



# STRONG HEART STUDY

## newsletter

INVESTIGATING CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

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## Stop Atherosclerosis in Native Diabetics Study Begins

The Stop Atherosclerosis in Native Diabetics Study (SANDS) began recruiting participants in April 2003. This is the first study ever to explore ways to prevent or reverse the progression of cardiovascular disease in American Indians with diabetes. The National Heart, Lung, and Blood Institute announced the funding of SANDS in September 2002. SANDS is a clinical trial that will be conducted in four geographic areas. Three areas are sites of the Strong Heart Study; Phoenix AZ, Lawton OK, and Rapid City SD. The fourth site is Chinle AZ so that members of the Navaho community will be able to participate in this program. We have reported previously in this newsletter that the Strong Heart Study found a rapidly increasing rate of heart disease in American Indian communities. Most of this appeared to be in individuals with diabetes. Their results also showed that both LDL cholesterol (the bad cholesterol, a type of fat in the blood) and blood pressure were strong risk factors; that is, individuals with higher levels of LDL or blood pressure had the greatest chance of developing heart disease. The SANDS clinical trial is testing a pre-

vention strategy that will treat LDL cholesterol and blood pressure to targets that are lower than currently accepted treatment guidelines. There is currently debate throughout the country about whether treatment targets in individuals with diabetes, because they are at such high risk for heart disease, should be lower for both LDL cholesterol and blood pressure. The SANDS study seeks to answer this question.

The study staff will recruit 124 diabetic men and women (at least 40 years of age) in each of the four centers. These individuals, after careful screening for other health problems, will be randomly assigned to either an intensive care group where their blood pressure will be lowered to 115/75 mmHg and their LDL to 75 mg/dl, or to a control group whose blood pressure and cholesterol will be treated to currently accepted targets, 130/80 mmHg and 100 mg/dl. Only FDA approved medications will be used in the program, and participants will be carefully monitored for side effects and the effectiveness of cholesterol and blood pressure lowering agents. Study participants will be seen often, at least four times a year, and study staff will also make sure

that they receive their regular diabetes care at their local IHS or tribal clinic. At the beginning and after three years, ultrasound will be used to measure thickness of the arteries in the neck and to measure heart function. These will be the endpoints of the study, and the rates of change will be compared in the aggressive and the usual care groups.

SANDS staff at all four centers will be closely aligned with their communities and will work closely with the community and tribal leaders throughout the five years of this program. Principal Investigators at the four field sites are Dr. Charlton Wilson, currently an internist at the Phoenix Indian Medical Center, Dr. Bryce Poolaw, Clinical Director of the Lawton Hospital and a member of the Kiowa community, Dr. James Galloway, IHS cardiologist, and Dr. Jeffrey Henderson, President of the Black Hills Center for American Indian Health and a member of the Lakota community. The SANDS and Strong Heart Staff are working hard to make this study a success and hope that its results will lead to better care and less heart disease for American Indians with diabetes.

# Strong Heart Study and Comm



Above, Dr. Jeff Henderson

Right, Marcia O'Leary

Below, Valarie Jernigan



Since the Strong Heart Study began in 1988, the SHS investigators have made every effort to help the Indian communities that participate in the study. One of the biggest benefits has been the large number of tribal members who have worked on the study, thereby gaining experience in the health-related research. The

human resources that have developed as a result of the SHS are very empowering for the participating tribes, because their capacity for conducting their own research has greatly increased. In addition, all the SHS employees have become more health conscious and have served effectively as health educators and role models for their communities, advising the

participants and the communities in how they can obtain the best health possible. On the other hand, the SHS has benefited greatly in many ways, too. Staff members from the local communities bring the perspectives of the communities directly to the study.

They represent the study in the most friendly and familiar way possible for the comfort and confidence of the participants. Having community members as an integral part of the study helps ensure the relevance of the study questionnaires and overall goals to the communities and that all aspects of the day to day workings of the study are conducted with cultural sensitivity.

Each center has many examples of employees who have contributed to the health of their communities in outstanding ways. Of the 138 people who worked on SHS at the Dakota Center since 1988, 64 are American Indians and 40 were health professional students at the time they first worked on SHS. Kurt Schweigman, MPH, a member of the

Oglala Sioux Tribe of Pine Ridge, SD, was a college student when he first worked on SHS in 1990. His work on SHS stimulated his interest in epidemiology. After graduation from the University of North Dakota, Kurt obtained an NIH Intramural Research Training Award and spent almost a year working at the National Heart, Lung, and Blood Institute where he gained work experience in epidemiology that resulted in a published paper. Kurt then earned a Masters of Public Health degree from the University of Oklahoma. During his training in Oklahoma, Kurt received support for his graduate work through the Minority Graduate Research Supplement program of the National Heart, Lung, and Blood Institute. Kurt worked as a graduate research assistant in the SHS Coordinating Center in OK at the Center for American Indian Health Research. Recently Kurt has returned to Rapid City, SD, to work on the EARTH project, a study of chronic diseases among American Indians and Alaska Natives.

Marcia O'Leary, RN, a life-long, non-Indian resident of the Cheyenne River Sioux Reservation, was a Presentation College - Lakota campus nursing student when she first worked on SHS in 1992. Marcia and her husband, Timothy O'Leary, a member of the Cheyenne River Sioux Tribe, have formed a Buy-Indian corporation, Missouri Breaks Research, Inc., Timber Lake, SD, which is the grant recipient for the Dakota Center

# unities: Tradition of Enrichment

SHS. Two Dakota Center SHS staff members, Danial Kougl and Lillian Brown, presented a poster at the 15th Annual IHS Research Conference, Scottsdale, AZ in May 2003.

Jeff Henderson, MD, MPH, a member of the Cheyenne River Sioux tribe, received an NHLBI Minority Supplement to work on the Strong Heart Study in 1998. Dr. Henderson subsequently formed the Black Hills Center for American Indian Health, which has received several large grants to conduct research on health problems afflicting Northern Plains American Indians. SHS data have been made available to Native American graduate students for research. The principal investigators and co-investigators have worked closely with the students in developing their thesis plans and dissertations. Chani Phillips, a member of the Cheyenne River Sioux Tribe, completed her PhD in psychology utilizing SHS data with the supervision of Dr. Tom Welty.

The Oklahoma Coordinating Center/Field Center has been fortunate to have 26 community members join the study as staff members, several of whom have served SHS throughout most of the study. Linda Poolaw and Stephanie Gomez have been with the SHS Oklahoma Center for about 10 years or more, and Juanita Cortez retired in 2001 after more than 10 years of service. All of the staff members have contributed greatly to the continued success of the project. Oklahoma SHS has actively

pursued the goal of promoting the interest and success of young American Indians in developing careers in health. As mentioned above, the NHLBI, the Dakota Center and the Oklahoma Center all have helped Kurt Schweigman develop his interests and career in epidemiology. Valarie Jernigan, a member of the Choctaw Tribe in Oklahoma, has just completed her graduate assistantship at the Oklahoma Center. Valarie is the seventh American Indian student in the Oklahoma Center to receive support through the NHLBI Minority Graduate Research Supplement program. Valarie obtained an MPH in Health Promotion Sciences in the College of Public Health at the University of Oklahoma Health Sciences Center. She worked as a graduate research assistant in the SHS Coordinating Center, learning as much as possible about the workings of a coordinating center, performing data entry and statistical analyses, working on papers to present at national scientific meetings and to publish in scientific journals. Valarie has worked on SHS data on access to health care, and she presented her findings at the IHS Research Conference in May 2003.

The Arizona Field Center has also had many community members join the study as staff members and as students working for brief periods of time. All interested community members have been encouraged to contact and work with the staff in order to pursue their own interests in health and/or

research occupations. Since the start of SHS, the Arizona Center has had 41 staff members representing different tribal communities. Many of these people have gone on with their career development in health-related fields. Some examples include: master's degrees in nursing, BS in nursing, radiography technician, certified ultrasound technician, and a degree in business administration. For example, Brian O'Leary, a member of the Cheyenne River Sioux Tribe, received a minority supplement from NHLBI through the MedStar Research Institute. He worked with Dr. Barbara Howard in the utilization of the SHS data to develop his thesis and dissertation. He is currently interning at Walter Reed Medical Center and will defend his dissertation in the fall of 2003. Others are taking classes towards degrees. The current staff includes two community members who presented posters at the Indian Health Service Research Conference in May 2003. The contribution of these community members to the Strong Heart project is essential and vital to the success of this project.

The SHS is very proud to have made these contributions to the human resources available to conduct research in Indian communities. We will continue this tradition as we plan for the fifth phase of the study.

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## Testing Possible Heart Disease Genes

**A**s you know, one of the main goals of SHS-Phase IV is to find out how genes we inherit from our parents affect our chances of having heart disease, diabetes, and risk factors for these diseases. The main way that this will be studied, is by "linkage analysis", which attempts to find the location of genes along the chromosomes, or DNA of a person. This testing is coming along well, and the results will start to be analyzed soon.

The other way of testing is called "candidate gene" analysis. This looks at certain changes in known genes that are thought to have a possible effect on heart disease. Most of these candidate gene changes have already been suspect-

ed of increasing the risk of heart disease in other, non-Indian populations. The researcher then checks to see if these changes are present more often in people who have the health problem.

In the near future, a number of candidate genes will be tested from SHS participants' samples. Research colleagues of Dr. Howard in Washington, DC, and others will be checking on the effects of the angiotensinogen gene on diabetes, obesity and kidney injury. Cornell University, which also reads all of the echocardiograms etc for SHS, will be investigating whether this same gene affects the enlargement of the heart that is common among SHS participants. Other researchers with Dr. Howard will be testing

whether differences in genes that produce some of the fat-carrying proteins in our blood, influence our risk for heart disease.

You may remember a newsletter article about a gene for mannose binding protein (MBP). The analysis is not yet complete, but there appears to be an increased risk for heart disease in people who have changes in this gene.

All of this testing is in a very early stage and whether these findings are confirmed and turn out to be helpful to doctors taking care of patients, is still unknown. We are excited though, to begin the process of learning about the effect of genes on our health.