



STRONG HEART STUDY

Cardiovascular Disease in American Indians

NEWSLETTER

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SECOND EXAMS COMPLETED: MUCH YET REMAINS

The healthy commitment of participants and communities and the dedication of Strong Heart Study staff has resulted in another stellar performance as the second examination phase of the Strong Heart Study came to an end.

Almost ninety percent of those able to participate in the second examination of the Strong Heart Study returned to get an update on their cardiovascular health. A slightly higher percentage of women than men returned for the second examination.

The good news is that a total of 3,674 individuals were examined and provided with the latest assessment of their health. Many of these individuals were found to have medical conditions requiring medical care and were referred for proper treatment. The bad news is that 500 deaths have occurred among the participants since the first examination. This reinforces the importance of our work and the invaluable contributions of participants and staff to define the risks and identify the opportunities to improve the health of people in the communities in which we are working.

With the conclusion of the second examination, greater effort will be devoted to collection of the details of hospitalizations and deaths of Strong Heart Study participants to properly determine their causes. This is laborious work requiring perseverance to gather all relevant information. A team of physicians will review the

gathered information and make the final decision for classifying the cause of hospitalizations and deaths in a standardized way. This information will then be used to determine factors that are related to who develops cardiovascular and other diseases.

As data are gathered from the physical exam, laboratory analyses and record reviews and corrected for errors, the files will be created to be used for data analyses. Meetings will be planned to share community results with tribal leaders and health professionals to

help communities to understand their status with regard to cardiovascular disease and risk factors.

At that time, we also will be able to incorporate the Exam II data into analyses that will be presented and published in the scientific literature.

To date, the Strong Heart Study has published or presented 37 abstracts at scientific meetings and published 11 manuscripts in scientific journals. Included in these publications are several that have been published in the *IHS Provider*. The *IHS Provider* contains information specifically for medical providers to American Indians and remains a high priority outlet to maximize the value of findings from the Strong Heart Study. With the continued dedication and enthusiasm of the staff and support of the communities, the Strong Heart Study will continue to provide data that serve to improve the health of the American Indian.

Initial Conclusions Reinforce Importance of Strong Heart Study

Study Protocols Insure Data Confidentiality

The Strong Heart Study Coordinating Center is located at the University of Oklahoma Health Sciences Center in Oklahoma City, Oklahoma. The Center is responsible for developing study protocols, compiling a manual of operations, preparing data collection forms and enforcing quality control of the exams. It also is in charge of study data entry, storage and analyses, and assists investigators in manuscript preparation.

All personnel with access to data collected for the study at the Center are required to sign a confidentiality pledge which states that they understand the sensitive nature of the data and that divulgence of any information will result in disciplinary action. The pledge also is co-signed by the principal investigator of the Oklahoma Center.

Completed data forms are placed in locked files in offices assigned to the study at the Coordinating Center. Only authorized staff members have access to the office and to the data forms. Data on computers at the Coordinating Center are safeguarded by passwords known only to authorized personnel. The passwords change periodically to ensure secrecy.

When statistical analyses are performed, no personal identifiers are used. All presentation of the study results are performed by using grouped data. There is no way that personal information will be disclosed. The Strong Heart Study guarantees the confidentiality of all the data collected.



How Does DNA Typing Relate to Lifestyle?

The recent attention on DNA and genetic testing on television and in the newspapers has led to a great deal of misunderstanding and confusion. In this article, we present a basic explanation of DNA typing, explain why it could be useful in the Strong Heart Study, and then explain how it is regulated.

Every cell in the body contains genes which are the functional units that determine all of the body's functions and reactions to the environment. Genes are composed of DNA, a string of amino acids. There is at least one gene for every physiologic process or characteristic; often more than one. If a person has a chronic health problem or an abnormality in some part of their metabolism, it could mean that one or more of their genes are not functioning in a normal manner.

Until very recently, the only way that scientists could learn what causes certain diseases or health problems was to start from the symptoms and then perform various blood tests and physical measurements to explore the underlying cause. Recently, scientists have learned how to map genes and determine their structure.

Using these methods we can attempt to identify the genetic factors causing or contributing to the cause of certain diseases or problems from the other direction: that is, by finding a change in the genetic material of people who have certain diseases or health problems, finding out what the gene usually produces in terms of an enzyme or essential body protein, and thus learning the cause of the health problem.

The Strong Heart Study is committed to understanding heart disease and its risk factors, including diabetes, in American Indians. We examine people, take regular blood samples and make measurements. The tools are now available, however, to allow us to examine heart disease, diabetes, and their risk factors from the other direction, by testing the DNA of people with these problems. This can be done in two ways: (1) by comparing sisters and brothers from different families or, (2) by recruiting large families and studying the DNA in each of their members.

In this way, we may be able to find genes which explain heart disease risk factors such as high blood pressure, the kidney disease that accompanies diabetes, and high blood cholesterol. This approach, coupled with our ongoing examinations, will increase the probability that we will be able to learn more about heart dis-

ease and diabetes. These methods should lead to ways to treat people with these problems and prevent their development in the younger members of the community.

The Strong Heart Study investigators are very aware of the concern within Indian communities about genetic studies and work closely with the communities to answer these concerns. Thus, the Study investigators focus only on heart disease, diabetes, and the risk factors like blood pressure, cholesterol, and kidney disease that are related to heart disease and diabetes. We have no intention of using the DNA to identify individuals, examine their ancestors or investigate other areas sensitive to the community. The DNA is obtained from white blood cells which are present in every blood sample. There is no intention to grow these cells or "immortalize" them in any way. The DNA material is simply extracted from the blood and stored.

We also submitted the plan for the family study to all participating communities in the Strong Heart Study and received approval from those communities. We

received approval, as well, from the local area's Indian Health Service Institutional Review Boards Research Committees.

A third safeguard exists through the fact that no names are ever attached to the DNA samples when they are tested. Thus, the data are anonymous. Publications of results of the

mapping will never be associated with the name of any individual or any family group. All participating tribes are consulted before publication of any results from the Strong Heart Study.

Finally, the DNA and, in fact, all of the blood samples obtained from Strong Heart Study participants, are controlled by the central laboratory for the Strong Heart Study. Only authorized persons can obtain these samples. Should the Strong Heart Study be terminated for any unforeseen reason, the Communities will be consulted on how to appropriately dispose of the specimens. In addition, if new information is available in the future which might suggest some further medical use of the DNA, plans would be brought before all participating communities for approval first.

In summary, we realize this is a complicated subject which cannot be easily explained in a small article. If any of our participants or community leaders have further questions, please call us at any time.

Genetic information provides crucial data to help researchers identify potential causes of health problems

Why Does Research Take So Long?

The National Heart Lung and Blood Institute has decided that further information is needed from The Strong Heart Study participants to clearly understand cardiovascular disease and risk factors in American Indians. With support from the IHS and the Tribes, the project will continue into Phase III and participants will be asked to return for another clinical examination.

The continuation of this project brings up a frequently asked question: **Why Does Research Take So Long?** The staff has been asked this before and it will be asked again as we invite people to remain involved with this study. This is a very reasonable question and an important one. It is difficult to understand why research can be conducted for years without finding cures for certain diseases.

Some diseases, like polio or smallpox had simple solutions. They were found to be caused by a single agent which is called a virus. Once this virus was identified, the scientists were able to alter the disease causing virus, inject our bodies with some of this killed or attenuated virus, and our bodies then built up a resistance or immunity to the specific disease. We never have to worry about the disease for which we are vaccinated, such as polio and smallpox. This has been so successful that these diseases have been eliminated

from our population.

However, when we study a disease as complicated as heart disease, there are multiple factors that work together to cause our bodies to develop heart (circulation) problems. Some of the things that are believed to fit into the picture for causing this disease are genetics (the inherited factors from our parents) and some are environmental (the things in our everyday life that are risk factors such as smoking, high fat diets, etc.). So because there is not one single factor that causes a person to have heart disease, it makes the research very complicated when we have to look at a multiple interaction of factors. It takes years of studying to see how these factors interface with each other.

We know there is no simple cure for heart disease. It appears to be a relationship of many factors, therefore we are getting the picture by finding one piece of the puzzle at a time. When we get enough single puzzle pieces we will then see the whole picture.

It is a very legitimate and reasonable question to continue to inquire about the years involved in the answer to some of our difficult diseases such as heart disease, diabetes, or cancer. With your continuing support, we hope to gain further insight into heart disease, and hopefully learn better treatment and prevention strategies before we learn the full answers about its cause. We appreciate your patience as we look for the answer to heart disease in the Indian Communities in this project.

Follow-up Surveys Important Parts of Strong Heart Study

An important part of the Strong Heart Study (SHS) is a follow-up survey of the health and vital status of all those who have participated in the SHS examinations. Death rates and causes of death are also monitored in the communities in which the SHS participants live. These data will give useful information on the general health status of the people in each of the three study centers and will identify the important causes of poor health and the leading causes of death. Such information can be used for planning programs to target the major health problems and to improve the health of Indian people. Surveillance activities will focus especially on the occurrence of heart disease and stroke. We are also interested in obtaining information about any medical procedures or tests of the heart that participants may have had since the first SHS examination.

Information about heart trouble or strokes is collected in two ways. First, participants are asked at the time of the Phase II examination whether they had any heart trouble or a stroke since the last examination. Second, medical records are reviewed to decide whether any heart problems have occurred.

Information about possible events is reviewed by a group of SHS doctors in order to decide what kind of problem the participant had. In a similar way, information is collected for persons in the community who have died. It is sometimes necessary to talk with family

members or others who may know something about the death when there is no information in the medical records. These review activities will allow the study to determine how many heart attacks and strokes have occurred in the SHS participants and to be sure that that is what they were. This information will, in turn, be related back to individual characteristics

and behaviors measured in the participants in order to try to better understand the causes of heart attacks and strokes in Indian people.

Analyses that compare individual characteristics or behaviors to the risk of disease are some of the most important results of the Strong Heart Study. Information gained from these links can be used to decide what changes need to be made to reduce the risk of heart disease, and to develop programs to improve the heart health of Indian communities.

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Why Do Health Researchers Publish?

People who engage in scientific research frequently get asked two questions by Indian people concerning publication of research papers. The first and most frequently asked is; "How much money do you make from your papers?" The second is; "Just why do you people write those papers?" These are good questions and worthy of response. Several M.D. and Ph.D.-level researchers were asked to reply.

Researchers are not paid directly for the research papers they produce. They are paid through grants to do research in their field of study. The people or institutions who give them the grant money usually request a report on the research results. This usually takes the form of a published research paper. The researcher writes a paper and submits it to other researchers in the same field for "peer review." Only after much re-writing does the paper get submitted to a scientific journal. Once published, the researcher has to pay for all reprints of the journal article that may be requested by other researchers around the world. That answers the first question.

To answer the second question: *why researcher publish*, several of the reasons given by researchers are listed below:

1. To make a living. In many research settings, a person must publish to move up in the organization, receive pay and pay increases and get job security.
2. Sharing important knowledge. By sharing

newly discovered knowledge and research procedures with other scientists, time and energy is not wasted re-inventing the wheel. Many investigators feel it is an obligation to disseminate important information to other researchers, physicians and the public. These obligations are met by publishing research results in scientific journals, which in turn are quoted by the general media.

3. Telling the world about something new helps in the process of building knowledge on a foundation of previously discovered facts. Many researchers feel it is their duty to publish newly discovered information.

4. Self-esteem and pride. Some researchers write papers and articles to scientific journals to maintain their reputations as scientists with expertise in a particular field.

5. Love of writing. Some researchers love to write and scientific journals offer the best outlet for their self-expression.

6. Love of their work. Some people have such a passion for their life's work they wish to share it; to pass on their knowledge and experiences to others.

In summary, medical researchers publish to tell a story. Like the Medicine Man's oral stories that served to maintain and improve the health and well-being of the tribe, medical researchers' stories are about their research projects, their results and their predictions.

**By publishing,
researchers share
what they have learned
about the world and help
others reach further in
their own searches**

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SHS

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