2. Mortality Survey

The most important feature of the mortality study is the identification and confirmation of the CVD deaths of interest.

2.1 ELIGIBILITY CRITERIA

Fatal events are selected according to the following eligibility criteria:

(1) Age. Only deaths at ages 35 to 74 are included
(2) Tribal Affiliation. The decedent must have been enrolled in one of study tribes.
(3) Place of Residence. The decedent must have lived within the study community. The residence recorded on the death certificate determines eligibility. People institutionalized at the time of death will be included.
(4) Time. Only deaths occurring between January 1, 1984 and December 31, 1988 are eligible.

2.2 DEFINITIONS OF CVD DEATHS

The following will be the primary events of interest:

(1) Definite fatal myocardial infarction (MI)
(2) Definite sudden death due to coronary heart disease (CHD)
(3) Definite fatal CHD
(4) Possible fatal CHD
(5) Definite fatal Stroke
(6) Possible fatal stroke
(7) Definite fatal congestive heart failure (CHF)
(8) Possible fatal CHF
(9) Other fatal CVD

All death certificates will be recoded by the study nosologist. After recoding the following ICD codes will be utilized to identify subjects for detailed mortality review: possible cardiovascular disease 250, 390-448, 518.4, 585, 798 and 799.

Criteria used for ascertaining the primary CVD deaths are the International Diagnostic criteria for acute myocardial infarction and acute stroke (44) and criteria for fatal CHF of the Framingham study (45):
2.2.1 Definite fatal myocardial infarction (MI)

(la) Definite MI within 4 weeks of death by criteria:

1. Evolving diagnostic ECG
   
   AND/OR

2. Diagnostic ECG and abnormal enzymes
   
   AND/OR

3. Prolonged cardiac pain and abnormal enzymes.
   
   OR

(lb) Acute MI diagnosed by autopsy
   
   AND

(2) No known nonatherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

2.2.2 Definite sudden death due to coronary heart disease (CHD)

(1) Death witnessed as occurring within 1 hour after the onset of severe cardiac symptoms (cardiac pain - see below, shortness of breath, fainting) or within 1 hour after the subject was last seen without symptoms

   AND

(2) No documentation of definite acute MI within, 4 weeks prior to death by criteria (see (l)a. in Section 2.2.1 for criteria for definite MI)

   AND

(3) No known nonatherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician report.

2.2.3 Definite fatal CHD

(1) Death certificate with consistent underlying or immediate cause(s)
   (ICD-9 codes 410-414)

   AND
(2) No documentation by criteria of definite acute MI within 4 weeks prior to death

AND

(3) Criteria for sudden death not met

AND

(4) No known nonatherosclerotic or noncardiac-atherosclerotic process or event that was probably lethal according to death certificate, autopsy report, hospital records, or physician records

AND

(5a) Previous history of MI according to relative, physician, or hospital records, or definite MI (see criteria above) or possible MI by criteria below:

One or more of the following categories:

1) Equivocal enzymes and equivocal ECG (with or without pain)
2) Equivocal enzymes and diagnostic ECG (no pain)
3) Abnormal enzymes and other ECG (no pain)
4) Abnormal enzymes and equivocal ECG (no pain)
5) Abnormal enzymes alone (no pain, ECG absent or uncodeable)
6) Prolonged cardiac pain and equivocal enzymes (ECG absent or uncodeable)
7) Prolonged cardiac pain and equivocal ECG (enzymes incomplete)
8) Prolonged cardiac pain and diagnostic ECG (equivocal or incomplete enzymes)
9) Prolonged cardiac pain alone (ECG and enzymes incomplete)
10) Prolonged cardiac pain, “other” ECG, equivocal enzymes
11) Prolonged cardiac pain, “other” ECG, incomplete enzymes

OR

(5b) Autopsy reporting severe atherosclerotic-coronary artery disease or old MI without acute MI (>50% proximal narrowing of two major vessels or >75% proximal narrowing of one more vessel if anatomic details given)

OR

(5c) Rapid death:

Death occurring greater than 1 and less than or equal to 24 hours after the onset of severe cardiac symptoms or after subject was last seen without symptoms.

* Definitions are given in Section 2.3.
2.2.4 Possible fatal CHD

(1) No documentation by criteria of definite acute MI within 4 weeks prior to death

AND

(2) No documentation by criteria of definite sudden death

AND

(3) No documentation by criteria of definite fatal CHD

AND

(4) Death certificate with consistent underlying or immediate cause (ICD-9 codes 410-414)

AND

(5) No known nonatherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

2.2.5 Definite Fatal Stroke

(1a) Cerebral infarction or hemorrhage diagnosed at autopsy

AND

(1b) No other disease process or event such as brain tumor, subdural hematoma, subarachnoid hemorrhage, metabolic disorder, or peripheral lesion that could cause localizing neurologic deficit or coma - according to death certificate, autopsy, hospital records, or physician records

OR

(2a) History of rapid onset (approximately <48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness

AND

(2b) Documentation of localizing neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of death with >24 hours duration of objective physician findings

AND

(2c) See list under (1b) above.
2.2.6 Possible Fatal Stroke

(1) Death certificate with consistent underlying or immediate cause (ICD-9 codes 431-437)

AND

(2) No evidence at autopsy examination of the brain, if performed, of any disease process other than cerebral infarction or hemorrhage that could cause localizing neurologic signs (see (1b) above).

2.2.7 Definite Fatal CHF

Two major or one major and 2 minor criteria must be present concurrently.

Major criteria

- Paroxysmal nocturnal dyspnea or orthopnea
- Neck vein distention
- Rales
- Cardiomegaly
- Acute pulmonary edema
- S3 gallop
- Increased venous pressure >16 cm water
- Circulation time ≥ 25 seconds
- Hepatojugular reflux

Minor criteria

- Ankle edema
- Night cough
- dyspnea on exertion
- Hepatomegaly
- Pleural effusion
- Vital capacity reduced by one-third from predicted
- Tachycardia (rate of ≥ 120/min)

Major or Minor criterion

- Weight loss ≥ 4.5 kg in 5 days in response to treatment. No known noncardiac process leading to massive fluid overload such as renal failure.

2.2.8 Possible Fatal CHF

Death certificate with consistent underlying or immediate cause, but neither autopsy evidence nor adequate pre-terminal documentation of the event.
2.2.9 Other Fatal CVD

1. Definite other fatal CVD

   (1a) Autopsy evidence consistent with other CVD as cause of death

   OR

   (1b) Death certificate with consistent underlying or immediate cause

   AND

   (2) Adequate documentation in medical records

2. Possible other fatal CVD

   Death certificate with consistent underlying or immediate cause, but does not satisfy any of the above criteria.

2.3 DEFINITION OF ABNORMAL ECG, ABNORMAL ENZYMES AND PROLONGED CHEST PAIN

2.3.1 Abnormal ECG

1. Evolving Diagnostic ECG

   An evolving pattern on serial ECGs of a diagnostic ECG. (An evolving pattern of changes [appearance or disappearance within lead groups: anterior (V₁-V₅); lateral (I, aV₅, V₅); or inferior (II, III, aV₅)] establishes the infarct as acute. Two or more ECG recordings during the hospitalization are needed for this classification.)

   To Qualify as a Q wave, deflection should be at least 0.1 mV (1 mm.) in amplitude. Possibilities:

   a. No Q wave in one ECG record followed by a record with a diagnostic Q wave.

   OR

   b. An equivocal Q wave and no major ST segment depression in one ECG followed by a record with a diagnostic Q wave PLUS a major ST segment depression.

   OR
c. An equivocal Q wave and no ST segment elevation in one ECG record followed by a record with a diagnostic Q wave PLUS ST segment elevation > 1 mm.

OR

d. An equivocal Q wave and no major T wave inversion in one ECG record followed by a record with a diagnostic Q wave PLUS a major T wave inversion.

OR

e. No Q wave and no ST Junction depression > than or = to .5 mm. and flat or downsloping ST segment depression followed by a record with an equivocal Q wave PLUS ST Junction and flat or downsloping ST depression of > .5 mm.

OR

f. No Q wave and no ST elevation > 1 mm. followed by a record with an equivocal Q wave PLUS ST elevation > 1 mm.

OR

g. No Q wave and no T wave findings diagnostic of infarction followed by a record with an equivocal Q wave PLUS T wave findings diagnostic of infarction.

2. DIAGNOSTIC ECG WITH Q WAVE
   a. Diagnostic Q and QS patterns.

3. DIAGNOSTIC ECG WITHOUT Q WAVE
   a. ST segment elevation PLUS T wave depression indicative of infarction. (T wave depression cannot be used in the presence of ventricular conduction defects.)

4. EQUIVOCAL ECG WITH Q WAVE
   a. ECG with Q and QS pattern possibly representing infarction.

5. EQUIVOCAL ECG WITHOUT Q WAVE
   a. ST junction (J) and segment depression or T wave inversions or ST segment elevations possibly representing infarction.

6. OTHER
   a. All other findings, including normal.
2.3.2 Abnormal Enzyme

To be able to be used to evaluate an MI, enzymes must have been measured within 1-4 days of admission or onset of acute event, whichever is later.

1. Abnormal Cardiac Enzymes

Enzymes are classed as "abnormal" if any enzyme values recorded meet any of the following criteria:

1a) CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or the CK-MB (heart fraction) is at least twice the upper limits of normal (if hospital uses quantitative criteria) or ≥ 10% of the total CK value, and total CK is at least twice the upper limit of normal.

AND

1b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value.

OR

2a) The ratio \( \text{LDH}_1 : \text{LDH}_2 > 1 \)

AND

2b) There is no evidence of hemolytic disease.

OR

3a) Total CK and LDH are both at least twice the upper limits of normal. (These increases do not have to occur on the same day.)

AND

3b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.
2. Equivocal Cardiac Enzyme

Enzymes are classed as "equivocal" if the criteria for abnormal enzymes are not met and if:

1) Either total CK or total LDH are at least twice the upper limits of normal.

OR

2) Both total CK and total LDH are between the upper limits of normal and twice the upper limits of normal. (These increases do not have to occur on the same day.)

OR

3) CK-MB = 5-9% of total CK or is "weakly present".

A summary of the enzyme diagnostic criteria, as related to total CK and LDH is given in the following algorithm:

<table>
<thead>
<tr>
<th>Twice Upper Limit of Normal</th>
<th>Equivocal</th>
<th>Equivocal</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL LDH</td>
<td>Normal</td>
<td>Equivocal</td>
<td>Equivocal</td>
</tr>
<tr>
<td>Upper Limit of Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Equivocal</td>
</tr>
</tbody>
</table>

Upper Limit of Normal

TOTAL CK

2.3.3 Prolonged Cardiac Pain

Pain having the following characteristics: Occurring anywhere in the anterior chest, left arm or jaw, which may also involve the back, shoulder, right arm, or abdomen on one or both sides and lasting for more than 20 minutes.
2.4 IDENTIFICATION AND CONFIRMATION OF CVD DEATHS

2.4.1 Procedure

The identification and confirmation of CVD deaths will involve the following steps: (1) identification of all deaths occurring in the eligible population during 1984-88, (2) obtaining all death certificates, (3) coding of all death certificates by the central nosologist, (4) identification of potential CVD deaths, (5) obtaining Coroner's/Medical Examiner's report, (6) review autopsy reports, (7) chart review, and (8) independent confirmation of CVD deaths by the Event Committee comprised of Dr. Maurice Sievers and Dr. Wm. James Howard.

STEP 1: Identification of all deaths

All deaths that satisfy the Eligibility Criteria (1) - (4) in Section 2.1 will be identified by each center from tribal records, IHS hospitals, BIA, State Department of Health and/or the National Death Index. The name, date of birth, date of death and place of death will be obtained for each eligible death. Persons who died out-of-state when visiting other states will be included.

STEP 2: Obtaining death certificates and reviewing charts

With the names of the decedents, dates of birth, dates of death, and places of death, copies of death certificates of all deaths will be obtained from the State Department of Health. The Death Certificate Form (Appendix 7) will be completed by the local data abstractor and mailed to the Coordinating Center.

STEP 3: Coding of death certificates by central nosologist

The local center will stamp the back of the death certificate, add the ID number immediately above the stamp and send only the death certificate to the central nosologist,

Mr. Karl E. Wise
36 Fox Grape Lane,
Southern Shores,
Kitty Hawk, NC 27949

for coding of the cause of death. The corresponding Death Certificate Forms will simultaneously be sent to the Coordinating Center. Mr. Wise will, in a standardized approach using ICD 9th Revision, record the codes on the back of the death certificate and return it to the Coordinating Center. The nosologist's codes will be entered into the computer. A copy of the codes will be sent to the Study Center by the Coordinating Center.

For quality assurance purposes, the Coordinating Center will send a random sample of approximately 10% of the death certificate to another nosologist, Janice Johnson of the Oklahoma State Department of Health, for independent recoding of the cause of death.
STEP 4: Identification of potential CVD deaths

Potential CVD deaths will be identified by each Study Center after receiving the codes from the Coordinating Center.

A potential CVD death is defined as having mention of any of the following anywhere on the death certificate.

- Any type of cardiovascular disease
- Diabetes
- Acute edema of lung
- Renal disease
- Sudden death, cause unknown

If there is any question as to whether a death should be considered a potential CVD death, the P.I. should be consulted.

The following steps are for the potential CVD deaths only.

STEP 5: Obtaining Coroner's/Medical Examiner's Report

If it is indicated on the death certificate that an autopsy was performed, the Coroner’s/Medical Examiner’s Report will be obtained by each study center. Photocopy the autopsy report, complete the Mortality Medical Records Abstract Form, attach both to the death certificate, and send the entire package, including Final Decision Form II, to Dr. Sievers for confirmation.

STEP 6: Review medical chart to see if the decedent was hospitalized within 6 weeks prior to death and fill out first section (Question 1-17) of Mortality Survey Medical Records Abstract Form (Appendix 9) in order to identify possible CVD events between 1984 and 1988. The Chart Request Form in Appendix 16 will be used to record charts needed from each involved hospital.

STEP 7: Confirmation of CVD deaths

a. If the decedent was hospitalized within 6 weeks prior to death, the Mortality Survey Medical Records Abstract Form will be completed. The Medical Records Abstract Form, the death certificate and the Coroner’s/Medical Examiner’s report, if available, will be sent to Dr. Sievers for confirmation.

b. If the decedent died prior to arrival at the hospital, upon arrival, or in any other non-hospital location (e.g., home, nursing home), and if available information is not sufficient to determine whether the death
was due to a cardiovascular problem, the attending physician, and an informant will be identified from the death certificate or other sources and contacted for an interview. The Physician’s Questionnaire (Appendix 10), Informant Interview Form (Appendix 11), and the Medical Records Abstract Form will be completed. These three forms as well as the death certificate and coroner’s/medical examiner’s report (if available) will be forwarded to Dr. Sievers. A Final Decision Form II (Appendix 12) will also be mailed to Dr. Sievers from the study center for recording his final decision. The study center will stamp the ID number and fill out the patient’s name on the Final Decision Form II for Dr. Sievers. Dr. Sievers will return the completed Final Decision Form II to the Coordinating Center for data entry. The Coordinating Center will forward a copy of the Decision Forms to the Study Center. For any equivocal cases Dr. Sievers will forward all information to Dr. Wm. James Howard for independent classification. In addition, Dr. Wm. James Howard will independently reclassify a random ten percent of deaths.

A flowchart describing the procedure outlined above and a checklist which should be followed to assure that all steps are completed are given in Appendices 13 and 14, respectively.

2.4.2 Review of Medical Charts of the Decedents

Unless the Coroner’s report is conclusive, medical records of the decedent will be reviewed and pertinent data abstracted using the Medical Records Abstract Form. For deaths that occurred in hospitals other than IHS hospitals, additional efforts will be made to secure medical information. If the patient was hospitalized in more than one facility without intervening discharge, all available medical records will be reviewed to complete the Medical Record Abstract Form. Discharge summaries, ECGs, X-ray reports, etc. will be photocopied and attached to the Form, when possible. If the patient died in a hospital as an in-patient, data accumulated in the period of hospitalization will be reviewed and abstracted. If the patient died out-of-hospital or died upon arrival at the hospital, available information in the medical records for relevant hospitalizations and outpatient visits prior to death will be reviewed and abstracted.

2.4.3 Informant Interview

Using name and address information from the death certificate, an attempt will first be made to contact and interview the spouse or a first-degree relative (i.e., son, daughter, or sibling) of the decedent, or someone else who witnessed the death. The following procedure will be followed:

1. Find the informant’s telephone number and/or address.
(2) If the telephone number is available, call him/her to request permission
to interview and to set up an interview appointment. The interview
may be conducted over the telephone, or if necessary, in person using
the Informant Interview Form.

(3) If phone contact is not possible, the local community health
representative or public health nurse will be asked to assist in arranging
the interview.

(4) If the informant cannot be contacted by phone or in person, a form
letter, a reply letter and a self-addressed and stamped envelope
(Appendix 15 a and b) will be sent asking the informant for permission
for an interview and convenient time for the interview. If the form
letter is sent and no reply is received in three weeks, another such letter
is sent by certified mail. If no reply is received within one month, no
further effort to contact the individual is made.

When the death is witnessed by someone other than a member of the
decedent’s family, both a family member and the witness are interviewed. In such a
case, the information from both interviews are recorded on separate Informant Interview
Forms. Up to three (the three best) Informant Interview Forms may be completed for
a given event.

2.4.4 Death Occurring Outside the Study Community

Eligible deaths outside of the study area, but within the State, will be
included in the above review and confirmation procedure. For eligible out-of-state
deaths, we will attempt to obtain an abstract or summary from the hospitals where
they died and interview an informant. Their local medical charts will also be reviewed.
3. MORBIDITY SURVEY

3.1 ELIGIBLE POPULATION

Cases of MI and stroke will be identified in the three study areas through the review of hospital records and through interviews of individuals who participate in the clinical examination. Persons eligible will be tribal members who have resided in one of the study communities for at least 6 months prior to the event who are 45-74 years of age at any time during the five-year interval 1984-1988, and who were discharged from the hospital with a diagnosis of CVD between January 1, 1984 and December 31, 1988.

3.2 SURVEILLANCE EVENTS

Two types of frequency measures will be used, total incidence and incidence rate. All cases of MI and stroke, as well as new cases (first occurrence), occurring during the study interval will be ascertained. Data obtained from review of medical records will be used to calculate total incidence and incidence rates of acute myocardial infarction and stroke. Only information for those events with discharge diagnoses between January 1, 1984 and December 31, 1988 for individuals aged 45-74 years at the onset of their events will be abstracted. The following types of CVD will be ascertained:

1. Acute Myocardial Infarction (ICD-9 code 410)
2. Stroke (ICD-9 codes 431-432, 434, 436)

Criteria used for defining acute myocardial infarction and stroke have been derived primarily from the International Diagnostic Criteria (44). The criteria for "diagnostic" cardiac enzymes are those of ARIC (46) and the International Diagnostic Criteria.

3.3 DIAGNOSTIC CRITERIA: NON-FATAL MYOCARDIAL INFARCTION

3.3.1 Definite Non-Fatal MI

Must meet one or more of the following criteria:

1. Evolving diagnostic ECG (defined in Section 2.3.1);

OR
2. Diagnostic ECG and abnormal enzymes (defined in Sections 2.3.1 and 2.3.2);

OR

3. Prolonged cardiac pain (defined in Section 2.3.3) and abnormal enzymes.

3.3.2 Possible Non-Fatal MI

Must meet one or more of the following criteria in the absence of findings that meet the criteria for Definite Non-Fatal MI:

1. Equivocal enzymes and equivocal ECG (with or without pain)
2. Equivocal enzyme and diagnostic ECG (no pain)
3. Abnormal enzymes and other ECG (no pain)
4. Abnormal enzymes and equivocal ECG (no pain)
5. Abnormal enzymes alone (no pain, ECG absent or uncodeable)
6. Prolonged cardiac pain and equivocal enzymes (ECG absent or uncodeable)
7. Prolonged cardiac pain and equivocal ECG (enzymes incomplete)
8. Prolonged cardiac pain and diagnostic ECG (equivocal or incomplete enzymes)
9. Prolonged cardiac pain alone (ECG and enzymes incomplete)
10. Prolonged cardiac pain, “other” ECG, equivocal enzymes
11. Prolonged cardiac pain, “other” ECG, incomplete enzymes

3.3.3 ECG Tracings to be Photocopied

The following ECG tracings are to be photocopied:

1. The last ECG obtained prior to this admission.
2. The first ECG recorded after admission or the occurrence of an in-hospital event,
3. The first ECG done each day thereafter, and
4. The last ECG recorded before discharge.

The photocopies of ECGs should be dated according to the date and time the ECG was done, and they should be arranged in chronological order from earliest to latest. The ECG series for each case will be reviewed independently by three cardiologists. Discrepancies will be adjudicated among the three readers. The series of three ECGs is assigned the highest category for which criteria are met, i.e., evolving diagnostic is greater than diagnostic is greater than equivocal is greater than other.

A summary of the diagnostic criteria for hospitalized, non-fatal myocardial infarction used in the Strong Heart Study is given in Table 3.1.
Table 3.1

Summary of Diagnostic Criteria for Hospitalized, Non-Fatal Myocardial Infarction (MI) in The Strong Heart Study

<table>
<thead>
<tr>
<th>Cardiac Pain</th>
<th>ECG Findings</th>
<th>Enzymes</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>Evolving Diagnostic</td>
<td>Abnormal</td>
<td>Definite MI</td>
</tr>
<tr>
<td>ECG</td>
<td></td>
<td>Equivocal</td>
<td>Definite MI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incomplete</td>
<td>Definite MI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal</td>
<td>Definite MI</td>
</tr>
<tr>
<td>Diagnostic ECG</td>
<td>Abnormal</td>
<td></td>
<td>Definite MI</td>
</tr>
<tr>
<td></td>
<td>Equivocal</td>
<td></td>
<td>Possible MI</td>
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<tr>
<td></td>
<td>Incomplete</td>
<td></td>
<td>Possible MI</td>
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<tr>
<td></td>
<td>Normal</td>
<td></td>
<td>No MI</td>
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<tr>
<td>Equivocal ECG</td>
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<tr>
<td></td>
<td>Equivocal</td>
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<td>Possible MI</td>
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<td></td>
<td>Incomplete</td>
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<td>No MI</td>
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<tr>
<td></td>
<td>Normal</td>
<td></td>
<td>No MI</td>
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<tr>
<td>Absent, Uncodeable,</td>
<td>Abnormal</td>
<td></td>
<td>Definite MI</td>
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<tr>
<td>or other</td>
<td></td>
<td>Equivocal</td>
<td>Possible MI</td>
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<td></td>
<td></td>
<td>Incomplete</td>
<td>No MI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal</td>
<td>No MI</td>
</tr>
<tr>
<td>Not present</td>
<td>Evolving Diagnostic</td>
<td>Abnormal</td>
<td>Definite MI</td>
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<td>Incomplete</td>
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<td>No MI</td>
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<td>No MI</td>
</tr>
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<td>No MI</td>
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<td>No MI</td>
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<td></td>
<td></td>
<td>Normal</td>
<td>No MI</td>
</tr>
</tbody>
</table>
3.4 DIAGNOSTIC CRITERIA: NON-FATAL STROKE

3.4.1 Definite Non-Fatal Stroke:

1. History of rapid onset (approximately <48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness

   AND

2. Documentation of localizing neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of onset with > 24 hours duration of objective physician findings

   AND

3. No other disease process or event such as brain tumor, subdural hematoma, subarachnoid hemorrhage, metabolic disorder, or peripheral lesion that could cause localizing neurologic deficit or coma according to hospital records.

3.4.2 Possible Non-Fatal Stroke:

1a. History of rapid onset (approximately <48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness,

   AND

1b. Documentation of localizing neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of onset with >24 hours duration of objective physician findings,

   OR

1c. Discharge diagnoses with consistent primary or secondary codes (ICD-9-CM codes 431, 432, 434, 436, 437),

   AND

2. No evidence by unequivocal physician or laboratory findings of any other disease process or event causing focal brain deficit or coma other than cerebral infarction or hemorrhage according to hospital records.

3.4.3 Unequivocal Laboratory Findings:

1. A computerized axial tomography (CAT) scan showing no definite findings of any disease process or event causing focal brain deficit or coma other than cerebral infarction or hemorrhage,
AND

2a. Showing a focal area of decreased or normal attenuation consistent with cerebral infarct,

OR

2b. Showing focal increased attenuation consistent with intracerebral hemorrhage.

A summary of the diagnostic criteria for hospitalized, non-fatal stroke used in The Strong Heart Study is given in Table 3.2.

Table 3.2

Summary of Diagnostic Criteria for Hospitalized, Non-Fatal Stroke in The Strong Heart Study

<table>
<thead>
<tr>
<th>Diagnostic Evidence</th>
<th>Onset/Duration Neuro. Deficit</th>
<th>Other Causes</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unequivocal physician or laboratory</td>
<td>Rapid/ &gt;24 hr.</td>
<td>Absent</td>
<td>Definite Stroke</td>
</tr>
<tr>
<td>Discharge Diagnoses of Stroke (431, 432, 434, 436, 437)</td>
<td>Rapid/ &gt;24 hr.</td>
<td>Absent</td>
<td>Possible Stroke</td>
</tr>
</tbody>
</table>

All other combinations No Stroke

3.5 PROCEDURE FOR IDENTIFICATION OF INCIDENT AND RECURRENT CASES

The morbidity survey will involve the following steps: 1) identification of potentially eligible cases from IHS user listings, discharge records of other community hospitals and personal interview at the clinical examination. 2) review of the medical records of potential cases to determine whether the age and tribal (residence) criteria are met, 3) determine whether one of the study events has, in fact, occurred and determine whether it is the first diagnosis of the event or a recurrent event, 4) abstract relevant information from the medical record for each documented event to allow independent confirmation of the diagnosis of a case.

STEP 1: Identification of potentially eligible cases.

In order to identify persons with events that may qualify as incident cases, IHS hospital discharge diagnosis listings and outpatient lists for 1984 through
1988 will be reviewed. All screening discharge diagnoses should be reviewed (see below). If included in the discharge listings, age and tribal (residence) eligibility should also be checked before recording a chart number for subsequent review. The names of all potential cases identified from the IHS listings will be reviewed by local staff, with tribal assistance, to determine if they are members of the study cohort. Other local hospitals will also be surveyed to obtain discharges for MI or stroke that may be American Indians. These lists will be compared to eligible tribal members lists to determine which records are to be abstracted. Participants at the clinical examination will also be asked if they had an MI or stroke during 1984-88. Positive answers will be confirmed by chart review. When reviewing IHS user lists or hospital discharge listings, names, chart numbers and other relevant information for pulling charts for review should be recorded on the Chart Request Form (Appendix 16). Potential cases will be identified using the following ICD-9 codes. The list of screening codes to be used in reviewing discharge diagnoses is broader than the study event codes in order that cases not be missed.

1. **MYOCARDIAL INFARCTION** (ICD-9 codes 402, 410-414, 427-428, 518.4)

   - 402  Hypertensive heart disease
   - 410  Acute myocardial infarction
   - 411  Other acute and subacute forms of ischemic heart disease
      - 411.0  Postmyocardial infarction syndrome
      - 411.1  Intermediate coronary syndrome
      - 411.2  Other - includes coronary insufficiency (acute), microinfarct of heart, subendocardial ischemia
   - 412  Old myocardial infarction
   - 413  Angina pectoris
   - 414  Other chronic ischemic heart disease
   - 427  Cardiac dysrhythmia
   - 428  Heart failure
      - 428.0  Congestive heart failure
      - 428.1  Left heart failure
      - 428.9  Heart failure, unspecified
   - 518.4  Acute edema of lung, unspecified

2. **CEREBROVASCULAR DISEASE** (ICD-9 430-438)

   - 430  Subarachnoid hemorrhage
   - 431  Intracerebral hemorrhage
   - 432  Other and unspecified intracranial hemorrhage
   - 433  Occlusion and stenosis of precerebral arteries - includes embolism, narrowing, obstruction or thrombosis of basilar, carotid, and vertebral arteries
   - 434  Occlusion of cerebral arteries
   - 435  Transient cerebral ischemia
   - 436  Acute, but ill-defined, cerebrovascular disease - includes CVA NOS, Stroke
   - 437  Other and ill-defined cerebrovascular disease - includes cerebral atherosclerosis, chronic cerebral ischemia, hypertensive encephalopathy, cerebrovascular disease or lesion not otherwise specified.
   - 438  Late effects of cerebrovascular disease
STEP 2: Review of medical record for eligibility

Medical records from each IHS facility will be reviewed at the time each of the 4500 participants is undergoing the physical examination phase of the study. If the examination participant is on the list of eligible cases created in STEP 1 or if he reports an MI or stroke during 1984 and 1988 in the medical history portion of the interview, STEP 3 and STEP 4 will be followed. Otherwise, the chart will first be reviewed in order to determine whether the participant experienced an eligible event. If the examination participant reports a history of MI or stroke in 1984-88, they will be asked at which hospital they were cared for so that records can be obtained. Release of clinical information forms will be obtained for all non-IHS facilities, if required by local Institutional Review Board (IRB) and the standard IHS Authorization For Release of Information may be used.

Eligible individuals who refuse to participate in the examination and those aged 75-80 will be interviewed in person or by phone for possible morbid events using the Interview Form for Non-participants in Appendix 17. Permission to review their medical records will also be obtained.

For those persons identified in STEP 1 who do not participate in the examination, those aged 75-80, and those who have been hospitalized at non-IHS facilities, charts will be requested and STEP 3 and STEP 4 will be followed. IHS charts of potential CVD decedents will also be reviewed for possible morbid events during 1984-1988.

If required by the local IRB, consent for release of clinical information will be obtained from the participant or the next-of-kin before any charts are reviewed.

STEP 3: Confirmation of event occurrence and incident status.

Because discharge diagnoses may be improperly recorded and a variety of associated codes will be screened, it is important to confirm that one of the events of interest has, in fact, occurred. Information in the record pertaining to the admission by which the potential case was identified (the index admission) should be reviewed. Check the discharge diagnoses listed on the face sheet of the admission and read the discharge summary.

If one of the survey events has occurred during the study interval, information about the event will be abstracted from the record. The next step is to determine whether the event was the first time such a diagnosis had been made. Myocardial infarction and stroke are defined as "new" if there is no mention in the medical record of a previous episode. We are interested in any occurrence of one of these events if it happened during the study interval, but will consider it as a "new" event only if that first occurrence was also within the study interval, i.e., 1984-1988 in an individual aged 45-74 years at the onset of symptoms.

In order to determine whether the event is new, information from the index admission must be reviewed. This includes reading the admission history and physical examination section of the record, any interim notes, and the discharge summary for indications of a previous event. If the medical record contains admissions prior to the index admission, the face sheets and discharge summaries of
these admissions should also be reviewed to determine whether a previous hospitalization was due to myocardial infarction or stroke. If a MI or stroke occurred prior to the index event, but within 1984-1988, then the abstractor should treat that event as the index event and repeat the process of review of prior admissions. Any event subsequent to the primary event should be reviewed. The IHS user listings can also be reviewed to determine whether the case was seen previously for the event of interest. All events of interest occurring during the study interval should be abstracted.

STEP 4: Medical record abstract for incident cases.

If the index admission is for one of the study events (whether or not it is the first occurrence), an appropriate medical record abstract form for that admission should be completed (Appendix 18(a)). If evidence is present suggesting that one or more myocardial infarctions or strokes occurred, a separate chart abstract form will be completed for each event. Separate events must have a 28 day period when the patient is discharged from an acute care facility after a previous event. During the chart review, the abstractor will determine whether the event is a first event (incident case) or a recurrent event so that incidence rates and total incidence for myocardial infarctions and strokes can be determined. (If the participant is a study death, the abstract of medical records for decreedents should also be completed.) If the medical record is not eligible for abstraction, the reason for exclusion (i.e., not age eligible, not tribal eligible, event occurred outside of the calendar years of the study, not a study event) should be entered on the listing of potential cases.

High resolution photocopies of ECGs taken as evidence of a myocardial infarction during the morbidity survey (see Section 3.3.3) should be arranged in chronological order from earliest to latest. ECG series for each case will be sent to the ECG Reading Center (Fitzsimons) with a completed Possible Myocardial Infarction ECG Analysis Field Sheet (Appendix 18(b)) and a blank ECG Center Sheet (Appendix 18(c)) with ID number stamped. The ECG series will be reviewed independently by three cardiologists and results recorded on the ECG Center Sheet which will then be returned to the Coordinating Center.

The Morbidity Survey Medical Records Abstract form, the ECG Analysis Field Sheet, the ECG Analysis ECG Center Sheet and the Morbidity Survey Decision form (Appendix 18(d)) will be sent to Dr. Arvo Oopik for confirmation by the Coordinating Center. Dr. Oopik will return the entire package with the completed Decision form to the Coordinating Center. For any equivocal cases Dr. Oopik will forward all information to Dr. Wm. James Howard for independent confirmation. In addition, Dr. Wm. James Howard will independently reclassify a random ten percent of cases.

3.6 RATIONALE FOR SELECTION OF EVENTS FOR THE MORBIDITY SURVEY

Myocardial infarction and stroke were selected as incidence surveillance events. Other types of CVD such as angina pectoris, rheumatic heart disease, congestive heart failure, and peripheral vascular disease are less readily identifiable from hospital records, since hospitalization may not be required. In addition, information necessary for independent classification may not be available, and it is more difficult to identify the first occurrence of these events. The physical examination phase of the study, in which prevalence of CVD will be assessed, is a more appropriate setting in which to ascertain the frequency of these events. Prevalence estimates from the physical examination will be based on a uniformly applied set of diagnostic procedures and disease definitions.
4. Procedures for Training & Quality Control of Mortality & Morbidity Surveillance

4.1 TRAINING

Interviewers will be centrally trained at the April 1989 training meeting in South Dakota. Training will include instructions in reviewing and abstracting of charts and instructions in transcribing of information on death certificates and medical examiner reports. Training will include:

1. Adherence to the standardized protocol
2. Techniques for locating information in the charts
3. Dealing with problems encountered in the charts
4. Post-abstraction responsibility for the data

The training sessions will consist of:

1. Explanation of the procedure for abstracting
2. Demonstration by the instructor of abstraction procedures
3. Performance of abstraction by the trainee with instructor observing
4. Abstraction of records by both the trainee and the instructor with verification for completeness, consistency and accuracy

4.2 QUALITY CONTROL

4.2.1 Ascertainment of Cause of Death

In the mortality study, for every tenth death, duplicated records will be sent to Dr. James Howard as well as to Dr. Sievers by each center. Dr. James Howard will independently make a judgement as to the cause of death and fill out Decision Form I or II. The Coordinating Center will then compare the results from both physicians. In addition, if Dr. Sievers feels a decision on a death is particularly equivocal, Dr. Sievers will send all information to Dr. James Howard and then they will arrive at a joint decision.

4.2.2 Data Abstraction

To assure consistency and accuracy in the chart abstractions and death certificate and medical examiner reports, a chart for morbidity, a chart for mortality, a death certificate and a medical examiner report will be circulated by the Coordinating Center to each center quarterly with personal identifiers deleted. All data abstract personnel will complete the necessary forms related to that circulated material and they will be judged at a central source for consistency and completeness.