APPENDIX 17

STRONG HEART STUDY
Non-Participant Form

ID number: 

Community code: (see instruction) 

This form is to be used for individuals who refuse to participate in the examinations and interview portions of the STRONG HEART STUDY so that accurate rates of hospitalization for stroke and myocardial infarction can be calculated and risk factors prevalence can be estimated for non-participants.

NAME: 

PHONE: ( ) 

ADDRESS: Street or Box # 

City, State, Zip 

Non-participants will initially be contacted by mail or telephone to complete this form, and then by personal interview. If attempts to complete the form are unsuccessful, the form should be completed by medical record review.

Record Date and Time of Attempted Contact. Three attempts should be made

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<tr>
<th>DATE</th>
<th>Method and Time of Contact (Letter, Phone or Home Visit)</th>
<th>Contact Successful YES or NO</th>
<th>Interview Completed Yes or Refused</th>
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How was non-participant form completed?

Mail □ Telephone □ Personal interview □ Medical chart review □

Form not completed --- Unable to contact patients □

No information in medical records □
What is your sex? Female ☐ Male ☐

Which IHS Hospital/Clinic do you usually go for health care? ________________________________

What is your IHS Hospital/Clinic chart number? ________________________________

The STRONG HEART STUDY will help us learn more about heart disease in Indians. Please answer a few questions that will help us a great deal.

1. How tall are you? _______ Feet _______ Inches.


3. Have you ever been hospitalized for heart attack, stroke or other problems in the last ten years?
   Yes ☐ No ☐

4. If yes, list which hospital(s), when and what the reason was?

   Hospital/Clinic __________________________ Town/State ______________ Date _______ Reason ______________
   i. ______________________________________
   ii. _____________________________________
   iii. ____________________________________

The Strong Heart Study would like to review your medical records to better understand heart disease and stroke in Indian people. We request your consent to release your medical records to the Strong Heart Study. Please sign the enclosed form and return it in the enclosed envelope. Thank you.

5. Do you smoke cigarettes now? (1=yes 2=no) ☐
   Yes ☐ No ☐
MEDICAL CONDITIONS: I'd like you to answer some questions about medical problems.

Has a medical person EVER told you that you had any of the following conditions?
(Please check the correct answer)

6. High blood pressure?
   Yes □ No □ I don’t know □

   If yes, are you taking any medication for your blood pressure?
   Yes □ No □ I don’t know □

7. Diabetes?
   Yes □ No □ I don’t know □

If you have diabetes, please answer the next two questions.

How old were you when you were first told by a medical person that you had diabetes?
Indicate the actual age.

   years

   What treatment do you take for your diabetes?
   None □ Insulin □ Pills □ Diet only □ I don’t Know □

8. Kidney failure?
   Yes □ No □ I don’t know □

9. Are you on dialysis (a kidney machine)?
   Yes □ No □ I don’t know □

10. Have you ever received a kidney transplant?
    Yes □ No □ I don’t know □

11. What is your birth date? □/□/□
    month   day   year

12. What is your Social Security Number?
    □□□□-□□□□

Thank you for answering these questions. Please sign and return this form in the attached envelope.

Signature ___________________________ Date ___________________________

Strong Heart Study  7/16/91  Page 206 a
Appendix 17 (b)

Procedure for Completing Non-Participant Form

The objective of the Strong Heart Study is to determine morbidity and mortality rates from myocardial infarctions and strokes and also to determine cardiovascular disease risk factor prevalence in American Indians. In order to accomplish this, it is important to learn as much as possible about eligible tribal members who do not participate in the physical examination portion of the Study. The Strong Heart Study Steering Committee has developed this form to be completed for non-participants.

The non-participant form can be mailed to participants with a cover letter (copy attached) and returned in a postage-paid envelope to the local Strong Heart Study office. Alternatively, the Strong Heart Study staff can contact the eligible tribal member by telephone and complete the non-participant form in that manner. If contact by mail and telephone is not successful, local community members should be queried with regard to residence of the non-participant and the forms should be completed by personal interview if possible.

If none of the above procedures is successful in completing the form, the IHS medical record should be reviewed and the form completed if the patient has been seen within the last two years. If a tribal member cannot be contacted by telephone, mail, or personal interview, and if no entry has been made in the medical record for the past two years, no form can be completed. It will be assumed that the tribal member has moved off the reservation or outside Indian country and is not eligible for the Study unless there is evidence that she/he still has residence. In this case the individual can be removed from the denominator and no attempt will be made to include this individual in the morbidity and mortality surveillance.
FORMID:SHMORB

Medical charts (IHS and/or other community hospitals) of all patients with the following ICD-9 codes listed as in the IHS utilization tape or hospital discharge codes will be reviewed. These ICD-9 codes include: 402, 410 to 414, 427, 428, 430-438, 518.4.

ID number:

Community code: (see instruction)

Social Security Number:

Degree of Indian blood, record in fractions.

If the fraction is not known, record the code from face of the chart (Item 7)

1. Were either of the following events diagnosed between January 1, 1984 and December 31, 1988?
   a. Possible Myocardial Infarction (events with codes 402, 410 to 414, 427, 428, 518.4)?
      1=yes, fill out the NEWMI form for each event
      2=no.
   b. Possible Stroke (events with codes 430-438) ?
      1=yes, fill out the NEWSTROKE form for each event
      2=no.

If the answers of 1 a, and b are both “NO”, STOP HERE

Abstrator code

Date abstract completed

Strong Heart Study 8/28/89
Morbidity Survey
Medical Records Abstract for Myocardial Infarction

FORMID: NEWMI

ID number:

If the event occurred in a Non-IHS facility, review the IHS chart for Questions 8-18.

1. a. Last Hospital code number

2. Date of ADMISSION to this hospital:

3. Date of discharge:

4. Was the patient transferred to or from another acute care hospital? (1=yes, 2=no)
   If no, go to Question 6.

   □
5. Hospitalizations.

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6. Enter the ICD-9 code numbers for the hospital discharge diagnoses recorded in all medical records and procedure codes exactly as they appear on the front sheet of the medical record and/or on the discharge summaries. Be sure they are ICD-9 codes. Record diagnoses if no codes are available.

1. 

2. 

3. 

4. 

5. 

6. 

7. 

8. 

9. 

10. 

11. 

12. 

7. Photocopy the discharge diagnoses as they appear on face sheet of medical records and/or discharge summaries for this ADMISSION. Attach copies.

******************************************************************************
If there is mention in the chart that the patient subsequently died prior to 1989, DON’T forget to fill out the MORTALITY survey form
******************************************************************************

8. Is there a history of a previous myocardial infarction?  (1=yes, 2=no) 

9. If yes,
   a. Date of most recent previous event:
      
      mo  day  yr
   b. Facility where hospitalized: ________________________________

10. Is there any history of angina pectoris or coronary insufficiency? (1=yes, 2=no, 8=uncertain, 9=not mentioned)
11. Is there any history of any other chronic ischemic heart disease?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

12. Is there any history of valvular disease?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

13. Is there any history of coronary bypass surgery?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

14. Is there any history of coronary angioplasty?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

15. Is there any history of hypertension (high blood pressure)?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

16. Is there any history of stroke?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)
   If yes, date of most recent event:
   ☐ ☐ ☐ mo ☐ ☐ day ☐ ☐ yr yr

17. Is there a history of congestive heart failure?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

18. Is there a history of diabetes?
   (1=yes, 2=no, 8=uncertain, 9=not mentioned)

19. Approximately how long was it from the onset of acute cardiac symptoms (pain in chest,
    left arm or shoulder or jaw) to arrival at the initial hospital?
    0= symptoms did not begin prior to arrival
    1= less than 20 minutes,
    2= at least 20 minutes, but shorter than an hour,
    3= at least one hour, but shorter than 2 hours,
    4= at least 2 hours, but shorter than 4 hours,
    5= at least 4 hours, but shorter than 6 hours,
    6= at least 6 hours, but shorter than 12 hours,
    7= at least 12 hours, but shorter than 24 hours,
    8= one day or longer
    9= not reported
20. Was there mention of an acute coronary heart disease (CHD) event with onset after arrival at the initial hospital? (1=yes, 2=no)

21. If yes, date of in-hospital CHD event:

22. a. Was there an acute episode(s) of pain or discomfort anywhere in the chest, left arm or shoulder or jaw, either within 72 hours prior to arrival to the initial hospital or in conjunction with the in-hospital CHD event in Question 20? (1=yes, 2=no, 9=unknown)

b. Date of onset of pain:

c. Did this pain or discomfort specifically involve the chest? (1=yes, 2=no, 9=unknown)

d. Did it last more than 20 minutes? (1=yes, 2=no, 9=unknown)

e. Was the pain or discomfort diagnosed as having a non-cardiac origin? (1=yes, 2=no, 9=unknown)

f. If yes, specify: ______________________________________________________________

22. g. Was coronary reperfusion (coronary angioplasty, bypass, intravenous or intracoronary thrombolysis) attempted in the first 24 hours after onset of the event? (1=yes, 2=no)

h. If yes, approximately how long was it between event onset and attempt at reperfusion?

1= less than one hour,
2= at least 1 hour, but shorter than 2 hours.
3= at least 2 hours, but shorter than 4 hours.
4= at least 4 hours, but shorter than 6 hours.
5= at least 6 hours, but shorter than 8 hours.
6= 8 hours or longer.
9= unknown.
23. For each of the following procedures, if performed during this hospital stay, please enter the appropriate code number and attach a copy of the report, if available.
   1= yes,  2= no or not mentioned
   
   a. Cardiac catheterization

   b. Coronary angiography

   c. Coronary angioplasty

   d. Swan-Ganz catheterization

   e. Echocardiography

   f. Coronary bypass surgery

   g. Intracoronary streptokinase, urokinase, or TPA reperfusion.

   h. Intravenous streptokinase, urokinase, or TPA reperfusion.

   i. Aortic balloon pump

   j. Radionuclide scan

   k. MRI scan

   l. Other: ________________________________________________________

24. Were any cardiac enzymes reported within **DAYS 1-4** after arrival at the hospital or after in-hospital CHD event?  (1=yes,  2= no)
25. If yes,
   a. Is there mention of the patient having either trauma, a cardiac surgical procedure, or rhabdomyolysis
      within one week prior to measurement of enzymes? (1=yes, 2=no)

   b. If yes, specify the date and reason.

   c. Reason: ____________________________________________________________

   *** Ignore the enzyme report corresponding to this trauma or cardiac surgical procedure. ***

   d. Is there any evidence of hemolytic disease during the hospitalization? (1=yes, 2=no)

   ********** FILL THE ENZYME TEST RESULTS IN THE FOLLOWING PAGE **********

26. Were any 12 lead ECG's taken during this admission? (1=yes, 2=no)

   *** If ECGs were taken, attach copies of required ECGs and interpretations, at least one per day. ***

   ******************************************* (see instructions) *******************************************

27. Narrative: (Attach photo-copy of discharge summary, and admitting history and Physical
    examination.)

28. Abstractor Number

29. Date abstract completed

   mo  day  yr
Medical Records Abstract
Stroke

FORMID: NEWSTROKE

ID number:

If the event occurred in a non-IHS facility, review the IHS chart for Questions 15-25.

1. A. Hospital code number

   B. Hospital name

   C. Hospital location

   D. Medical record number

2. Date of ADMISSION to this hospital:

   mo  day  yr

3. Date of discharge:

   mo  day  yr

4. Was the patient transferred to or from another acute care hospital? (1=yes, 2=no)

   If no, go to Question 6.
5. Hospitalizations.

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6. Enter the ICD-9 code numbers for hospital discharge diagnoses and procedure codes exactly as they appear on the front sheet of the medical record and/or on the discharge summaries. Be sure they are ICD-9 codes. Record diagnoses if no codes are available.

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7. Photocopy the discharge diagnoses as they appear on face sheet of medical records and/or discharge summaries for this admission. Attach copies.

*********** If there is mention in the chart that the patient subsequently died prior to 1989, ***********
*************** DON'T forget to FILL OUT the mortality survey form ***************
*************** ************************************************************

8. Was the primary diagnosis:
   0. Thrombotic infarction
   1. Subarachnoid hemorrhage
   2. Intraparenchymal hemorrhage
   3. Lacunar infarction
   4. Embolic infarction
   5. Atherosclerotic infarction
   6. Other, unknown infarction
   7. Unknown type stroke
   8. Transient Ischemic Attack (TIA)

Taking into account all of the available information, is there evidence of:

9. A focal (localized) neurological deficit that lasted more than 24 hours? (1=yes, 2=no)  
   
   
   
   Strong Heart Study 4/16/90 Page 218
10. Change in state of consciousness that lasted more than 24 hours. (1=yes, 2=no) 

11. Rapid (sudden) onset of localizing neurological deficit and/or change in state of consciousness (approximately less than 48 hours from onset to time of admission or maximum acute neurologic deficit) (1=yes, 2=no)

12. Time from onset of symptoms to admission or maximum neurologic deficit and/or change in state of consciousness. Choose shortest time, in hours. 1=less than or equal to one hour, 99=unknown.

13. Which (if any) of the following physical findings were present? (1=yes, 2=no, 9=not mentioned)
   a. Abnormal gait
   b. Romberg
   c. Weakness or drift
   d. Asymmetry of reflexes
   e. Babinski (positive)
   f. Loss of visual fields
   g. Aphasia or apraxia
   h. Change in mental status
   i. Headache
   j. Loss of consciousness
   k. Other:

14. Lumbar puncture (LP) evidence of hemorrhage? (1=yes, 2=no, 3=not done, 9=unknown)
15. Is there a history of a prior myocardial infarction? (1=yes, 2=no)

If yes, date of most recent event:

16. Is there any history of angina pectoris or coronary insufficiency? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

17. Is there any history of any other chronic ischemic heart disease? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

18. Is there a history of valvular disease or cardiomyopathy? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

19. Is there a history of coronary bypass surgery? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

20. Is there a history of coronary angioplasty? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

21. Is there a history of hypertension (high blood pressure)? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

22. Is there a history of prior stroke? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

If yes, DATE of most recent previous event:

23. Is there a history of transient ischemic attack (TIA)? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

24. Is there a history of congestive heart failure? (1=yes, 2=no, 8=uncertain, 9=not mentioned)

25. Is there a history of diabetes? (1=yes, 2=no, 8=uncertain, 9=not mentioned)
26. Which (if any) of the following diagnostic tests were performed?
   (1=yes, 2=no, 9=not mentioned)
   (If yes, please attach copies of interpretation)
   a. Computerized Axial Tomography (CAT) of the head
   b. Magnetic Resonance Image (MRI) of the head
   c. Carotid ultrasound/doppler
   d. Electrocardiogram
   e. Angiography
   f. Other
   Specify: ________________________________

27. Was there evidence from computerized axial tomography (CAT) scan of either cerebral infarction or hemorrhage without evidence of other disease process or event?
   (1=yes, 2=no, 3=not done, 9=unknown)
   If yes,
   a. did scan show a focal area of decreased or normal attenuation consistent with cerebral infarct?
      (1=yes, 2=no, 3=not done, 9=unknown)
   b. did scan show focal increased attenuation consistent with intracerebral hemorrhage?
      (1=yes, 2=no, 3=not done, 9=unknown)
28. Has the patient been diagnosed or treated for:  (1=yes, 2=no, 9=unknown)
   a. Atrial fibrillation
      [ ]
   b. Other arrhythmias
      [ ]
   c. Claudication in the lower limbs
      [ ]
   d. Brain tumor
      [ ]
   e. Subdural hematoma
      [ ]
   f. Metabolic disorder
      [ ]

   Specify: ____________________________________________

   g. Other neurological disorder(s)
      [ ]

   Specify: ____________________________________________

29. Narrative (Attach photocopies of Discharge summary, Admitting History, and Physical examination.)

30. Abstractor Code
    [ ]

31. Date abstract completed
    [ ] [ ] [ ]
    mo  day  yr
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. ECG series for each case will be reviewed independently by three cardiologists at the ECG Reading Center (Fitzsimons). When possible, a baseline ECG obtained most recently, but prior to the event in question, should be labeled and included as the top tracing.

ID number:

Community code:

Social Security Number:

1) Baseline ECG
   Available : Date
   Time (24 hr. clock)
   Not Available :

2) First Prolonged ( > $\frac{1}{2}$ hour ) symptom onset
   Available : Date
   Time (24 hr. clock)
   Not Available :

3) Record Patient ID number, Date, and Time on each ECG submitted in the above format.

4) Attach this cover sheet to the front of each group of ECGs submitted for analysis.
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. ECG series for each case will be reviewed independently by three cardiologists at the ECG Reading Center (Fitzsimons). When possible, a baseline ECG obtained most recently, but prior to the event in question, should be labeled “BASELINE” and included as the top tracing.

ID number:

1) ECG READER ID number:

***** The series of ECGs will be assigned the highest category for which *****
**** criteria are met, i.e., evolving diagnostic > diagnostic > equivocal > other. ****
EVOLVING DIAGNOSTIC

Definition: An evolving pattern on serial ECGs of a diagnostic ECG. (An evolving pattern of changes [appearance or disappearance within lead groups: anterior (V₁-V₅); lateral (I, aV₅, V₆); or inferior (II, III, aV₆)] establishes the infarct as acute. Two or more ECG recordings during the hospitalization are needed for this classification.)

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

Possibilities:

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

OR

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

OR

☐ An equivocal Q wave and no ST segment elevation in one ECG record followed by a record with a diagnostic Q wave PLUS ST segment elevation > than or = to 1 mm.

OR

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

OR

☐ No Q wave and no ST Junction depression > than or = to 0.5 mm and flat or downsloping ST segment depression followed by a record with an equivocal Q wave PLUS ST Junction and flat or downsloping ST depression of > than or = to 0.5 mm.

OR

☐ No Q wave and no ST elevation > than or = to 1 mm. followed by a record with an equivocal Q wave PLUS ST elevation > or = to 1 mm.

OR

☐ No Q wave and no T wave findings diagnostic of infarction followed by a record with an equivocal Q wave PLUS T wave findings diagnostic of infarction.
DIAGNOSTIC ECG WITH Q WAVE

☐ Diagnostic Q and QS patterns.

DIAGNOSTIC ECG WITHOUT Q WAVE

☐ ST segment elevation PLUS T wave depression indicative of infarction. (T wave depression cannot be used in the presence of ventricular conduction defects.)

EQUIVOCAL ECG WITH Q WAVE

☐ ECG with Q and QS pattern possibly representing infarction.

EQUIVOCAL ECG WITHOUT Q WAVE

☐ ST junction (J) and segment depression or T wave inversions or ST segment elevations possibly representing infarction.

OTHER

☐ All other findings, including normal.

UNCODEABLE ECG

☐ 1) Missing Leads
   2) Baseline drift (> 1 in 20) if it obscures ST-T segment.
   3) Muscle tremor giving > 2 mm peak-to-peak oscillation.
   4) Other technical errors making Q wave measurements impossible
   5) Major abnormal QRS conduction patterns (BBB, pacer, etc.)
APPENDIX 18 (d)
THE STRONG HEART STUDY
Morbidity Survey
DECISION FORM

ID number:

Participant's name: ________________________________

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Disposition: 1. Regular 2. QC case 3. Equivocal case

A. DIAGNOSIS (enter appropriate code number):

1. Definite non-fatal myocardial infarction
2. Possible non-fatal myocardial infarction
3. Definite non-fatal stroke
4. Possible non-fatal stroke
5. Other, specify: ________________________________

B. Criteria used: (Please check one box in each field)

1. MYOCARDIAL INFARCTION
   a. PROLONGED CARDIAC PAIN Present
      Absent
   
   b. ECG FINDINGS
      Evolving diagnostic ECG
      Diagnostic ECG
      Equivocal ECG
      Absent, uncodable, or other

   c. CARDIAC ENZYMES
      Abnormal
      Equivocal
      Incomplete
      Normal

COMMENTS:

______________________________________________

______________________________________________

Strong Heart Study 7/16/91 Page 226A
2. STROKE

a. DIAGNOSTIC EVIDENCE
   Unequivocal physician or laboratory
   Discharge diagnoses of stroke (431,432,434,436,437)
   Neither of above

b. ONSET/DURATION OF NEUROLOGICAL DEFICIT
   Rapid/ > 24 hours
   Rapid/ ≤ 24 hours
   Protracted/ > 24 hours
   Protracted/ ≤ 24 hours

 c. OTHER CAUSES
    Present
    Absent

d. TYPE OF STROKE:
   1. Thrombotic infarction
   2. Subarachnoid hemorrhage
   3. Intraparenchymal hemorrhage
   4. Lacunar infarction
   5. Embolic infarction
   6. Atherosclerotic infarction
   7. Other, unknown infarction
   8. Unknown type stroke

COMMENTS:

C. Does the diagnosis in Section A (DIAGNOSIS) agree with your clinical impression?
   1. Yes  2. No
   If "No", what is your diagnosis?

   Why?

Coder

Date completed

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INSTRUCTIONS FOR MORBIDITY SURVEY: MEDICAL RECORDS ABSTRACT

I. GENERAL INSTRUCTIONS

The Medical Records Abstract for the Morbidity Survey is completed for each hospitalized MI and stroke that occurred in an eligible tribal member between 1984 and 1988. The purpose of the abstract is to provide sufficient information to determine whether the event meets the study’s criteria for MI or stroke. Data to be abstracted for each event, regardless of type, is included on the face sheet of the abstract form (SHMORB). Separate abstract forms, designated NEWMI and NEWSTROKE, are used for MI and stroke respectively.

NEWMI and NEWSTROKE forms are to be completed for each event of interest. Each event should be thought of as a separate occurrence. Sometimes, a patient may have been hospitalized at more than one facility for the diagnosis and treatment of a single event. For example, a patient may come to an IHS hospital with severe chest pain and be transferred to another hospital for acute care. Since you will usually be first abstracting an IHS chart, in this example you may have information from the initial IHS admission as well as copies of data from the acute care hospital detailing the patient’s hospital course. Both sets of information should be used to complete the abstract, since they both apply to the same single event.

The ID number has 6 digits: the first digit identifies the study center (1=SD, 2=OK, 3=AZ), the second digit identifies vital status (1=dead, 0=alive), and the last four digits identify the individual. For this form, the second digit is 0 (alive) for all subjects. The community code has 3 digits and is the standard IHS community code.

II. DETAILED INSTRUCTIONS FOR EACH QUESTION - FACE SHEET

Ques Instructions

Find out from chart the degree of Indian blood of the patients.

1. Determine whether the patient was discharged with a diagnosis of possible MI (ICD-9 codes of 402, 410-414, 427, 428, 518.4) or possible stroke (ICD-9 codes 430-438) between January 1, 1984 and December 31, 1988. It is possible that both of these events might have occurred separately but within the time interval of interest. If this is the case, record a 1 (yes) for each item and complete both a MI and stroke form. Separate abstracts should be completed for each event when more than one MI or more than one stroke occurred during the study interval. Begin with the first occurrence of the event in the medical record that was within the study interval. For example, if a patient had a discharge diagnosis of MI in 1984 and another in 1987, abstract the 1984 admission first. If none of the discharge diagnoses correspond to these ICD-9 codes or to the conditions covered by these codes, do not continue with the abstract. If you have any questions as to whether a chart should be abstracted, contact the study coordinator.
DETAILED INSTRUCTIONS FOR EACH QUESTION - NEWMI ABSTRACT

Enter the ID number.

1. Enter the hospital code number, name, city and state and the medical record number of the chart in the appropriate boxes.

Question 1 should be answered as the last hospital to which the patient was admitted for this event, and question 5 should be the next-to-last. That is, if the patient was hospitalized at more than one facility for a single event, information about the hospitals should be entered in reverse chronological order. The statement at the bottom of the first page of the NEWMI form ("This section can also be used .....") is not relevant to the morbidity survey and should be ignored. Likewise, for both the NEWMI and NEWSTROKE forms, the date fields given in question 5 should read only "Discharge Date" not "Discharge Date or Date of Death", since by definition, these are non-fatal events.

2. Enter the date of admission for the event you are abstracting.

3. Enter the date of discharge from the hospital for the event you are abstracting.

4. If the patient was transferred to or from another acute care hospital, record a 1 in the code box. This question asks only about acute care facilities, and does not include convalescent care, long-term custodial care, or outpatient clinics or physicians’ offices.

5.a.-d. If one or more transfers occurred, record the hospital name and location, the date of admission, date of discharge and the chart number of the medical record for the subject at the transfer hospital, if available.

6. Print the ICD-9 codes of the discharge diagnoses and procedure codes as listed on the front sheet of the discharge summary. Record them in the order they are listed in the chart. Be sure these are ICD codes and not another coding system such as APC. If the codes are not ICD-9 or if there are no codes in the chart, leave the box blank and print the diagnoses given. The ICD-9 codes will be done at the Coordinating Center.

7. Photocopy the front sheet of the discharge summary, being sure to include the discharge diagnoses. Be sure that personal identifiers are omitted in the photocopying process and that the ID number is printed on the photocopy.

8. This question is intended to determine whether the patient had a MI prior to the current admission you are abstracting. To determine this, review the admission history and physical exam for the current admission. It may also be necessary to review previous admissions in the chart to be sure that there is no prior history. It is very important that you make a thorough search through the chart to determine whether the patient has had a previous MI.
9. If a previous MI occurred, enter the date of the MI that occurred closest in time (i.e., most recently) to the event you are currently abstracting. Print the name and location of the facility where the patient was hospitalized for the MI.

10.-18. These questions, like Question 8, are intended to identify specific conditions or procedures which the patient may have had prior to the admission you are abstracting. Review the admitting history and physical examination and the face sheets (and records, if necessary) of previous admissions to determine whether any of these are present.

Questions 10-18 ask about a history of specific medical conditions prior to the event you are abstracting. These should be answered a "yes" (code 1) only if they have been specifically diagnosed by a physician. Exceptions are questions 15 (history of hypertension) and 18 (history of diabetes). For these two questions, if there is no specific diagnosis given by a physician, they should still be coded as "yes" (code 1) if either of the following is noted in the chart:

a) the patient is on treatment (i.e., antihypertensive medication or hypoglycemic agents) or

b) for hypertension, there are two or more occasions when blood pressure readings of systolic >= 140 mmHg or diastolic >= 90 mmHg were recorded; for diabetes, there are two or more occasions when the fasting glucose was >= 140 mg/dl or 2 hour post-glucose load value was >= 200 mg/dl.

Question 11 asks about a history of "any other chronic ischemic heart disease". This includes ischemic heart disease other than that defined by a prior MI or history of angina, such as non-specific diagnoses of "ischemic heart disease", "coronary heart disease", etc. In the absence of a prior MI or history of angina, such diagnoses may have been made by a physician on the basis of test results, such as positive tread mill test.

19. The NEWMI form is intended to collect all available information regarding each possible MI, so it is important to think about each event, even if the patient was hospitalized at more than one facility for that single event. Question 19 asks about the timing between the onset of acute cardiac symptoms and first contact with a hospital. Thus, "this hospital" means the first one to which the patient went after the onset of acute cardiac symptoms.

Acute cardiac symptoms are defined as pain in the chest, left arm or shoulder, or jaw, and may be accompanied by sweating, faintness, nausea or dizziness. If the time is not specifically stated in the medical record, but it is possible to accurately calculate the time based on information given regarding onset of symptoms and arrival at the hospital, calculate the time yourself and enter the appropriate code. If there is any doubt about the timing of symptoms and arrival at the hospital, code as 9. If symptoms began after admission to the hospital, code as 0 (did not begin prior to arrival). This is trying to determine how long it requires to receive medical care.
In some instances, the event of interest will have occurred in the hospital (the patient being originally hospitalized for something else). If this is the case, code as 1 (yes). If the acute event occurred prior to admission (this would include events in the emergency room), code as 2 (no).

If the answer to Question 20 is “yes”, record the date of the in-hospital MI.

This series of questions deals with the timing and nature of the cardiac pain and medical procedures that may have been used within the first 24 hours of the onset of the acute event. Review the admitting history and physical exam or the notes in regard to an in-hospital event to determine whether an acute (sudden) episode of pain or discomfort occurred as described in Question 22.a. Record the date of onset of pain. If there was no pain, draw double lines through the boxes for the date. 22.c. code as instructed. Question 22.d. asks whether the pain or discomfort was diagnosed as having non-cardiac origin. This would include gastrointestinal problems, pulmonary disease, or skeletal muscle as the source of the pain. If a non-cardiac origin was diagnosed as the source of the pain, specify the diagnosis. Because early intervention may prevent the full-blown clinical presentation of MI from developing, it is important to note whether coronary reperfusion (coronary angioplasty, bypass, intravenous or intracoronary thrombolysis) was attempted within the first 24 hours after the onset of acute symptoms. If so, code 22.f. as 1 (yes), otherwise code as 2 (no). If 22.f. is coded as 1, code 22.g. according to the approximate time between the onset of symptoms and the attempt at reperfusion.

Question 22a. should read "... either within 72 hours prior to arrival to this hospital (meaning the first one) or in conjunction with the in-hospital CHD event defined in Question 20". It should be Question 20, not Question 23.

Question 22h. should read, "If yes, approximately how long was it .....". That is, if the answer to Question 22g. "Was coronary reperfusion ..... attempted in the first 24 hours after onset of the event?" is "no", then you should not answer 22h. and should draw double lines through the box.

For each of the tests and procedures listed, code whether or not it was done during this admission. If the procedure was performed, attach a photocopy of the results and interpretation to the abstract. Be sure that personal identifiers are removed from the report, but that the ID number is printed on each page that is photocopied.

Only codes 1 (yes) and 2 (no) should be used. If a procedure is not mentioned in the chart, code as 2 (no). Codes 8 (uncertain) and 9 (not mentioned) don’t make much sense in these instances. However, codes 8 & 9 should still be used, when necessary, for other questions, such as those related to the presence or absence of specific physical findings.

Determine whether any cardiac enzyme studies were done within 1-4 days after arrival at this hospital or after an in-hospital event. Cardiac enzymes include CPK (CK), SGOT and LDH.

If cardiac enzyme studies were done within the appropriate time frame after the event, determine whether there is any mention of trauma, a cardiac surgical procedure, or rhabdomyolysis within one week before the measurement of enzymes. If one of these conditions was present in the
appropriate time frame, complete parts b. and c. of Question 25. If the exact date in part b. is unknown, but it was clearly within the specified time frame, draw double lines through the boxes for the date. For part d., determine whether there is evidence of hemolytic disease during this hospitalization.

If cardiac enzymes were done during the appropriate time frame after the event, and the answers to Question 25 are “no”, complete the Enzyme Test Form. In some cases, information about cardiac enzymes may only be available from discharge summaries, i.e., no lab slips are available. In this circumstance, record the information available from the discharge summary on the enzyme form, and indicate at the top of the enzyme form that these data come from the discharge summary only.

26. Code as instructed. If yes, attach copies of required ECGs and interpretations. These include: the most recent ECG prior to this admission, the first ECG recorded after admission or the occurrence of an in-hospital event, the first ECG done each day thereafter, and the last ECG recorded before discharge. Be sure that personal identifiers are removed, but also that the ID number is recorded on each ECG attached. ECGs should also be dated so that it is possible to determine the order in which they were done.

27. Attach a photocopy of the Discharge Summary and of the Admitting History and Physical Examination pages from the chart. Again, follow the same instructions with respect to personal identifiers and ID number.

28. Enter your code number.

29. Enter the date the abstract was completed.

DETAILLED INSTRUCTIONS FOR EACH QUESTION - NEWSTROKE

**Ques**

**Instructions**

Enter the ID number, community code and patient’s social security number. If the patient does not have a social security number, draw double lines through the boxes.

1.-7. Complete using the same instructions as given above for Questions 1.-7. NEWMI.

8. Record in the box the number which corresponds to the primary diagnosis of type of stroke. If the record says only “cerebral infarction” use code 6. If the chart says only “stroke” or CVA, use code 7. **IF IT WAS A THROMBOTIC INFARCTION, USE CODE 9.**

Recent experience with the quality-control abstracting suggests the need to add another code option to question 8. A patient admitted to the hospital and discharged with a diagnosis of CVA was transferred to another hospital for neurological work-up. The final diagnosis based on this work-up was “Bell’s palsy”. If the final diagnosis turns out to be a neurological condition other than stroke, code Question 8 with a “9” and print the diagnosis below the list of codes. Since the forms have already been printed, you will have to remember to use this code when needed.
9. Review the information for the current admission to determine whether the patient had a focal (localized) neurologic deficit, and if so, whether the deficit lasted more than 24 hours. Focal neurologic deficit would include hemiplegia, sensory impairment in part of the face, arm and leg, aphasia, motor speech disorder, distortion of visual coordinates, paralysis of conjugate gaze, paresis (weakness) on one side of the body, and other neurological abnormalities which can be localized to a particular structure or area in the brain.

10. Change in state of consciousness includes altered awareness or ability to concentrate, stupor, and coma. Determine from review of the admission whether the patient had a change in state of consciousness that lasted more than 24 hours.

11. Determine whether the patient had a rapid onset of localizing neurologic symptoms. Rapid onset is defined as approximately within 48 hours from onset of symptoms to time of admission or the maximum expression of the acute neurologic deficits.

12. Determine the time from the onset of neurological symptoms to admission or maximum neurologic deficit and/or change in state of consciousness. Enter the shortest time in hours reported in the chart. If the time is not specifically stated in the chart, but it is possible to accurately calculate the time from information given about the time of onset of symptoms and the time of admission, calculate the time yourself and enter the time in hours. Choose the shortest time if more than one interval can be determined. If it is not possible to determine an interval of time, code as 99. Time intervals are coded in hours (round parts of an hour according to rounding rules for intervals).

13. This question includes a list of neurologic signs and symptoms. After review of the chart for this admission, determine whether each of these was present. Codes for “yes” (finding was mentioned as present), “no” (finding was mentioned as not present or negative), and “not mentioned” should be used for each item. Consult the list of key words if you are uncertain about the definition of any of these terms. “Weakness or drift” refers to unilateral paresis or loss of strength in one side of the body. It does not include malaise or a generalized feeling of weakness.

14. If a lumbar puncture (LP) was done, was there evidence of blood in the cerebral spinal fluid? If an LP was not done, code as 3.

15. This question is intended to determine whether the patient had a MI prior to the current admission you are abstracting. To determine this, review the admission history and physical exam for the current admission. It may also be necessary to review previous admissions in the chart to be sure that there is no prior history.

If a previous MI occurred, enter the date of the MI that occurred closest in time to the admission you are currently abstracting.

16.-25. These questions are intended to identify specific conditions or procedures which the patient may have had prior to the event you are abstracting. This information may be given in the admitting history and physical examination of the current admission, but it may also be necessary to check
these sections and the discharge sheet for all prior admissions included in
the record. After review of the record for each of these items, record the
appropriate response. These questions should be answered as "yes" (code 1)
only if they have been specifically diagnosed by a physician. Exceptions are
questions 13 (history of hypertension) and 16 (history of diabetes). For
these two questions, if there is no specific diagnosis given by a physician,
they should still be coded as "yes" (code 1) if either of the following is noted
in the chart:

1) the patient is on treatment (i.e., antihypertensive medication or
hypoglycemic agents) or

2) for hypertension, there are two or more occasions when blood pressure
readings of systolic >= 140 mmHg or diastolic >= 90 mmHg were recorded;
for diabetes, there are two or more occasions when the fasting glucose was
>= 140 mg/ml or the 2 hour post glucose load value was >= 200 mg/dl.

Question 17 asks about a history of "any other chronic ischemic heart
disease". This includes ischemic heart disease other than that defined by a
prior MI or history of angina, such as non-specific diagnoses of "ischemic
heart disease", "coronary heart disease", etc. In the absence of a prior MI
or history of angina, such diagnoses may have been made by a physician on
the basis of test results, such as positive tread mill test.

26. For each of the diagnostic tests listed, code whether or not the test was
done. Only codes 1 (yes) and 2 (no) should be used. If a procedure is not
mentioned in the chart, code as 2 (no). Ignore codes 8 and 9. For those
tests done, attach copies of the results and interpretation, again following
the same procedures regarding identifiers and ID number.

27. If a CAT scan was done, review the report of the results to determine
whether there was evidence of either cerebral infarction or hemorrhage, but
no evidence of other types of disease processes or events. Using the results
reported, answer parts a. and b. If you have any questions about how to
interpret the CAT scan results, consult the study coordinator.

28. Review the patient's medical history in this admission (and others prior to
it, if necessary) to determine whether he/she had a history of any of the
conditions listed prior to the current admission. "Metabolic disorder"
includes conditions other than diabetes, such as thyroid disorders (e.g.,
goiter, hypothyroidism), and Cushing's syndrome. Specify the metabolic
disorder or other neurological disorder, if present.

29. Attach a photocopy of the Discharge Summary and of the Admitting
History and Physical Examination pages from the chart. Again, follow the
same instructions with respect to personal identifiers and ID numbers.

In addition to the other items which are to be photocopied and attached to
the NEWSTROKE abstract, PHOTOCOPY AND ATTACH THE
NEUROLOGICAL CONSULTATION REPORT, if a consult was done.

30. Enter your code number.

31. Enter the date the abstract was completed.
APPENDIX 19

SAMPLE CONSENT FORM FOR PARTICIPATION
IN A RESEARCH PROJECT

Introduction

We are inviting you to participate in a research study designed to evaluate the amount of heart disease that is present in individuals 45-74 years old in your community. It is important that you read and understand the following general principles which apply to all participants in our studies.

1. Participation is entirely voluntary.

2. Personal benefit may not result from your participation in this study, although knowledge may be gained that will benefit others.

3. Withdrawal from the study may be accomplished at any time without jeopardy or prejudice. Please feel free to ask any questions you may have of those discussing the project with you.

The examination to identify cardiovascular disease and its correlates will include:

1. Oral Glucose Tolerance Test - You will be asked to drink a cola-flavored beverage containing 75 grams of carbohydrate. Blood samples will be taken before the drink, and two hours afterward for the determination of glucose and other substances in the blood. A total of up to four ounces of blood may be taken from your arm. Sometimes the glucose beverage might cause mild diarrhea.

2. Electrocardiogram (heart tracing)

3. Physical Examination - This will include measurement of blood pressure, height and weight, thickness of fat tissue, and body fat.

4. Health Interview - This will include questions concerning many aspects of your general health, questions related to chest pain and pains in your legs, questions about your dietary habits, and physical activity.

All of the tests are standard medical examinations and carry a very low risk of any side-effects. Withdrawal of blood from the arm occasionally results in some bruising and minor discomfort for a day or two.

If the doctor finds problems which require immediate attention, you will be referred to the Indian Health Service for appropriate tests and emergency treatment and we will help arrange for any necessary follow-up treatment.

I understand the above explanation and have been given the opportunity to ask any questions that I may have. If I wish, I may have a copy of this consent form. I agree to allow the results of the examination and any information in my medical record to be used for statistical purposes to further medical knowledge. I understand that any medically important information will be included in my Indian Health Service medical record, and I may request and authorize, by signature, its release to other agencies or persons as I feel appropriate.
I have been assured there is little likelihood that harm will result from my participation as a subject in this study and that I may withdraw from any part of the examination and that this action will not in any way prejudice my right to receive proper medical treatment at the present time or in the future. I understand that in the unlikely event of injury established as a result of my participation in the research, appropriate short-term medical care including hospitalization will be provided by the Indian Health Service. Neither the Indian Health Service, the Federal Government, nor Foundation has provisions for financial compensation in the event of such injury. I understand that Drs. who are in charge of these investigations, should be contacted if any injuries occur. Their telephone number is

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Investigator’s signature/date  Volunteer’s signature/date

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Witness’ Signature