize the OneTouch[®] Ultra[®] (LifeScan) blood glucometer (Figure 3.5.3) as an additional measure of glycemia. Each glucometer is coded to the correct test strip lot number, and is then verified to be working properly using the quality assurance method that is provided with each machine. New lots of test strips are opened

every 3 months. All strips are stored at room temperature, and are never left exposed to light or surrounding environment. Once this step is done, health care staff in the BRAID project collect blood for the glucometer using a OneTouch[®] Ultra[®] test strip (see Figure 3.5.3). The blood for the glucometer is directly collected onto the strip which has been loaded into the glucometer before any sample has been absorbed. The test strip utilizes 1uL of blood. Following this, the blood was collected for the DCA 2000[®] and the Cholestech LDX[®] analyzers. A sterile cotton swab is then administered to the finger where the puncture had taken place. The individual being tested is then asked to place pressure on this finger until the bleeding has ended.

Now that the blood is collected, the next phase is to administer the blood into the reagent cartridges for the Cholestech LDX[®] and the DCA 2000[®] analyzers. For the DCA 2000[®] the capillary holder (shown in Figure 3.5.1) is then placed into the reagent cartridge (Figure 3.5.1). This reagent cartridge is then placed into the DCA 2000[®] analyzer (Figure 3.5.4), where the results will be analyzed and displayed. Once the reagent cartridge is loaded for the DCA 2000[®], the reagent cartridge for the Cholestech LDX[®] is loaded into the analyzer (Figure 3.5.5). The DCA 2000[®] takes 6 minutes to complete, whereas the Cholestech LDX[®] takes approximately 4 minutes to complete. The DCA 2000[®] A1c determines both the concentrations of the HbA1c molecule and the total haemoglobin. The ratio of these two quantities is expressed as a percentage HbA1c (A1c). Figure 3.5.6 gives an overview of the collection procedure.

Figure 3.5.1 – Capillary holder, and reagent cartridge for the DCA 2000[®] analyzer (Bayer diagnostics)

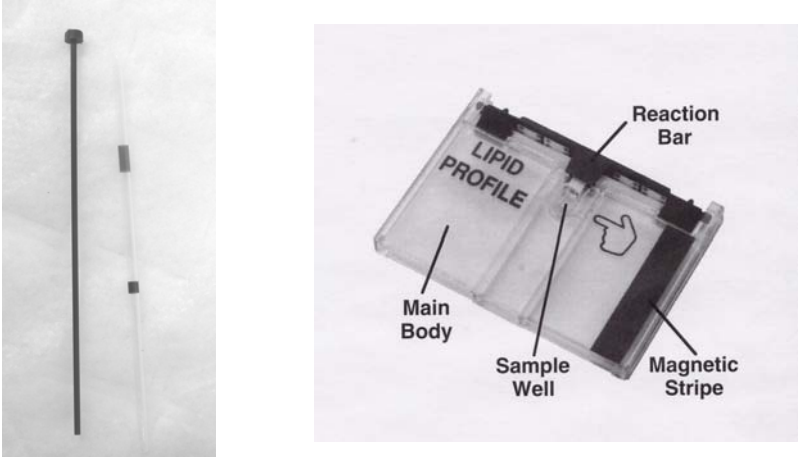


Figure 3.5.2 – Capillary tubes and reagent cartridge for the Cholestech LDX[®] analyzer (Cholestech Corporation)



Figure 3.5.3 – OneTouch® Ultra glucometer® (LifeScan) and test strip



Figure 3.5.4 – DCA 2000® analyzer (Bayer technologies)



Figure 3.5.5 – Cholestech LDX[®] analyzer (Cholestech Corporation)

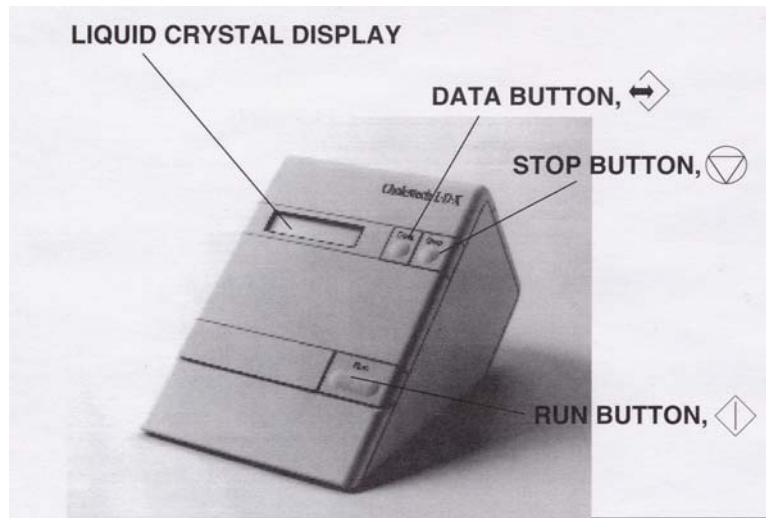
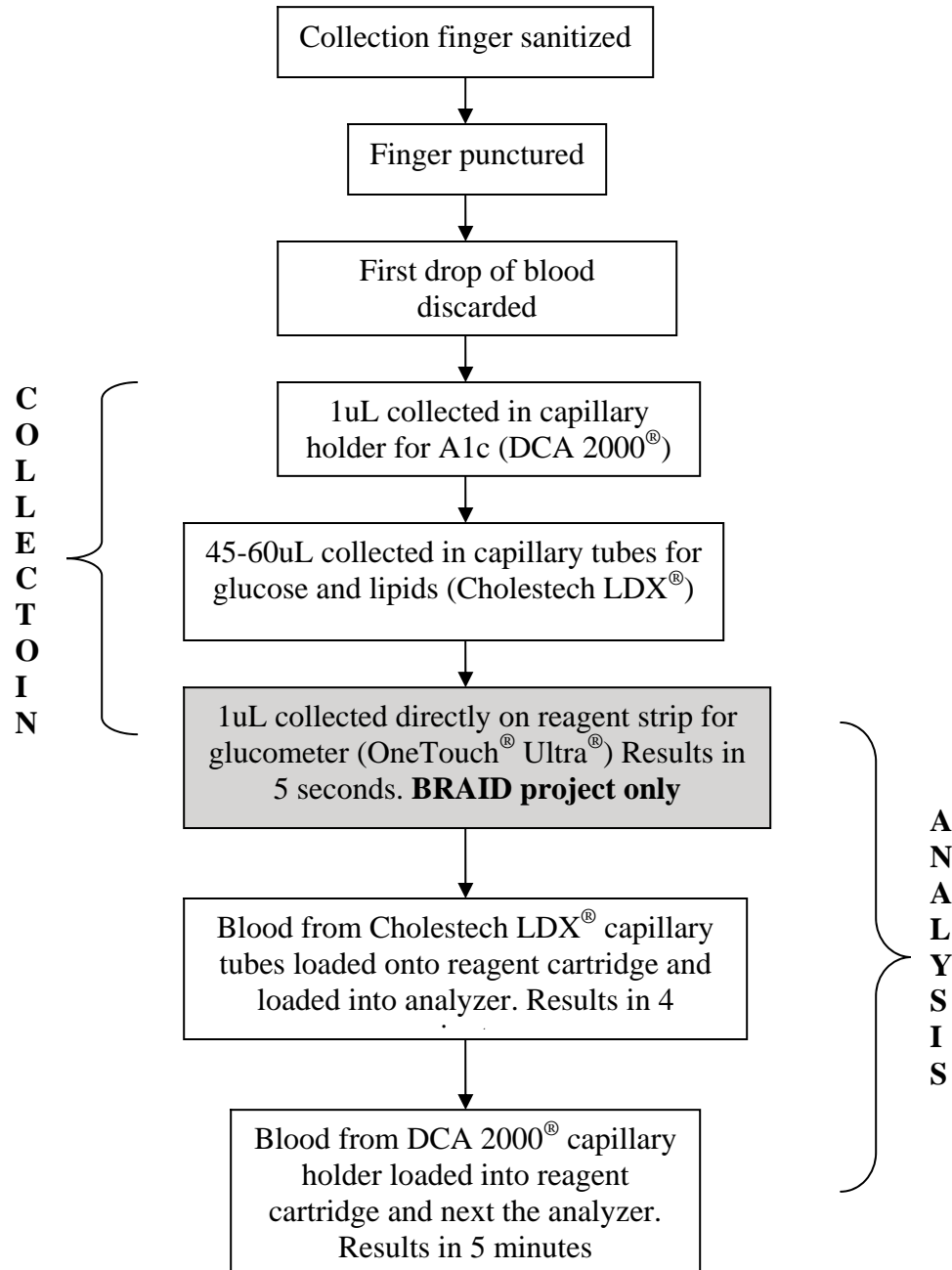


Figure 3.5.6 – Schematic overview of blood collection and analysis



3.6 – Data collection, counselling, and education

Once the results have been printed and displayed, the data is collected and entered into a computer. The data for the DCA 2000[®] does not have to be corrected and is therefore directly entered onto each individual's chart immediately. However the data for the Cholestech LDX[®] must be corrected, using the same procedure use for the quality control discussed previously. Data for each patient is entered into the "Cholestech LDX[®] regression sheet" and is converted. Finally, this data is then entered onto each individual's chart. Now that the blood collection and results have been completed, a health care professional reviews the data and then discusses these results with the individual who is being tested. During this discussion a brief educational session on nutrition and lifestyle is completed. Also administered at the time (BRAID and MDSI projects only) is the seven question "American Diabetes Association Risk Questionnaire" (ADA Score) as shown in Figure 3.6.1. 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 (Table 3.8.3) Three additional questions are being asked (see questionnaire Figure 3.6.1), to determine any influence of heredity, medications, or history of gestational diabetes in women on the frequency of diabetes. These values were not scored, rather answered as yes or no. Individuals have the option to receive a copy of their results immediately, or have them sent to them by mail. Individuals can also have results sent to a family doctor, and/or the local health care centre. All individuals with significant abnormal findings were referred and encouraged to see their doctors.

Figure 3.6.1 – American Diabetes Association Risk Questionnaire and additional BRAID project questions.

The BRAID project

Name:

If the client answers **YES** to any of these questions, they receive the appropriate point(s).

ADA Risk Questionnaire

Question	Points
1. (For women) have you delivered a baby weighing more than 9 pounds (4 kg)?	1
2. Do you have one or more siblings (brother or sister) with diabetes?	1
3. Do you have one or more parents with diabetes?	1
4. Body Mass Index of more than 27 (as previously calculated)	5
5. Less than 65 years old and little or no physical activity in most weeks?	5
6. Between the ages of 45 and 64?	5
7. Over 65 years old?	9
Total	

Questionnaire	Yes/No	Additional Info
Medications (lipids, Hg, other)		Please list:
Grandparents with Diabetes?		
Gestational Diabetes		Date:

3.7 – Statistical Analysis

All analyses were carried out using SPSS 13.0 statistical software, unless otherwise mentioned. Data was collected until June 30 2004 (with the exception of SLICK which was collected until July 2003) into three separate databases. These databases were then amalgamated into one single database called the “BRAID database”. This dataset was eventually imported into SPSS and analyzed. Simple frequency distributions were completed on all of the data collected. Linear and logistic regression modelling was carried out on certain risk factors to determine their relationship to diabetes and prediabetes. Categorical variables such as those relating to familial contribution and gestation diabetes were analyzed using a chi-square and logistic regression analysis. Multiple regression analysis was conducted to illustrate the contribution of each continuous variable to glucose. ROC (receiver operating characteristic) analysis was carried out on the DCA 2000[®] A1c comparing it to the standard (fasting Cholestech LDX[®] blood glucose) used in this thesis, which was used for the diagnosis of diabetes and prediabetes. A further ROC analysis was done in the BRAID project with the glucometer and comparing it to the standard Cholestech LDX[®] glucose. An independent t-test was performed to compare the means of the continuous variables between two groups. The SLICK and MDSI projects were grouped in to an “opportunistic” group, and the BRAID project is referred to as the “population” group. This analysis describes any significant differences between opportunistic screening and population based screening in this study. The prevalence of the metabolic syndrome was computed only on individuals who had the five risk factors (see Table 3.8.3) collected and were ≥ 18 years of age. The prevalence of the condition was compared between the two groups. Summary of the analysis conducted is displayed in Table 3.7.1 below.

Table 3.7.1 Analyses conducted

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.

3.8 – Diagnostic Criteria

Diagnostic criteria for classifying individuals based on glycemia was taken from the Canadian Clinical Practice Guidelines (Canadian Diabetes Association Clinical Practice Guidelines Committee, 2003b). The criteria are shown in Table 3.8.1.

Table 3.8.1 – Diagnostic criteria for glycemia (Canadian Diabetes Association Clinical Practice Guidelines Committee, 2003c)

Criteria	Defining level
Normal	Fasting < 5.7mmol/L
Prediabetes (IFG)	Fasting: $\geq 5.7 < 7.0$ mmol/L
Diabetes	Fasting: ≥ 7.0 mmol/L Random: ≥ 11.1 mmol/L

An A1c standard for the diagnosis of diabetes has not been clearly established. For the purpose of this study we are using the following criteria for A1c suggested by Rohlfing et al. (Table 3.8.2) (Rohlfing et al., 2000b).

Table 3.8.2 – A1c criteria for the BRAID study

Criteria	Defining level
Normal	< 5.5%
Upper limit of normal (1SD)	$\geq 5.5\% < 6.1\%$
High risk (2SD)	$\geq 6.1\%$

SD: Standard deviation

The metabolic syndrome has gathered recent interest in the literature (discussed in Chapter 1.5). The risk factors associated with the condition are shown in Table 3.8.3. If an individual has three or more of the risk factors mentioned, they have the metabolic

syndrome as defined by the National Cholesterol Education Program (2001). The risk factors were collected in all three projects; however only individuals who were tested for at least 4 of the 5 criteria were included in the analysis. A simple frequency distribution for the criteria was done using SPSS to calculate who had the risk factors, and how many were positive for the syndrome. Linear regression modelling was then done (using SPSS) on each of the risk factor of the metabolic syndrome to determine the specific relationship to diabetes and prediabetes.

Table 3.8.3 – Criteria for the metabolic syndrome (≥ 18 years)

Risk factor	Defining level- NCEP –ATP III
Glucose	Fasting: $\geq 6.1 < 7.0$ mmol/L
High Density Lipoprotein	Men: < 1.0 mmol/L Women: < 1.3 mmol/L
Triglycerides	≥ 1.7 mmol/L
Blood Pressure	$\geq 130/85$ mm Hg
Waist circumference	Men: > 102 cm Women: > 88 cm

Other risk factors that were measured in the three projects were height and weight, which was calculated as BMI (kg/m^2), LDL cholesterol, and total cholesterol. The MDSI and BRAID projects also used the American Diabetes Association risk questionnaire (Figure 3.6.1) as an extra screening tool to test its validity in Aboriginal communities of Alberta. Analysis was done using a simple frequency distribution to determine how many individuals had risk factors for diabetes. Linear regression modelling was then done (using SPSS) on each of the risk factors to determine the specific relationship to diabetes and prediabetes.

Table 3.8.4 – Other risk factors and their criteria

Risk factor	Defining level: At risk	Defining level: High risk
Obesity – (BMI)	$\geq 25 < 30 \text{ kg/m}^2$	$\geq 30 \text{ kg/m}^2$
ADA Risk Score (BRAID & MDSI project only)	≥ 10	
Low Density Lipoprotein	$> 3.4 \text{ mmol/L}$	

CHAPTER 4

RESULTS

4.1 – Study dataset, demographics and information collected

1170 unique individuals were screened in the BRAID study. All individuals had no prior knowledge of having diabetes, were not on medications for diabetes, and had no exclusions to screening (a complete list of exclusion criteria is provided in chapter 3). All 1170 individuals were of Aboriginal ancestry. Of the 1170 unique individuals, 251 were screened in the BRAID project, 562 in the MDSI project, and 357 in the SLICK project. A total of 43 communities were visited by the three projects from January 2002 to July 2004. MDSI visited 8 unique communities from November 2003 to July 2004, SLICK visited 34 unique communities from January 2002 to July 2004, and the BRAID project was only involved with one single First Nation community¹. Table 4.1.1 summarizes this data.

Table 4.1.1 – Project, study, and community statistics

Project	STUDY			Total
	BRAID	MDSI	SLICK	
Number Screened (unique)	251	562	357	1170
Communities Visited (unique)	1	8	34	43
Potential Population Available for Screening	450	3694	43144	47288
Percent Screened	55.8%	15.2%	0.8%	2.5%

Out of 1170 clients, 728 (62.2%) were female, and 442 (37.8%) were male. The breakdown of gender in the three projects is shown in Table 4.1.2. BRAID has the most balanced gender ratio of the three projects, followed by MDSI, and then SLICK. Recruitment was

¹ The specific communities involved in this study are not mentioned throughout this document for privacy of the communities and the individuals screened.

not knowingly directed at women in any of the three projects. It is presumed women were more interested in being screened, or were more available. The fact that Aboriginal women are known to have a higher prevalence of diabetes than men is also a presumable factor.

Table 4.1.2 – Breakdown of gender and age in the three projects

	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%

The BRAID project screened many more individuals in the 5-19 age category as compared to the MDSI or SLICK project; conversely, SLICK and MDSI screened more individuals in the >60 years age categories.

The projects also collected a variety of other information such as: history of gestational diabetes (GDM) or baby over 9 lbs, any siblings with diabetes, any parents with diabetes, and any grandparents with diabetes at the time of screening. The question regarding “Grandparents with diabetes” was not administered to the SLICK participants. The American Diabetes Association Risk Assessment Questionnaire (ADA Score) was administered in the MDSI and BRAID projects.

4.2 – Assessment of hypothesis 1: use of portable technology

Hypothesis 1 states that “portable technology is comparable to standard laboratory methods for the determination of diabetes and prediabetes”. Regression and ROC (Receiver Operating Characteristic) analysis were done on the portable technology to assess its performance. ROC analysis is a useful tool to help decide a threshold at which a new diagnostic tool will be comparable to a standard tool that is already in use. The area under the curve (AUC) provides an idea of the accuracy of the test, the higher the AUC the better the accuracy. Two other important determinants of the ROC analysis are the sensitivity and specificity. Sensitivity refers to the ability of a diagnostic tool to predict “true positive” cases, whereas specificity refers to predict “true negative” cases. A diagnostic tool that has a high sensitivity and high specificity is the most useful. Sensitivity is also used interchangeably with the term true positive fraction (TPF), and specificity with true negative fraction (TNF). From the sensitivity and specificity one calculates diagnostic accuracy. Diagnostic accuracy is measured by the formula provided in Equation 4.2.1. P(D+) refers to the prevalence of the disease in the population using the standard diagnostic tool (Cholestech LDX[®] in this study), and P(D-) is the simply 1 – P(D+), signifying absence of disease

Equation 4.2.1 – Determining diagnostic accuracy (Metz, 1978)

$$\text{Accuracy} = [\text{Sensitivity} \times P(D+)] + [\text{Specificity} \times P(D-)]$$

For each decision point that a user defines (e.g. the cut-off point for the diagnostic gold standard) a sensitivity and specificity are produced. These values are used to calculate the diagnostic accuracy of the new test using Equation 4.2.1.

In this study the terms “probable” diabetes and prediabetes are used, throughout, because in the absence of symptoms measurements should be repeated once; however single measurements are acceptable for epidemiological investigations. In addition there are no guidelines to date that approve the use of portable technology in these determinations.

4.2.1 – Performance analysis of portable technology: (DCA 2000[®] A1c, and fasting OneTouch[®] Ultra[®] glucometer)

DCA 2000[®] A1c was compared to fasting Cholestech LDX[®] glucose in the project to assess its probability of predicting states of glucose tolerance. Firstly, regression analysis was completed on the A1c to determine its “fit”. The A1c performed well in the regression analysis having a correlation coefficient of 0.734 ($R^2 = 0.539$). The fasting OneTouch[®] Ultra[®] also performed very well compared to the fasting Cholestech LDX[®] glucose ($R = 0.817$, $R^2 = 0.667$). A further analysis on sensitivity and specificity was performed (ROC). Figure 4.3.1 and Figure 4.3.2 display the ROC curves for both the DCA 2000[®] A1c, and the OneTouch[®] Ultra[®] capillary glucose respectively. The area under the curve for the A1c is 0.862 (S.E. = 0.052) and 0.939 (S.E. = 0.029) for the capillary glucose. The glucose criteria utilized was a fasting glucose ≥ 7.0 mmol/L representing diabetes. The sensitivity and specificity for the fasting OneTouch[®] Ultra[®] glucometer using 7.0mmol/L as the cutoff was 0.600 and 0.995 respectively, which has a diagnostic accuracy of 0.982 (scale 0-1). The glucometer had the best diagnostic accuracy for diagnosing diabetes at a

glucometer value of 7.10mmol/L. The DCA 2000[®] A1c has a sensitivity and specificity of 0.65 and 0.95 respectively using 6.1% as a diagnostic point, and a diagnostic accuracy of 0.938. The optimum point for diagnosing diabetes using the A1c in this study for was 7.05%, which produced a diagnostic accuracy of 0.981.

Figure 4.2.1 – ROC curve for DCA 2000[®] A1c using Cholestech LDX[®] standard glucose criteria for diabetes

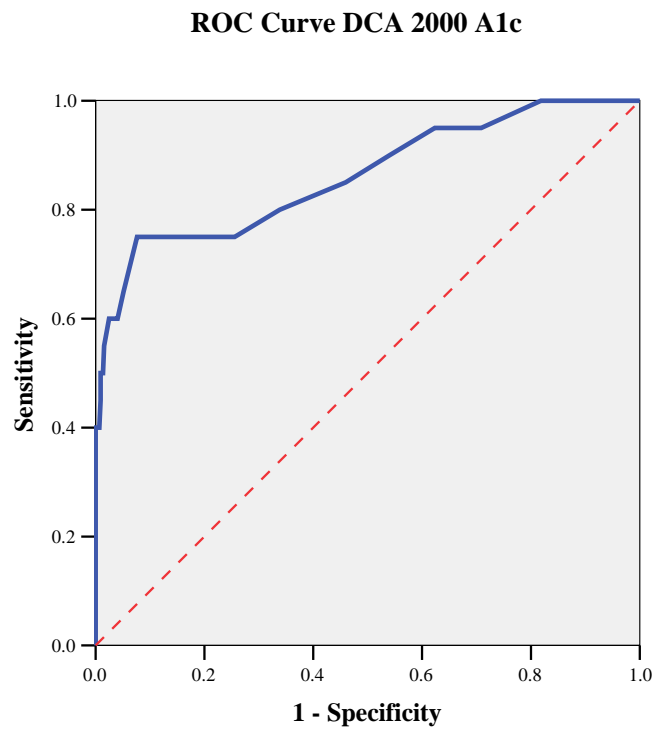
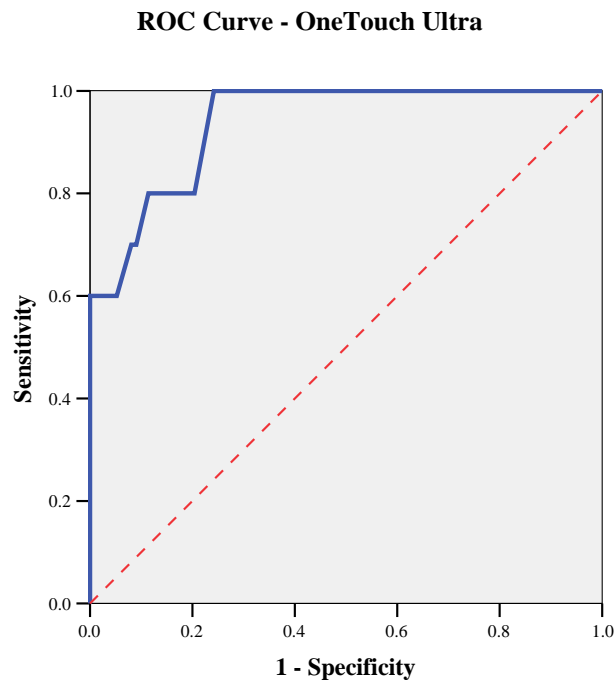


Figure 4.2.2 – ROC curve for fasting OneTouch® Ultra® glucose using Cholestech LDX® standard glucose criteria for diabetes



When using glucose criteria for “prediabetes” the ROC curves for both the A1c and the capillary glucose drift downwards, displaying a smaller area under the curve as shown by Figure 4.3.3 and 4.3.4 below. The glucose criteria used for prediabetes was a fasting glucose between 5.7 and 7.0mmol/L.

Figure 4.2.3 – ROC curve for DCA 2000[®] A1c using Cholestech LDX[®] standard glucose criteria for prediabetes (IFG only)

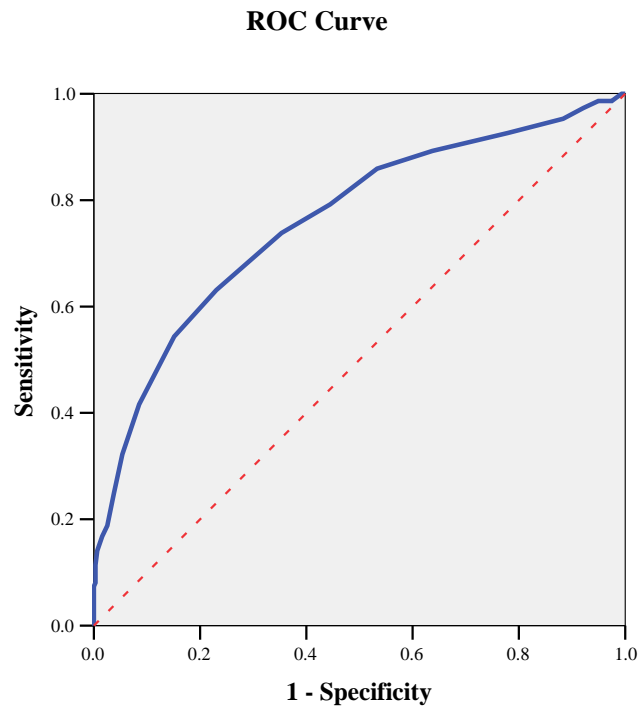


Figure 4.2.4 – ROC curve for fasting OneTouch[®] Ultra[®] using Cholestech LDX[®] standard glucose criteria for prediabetes (IFG only)

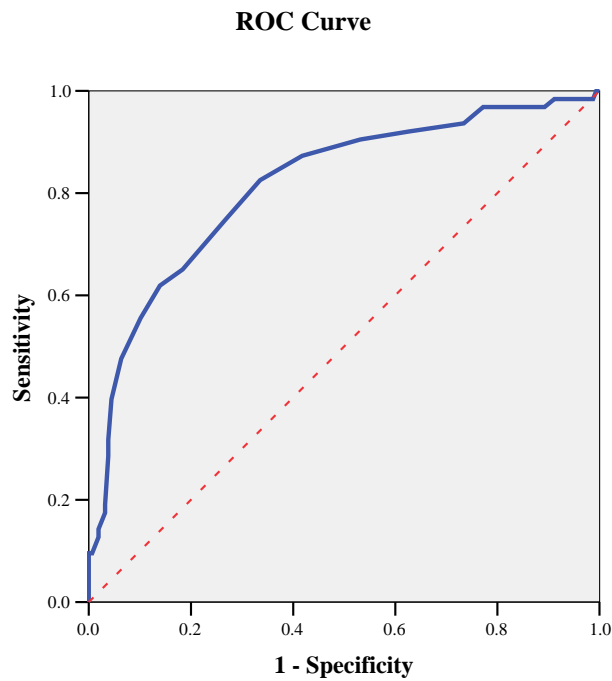


Table 4.2.1 shows the area under the curve for the two instruments with respect to diagnosing diabetes and prediabetes. Table 4.2.2 describes the sensitivity and specificity for both instruments using two different cut points, one for diabetes, and one for prediabetes.

Table 4.2.1 – Area under the ROC curve for DCA 2000[®] and OneTouch[®] Ultra[®]

	AUC A1c (S.E)	AUC Fasting Capillary Glucose (S.E)
Probable Prediabetes 2003 criteria (CDA, 2003a) ($\geq 5.7 < 7.0$ mmol/L)	0.760 (0.025)	0.814 (0.033)
Probable Diabetes (≥ 7.0 mmol/L)	0.862 (0.052)	0.939 (0.029)

Table 4.2.2 – Sensitivity and specificity of portable technology for the diagnosis of probable diabetes and prediabetes using Cholestech LDX[®] as standard

Diagnostic Reading	Sensitivity	Specificity	Diagnostic Accuracy
A1c $\geq 6.1\%$	0.65	0.94	0.938
A1c $\geq 5.5\%$	0.74	0.65	0.663
A1c DM optimal – 7.05%	0.40	1.00	0.981
Fasting Glucometer ≥ 7.0 mmol/L (Probable Diabetes)	0.60	0.995	0.982
Fasting Glucometer DM optimal – 7.10mmol/L	0.60	1.00	0.987
Fasting Glucometer $\geq 5.7 < 7.0$ mmol/L (Probable Prediabetes)	0.556	0.899	0.840

DM: Diabetes Mellitus

In summary the DCA 2000[®] and the fasting OneTouch[®] Ultra[®] perform well in the field for the detection for diabetes. The optimal cut point for prediabetes as measured by a glucometer was not possible to determine because prediabetes is a range having an upper and lower cut point.

4.3 – Portable testing results in all groups combined

The following tables and figures describe the results of portable testing in the combined dataset. Opportunistic and population based screening groups were combined and analyzed to look at the distribution of the data in 1170 unique Aboriginal individuals in Alberta.

Table 4.3.1 – Comparison of glycemc categories detected by Cholestech LDX[®] standard vs. portable technology

	Cholestech LDX[®]	OneTouch[®] Ultra[®] glucose
Probable Diabetes	3.18%	2.17%
Probable Prediabetes (fasting only)	28.3% **	20.1%

** p<0.01

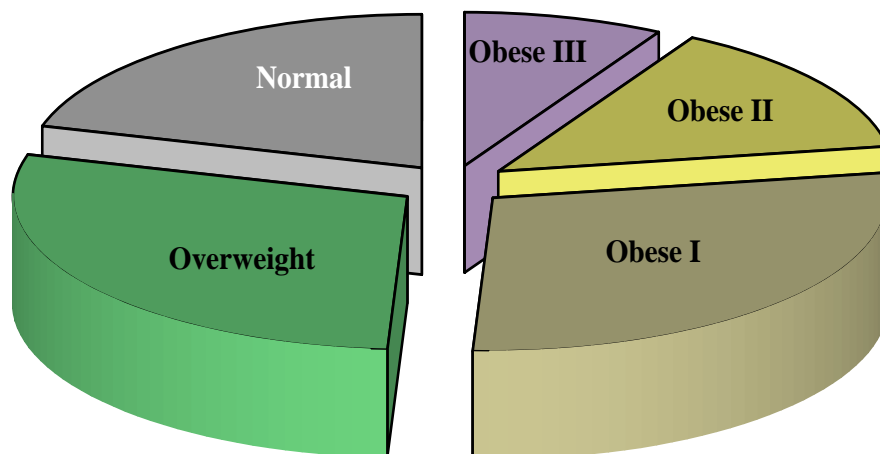
Table 4.3.2 – Total prevalence of probable diabetes, probable prediabetes, the metabolic syndrome, and risk factors tested with portable technology

	The BRAID study	
	N = 1170	
	Positive or High Risk: N (%)	Total N
Probable Diabetes	3.18%	1132
Probable Prediabetes (fasting only)	28.3%	473
Hemoglobin A1c ($\geq 6.1\%$)	8.92%	1143
Hemoglobin A1c ($\geq 5.5\%$)	40.2%	1144
Metabolic Syndrome (≥ 18 years)	50.4%	357
Body Mass Index (Obese)	51.7%	1160
Increased waist circumference (≥ 18 years)	71.1%	957
Blood pressure (≥ 18 years)	35.9%	950
HDL cholesterol (≥ 18 years)	61.1%	640
LDL cholesterol (≥ 18 years)	23.1%	632
Triglycerides (≥ 18 years)	54.1%	637
ADA Score (≥ 10)	38.7%	788

Table 4.3.3 – Age and gender specific prevalence of diabetes and prediabetes in the BRAID study

	Diabetes %	Prediabetes % (IFG only)
Gender		
Female	3.3	26.6
Male	3.0	34.5
Age Category		
6-19	0.5	19.8
20-39	2.6	26.4
40-59	3.8	35.1
60-79	8.2	41.7
>80	0.0	66.7

Figure 4.3.1 – Distribution of BMI in the total population screened



BMI Categories: Normal 18.5 – 24.9, Overweight 25.0 – 29.9, Obese I 30.0-34.9, Obese II 35.0 – 39.9, Obese III >40.0

Apart from risk assessment, four questions related to familial and gestational contribution to diabetes were asked. All females were asked if they had either a baby over 9 lbs or gestational diabetes. The 2nd question referred to parental genetic contribution to diabetes. The third question asked, “do you have grandparents with diabetes” and the last question asked if the individual had any siblings with diabetes. Table 4.3.4 shows that individuals with increased glucose had a significant familial contribution as compared to those with normal glucose. Females with gestational diabetes or a baby over 9lbs were not more likely to have increased glucose, however individuals who had parents or grandparents with diabetes were 1.48 and 1.45 times more likely to have prediabetes or diabetes ($p<0.05$) as compared to those with normal glucose. Individuals who had siblings with diabetes were 1.62 times more likely to have prediabetes or diabetes ($p<0.01$).

Table 4.3.4 – Familial contribution to increased glucose

GROUP:	Total prevalence:	Normal%	Glucose PDM or DM	Odds Ratio
GDM or baby over 9lbs (N = 715)	16.5%	15.7%	20.9%	1.42
Siblings with DM (N =797)	28.2%	25.8%	36.1%	1.62**
Parent with DM (N =793)	37.9%	35.3%	44.7%	1.48*
Grandparent with DM (N =557)	37.1%	35.4%	44.4%	1.45*

PDM: prediabetes DM: diabetes mellitus, * $p<0.05$, ** $p<0.01$

4.3.1 –Predictors of glycemia

Logistic regression analysis was performed for the total population to assess the relationship of each risk factor to diabetes. This analysis explores what significantly predicts diabetes in this study, and expresses it as the odds of the disease occurring. An odds value >1 signifies that as the units of the predictor increase so too does the diabetes risk. If odds values are <1 , the diabetes risk decreases as the units of the predictor increase. The following risk factors were assessed: Age (in categories), blood pressure (systolic and diastolic separately, ≥ 18 years), BMI, waist circumference (≥ 18), lipids (≥ 18), and ADA risk score.

Table 4.3.5 below describes the odds estimate for each risk factor collected. Age was significantly correlated with probable diabetes and being over the age of 44 placed an individual at 3.44 times higher risk of having diabetes. Waist and BMI were significantly associated with risk of diabetes. Total cholesterol, HDL cholesterol, and triglycerides were significantly associated with probable diabetes. As compared to people with low triglycerides, individuals with high triglycerides were approximately 1.7 times more likely to have diabetes. HDL cholesterol had an odds ratio <1 due to its negative correlation to diabetes risk, therefore an increase in HDL cholesterol was associated with a significant decrease in diabetes risk. Individuals who had a sibling or parent with diabetes had a significant increase in diabetes risk. An ADA score ≥ 10 was also associated with increased odds of having diabetes.

Table 4.3.5 – Regression analysis on risk factors for diabetes

	Regression Coefficients	
	Odds	Significance
Age	1.04 **	0.001
≥45 years	3.44 **	0.001
Waist Circumference	1.03 **	0.004
BMI	1.09 **	<0.001
Systolic BP	1.02	0.074
Diastolic BP	1.03	0.136
TC	1.43 **	0.009
LDL	1.37	0.103
HDL	0.089 **	<0.001
Triglycerides	1.70 **	<0.001
GDM or baby > 9lbs (females only)	1.05	0.927
Sibling with DM	3.03 **	0.002
Parent with DM	2.48 *	0.010
Grandparent with DM	1.05	0.922
ADA score	1.19 **	<0.001

BP: blood pressure, LDL: Low density Lipoprotein cholesterol, HDL: High Density Lipoprotein cholesterol, TC: total cholesterol, DM: Diabetes Mellitus, GDM: Gestational Diabetes, *p<0.05, ** p<0.01

4.4 – Hypothesis 2: Opportunistic vs. Population based screening

The objective of hypothesis 2 is to compare the opportunistic group to the population based group and determine if there is any significant difference between the two regarding diabetes, prediabetes, and risk factors. Throughout, the terms “probable” diabetes and “probable” prediabetes are used as explained above. To recap, the opportunistic group was a sample of people from various Aboriginal communities who were screened because

they presented and were presumably worried about their risk for diabetes. The population group was a representation of a single community where a majority of the population was screened. The two groups are compared with respect to age and gender in Table 4.4.1. Independent t-tests were completed to assess the possibility of a significant difference between group means. Levene's statistic was calculated to determine if variance between the groups was normal (Levene's $p > 0.05$) and only then was normal the t-statistic was calculated.

Table 4.4.1 – Demographic comparison of opportunistic and population based screening

Criteria	Opportunistic		Population	
	N	X1: Mean (C.I) X2: Percent	N	X1: Mean (C.I) X2: Percent
1. Age (years)	919	40** (38.63, 0.87)	250	30(27.59, 31.91)
2. Sex	M: 334 F: 585	M: 36 % F: 64%	M: 107 F: 143	M: 43% F: 57%

** $P < 0.001$, M: Males, F: Females

There is a significant difference in age between the two groups ($p < 0.001$) and it will therefore be controlled for in the analysis of all variables. There was no significant difference in the gender ratio between the two groups. Table 4.4.2 below describes the similarities and difference between the two populations with respect to diabetes, prediabetes, the metabolic syndrome, and risk factors, corrected for age.

Table 4.4.2 – Opportunistic and Population based prevalence of diabetes, prediabetes, the metabolic syndrome, and risk factors corrected for age

	The BRAID study	
	Positive or High Risk	
	Opportunistic	Population
Probable Diabetes	2.93%	4.12%
Probable Prediabetes (fasting only)	32.3%	23.9%
Hemoglobin A1c ($\geq 6.1\%$)	9.60%	6.48%
Hemoglobin A1c ($\geq 5.5\%$)	40%	41.3%
Metabolic Syndrome (>18 years)	50%	51%
Body Mass Index (Obese)	53.1% **	46.8%
Increased waist circumference (≥ 18 years)	70.2% **	77.6%
High Blood pressure (≥ 18 years)	33.8% **	24.8%
Low HDL cholesterol (≥ 18 years)	54.9% **	69.1%
High LDL cholesterol (≥ 18 years)	30.5% **	22.5%
High Triglycerides (≥ 18 years)	46.5% *	39.2%
ADA Score	45.2%	34.6%

M:Males F:Females NA: Not Applicable. Difference between means (t) * $p < 0.05$, ** $p < 0.01$

Age correction was completed using analysis of covariance controlling for age. After correcting for age, there was no significant difference between opportunistic screening and population based screening for individuals diagnosed with “probable diabetes” and “probable prediabetes”. A1c $\geq 5.5\%$ and A1c $\geq 6.1\%$ was not significantly different between the two groups. A significant difference in obese individuals, LDL and HDL cholesterol, and triglycerides was seen between the two groups. Systolic and Diastolic blood pressure were also shown to be significantly different between the two groups after correcting for age. Comparison of inter-group (opportunistic vs. population) differences in regards to familial and gestational contribution to diabetes was not possible due to the low numbers of individuals found with undiagnosed diabetes. Table 4.4.3 compares the prevalence of gestational diabetes, siblings with diabetes, parents with diabetes, and grandparents with diabetes between the two groups. The groups were not significantly different in any of the categories.

Table 4.4.3 – Gestational and familial history of diabetes between groups

	Opportunistic	Population
	%	%
GDM or baby over 9lbs (females only)	15.9%	17.5%
Siblings with DM	29%	25.4%
Parents with DM	37.8%	38.2%
Grandparents with DM	37.5%	36%

Figure 4.4.1 shows the distributions of glucose between the two groups and figure 4.4.2 shows the distribution of A1c.

Figure 4.4.1 – Opportunistic vs. Population – Fasting glucose

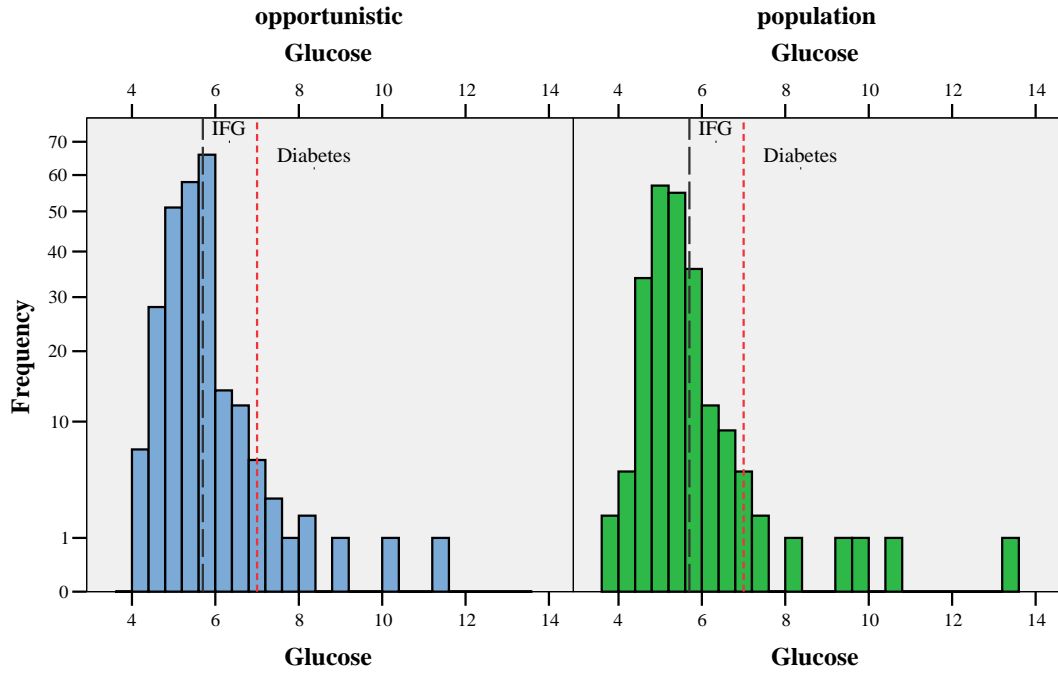
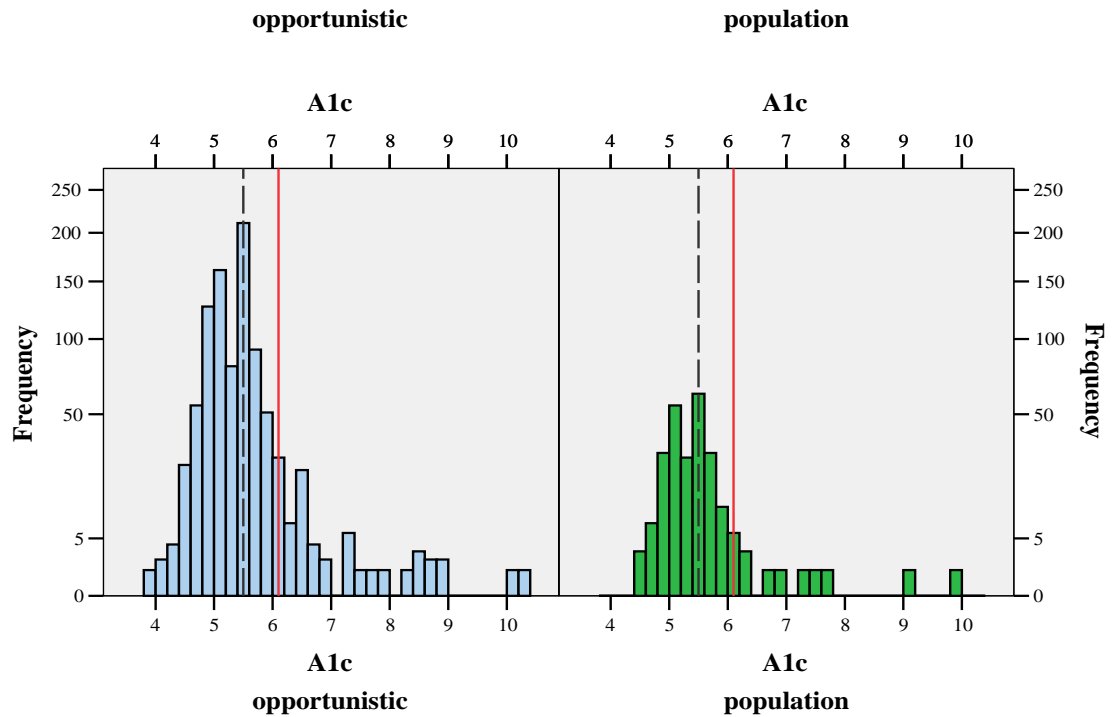
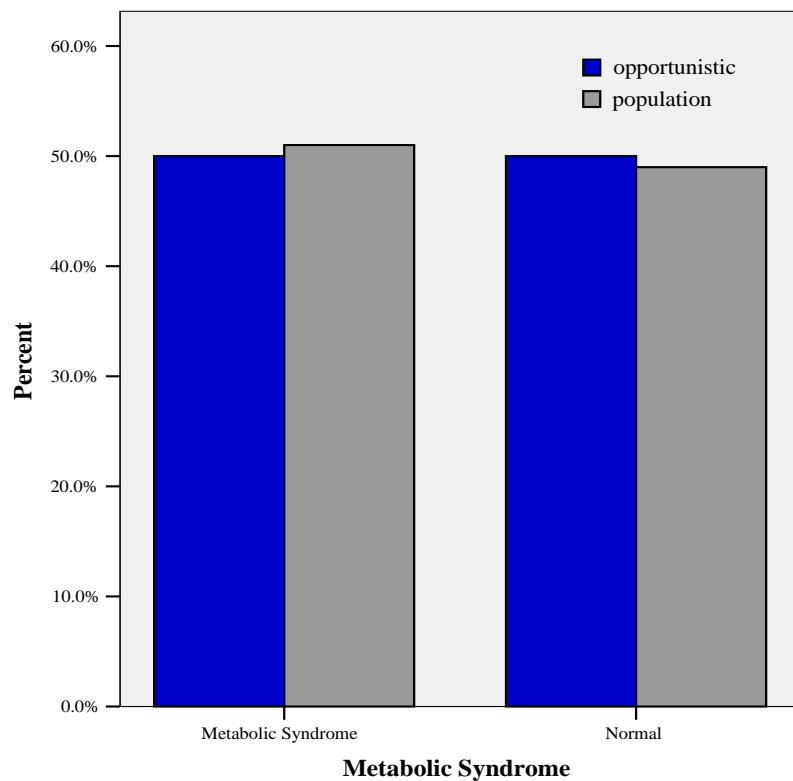


Figure 4.4.2 – Opportunistic vs. Population – A1c



The metabolic syndrome prevalence was not significantly different between the two groups, despite some significant differences in the individual metabolic syndrome components. Waist circumference, high triglycerides, and low HDL cholesterol were the most frequent contributors to the metabolic syndrome (Table 4.3.2 and 4.4.2). Figure 4.4.3 illustrates the prevalence in both the opportunistic group and the population based group.

Figure 4.4.3 – Frequency of the Metabolic Syndrome detected by Opportunistic vs. Population based screening strategies



The mean ADA score for the opportunistic group was 7.19 (6.78, 7.60) and 6.40 (5.76, 7.05) for the population group. A significant difference did not occur between the two groups when corrected for age.

CHAPTER 5

DISCUSSION

5.1 – Introduction

Although the SLICK, BRAID and MDSI projects are different with respect to their target population, research question and methods, there are similarities. The three projects have a fundamental objective: to reduce the burden of diabetes on Aboriginal people. The projects are also connected by one principal investigator, and from one project could be transferred to another. Weekly and at least monthly meetings allow discussion of issues and challenges that are occurring in the field. From data collection and quality assurance, to community feedback and translation, the three projects are intertwined. The BRAID study looked at an aspect of pooled data that the three projects have collected.

5.2 – Hypothesis testing

In the BRAID study 1170 Aboriginal people in Alberta were screened for diabetes and its risk factors. Over 60% were women. Recruitment was not knowingly directed at women in any of the three projects. It is presumed women were more interested in being screened, or were more available. Women may have had more reason to come forward, the 1991 Aboriginal peoples survey (APS 1991) reported a predominance of Aboriginal women with diabetes (Health Canada, 1997).

Testing of hypothesis 1 illustrated that portable technology was a useful tool for detecting diabetes as compared to the “standard”. The OneTouch[®] Ultra[®] glucometer used in fasting individuals was an accurate tool for detecting undiagnosed diabetes. The

diagnostic accuracy using standard glucose criteria for diabetes (7.0mmol/L) was 0.982. Therefore, in this study 98.2% of the time the glucometer accurately detected diabetes as compared to the standard. Receiver operating characteristics (ROC) analysis showed that this accuracy could be further improved to 98.7% by using a cut-off point of 7.10mmol/L; however the clinical benefit to be gained from this improvement is minimal.

The DCA 2000[®] A1c also performed well for detecting diabetes with a diagnostic accuracy of 0.938 using 6.1% (2SD from the mean) as a cut point. 93.8% of the time the A1c was accurate at detecting diabetes, however at an optimal cut point of 7.05%, the A1c was accurate at detecting diabetes in 98.1% of cases. This suggests that if this technology were to be used in the field, a cut point of 7.05% should be used. The sensitivity and specificity for the A1c \geq 6.1% using the DCA 2000[®] in the BRAID study was 0.65 and 0.94 respectively. These results are very similar to the United States third National Nutrition and Health Examination Survey (NHANES III) which looked at 6559 individuals, and found a sensitivity and specificity of 0.63 and 0.97 using venous blood. This study concluded that A1c is a highly specific and convenient alternative to diabetes screening when using a cut off of 2 standard deviations above the mean. Furthermore, a recent study conducted in 1253 veterans in the United States showed that in those who did not have diabetes at recruitment the A1c value was highly predictive of the development of diabetes within 3 years (Edelman et al., 2004). Individuals with an A1c in the “high normal range” (5.6 to 6.0%) had an incident rate of

2.5% per year, and those with an “elevated” A1c (6.1-6.9%) progressed at a rate of 7.8% per year.

Prediabetes refers to a condition where glucose is elevated, but does not reach the diagnostic criterion for diabetes. However it is increasingly recognized as a risk factor not only for diabetes, but also for cardiovascular disease which accounts for the largest burden of dysglycemia-related morbidity and mortality. The diagnostic criteria and strategies for testing for prediabetes are not as well established as compared to diabetes. For instance there is much confusion about the relative importance of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) in their contribution to prediabetes. IFG is diagnosed by a fasting glucose measurement; IGT requires a 2hr glucose tolerance test. Therefore a simple test for diagnosing prediabetes would be desirable. ROC analysis showed that the OneTouch[®] Ultra[®] glucometer and the DCA 2000[®] were not very accurate in detecting prediabetes. Diagnostic accuracy was considerably lower for both instruments as compared to accuracy for diagnosing diabetes. The area under the curve (AUC) was significantly lower for detecting prediabetes as compared to diabetes. The glucometer was accurate 84% of the time using the accepted range between ≥ 5.7 and < 7.0 mmol/L. The A1c was only accurate 66.3% of the time using a cut point of 5.5% (1 SD from the mean). From the AUC and the diagnostic accuracy, screening for prediabetes using this portable technology can not be recommended at this time.

Regarding hypothesis 2, comparison of opportunistic and population groups was conducted with respect to diabetes, prediabetes, diabetes and cardiovascular risk factors, and the metabolic syndrome. It was expected that individuals who were screened in an opportunistic paradigm would have some prior inclination to be tested, i.e. were previously told by a health care professional or family member about some health risk. It was thought that the population based screening group would be a more complete representation of an Aboriginal population and would therefore have significantly lower prevalence. For diabetes, prediabetes, $A1c \geq 6.1\%$, $A1c \geq 5.5\%$, ADA risk score, and the metabolic syndrome there was no significant difference between the two groups, failing to confirm hypothesis. Confirming hypothesis 2, however, the opportunistic group had significantly increased levels of obesity, blood pressure, triglycerides, and LDL cholesterol. This suggests that the differences in favour of the hypothesis were more pronounced with respect to cardiovascular risk factors than to diabetes risk factors. The fact that increased waist circumference and increased low HDL cholesterol, however, were more frequent in the population based group, probably explains why we were not able to show a difference with respect to the metabolic syndrome.

5.3 – Prevalence of diabetes, prediabetes, and diabetes risk factors

Consistent with other studies, the strongest predictors of diabetes were age, family history, BMI and waist circumference, and abnormal lipids. The ADA score was also a significant predictor of diabetes. Many studies have shown the impact of family history on diabetes risk (Mitchell et al., 2004; Meigs et al., 2000). The presence of familial history of diabetes in the BRAID study was similar in both groups. When looking at

total prevalence of family history of diabetes with respect to elevated glucose; those with a sibling with diabetes, parent with diabetes, or grandparent with diabetes were at significantly higher risk of increased glucose (≥ 5.7 mmol/L). Having a sibling with diabetes was shown to be the most important contributor to increased glucose with an odds ratio of 1.62. Gestational diabetes or having a baby over 9lbs did not significantly increase the likelihood of having an elevated glucose. This is contrary to many other studies. We did not collect information regarding the interval transpired since presence of gestational diabetes or having a baby over 9lbs. Since the mean age of the females in this study was 37, it is possible that type 2 diabetes had not yet had time to develop.

Total prevalence of undiagnosed diabetes in the study was 3.18%, and was not significantly different between the two groups. This finding is similar to the prevalence found in Quebec Aboriginals by Deslisle and Ekoe in 1993, and to Dannenbaum in the James Bay Cree (3.7% and 2.5% respectively) (Dannenbaum, 2001; Delisle and Ekoe, 1993). This is lower, however, than the prevalence found by Harris in Sandy Lake prior to 1997 (10.7%) and to Knowler in the Pima Indians in 1978 (13.9%) (Knowler et al., 1978; Harris et al., 1997b). These differences may be due to the discrepancies in age of the populations studied. The Sandy Lake and the James Bay Cree studies were conducted in subjects over 10 years of age. The study in Quebec was performed in those over 15 years of age, and the Pima Indians were studied after 25 years of age. There were also differences in the testing strategies (fasting glucose, OGTT, A1c) and cut-offs utilized. Additionally in this regard Young found differences in the prevalence of undiagnosed diabetes in Manitoba according to the use of older and newer diagnostic

criteria for diabetes e.g. 7.8mmol/L prior to 1998 (Young and Mustard, 2001). Furthermore, differences in undiagnosed diabetes maybe accounted for by the dates in which a study was done, for instance the report in the Pima Indians was published in 1978. At this time, there would have been less awareness of the existence of undiagnosed diabetes or of the epidemic of type 2 diabetes in Aboriginals. The high prevalence in the Sandy Lake study may be due to the presence of the “Oji-Cree thrift gene” (Hegele, 2001). More recent studies, including ours, tend to show a lower prevalence of undiagnosed of diabetes.

The highest rate of undiagnosed diabetes reported in Aboriginals was in the Strong Heart Study, where the prevalence was 14.4% in those aged 45-74 years. By contrast Leiter reported a prevalence of only 2.2% in those over 40 in the general population (Leiter et al., 2001). The BRAID study showed a prevalence of 4.9% in those over 40. The youngest individuals diagnosed in the study were 18 and 21 years of age and were detected in the population based screening project (BRAID). This is consistent with the fact that type 2 diabetes has been reported in Aboriginal youth in other studies (Dean et al., 2003; Dean et al., 1998). Dean found a prevalence of approximately 1% in her studies of children aged 4-19, and in children aged 6-19 the prevalence in the BRAID study was 0.5%.

The prevalence of prediabetes was high in this study. The total overall prevalence of prediabetes (IFG only) in all the projects was 28.3%. Due to lack of recent studies with new criteria for prediabetes it is difficult to compare to other studies. All the studies in

Table 1.3.1 used criteria prior to 2003 (IFG ≥ 6.1 <7.0mmol/L), whereas our study used “new” criteria (IFG ≥ 5.7 <7.0mmol/L). A recent analysis of the NHANES III compared IFG by old and new criteria in those 40-74 years of age in the U.S population. By old criteria there were 13 million persons with IFG, by new criteria the figure was 35 million. Using old criteria our prevalence of IFG was 10.8%. With a cut off of 6.1mmol/L the Manitoba Heart Health study showed a prevalence of 5% in females and 7.5% in males, the James Bay Cree study found 4.7% in both sexes, the Strong Heart Study found 21.2%, and the ARIC study found 32%. The last two studies were done in older age groups. With the old criterion the prevalence of prediabetes in the BRAID study is twice as high as that in the James Bay Cree, a population with a similar age distribution studied recently (Dannenbaum, 2001). In comparison to the Sandy Lake study, we did not find a pronounced male/female difference. Our prevalence for females was 9.5% vs. 12.9% for males whereas Harris et al found 19.8% vs. 7.1% respectively (Harris et al., 1997b). Our calculated prevalence of 28% with the new criteria was found in those aged 6-91, and the age specific prevalence shown in Table 4.3.3 shows a worrisome rate of 19.8% in the youngest age group (5-19 years). Therefore in spite of differences in measurement strategies it appears there is cause for concern in regards to rates of prediabetes in our study.

5.4 – The metabolic syndrome and cardiovascular risk factors

The overall prevalence of the metabolic syndrome in the BRAID study was 50.4% using NCEP/ATPIII criteria. Table 5.4.1 shows the results from the BRAID study compared to other studies from around the world.

Table 5.4.1 – Prevalence of the Metabolic Syndrome in the BRAID study compared with other countries Adapted from: (Cameron et al., 2004)

Country	Age Group	Men %	Women %
BRAID study	≥18	43.7	54
BRAID study	≥40	41.2	68.1
India	20-75	36.4	46.5
Mexico	20-69	26.6	
Oman	>20	19.5	23
Ireland	50-69	21.8	21.5
Turkey	>31	27	38.6
Mauritius	>24	10.6	14.7
France	30-64	10	7
USA Natives	45-49	43.6	56.7
USA Filipina	50-69	—	34.3
USA	30-79	26.9	21.4
USA (Non-Hispanic White)	30-79	24.7	21.3
USA (Mexican American)	30-79	29	32.8

Subjects in the BRAID study had the highest prevalence of all groups indicating their high diabetes and cardiovascular risk. Very little information is available about North American Aboriginals. In addition to the US Natives shown in Table 5.4.1 above, a study performed in the Inuit of Northern Canada (aged 25-64) has shown a low prevalence of 13.1% (Pollex et al., 2004).

Other risks associated with the metabolic syndrome are: polycystic ovarian syndrome (PCOS), non-alcoholic fatty liver disease (NAFLD), and cancer. NAFLD can be a cause of cirrhosis through its association with non-alcoholic steatohepatitis (NASH) (Matteoni et al., 1999). Indeed, pediatric NASH is becoming a cause of great concern and appears to affect ethnic minorities disproportionately (Schwimmer et al., 2003). Cancers thought to be associated with the metabolic syndrome and obesity in increasing order of relative risk are: prostate and colon (1.35-1.99), breast, uterus and kidney (2.0-4.9), and esophagus (>5.0) (Blackburn, 2003).

5.5 – Limitations

The three projects involved in this study had slightly different methodologies, notably the collection of two questions: gestational diabetes history, and grandparents with diabetes. These two items were not collected in the SLICK project. The questions were included in the MDSI and BRAID projects which were initiated at a later time. Another limitation was that in SLICK and MDSI the majority of samples were collected in the random state, as it was difficult to recruit all patients to come fasting. In the BRAID project a greater effort was taken to request individuals to fast for ≥ 8 hours before being screened. Therefore in the BRAID study the results reported for prediabetes (IFG), and hyperlipidemia rely more on the patients from the BRAID study. In the BRAID project 91.6% of subjects were fasting (n=229), whereas only 27% were fasting in the SLICK and MDSI projects combined (n=252).

The portable technology that was utilized in this study had potential limitations. The instruments utilized were not standard and the use of capillary blood is not standard;

however a rigorous quality assurance process was in place that yielded performance characteristics acceptable in any standard lab (See methods section 3.4). In particular, the use of the fasting Cholestech LDX[®] as the standard for the calculations regarding diabetes and prediabetes could be challenged. The ideal gold standard would be a 2 hour oral glucose tolerance test performed on venous blood. This was not logistically possible in the BRAID study, but is presently underway in the MDSI project. Glycemic categories were assigned on the basis of a single measurement, in order to keep things simple, and not to discourage recruitment. This was also not ideal.

In our population based sample, a recruitment of only 56% was achieved. Although the BRAID project is ongoing, complete ascertainment will likely never succeed because of the reluctance of some individuals to be screened. The causes for this possible reluctance have been described in section 1.7 and include, but are not limited to, fear of diagnosis of diabetes and its implications. In addition, unfortunately, in any Aboriginal community there is a small but significant portion of the population that is unavailable for screening because of multiple stressors.

5.6 – Lessons Learned and Future directions

Portable testing utilized in this study proved to be accurate for screening for type 2 diabetes in Aboriginal populations. Therefore fasting glucometer or random A1c testing can be used for community based screening programs, which are recommended by the Canadian Diabetes Association (see chapter 1.7). The cost of a single test strip

used in the OneTouch[®] Ultra[®] is \$1.00, as compared to \$18 dollars (includes lipids) for the Cholestech LDX[®], and approximately \$8 for the A1c.

Of particular benefit, the A1c is not affected by the fasting or random state, which allows individuals to be screened with a larger window of opportunity to access screening services. However the A1c requires a rigorous quality control process that limits its use in screening for small numbers of individuals, and makes infrequent use impractical. Unfortunately a random glucometer reading was not assessed in this study, but this is being looked at in MDSI. MDSI is also performing Oral Glucose Tolerance tests to give more information than can be provided in this thesis. Further research is required to learn the most practical way to detect prediabetes.

In all individuals screened, high A1c was more prevalent than undiagnosed diabetes. This might suggest that individuals who had a high A1c should be administered an oral glucose tolerance test to confirm the absence or presence of the disease, or be followed for the development of diabetes. A prospective study looking at these individuals with high A1c and normal glucose might prove beneficial, as A1c may perform well as a predictor of diabetes in longitudinal studies (Edelman et al., 2004). Fortunately all individuals screened in the BRAID study will be followed, as all projects, BRAID, SLICK and MDSI are on-going. These on-going projects will attempt to assess changes in lifestyle, anthropometric measurements, laboratory measurements, disease states, and health care utilization, amongst some or all of these individuals.

Recruitment for this study proved to be difficult. Merely travelling to a rural Aboriginal community is not enough. Intensive recruitment strategies and collaborations with community health workers are vital to the success of any future screening programs. Translation of the data collected and analyzed in the community through reports, discussions and meetings is also integral to a successful relationship. In summary, community partnership should be placed high on the priority list, and community involvement in the research is crucial.

5.7 – Conclusion

Based on this data it could be argued that population based screening for undiagnosed diabetes and prediabetes should be recommended for Aboriginal people age 6 and over. This is in contrast to the recommendations of the American Diabetes Association that favours testing only in the medical setting. The Canadian Diabetes Association favours “community based screening” (Grade D, consensus) although it does not recommend the tests that should be utilized. This thesis provides a contribution towards understanding which tests are feasible.

The prevalence of prediabetes in the BRAID study is the highest recorded in an Aboriginal population based screening initiative in Canada. These individuals are certain to progress to diabetes in due time if interventions are not implemented. Fortunately the resources are in place to tackle the burden. Without such resources, community based screening programs should not be implemented.

From the information presented, it is evident that diabetes is a major health concern facing Aboriginal people today, with indications that the situation may worsen in the coming years if changes are not made. Although diabetes has, affected and will continue to affect the lives of many Aboriginal people, one must hope that through education, research, and advocacy, the number of people affected by this silent killer will be greatly reduced in upcoming years.

APPENDIX 3A - INFORMATION SHEET AND CONSENT FORM FOR THE SLICK PROJECT

INFORMATION SHEET

“The Alberta First Nations Project to *Screen for Limbs, I-Eyes, Cardiovascular and Kidney (SLICK) Complications Using Mobile Diabetes Clinics*”

Contacts:

Community Contact:

Dr David Strong (First Nations and Inuit Health Branch Doctor)
phone: 780-910-6689

Dr Ellen Toth (Diabetes Doctor, University of Alberta)
phone: 780-407-6223 office, 445-2044 pager

Dr Mark Greve (or Dr Chris Rudnisky) (Eye doctors, Royal Alexandra Hospital)
phone: 780-477-4924

Purpose: The SLICK project will check you for complications of your diabetes.

Background: Diabetes can cause blindness, kidney problems, heart problems, and foot problems. We want to check you to make sure that your diabetes is well controlled, and to find out whether you have early signs of problems. These are the same tests you would have if you saw a diabetes specialist.

- **We will be doing this with all First Nations people in Treaties 6, 7 and 8. We want to put together all the information on those tested and summarize what we are doing as it might be helpful to other First Nations’ Communities.**
- **Your chiefs and council have approved this project.**

Procedures: You will have your blood pressure and weight checked. A photographer will take pictures of your eyes for specialists to look at. The specialists will send the results to the Health Unit to let you know if your eyes are normal, have problems, or if you need treatment. A nurse will take blood from finger pokes to see your sugar and cholesterol levels. A sample of urine will also be taken to see if your kidneys are healthy, and your feet will be checked. If your results indicate your diabetes needs help the staff at the Health Unit will help you arrange visits with doctors, nurses, or dieticians.

- You will also be asked for information about your diabetes such as how long you have had it, how many members have it in your family.

We would like to record your results and answers in a computer so that we can describe the results of these diabetes tests in all diabetic First Nation’s people. **However you do not have to agree to this to get tested.** You will have all your personal results given to you and

discussed with you. Your answers to the survey will be sent anonymously to evaluators who will assess the success of the SLICK program.

Benefits: Having these tests will be helpful to you to know if your diabetes is causing you problems now or if there are early signs of trouble that can be treated now to prevent future problems. These are the kind of tests you would get in a city if you went for a check on your diabetes.

- Keeping your tests and answers in a computer will help us develop or improve diabetes services in your community, and hopefully in other First Nations' communities.

- **Privacy and Confidentiality:** You will be given all your results. We will also send them to whichever doctor/s you wish. If you allow us, we will enter your results in the computer. When we look at the results and answers in the computer, your name and any identifying information will be hidden. We will share the anonymous summarized results with you, with your leaders, and with Health Canada. We may present the anonymous results to others such as doctors, students, or administrators. When we communicate with others, we will never talk about individual people, and we will never identify communities by name.

Freedom to withdraw: You do not have to have these tests done. You do not have to allow us to enter your results in the computer in order to receive the SLICK services. If you do not want to participate in the SLICK project we will offer you other available options.

Risks: You may find the blood tests pokes hurt slightly. You may feel upset, anxious or discouraged because your diabetes is not well controlled or you are developing problems from it. Please talk about this with the team. You may feel your community has too much diabetes. This is one of the reasons why we are here! We want to help your community deal with diabetes.

The eye drops may sting a little and the bright lights may be uncomfortable. Your eyes will be dilated and your vision blurred for about two hours after the examination. You will not be able to drive till this resolves. You may experience some uncomfortable side effects due to these drops including:

1. Irritable and stinging eyes.
2. Blurry vision or glare.
3. Irregular shaped pupils.
4. Minor eye redness or pain and some tears.

These are normal effects that most people will experience when given eye drops of this type. Most of these symptoms will go away when the effects of the eye drops have worn off fully in 6 hours.

If you experience the following symptoms 4 to 24 hours after being given eye drops:

1. Extreme pain in the eye with sudden loss of vision.
2. Nausea and vomiting.
3. Extremely watery eyes.

PLEASE INFORM THE SLICK NURSES. IF THE SLICK STAFF ARE NOT AVAILABLE OR YOUR SYMPTOMS OCCUR AT NIGHT, PROCEED TO YOUR NEAREST PHYSICIAN OR EMERGENCY ROOM IMMEDIATELY. PRESENT THIS INFORMATION SHEET TO YOUR DOCTOR WHEN YOU ARE BEING EXAMINED.

Information for Physicians

This patient has volunteered in the SLICK project. As a part of the assessment, the patient was given the mydriatic agent Diophenyl-T (Tropicamide 1%, and Phenylephrine 2.5%) for the purposes of taking retinal images. If the person presents with the above symptoms as well as the following signs:

1. Mid-dilated, non reactive pupil.
2. Hazy, edematous cornea with conjunctival injection and copious tearing.
3. Narrow anterior chamber on slit lamp exam, or oblique penlight examination.
4. Elevated intraocular pressures via tonometry if possible, or direct palpation.
the patient may be suffering from an acute attack of angle-closure glaucoma.

Please call The Royal Alexandra Hospital switchboard in Edmonton at (780) 477-4111 and ask to speak with the Ophthalmology resident on-call. The residents are familiar with the project and will assist you with this patient.

Additional contacts: If you have any questions or concerns about any part of this study, please contact Dr Toth or the other the study staff listed at the top of this document. If you have any complaints about SLICK you may contact the Patient Concerns Office at 780- 407-1040. There is an independent person there to deal with complaints. If you have any questions about the SLICK evaluation survey (questionnaire being used to assess the impact of SLICK), please contact Ms Neera Data or Dr Penny Jennett at the Health Telematics Unit in Calgary: (403) 220-2881

CONSENT

“The Alberta First Nations Project to *Screen for Limbs, I-Sight, Cardiovascular and Kidney* (SLICK) Complications Using Mobile Diabetes Clinics”

Contacts:

Community Contact:

Dr David Strong (First Nations and Inuit Health Branch Doctor)
phone: 780-910-6689

Dr Ellen Toth (Diabetes Doctor, University of Alberta)
phone: 780-407-6223

Dr Mark Greve (or Dr Chris Rudnisky) (Eye doctors, Royal Alexandra Hospital)
phone: 780-477-4924

Do you understand that you have been asked to participate in a project? Yes No

Have you read and received a copy of the attached Information Sheet? Yes No

Do you understand the benefits and risks involved in taking part in this project? Yes No

Have you had an opportunity to ask questions and discuss this project? Yes No

Do you understand that you are free to refuse to participate or withdraw from this project at any time? You do not have to give a reason and it will not affect your care. Yes No

Has the issue of confidentiality been explained to you? Do you understand who will have access to your records? Yes No

Do you want the SLICK team to send the results of your test to your doctor? Yes No

If YES please give us your doctor's name: _____

This project was explained to me by: _____

I agree to have blood and urine tests for this project.	Yes	No
I agree to have eye drops and photographs of my eyes.	Yes	No
I agree for my results to go into a computer.	Yes	No

_____	_____	_____
Signature of Participant and/or Parent /Guardian	Date	Witness

_____	_____
Printed Name/s	Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____	_____
Signature of SLICK team member	Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE PARTICIPANT

BENEFITS: You may benefit from knowing whether you do or do not have diabetes. You may also benefit if you know you are at risk for getting it.

RISKS: You may not like finding out if you have diabetes or are at risk of getting it. You may experience minor pain and bruising from having blood tests.

IS THIS RESEARCH? Yes. Dr. Toth is a specialist and researcher at the University of Alberta and she is interested in finding better ways to find and help people with diabetes. In the past and even today there are many examples of researchers abusing the trust of Aboriginal people. Sometimes they have taken data and information. This project has been requested by some of your people. It is being done together with Alberta Health and Wellness and the University of Alberta.

PRIVACY AND CONFIDENTIALITY: You will be given all your results telling you what they mean. We will also send them to your doctor if you wish. All of your information will be kept confidential. Only people involved with the study who need to know will see your information. We will never use your name if the results of the community are discussed in public or published in research magazines.

ALTERNATIVE DIAGNOSIS AND VOLUNTARY PARTICIPTION: You do not have to take part in this study. You can change your mind about taking part at any time. It will not affect your care. If you wish to be tested for diabetes you can speak to your MDSI contact.

ADDITIONAL CONTACTS: If you have any questions or concerns about any part of this study, please contact Dr. Toth or the other study staff listed at the top of this document. If you have any complaints about MDSI you may contact the Patient Concerns Office at (780) 407-1040. There is an independent person there to deal with complaints. If you have any questions about the MDSI evaluation survey (questionnaire being used to assess the impact of MDSI), please contact Dr. Toth.

STUDY TITLE: Mobile Screening Initiative for Diabetes and its Complications in Off-Reserve Aboriginal Communities - (Mobile Diabetes Screening Initiative – MDSI)

CONTACTS: Dr. Ellen Toth Diabetes Doctor, University of Alberta
Phone: (780) 407-6223

Dr. Mark Greve Eye doctor, Royal Alexandra Hospital
Phone: (780) 477-4924

Donna Prokopczak Study Assistant Manager, University of Alberta
Phone: (780) 407-1627

Local contact:

I understand that I am participating in a research study. An MDSI team member has explained the benefits and risks involved in taking part in this study. I have received and read a copy of the attached information sheet.

I understand who has access to my records and that my results will be remain confidential.

I also understand that I am free to refuse to participate or withdraw from this study at any time. I do not have to give a reason to withdraw and it will not affect my care.

This study was explained to me by: _____.

If at anytime I have further questions I may ask an MDSI team member.

I agree to have blood and urine tests for this study Yes No

I agree to have eye drops and photographs of my eyes Yes No

Signature of Participant and/or Parent/Guardian Date Witness

Printed name/s

Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Study Team Member

Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS FORM AND A COPY GIVEN TO THE PARTICIPANT

APPENDIX 3C – INFORMATION SHEET AND CONSENT FORM FOR THE BRAID PROJECT

INFORMATION SHEET

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

Contacts: Ellen L. Toth MD, diabetes doctor - 780-407-6223
Norry Kaler - 780-951-0679

Local contact:

INTRODUCTION: First Nations' people have a lot of diabetes. Diabetes is reaching epidemic proportions in some communities, and is causing a lot of problems.

People with diabetes suffer from having to look after it with diet, exercise, pills, and sometimes needles (insulin), and can also suffer complications with damage to eyes, kidneys, heart, nerves and feet.

It would be easier to prevent diabetes than its complications. However to identify risk of diabetes fasting blood tests or glucose tolerance tests are needed.

PROCEDURES: We would like to blood tests to assess risk of diabetes.

If you want to volunteer we will ask you some questions, weigh you and measure you, check your blood pressure, and then do some finger tip blood tests as well as the breath test.

From the blood test results we will be able to tell you immediately whether you are at a high or low chance of having diabetes. The breath tests results will take a week to come back, and we will make sure you get those results as well with an explanation of what they mean.

BENEFITS: You may benefit from knowing whether you do or do not have diabetes, or if you are at risk for getting it.

By helping us test the breath test you will be helping us and the company gain more information about whether people will accept the breath test.

RISKS: You may not like finding out if you have diabetes or are at risk of getting it. You may experience minor pain and bruising from having blood tests.

IS THIS RESEARCH? : Yes. Dr Toth is a specialist and researcher at the University of Alberta and is interested in finding better ways to diagnose and help people with diabetes. She works with other researchers at the University and with companies. In the past and even today there are many examples of researchers abusing the trust of First Nations'

people and taking away data and information. You can decide whether you want to trust this research team.

CONFIDENTIALITY: You will be given all your results with an explanation of what they mean. We will also send them to your doctor if you wish. All your information will be kept confidentially in a computer. Only people involved with the study who need to know will see your information, and you will never be identified by name if the results of the community are discussed in public or published in research magazines.

ALTERNATIVE DIAGNOSIS AND VOLUNTARY PARTICIPATION: You do not have to participate in this study. If you wish to be tested for diabetes you can speak to your doctor or your Health Unit Staff. You can change your mind about participating at any time, without it affecting your care.

If you have any complaints about any part of this study, you may contact the Patient Relations Office of the Capital Health Authority at (780) 407-1040. This office has no affiliation with the study staff.

CONSENT

The BRAID program
Breath Tests to Reduce Aboriginal Incidence of Diabetes

Contacts: Ellen L. Toth MD, diabetes doctor: 780-407-6223

Norry Kaler : 780 951 0679

Local Contact:

Do you understand that you have been asked to participate in a study? Yes No

Have you read and received a copy of the attached Information Sheet? Yes No

Do you understand the benefits and risks involved in taking part in this study? Yes No

Have you had an opportunity to ask questions and discuss this study? Yes No

Do you understand that you are free to refuse to participate or withdraw from this study at any time? You do not have to give a reason and it will not affect your care. Yes No

Has the issue of confidentiality been explained to you? Do you understand who will have access to your results? Yes No

Do you want the results to be sent to your doctor? Yes No

If YES please give us your doctor's name: _____

This project was explained to me by: _____

I agree to have blood tests and a breath tests for this project. Yes No

I agree for my results to go into a computer. Yes No

Signature of Participant and/or Parent /Guardian Date Witness

Printed Name/s Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Braid Study team member Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE PARTICIPANT

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