

THE UNIVERSITY

June 21, 2005

IRB Chair
Tribal Institutional Review Board
45 Rand Road
Rapid City, SD 57701

Dear IRB Chair:

Attached is the protocol entitled “Pre-Diabetes and Diabetes on the Reservation: A School-Based Youth Screening Program” for your review during the July 12, 2005 IRB meeting.

We propose to conduct a school-based diabetes program for the six schools on the Reservation. We are currently working closely with the IHS Service Unit and Service Unit Director. The screening will provide the tribe and IHS Service Unit with information regarding their youth and rates of pre-diabetes and diabetes to assist them in planning intervention activities. In addition, the screening will have direct benefits for the youth.

We have obtained approvals from The University IRB (see attached) and the Area IHS IRB (see attached) pending approval from your IRB. Once receive approval from all three IRBs, we will initiate contact with school principals and school boards. We hope to begin activities for this project in September 2005.

We eagerly await favorable review. Thank you very much for your consideration. Please do not hesitate to contact me with any questions.

Sincerely,

John Smith, MSN

RESEARCH PROPOSAL

A School-Based Youth Screening Program for Diabetes Type 2

Submitted by

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Summary

One of the most important functions of public health programs is the provision of screening services for individuals at risk for various diseases. Screening tests can provide early identification of health problems at a time when the problems can be successfully treated or in some cases prevented altogether. Public health experts have developed criteria to determine whether it is beneficial to screen asymptomatic individuals for a given disease. In Indian communities diabetes is a disease that meets these criteria:

1. Diabetes causes a high burden of disease.
2. Diabetes is detectable by testing long before symptoms occur, and even before the disease is irreversibly established.
3. The diabetes screening tests are available and reliable.
4. Diabetes can be prevented by changes in lifestyle or by medication, as was recently proven by the Diabetes Prevention Program study.

Given the above circumstances, the University proposes a research study to determine the prevalence of diabetes among Indian youth at Tribe:

Goal: To determine the prevalence of diabetes, impaired glucose tolerance, impaired fasting glucose, and insulin resistance syndrome in youth and adolescents who live on or near the Reservation.

Design: The study will be a cross-sectional prevalence study of children attending grades 3-12 through a school-based screening program at six elementary, middle, and high schools on or near the Reservation.

Methods: Implement a voluntary, systematic screening program that collects demographic information, biometric measures, family history of diabetes, activity history, and biochemical markers for diabetes, impaired glucose tolerance, impaired fasting glucose, and insulin resistance syndrome.

Analyses: Prevalence will be calculated with demographic and other subset analyses.

I. BACKGROUND & NEED

The Centers for Disease Control and Prevention has recognized in the past decade that type 2 diabetes mellitus (diabetes)¹ has been steadily rising, not only in the general population, but even more alarmingly in children as well. The number of persons with diabetes has increased 49% over the past decade; presently, 10.5 million persons have been diagnosed with diabetes, while 5.5 million persons are estimated to have the disease but are undiagnosed. Over the past decade, diabetes has remained the seventh leading cause of death in the United States, primarily from diabetes-associated cardiovascular disease. The national increase in the prevalence of diabetes and its complications has been far exceeded among Indians, in whom the highest prevalence in the world has been reported:

- Indian populations suffer 280% higher rates of diabetes than non-Indian populations.
- In some Indian groups half of all adults over age 35 have glucose intolerance.
- Diabetes in youth is increasing (68% from 1990–98).
- Indian populations have higher complication rates than non-Indian populations.
 - Blindness is 24–49% higher.
 - Kidney failure is 600% higher.
 - Amputation is 350% higher.
- Indian populations have 166% higher mortality rates from diabetes than non-Indian populations.

Diabetes among youth

Type 2 diabetes is seen with increasing frequency in children younger than 15 years of age, and now accounts for as much as 45% of newly diagnosed cases of diabetes in the pediatric population. Type 2 diabetes among youth is a relatively new and potentially catastrophic public health issue (Dean 1998; Rosenbloom 1999). The progression of the complications of diabetes such as neuropathy, retinopathy, nephropathy, usually occurs within about 20 years of the onset of the disease. All available evidence indicates that the progression of complications occurs on the same time trajectory whether the onset of diabetes is early or late in life. In the past, when the onset of the disease was rarely before the age of 40, most complications occurred in the elderly. For these individuals, most of their lives were spent without the burden of blindness, renal failure, and lower extremity amputations. However, for individuals who develop diabetes before the age of 20, it is highly likely they may develop these complications by the age of 40. The probable outcome will be a vast increase in prevalence of the long-term complications of diabetes (Harris et al, 1999; Dean, 1998; Rosenbloom, 1990). The long-term complications are also associated with increased mortality. Clearly this will cause a major decrease in the overall quality of life, as well as a decrease in life expectancy of many Indian people.

Like their parents, Indian youth also appear to suffer disproportionately higher rates when compared to the other ethnic groups. Type 2 diabetes occurs most frequently in children who

¹ Diabetes is a chronic disease that usually manifests itself as one of two major types: type 1, mainly occurring in children and adolescents 18 years and younger, in which the body does not produce insulin and thus insulin administration is required to sustain life; or type 2, which has historically occurred primarily in adults over 40 years of age, in which the body's tissues become unable to use its own limited amount of insulin effectively.

have a strong family history of diabetes, children who are overweight, children exposed to diabetes in utero, and children who present with acanthosis nigricans (Harris 1996; Dabelea 1998; Dean 1998; Harris 1997).

Diabetes in the pediatric population is associated with increased rates of dyslipidemia, hypertension, vaginal moniliasis (Fagot-Campagna 2000), polycystic ovary syndrome, and compromised immune systems, as well as non-medical costs. Hyperinsulinemia, a condition found in insulin resistance, has known negative cardiovascular effects, but it has not been thoroughly studied in youth. Other issues of concern are the burden of daily treatment and social stigmatization of having an adult health problem.

Given the grave scenario of many Indians developing diabetes during their youth or early adult life and then developing complications of diabetes in mid-adult life, there is a clear imperative to develop effective screening and prevention programs for diabetes and pre-diabetes among children (Dean 1998; PinHaus-Hamiel 1996; Glaser 1997). An effective, comprehensive screening program will not only identify those with diabetes, but will also identify those most at risk for developing diabetes during adult years through newer detection methods for IGT, IFG, and IRS.² Within the Tribe, there are no known screening programs and primary interventions targeting the pediatric population.

Preventing Diabetes

Increasingly diabetes is being thought of as a disease that occurs on a continuum, as shown below.



² Case definition for diabetes and pre-diabetes:

According to the American Diabetes Association, the diagnosis of diabetes is defined as: (1) Fasting plasma glucose ≥ 126 mg/dl (7.0 mmol/L); or (2) 2-hour oral glucose tolerance test (OGTT) ≥ 200 mg/dl (11.1 mmol/L); or (3) Symptoms of diabetes and casual plasma glucose > 200 mg/dl, with second test on a subsequent day to confirm diagnosis

There are two pre-diabetes impaired glucose handling states: impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). Both of these are particularly good markers for the eventual development of diabetes (ADA 2000). They are due to a milder, but measurable, decrease in biologic response to a given amount of insulin, and are characterized by high insulin levels. Pre-diabetes is defined as: (1) Impaired glucose tolerance (2-hour OGTT with values between 140-199 mg/dl); or (2) Impaired fasting glucose (fasting plasma glucose of 111-125 mg/dl).

Until recently there was no proof that the continuum could be interrupted in individuals who were at high risk for developing diabetes and its complications. In February 2002 National Institutes of Health (NIH) issued a report on the findings of its Diabetes Prevention Program (DPP) study, which was stopped after only 2.8 of the proposed 5 years because of clear and convincing evidence of the results (Knowler 2002). The primary goal of the DPP was to prevent or delay the onset of diabetes in persons identified at highest risk of developing diabetes—those with IGT or IFG. This NIH study was a randomized, controlled, multi-center prospective study with 3,234 overweight adults with IGT.³ The 3, participants were randomized into three arms of the study: intensive lifestyle, medication (Metformin), and placebo. Findings from the study show that both interventions (lifestyle and medication) were well accepted and safe; the intensive lifestyle intervention resulted in the reduction of diabetes by 58% while the Metformin reduced the development of diabetes by 31%. Both interventions were effective in men and women, and all ethnic groups, and the intensive lifestyle intervention was effective in all age groups, including those greater than 60 years old. Finally, the intensive lifestyle intervention was more effective than Metformin.

Sixteen million persons have pre-diabetes in the United States. The majority of these persons will develop diabetes within ten years. Fifty percent of newly diagnosed diabetics have complications at the time of diagnosis, and fifty percent of pancreatic beta cell function is already lost at the time of diagnosis. Abnormal glucose metabolism probably predates diagnosis by 5-10 years. We now know from the DPP that progression from pre-diabetes to diabetes can be prevented. In order to intervene at the pre-diabetes stage, we must first identify who has this condition.

Need for Screening

In April 2002 the American Diabetes Association (ADA) issues recommendations and guidelines for active screening for diabetes. This report primarily addressed clinic-based screening for adults. However, in recognition of the increasing magnitude of the problem of diabetes among youth, the ADA has also released the following guidelines for screening of children: (ADA 2000)

If overweight or obese, defined by

- BMI >85th percentile for age and sex
- Weight >85th percentile for height
- Weight >120% of ideal for height

Plus two risk factors:

- 1st or 2nd degree relative with diabetes
- High-risk racial or ethnic group
- Signs or conditions associated with IRS (Acanthosis nigricans; Hypertension; Dyslipidemia; Polycystic ovary syndrome)

Then screen every two years beginning at age 10 or puberty.

³ The average age of participants was 51 years (range 25-85 years), with 45% from multi-ethnic groups. Five percent (171) of the participants were Indians from Zuni, Shiprock, Gila River, Salt River, and the Phoenix Indian Medical Center.

In order to pull together the state of the art knowledge of diabetes, including screening and prevention activities, the American College of Endocrinology (ACE) Diabetes held a Diabetes Consensus Conference in January 2002. The ACE report from this conference states:

Despite the reasons cited in opposition to [diabetes] screening and intervention programs, the increasing prevalence of diabetes in our high-risk populations, especially in minority children and young adults, makes comprehensive screening essential if a positive effect is to be achieved on the prevention of diabetes and improved outcomes for those who have diabetes.

ACE also state that comprehensive (i.e., community-based) screening for IGT or diabetes may be considered in settings in which:

- The high-risk group being screened is likely to be able to attend the screening.
- Expert information will be made available to those screened.
- A relevant treatment plan will be made available to those screened that have abnormal results.
- Adequate funding for the screening and treatment program is available.

The proposed Tribal youth screening program certainly meets all of these criteria.

Schools are the most promising venue for primary prevention targeting the pediatric population. In some Indian communities, numerous innovative type 2 prevention programs have been implemented (Morrison 1998; Cook 1998; 1998; Marlow 1998; Chiasson 1998; Macaulay 1997; TeufelParker 1999). They range from a comprehensive screening and fitness program (utilizing three full-time fitness instructors, local medical staff, a gymnasium, a swimming pool, and a fully equipped weight room) to a coalition of community volunteers dedicated to improving the physical fitness and eating habits of local school children (Hood 1997).

In summary, the growing incidence rate of diabetes and pre-diabetes in Indian populations foreshadows a cohort who will likely experience more morbidity and mortality in the years to come. There are numerous and complex key determinants but the identified environmental and behavioral factors are potentially modifiable or removable. Since intervening with pre-diabetes in adult populations has now been proven successful, it is imperative to develop and implement prevention programs geared toward children. There will need to be two levels of prevention interventions: (1) Education for the entire community; and (2) intensive education and support services for those individuals with pre-diabetes, who are at the highest risk and have the greatest immediate need for assistance. The DPP has shown that such intensive intervention can be successful.

II. STUDY ACTIVITIES

Goals

1. Identify diabetes and pre-diabetes among children in grades 3-12 on the Reservation in order to improve their health outcomes.
2. Determine the prevalence of diabetes and pre-diabetes in order to inform efforts toward prevention and intervention.

Objective

1. Establish a screening program at each of six schools on the Reservation.
2. Screening all children grades 3-12 within one school year.
3. Provide intensive health education to all children (and their families) found to have diabetes or pre-diabetes.

Sample Size & Analysis

Total students in grades 3-12 for the six schools are 1404, with 1229 known Indian students. We will offer screening to all Indian students in grades 3-12. Students who are diabetic, pregnant, acutely ill, or have a chronic illness will be excluded.

Basic descriptive statistics of the prevalence of:

1. Diabetes
2. Pre-diabetes: IGT, IFG, IRS
3. Each of the data elements collected.

These will be stratified by age and gender.

Overview of activities

Screening will be done in local school settings. After obtaining permission from each school's principal and school board, a meeting will be held with the teachers. There, we will discuss diabetes, the rising emergence in Indian youth, the prevention studies conducted and their findings thus far, and the details of the screening. Teachers will be informed of the time lines, and will have the opportunity to address any concerns not yet foreseen by the investigators.

A letter will be sent to the parents one month prior to the screening. This will explain the emerging problem of pediatric diabetes, the purpose of the study, and an invitation to attend a dinner and presentation at the school. This presentation will be conducted by one of the primary investigators. Information regarding the results of the Diabetes Prevention Program, what we know about diabetes now, its progression, and the goal of primary prevention will be discussed. Screening parameters with rationale and logistics will also be discussed, and questions will be answered. Parents will be informed that participation is voluntary, and no IHS or tribal services will be lost because of non-participation. They will be given the opportunity to sign a consent form for their child at the meeting, or to send it to school with their child. Parents will also be encouraged to talk to their children regarding the screening, as each child must also assent to

their participation. Parents will be allowed and encouraged to come to the school the day of the screening to re-assure their children.

Within one week of the parental meeting, the primary investigators will meet with each classroom to talk with the students. Age appropriate discussions about diabetes in their own families and other families on the reservation, and our hopes of preventing it in future generations will ensue. It will be explained that we will be conducting a screening program at the school, and children's questions will be addressed. We will outline how the screening will be conducted, what they can expect, the need for them not to eat or drink anything but water the morning of the screening, and the breakfast and incentives to follow. Children will be informed that their participation is voluntary, and if they choose to participate they will need to sign an assent form, as well as receive consent from their parents. Children will be offered an incentive to return their parents permission slip to their teachers. We will emphasize to all children that the incentive is for simply returning the form, regardless of whether the child participates or not. Parents will be invited to join on the day of the study, and be screened as well. A week and then a day prior, letters and permission slips to the parents will be sent with each student reminding them to keep the children fasting through the morning. The name and phone number of the investigators will be on the letters, with an invitation to call if further information is desired. All students in grades 3-12 will be invited to participate, and each grade that is scheduled for screening will be addressed individually, so as to create a more comfortable milieu for questions and answers. Students who participate in the study will be offered a breakfast as well as a token incentive, such as a T-shirt or a pedometer.

Detailed Description of the Screening at the School

There are six area schools that will be screened over a one-year period. Since the students need to be in a fasting state for the lab tests, the screening time will be limited to the early morning hours, and no more than forty students will be screened during any one day.

The screening team will consist of at least one physician, nurse practitioner, or certified diabetes educator (all IHS employees) to oversee, organize, and conduct any post-screening consultation necessary, 1-2 patient registration persons (IHS employees), 2 RNs or LPNs (IHS employees) to complete the consent form and history and questionnaire duties, 2 nurses (Tribal and IHS employees) to perform the finger sticks and blood pressures, 2 laboratory technologists (IHS employees or possibly contracted phlebotomists) to do the venous draw, and 1 tribal health educator and 1 tribal exercise trainer to perform the biometric measurements. Each student will spend approximately five minutes at each of the five stations. Transit time will be approximately 30-45 minutes per student, with 10 students undergoing the screening process at any given time. It is anticipated that approximately 20-30 students will be screened per morning session (7 to 9 am). This time constraint is necessary since the students will be fasting.

Each station will be curtained to assure privacy and confidentiality. The screening will begin at the reception area where a CHR will have a folder with a screening worksheet, as well as the parental consent form. The student will be escorted to the mandatory next station where a nurse will review the Assent Script. This is to assure that pre-test counseling will be done in a

developmentally correct and sensitive fashion. It will be reiterated to the students and the parents, if present, that the student, at any time, may decline to continue, or refuse a portion of the study. A questionnaire for the students regarding diet, physical activity, and family and personal medical history will also be conducted at this station. Questions from the ADA brochure, "Diabetes and American Indians: Are You at Risk?" will be adapted for the students' reading levels by the station manager.

The student will then go to a curtained area where a nurse will measure the height, weight, blood pressure, and examine the skin on the student's neck for acanthosis nigricans. Each station will report results in the student's folder, which will be hand carried by the station 'manager' to the next available station. Students will then be taken to another curtained area where a fitness instructor and a health educator will measure percent body fat from bio-impedance.

The student will then be escorted to one of two stations, which will perform a capillary finger stick to check for fasting capillary glucose (One Touch Ultra glucometer), fasting lipid levels (name of device), and HbA1c (DCA 2000+) and a 0.5 cc venous sample for a fasting insulin level. Only one student will be screened at each station at any one time. If a student has a capillary glucose value over 350 mg/dl, that student's parent or guardian will be contacted to facilitate immediate care.

Results of the screening will be given to the students that day and will be sent to the parents by mail. The letter will highlight results of concern, and include educational material to aid in the interpretation of the results.

Following the screening

If a student has an elevated fasting insulin level, elevated triglycerides, or a fasting glucose of greater than 126 mg/dl, a personal telephone call will be made to the parent, and an appointment made for definitive testing (2 hour OGTT). A consultation following definitive testing will be scheduled with either the Nurse Practitioner or MD. A handout listing referral appointments and phone numbers to registered dietitians, certified diabetes educators, and fitness instructors, as well as websites on diabetic topics, will be given to each student-parent pair.

All students testing positive for insulin resistance, impaired glucose tolerance, or impaired fasting glucose will be offered participation in a bi-weekly lifestyle intervention classes. Topics to be included in these classes will include nutrition (Registered Dietitian), exercise therapy (Health Educator or Fitness Instructor), diabetes basics (Certified Diabetes Educator), healthy shopping and cooking (WSU Extension Office), and medications for diabetes (Certified Diabetes Educator).

Otherwise, screening will be done as per the ADA pediatric guidelines until the students reach age 18. It is felt that the majority of positive findings will not be overt diabetes, but rather IRS, IFG, or IGT. It is the intention of the investigators to detect as many of those with the pre-diabetes states, so parents and children will be given an opportunity to seriously consider lifestyle changes, and potentially prevent the actual onset to diagnosis of diabetes.

Program Time Line

We intend to offer the training to the six schools seriatim. Preparation time before the start of the actual screening will be at least two months. Preparation time will overlap with screening, so that preparation for the next school's screening will be ongoing during the current school's screening. During this time, discussion with local school principals and school boards, acquiring approval, as well as generalized public service announcements, and flyers distributed throughout the reservation, gathering of testing resources, and coordination with all participating personnel will take place. Thus, it may require up to four to six weeks of testing per school. For each school, a team of a head physician or nurse practitioner, and ten assistants will be required. Of the ten assistants, two will need to be certified in phlebotomy and two trained in biometric measurements and blood pressure measurement. Given the usual delays, the time for publicity and negotiations with the schools, one school year will be allocated for the actual study process with six weeks devoted to each of the schools (summer cannot be used). Thus, in Year 1 we intend to do the training in all six schools. In the event that we are unable to complete all six, the remaining schools will be finished at the beginning of the next school year. We are anticipating a total of 2 years to complete the school screenings.

Data

Data Elements

No personal identifiers will be collected. The data elements to be collected or calculated will be: date of birth, gender, height, weight, BMI, percent body fat from bio-impedance, fasting plasma glucose, fasting insulin level, fasting lipids, HbA1c, presence of diabetic family history and acanthosis nigricans, birth weight, presence of maternal diabetes during pregnancy, and history of polycystic ovary syndrome.⁴

Data Confidentiality

All individuals involved with conducting this screening program have extensive experience working with confidential patient data. All data collected during this screening program will be managed with the usual high standard of confidentiality for medical data. All data will be entered into the student's IHS chart, as well as the youth diabetes screening registry. Only a limited list of investigators will have access to this physically and electronically secured data. All printed

⁴ Measuring insulin resistance: Since the Fasting Plasma Glucose (FPG) and OGTT tests lack some degree of sensitivity, insulin resistance actually occurs before it is detected in screening. In addition, FPG and OGTT measure glucose rather than insulin levels. The gold standard of measuring insulin resistance is the euglycemic-hyperinsulinemic "clamp" test. This test is performed by administering insulin in a logarithmically decreasing dose, followed by a constant infusion rate, for two to four hours. By adjusting the infusion rate of a 20% glucose solution, the serum glucose (measured every 5 minutes) is kept at 90 mg/dl. This clamp method, however, is clearly too costly and cumbersome to use in screening. Several groups have proposed surrogate tests, which are more feasible to perform and improve upon the insensitivity of the FPG and OGTT to detect insulin resistance. One of these groups, McAuley, et al (2001) developed a formula using the weighted combination of fasting insulin and a fasting triglyceride level, with good correlation to the euglycemic-hyperinsulinemic "clamp" test. These test results will be plugged into the logarithmic formula set up in a spreadsheet program to determine the presence and degree of insulin resistance that a particular student has.

data not stored in the medical record will be kept in the locked files of the P.I. All electronic data not stored in the clinic RPMS system will be in files on the PC of the P.I., which is password protected. Hard copy "Data Worksheets" will be kept in a locked file in the Diabetes Program Directors office. Computer data will be password secured on the Director's Computer.

Data Ownership

The individual data recorded in the medical records will become part of the IHS Service Unit records, and will be governed by federal regulations concerning identified medical information.

Intended Use of Study Findings

The data collected by this research study will be used at two levels:

1. Data for individuals will be used by study staff and clinic medical staff to provide the best possible services for individuals at high risk for diabetes. Having accurate and timely information on a child's risk for diabetes will help families make the difficult lifestyle changes necessary to prevent diabetes. Just as individuals with pre-diabetes were the focus of the Diabetes Prevention Program, the tribal health care programs will provide intensive lifestyle intervention and counseling to those identified as having diabetes or pre-diabetes.
2. Aggregate data will be analyzed and reported to the Tribe. These data will for the first time give tribal leaders knowledge of the extent of the problem that diabetes poses for the community. Leaders of the Tribe understand that their community may have a large proportion of high-risk youth who may benefit from early detection of silent (i.e., asymptomatic) diabetes and pre-diabetes. From a broad perspective, knowledge of the prevalence of diabetes and pre-diabetes will help leaders and planners to target resources most effectively.
3. Aggregate data and information on the efficacy of the screening will be analyzed and published in a reputable journal.

Conclusion

In the year 2002 American Indians bear a heavy burden from diabetes, and this is expected to grow in the future. Without the foresight to develop more aggressive preventive approaches to diabetes, Indians will surely increase in their disproportionate burden of the costs of diabetes. Only a collaboration of community engagement, sensitive and well-designed research, and public health practice can change this trend. By conducting this diabetes and pre-diabetes prevalence study, the Tribe is approaching this complex issue in a feasible and reasonable manner. With the information the study will produce, the Tribe can better predict the future prevalence of diabetes and cost. They will be able to make informed decisions on allocating financial resources to education, health care providers, facilities, and schools. Families will have more accurate information on the level of risk of diabetes for their children, and will be able to use this information to improve the health of their children.

Last, until now diabetes has been a relentless disease of chronic management and serious impairment of quality of life for Indians, but now there is hope that we do not have to start the

new century accepting this as a fixed premise. Armed with the knowledge of their personal risk and the knowledge of the success of prevention measures, tribal members will be more likely to change their basic lifestyles to prevent themselves, their children, and their children's children from developing diabetes. No longer must people passively accept the inevitability of diabetes. With this proposed screening and prevention program, the Tribe will have the option of NOT surrendering to diabetes!

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Sample Protocol for Training Purposes
A School-Based Youth Screening Program for Diabetes Type 2

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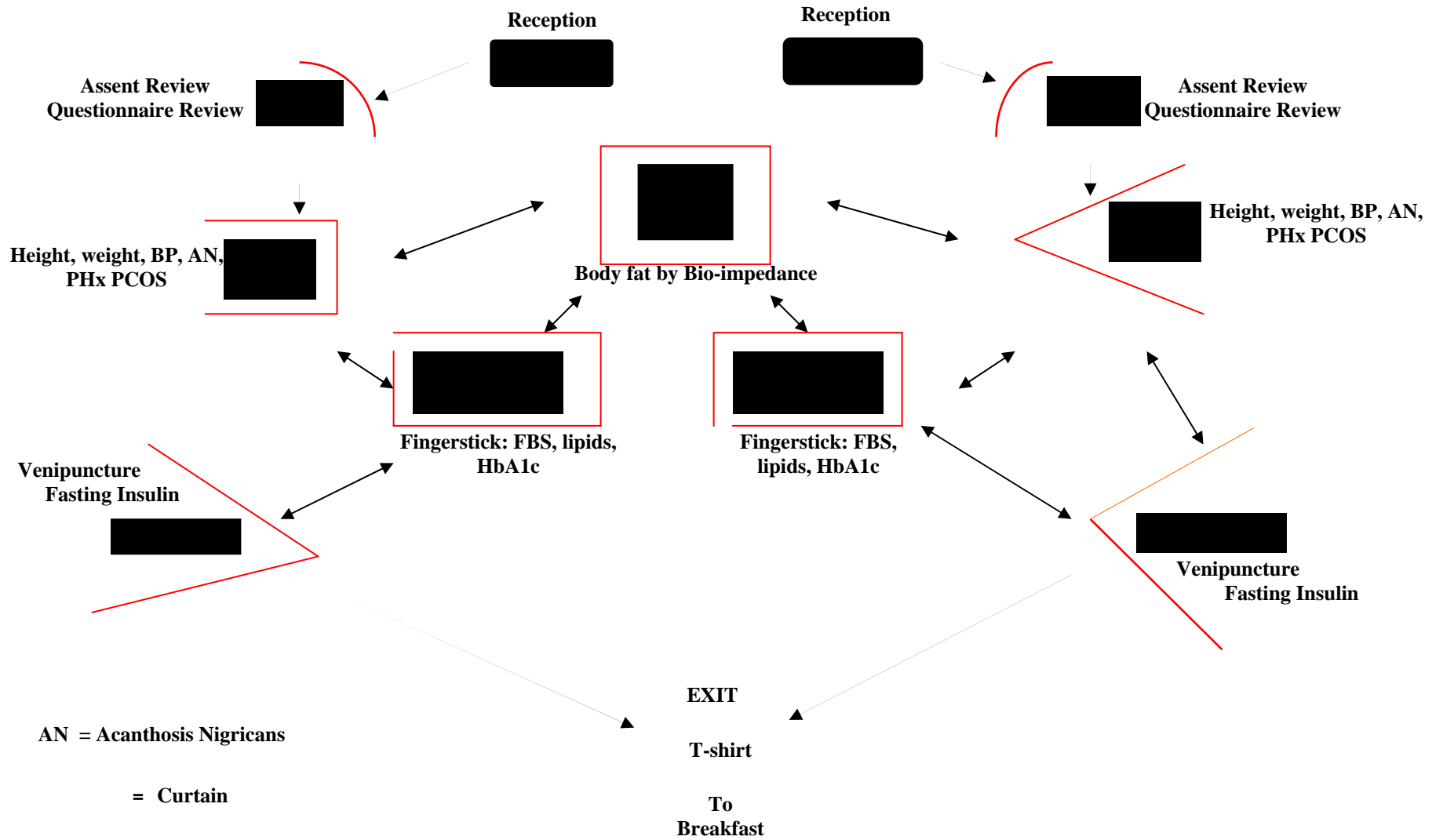
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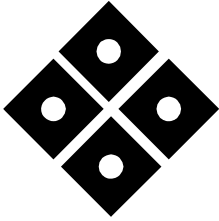
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APPENDIX: SCREENING FLOW CHART



APPENDIX: INTRODUCTION LETTER FOR PARENTS



A School-Based Youth Screening Program for Diabetes Type 2

July 1, 2005

Have You Heard?

New research has found that *Diabetes Can Be Prevented*!!!!!! Let me tell you how!

Many persons you know on our reservation have diabetes.... you may even have diabetes or have family members who have diabetes. As many of you may know, we now have wonderful new medications that can really help a person with diabetes live a fairly normal and long life. What you may not know is that diabetes is becoming an epidemic.... especially in Indian Country and especially among Indian youth (there has been a 68% increase in incidence of Type 2 diabetes in children in the last ten years!)

This year, a large study was completed in many centers across the US and involving many anglo- and ethnic American peoples in an attempt to show that diabetes can be prevented. This study was called the Diabetes Prevention Program study. The study showed that they were able to help 58% of persons who had “pre-diabetes” from going on and getting diabetes. We now have tests that let us assess if a person is “on the road” to getting diabetes. I have enclosed an article written about one of the American Indian participants in the study to help you learn more about the study and the things they found out.

Based on this study, we are conducting a screening program in all of the reservation schools to help parents of school children learn if their children are at risk or even may have diabetes and don't know it. All students attending _____ School are eligible for screening. We are testing fasting blood sugar and insulin levels, cholesterol and lipids, height and weight, blood pressure, and asking questions about family history and lifestyle. A doctor, or a nurse practitioner, or a Certified Diabetes Educator will be at every screening, and the results of your child's tests will be sent to you.

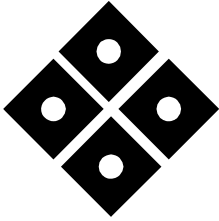
We understand that this screening may bring up many questions for you, so we have arranged for an informal luncheon meeting on _____ at _____ to explain our program, all the new information that has recently developed concerning diabetes and “pre-diabetes”, what the screening will involve, and how you can help your child by knowing what will be happening to them.

No child will be screened without your written consent, as well as your child's consent. You are invited to bring or send any family members that may be involved with the care of your children, as well as your children. We will also give you information on how diabetes can be prevented or delayed, and the exciting programs we have which will help you and your family if your child were to be found to have one of these pre-diabetes conditions. We will tell you about other professionals who are on board to assist.

So **please**, come and eat and learn about this exciting screening program we have and what we hope to learn and do! Let's stop the epidemic right here on the Reservation! No surrender to diabetes for us! If you attend, please call one of the below numbers so we can plan the food! Door prizes also available!

John Smith, MSN, Principal Investigator, The University: (555) 555-5555
Jane Doe, RN, Diabetes Educator, IHS Service Unit: 555) 555-5555

APPENDIX: REMINDER LETTER FOR PARENTS



**A School-Based Youth Screening Program
for Diabetes Type 2**

July 1, 2005

REMINDER!!!!!!

This letter is a reminder that your child who attends School has the opportunity to be screened for diabetes and “pre-diabetes” on _____.

It is very important that if your child is going to be participating in the screening that they not eat anything after 9pm the night before.

REMEMBER! You are more than welcome to accompany your child during the screening, and even be screened yourself.

Please find attached the parental consent form. Your child cannot be screened without this signed form. Your child may bring it with them to school, or you have time to mail it before the screening.

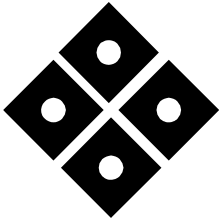
Hope to see you there!

If you have any questions, please contact:

**John Smith, MSN, Principal Investigator, The University: (555) 555-5555
Jane Doe, RN, Diabetes Educator, IHS Service Unit: 555) 555-5555**

**Attachment: Parental Consent Form
Diabetes: Are You at Risk?**

APPENDIX: PARENTAL CONSENT FORM



A School-Based Youth Screening Program for Diabetes Type 2

July 1, 2005

Parental Informed Consent for Diabetes Screening

The Diabetes Prevention Program is providing a health screening for American Indian children in grades 3-12. This is part of a research project to find children who are at high risk for diabetes. We also want to find children who may have diabetes but do not know it. We will do the screening in all the schools on the reservation. We want to check as many as possible.

You child is not required to participate. There will be no penalty and you nor any members of your family will lose no services from the Tribe, IHS, or others. If your child participates in the screening, they may withdraw at any time during the testing. You may choose to visit your own doctor for these tests, which may involve some cost. You may also choose to do nothing.

We will ask to take several drops of blood from a finger-stick. We will test your child's blood sugar and cholesterol and lipids (the 'good' cholesterol and 'bad' cholesterol). We will send you the results in the mail and/or call you if there are any abnormal results. We will then tell you what the results mean. If your child needs further testing, we will help you arrange that testing. The finger-stick may sting for a few seconds.

We will ask to draw some blood from your child's vein. This is the same thing that happens when your child has a physical. This can cause some pain, stress, and perhaps a small bruise. We will test your child's insulin level. Drawing this blood sample will let us do the best tests for detecting diabetes and pre-diabetes. IHS Clinic staff will draw the blood. Again, we will send you these results in the mail and be available if you have any questions.

We will ask to check your child's height, weight, and blood pressure. This, as well as all the tests we do, will be done behind a curtained area. This is to assure your child's privacy and dignity.

We will ask your child a few questions. We will ask about diabetes in your family, about their activity level, and whether or not they ate before the screening.

We will keep this information confidential. Lab results will go into your child's IHS chart, as well as into an IHS Children's Diabetes Screening Registry. After that, your child's name and

date of birth will be removed before entering any data into a research database. The clinic staff will contact you if you are at high risk for diabetes. We will ask you to come to the IHS Clinic or to your regular provider if any further testing may be necessary.

If you have questions, please contact XX.

If you have a complaint or a concern, contact Service Unit Director at (555) 555-5555. You may also make a toll-free call to the IHS switchboard (800-555-5555) and ask for Jane Doe.

Both your family and the entire reservation community will benefit. You will benefit by finding out if your child has diabetes or if your child is at high risk for developing diabetes. If your child should have unknown diabetes or if they may be at high risk, the IHS clinic or your regular doctor can help you child stay healthy and give you the information and services you need to help your child prevent or delay getting diabetes in the future. The community will benefit since the screening will help us better plan our health care services. We are committed to stopping this epidemic. This research may even benefit other tribes in our area.

Yes, I want to participate in the Screening Program for type 2 diabetes. I agree to allow my child take part in the medical tests and have the data collected for research purposes. My child and I are free to withdraw at any point during the testing.

Non-coercion disclaimer: “Taking part is voluntary. You may refuse to take part without any penalty or loss of care or services by IHS or others. You may stop taking part at any time, without penalty or loss of care or services to which you are otherwise entitled.”

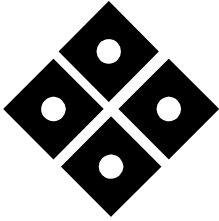
Signature of parent or legal guardian

Date

Signature of Diabetes Team Member

Date

APPENDIX: CHILD ASSENT SCRIPT



**A School-Based Youth Screening Program
for Diabetes Type 2**

July 1, 2005

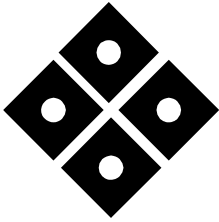
Assent Script for Diabetes Screening

	Yes	No
Do you understand that you are not required to take part in the screening?	<input type="radio"/>	<input type="radio"/>
Do you understand that you are not required to complete all the tests?	<input type="radio"/>	<input type="radio"/>
Do you understand that if you choose to take part in the screening, you are free to stop at any time?	<input type="radio"/>	<input type="radio"/>
Do you understand that if you do not take part in the screening, there will be no penalty and you will not lose any services?	<input type="radio"/>	<input type="radio"/>
Do you agree that we may take blood from a vein?	<input type="radio"/>	<input type="radio"/>
Do you agree that we may take a two drops of blood from a finger-stick?	<input type="radio"/>	<input type="radio"/>
Do you agree that we may weigh you, measure your height, take your blood pressure, and test your body fat?	<input type="radio"/>	<input type="radio"/>
Do you agree that we may ask you a few questions?	<input type="radio"/>	<input type="radio"/>

Signature of volunteer **Date**

Signature of witness **Date**

APPENDIX: SCREENING TIMELINE FOR TEACHERS



**A School-Based Youth Screening Program
for Diabetes Type 2**

July 1, 2005

Screening Program Timelines

School _____

Grade to be screened _____

Teacher(s) _____

Letters (describing program and orientation invitation) to parents _____

Date of Parents Orientation _____

Date of Class/Student Orientation _____

Students arrive in classroom at _____

Brought to gymnasium/auditorium for screening at _____

Number of students _____

Expected transit time through screening stations _____

Breakfast for screened students' from _____ **to** _____

Estimated resumption of class _____

Contact Person:

John Smith, MSN, Principal Investigator, The University: (555) 555-5555

Jane Doe, RN, Diabetes Educator, IHS Service Unit: 555) 555-5555

APPENDIX: SCREEN SHOT OF DATA ENTRY FORM

The screenshot displays a Microsoft Access window with a menu bar (File, Edit, View, Insert, Format, Records, Tools, Window, Help) and a toolbar. The main area shows a data entry form titled "DM Data" with the following fields:

Index number	<input type="text"/>	% Body fat	<input type="text"/>
Gender	<input type="text"/>	Cuff Size:	<input type="text"/>
DOB	<input type="text"/>	Systolic	<input type="text"/>
LBW	<input type="checkbox"/>	Diastolic	<input type="text"/>
HBW	<input type="checkbox"/>	Capillary glucose	<input type="text"/>
Mother/father +DM	<input type="checkbox"/>	Cholesterol:	<input type="text"/>
Sister/brother +DM	<input type="checkbox"/>	Insulin	<input type="text"/>
Mother +GDM	<input type="checkbox"/>	Venous glucose	<input type="text"/>
2+ hrs video/TV	<input type="checkbox"/>	Acanthosis	<input type="checkbox"/>
Questionnaire Score	<input type="text"/>	Adult	<input type="checkbox"/>
Height	<input type="text"/>		
Weight	<input type="text"/>		
BMI	<input type="text"/>		

Record: of 1

A red "STOP" sign icon is located in the bottom right corner of the form.

The Windows taskbar at the bottom shows the Start button, several open applications (including "who_is_the_creator - Mic...", "DM Database : Database", and "DM Data"), and the system tray with the time 12:38 PM.