

# STRONG HEART STUDY

*Cardiovascular Disease in American Indians*

NEWSLETTER

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## PROTOCOL PLANNING PHASE COMPLETED

Awards for the Strong Heart Study were announced the last week of September, 1988 and the investigators have been moving at a furious pace ever since. A conference call was arranged on October 5, 1988 to provide short introductions and assignments so that the first meeting would be substantive and productive.

On November 2-3, 1988 representatives of the grantees met in the Parklawn Building in Rockville, Maryland. This opening gesture to locate the initial meeting at the headquarters of the Indian Health Service (IHS) was symbolic as well as practical. IHS will be essential to the success of the program. While Dr. Rhoades, IHS Director, was unable to attend the meeting, he was represented by members of the Division of Program Statistics who provided a thorough review of available data on American Indian populations, morbidity and mortality. Half day sessions were directed to: 1) definition of the population, and strategies for morbidity and mortality surveillance under the direction of Dr. Elisa Lee. 2) issues for the examination protocol by Dr. Tom Welty and 3) issues for the central laboratory by Dr. Barbara Howard. The final item was the election of members of the Steering Committee. They include Drs. Barbara Howard (Chairman) and Anh Le from Medlantic Research Foundation, Drs. Elisa Lee and Andrew Cucchiara from the University of Oklahoma, Drs. Thomas Welty and Arvo Oopik from the Aberdeen Area IHS and Richard Fabsitz from the National Heart, Lung, and Blood Institute (NHLBI).

Between December 1988 and February 1989, 2 meetings were held in Bethesda and one conference call was made to discuss refinement of the protocol and forms. Important decisions at these meetings included limiting the study population to individuals 35-74 years old for

the mortality survey and 45-74 for the morbidity survey and the examination, adopting the name Strong Heart Study, limiting morbidity endpoints to myocardial infarction, congestive heart failure and stroke, using Marquette MAC-PC for the ECGs, reading ECG's centrally at Fitzsimons Army Hospital under the direction of Dr. Oopik, selecting laboratory measurements, and electing Dr. Linda Cowan of Oklahoma to the Steering Committee. Preliminary information on an effort to provide NHLBI support for minority training programs to involve Indians in the study was presented by Richard Fabsitz.

On February 21-23, 1989 the Steering Committee met in Oklahoma City. Highlights included a decision to do a pilot study of 5-10 subjects at each center, adopt the International Criteria for myocardial infarction and stroke and the modified Framingham criteria for congestive heart failure. This meeting also provided an opportunity for the Steering Committee to exchange views with members of the Seven Tribes of Southwestern Oklahoma (Apache, Caddo, Comanche, Delaware, Fort Sill Apache, Kiowa and Wichita). Both groups benefited from the exchange which clearly helped in understanding the goals of the study and how best to make this effort a success.

In March 21-22, 1989 the Steering Committee met in Phoenix, Arizona. Members of the Gila River and Salt River Indian Communities, as well as staff of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), were present and provided a thorough review of the issues in implementing this study in these communities. Steering Committee topics of major interest included the development of a proposal to IHS for a diet study of a subgroup of 300 subjects from the

Dakota and Oklahoma centers to duplicate the Arizona study that is in progress, modifications to the protocol for the assessment of diabetes and refinement of the protocol and forms. The Steering Committee also had the opportunity to visit the new clinic at the Gila River Indian Community and talk with NIDDK personnel about the coordination of our study with their study.

In April 16-19 the Steering Committee and key personnel from each clinic site as well as consultants from many locations met in Rapid City, South Dakota to train field center personnel on the standardization of data collection methods and strict adherence to the study protocol. All participants in the training session were given the opportunity to meet and share their thoughts on the study with members of the Sioux Tribes participating in the Dakota study center. Following the training session the Steering Committee met to review the results of training and discuss

modifications to the protocol determined during the week.

On June 7-10 the Steering Committee met in Bethesda, Maryland to review and modify the protocol following the pilot testing at each of the field centers. Many small problems were pinpointed as a result of the pilot, but no major problems were identified.

The Strong Heart Study Steering Committee completed Phase 1 of the study with a sense of pride in what had been accomplished during the short time span and a positive attitude as we enter the data collection phase. While we recognize that there is much hard work ahead, we also recognize the strong commitment to make this study a success that exists on the part of the Steering Committee members, the staff at each field center and each central laboratory, the personnel at various government agencies including NHLBI, NIDDK and IHS, and most importantly the American Indians who will be studied.

## SUMMARY OF TRAINING

Training for staff from all 3 sites of the STRONG HEART STUDY was conducted April 16-19, 1989 at the Black Hills Training Center, Rapid City, South Dakota so that cardiovascular research on American Indians in Lawton, Sacaton, Phoenix, Pine Ridge, Eagle Butte, and Ft. Totten Service Units will be conducted according to a standardized protocol, and the results from different Tribal groups will be comparable.

The following objectives were achieved at the training sessions:

- 1) Train research project staff in the use of standardized interviews.
- 2) Standardize techniques for blood drawing, administration of a glucose load, the follow-up blood sugar, handling of blood specimens and urine specimens, as well as shipping procedures.
- 3) Standardize physical assessment techniques for:
  - a. Sitting blood pressure measurement right arm, three times.
  - b. Supine blood pressure both ankles

and right arm using Doppler - two times.

- c. Physical exam : heart, lung, pulses.
  - d. Impedance measurements for % body fat.
  - e. Measurement of height, weight, abdominal circumference at umbilicus-supine, and hip circumference-erect.
- 4) Take electrocardiograms and transmit them to Fitzsimons Army Hospital for reading by a cardiologist.
  - 5) Interpret preliminary results to the patient and refer for follow-up of problems needing medical evaluation or treatment.
  - 6) Establish data editing and data entry procedures.
  - 7) Practice completion of morbidity and mortality data collection forms from medical records.

Participants were certified in the specific components of the exam and plans were made for follow-up certification and quality control procedures.

## PILOT COMPLETED MAY 15 - JUNE 2, 1989

Because of the complexity of the Strong Heart Study and the large number of forms and procedures which it involves, it was unanimously decided by the Steering Committee to conduct a pilot study for a three week period, during which each center would conduct examinations among their planned target population and also perform chart reviews for both the mortality and morbidity surveys. The aim of this pilot was to provide a thorough field test of all of the procedures and forms used in order to identify problems with procedures and inconsistencies or errors in the forms. Naturally, the pilot study was approached with some anxiety, both on the part of the Steering Committee, who would finally see the application of all of the procedures and forms which they had designed and also by the on-site personnel who actually had to perform all of these procedures and complete all of the appropriate forms.

The Steering Committee met on June 7th thru 10th, to review the results of the pilot study and to perform a final evaluation of each of the procedures and forms involved in the study. We are happy to report that the pilot study was unanimously judged to be successful by both the Steering Committee and the participants. No major problems were identified which would require elimination or major modification of any of the procedures. Several areas requiring improvement were noted:

1. Large families made the collection of family history data very time consuming (eg. 23 siblings and 16 children), and it will be necessary to find a way to shorten this section.
2. Several problems with the ECG equipment and data transfer were identified:
  - a. No modem in Sacaton and disk incompatibility with the MAC-12 and CAPOC.
  - b. Four ECGs were obliterated before transmission.
  - c. Five ECGs were transmitted, but no record found at Fitzsimons.
3. The Imex Dopplers don't function properly. The company has found a design flaw that drains the battery. Equipment will be modified and returned.
4. The blood drawing had a few flaws:
  - a. Glutol has to be measured to 75g and an equal amount of water added.
  - b. The caps were not sufficiently tightened at the Dakota center and the samples leaked.
  - c. More plasma is needed in the 14 ml tube which is the first priority tube to be filled.
5. Chart review may require consent for the people who are still alive. There is a definite possibility of a fee requirement to obtain hospital records. This fee was not part of the original budgets.
6. Interview of non-participants will be necessary to ascertain morbidity.
7. Finding charts for mortality review becomes more difficult with passage of time, so 1984 should be done immediately.
8. An Accuchek glucose will be added as a first step in the protocol to reduce the number of unnecessary GTT's to save money, time and side effects.
9. The drug list needs to be simplified, and the dosage eliminated from the form.
10. Referral procedures need to be clarified. Disposition of the hard copy of the ECG for the IHS file will vary by center. A procedure for immediate referral for an abnormal ECG has been added.

Finally, the Steering Committee identified numerous changes to be made both in the manual and in the individual forms. It was agreed that the modifications to the forms would be made first by the Coordinating Center. The Steering Committee then unanimously decided that the study could be initiated on June 21, 1989. The final revision of the manual should follow shortly thereafter.

## PREPARATION OF THE MANUAL

One of the major tasks of the Steering Committee during the planning phase was to develop a common protocol for the study, and one of the most urgent responsibilities of the Coordinating Center was to produce an operations manual which included data collection forms. As the Steering Committee moved at an expeditious pace, the Coordinating Center followed diligently in generating the manual and data forms.

Since the first meeting of the Steering Committee, each member has been assigned to work on part of the manual. The Coordinating Center was responsible for the overall compilation and editing of the manual as well as for designing the data forms. Through a collective effort, the first draft of the manual, including a set of data forms, was completed on February 21, 1989. Some of the criteria used as well as forms were adapted from the ARIC manual.

The Steering Committee meeting in Oklahoma City resulted in many changes and improvements in the protocol. The manual and data forms were immediately revised, accordingly. The second and the third drafts were sent to the Steering Committee members on March 8 and March 17, respectively prior to the meeting in Phoenix. Additional refinements of the protocol and data forms were made at the Phoenix meeting. The Steering Committee decided that it would be essential to have a semi-final manual for the training session in Rapid City; detailed

instructions for chart review, physical examination, personal interview, and laboratory procedure were required. On April 10, 1989, a 320-page "semi-final" manual was delivered to every center.

The "semi-final" manual facilitated the training session; however, the feedback of the participants and the communities called for further modifications of the protocol and, consequently, the manual and data forms. All of the changes had to be made before the end of May in preparation for the pilot study. The Coordinating Center staff returned to Oklahoma City and went to work immediately. On May 18, a new version (340 pages) was printed and delivered.

After the pilot study, the entire manual was reviewed page by page and modifications were noted at the June 7-10 Steering Committee meeting. The data forms were again revised and sent to the field centers on July 3. The last revision of the manual, a 378-page volume with six sections and 35 appendices including 20 data forms was completed on July 11.

The prompt development of the manual and data forms has contributed significantly to the success of this planning phase of the study. The Steering Committee and the Coordinating Center are appreciative of the excellent input from the Indian communities, our consultants, co-investigators and staff. More revisions may still be required; we will continue to work assiduously.

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Strong Heart Study  
Coordinating Center  
Dept. of Biostatistics & Epidemiology  
University of Oklahoma Health Sciences Center  
P.O. Box 26901  
Oklahoma City, OK 73190