STRONG HEART STUDY
newsletter
INVESTIGATING CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

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SHS Coordinating Center Uses Secure Methods to Protect Participants' Information

Since the beginning of the Strong Heart Study, the Coordinating Center (CC), based in Oklahoma City, has been here to serve the study. Before the beginning of each round of examinations, the CC helps investigators finalize the study protocol, compiles a manual of operations, develops data collection tools, establishes computer databases, designs data management and quality control procedures, creates programs for data entry, develops secure mechanisms to transmit data from field clinics to the CC, and organizes training sessions to ensure that all the SHS staff understand the study protocols and are familiar with examination and data-handling procedures. When examinations start and data collection begins, the CC vigilantly monitors the progress and inspects the data's quality. When the data have been collected, the CC performs most of the statistical analyses to assist investigators to report SHS findings.

In the current phase of the study (Phase IV), the programmers in the CC have used Microsoft Access database software to create custom applications for data entry. While writing the data entry programs, we also inserted many special functions -- such as logic checks to minimize unnecessary data errors, and coding for "skip patterns" to correspond with those that appear in the data collection forms – to speed up the data entry process.

A major improvement in the data processing for this round of examinations is that we are taking greater advantage of the widespread availability of internet access and high-speed connections. We use Terminal Services technology, which involves the data entry personnel at the field clinic sites connecting their computers to the CC's data entry server computer through the internet, for each data entry session. This sets up "real-time" transmission of data from the field centers to the CC as it is being entered by field staff. In fact, the Access application runs exclusively on the CC's computer, while the field center computers only need to be running the communications software. This allows the CC's programming staff to be very efficient in maintaining software installations and addressing program revision needs.

As the data are keyed in, they are saved in the CC's server computer immediately. The highly reliable nature of the internet communications software employed ensures data transmission integrity. It is very rare for any data to be lost during transmission, because if data entry is interrupted by a power surge or drop (we prescribe the use of battery back up systems to help prevent this) or a sudden loss of internet connection, data entry staff can simply reestablish the connection to the data entry server, which will normally allow the data entry process to resume at the point where it was interrupted. And since the Terminal Services connections are strictly password-protected and apply very strong (128-bit) encryption technology to all communications between the field center's computer and the CC's data entry server, it is virtually impossible for confidential data to be successfully intercepted during the data entry process.

As a first step in working with incoming data, the CC's data manager transfers newly-entered data out of the data entry server on a weekly basis. The data manager performs regular quality checks, and, after stripping all personal identifiers, distributes these "raw" data to the CC's programmers or data analysts for second-level data clean-up purposes only. Later, the cleaned-up data along with the derived variables will be distributed to the interested investigators upon their request.

The CC is also diligent in backing up the data. Our data back-up procedures include several layers of safeguards to protect against data loss. We have a daily back-up, weekly back-up, and monthly back-up, so that if an accident such as a hard drive failure ever occurs, the damage will be minimal. Our back-up data are stored in cartridge disks, CD-ROM, and archival tapes. All the back-up media are stored in locked offices, and regularly-updated copies are housed in an industrial-rated fire-resistant safe. Those media are only accessible by the CC's principal investigator, system administrator, and data manager. All the CC's staff, including statisticians, have signed a pledge to maintain the confidentiality of the data under the CC's guard.

Funding Search Continues

As the Strong Heart Study (SHS) investigators and staff talked to participants and tribal leaders, everybody agreed that it is essential to translate the information from the SHS into intervention programs that can help to decrease or prevent the increasing occurrence of heart disease. The SHS investigators believe that their findings are ready for translation into a clinical intervention. The SHS found that most of the heart disease is in people with diabetes, that cholesterol levels are strong predictors of heart disease, and that elevated blood pressure is a risk factor for heart disease (coupled with its effect on increasing protein excretion from the kidney). Excellent medications are now available in the US for lowering LDL cholesterol and blood pressure. While these drugs have not been tested in studies in Indian communities, they have been tested in many other populations and approved by the FDA. The SHS investigators believe that if these current treatment strategies to lower blood pressure and cholesterol are applied to diabetic American Indian patients, they will result in lower rates of heart disease. In order to implement this strategy into medical practice, it is necessary to test it with a randomized trial. This means that a study must be performed where the participants will be divided into two groups, one of which will have current treatment for cholesterol and blood pressure, and the other group will receive more aggressive treatments so that their blood pressure and cholesterol levels will be lowered even further. The SHS has shown that the ultrasound pictures of the heart and of the blood vessels in the neck both show changes in individuals with diabetes that are reflective of cardiovascular disease. These measures can be used in the study to determine whether the aggressive blood pressure and cholesterol treatments are effective. The SHS investigators met and planned a study, which will be conducted in the three existing SHS communities and also in Chinle, Arizona in order to involve the Navaho people who also appear to be having greatly increased rates of diabetes and heart disease.

Attempts to obtain funding for this program are ongoing. We initially applied, along with many other people throughout the country, to be part of a very large consortium to test strategies for lowering heart disease in individuals with diabetes. Our center was not accepted to be part of that program. In retrospect, this is probably fortunate, since that program will be extremely complex and have a very long term follow-up with many interventions that the participants will need to undergo. SHS investigators have planned a simpler, shorter term (3-years) study involving only blood pressure and cholesterol lowering. The National Heart, Lung and Blood Institute agreed to accept an application for independent funding of this project. It was submitted last year. Current procedures for obtaining research funding involve a very rigorous peer review process. The application underwent that process, and, while it received an encouraging score, enough questions were raised that it could not be funded without resolving some of the issues related by the review committee. The investigators came together and rewrote the proposal (which now totals about 400 pages including appendixes), and this has been resubmitted to the National Heart, Lung and Blood Institute . It will undergo review by the Fall Review Committee. We are all hoping for a favorable review this time, because SHS would like very much to start as soon as possible to test and prove that the intervention suggested by our data will be effective in reducing heart disease in people with diabetes. If we can prove this, then the interventions will be adopted by care providers throughout Indian country.

Stepping Out ... and Counting

By now, many of you may have been told about the pedometer that is being used during the Strong Heart Study phase IV campaign. You may have wondered what it is and why you will be asked to wear one. In order to make this process a little easier, we would like to provide you with some important information that will help you understand what the pedometer is, what it does, and why you will be asked to wear it.

- **What is a pedometer?**

A pedometer or movement meter is a small battery operated device about the size of a matchbook. It is very light weight and can be clipped to your pants or skirt.

- **What does the pedometer do?**

The pedometer captures movement, mostly walking, that you do throughout the day.

- **Why are we asking you to wear a pedometer?**

The answer is very simple. By wearing the pedometer or movement meter, you will help us to help you. We would like to assess the movement that you do during the day for a seven-day period. The numbers produced from your pedometer will help the Strong Heart Study staff determine what a typical week of movement looks like for you. This information will help us to provide you with valuable feedback.

In order to capture a typical week of movement from you, we ask that you do not change your physical activity levels during the week that you are asked to wear the pedometer. Keep doing what you would normally do during the week. Remember, everyone is different in regard to activity and movement level; the SHS staff will be pleased to receive your seven day record regardless of the level it shows.

We look forward to making this phase of the project successful and hope this information helps you to better understand the pedometer and its usefulness. If you have any further questions or concerns about the movement meter, please feel free to contact a SHS staff member who will be able to answer your questions.

SHS Data Adds to Indian Health Knowledge

The Strong Heart Study staff continue to examine community members who are part of large families that will shed light on genetic as well as environmental contributors to cardiovascular disease in American Indians. Almost 1200 examinations had been completed as reported in the October meeting of the Strong Heart Study investigators. The Dakota Center continued to set the pace with 412 examinations completed. It was followed by Arizona with 388 and Oklahoma with 358. All three centers were ahead of the pace that was planned for this examination phase which is a tribute to the enthusiastic community support for the study and to the continuing excellence of the SHS staff in recruiting and implementing the exam. We appreciate everyone's effort in making this study a success to date; keep up the good work!

Earlier data from the Strong Heart Study are getting good visibility in areas where it counts. SHS investigators attended the Association of American Indian Physicians in August, where they presented two papers and three posters related to Strong Heart Study data. Several of the presentations won awards for excellence. American Indian physicians and researchers attending the conference were pleased to have SHS results and noted that they hoped to see more in the future.

In addition, the Strong Heart Study data book has been printed and is being made available to study community leaders, health care workers, and study participants; other American Indian communities; political leaders; and biomedical researchers to keep them informed on the health status of American Indians and to provide guidance in decision making about allocation of resources for health care needs. We hope this data book will be seen as a sign of appreciation for the participants in the Strong Heart Study and used by the communities and medical community to improve the health of current and future generations.

STRONG HEART STUDY COORDINATING CENTER
University of Oklahoma Health Sciences Center
Center for American Indian Health Research
College of Public Health
P.O. Box 26901
Oklahoma City, OK 73190-3040

Genetics

Where's the Beef?

fourth in a series of articles by Lyle Best, MD

We have heard so much about the promise of genetics in the past number of years that some people have wondered whether this is just another example of media "hype" and no practical results. If you were expecting genetics to change the genes you inherited so that you can eat all the cheeseburgers you want, or produce an unlimited supply of genetically matched pigs' hearts that can be transplanted whenever your heart fails....then you have been disappointed. Still, genetic discoveries have led to some little-known medical advances that are used everyday.

Many of you probably take cholesterol lowering medication with a name that ends with "...statin." There are only a few medicines that we know can prevent heart attacks and death if used properly, and this group of cholesterol medications has proven to be one of the best. How these medications were discovered tells us much about the way genetics can improve our health.

In the middle 1950's studies much like SHS (except in white communities) showed that high cholesterol levels made heart disease much more likely. Genetic scientists knew of families that had very high levels of cholesterol because of mutations in genes they passed from one generation to the next. In 1973 two Nobel prize winning researchers discovered that a gene in these families failed to produce the proper form of a cholesterol receptor on liver cells. In the late 1980's the "statin" group of medicines was developed from some kinds of fungus; and by the early 1990's the benefit of these medicines was being proven in tests involving thousands of participants around the world.

Many of you use insulin to help control diabetes, or you may have used a clot-dissolving medicine to stop a heart attack that was developing. Although insulin was discovered in the 1920's and was extracted from the byproducts of pork and beef slaughter for many years; in the 1970's genetic methods were used to produce insulin from yeast that was identical to human insulin and avoided possible contamination from viruses that animals might carry. The drugs used to dissolve clots and stop heart attacks and strokes are also made using genetic methods, as are 50-60 vaccines and other important medicines that we use every day.

So while genetics hasn't perhaps been as important as some people predicted a few years ago, it has still provided many benefits and the best is probably still to come.