THE STRONG HEART STUDY VII

CARDIOVASCULAR DISEASE IN AMERICAN

INDIANS MORTALITY SURVEY – FINAL DECISION

ID number:

Date of death: Age at death:
month / day / year

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), 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 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%.

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-I02	Acute rheumatic fever	☐
393-398	I05-I09	Chronic rheumatic heart disease	☐
402	I11	Hypertensive heart disease	☐
404-405		Hypertensive disease	☐
410-414	I20-I25	Ischemic heart disease	☐
415-417		Diseases of pulmonary circulation	☐
420-429		Other forms of heart disease	☐
429.2		Cardiovascular disease, unspecified	☐
431-437		Cerebrovascular disease	☐
799		Ill-defined or unknown	☐
	I13	Hypertensive heart and renal disease	☐
	I27	Other pulmonary heart disease	☐
	I30-I52	Other forms of heart disease	☐
443.9	I73.9	Peripheral vascular disease	☐

Comment: _____

ADMINISTRATIVE INFORMATION:

Reviewer code: _____

Review date: _____
month / day / year

Coordinating Center Use Only

Reviewer:
First review ☐ Second review ☐ Stroke review ☐ Adjudication ☐

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