SHS Continues the Push To Complete Exam III

As the Strong Heart Study enters the final months of the last exam, more than 2,600 participants have been examined for the third time. However, more than 1000 individuals still need to be examined by the end of August to give everyone the opportunity to be included in this final phase of the original sample.

Furthermore, for those who have shown evidence of sleep apnea (trouble breathing during sleep) or asthma, additional exams and data collections are needed. Each center is attempting to complete 200 exams for sleep apnea and 200 exams for asthma among the Strong Heart Study participants to meet the goals for those studies. This requires an enormous amount of work on the part of the dedicated Strong Heart Study staff and a great deal of cooperation on the part of the participants.

The participants and investigators of the Strong Heart Study have developed a reputation for reliability in meeting the tough goals that have been set. As a result, the data to answer many public health questions for American Indians are now available and are being used to meet local and national needs. Your continued support and participation will help provide the very best information upon which decisions are based and policies are made.

The Strong Heart Study reputation also has made possible the opportunity to propose additional studies to respond to the needs of the American Indian communities. Studies focusing on the younger members of participating families have been shown to be feasible with the earlier family pilot study.

With the continued high participation rates and ongoing support from communities, study investigators have found themselves presented with the opportunity to propose a larger-scale family study. This study, currently in the planning stages, will include even more young people and will seek to answer additional questions about the development of heart, lung, and blood diseases and their associated risk factors such as diabetes, high blood pressure, and high cholesterol.

We here at the Strong Heart Study heartily encourage those who have not yet come in for the third examination to take advantage of this opportunity before the exams end this summer. The work that we all can accomplish in the last few months of this undertaking will make the difference between a good and a great study. We appreciate your continued support.
The Strong Heart Family Study is off to a great start. The purpose of this study is to determine why heart disease and diabetes seem to run in families. In 1997, over 900 members of 32 large families were recruited to participate in the Family Study from communities in Arizona, Oklahoma, and the Dakotas. So far, 302 people in 12 families have been recruited from the Gila River and Salt River communities in Arizona, 307 people

**THE STRONG HEART FAMILY STUDY:**

**GENETIC LINKS BETWEEN PEOPLE WITH DIABETES AND HEART DISEASE ARE EXPLORED IN FAMILY STUDY**

in 11 families from Lawton and Anadarko in Oklahoma, and more than 300 people in 9 families from the Cheyenne River Reservation in South Dakota. The families include parents, grandparents, children, grandchildren, aunts, uncles, and cousins. Our goal is to include families from all the Strong Heart communities in the next phase of the Family Study.

Each family member was given a physical examination and then answered questions about his or her diet, levels of exercise, tobacco use and smoking, and other factors that appear to influence risk of heart disease and diabetes. Confidentiality is maintained by coding all the information so that no one can be identified by name.

In the physical exams, a blood sample was collected from each family member and the traits associated with heart disease and diabetes (such as levels of cholesterol and glucose in the blood) were measured. The next step will be to examine these risk factors in each family. We will be looking to see if we can detect any patterns within families. Such patterns may provide evidence that the trait is influenced by genes. We will then try to pinpoint the locations of the genes by studying the DNA obtained from blood samples. None of the samples taken will be used to grow additional cells (or be "immortalized"). Our ultimate goal is to identify the genes associated with heart disease and diabetes and determine why they cause these debilitating diseases in many members of some families.

We would like to extend the Strong Heart Family Study to include more families. Someday, we may be able to tell you whether and how you can modify your lifestyle in order to lessen the effects of harmful genes that cause heart disease and diabetes.

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**Introducing New Investigators**

**Jeffrey Henderson, M.D.,** an enrolled member of the Cheyenne River Sioux Tribe of South Dakota and board-certified internist, joined the Strong Heart Study as a co-investigator in January 1998. He received a Minority Investigator Supplemental Grant to allow him to join the SHS team and enhance his research skills and capabilities. Dr. Henderson is investigating the use of prescription medicines in the SHS participants to determine whether inappropriate use of drugs may contribute to some of the participants’ health problems.

Dr. Henderson’s presence helps ensure that Strong Heart Study participants receive appropriate follow up for any abnormalities detected during the Phase III examinations. Dr. Henderson is also a member of the SHS Steering Committee.

Dr. Henderson is also one of three native investigators at the Native Elder Health Resource Center at the University of Colorado which will provide additional experience in the conduct of research in American Indian communities. He has incorporated the non-profit Black Hills Center for American Indian Health, a multi-faceted organization whose aim is to enhance the physical, mental, social and cultural well-being of American Indians through research, service, education and philanthropy. He is submitting an application to study the prevention of heart disease among persons with diabetes.

**Susan Marion, Ph.D.,** has been working with the Dakota Center as a co-investigator for the past four years. Her background in anatomy and in the study of diseases of the eye have provided useful contributions to the study. She helped establish the computerized data entry program and a way to track the distribution of results to SHS participants and hospitals. She oversees the day-to-day activities in the Dakota Center. She has also been analyzing the data from the pulmonary disease component of the study and writing papers of those results. She plans to continue as an investigator in Phase IV of the Strong Heart Study which will begin in June 2000, if it is funded. Marion recently was appointed as a member of the SHS Steering Committee. She is also the Principal Investigator of the Strong Heart Study part of the Sleep Heart Health Study which is an ongoing study of sleep disorders in Strong Heart Study participants (see the article about the Sleep Study on page 4).
CLINICAL TRIALS: WHAT THEY ARE AND WHY THEY ARE IMPORTANT

The medical profession has made great strides in treating a number of important human diseases, but much is left to be learned. There are large gaps in our knowledge of how to prevent and treat the major chronic diseases—heart disease, diabetes, and cancer—that occur in all populations in the United States.

Gaps occur because these diseases are not due to a single bacterium or chemical and thus a simple antibiotic or vaccine will not sufficiently treat the condition. These diseases are caused by multiple factors; some of which are understood and some are yet to be discovered.

The Strong Heart Study is an epidemiologic study that examines a large number of people, measures as many factors as possible that might be related to heart disease, and then follows the participants over time to determine which factors are more important in predicting the type and severity of heart disease. This study has provided many important findings. For example, the results now show conclusively that diabetes and higher cholesterol levels are strong predictors of heart disease in American Indians.

The next step now focuses on the prevention of heart disease among Indians with diabetes. Since we know that cholesterol and blood pressure predict heart disease, the assumption that if we reduce cholesterol or lower blood pressure, we might prevent heart disease, would seem logical. However, an idea like this needs to be proven by a clinical trial before we can be certain.

History is full of examples wherein past epidemiologic studies have pointed to certain predictors of disease. Yet when trials were conducted to change the predictors, the desired results were not always achieved. For example, lowering cholesterol or blood pressure might not reduce heart disease if the drugs used to do this have adverse effects on other aspects of health.

Conducting a clinical trial properly is a long and difficult process. Testing the idea that a reduction of cholesterol or a lowering of blood pressure will prevent heart disease requires a large number of diabetic individuals to volunteer for random placement in several groups. Each group may receive medicines or treatments to lower cholesterol and blood pressure at different dosages. The groups then need to be followed for a long enough period of time to be able to observe the extent to which the treatments affected the development of heart disease. A large enough number of people and a long enough time period is needed to validate the results.

Clinical trials take work on the part of the researchers and also take time and effort for participants who must attend clinic visits, take their study medications, and report on their health at regular intervals. However, participants who enter trials can gain a number of benefits including regular access to obtaining the best possible medical care. In addition, participants have the satisfaction of knowing they are helping answer important questions about complicated health problems that will benefit their health and the health of their children and grandchildren.

Although clinical trials can be difficult to understand and conduct, it is important that they begin now in American Indian communities. In the past, physicians and health care providers had to rely on the results of information gathered from other populations. This information may not apply to American Indians and there are special aspects of health and health needs that are not thoroughly addressed from studies in other parts of the country in other populations in the United States.

The Strong Heart Study staff in all of our centers would be happy to discuss these issues with you further if there are questions.

Arizona Strong Heart Participant Celebrates 80th Birthday

Approximately 200 family members and friends from the Salt River Indian Community in Arizona gathered this past January to honor Pima-Maricopa community member and SHS participant, Bernice Phillips in recognition of her 80th birthday.

Bernice Phillips is an Arizona Strong Heart participant who was celebrated at a birthday party in December. The crowd of supporters and well-wishers gathered for a dinner of marvelous homemade native food such as "chumuth" (thin tortillas cooked over mesquite wood fires), pinto beans, and chili stew (shredded beef with chilies).

Bernice was born and has lived her entire life in the Salt River Pima-Maricopa Indian Community. She raised seven children there and now has 21 grandchildren, 34 great grandchildren and one great great grandchild.

She has worked for several tribal departments during her life and her family is very proud of her personal accomplishments. Bernice is blessed and is very healthy in all aspects.

All of us with the Strong Heart Study wish Bernice Phillips many more happy birthdays.
First Reports From The Sleep Heart Health Study

Over 600 of participants of the Strong Heart Study agreed to help with the Sleep Heart Health Study several years ago by allowing us to record their sleep for one night. This was the first scientific study of sleep to include American Indians.

The first of 36 papers currently being written describing the results of this study was published in February 1999, and the paper showed that those who had numerous pauses in breathing during their sleep were more likely to be sleepy during the daytime. This daytime sleepiness increased attention deficiencies and could have serious consequences: such as an increased risk of having an automobile accident.

All participants were asked whether they were likely to fall asleep during the following situations: a) sitting and reading, b) watching TV, c) sitting inactive in a public place (for instance, a theater or meeting), d) riding as a passenger in a car for at least an hour, e) lying down to rest in the afternoon, f) sitting and talking to someone, g) sitting quietly after a lunch without alcohol, h) in a car, while stopped for a few minutes in traffic. The answers were added up to give an overall daytime sleepiness score for each person that ranged from zero (never sleepy during the day) to 25 (very likely to fall asleep in all of the situations mentioned).

The average score for everyone was about 8, and men reported being a little sleepier during the day than women. About one-fourth of the people in the study had what we consider “excessive daytime sleepiness” – a score above 11.

The 600 American Indians in the study slept for one night with a dozen wires and electrodes connected to their head plus a red light on their finger and bands around their chest and stomach. The most important thing measured was the number of times per hour of sleep that their breathing became shallow or stopped for ten seconds or more (respiratory disturbances or sleep apnea). This occurs about five times each hour in healthy adults, more frequently in men than in women, and more frequently in older adults than middle-aged adults. The frequency of these episodes was much higher – an average of 15 per hour – among those who were overweight. After adjusting the calculations for age and body weight, American Indians appeared no more likely than Caucasians to have higher levels of sleep apnea.

This first paper from the Sleep Heart Health study found that adults with 30 or more sleep apnea per hour of sleep were almost twice as likely to report excessive daytime sleepiness (compared to the more normal people with less than 5 apnea per hour). Sleep apnea cause a person to be more restless at night and to get less restorative deep sleep. These results are very important because “falling asleep at the wheel” is the cause of more than 15% of automobile accidents, and people are grumpier and get less work done when they are sleepy during the day.

To read the complete paper upon which this report is based, refer to the February, 1999 edition of the American Journal of Respiratory and Critical Care Medicine. The article is titled “The relation of sleepiness to respiratory disturbance index: the Sleep Heart Health Study” by Daniel J. Gottlieb, et al.