Morbidity & Mortality Surveillance

Manual of Operations Volume II

Strong Heart Study Phase VII

September 28, 2023

Version 2.1

The National Heart, Lung, and Blood Institute of the National Institute of Health

For copies, please visit The Strong Heart Study website

or contact

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1. Mortality Surveillance

1.1 Eligible Population

The participants of the Strong Heart Study and Strong Heart Family Study are monitored in an on-going fashion to identify deaths and to determine causes of those deaths. Deaths are documented and abstracted whenever recognized by the Center staff. Of the original members of the Phase I cohort and the Family Study participants, it is estimated that as of February 15, 2019 (beginning of Phase VII), 3,174 surviving individuals are eligible for mortality surveillance for Phase VII.

1.2 Sources of Data

The following sources will be monitored on a regular basis to identify deaths in the cohort and family participants as they occur: local newspapers and community notices, community and tribal members, and Indian Health Service (IHS), tribal and Bureau of Indian Affairs (BIA) records. The respective State Health Departments will be contacted to obtain death certificates in the study communities for the deceased participants. Additionally, information will be obtained from the following sources:

1. A combined list from all three centers of deceased and lost to follow-up participants will be sent to the National Death Index for ascertainment of vital status (for lost to follow-up) and to obtain lists of ICD–9 and ICD–10 codes for cause of death.
2. A combined list of participants from all three centers will be sent to the Centers for Medicare and Medicaid Services to obtain information of the terminal hospital admission and all other admissions within one year of death.
3. A list of participants will be sent to the North American Association of Central Cancer Registries or specific state cancer registries to request cancer type, information about diagnosis (date, stage, grade, age at diagnosis, location and spread of tumor), treatment information, and outcomes.

1.2.1 Data for Cardiovascular (CVD) Events

All deaths will be investigated, regardless of the cause indicated on the death certificate. In order to conduct an independent, standardized review of participant deaths, the following types of information will be collected.

1. Discharge summary of the terminal hospital admission and all other admissions within one year of death
2. Emergency room report and related information
3. Ambulance report and any clinical notes regarding those dead on arrival
4. Autopsy report (if done)
5. Pathology report (if done)
6. Laboratory reports from the terminal visit (or those obtained closest to the date of death) for tests relevant to the possible causes of death, including X-ray, ECG, enzymes, liver function tests, cultures, etc. For non-CVD deaths, cause-specific tests will be used.
7. Consultation reports regarding diagnoses pertinent to possible causes of death

8. Medical examiner, coroner reports / police reports for unattended, out-of-hospital deaths, and special tests, such as toxicology studies.
9. Informant interview when medical records data are not sufficient or for deaths listed as "unknown" in death certificate.
10. If not hospitalized in the year prior to death, copies of notes and test results from the last IHS outpatient visit (IHS records only).

CVD deaths are documented and reviewed by the SHS Mortality Review Committee. Underlying and contributing causes of death will be coded. Each death will be coded by two members of the review committee, and discrepancies in CVD diagnosis will be adjudicated by Dr. James Howard and the Mortality Committee.

1.2.2 Data for Non-Cardiovascular Events

The following information should be collected for specific types of non-CVD causes listed:

1. CANCER:
   a. Pathology report on which the original diagnosis was based, or if not available, then abstract:
   b. Any diagnostic reports that may help to determine the ***primary*** site of the tumor (i.e., X-ray, CT, MRI, ultrasound) or a later report with information on cell type and origin of the tumor.

2. INFECTIONS:
   a. Culture results or, if not available or culture negative
   b. Diagnostic serology
   c. TB or other skin test results, if relevant
   d. CBC and differential
   e. Temperature record from nurses notes.

3. LIVER DISEASES OR OTHER GI CONDITION:
   a. Liver function tests (SGOT, Alkaline phosphatase, GGT, Bilirubin (direct and indirect), LDH, CPK, Ammonia levels)
   b. Biopsy results
   c. Reports of other diagnostic tests (e.g., CT, MRI, endoscopy).

4. MULTI-SYSTEM PROBLEMS:
   a. Obtain all consultant reports when the cause is not clear-cut (e.g., cancer, septic shock, gunshot wound).

5. INTENTIONAL OR UNINTENTIONAL INJURY:
   a. Police and EMS reports, if available.
   b. Alcohol use information, including blood alcohol.

In addition, the SHS Mortality Review Committee will review the material obtained for each non-CVD death among SHS participants. Underlying and contributing causes of death will be coded. Each death will be coded by two members of the review committee.

1.3 Summary of Procedures for Mortality Surveillance

Eligible deaths outside of the study area are also included in the review and confirmation procedure.

The identification and confirmation of CVD deaths will involve the following steps: (1) identification of all deaths, (2) obtaining all death certificates, (3) obtaining Coroner's/Medical Examiner's report, (4) review medical records, and (5) independent confirmation of cause of death by the Mortality Review Committee.

1. Identification of all deaths
   All deaths will be identified by each center from tribal records, IHS hospitals, BIA, State Department of Health and/or the National Death Index. Persons who die out-of-state will be included.

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.

3. Obtaining Coroner's/Medical Examiner's / Police Report
   If it is indicated on the death certificate that an autopsy was performed, the autopsy report and Coroner's/Medical Examiner's Report will be obtained by each study center. Police report should also be obtained for injury deaths, if available. Photocopy the autopsy report, complete the Photocopy Checklist.

4. Review of Medical Chart
   Review medical chart to see if the decedent was hospitalized within one year prior to death and fill out Morbidity Survey Medical Records Abstract Checklist.

5. Confirmation of Cause of Death
   a. If the decedent was hospitalized within one year prior to death, the Morbidity Survey Medical Records Abstract Checklist will be completed for each morbid event. Mortality Survey Packet Checklist, the death certificate, the autopsy report, the Coroner's/Medical Examiner's report, and police report, if available. Checklist for Medical Records Review Mortality Surveillance with relevant medical records information, and Morbidity Survey Medical Records Abstract Checklist with relevant medical records are scanned into PDF files with redacted PHI. The PDF file will be uploaded to Reviewer Assignment & CC tracking form on REDCap.

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, the attending physician or nursing home staff, and an informant will be identified from the death certificate or other sources and contacted for an interview. The Informant Interview Form, and the Mortality Survey Packet Checklist will be completed. These two forms as well as the death certificate, autopsy report, and coroner's/medical examiner's report (if available) will be scanned into PDF files with redacted PHI. The PDF file will be uploaded to Reviewer Assignment & CC tracking form on REDCap.

c. The Informant Interview is done for: 1) deaths that were not medically attended, and 2) those that are requested by a member of the Mortality Review Committee. If there is any question as to whether or not an interview is needed in a particular circumstance, field staff should consult with their local Mortality Review Committee physician.

d. The two mortality reviewers will return the completed Final Decision Form to the Coordinating Center for data entry. Discrepancies in CVD diagnosis will be adjudicated by Dr. James Howard.

2. Morbidity Surveillance

2.1 Eligible Population

Non-fatal events, cardiovascular events and other events of interest will be identified among surviving SHS cohort members and the SHS Family Study participants in the three study areas through annual contacts or review of medical records, and through interviews of the participants at their Phase VII examination. Events of interest are those occurring since the last follow-up. Some prior events that were inadvertently missed may also be picked up during Phase VII surveillance.

2.2 Identification of New and Recurrent Events of Interest

Identification of non-fatal CVD events in the SHS cohort will continue in Phase VII. Participants will first be recruited and consent to the SHS-VII. Once consent is obtained, the participant will be contacted annually or their IHS records will be reviewed. These events include non-fatal myocardial infarction (MI), coronary heart disease, stroke, new diagnoses of congestive heart failure (CHF) and atrial fibrillation (AFIB), kidney failure, liver diseases, cancer, and inflammatory conditions. Persons will also be asked whether certain treatments or diagnostic procedures were done, including cardiac bypass surgery or angioplasty, cardiac catheterization, treadmill testing, and renal dialysis or renal transplant.

Criteria used to define acute MI, stroke, and congestive heart failure in Phase VII are the same as those previously used by the SHS. These criteria were derived primarily from the International Diagnostic Criteria, the Atherosclerosis Risk In Communities study (ARIC), and the Framingham Study and are described in detail previously. The criteria for 'diagnostic' cardiac enzymes used in the SHS are those of ARIC and the International Diagnostic Criteria. All available information concerning the event is reviewed by a member of the SHS Morbidity Review Committee to determine whether the study criteria have been met. Reports of cardiac surgery, angioplasty, cardiac catheterization, and treadmill testing are also validated by review of information obtained from medical records.

In addition to the CVD events, cancer, liver diseases, and certain inflammatory conditions are added to the Phase VII surveillance.

2.3 Procedures for Morbidity Surveillance

The morbidity survey will involve the following steps:

2.3.1 Identification of Potentially Eligible Case

In order to identify persons with events that may qualify as incident cases, IHS hospital computerized medical records (PCC, patient care component) or their IHS medical records are reviewed. All screening discharge diagnoses should be reviewed (see below); in addition to tests and procedures of interest to the SHS. Other local hospitals will also be surveyed to obtain discharges for MI or stroke that may be SHS participants. Participants in the Phase VII examinations will be asked if they had a CVD event of interest since their last SHS examination. Positive answers will be confirmed by chart review. Potential cases will be identified using the

following ICD-9 or ICD-10 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-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Hypertensive heart disease	I11.X	402
Acute myocardial infarction	I21.X	410.X
Other acute and subacute forms of ischemic heart disease	No Equivalent Code	411
Post-myocardial infarction syndrome	I24.1 (Dressler's syndrome)	411.0
Intermediate coronary syndrome	I20.0 (Unstable angina)	411.1
Other acute and subacute forms of ischemic heart disease	124.0, 124.8	411.8X
Old myocardial infarction	I25.2	412
Angina pectoris	I20.X	413.X
Other forms of chronic ischemic heart disease	I25.X	414.X
Cardiac dysrhythmias	I46.9, I47.X, I48.X, I49.X, R00.1	427.X

Participants for whom *three separate admissions* that included atrial fibrillation have already been abstracted and morbidity packets forwarded for review *need NOT have additional, subsequent admissions for atrial fibrillation abstracted.* If they are admitted for <u>other</u> SHS events or procedures, these other events SHOULD be abstracted.)

Disease	**ICD – 10**	**ICD – 9**
Heart failure	No Equivalent Code	428.
Congestive heart failure, unspecified	I50.9 (Heart failure, unspecified)	428.0
Left heart failure	I50.1 (Left ventricular failure)	428.1
Systolic heart failure	I50.20 - I50.23	428.2X

Participants for whom *three separate admissions* that included congestive heart failure have already been abstracted and morbidity packets forwarded for review *need NOT have additional, subsequent admissions for congestive heart failure abstracted.* If they are admitted for <u>other</u> SHS events or procedures, these other events SHOULD be abstracted.

Disease	**ICD – 10**	**ICD – 9**
Acute edema of lung, unspecified	J81.0 Acute pulmonary edema	518.4

2. Cerebrovascular Disease (ICD-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Subarachnoid hemorrhage	I60.9 Nontraumatic subarachnoid hemorrhage, unspecified	430
Intracerebral hemorrhage	I61.9 Nontraumatic intracerebral hemorrhage, unspecified	431
Other and unspecified intracranial hemorrhage	No equivalent ICD-10-CM Code	432
Nontraumatic extradural hemorrhage	I62.1	432.0
Subdural hemorrhage	I62.00 Nontraumatic subdural hemorrhage, unspecified	432.1
Unspecified intracranial hemorrhage	I62.9 Nontraumatic intracranial hemorrhage, unspecified	432.9
Occlusion and stenosis of precerebral arteries - includes embolism, narrowing, obstruction or thrombosis of basilar, carotid, and vertebral arteries	I63.X, I65.X	433, 433.0X, 433.1X, 433.2X, 433.3X, 433.8X, 433.9X
Occlusion of cererbral arteries	I63.X, I66.X	434, 434.0X, 434.1X, 434.9X
Transient cerebral ischemia	G45.X, I67.848	435, 435.0 – 435.3, 435.8, 435.9
Acute, but ill-defined, cerebrovascular disease, - includes CVA, NOS, Stroke	I67.89 Other cerebrovascular disease	436
Other and ill-defined cerebrovascular disease - includes cerebral atherosclerosis, chronic cerebral ischemia, hypertensive encephalopathy, cerebrovascular disease or lesion not otherwise specified	G45.4, I67.X	437, 437.0 – 437.9
Late effects of cerebrovascular disease	I69.9X	438, 438.0X – 438.9X

3. End Stage Renal Disease (ICD-10 and ICD-9 Codes)

Disease/Procedure	**ICD – 10**	**ICD – 9**
Hemodialysis	5A1.D00Z, 5A1.D60Z	39.95
Peritoneal dialysis	3E1.M39Z	54.98
Kidney transplant	0TS.00ZZ, 0TS.10ZZ 0TY.00Z0, 0TY.00Z1, 0TY.00Z2, 0TY.10Z0, 0TY.10Z1, 0TY.10Z2,	55.6, 55.61, 55.69
Chronic kidney disease (CKD) that includes CKD stage I-V, end stage renal disease, and other CKD	N18.1 – N18.6, N18.9	585, 585.1 – 585.6, 585.9
Renal failure, unspecified	N19	586

It is only necessary to identify and collect chart information for the FIRST time one of these diagnoses was made.

4. Chronic Valvular Heart Disease (ICD-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Diseases of mitral valve	I05.0 – I05.2, I05.8	394, 394.0 – 394.2, 394.9
Diseases of aortic valve	I06.0 – I06.2, I06.8, I06.9	395. 395.0 – 395.2, 395.9
Diseases of mitral and aortic valves	I08.0, I08.8, I08.9	396
Mitral valve disorders	I34.0, 134.8	424.0
Aortic valve disorders	I35.0 - I35.2, I35.8, I35.9	424.1

5. Aortic Aneurysm (ICD-10 and ICD-9 Codes)

Disease	**ICD – 10**	**ICD – 9**
Dissection of aorta	I71.00 – I71.03	441.0, 441.00 - 441.03
Thoracic aneurysm, ruptured	I71.1	441.1
Thoracic aneurysm without mention of rupture	I71.2	441.2
Abdominal aneurysm, ruptured	I71.3	441.3
Abdominal aneurysm without mention of rupture	I71.4	441.4
Aortic aneurysm of unspecified site, ruptured	I71.5	441.5
Thoracoabdominal aneurysm, ruptured	I71.6	441.6
Thoracoabdominal aneurysm, without mention of rupture	I71.7	441.7
Aortic aneurysm of unspecified site without mention of rupture	I71.9	441.9

6. Procedures for Treatment of Peripheral Vascular Disease (ICD-10 and ICD-9 Codes)

Procedures	**ICD – 10**	**ICD – 9**
Aorta-iliac-femoral bypass	041X	39.25
Other (peripheral) vascular shunt or bypass	031X, 041X, 051X, 061X	39.29
Angioplasty of other non-coronary vessel(s)	027X, 037X, 047X, 057X, 067X	39.50
Lower limb amputation, not otherwise specified	0Y6.CX, 0Y6.DX, 0Y6.HX, 0Y6.JX	84.10
Arteriography of femoral and other lower extremity arteries	B40.FX, B40.GX, B40.JX, B41.FX, B41.GX, B41.JX	88.48

7. Cancer
   a. Only abstract records that mention diagnoses for these conditions. Do not abstract further records of treatment for these conditions.

   b. If pathology report is available indicating the type of cancer, include this report in the PDF file for the reviewers; and check the "Pathology" checkbox in the Mortality Surveillance Checklist (for mortality event) or put a check mark in the "Yes" column in the "Other, specify:" item in the Morbidity Surveillance checklist for morbidity event.

8. Liver Disease
   Only abstract records that mention diagnoses for these conditions. Do not abstract further records of treatment for these conditions.

9. Inflammatory Conditions
   For inflammatory conditions, field centers should abstract the following diagnoses:
   Osteoarthritis
   Rheumatoid arthritis
   Systemic lupus erythematosus (SLE)
   Psoriatic arthritis
   Ulcerative colitis
   Crohn's disease
   Regional ileitis
   Sjogren's syndrome
   Scleroderma
   Juvenile rheumatoid arthritis
   Ankylosing spondylitis
   Iritis, uveitis
   Thyroiditis
   Anti-phospholipid syndrome
   Dermatomyositis
   Polymyalgia rheumatic
   Any form of "nephritis" and IgA nephropathy
   Kawasaki disease
   Mixed connective tissue disease
   Polyarteritis nodosa
   Primary sclerosing cholangitis (should have been captured by screen for hepatic disease as well)
   Raynaud's phenomenon
   Temporal arteritis

2.3.2 Confirmation of Event Occurrence

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 by the abstractor. 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 photocopied from the record. If it is determined that the event is not an eligible SHS event, no information need be collected. Data should be obtained for all events of interest occurring during the study interval.

2.3.3 Medical Record Data Collection

If the index admission is for one of the study events (whether or not it is the first occurrence), an appropriate Morbidity Survey Medical Records Abstract Checklist for that admission should be completed. If evidence is present suggesting that one or more myocardial infarctions or strokes occurred, a separate medical record abstract and checklist 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. ***If the participant is a study death, the abstract of medical records for decedents should also be completed***. If the medical record is not eligible for abstraction, the reason for exclusion (i.e., event occurred outside of the calendar years of the study, not a study event) should be entered on the master list of hospitalization and outpatient visits.

High resolution photocopies of ECGs taken as evidence of a myocardial infarction during the morbidity survey should be arranged in chronological order from earliest to latest.

2.3.4 Confirmation and Diagnosis

The collected medical records of the interested events will be redacted for PHI and scanned into PDF file. The scanned file will then be uploaded to the SHS Morbidity & Mortality Surveillance 2022-2026 REDCap database.

2.3.5 CMS Data Acquisition

We will obtain Centers for Medicare and Medicaid Services (CMS) data for those who give us the permission to use them. CMS data will capture events missed during regular surveillance. If any is found, we will follow the procedure described above to prepare the packet for review.

2.3.6 Linkage to Cancer Registries

A list of participants will be sent to the North American Association of Central Cancer Registries or specific state cancer registries to request cancer type, information about diagnosis (date, stage, grade, age at diagnosis, location and spread of tumor), treatment information, and outcomes

3. Morbidity and Mortality Surveillance Procedures

3.1 Guidelines for Outpatient Tests

These guidelines should be used in the PDF files for the reviewers:

1. Echocardiogram
   a. Do not include reports showing only mild valvular abnormalities; include reports with moderate and severe valvular abnormalities
   b. Do not include reports only showing left atrial enlargement.
   c. Do not include reports only showing small pericardial effusion.
   d. Do not include reports only showing left ventricular hypertrophy.
   e. If multiple outpatient echocardiograms were done during the time frame of 2009 to present, include only the latest report – unless earlier reports show important findings that are not present in the latest report.

2. Carotid Ultrasound
   a. Do not include reports showing less than 70% obstruction. However, in the presence of stroke or TIA, carotid ultrasound reports showing any degree of obstruction or no obstruction should be included.

3. Stress Test
   a. Do not include normal reports

4. Holter Monitor
   a. Upload only the cover page that contains summary of findings\

5. Computed Tomographic Calcium Scoring
   a. In the event when this test is done as a stand-alone test, reviewers will only complete Cardiovascular Test and Procedures Abstract form.

3.2 Guidelines for Abstracting Recurrent CHF and AFIB Events

For recurrent CHF and AFIB events, abstract no more than three hospitalizations or outpatient visits for these events.

3.3 Guidelines for Abstracting Non-CVD Events

Only abstract records that mention diagnoses of inflammatory conditions, cancer, or liver diseases. Do not abstract further records of treatment for these conditions.

1. For inflammatory conditions, field centers should abstract the following diagnoses:

   Osteoarthritis
   Rheumatoid arthritis
   Systemic lupus erythematosus (SLE)
   Psoriatic arthritis
   Ulcerative colitis
   Crohn's disease
   Regional ileitis
   Sjogren's syndrome
   Scleroderma
   Juvenile rheumatoid arthritis
   Ankylosing spondylitis
   Iritis, uveitis
   Thyroiditis
   Anti-phospholipid syndrome
   Dermatomyositis
   Polymyalgia rheumatic
   Any form of "nephritis" and IgA nephropathy
   Kawasaki disease
   Mixed connective tissue disease
   Polyarteritis nodosa
   Primary sclerosing cholangitis (should have been captured by screen for hepatic disease as well)
   Raynaud's phenomenon
   Temporal arteritis

2. For cancer diagnoses:

   If pathology report is available indicating the type of cancer, include this report in the PDF file for the reviewers; and check the “Pathology” checkbox in the Mortality Surveillance Checklist (for mortality event) or put a check mark in the “Yes” column in the “Other, specify:” item in the Morbidity Surveillance checklist for morbidity event.

3.4 Pre-Scanning Procedures

1. Stamp SHS ID number: on each page of participants' medical records.

2. Redact Participant Personal Information: Participants' personal information must be redacted (either with a secure redacting marker or by using the redaction tool in Adobe Acrobat) before uploading their files to the SHS REDCap site.

3. Scanning Order for Multiple Events:
   a. For participants with multiple events, organize events in reverse chronological date order, i.e., put latest event at the beginning and earliest event at the end.
   b. All events should be separated by Morbidity and/or Mortality Checklists.
   c. Using Morbidity Checklist for outpatient tests, procedures, and consultations will be left up to the discretion of the field sites.

4. Scanning Documentation Order for Each Event: Organize medical records for each event in the Scanning Documentation Order provided in **Appendix 1**.

5. For Mortality Files organize medical records in the following order:
   a. Put the Mortality Survey Packet Checklist and include death certificate, autopsy report (if done) and informant interview (if done).
   b. Then the Mortality Checklist and include the most recent discharge summary or other clinical information immediately preceding the death.
   c. Then previous CVD related discharges for past year in reverse chronological date order. Non-CVD discharges not needed in most cases.

6. For Morbidity Files: A single PDF File should be created even if a participant had multiple events.

3.5 Post-Scanning Procedures

1. Naming of PDF File: Name the PDF file using the format shown in the examples below:
   a. Name Morbidity file as follows: 203557MB2019-03-26-P7-RI (wherein 203557 denotes the SHS ID number; MB denotes Morbidity; 2019 denotes the year of event, 03 denotes the month of event, and 26 denotes the date of event, P7 denotes Phase VII, RI denotes the first round of abstraction in Phase VII. For subsequent rounds of abstractions, add R2 to denote second round of abstraction or R3 to denote third round of abstraction, and so on.

   b. Name Mortality file as follows: 203231MT2013-10-02 (wherein 203231 denotes the SHS ID number; MT denotes Mortality; 2013 denotes the year of death, 10 denotes the month of death, and 02 denotes the date of death). Date of death should be based on the date shown on the death certificate.

   c. Make sure to add a "0" in front of a single digit day and month in the PDF file name.

d. For hospitalization/outpatient visit involving stroke, the PDF file for the stroke reviewer should be named according to the following example: 203557MB2019-03-17-STK-P7-R1 (wherein 203557 denotes the SHS ID number; MB denotes Morbidity; 2019 denotes the year of event, 03 denotes the month of event, 26 denotes the date of event; STK denotes stroke event, P7 denotes Phase VII, and R1 denotes the first round of abstraction in Phase VII. For subsequent rounds of abstractions, add R2 to denote second round of abstraction or R3 to denote third round of abstraction, and so on.

e. For participants belonging to the Gila River Indian Community (GRIC), add GI at the end of the file name as follows: 203557MB2011-05-17GI (for morbidity file); 203231MT2013-10-02GI (for mortality file); 203557MB2011-05-17-STKGI (for stroke file); 203557MB2016-06-15R2GI (for round 2 of morbidity file).

2. Create Bookmarks in PDF File: Create separate book marks for each event and for sections under each event.

3. Activate Text Recognition Feature in PDF File

4. Redact Participant Personal Information: Participants' personal information must be redacted (by using the redaction tool in Adobe Acrobat) before uploading their files to the SHS REDCap database.

5. Upload PDF Files into the M&M Reviewers' Folders on the SHS REDCap Website: All PDF files should be uploaded to the Reviewer Assignments & CC Tracking data collection instrument under *Attach review PDF packet*. The type of review (Morbidity (including Stroke), Mortality (including Stoke, and Adjudication) and the reviewer will be assigned on REDCap.

6. Uploading Charts / Assigning Reviewers for Non-fatal Stroke Events:
   a. First, non-fatal stroke case should be sent to regular morbidity reviewers.

   b. If it comes back as stroke (definite, possible and TIA), then the case will be sent to stroke reviewer for confirmation (like we have done so in SHS-1 through 5).

   c. In such case, CC will ask field to upload just that event (if it was among many events of that cycle of surveillance then cut off all the other events) to the REDCap.

3.6 Notify M&M Reviewer and Coordinating Center (CC)

1. When a PDF file is uploaded on REDCap and a reviewer is assigned, an automatic email will be generated and sent to the selected reviewer(s). The Coordinating Center's email (shs@ouhsc.edu) will also automatically be copied in the email.

2. The reviewer will receive an email that there is a chart ready for review. Reminder emails will be sent every 30 days for 3 months.

3. Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual.

3.7 List of Morbidity and Mortality Reviewers

Following is a list of SHS M&M reviewers along with their email addresses:

Morbidity Reviewers:

1. Dr. Lyle Best: lbest@restel.com
2. Dr. Jason Deen: jason.deen@seattlechildrens.org
3. Dr. Richard Devereux: rbdevere@med.cornell.edu
4. Dr. Huimin Wu huimin-wu@ouhsc.edu
5. Dr. Nupoor Narula nun9005@med.cornell.edu

Mortality Reviewers:

1. Dr. Dorothy Rhoades: Dorothy-Rhoades@ouhsc.edu
2. Dr. Gernot Pichler: gernotpichler@gmx.at
3. Dr. Lyle Best: lbest@restel.com
4. Dr. Richard Devereux: rbdevere@med.cornell.edu
5. Dr. Stacey Jolly: jollys@ccf.org

Stroke Reviewers:

1. Dr. Alexander Merkler: alm9097@med.cornell.edu
2. Dr. Santosh Murthy: sam9200@med.cornell.edu

Mortality Adjudicator

1. Dr. William Howard: wjh1@comcast.net

3.8 Instructions to Access SHS M&M REDCap Website

1. Go to the SHS REDCap website
2. Enter your Username and Password
3. Click on Log in
4. If there are issues with logging into REDCap, please email the Strong Heart Study Coordinating Center at shs@ouhsc.edu with the subject line "Issues with REDCap log in"

3.9 Procedures for Reviewers to Access PDF Files

1. Click on SHS Morbidity & Mortality Surveillance 2022-2026 project in REDCap.
2. Select the respective Reviewer Assignment Report under the Reports section on the left hand of the screen. These reports provide the pending charts for review for each reviewer.
3. To access the participants chart, click on the Record ID number. REDCap will be redirected to the Reviewer Assignment & CC Tracking page.
4. Click the PDF file that was uploaded under Attach review PDF packet. The reviewer will be directed to download the PDF file.

Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual.

3.10 Responsibility or M&M Reviewer After Completing Chart Reviews

Reviewers have two choices in completing chart reviews:

1. The reviewer can use the provided fillable PDF forms to complete their decision process and email the completed PDF forms to the CC at shs@ouhsc.edu. The CC will be responsible for entering the decision forms into the REDCap database.
2. The review can log in to REDCap and enter their decisions directly into the decision form data collection instruments.

Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual

3.11 Tracking Uploaded Events

The CC will track uploaded events on a monthly basis. These tracking reports will be sent to the Steering Committee prior to their monthly meeting. Specific information and more details are provided in the SHS M&M Surveillance Data Management Manual.

Appendices

Appendix 1 Scanning Documentation for Each Event

1 – Hospital Admin Documents
- – Hospital Face Sheet – ICD9-CM Codes
- – Physician Attestation; Coding Abstract

2- Discharge Summary
- – Discharge Summary
- – Outpatient/Short Stay Record

3 – Physician Documents
- – History and Physical/Physical Exam
- – Emergency Room/Emergency Department report

4 – Consultations
- – Consult

5 – ECGs
- – 12-Lead ECG tracings, all days

6 – Labs
- – Cardiac Enzyme Reports (e.g., Troponin I, Troponin T, CKMG, CK or CPK), all days
- – Lab: Brain B-type natriuretic peptide (BNP), pro-BNP
- – Lab: Blood urea nitrogen (BUN), creatinine
- – Complete blood count (CBC)
- – Lab: Electrolyte Reports

7 – Imaging
- – Chest X-ray Report all days
- – Stress Test by treadmill ECG echo or nuclear perfusion scintigraphy report
- – Carotid Artery Angiography, Doppler flow study
- – Doppler flow study report
- – Echocardiogram and Doppler (all reports of 2-D, transesophageal-TEE, or transthoracic-TTE)
- – Ventilation/Perfusion Lung Scan Report
- – Pulmonary Angiogram
- – CT Scan Report
- – MRI Report
- – Radiology and/or bone scan reports/isotope or nuclear med bone scan
- – Nuclear Scans, e.g., thallium, Myoview®, sestamibi, RVG/MUGA
- – Reports of cardiac MRI/MR angiography
- – Reports of Cardiac CT scan /CT angiography
- – Reports of angiograms of head, neck or brain (MRA, CT, or catheter based)
- – Reports of angiograms of the lower extremities (MRA, CT, or catheter-based angiography)

7 – Imaging (continued)
- – Reports of Segmental Doppler assessment of the lower extremities
- – Reports of Abdominal Ultrasound of aorta or other arteries
- – Reports of Head/Brain CT scans
- – Reports of head/brain MRIs

8 – Op and Procedures
- – Coronary Artery Bypass Graft (CABG)
- – Percutaneous Coronary Intervention (PCI): PTCA; Coronary Stent/Atherectomy
- – Operative or Procedure Report
- – Cardiac catheterization including coronary angiograms and arteriograms and contract ventriculogram
- – Venogram report
- – Operative/Procedure reports (including Aortic Stent Graft)
- – Operative/Procedure reports (including angioplasty and /or stent of lower extremities)

9 – Pathology
- – All pathology reports
- – Cytology reports, all

10 – Fatal Events
- – Death certificate
- – Autopsy or Medical Examiner/Coroner's report
- – Emergency Medical Services (EMS) or ambulance report

11 – Miscellaneous
- 99 – Miscellaneous document, specify

Appendix 2 Morbidity and Mortality Data Collection Forms

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Medical Records Abstract Checklist for Non-Fatal CVD Events or Procedures

ID number:

|___|___|___|___|___|___|

1. a. Hospital name:_____

   b. Hospital location _____

2. Date of ADMISSION to this hospital or date of this OUTPATIENT visit:

   |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Date of discharge:

   |___|___|/|___|___|/|___|___|___|___|
   month day year

4. Was the patient transferred to or from another acute care hospital?

   Yes |___|1 ***(be sure information is listed on M&M master list form)*** No |___|2

5. Record the hospital discharge diagnoses and procedure recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. You can include any ICD-10 codes if they are available.

1. _____	9. _____
2. _____	10. _____
3. _____	11. _____
4. _____	12. _____
5. _____	13. _____
6. _____	14. _____
7. _____	15. _____
8. _____	16. _____

RENAL DIALYSIS AND KIDNEY TRANSPLANT

6. Has the participant received a kidney transplant? Yes |___| 1 No|___|2

   If yes, was the transplant done this admission? Yes |___| 1 No|___|2

   If no, date of first transplant: |___|___|/|___|___|/|___|___|___|___|
   month day year

7. Was the participant receiving kidney dialysis during this hospital or outpatient visit?

   Yes |___| 1 No|___|2

   If yes, was dialysis started during this admission? Yes |___| 1 No|___|2

Obtain the following medical records (when available) for each hospitalization or outpatient visit since this participant's last morbidity chart review (and assemble them for each admission). Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets), including Diagnoses	_____	_____	_____
Discharge Summary	_____	_____	_____
Admitting History and Physical Exam	_____	_____	_____
ECGs (see instruction)	_____	_____	_____
Cardiac enzyme report (days 1 to 4)	_____	_____	_____
Neurology Consult Report	_____	_____	_____

Reports of Procedures:

1. Echocardiogram	_____	_____	_____
2. Coronary angiogram	_____	_____	_____
3. Exercise tolerance test (Treadmill)	_____	_____	_____
4. Cardiac catheterization	_____	_____	_____
5. Coronary bypass	_____	_____	_____
6. Coronary angioplasty	_____	_____	_____
7. Swan-Ganz catheterization	_____	_____	_____
8. Intracoronary or I.V. streptokinase, or TPA reperfusion	_____	_____	_____
9. Aortic balloon pump	_____	_____	_____
10. Radionuclide scan	_____	_____	_____
11. CAT or CT of the head	_____	_____	_____
12. Magnetic Resonance Image (MRI) of the head	_____	_____	_____
13. Carotid ultrasound/Doppler	_____	_____	_____
14. Lumbar puncture	_____	_____	_____

15. Angiography (including vessels in the lower extremities) _____ _____ _____
16. Peripheral Angioplasty (lower extremity vessel(s)) _____ _____ _____
17. Surgical revascularization of peripheral vessel(s)) _____ _____ _____
18. Amputation _____ _____ _____
19. Chest X-ray _____ _____ _____
20. Carotid endarterectomy _____ _____ _____
21. CAT or CT of abdomen or other part of the body _____ _____ _____
22. MRI of abdomen or other part of the body _____ _____ _____
23. Other, specify: _____ _____ _____ _____
24. Other, specify: _____ _____ _____ _____
25. Other, specify: _____ _____ _____ _____
26. Other, specify: _____ _____ _____ _____
27. Other, specify: _____ _____ _____ _____
28. Other, specify: _____ _____ _____ _____
29. Other, specify: _____ _____ _____ _____
30. Other, specify: _____ _____ _____ _____
31. Other, specify: _____ _____ _____ _____
32. Other, specify: _____ _____ _____ _____

Be sure to include Tracking Sheet in the packet

ADMINISTRATIVE INFORMATION:

SHS staff code: |___|___|___|

Completion date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Morbidity Survey – DECISION

ID number: |___|___|___|___|___|___|___|

Date of this event: |___|___|/|___|___|/|___|___|___|___|
month day year

A. DIAGNOSIS (enter appropriate code number):

01. Definite non-fatal myocardial infarction |___|___|

1b. Probable non-fatal myocardial infarction |___|___|

02. Possible non-fatal myocardial infarction |___|___|

03. Definite non-fatal stroke |___|___|

04. Possible non-fatal stroke |___|___|

06. Definite CHD |___|___|

07. Possible CHD (those with some, but not all, criteria or with equivocal criteria for definite CHD) |___|___|

08. TIA |___|___|

09. Other CVD, specify: _____ |___|___|

10. Non–CVD, specify: _____ |___|___|

11. ESRD (dialysis or transplant): _____ |___|___|

12. Heart Failure (**Please fill out the HF PROCEDURE FORM**) |___|___|

B. Criteria used:

1. MYOCARDIAL INFARCTION (Please check all applicable criteria)

A. Definite MI |___|
1. Evolving diagnostic ECG*, or |___|
2. Diagnostic biomarkers (2 x ULN)* |___|

B. Probable MI |___|
1. Positive ECG findings plus cardiac symptoms or signs without available biomarkers, or |___|
2. Positive ECG findings plus equivocal biomarkers |___|

C. Possible MI |___|

1. Equivocal biomarkers plus nonspecific ECG findings, or |___|
2. Equivocal biomarkers plus cardiac symptoms or signs, or |___|
3. Missing biomarkers plus positive ECG |___|

**** For ECG and cardiac biomarker definition, please refer to: SHS VI Manual, Section 2.3.***

COMMENTS: _____

_____

_____

2. STROKE

A. Definite non-fatal stroke |___|

1. Stroke of unknown type etiology: Definite stroke of unknown etiology when CT or MRI not done. Information is inadequate to diagnose ischemic (infarction), intracerebral hemorrhage, or subarachnoid hemorrhage. |___|
2. Definite ischemic stroke: CT or MRI scan within 14 days of onset of a focal neurological deficit lasting more than 24 hours with evidence of brain infarction (mottled cerebral pattern or decreased density in a defined vascular territory), no intraparenchymal or subarachnoid hemorrhage by CT/MRI, (or lumbar puncture if done). A nonvascular etiology must be absent. |___|
3. Definite primary intracerebral hemorrhage: Focal neurological deficit lasting more than 24 hours. Confirmation of intraparenchymal hemorrhage in a compatible location, not caused by trauma, with CT/MRI scan within 14 days of stroke. |___|
4. Subarachnoid hemorrhage: Sudden onset of a headache, neck stiffness, loss of consciousness. There may be a focal neurological deficit, but neck stiffness is more prominent. Blood in the subarachnoid or intraventricular space by CT/MRI - not caused by trauma. |___|
5. Non-fatal stroke after cardiovascular invasive interventions: Stroke associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions. |___|
6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery. |___|

B. Possible non-fatal stroke |___|

a. History or 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 |___|

2a. Discharge diagnosis with consistent primary or secondary codes (ICD-9-CM codes: 431, 432, 434, 436, 437; ICD-10-CM: I61.9, I62.1, I62.00, I62.9, I66.09, I66.19, I66.29, I63.30, I63.40, I66.9, I63.50, I67.89, I67.2, I67.81, I67.82, I67.89, I67.4, I67.1, I67.7, I67.5, I67.6, G45.4, I67.89, I67.9), and |___|

2b. 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. |___|

C. Ischemic stroke subtype classification (complete for cases of definite ischemic stroke).

[ ] 1. Large-artery atherosclerosis: Clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis, and clinical findings of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large- artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

*Probable |___| *Possible |___|

[ ] 2. Cardioembolism: Patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolic stroke. Clinical and brain imaging findings are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

*Probable |___| *Possible |___|

[ ] 3. Small-artery occlusion (lacune): Patients whose strokes are often labeled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction (aphasia, neglect, restricted motor involvement, etc.). A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent, and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

*Probable |___| *Possible |___|

* A **probable** diagnosis is made if the clinical findings, neuroimaging data,

and results of diagnostic studies are consistent with one subtype and other etiologies have been excluded. A **possible** diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype but other studies are not done.

[ ] 4. Acute stroke of other determined etiology: Patients with rare causes of stroke, such as non atherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of these unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

[ ] 5. Stroke of undetermined etiology: In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely etiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined etiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

COMMENTS: _____

_____

_____

3. DEFINITE CORONARY HEART DISEASE (CHD)

a. Cardiac cath proven coronary artery disease (1 or more vessels ≥ 50% stenosis), ***or*** |___|

b. PTCA, ***or*** |___|

c. Coronary artery bypass grafting, ***or*** |___|

d1. Abnormal stress ECG, **and** |___|

d.2. Abnormal imaging, ***or*** |___|

e. Positive functional test of ischemia (such as treadmill) |___|

COMMENTS: _____

_____

_____

4. HEART FAILURE (***if yes, fill out Heart Failure form)***

Two major criteria or one major and two minor criteria:

a. Major criteria
- [ ] i. Paroxysmal nocturnal dyspnea or Orthopnea
- [ ] ii. Neck vein distention
- [ ] iii. Rales
- [ ] iv. Cardiomegaly
- [ ] v. Acute pulmonary edema
- [ ] vi. S3 gallop
- [ ] vii. Increased venous pressure >16cm water
- [ ] viii. Circulation time ≥ 25 seconds
- [ ] ix. Hepatojugular reflux

b. Minor criteria
- [ ] i. Ankle edema
- [ ] ii. Night cough
- [ ] iii. Dyspnea on exertion
- [ ] iv. Hepatomegaly
- [ ] v. Pleural effusion
- [ ] vi. Vital capacity reduced by one-third from maximum
- [ ] vii. Tachycardia (rate of ≥ 120/min.)

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment

AND

d. [ ] No known non-cardiac process leading to fluid overload such as renal failure

COMMENTS: _____

_____

_____

5. OTHER NON-FATAL CARDIOVASCULAR DISEASE

a. Purposely left blank – CHF moved to #4 above

b. Purposely left blank – CHF secondary to ESRD has been included in Diagnosis code 10 (Question A of this form).

- [ ] c. Cardiomyopathy
- [ ] d. Valvular Heart Disease
- [ ] e. Left Ventricular Hypertrophy
- [ ] f. Atrial Fibrillation
- [ ] g. Non-coronary heart surgery or carotid or other vascular surgery (does not include procedures for PVD)
- [ ] h. Pacemaker implantation
- [ ] i. Positive non-coronary angiography (does not include procedures for PVD)
- [ ] j. Arrhythmia

[ ] k. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides; diagnosis = 07)
[ ] l. PVD (either peripheral arterial surgical procedures, angiogram or amputation)
[ ] m. Aortic aneurysm

If there was coronary or peripheral vascular procedure done, fill out CVD Test Procedures form or Peripheral Vascular Procedure form.

COMMENTS: _____

_____

_____

_____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Cardiovascular Test Procedures Abstract

ID number: |___|___|___|___|___|___|

1. **WAS CATHETERIZATION/ANGIOGRAM DONE?**
   Yes |___|1 No (***Go to Q18***) |___|2 Yes, but no report |___|3

2. If YES, When? |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Where: _____
   Hospital/Clinic City/State

Was Any Vessel ≥ 50% Stenotic in ...

		Yes	No	Uncertain	Unknown
4.	Left Main:	|___|1	|___|2	|___|8	|___|9
5.	Left anterior descending:	|___|1	|___|2	|___|8	|___|9
6.	Right coronary:	|___|1	|___|2	|___|8	|___|9
7.	Circumflex artery:	|___|1	|___|2	|___|8	|___|9

8. ***Ejection Fraction (%):*** |___|___|___|

777= normal, % not specified 888=abnormal, % not specified
999=unknown/no response

9. ***Left Ventricular Function:*** Normal |___|1 Assessed, results not specified |___|3
Depressed |___|2 Not assessed (***Go to Q17***) |___|9

10. ***Was Akinetic Wall Observed?***

Yes |___|1 No (***Go to Q15***) |___|2 Uncertain |___|8 Unknown|___|9

		Yes	No	Uncertain	Unknown
11.	Anterior:	|___|1	|___|2	|___|8	|___|9
12.	Inferior:	|___|1	|___|2	|___|8	|___|9
13.	Apex:	|___|1	|___|2	|___|8	|___|9
14.	Diffuse:	|___|1	|___|2	|___|8	|___|9

Finding of Valvular Function:

		Yes	No	Uncertain	Unknown
15.	Mitral regurgitation:	|___|1	|___|2	|___|8	|___|9
16.	Aortic regurgitation:	|___|1	|___|2	|___|8	|___|9
17.	***Was Angioplasty performed?***	|___|1	|___|2	|___|8	|___|9

18. WAS COMPUTED TOMOGRAPHIC CALCIUM SCORING DONE?

Yes |___|1 No **(*Go to Q22*)** |___|2 Yes, but no report |___|3

19. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

20. Where: _____
Hospital/Clinic City/State

21. **Agatston score:** |___|___|___|___|

22. WAS TREADMILL EXERCISE TEST DONE?

Yes |___|1 No **(*Go to Q29*)** |___|2 Yes, but no report |___|3

23. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

24. Where: _____
Hospital/Clinic City/State

25. Treadmill ECG:

Normal |___|1 Borderline |___|2 Abnormal |___|3 Inconclusive |___|8 No report |___|9

26. Maximum heart rate (beats/minute): 999=no report |___|___|___|

27. Maximum systolic blood pressure (mmHg): 999=no report |___|___|___|

28. Treadmill time (round to nearest whole number minute): 99=no report |___|___|

29. WAS THALLIUM TEST, OR OTHER NUCLEAR IMAGE TEST DONE?

Yes |___|1 No **(*Go to Q34*)** |___|2 Yes, but no report |___|3

30. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

31. Where: _____
Hospital/Clinic City/State

32. What Stress: Exercise |___|1 Adenosine |___|2 Dobutamine |___|3 Other Drug |___|4

If Other drug, please specify: _____

33. Test results: Positive |___|1 Negative |___|2 Equivocal |___|3 No report |___|9

ADMINISTRATIVE INFORMATION:

34. Reviewer code |___|___|___|

35. Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Peripheral Vascular Procedures/Revascularization Abstract

ID number: |___|___|___|___|___|___|

1. **Was peripheral angiogram (ICD-9 procedure code 88.48, ICD-10: B40.X, B41.X) done?**

Yes |___|1 No |___|2 **(Go to Q2)** Yes, but no report |___|9

a. If yes: Contrast angiogram |___| MR angiogram |___| CT angiogram |___|

b. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

d. Was any vessel ≥ 50% stenotic?

i. Aorta: Yes |___|1 No |___|2 Uncertain|___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

ii. Iliac: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

iii. Femoral: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

iv. Popliteal or lower: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

v. Carotid stenosis Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

e. Was there evidence of previous revascularization? Yes |___|1 No |___|2

2. **Was peripheral angioplasty or surgical revascularization done?**

Yes, angioplasty |___|1
(ICD-9 procedure code 39.50)
(ICD-10: 027X, 037X, 047X, 057X, 067X)

Yes, revascularization |___|3
(ICD-9 procedure code 39.25 and 39.29)
(ICD-10: 031X, 041X, 051X, 061X)

No |___|2 **(Go to Q3)** Yes, but no report |___|9

a. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

b. Where: _____

3. **Was amputation (ICD-9 procedure codes 84.10 – 84.19, ICD-10: OY6.X) performed?**

Yes |___|1 No |___|2 **(Go to Q4.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. Which part?

Upper body, Arm=1, Hand=2, Finger=3, |___|

Lower body, Above knee=1, Below knee=2 |___|
Foot=3, Toe(s)=4

b. When: |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

4. **Was carotid angioplasty/stenting done?**

Yes |___|1 No |___|2 **(Go to Q5.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

5. **Was carotid endarterectomy done?**

Yes |___|1 No |___|2 **(Go to end.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. When: |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

ADMINISTRATIVE INFORMATION:

5. Reviewer code: |___|___|___|

6. Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

Instructions: The same procedures used for the ongoing surveillance in each center should be used, including evaluation of clinic charts and/or use of the IHS computerized records as well as direct contact with participants when necessary.

The purpose of this study is to derive an estimate of the proportion of participants who have undergone diagnostic or therapeutic procedures documenting definite lower extremity peripheral arterial disease since the Phase III SHS examination, and the proportion thereof for whom the necessary records are still available. Therefore, medical records for hospitalizations or outpatient encounters dealing with the diagnostic or procedural codes listed below and occurring since 1 January 1998 should be requested and reports of the procedures of interest should be obtained. Earlier events that correspond to the same procedures should be noted but charts need not be abstracted.

The following diagnostic codes should be identified:
For Peripheral Angiograms: ICD-9 procedure code **88.48**
ICD-10: **B40.X, B41.X**
For Peripheral Angioplasty: ICD-9 procedure code **39.50**
ICD-10: **027X, 037X, 047X, 057X, 067X**
For Peripheral Surgical Revascularization: ICD-9 procedure codes **39.25 and 39.29**
ICD-10: **031X, 041X, 051X, 061X**
For Amputation: ICD-9 procedure codes **84.10-84.19**
ICD-10: **OY6.X**
For Carotid Endarterectomy: ICD-9 procedure code **38.12**
ICD-10: **03CX**
For Angioplasty: ICD-9 procedure code **00.61**
ICD-10: **037X, 03CX, 057X**
For Stenting: ICD-9 procedure code **00.45**
ICD-10: **027X**

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

HEART FAILURE PROCEDURES

SHS ID: |___|___|___|___|___|___|___| Date of Event: |___|___|/|___|___|/|___|___|___|___|
month day year

A. ATRIAL FIBRILLATION AT TIME OF HF? Yes |___| 1 No |___| 2 Unknown |___| 9

B. WHICH IMAGING STUDY WAS PERFORMED DURING THIS ADMISSION? Please check ALL that were done. If more than one imaging study was done in the same admission, please use one of these forms for EACH IMAGING STUDY to record the results of that study.

|___|1 Echocardiogram

|___|2 Nuclear Imaging

|___|3 Invasive Angiogram

|___|4 CT Angiogram

|___|5 MRI Angiogram

|___|6 Other, Specify: _____

|___|7 Not sure, no results found in chart

|___|8 None

If not sure or none, skip to Q8.

1. Name of test: _____

2. Date of test: |___|___|/|___|___|/|___|___|___|___|
month day year

3. Facility name: _____

   City/State: _____

4. Ejection fraction: Measured: |_____|% Estimated: |_____|%

   If % not stated, 777 = normal, or range ≥ 50% 888 = abnormal, or range < 50% 999 = unknown/no response

5. Ejection fraction interpretation: Normal |___| 1 Depressed |___| 2 NR |___| 9

6. Segmental wall motion abnormalities? Yes |___| 1 No |___| 2 NR |___| 9

   If yes, degree of abnormality: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

7. Transmitral time: E Velocity: ____cm/sec A Velocity: _____ cm/sec Peak E/A Ratio: _____

   Decel. Time: _____msec IVRT: ____ Septal E':_____ Peak S':_____ Septal A':____

8. **Valvular disease?** Yes |___| 1 No |___| 2 Unknown |___| 9

If No or Unknown, go to Q9.

If Yes,

a. Mitral regurgitation/insufficiency:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

b. Mitral stenosis: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

c. Aortic regurgitation/insufficiency:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

d. Aortic stenosis: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

e. Tricuspid regurgitation:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

9. **Right ventricular systolic pressure/PA systolic pressure (mmHg):** **|___|___|___|**

If not stated, 777 = normal 888 = abnormal 999 = unknown/no response

C. B-TYPE NATRIURETIC PEPTIDE (BT-BNP):_____pg/ml. Upper Limit of Normal:_____pg/ml

N-TYPE NATRIURETIC PEPTIDE (NT-BNP): _____ pg/ml. Upper Limit of Normal:_____pg/ml

D. CARDIOMYOPATHY DIAGNOSIS: Ischemic: ____ Non-Ischemic: _____ Hypertrophic:

Valvular disease: ____ Acute MI:_____ NR |___| 9

No cardiomyopathy _____

ADMINISTRATIVE INFORMATION:

Reviewer Code: |___|___|___|

Review Date: |___|___|/|___|___|/|___|___|___|___|

Month day year

STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CHECKLIST FOR MEDICAL RECORDS REVIEW
MORTALITY SURVEILLANCE -- CVD and NON-CVD

Admission date: |___|___|/|___|___|/|___|___|___|___| ID Number: |___|___|___|___|___|___|
mo day year

For each hospital admission WITHIN the YEAR prior to death, obtain electronic records or photocopies of each of the following sections of the medical history (when available) and assemble them for each admission. Be sure that photocopies are legible.

1. a. Hospital name: _____

b. Hospital location _____

2. Date of discharge: |___|___|/|___|___|/|___|___|___|___|
month day year

3. Record the hospital discharge diagnoses and procedures recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. You can include any ICD-10 codes if they are available.

1. _____ 8. _____
2. _____ 9. _____
3. _____ 10. _____
4. _____ 11. _____
5. _____ 12. _____
6. _____ 13. _____
7. _____ 14. _____

RENAL DIALYSIS AND TRANSPLANT

Provide answers to Question 4 only for the last admission within 12 months prior to death.

4. Was the participant receiving kidney dialysis during this hospital visit? Yes |___| 1 No|___|2

If yes, was dialysis started during this admission? Yes |___| 1 No|___|2

Did participant request stopping dialysis during this hospitalization? Yes |___| 1 No|___|2

5. Has this participant ever had a kidney transplant? Yes |___|1 No |___|2

6. **<u>FOR MORTALITY REVIEW:</u> Obtain the following medical records (when available) for this final admission. In addition, obtain these medical records for each hospitalization WITHIN the YEAR prior to death (and <u>assemble</u> <u>them</u> <u>for</u> <u>each</u> <u>admission</u>).**
<u>FOR MORBIDITY REVIEW:</u> Obtain the following medical records (when available) for each hospitalization or outpatient visit since this participant's last morbidity chart review (and <u>assemble</u> <u>them</u> <u>for</u> <u>each</u> <u>admission</u>). Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets)	|___|1	|___|2	|___|9
Discahrge Summary	|___|1	|___|2	|___|9
Admitting History and Physical Exam	|___|1	|___|2	|___|9
ECGs	|___|1	|___|2	|___|9
Cardiac Enzyme (including Troponin)	|___|1	|___|2	|___|9
Reports of results of:			
Chest X-ray	|___|1	|___|2	|___|9
Echocardiogram	|___|1	|___|2	|___|9
Angiogram	|___|1	|___|2	|___|9
Exercise tolerance test (Treadmill)	|___|1	|___|2	|___|9
Cardiac catheterization	|___|1	|___|2	|___|9
CT (CAT) scan	|___|1	|___|2	|___|9
MRI	|___|1	|___|2	|___|9
Carotid ultrasound	|___|1	|___|2	|___|9
Lumbar puncture	|___|1	|___|2	|___|9
Creatinine	|___|1	|___|2	|___|9
Liver Function test	|___|1	|___|2	|___|9
Pathology	|___|1	|___|2	|___|9
Cultures	|___|1	|___|2	|___|9

Other Laboratory results, SPECIFY:

_____	|___|1	|___|2	|___|9
_____	|___|1	|___|2	|___|9
_____	|___|1	|___|2	|___|9
Operative reports:			
Coronary bypass	|___|1	|___|2	|___|9
Angioplasty	|___|1	|___|2	|___|9
Swan-Ganz catheterization	|___|1	|___|2	|___|9
Non-CVD operation	|___|1	|___|2	|___|9
For terminal Event Only:			
Ambulance report	|___|1	|___|2	|___|9
ER Admission and Discharge Summary	|___|1	|___|2	|___|9
Any clinical notes regarding DOA	|___|1	|___|2	|___|9
Autopsy Report/ Coroner's Report	|___|1	|___|2	|___|9
From IHS clinic chart (if available), photocopy notes and test results from the most recent visit prior to death	|___|1	|___|2	|___|9

ADMINISTRATIVE INFORMATION:

Abstractor Number |___|___|___|

Date abstract completed: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Mortality Survey Packet Checklist

ID number: |___|___|___|___|___|___|___|

1.	Death Certificate	Yes |___|1	No |___|2
2.	Autopsy performed	Yes |___|1	No |___|2
3.	Autopsy report	Yes |___|1	No |___|2
4.	Medical Records Checklist	Yes |___|1	No |___|2
5.	Copy reports as specified	Yes |___|1	No |___|2
6.	Check if the decedent is eligible for the morbidity survey and proceed as required by the morbidity survey protocol.	Yes |___|1	No |___|2
7.	Check if tracking form was sent	Yes |___|1	No |___|2
8.	Informant Interview Form	Yes |___|1	No |___|2

9. Was he/she in a nursing home at the time of death?

   Yes |___|1 No |___|2 Unknown |___|9

10. Was he/she receiving care from a home hospice care program at the time of death?

    Yes |___|1 No |___|2 Unknown |___|9

ADMINISTRATIVE INFORMATION:

SHS staff code: |___|___|___|

Completion date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

Mortality Survey – Final Decision

ID number: |___|___|___|___|___|___|___|

Date of death: |___|___|/|___|___|/|___|___|___|___| (month / day / year) Age at death: |___|___|

A. Cause of death, choose from the list below:

Cause of death: |___|___|

Contributory cause of death 1: |___|___|

Contributory cause of death 2: |___|___|

01 = Definite myocardial infarction
1a = Probable myocardial infarction
02 = Definite sudden death due to coronary heart disease
03 = Definite coronary heart disease
04 = Possible coronary heart disease
05 = Definite stroke
06 = Possible stroke
07 = Definite congestive heart failure
08 = Possible congestive heart failure
09 = Other cardiovascular diseases, specify: _____

If is Non-CVD death, choose one from the following list and complete the evidence code:

Evidence Code: |___|___|
(up to 3 Codes) |___|___|
|___|___|

21 = Malignant neoplasm;
primary site:_____
22 = Unintentional injury and adverse effects/MVA
23 = Unintentional injury and adverse effects/all other
24 = Chronic obstructive pulmonary disease and allied conditions
25 = Pneumonia and influenza
26 = Diabetes mellitus
27 = Chronic liver disease and cirrhosis
28 = Suicide
29 = Homicide and legal intervention
30 = Nephritis, nephrotic syndrome and nephrosis
31 = ESRD
32 = Septicemia
33 = HIV/AIDS
88 = Other, specify: _____
99 = Can not be determined.

01 = Pathology Report
02 = Clinical Diagnosis only
03 = Pulmonary function test
04 = Blood glucose test
05 = Abnormal liver function tests
06 = Abnormal kidney function test
07 = Positive culture (blood or sputum)
08 = Positive antibody test
09 = Positive blood test (any type)
10 = Autopsy
11 = Police/Coroner's investigation
12 = Other medical records evidence
Specify: _____

Was the death alcohol related? Yes |___|1 No |___|2 Unknown |___|9

B. Criteria used for the cause of death: (Please check the appropriate boxes.)

01. Definite fatal myocardial infarction

[ ] 1(a) Definite MI within 4 weeks of death by criteria: Yes No

1.	Evolving diagnostic ECG*, or	|___|1	|___|2
2.	Diagnostic biomarkers (2 x ULN)*	|___|1	|___|2

OR

[ ] 1(b) Acute MI diagnosed by autopsy

AND

[ ] 2. No known non-atherosclerotic or noncardiac-atherosclerotic condition that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

1a. Probable fatal MI

[ ] 1. Death within 28 days of hospital admission, cases defined as:

		Yes	No
1a.	Positive ECG findings plus cardiac symptoms or signs Without biomarkers, or	|___|1	|___|2
1b.	Positive ECG findings plus equivocal biomarkers	|___|1	|___|2

OR

[ ] 2. Death within 6 hours of hospital admission with cardiac symptoms and/or signs. Other confirmatory data (biomarkers, ECG) are absent or non-diagnostic. \|___\|1 \|___\|2

**** For ECG and cardiac biomarker definitions, please refer to: SHS VI Manual, Section 2.3.***

02. Definite sudden death due to CHD

[ ] 1. Death witnessed as occurring within 1 hour after the onset of cardiac symptoms (prolonged cardiac pain, shortness of breath, fainting) or within 1 hour after the subject was last seen without symptoms.

AND

[ ] 2. No documentation of acute MI within 4 weeks prior to death.

AND

[ ] 3. No known non-atherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records or physician report.

03. Definite fatal CHD

[ ] 1. Death certificate with consistent underlying or immediate causes, **AND**
[ ] 2. No documentation of definite acute MI within 4 weeks prior to death, **AND**
[ ] 3. Criteria for sudden death not met (above), **AND**
[ ] 4. No known non-atherosclerotic or noncardiac-atherosclerotic process or event that was probably lethal according to death certificate, autopsy report, hospital records, or physician records,

AND

[ ] 5(a) Previous history of MI according to relative, physician, or hospital records,
OR
[ ] 5(b) 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
[ ] 5(c) 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 (without meeting criteria for Probable MI),
OR
[ ] 5(d) Angiogram reporting severe (≥ 50% narrowing) atherosclerotic coronary artery disease,
OR
[ ] 5(e) Other positive physical signs or lab findings.

04. 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,
AND
[ ] 5. No known non-atherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

05. Definite fatal stroke (**also complete 6.1, 6.2 and Supplemental Form**)

[ ] 1a. Cerebral infarction or hemorrhage diagnosed at autopsy,
AND
[ ] 1b. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,
OR

[ ] 2a. History of rapid onset (approximately 48 hours from onset to time to admission or maximum acute neurologic deficit) of focal neurologic deficit with or without change in state of consciousness,

AND

[ ] 2b. Focal neurologic deficit within 6 weeks of death documented by unequivocal physician or laboratory findings with 24 hours duration of objective physician findings,

AND

[ ] 2c. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,

06. Possible (Undocumented) fatal stroke

[ ] 1. Death certificate consistent with underlying or immediate cause (ICD-9, code 431 – 437, ICD10: I61.X – I63.X, I65.X-I67.X, G45.X), but neither autopsy evidence nor adequate pre-terminal documentation of the event,

AND

[ ] 2. No evidence at autopsy examination of the brain, if performed, of any disease process that could cause focal neurologic signs that would not be connected with cerebral infarction or hemorrhage.

OR

[ ] 3. Focal neurological deficit and death within 24 hours, without MRI or other diagnostic image.

<u>Stroke subtype classification (complete for cases of definite fatal stroke).</u>

[ ] 1. Stroke of unknown type etiology: Definite stroke of unknown etiology when CT or MRI not done. Information is inadequate to diagnose ischemic (infarction), intracerebral hemorrhage, or subarachnoid hemorrhage.

[ ] 2. Definite ischemic stroke: CT or MRI scan within 14 days of onset of a focal neurological deficit lasting more than 24 hours with evidence of brain infarction (mottled cerebral pattern or decreased density in a defined vascular territory), no intraparenchymal or subarachnoid hemorrhage by CT/MRI. A nonvascular etiology must be absent.

[ ] 3. Definite primary intracerebral hemorrhage: Focal neurological deficit lasting more than 24 hours. Confirmation of intraparenchymal hemorrhage in a compatible location, not caused by trauma, with CT/MRI scan within 14 days of stroke.

[ ] 4. Subarachnoid hemorrhage: Sudden onset of a headache, neck stiffness, loss of consciousness. There may be a focal neurological deficit, but neck stiffness is more prominent. Blood in the subarachnoid or intraventricular space by CT/MRI, not caused by trauma.

[ ] 5. Non-fatal stroke after cardiovascular invasive interventions: Stroke associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions.

[ ] 6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery.

Ischemic stroke subtype classification (complete for cases of definite ischemic stroke).

[ ] 1. Large-artery atherosclerosis: Clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis, and clinical findings of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large- artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

*Probable |___| *Possible |___|

[ ] 2. Cardioembolism: Patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolic stroke. Clinical and brain imaging findings are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

*Probable |___| *Possible |___|

[ ] 3. Small-artery occlusion (lacune): Patients whose strokes are often labeled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction (aphasia, neglect, restricted motor involvement, etc.). A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent, and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

*Probable |___| *Possible |___|

* A **probable** diagnosis is made if the clinical findings, neuroimaging data, and results of diagnostic studies are consistent with one subtype and other

etiologies have been excluded. A **possible** diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype but

[ ] 4. Acute stroke of other determined etiology: Patients with rare causes of stroke, such as non-atherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of these unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

[ ] 5. Stroke of undetermined etiology: In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely etiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined etiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

07. Definite fatal congestive heart failure (**Please fill out the HF PROCEDURE FORM**)

Two major criteria or one major and two minor criteria:

a. Major criteria
- [ ] i. Paroxysmal nocturnal dyspnea or Orthopnea
- [ ] ii. Neck vein distention
- [ ] iii. Rales
- [ ] iv. Cardiomegaly
- [ ] v. Acute pulmonary edema
- [ ] vi. S3 gallop
- [ ] vii. Increased venous pressure >16cm water
- [ ] viii. Circulation time ≥ 25 seconds
- [ ] ix. Hepatojugular reflux

b. Minor criteria
- [ ] i. Ankle edema
- [ ] ii. Night cough
- [ ] iii. Dyspnea on exertion
- [ ] iv. Hepatomegaly
- [ ] v. Pleural effusion
- [ ] vi. Vital capacity reduced by one-third from maximum
- [ ] vii. Tachycardia (rate of ≥ 120/min.)

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment

AND

d. [ ] No known non-cardiac process leading to fluid overload such as renal failure

08. Possible fatal congestive heart failure

[ ] Death certificate or medical records with consistent underlying or immediate cause, but neither autopsy evidence nor adequate pre-terminal documentation of the event.

09. Other fatal cardiovascular diseases

[ ] i. Death certificate or medical records with consistent underlying or immediate Cause. Check that applies.

[ ] ii When death certificates are the only source of information: ICD9: 390 to 398, 402, 404 to 429; ICD 10: I00 to I09, I11, I13, I20 to I25, I27, I30 to I52. Check that applies.

ICD – 9	**ICD – 10**	**Disease**	
390-392	I00, I01.X, I02.X	Rheumatic fever/chorea with/without heart involvement	[ ]
393-398	I05.X - I09.X	Chronic rheumatic heart disease	[ ]
402	I11.X	Hypertensive heart disease	[ ]
404-405	I13.X, I15.X	Hypertensive disease	[ ]
410-414	I20.X, I21.X, I24.X, I25.X	Ischemic heart disease	[ ]
415-417	I26 – I28.X, T80-T82.X	Pulmonary Heart Disease, or other diseases of pulmonary circulation	[ ]
420-429	I23.X, I25.X, I30.X, I31.X, I32, I33.X, I34.X - I40.X, I41, I42.X-I45.X, I46.9, I47.X – I51.X, I97.X, R00.1,	Other forms of heart disease	[ ]
429.2	I25.10	Cardiovascular disease, unspecified	[ ]
431-437	I61.X – I63.X, I65.X-I67.X, G45.X	Cerebrovascular disease	[ ]
799	R09.X, R41.X, R45.X, R53.81, R64, R68.X, R69, R99	Ill-defined or unknown	[ ]
443.9	I73.9	Peripheral vascular disease, unspecified	[ ]

Comment: _____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

Coordinating Center Use Only

Reviewer:
First review |___|1 Second review |___|2 Stroke review |___|3 Adjudication |___|9

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SUPPLEMENTAL STROKE FORM - Mortality and Morbidity Surveys

(Complete for mortality codes 5 or 6 and morbidity codes 3, 4 or 8)

ID number: |___|___|___|___|___|___|___|___|

Date of this event: |___|___|/|___|___|/|___|___|___|___|
Month day year

A. ISCHEMIC STROKE LOCATION

		YES	NO
1.	Right hemisphere	|___|1	|___|2
2.	Left hemisphere	|___|1	|___|2
3.	Basilar	|___|1	|___|2
4.	Hemispheric and Basilar	|___|1	|___|2
5.	Unknown	|___|1	|___|2

B. BRAIN IMAGING

6. *HEAD CT*

	Yes	|___|1
	No (go to Q 7)	|___|2
	Yes, but no report	|___|3
6.1 If yes, timing of Head CT	<48 h since symptom onset	|___|1
	≥48 h since symptom onset	|___|2
	Unknown	|___|3

7. *BRAIN MRI*

Yes	|___|1
No (go to Q 8)	|___|2
Yes, but no report	|___|3

C. NEUROVASCULAR IMAGING

8. *CAROTID DUPLEX*

Yes	|___|1
No (go to Q 9)	|___|2
Yes, but no report	|___|3

9.	*TRANSCRANIAL DOPPLER (TCD)*	Yes	|___|1
		No, (go to Q 10)	|___|2
		Yes, but no report	|___|3
10.	*MAGNETIC RESONANCE ANGIOGRAPHY* (*MRA)*	Yes	|___|1
		No (go to Q 11)	|___|2
		Yes, but no report	|___|3
11.	*CT ANGIOGRAPHY*	Yes	|___|1
		No (go to Q 12)	|___|2
		Yes, but no report	|___|3
12.	*ANGIOGRAPHY*	Yes	|___|1
		No, (go to Q 13)	|___|2
		Yes, but no report	|___|3

D. STROKE DEFICIT

13. MODIFIED RANKIN SCALE (0-6) |___|
(Code Maximal Severity Within 7 Days of Stroke)

0 = no symptoms at all
1 = no significant disability despite symptoms: able to carry out all usual duties and activities
2 = slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
3 = moderate disability: requiring some help, but able to walk without assistance
4 = moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance
5 = severe disability: bedridden, incontinent, and requiring constant nursing care and attention
6 = death
9 = information insufficient for coding

E. STROKE TREATMENT

14.	Intravenous thrombolysis	Yes	|___|1
		No	|___|2
15.	Presentation within 3 hours from symptom onset	Yes	|___|1
		No	|___|2
F.	**BRAIN EXAMINATION AT AUTOPSY**	Yes	|___|1
		No	|___|2
		Yes, but no report	|___|3

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

If you have any comments on this case, please use the space below:

THE STRONG HEART STUDY VII
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORTALITY SURVEY
INFORMANT INTERVIEW

ID number: |___|___|___|___|___|___|

A. DECEDENT (*Completed by study center staff prior to interview.)*

1. Name: _____
Last First Middle

2. Date of death: |___|___|/|___|___|/|___|___|___|___|
month day year

B. RECORD OF CALLS or HOME VISIT TO COMPLETE INTERVIEW

	DATE (mo/day/yr)	TIME (24 hr clock)	Method of contact 1=Phone 2=Home Visit 3=Other	Contact successful 1=Yes 2=No	Interview Completed 1=Yes 2=No 9=Refused
1)	_____	_____	_____	_____	_____
2)	_____	_____	_____	_____	_____

C. Person Providing Information (*Completed by study center staff prior to interview.)*

3. a. Name: _____
Last First Middle

b. Address: _____

c. Telephone: ( ) _____

4. Before we get started, could you please tell me what was your relationship to the deceased?

You are the _____ of the deceased.

5. What did the patient die from?

_____
_

6. Were you present when he/she died?

Yes |___|1 (Go to Q8) No |___|2 Unknown |___|9

7. If no, how long before he/she died did you last see him/her?

1 hour or less	|___|1	More than 24 hours	|___|3
24 hours or less	|___|2	Unknown	|___|9

8. Do you know of anyone else who may have been present at about the time of his/her death?

Yes |___|1 No |___|2 Unknown |___|9

If yes can you give me that person's name and contact information:
Contact information_____
_____
_____

9. Please describe the events that occurred at the time of death, specifically, did he/she manifest any of the following conditions: chest pain, shortness of breath, agitation, sudden collapse or loss of consciousness, sudden weakness, slurred speech, etc. Please tell me what you know of his/her general health, health on the day he/she died, and of the death itself. This information will be reviewed by a physician and will help to better understand the cause of your loved one's death. ***(Record summary verbatim and ask pertinent questions when appropriate attach additional sheet if needed)*** Probing Questions: Are you aware of any illnesses the individual had prior to death? If yes – how long did the person have the illness? Was the individual involved in any accidents or trauma prior to death? If yes – what type and how long prior to death.

The next set of questions deal specifically with the last episode of pain or discomfort that occurred before his/her death. This is defined as starting at the time you noticed discomfort that caused him/her to stop or change what he/she was doing. ***NOTE TO INTERVIEWERS: If the informant has already answered these questions in the description of circumstances, just fill out the correct answer(s) as noted below.*** **Respect the informant's wishes about continuing the interview and record answers to as many of the following questions as possible.**

10. Did his/her last episode of pain or discomfort specifically involve the chest?
Yes |___|1 No |___|2 Unknown |___|9

11. Did he/she experience pain or discomfort in his/her chest, left arm or shoulder or jaw either just before death or within 3 days (72 hours) of death?
Yes |___|1 No |___|2 Unknown |___|9
(If NO or Unknown go to Q15)

12. Did he/she take nitroglycerine because of this last episode of pain or discomfort?
Yes |___|1 No |___|2 Unknown |___|9

13. Did he/she take any other medicine for chest discomfort prior to death? Yes_____ No____
If yes what?_____

14. How long was it from the beginning of his/her last episode of pain or discomfort to the time he/she stopped breathing on his/her own? ***(use the shortest interval known to be true)***

5 minutes or less	|___|1	24 hours or less	|___|4
10 minutes or less	|___|2	More than 24 hours	|___|5
1 hour or less	|___|3	Unknown	|___|9

15. Did he/she ever have dialysis for kidney failure? Yes No Unknown
|___|1 |___|2 |___|9

a. If yes, what year did he/she start dialysis? |___||___||___||___|

b. How many times per week did he/she receive dialysis? |___||___|

c. Did he/she stop dialysis before death? Yes No Unknown
|___|1 |___|2 |___|9

If yes, how long before death? |___||___|/ |___||___|/ |___||___|
days months years

16. Within 3 days of death, or just before he/she died, did any of the following symptoms begin for the first time or did the patient complain of any of these symptoms:

		Yes	No	Unknown
a.	Shortness of breath?	|___|1	|___|2	|___|9
b.	Dizziness?	|___|1	|___|2	|___|9
c.	Palpitations (pounding in the chest)?	|___|1	|___|2	|___|9

d.	Marked or increased fatigue, tiredness, or weakness?	|___|1	|___|2	|___|9
e.	Headache?	|___|1	|___|2	|___|9
f.	Sweating?	|___|1	|___|2	|___|9
g.	Paralysis?	|___|1	|___|2	|___|9
h.	Loss of speech?	|___|1	|___|2	|___|9
i.	Attack of heartburn or indigestion or abdominal discomfort?	|___|1	|___|2	|___|9
j.	nausea or vomiting?	|___|1	|___|2	|___|9
k.	Other? specify: _____	|___|1	|___|2	|___|9

<u>These next questions are about his/her medical history</u>
<u>Please provide as much information as possible</u>

17. Before his/her final illness, had he/she ever had pains in the chest from heart disease, for example, angina pectoris?
Yes |___|1 No |___|2***(If no, go to Q20?)*** Unknown |___|9

18. Did he/she ever take nitroglycerin for this pain?
Yes |___|1 No |___|2 Unknown |___|9

19. Any other medications such as aspirin, tums or other antacids?
Yes |___|1 No |___|2 Unknown |___|9

20. Did he/she ever have any of the following medical condition or procedures before his/her final illness?

		Yes	No	Unknown
a.	heart attack?	|___|1	|___|2	|___|9
b.	stroke?	|___|1	|___|2	|___|9
c.	heart failure?	|___|1	|___|2	|___|9
d.	any other heart disease or heart condition If yes, specify:_____	|___|1	|___|2	|___|9
e.	coronary bypass surgery (CABBAGE)	|___|1	|___|2	|___|9
f.	coronary angioplasty (balloon angioplasty)	|___|1	|___|2	|___|9
g.	insertion of pace maker (defibrillator)	|___|1	|___|2	|___|9
h.	any other heart surgery?	|___|1	|___|2	|___|9

The next few questions are about his/her health in the <u>year</u> prior to death

21. Was he/she hospitalized or taken to a clinic

	Yes	No	Unknown
In the year prior to death?	|___|1	|___|2	|___|9
In the month prior to death?	|___|1	|___|2	|___|9
In the 7 days prior to death?	|___|1	|___|2	|___|9

22. Were any hospitalizations for heart attack or chest pain?
Yes |___|1 No |___|2 Unknown |___|9

23. Was a hospitalization for heart surgery? Yes |___|1 No |___|2 Unknown |___|9

24. What was the date of the ***<u>last</u>*** hospital admission? |___|___|/|___|___|/|___|___|___|___|
(If unknown, draw two lines across the boxes) month day year

If the information in questions 25- 28 is already known to you, skip to Q29.

25. Can you tell me the name and location of the hospital? ***(If unknown, check the box.)*** |___|
    a. Name: _____
    b. Address: _____
    City/town: _____
    State-Zip: _____

26. Was he/she seen by a physician anytime in the year prior to death?
    Yes |___|1 No |___|2 Unknown|___|9

27. Can you tell me the name and address of this physician or healthcare facility? |___|
    IHS only
    a. Name: _____
    b. Address: _____
    City/town: _____
    State-Zip: _____

28. Can you tell me the name and address of his/her usual physician?
    If same as Q27, check here. |___|
    a. Name: _____
    b. Address: _____
    City/town: _____
    State-Zip: _____

29. Now, think back to about <u>one month</u> before he/she died. At that time, was he/she sick or ill; were his/her activities limited, or was he/she normally active for the most part?

Sick/ill/limited activities |___|1 Normally active |___|2 Unknown |___|9

30. Was he/she being cared for at a nursing home or at another place at the time of death?
    Yes, nursing home, specify |___|1_____
    Yes, at home |___|2
    Yes, other, specify |___|3 _____
    No |___|4
    Unknown |___|9

The next few questions are concerned specifically with emergency medical care he/she may have received just prior to or at the time of death.

31. Was he/she taken to a hospital/clinic in the week before his/her death? Yes |___|1 No |___|2

32. If Yes, could you tell me the name and location of this facility:

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

33. Is there someone else whom we could contact, who might know more about the circumstances surrounding his/her death or his/her usual state of health?

Yes |___|1 No |___|2 Unknown |___|9

(If Yes, complete the front of the second Informant Interview)

34. Did informant provide consent to gather further information?

Yes |___|1 No |___|2 Not applicable |___|3

(If Yes, ask the informant to sign the consent form for us to review the decedent's medical records)

35. How reliable was the participant in completing the questionnaire?

Very reliable |___|1 Reliable |___|2 Unreliable |___|3 Very unreliable |___|4 Uncertain |___|5

ADMINISTRATIVE INFORMATION:

36. Interviewer code: |___|___|___|

37. Interview date: |___|___|/|___|___|/|___|___|___|___|

month day year
