

Jackson Heart Study Protocol

Manual 10

Morbidity and Mortality Classification Manual

Version 1

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FOREWORD

Morbidity and Mortality Classification Manual, is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the General Description and Study Management of the JHS. Manual 2 describes the operation of the Cohort Component Procedures. This new edition of Manual 10 (Version 1) describes Cohort Morbidity and Mortality Methods. Detailed Manuals of Operation for specific procedures, including those Family Study, Blood Pressure, Electrocardiography, Echocardiography, Ultrasound Assessment, Pulmonary Function Assessment, and Specimen Collection and Processing make up Manuals 3 through 9. Manual 11 detailed the Data Management System.

JHS Protocols and Manuals of Operation

MANUAL	TITLE
1	General Description and Study Management
2	Cohort Component Procedures
3	Family Study
4	Blood Pressure
5	Electrocardiography
6	Echocardiography
7	Ultrasound Assessment
8	Pulmonary Function Assessment
9	Specimen Collection and Processing
10	Morbidity and Mortality Classification Manual
11	Data Management System
12	Quality Control

Manual 10. Morbidity and Mortality Classification Manual

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1.0 INTRODUCTION

JHS cohort morbidity and mortality includes monitoring and validating events among cohort participants. In addition to hospitalized myocardial infarction (MI) and coronary heart disease (CHD) endpoints, clinically recognized strokes among cohort participants are also identified and validated through cohort morbidity and mortality procedures. Hospitalized and outpatient events of congestive heart failure (CHF) among cohort participants are also identified.

This manual details the procedures for identifying and validation of selected events among the JHS cohort. Section 2 describes the procedures by which potential events in the cohort are identified (i.e., death registries, hospital discharge indexes). Section 3 details procedures for collecting the additional information needed once an event has been identified. Diagnostic criteria are documented in Section 4, and review and classification procedures are described in Section 5. The procedures for obtaining information on certain indicators of medical care are described in Section 6. Procedures for linkage of multiple events are described in Section 7. Section 8 briefly discusses the reliability of record abstraction. Sections 9 and 10 detail the cohort morbidity and mortality procedures for identifying CHD events (section 9) and clinical stroke (section 10) among the JHS cohort. Procedures for identifying and classifying congestive heart failure among the cohort are outlined in section 11. Section 12 describes how the Morbidity and Mortality Classification Committee (MMCC) functions and section 13 outlines the quality control measures used in JHS cohort morbidity and mortality.

JHS morbidity and mortality methods evolved from those used for the Atherosclerosis Risk in Communities (ARIC) Study. ARIC methods have been published (White et al., 1996). Additional information on trends in event rates using surveillance methods has been published (Rosamond et al., 1998). CHD events occurring among cohort participants are ascertained through cohort follow-up. Methods for stroke classification and event rates have also been published (Rosamond et al., 1999).

2.0 DIAGNOSTIC CRITERIA

2.1 Fatal Coronary Heart Disease (CHD)

2.1.1 Definite Fatal Myocardial Infarction (MI)

Must meet criteria 1. AND 2. below:

1. No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.
2. Definite hospitalized MI within four weeks of death; use criteria in Section 2.2.2 for Definite Hospitalized MI.

2.1.2 Definite Fatal CHD

Must meet ALL of the following criteria:

1. Lack of sufficient evidence to diagnose Definite Fatal MI according to the criteria given in Section 2.1.1.
2. No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.
3. Presence of one or both of the following findings:
 - a) A history of chest pain within 72 hours of death;
 - b) A history of ever having had chronic ischemic heart disease such as coronary insufficiency or angina pectoris.

2.1.3 Possible Fatal CHD

Must meet ALL of the following criteria:

1. Lack of sufficient evidence to diagnose Definite Fatal MI or Definite Fatal CHD according to the criteria in Sections 2.1.1 and 2.1.2.
2. No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.
3. Death certificate with consistent underlying cause of death, i.e., ICD10 codes: 410-414, 427.5, 429.2, and 799.

2.1.4 Non-CHD Death

All deaths that do not meet the above criteria for Definite Fatal MI, Definite Fatal CHD, or Possible Fatal CHD.

2.1.5 Chronology of Death

The time interval from onset of acute symptoms to time of death is recorded, where possible, for all CHD deaths. For out-of-hospital deaths, their time interval is ascertained by their MMCC reviewer and recorded on the final diagnosis form.

2.1.6 Limitation of Activity

For out-of-hospital CHD deaths it is noted whether the decedent's activity was limited in the month before death because of sickness or illness.

2.2 Hospitalized Myocardial Infarction (MI)

2.2.1 Introduction

JHS plan is to establish a well-standardized process for the identification of hospitalized coronary disease of an acute nature. The criteria presented are based on two source documents: the findings of the Community Cardiovascular Cohort Surveillance Program (CCSP) Pilot Study and the results of the Minnesota Heart Survey¹⁻³, as well as other surveillance studies. The diagnostic criteria presented here approximate those contained in the above-mentioned documents. The differences in diagnostic criteria are the lack of a duration requirement for cardiac pain, and the use of the more sensitive and specific CK-MB and LDH isoenzymes and inclusion of troponin proteins. The description of diagnostic criteria to follow includes troponins in the category of "cardiac enzymes" even though they are technically structural proteins and not enzymes. The combinations of pain, ECG and enzyme categories required for each diagnosis below are approximately the same as those contained in the above-mentioned documents.

It is recognized that aggressive treatment of early signs and symptoms of acute coronary events, such as coronary artery bypass graft or thrombolytic therapy, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately. The use of such modalities is recorded and subject to data analysis, but not employed in the criteria for diagnosis.

2.2.2 Definite Hospitalized MI

Definite hospitalized MI must meet one or more of the following criteria:

1. Evolving diagnostic ECG pattern (ED1 - ED7, section 2.2.6.2)
- OR
2. Diagnostic ECG pattern (D1 or D2, section 2.2.6.4) and abnormal enzymes (Table 2.1);
- OR
3. Cardiac pain and abnormal enzymes; (Table 2.1)
- AND
- a) Evolving ST-T pattern (EV1 - EV8, section 2.2.6.3)
- OR
- b) Equivocal ECG pattern (E1 - E4, section 2.2.6.5)

2.2.3 Probable Hospitalized MI

Probable hospitalized MI must meet one or more of the following criteria in the absence of sufficient evidence for Definite Hospitalized MI:

1. Cardiac pain and abnormal enzymes OR
2. Cardiac pain and equivocal enzymes and
 - a) Evolving ST-T pattern OR
 - b) Diagnostic ECG pattern OR
3. Abnormal enzymes and evolving ST-T pattern

2.2.4 Suspect Hospitalized MI

Suspect hospitalized MI must meet one or more of the following criteria in the absence of sufficient evidence for Definite or Probable Hospitalized MI.

1. Abnormal enzymes OR
2. Cardiac pain and incomplete enzymes and
 - a) Diagnostic ECG pattern OR
 - b) Evolving ST-T pattern OR
3. Cardiac pain and equivocal enzymes OR
4. Equivocal enzymes and
 - a) Diagnostic ECG pattern OR
 - b) Evolving ST-T pattern OR
 - c) Equivocal ECG pattern

The criteria for Definite, Probable, Suspect, and No Hospitalized MI are summarized in Table 2.1.

2.2.5 Definition of Cardiac Pain

Pain having both the following characteristics:

1. It occurs anywhere in the anterior chest, left arm or jaw AND
2. Absence of a definite non-cardiac cause of pain. (If there is evidence of a non-cardiac cause, the pain diagnosis is downgraded by computer to "not present".)

Table 2.1. Summary of JHS Diagnostic Criteria for Hospitalized MI

Cardiac Pain	ECG Finding	Enzymes	Diagnosis
Present	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
	Evolving ST-T Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
Equivocal	Abnormal	Definite MI	
	Equivocal	Suspect MI	
	Incomplete	No MI	
	Normal	No MI	
Absent, Uncodable, or Other	Abnormal	Probable MI	
	Equivocal	Suspect MI	
	Incomplete	No MI	
	Normal	No MI	
Not Present, Unknown or Missing	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Evolving ST-T Pattern	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
Equivocal ECG Pattern	Abnormal	Suspect MI	
	Equivocal	Suspect MI	
	Incomplete	No MI	
	Normal	No MI	
Absent, Uncodable, or other	Abnormal	Suspect MI	
	Equivocal	No MI	
	Incomplete	No MI	
	Normal	No MI	

2.2.6 Definitions of Electrocardiographic Criteria

The ECG series is assigned the highest category for which all criteria are met, i.e., evolving diagnostic is greater than diagnostic is greater than evolving ST-T patterns is greater than equivocal is greater than other. The ECGs are coded using Minnesota Code.

2.2.6.1 Evolving Diagnostic Q Waves

An evolving Diagnostic Q Wave pattern is defined as an evolving pattern on serial ECGs of ECG changes within lead groups, i.e., anterior (V1 - V5); lateral (I, aVL, V6) or inferior (II, III, aVF). Two or more ECG recordings during the hospitalization are needed for this classification.

2.2.6.2 Evolving Diagnostic ECG (Judged within lead group)

ED1 through ED7 cannot be assigned if a 7-1-1 code is present. ED2 through ED7 cannot be assigned if a 7-2-1 or 7-4 code is present.

- ED1. If the following condition is met for any lead group, then ED1 is positive. Either no Q-code or a 1-2-6 code in reference ECG followed by a record with a Diagnostic Q-code in the same lead group OR any code 1-3-x or 1-2-8 in reference ECG followed by a record with any code 1-1-x in the same lead group and there is no 7-1-1 code in either ECG, then ED1 is positive.
- ED2. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG but followed by a record with a Major ST-segment Depression in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED2 is positive.
- ED3. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG but followed by a record with a Major T-wave Inversion in the same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED3 is positive.
- ED4. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG but followed by a record with the ST-segment Elevation in that same lead group and there are not 7-1-1, 7-2-1 or 7-4 codes in either ECG, the ED4 is positive.
- ED5. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG but followed by a record with a Major ST-segment Depression in that same lead group and there are not 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED5 is positive.
- ED6. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG but followed by a record with a Major T-wave Inversion in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED6 is positive.
- ED7. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG but followed by a record with an ST-segment Elevation in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED7 is positive.

2.2.6.3 Evolving ST-T Pattern (Judged within lead group)

This diagnosis cannot be assigned if a 7-1-1 or 7-2-1 or 7-4 code is present.

- EV1 Either 4-0 (no 4-code), 4-4 or 4-3 in reference ECG followed by a record with 4-2 or 4-1-2 or 4-1-1; OR 4-2 in reference ECG followed by a record with 4-1-2; OR 4-2, 4-1-2 or 4-1-1 in reference ECG followed by a record with 4-0, 4-4 or 4-3; OR 4-1-2 in reference ECG followed by a record with 4-2,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.
- EV2 Either 4-2 or 4-1-2 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-2 or 4-1-2 ,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.
- EV3 Either 5-0, 5-4 or 5-3 in reference ECG followed by a record with 5-2 or 5-1 OR 5-2 or 5-1 in reference ECG followed by a record with 5-0, 5-4 or 5-3,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.
- EV4 Code 5-2 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-2,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.
- EV5 Code 9-0 in reference ECG followed by a record with 9-2 OR 9-2 in reference ECG followed by a record with 9-0,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.
- EV6 Code 4-1-1 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-1-1,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.
- EV7 Code 5-1 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-1,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.

EV8 Code 5-2 in reference ECG followed by a record with 5-2 OR 5-2 in reference ECG followed by a record with 5-2,
 PLUS
 no Q-code in both the reference ECG and the follow-up ECG.

2.2.6.4 Diagnostic ECG

- D1 (Diagnostic Q wave)
 An ECG record with any Diagnostic Q-code (Minn. code 1-1-1 through 1-2-5 plus 1-2-7).
- D2 An ECG record with ST-segment elevation code 9-2 PLUS (T-wave inversion code 5-1 or 5-2 in the absence of 7-2-1 or 7-4).

2.2.6.5 Equivocal ECG

- E1 (Equivocal Q wave)
 An ECG record with an Equivocal Q-code [(Minn. code 1-2-8 in the absence of 7-2-1 or 7-3) or (any 1-3 code)].
- E2 An ECG record with ST-segment depression (code 4-1-X or 4-2 or 4-3 in the absence of 7-2-1 or 7-4).
- E3 An ECG record with T-wave inversion (code 5-1 or 5-2 or 5-3 in the absence of 7-2-1 or 7-4).
- E4 An ECG record with ST-segment elevation code 9-2 (in the absence of 7-2-1 or 7-4).

2.2.6.6 Other ECG

- 01 Reference ECG coded 7-1-1.
 02 Any ECG coded 7-1-1.
 03 OTHERWISE Normal ECG(s), defined as 1.0 in "clear" field of all ECGs.
 04. Other findings including 1-2-6.

2.2.6.7 Uncodable ECG

- U1 Technical errors coded 9-8-1 by Minnesota Code.

2.2.6.8 Absent ECG

- A1 No ECG available for coding.

2.2.6.9 Minnesota Coding Procedures

The following ECG tracings are identified:

1. The first codable ECG after admission;
2. The last codable ECG recorded before discharge; and
3. The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event. Photocopies of the hospital ECGs are sent to the Minnesota Coding Center in Minneapolis for Minnesota Coding, using the Minnesota Coding for hospitalized ECGs. Each ECG is read one time blinded. For cohort, serial change rules are not applied.

2.2.7 Definitions of Cardiac Enzyme Criteria

All pertinent enzyme results (as defined below) recorded on days 1 through 4 after hospital admission of an in-hospital CHD event are abstracted. Information on non-ischemic cause for elevated enzymes is abstracted exclusively from the discharge summary on the medical chart. For the purposes of this

manual, the category of cardiac enzymes includes cardiac troponins, even though troponin is a structural protein of cardiac muscle and not an enzyme.

2.2.7.1 Abnormal Cardiac Enzymes

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

1. a) CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or CK-MB is at least twice the upper limits of normal (if the laboratory gives a normal range) or, if no normal range is given, the CK-MB (heart fraction) is greater than or equal to 10% of the total CK value or, if the upper limits of normal is zero and the CK-MB is positive,
AND
 - b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value.
- OR
2. a) The ratio LDH1 : LDH2 > 1, or if LDH2 is missing and LDH1 is at least twice the upper limit of normal,
AND
 - b) There is no evidence of hemolytic disease.
- OR
3. a) Total CK and total LDH are both at least twice the upper limit of normal. (These increases do not have to occur on the same day.)
AND
 - b) There is no known non-ischemic cause (surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.
- OR
4. a) Troponin is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or is at least twice the upper limits of normal,
AND
 - b) There is no known non-ischemic cause (surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.

2.2.7.2 Equivocal Cardiac Enzymes

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

1. Either total CK or total LDH are at least twice the upper limits of normal.
OR
2. Both total CK and total LDH are between the upper limits of normal and twice the upper limits of normal. (These increases do not have to occur on the same day.)
OR
3. CK-MB is "weakly present" or between the upper limits of normal and twice the upper limits of normal or $5\% \leq \text{CK-MB} < 10\%$.
OR
4. If LDH1 is present and LDH2 is missing, and LDH1 is between the upper limits of normal and twice the upper limits of normal.
OR
5. Troponin is "weakly present", or troponin levels are between the upper limits of normal and twice the upper limits of normal.

2.2.7.3 Spurious Enzymes

If enzymes met one of the following criteria, the "abnormal" enzymes were considered spurious, and were downgraded to "equivocal".

1. If the first abnormal CK-MB is at or after the date of trauma, cardiac procedure or rhabdomyolysis.
2. If LDH1/LDH2 is abnormal and there is evidence of hemolytic disease.
3. If both total CK and total LDH are abnormal, and there is evidence of hemolytic disease, or the first abnormal total CK/total LDH is at or after the date of trauma, cardiac procedure or rhabdomyolysis.
4. If the first abnormal troponin is at or after the date of trauma, cardiac procedure or rhabdomyolysis.

3.0 EVENT CLASSIFICATION-DETERMINING WHICH EVENTS GET MMCC REVIEW

3.1 Hospitalized Events

Hospitalized events are classified using a computer algorithm based on criteria given in Section 2.2. Most non-linked hospital events and some linked events have an automatic computer classification for MI. Linked and non-linked hospitalized events that require MMCC review before final hospitalized MI diagnosis (Section 3.1.1) include the following:

- 3.1.1 Hospitalized events (linked to at least one other eligible hospitalization within 28 days or non-linked) if:
- a) the final computer diagnosis is "Definite MI" but discharge codes from hospitalizations for the event do not include 410 or 411. (Note: Computer "Definite MI" + 410-411 discharge codes lead to automatic classification of Definite MI.)
 - b) the computer diagnosis is "No MI" and hospital discharge ICD9-CM codes from at least one of the hospitalizations for the event include 410. (Note: Computer "No MI" + No 410 discharge code from any hospitalization in the event lead to automatic classification of "No MI.")

This review of linked and non-linked hospitalizations is done, when needed, by one MMCC member for hospitalized MI diagnosis.

- 3.1.2 Special Automatically Classified Cases (No MMCC Review required):

- a) If no chart can be located for all hospitalizations for the event, an automatic classification of "Unclassifiable" is given.
- b) No discharge codes for any hospitalizations for the event contains 410-411 codes, there is no mention of acute MI in discharge summary, there is no more than one ECG, and there is no Cardiac Enzyme above the normal limits, an automatic classification of "No MI" is given. (Note: These are the cases that skip out of the HRA form at question 20.)

3.2 In-hospital Deaths (MI and Death Classification)

Non-linked in-hospital deaths are reviewed for death diagnosis by two MMCC reviewers (after final MI classification by computer algorithm) and adjudicated by a third reviewer if needed. Linked in-hospital deaths (including >28 day linked deaths) are reviewed for death and MI if needed by one MMCC reviewer. The following cases, however, need no MMCC review.

- 3.2.1 Those with ICD-10 codes for underlying cause of death and a final computer diagnosis of "Definite MI," and the date of death and date of MI are within 28 days. The corresponding ICD-10 underlying cause of death codes are (I20-25, I46-49, I51.6, R99, J96) (Note: These cases are classified directly as "Definite Fatal MI")
- 3.2.2 Those with ICD-10 codes for underlying cause of death for which the final computer diagnosis of "Definite MI" could not be made according to JHS criteria but who had pain of cardiac origin or a history of MI, angina pectoris, or coronary insufficiency. (Note: These cases are classified directly as "Definite Fatal CHD")
- 3.2.3 Those with ICD-10 codes for underlying cause of death not including for which the diagnosis of a Definite MI could not be made according to JHS Criteria and
1. No pain of cardiac origin, and
 2. No history of previous MI, angina pectoris or coronary insufficiency.
- (Note: These cases are classified directly as "Non-CHD death")

3.3 Out-of-Hospital Deaths

- 3.3.1 All out-of-hospital deaths are reviewed by two members of the MMCC for death diagnosis except those with death certificate ICD-10 codes for underlying cause of death (I20-25, I46-49, I51.6, R99, J96) and a catchment's area hospital admission within 28 days with a final diagnosis of "Definite MI". (Note: Cases are classified as "Definite Fatal MI.")

This review for death diagnosis is done after final MI classification, in case there is an eligible linked hospital admission within 28 days of death, and is done by two MMCC reviewers, then adjudicated by a third reviewer if there is no agreement between the two reviewers.

- 3.3.2 "Definite" and "Possible" CHD deaths are classified as to time from first symptoms to death.

3.4 Case Law Used by MMCC

An important function of the MMCC is to maintain complete records of any clarifications of JHS diagnostic criteria required to reach diagnostic decisions. Such "case law" is systematized for convenient reference purposes and, when appropriate, incorporated into the JHS diagnostic protocol. New case law is developed as a result of discussions with the MMCC and is approved by the Chair of the MMCC before adoption.

The following are general cohort morbidity and mortality rules established as case law.

Final Classification Rules

1. When the death certificate is the only available document, and the ICD code is compatible with CHD (ICD-10:I20-25, I46, I51.6, R99, J96) then final JHS classification of cause of death is usually "Possible CHD," unless there is (I) a demonstrable coding error, or (II) an explicit non-CHD probable cause of death (such as malignant hypertension with renal failure). Analogously, for other ICD codes the classification of cause of death is usually "Non-CHD".
2. The classification "Diagnosis Unclassifiable" will be reserved for cases not meeting JHS criteria for CHD diagnosis, but in whom a specific non-atherosclerotic or non-cardiac atherosclerotic process cannot be identified.
3. In the case of conflicting information, the more inclusive cause of death (e.g., Definite CHD rather than Definite MI) is preferred.
4. Stroke qualifies as a "yes" answer to "a non-atherosclerotic or non-cardiac atherosclerotic process," if judged to be the probable cause of death.
5. If the decedent was debilitated from a potentially lethal non-atherosclerotic or non-cardiac process and had a related downhill course, with no symptomatic evidence of a recent coronary event, the death is classified a non-CHD.
6. In cases of "Definite" or "Probable MI," treated or aborted with TPA or similar clot-dissolving therapy, in which the patient dies of a direct complication or adverse effect of this therapy (i.e., hemorrhage), a final death classification of "Definite fatal CHD" should usually be assigned.
7. If a patient having an elective coronary artery by-pass graft (CABG) dies as a complication of surgery, a final death classification of "Definite fatal CHD" should usually be assigned.
8. Generally, "hypertensive heart disease" will not be considered a "non-atherosclerotic cause

of death”.

Chronology

9. Death is assumed to have occurred at the time the patient stops breathing on his/her own and does not recover.
10. Symptoms are assumed to begin when the patient changes his/her activity. If symptoms come and go, the onset of symptoms is the time when they crescendo, leading to death.
11. In cases where timing of symptoms or death is unknown, the best estimate of the chronology is to be made.
12. Symptoms of CHD leading to a hospital admission for CHD are usually considered to be related to a subsequent death from CHD, which occurs either before discharge or within 28 days of admission, whichever ever occurs first. Deaths of doubtful chronology admitted for the investigation or treatment of CHD are classified as deaths occurring in > 24 hours if admitted for at least 24 hours.
13. Unknown chronology of death of an institutionalized patient is usually considered to be < 24 hours.

Evidence

14. The relative credibility of conflicting witnesses is established from all the available evidence, i.e., there is no fixed hierarchy of credibility (such as physician overriding a lay informant). However, as a general rule:
 - (i) A knowledgeable physician takes priority for medical history.
 - (ii) A witness takes priority for events around death and timing of death.
15. A clinical history of atherosclerotic heart disease (ASHD) or CHD counts as evidence of previous manifestations of CHD. If the event under consideration is the first manifestation of CHD, it does not qualify as a “history” of CHD.
16. A history of CABG or coronary angioplasty at any time prior to death is equivalent to a positive history of CHD.
17. Mention in the chart or documented previous angiographic evidence of CAD is regarded as equivalent to recorded history of CHD when evaluating whether there was a past history of ischemic heart disease. However, evidence of CAD on catheterization at the time of the event under consideration is not a “history of CHD”.

The following are case laws developed and approved by the MMCC specifically for use with COHORT

Reviews

1. For cohort morbidity and mortality events, autopsy or unequivocal angiographic evidence of old MI or other chronic CHD counts as evidence of a history of CHD.
2. For cohort morbidity and mortality events, autopsy reports may be used to judge cause of death and in most cases take precedence. Autopsy evidence of an acute MI or MI within 4 weeks may be used to answer “Yes” to “Was there a definite MI within 4 weeks of death” Such

evidence includes acute coronary arterial thrombosis deemed sufficient to produce acute MI, even in the absence of evidence for acute myocardial tissue necrosis.

3. The diagnosis of "Definite MI" based upon "Evolving Diagnostic" ECG may be downgraded to the algorithm diagnosis which would be obtained if the ECG were "Diagnostic," and the diagnosis of "Probably MI," based upon "Evolving ST-T" ECG may be downgraded to the algorithm diagnosis which would be obtained if the ECG were "Equivocal," but only if:

- ♦ the clinical history is compatible with the downgraded diagnosis, and
- ♦ "Evolving Diagnostic" or "Evolving ST-T" ECG is suspicious because (1) a non-MI cause of the ECG abnormality is identified, or (2) a hospital ECG interpretation contradicts it.

4. Changes in hospital pain or enzyme classification are permitted only in restricted circumstances based on strong clinical judgment. When a reviewer makes a change in classification, the change should be reflected in the reviewer's answer to Item 7b (physician "preferred diagnosis"), not in the answers to Items 3, 5 or 6.

a. The JHS protocol, not individual hospital physician's judgment, determines what exact enzyme level qualified as "elevated."

b. Reviewers may downgrade enzyme classification on the basis of an identified non-cardiac or non-ischemic cause, but only if enzymes review has not already occurred.

c. Reviewers may downgrade the pain classification on the basis of an identified non-cardiac or non-ischemic cause, but only if pain review has not already occurred.

d. Changes in pain or enzyme classification are permitted when the narrative summary clearly contradicts the pain, enzyme, or ECG information abstracted and an JHS abstractor's error appear probable.

e. If enzymes have been downgraded from "Abnormal" to "Equivocal" driving the JHS algorithm diagnosis from "Definite MI" to "Suspect MI," or "Probable MI" to "Suspect MI," a reviewer who disagrees with the prior downgrading of enzymes should request another review of the decision to downgrade before completing classification of the case. Cases in which there remains continued disagreement as to whether enzymes should be downgraded should be sent for adjudication. The adjudicator in such cases may assign a more likely diagnosis of "Probable MI," but may not upgrade the diagnosis to "Definite MI."

f. An angina equivalent (e.g. pulmonary edema, exhaustion, syncope) may be considered similar to chest pain in recording a "preferred diagnosis."

5. Upgrading the MI diagnosis in hospital deaths, e.g., from "No MI" to "Suspect" or "Definite MI," is not permitted on the basis of the judgment that had the patient lived, the enzymes or ECG would have provided sufficient evidence for the upgraded diagnosis.

6. Upgrading the MI diagnosis in cases of delayed hospitalization is not permitted on the basis of the judgment that had the patient been hospitalized earlier the enzymes or ECG would have provided sufficient evidence for the upgraded diagnosis⁷. When the discharge summary clearly indicates a perioperative MI and JHS chest pain are "absent," a diagnosis of "Probable" (but not "Definite") "MI," may be assigned if the algorithm criteria for "probable" or "Definite MI" would have been met had chest pain been "present."

If a reviewer believes the ECG DX and the discharge summary were so discrepant as to suggest a missing ECG that might change the MI DX, the reviewer should not review the case and notify the Coordinating Center of the problem. The CSCC will check at the coding center as to whether the appropriate tracings were in the system. If this were done, and if the tracings were appropriately included and coded, then the procedures should mandate acceptance of the ECG criteria. On the other hand, if a request for a check should reveal missing ECG or a programming error, such could then be corrected as needed.

3.5 MMCC Final Diagnosis Forms

When a member of the MMCC reviews a case, he/she completes a MMCC Final Diagnosis Form CDX (See Appendix VI) and returns it to the Coordinating Center for processing. The CDX form is used for evaluating events among cohort participants.

4.0 MEDICAL CARE ASSESSMENT

Medical care elements which are recorded in cohort members include the participant's access to and use of providers for routine and special care, use of all prescription and over-the-counter medications, records of all hospitalizations for all reasons, records of all cardiovascular procedures and all cardiovascular diagnoses received, and detailed information on hospitalizations for CHD and stroke.

For out-of-hospital deaths, the Physician Questionnaire and Informant Interview Form allow collection of information about physician visits prior to the acute event, utilization of physician and emergency services during the acute event, history of hospital admission within one month prior to death, receipt of cardiopulmonary resuscitation, delay in receiving definitive care, use of nitrates and digitalis shortly before death, and history of coronary bypass surgery. The potential for cardiopulmonary resuscitation is assessed by the information on whether death was witnessed and the location of death.

For events that include abstraction of the full hospital record, additional data on medical care are obtained. These data include information on transportation to the hospital, time of arrival, receipt of cardiopulmonary resuscitation, use of a number of procedures, and medications for treatment of the cardiovascular event (such as angioplasty and beta blocking agents), and the use of diagnostic procedures (such as cardiac catheterization and echocardiography).

5.0 LINKAGE OF MULTIPLE EVENTS

Since many deaths are listed on both the hospital discharge index and the state death index, survey personnel must compare these lists carefully to avoid duplicating the investigation of in-hospital deaths.

If an eligible in-hospital death is found first from the death certificate lists, the case is flagged and it is linked with the hospital chart when that record is found. The linked forms are given the same event ID number. An in-hospital chart is abstracted, and the death certificate obtained as soon as possible. Again, only one event ID number is assigned to these forms.

If an eligible hospital record indicates that a patient was transferred directly from another acute care hospital, or that the patient upon discharge is being transferred directly to another acute care hospital, the record for the other hospitalization is abstracted onto another Hospital Record Abstraction Form (HRA). The two forms initially have different hospitalization ID numbers.

On occasion, it is difficult to differentiate between two or more successive admissions for the same event and two or more different events in the same person. As it is often difficult to make this distinction on the basis of ECG, enzyme or pain characteristics, a simple rule is followed: a CHD death or a hospital admission for MI occurring within 28 days of a previous admission for MI is regarded as the same event, for purposes of calculating rates.

Over the duration of the JHS cohort morbidity and mortality, increasing numbers of cohort members are hospitalized for cardiovascular conditions more than once. Others are hospitalized and subsequently die of CHD. These events can be linked for future use. Sufficient information for correct identification of these patients is collected, where hospitals permit, and matching procedures based on these identification variables are conducted. Patient initials, last name, SSN, sex, race, and date of birth of all JHS cohort morbidity and mortality participants are compared. If the similarity is beyond a threshold level, these cases are sent out to the Examination Center in the form of a data check for investigation. The Examination Center then determines if these events belong to the same participant and records their findings on all Cohort morbidity and mortality Event Inventory/Linkage Summary (SXI) forms for this participant. The Coordinating Center also produces a listing of possible linkages suggested from cohort morbidity and mortality forms. Various forms (HRA, IFI, COR) contain questions as to whether the person had been hospitalized within 4 weeks prior to this event. The Examination Center uses this listing to find linked hospitalizations that have not yet been abstracted. Any positive findings from this investigation are also recorded on the SXI form.

6.0 COHORT MORBIDITY AND MORTALITY

6.1 Introduction

The aim of cohort morbidity and mortality is to identify all hospitalizations for each cohort participant and validate the diagnosis of all potential congestive heart failure (CHF), coronary or cerebral vascular disease events. Ascertainment and validation of all out-of-hospital fatal events that are cardiac related are also completed.

6.1.1 Identification of Events

In addition to the procedures for identification of potentially eligible events used in ARIC manual 3, Version 6, cohort morbidity and mortality also uses information obtained from the annual follow-up interviews. When the annual follow-up interview indicates that the participant has either died or been admitted to a hospital (for any reason), the medical record or death certificate is obtained, and information abstracted into a computer data base system. The JHS records the occurrence of all hospitalizations but only investigates selected kinds of medical events for cohort participants. These include: 1) hospitalized MI and stroke, 2) death from CHD, stroke and all-causes, 3) congestive heart failure. The identification and classification of clinical stroke and congestive heart failure events will be covered separately in Section 10 and 11 respectively. This section (section 6) describes the identification, investigation and diagnosis of cardiac related hospitalized and fatal events. JHS also records the occurrence of a number of non-hospitalized, non-fatal events, events identified through the routine operations of the JHS clinics and annual follow up interviews, such as angina pectoris and peripheral vascular disease, including intermittent claudication. These are generally defined using standard instruments, such as the Rose Questionnaire, and their identification and diagnosis are described elsewhere.

6.1.1.1 Identification of Hospitalized CHD Events

All hospitalized events occurring in cohort members are identified. Cohort events are deemed eligible based on the following criteria: 1) a valid cohort ID; 2) occurrence must be after the participant's baseline (visit 1) examination; and 3) an eligible CHD discharge code and/or a CHD key word in the discharge summary. Hospital admissions may be identified initially through review of hospital discharge indexes or information elicited during the annual follow-up interview. Hospital chart abstraction is carried out whenever needed to identify MI. All events discharged with specified diagnostic codes are abstracted onto the Hospital Record Abstraction Form (HRA). In order to assure completeness of ascertainment, the discharge summary information is reviewed for events discharged with certain screening codes more remotely related to MI. If an MI is suggested, the chart is abstracted. In addition, all discharge diagnoses for all hospitalizations are recorded.

6.1.1.2 Obtaining Access to Hospital Medical Records

A critical feature of the process of hospitalized event identification among cohort members is obtaining information from medical records. Hospital cooperation is sought for the cohort morbidity and mortality components of the JHS. The protocol sent to hospital administrators emphasizes the fact that, for cohort members, JHS obtains signed hospital record release forms. On occasion, there may be a need to carry out special negotiations with out-of-area hospitals where cohort member was hospitalized.

A critical feature of cohort morbidity and mortality is obtaining information from medical records. Without complete cooperation of hospitals, the usefulness of event rates in any community is limited. Cooperation is sought through hospital administration, medical records directors, hospital ethics committees, and influential medical staff.

It is sometimes necessary to compromise with the hospital review committees and house staff. Again, the major consideration is confidentiality. Some hospitals will not permit the abstraction of a patient's name. It is important to obtain the name because this is the surest method to reduce redundancy in the

records and determine case fatality after discharge. However, less optimal procedures are available. The first is to seek permission to code the name and record addresses, social security numbers, and birth dates. If these are available, the likelihood of redundancy can be reduced by sorting lists of individuals by birth dates or social security numbers.”

6.1.1.3 Hospital Discharge Index

Eligible hospitalized events are identified from the discharge index of each hospital surveyed. Discharge indices are obtained directly from the hospital or from an indexing service.

Using the discharge index for each hospital, all hospitalized events occurring in JHS cohort members are identified. However, only special diagnoses require hospital chart abstraction. Hospital chart abstraction onto the Hospital Record Abstraction Form is carried out for all of the hospitalizations with the following ICD9-CM primary or secondary discharge diagnosis codes:

MI: 402, 410 – 414, 427, 428 and 518.4

A list of diseases included in these ICD9-CM rubrics is presented in Appendix I.

Hospital chart discharge summaries are reviewed for the following screening codes:

Diabetes: 250
Diseases of the circulatory system... 390-459
Other Dyspnea and respiratory abnormalities 786.02; 786.09

Cardiovascular symptoms: signs and ill-defined conditions:

794.3 (Abnormal function study)
798 (Sudden death, cause unknown)
799 (other)
35.0 35.39; 35.9 – 35.99 Operations on valves and septa of heart
36 – 36.3 Operations on vessels of heart
37.21 – 37.23 Diagnostic procedures on heart and pericardium
37.6 – 37.66 Implantation of heart assist system
88.50 – 88.58 Angiocardiology using contrast materials
88.72 Diagnostic ultrasound of heart
92.05 Cardiovascular and hematopoietic scan and radioisotope
Function study

Should any mention of MI on the present admission (or synonyms for these conditions) be uncovered by the review of discharge summaries for the above conditions, hospital chart abstraction onto the Hospital Record Abstraction Form is undertaken.

A number of hospitalized events for cohort members are fatal. Hospital abstracting for these events is the same as for non-fatal events, regardless of whether the ICD10 code for cause of death from the death certificate satisfies the eligibility criteria for fatal events.

6.1.1.4 Hospitalized Events Occurring Outside the Study Community

Review of death certificates or annual follow-up interviews may reveal that the cohort member was hospitalized outside the study area. Hospitalization may occur outside the study area for the following reasons:

1. A major hospital catchments area for the region exists outside of the area (e.g., tertiary care hospital referral centers).

2. Residents who work outside of the geographic area may be admitted to an out-of-area hospital if they have an event requiring admission on an emergency basis.
3. A resident may have an event while in transit outside of the geographic area for recreation or social activities.
4. A cohort member may have moved from the study community.

Every effort is made to identify discharge diagnoses for such events and, if applicable, review the hospital chart. In soliciting access to discharge indexes and, occasionally, medical charts, a letter briefly describing the JHS cohort study is sent to the hospital administrator as well as the director of medical records, along with a copy of the JHS hospital record release form, signed by the participant at the time of the first exam. In some situations, it is also useful to send an abbreviated protocol. Additional contacts, including telephone conversations, with the hospital administrator or the head of the proper department (cardiology, neurology, etc.) may be necessary. No major obstacles are expected in obtaining access to medical charts, in view of the consent for such access provided by JHS cohort members. Cohort participants who deny access to medical records are not investigated.

6.1.1.5 Range of Facilities Covered for Hospitalized Events

Events occurring to cohort members in acute care hospitals are investigated, regardless of where the hospital is located. Events in other institutions providing medical care (such as nursing homes, rehabilitation hospitals, long-term chronic disease hospitals and psychiatric hospitals) are not investigated. Cohort events in hospitals in the study community are identified by review of the discharge indexes from these hospitals and by the annual follow-up interview. The annual follow-up interview also allows identification of events occurring in or leading to admission to acute care hospitals out of the study community. Events in out-of-area hospitals will generally have to be investigated by requesting a complete copy of the medical record to be mailed to the Examination Center.

6.1.2 Identification of Deaths

6.1.2.1 Death Certificates

JHS obtains a monthly printout from the state department of health of deaths in the community, from which cohort deaths are identified. Deaths occurring in cohort members are also identified if the member has moved out of the study community. Methods include systematic review of death certificates, annual follow-up interview, hospital chart review, use of obituary notices and other means. The corresponding death certificate is located and abstracted onto the JHS Death Certificate Form (DTH). ICD10 codes for both the underlying and contributory causes of death are recorded for all deaths.

6.1.2.2 Deaths Occurring Outside the Study Area

Deaths outside of the study area but within the state are included on State Health Department monthly printouts, but some delay between the death and death registration is expected. The delay for out-of-state deaths is even greater, and they may appear only on final death files at the State Health Department. If the death certificate file is reviewed for the JHS prior to receipt of the out-of-area certificates, a subsequent review is undertaken to identify these deaths. If the location of an out-of-area death is learned through the annual interview with a participant's proxy, a copy of the death certificate can be obtained directly.

Deaths occurring outside the study community are also identified through the National Death Index and, by monitoring of obituaries.

6.1.2.3 Identification of Deaths Requiring Special Investigation

Deaths in cohort members that occurs out-of-hospital (as defined in Section 6.2.1.2) require a special investigation to determine whether or not they died of CHD if their death certificates have any of the following ICD10 codes for the underlying cause:

E10-E14, I10-I11, I20-I25, I46-I51, I70-I9(except I97.2), J81, J96, R96, R98 and R99.

For a listing of disease categories see Appendix I.

Deaths in hospitalized cohort members which occur before an ECG or a complete set of enzymes is obtained also require special investigation, if the death certificate has one of the death certificate codes as shown.

The special investigation required for these deaths is described in Section 6.2.1.2.

6.2 Event Investigation

For the hospitalized event of MI, investigation entails review of the hospital record. Investigation of the fatal events occurring in cohort members includes review of the death certificate and hospital record where available (Section 6.1).

6.2.1 Procedures for Fatal CHD

The Death Certificate (DTH) Form is completed for all eligible fatal events. A worksheet and the Surveillance Event Inventory/Linkage Summary (SXI) Form are used to monitor selection and completion of investigation forms. One or more of the following data forms may be completed: Hospital Record Abstraction (HRA) Form, Stroke (STR) Form, Informant Interview (IFI) Form, Physician Questionnaire (PHQ), and the Coroner/Medical Examiner Report (COR) Form. Autopsy reports for cohort members are copied.

For out-of-hospital deaths and some inadequately diagnosed in-hospital events, investigations include physician questionnaires, interviews with next-of-kin and collection of other information (see below).

6.2.2 Out-of-Hospital CHD Deaths

CHD deaths occurring outside of regular acute care hospitals are categorized as "out-of-hospital CHD deaths". This includes deaths in nursing homes and other chronic care facilities. It also includes persons dead on arrival at acute care hospitals, dying in outpatient departments or emergency rooms, or admitted without vital signs. For purposes of defining out-of-hospital death, "no vital signs" means no pulse rate or no systolic blood pressure. A person admitted on a respirator who never had a pulse rate or a systolic blood pressure off the respirator is also considered an out-of-hospital death.

For out-of-hospital deaths information is sought from the decedent's family and physician(s) within 6 months after death. The family member is contacted for an interview, and the physician is sent a questionnaire. Whenever possible, the informant is the spouse or another family member of the decedent. Also, the informant may be someone else who witnessed the death. Some death certificates contain the names of the spouse and a witness.

If neither an Informant Interview (IFI) nor a Physician Questionnaire (PHQ) form can be completed, then the Hospital Discharge Indices from eligible hospitals are checked for the period covering 28 days before death. If an ICD code eligible hospitalization is found, a HRA is abstracted, regardless of discharge day.

6.2.3 Procedures for Fatal Events

The Cohort Eligibility Form (CEL) and the DTH Form are completed for all fatal events occurring in cohort members. One or more of the following forms may also have to be completed: 1) Hospital Record Abstraction Form (HRA), 2) Informant Interview Form (IFI), 3) Physician Questionnaire (PHQ), and 4) Coroner/Medical Examiner Report Form (COR) and their supplements.

The DTH Form is completed and submitted to the Coordinating Center prior to or concurrent with submission of other forms. Occasionally it is necessary to obtain certificates for deaths occurring out-of-state to study area residents by writing to the state in which the death occurred.

A proportion of fatal events (in-hospital or out-of-hospital) are coroner or medical examiner's cases. This means that the county coroner or state medical examiner has performed an investigation of the circumstances of death in order to ascertain whether the causes were natural. In this case, the coroner/medical examiner signs the death certificate. In general, the coroner/medical examiner takes cases of unexpected death where no physician was in attendance during the 24 hours prior to death. During this investigation, the coroner/medical examiner may or may not order an autopsy. Any death where a legal question is likely to arise (e.g., after surgery, during an automobile accident, etc.) will probably be a coroner/medical examiner case. If a death is certified by a coroner/medical examiner, the Coroner/Medical Examiner Form is completed and submitted to the Coordinating Center. If an autopsy is performed, a copy of that report is sent to the Coordinating Center.

Specific procedures for investigating in-hospital and out-of-hospital deaths and requirements for completion of the other forms listed above are given in the next two sections.

6.2.1.1 In-Hospital Deaths

In-hospital deaths may be identified initially from death certificates or hospital discharge indexes. Hospital records for these events are abstracted if eligible as hospitalized events according to the rules. The Death Certificate Form is also completed and sent to the Coordinating Center for all deaths.

If the in-hospital death is initially identified from the hospital discharge index, the death certificate printout must be crosschecked to avoid duplication. If the in-hospital death is initially identified from the death index, the hospital discharge index must be crosschecked. Occasionally the hospital lies outside the catchment's area for the JHS community. In this case, this fact is noted on the Death Certificate Form and an attempt is made to find and, if eligible, abstract the hospital record.

Cohort members who die in the emergency room, are pronounced dead on arrival at the hospital, or are admitted without vital signs are reclassified as out-of-hospital deaths. Only the administrative data of the Hospitalized Event Form are recorded for patients without vital signs. If the death is first identified from the death index and if the death certificate indicates "dead on arrival," an attempt is made to find the hospital record in order to verify this information.

If the hospital record indicates that the cohort member has been transferred directly from another acute care hospital or is transferring directly to another such hospital, the record for the other hospitalization is found and reviewed.

6.2.1.2 Out-of-Hospital Deaths

Out-of-hospital deaths with one of the eligibility codes given in Section 6.1.2.3 require a special investigation into the cause of death. For this purpose out-of-hospital death is defined to include:

1. Deaths occurring outside of regular acute care hospitals.
2. Deaths occurring in hospital emergency rooms or outpatient departments.
3. Persons who were either dead on arrival or were admitted without vital signs. For purposes of defining out-of-hospital death "no vital signs" means no pulse rate and systolic blood pressure (or admitted on a respirator with no pulse rate or systolic blood pressure at any time off the respirator).

When the special investigation for out-of-hospital deaths is required, the information from the decedent's family and physician must be obtained within 6 months after death if feasible. The former is contacted for an interview, the latter by questionnaire. Often the informant is the spouse or other family member of the decedent. On other occasions the informant is someone else who witnessed the death or someone whose name is mentioned on the death certificate.

First an attempt is made to contact and interview the spouse or a first-degree relative (i.e., son, daughter, or sibling) of the decedent, or someone else who lived with the decedent. If another person witnessed the death, this person is interviewed as well. Using the information provided by the participant at the time of the clinic interview, the informant's telephone number can be identified, and a "Format 1" letter sent (Appendix II). If a number cannot be found when reviewing information in the clinic interview, a reverse ("criss-cross") directory is used. If the informant's telephone number is still unavailable, a "Format 2" letter is sent asking the informant to provide a telephone number on the enclosed, self-addressed stamped post card. A copy of the participant's consent form is attached to the letter to the informant. These letters are sent with both the interviewer and the Examination Center Principal Investigator's signatures. After enough time elapses for the "Format 1" letter to arrive, or after receiving the reply post card to the "Format 2" letter, the interview is conducted using the Informant Interview Form. This interview may be conducted over the telephone, or if necessary, in person. If no reply is received, a "Format 4" letter is sent to next-door neighbors (identified by the reverse telephone directory) to request information on the whereabouts of the potential informant. A "Format 4" letter is also sent to the neighbor(s) when an informant's telephone number is initially available, but attempts at telephone contacts are unsuccessful. If no reply is received from the neighbor(s), no further effort is needed.

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

Information is sought from physicians by sending the Physician Questionnaire. From both the clinic and informant interviews an attempt is made to identify the physician(s) who attended the decedent during the four weeks period prior to death. One questionnaire is sent to the physician who signed the death certificate. Another questionnaire is sent to the physician (if any, and if different from the first) who saw the patient for heart disease during the 28 days prior to death. Release-of-Information Forms signed by the deceased cohort participant are attached to these letters. If there is no response after four weeks of the initial mailing to the physician, a follow-up letter and another copy of the Physician Questionnaire are sent. If there is no response after eight weeks of the initial mailing, the physician is contacted by telephone. Up to two (the two most complete) Physician Questionnaires may be completed for a given event.

If the decedent died in a nursing home, personnel are asked to complete a Physician Questionnaire based on the nursing home record. JHS/ARIC may offer to assist with abstraction if this would be helpful.

A Release of Information Form may be needed.

If information provided by the informants or physicians indicates that a person who died out-of-hospital was hospitalized within 28 days prior to death for MI or heart surgery, an attempt is made to ascertain the discharge diagnoses and, if applicable, review and abstract the hospital record. Requests to hospitals include copies of the JHS/ARIC release forms.

6.2.1.3 Procedures for Hospitalized Events

For hospitalized events with one of the discharge diagnosis codes for MI (402,410-414, 427, 428, 518.4), the Cohort Eligibility Form is completed. For a possible MI, the Hospital Record Abstraction Form is used for hospital record abstraction. For the special case of MI, for events with discharge codes other than ICD9 410 or 411, if the patient was discharged alive with no ECGs taken and no cardiac enzymes measured, only the administrative information on the Hospital Record Abstraction Form is completed.

For certain ICD9 procedure and diagnosis codes (35-39, 88.5, 88.72, 92.05, 250, 390-459, 786.02, 786.09, 794.3, 798, 799), which refer to conditions, more remotely related to MI, the medical record is obtained and its discharge summary reviewed. Any evidence in the discharge summary of the occurrence of MI requires the use of the Hospital Record Abstraction Form.

For all remaining ICD9 codes, the discharge lists are perused and only the discharge diagnoses recorded. These latter codes do not lead to hospital abstraction.

Abstracting of cardiac enzyme levels and ranges, copying of ECGs and treatment of transfer status follow guidelines specified for ARIC in manual 3, Version 6.

6.2.1.4 Summary of Cohort Investigations

Event Type	CEL	DTH	PH Q	IFI	FORM CO R	HRA (Full)	HRA (Part)	SXI*
Out-of-Hospital Death (CHD eligible)	Y	Y	Y	Y	Y			Y
Hospital Death (no vital signs at arrival, CHD eligible)	Y	Y	Y	Y	Y*		Y	Y
Hospital Death (vital signs at arrival, CHD eligible)	Y	Y			Y*	Y		Y
Hospitalized Case (discharged alive, CHD eligible)	Y					Y		Y
Hospitalized Case (not CHD eligible)	Y							
Death (not CHD eligible)	Y	Y						Y

* If a death is certified by a coroner/medical examiner, the Coroner/Medical Examiner Form is completed and submitted to the Coordinating Center. If an autopsy is performed, a copy of that report is sent to the Coordinating Center.

6.2.1.5 Summary of CHD Event Investigations

The following scheme summarizes the forms completed for eligible events:

1. Out-of-hospital CHD death (died in outpatient department, includes DOA, ER admitted without vital signs)
 - a) Death Certificate (DTH) Form.
 - b) Up to two Physician Questionnaires (PHQ) and three Informant Interview (IFI) Forms.
 - c) Coroner Form on all coroner/medical examiner's (COR) cases and Hospital Record Abstraction (HRA) Form on cases admitted to a catchment's area hospital in past 28 days with heart conditions meeting JHS screening codes regardless of day of discharge.
2. *Hospital CHD deaths, no vital signs in-hospital
 - a) DTH.
 - b) First part of HRA.
 - c) PHQ, IFI, COR.
3. *Hospital CHD death, vital signs sometime in hospital
 - a) DTH, HRA (full).
4. *Hospitalized CHD case, discharged alive
 - a) HRA (full).

*If a patient also transferred to or from a catchment's area hospital, complete an additional Hospital Record Abstraction form.

6.3 Diagnostic Criteria

Events occurring among cohort participants receive a computer derived diagnosis classification into fatal diagnostic categories (definite fatal myocardial infarction, definite fatal CHD, possible fatal CHD, non-CHD death) and MI categories (definite, probable, suspect, and no). However, for cohort events, the final diagnosis classification is determined by MMCC review. The only exceptions are those outlined in Section 6.4.1.1.

6.3.1 Hospitalized Myocardial Infarction (MI)

As described in Section 6.1.1, all hospitalized events occurring in cohort members are identified; detailed chart abstraction is carried out only when acute MI is suspected. In addition, hospitalization for mild and chronic manifestations of ischemic heart disease, such as angina pectoris and congestive heart failure. (So-called silent infarctions are not identified from the hospital records, but from ECG changes occurring to cohort members between their baseline and follow-up examinations.) Both Q-wave (transmural) and non-Q-wave (non-transmural) infarctions are sought in all hospital records abstracted.

It is recognized that aggressive treatment of signs and symptoms of impending myocardial infarction, such as angioplasty, Coronary Artery Bypass Graft or thrombolytic therapy, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately. The use of such modalities are recorded and subject to data analysis, but are not employed in the criteria for diagnosis. A computer derived diagnostic classification is created for all eligible cohort events. These categories (definite MI, probable MI, suspect MI and No MI) follow the same criteria outlined in the cohort morbidity and mortality section 2.2.2 to 2.2.4.

6.3.1.1 Definition of Cardiac Pain

1. Pain occurring anywhere in the anterior chest, left arm or jaw, and
2. Absence of a definite non-cardiac cause of chest pain.

6.3.1.2 Definitions of Electrocardiographic Criteria:

The ECG series is assigned the highest category for which criteria are met, i.e., evolving diagnostic ECG patterns are higher than diagnostic ECG patterns, which are higher than evolving ST-T patterns, which are higher than equivocal ECG patterns, which are higher than other, which are higher than uncodable.

To fit an evolving ECG Pattern (Evolving Diagnostic and Evolving ST-T) two or more recordings are needed. Changes must occur within lead groups, i.e., lateral (I, aVL, V6), inferior (II, III, aVF), or anterior (V1-V5) and be confirmed for all codes by Serial ECG comparison.

Example

Reference ECG codes: 1-3-4 4-0 5-0 9-0
 Follow-up ECG codes: 1-2-4 4-0 5-2 9-0

To be considered Evolving Diagnostic (pattern ED3) both the 1-2-4 and the 5-2 must be determined to be Significant Increase by Serial Change rules. If the 1-2-4 change is not Significant Increase and the 5-2 change is Significant Increase, then the change would fit Evolving ST-T (pattern EV3). If the 5-2 change is not Significant Increase, then pattern would

be Diagnostic ECG (pattern D1) because of the 1-2-4, regardless of whether or not the 1-2-4 change is Significant Increase.

Minnesota Coding Procedures

The following ECG tracings are identified:

1. The first codable ECG after admission;
2. The last codable ECG recorded before discharge; and
3. The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event.

Photocopies of the cohort hospital ECGs are sent to the Minnesota Coding Center in Minneapolis for Minnesota Coding, using the Cohort Hospital ECG Form (ECG) shown in Appendix P of Manual 5. ECGs are read three times, blinded; the final codes are adjudicated by a senior coder. Minnesota Code criteria are in Appendix E of Manual 5.

The data from the ECG form is entered and a determination is made at the Coordinating Center by computer algorithm as to whether or not the Minnesota Code change criteria are met. A list of those IDs that fit the change criteria (i.e., any pattern ED1 through ED7 or EV1 through EV5, defined above) is sent to the ECG Coding Center. ECGs for these IDs are examined side by side for Serial ECG change.

Simultaneous ECG comparison is performed on the final Minnesota codes using the first codable ECG of the hospitalization as the reference. Serial ECG changes are determined three times, blinded. Serial change categories are 1) significant increase, 2) decrease (4-, 5-, and 9-2 codes, but not for Q-codes), 3) no change (this implies no increase for Q-codes) or 4) technical problem. The final categories are adjudicated by a senior coder and added to the EKG Form.

As an example, the JHS protocol defines a new Minnesota code 1-2-7 as a potential ischemic event. Persons with this severity of ECG change will have simultaneous ECG comparison. The ECG comparison procedure (for this case) requires a ≥ 1 mm R-wave amplitude decrease between corresponding leads of the reference and comparison ECGs. The criteria for 1-2-7 are QS patterns in V1, V2 and V3. If the reference ECG has R-waves that are ≥ 1 mm tall in V1 or V2 or V3, when comparing these ECGs side by side, and the R-waves in the reference ECG appear to decrease the appropriate amount (at least 1 mm), then a "significant increase" is noted on the Appendix O form. If the reference ECG has R-waves < 1 mm tall, it cannot fulfill the change criteria and no change (or no increase) is noted.

6.4 Event Determination

Final assignment of diagnostic categories for all cohort events of interest in the JHS is made by the MMCC, after initial assignment to diagnostic categories is carried out by computer algorithm. The final classification of a cohort event is that preferred by the MMCC review process. This section describes the procedures by which these determinations are made.

Computer-generated summaries of all relevant coded information from the data collection forms are provided to the MMCC in summary form (Event Summary Form (ESF)) for review. In addition, the MMCC considers remarks by family interviewers, hospital record abstractors, or clinic examiners or other uncoded information recorded on the data collection forms. These are recorded in the form of note logs in the database and made available for use by the committee. All cohort events (with some exception noted below) are reviewed by two members of the MMCC. The final diagnosis decision made by the MMCC reviewer is recorded on the CDX form.

For types of events which often are not classifiable by computer algorithm, e.g., out-of-hospital deaths, the diagnostic criteria given in Section 3.3 may not be specific enough to permit unequivocal

classification of each event by the MMCC. If the MMCC discovers a rule which helps standardize this process, it either 1) makes a recommendation to the JHS Steering Committee for further specification of the JHS diagnostic criteria or 2) records the rule as a part of the "case law" for its own use in classifying similar events.

In addition to diagnosing all cohort clinical events, the MMCC provides other information about these events. Examples include clinical judgments required prior to making diagnoses and resolution of conflicting evidence regarding the time interval between onset of symptoms and death. These are discussed in the appropriate sections below.

6.4.1 Diagnosis of Coronary Heart Disease

6.4.1.1 Hospitalized MI

The following cohort cases are automatically classified (do not require MMCC review). These account for 10-15% of the total number of cohort events.

1. The computer assigns a diagnosis to cohort events that skip out of the HRA form and no 410-discharge code is present. These events are automatically classified as NO_MI by the JHS diagnostic algorithm.
2. The computer also assigns a final diagnosis of NO_MI for cohort events with no 410 codes, no pain, normal or incomplete enzymes, and ECG finding that is absent, uncodable, or other.

All non-linked, non-fatal hospitalized CHD events where discharge codes do not include 410, chest pain is absent or present, enzymes are normal or incomplete, and ECG findings are equivocal, absent, or uncodable will automatically be assigned a final diagnosis of NO_MI by the computer.

All non-linked, non-fatal cohort cases that are not automatically classified by the computer will only be reviewed by one MMCC reviewer (instead of 2) and the computer. A second MMCC reviewer will adjudicate disagreements between the reviewer and the computer.

All other events including linked non-fatal hospitalizations, fatal hospitalization (linked and non-linked), and out-of-hospital death (linked and non-linked) are reviewed by two MMCC reviewers and an adjudicator if necessary. The only exception is for linked greater than 28-day deaths. These special reviews are sent to one MMCC reviewer with no adjudications.

6.4.1.2 CHD Death

Narratives recorded by family interviewers and other uncoded information is important in diagnosing deaths that occurred out-of-hospital. For many out-of-hospital events, the MMCC must resolve conflicting information collected from several informants. In-hospital deaths meeting the criteria for "Definite MI" require MMCC review for a possible Non-CHD cause of death before being classified as "Definite Fatal MI".

A computer diagnosis of "Definite Fatal MI", "Definite Fatal CHD" or "Non-CHD Death" is provided for those events for which all the necessary coded information is available and unequivocal. Except for a sample of unequivocal computer diagnosed Non-CHD Deaths, all cohort deaths require MMCC review and classification.

All out-of-hospital deaths classified as "Definite Fatal CHD" or "Possible Fatal CHD" requires an MMCC determination of the interval between the onset of symptoms and death. Differences between reviewers in time interval are not adjudicated.

6.4.2 Event Summary Forms (ESF)

Event summary forms for cohorts include information that is taken from various cohort forms (AFU and clinic visit forms). The information includes visit exam reports, annual follow-up information, previous cohort diagnosis for MI, and previous diagnosis for stroke. Autopsy reports, if available, can also be included for cohorts. For cohorts, it is the reviewer's decision whether to downgrade the "spurious" enzymes. The reviewer is given the downgraded enzyme values, original enzyme values, and 2 pages of additional enzyme data.

6.4.3 Additional Cohort Forms

The Cohort Eligibility Form (CEL) is used to determine if a cohort event is eligible for cohort morbidity and mortality. Data from the CEL is run through various data and code checks against other cohort morbidity and mortality forms such as the DTH and HRA. The Annual Follow Up Form (AFU) data pertaining to Rose angina are printed out on the cohort ESF and is also used to locate any possibly missing cohort events that are cohort morbidity and mortality eligible.

6.5 Diagnosis of Prevalent MI at Baseline and Interim MI Between Clinic Visits

6.5.1 Procedures

6.5.1.1 Minnesota Coding

Cohort 12-lead ECGs will be taken during Examination Center visits. One ECG is taken at the baseline exam and a second ECG is taken at the follow-up exam three years later.

Abnormal ECGs and a 10% selection of normal ECGs will be transmitted from the Epicare Computer Center to the Minnesota Coding Center in Minneapolis. These ECGs will be coded visually by the Minnesota Code. ECGs are read three times, blinded; the final codes are adjudicated by a senior coder.

6.5.1.2 Adjudication

The visual Minnesota Codes will be sent to the Coordinating Center for comparison with the computer-generated codes. Adjudication between the visual code and the computer code will be performed by two electro cardiographers only on ECGs that have a discrepancy involving any Q-code, or any 4-2, 4-1-2, 4-1-1, 5-2, 5-1 or 9-2. The Coordinating Center determines the IDs that have any of these discrepancies and will send a report form to the Minnesota Coding Center listing the ID, acoustic, date and time of ECG, the visual codes and the computer codes. These ECGs are examined and the adjudicated codes are recorded on the report form, which is returned to the Coordinating Center.

6.5.1.3 Serial ECG Coding

The Coordinating Center adds the adjudicated codes to the database as the definitive Minnesota Codes for the ID involved.

When two ECGs from different Examination Center visits are available, a determination is made at the Coordinating Center as to whether or not Minnesota Code change criteria are met. A list of those IDs that fit the change criteria (i.e. any pattern ED1 through ED7) is sent to the ECG Coding Center. ECGs for these IDs are examined side by side for Serial ECG change.

Simultaneous ECG comparison is based on the final Minnesota Codes. Serial ECG changes (significant increase, no increase or technical problem) are determined three times; the final categories are adjudicated by a senior coder and added to the Appendix O form. The simultaneous ECG evaluation procedure uses the ECG of the first clinic visit as the reference ECG for comparison.

JHS requires Minnesota Code change plus agreement by simultaneous ECG comparison before declaring the ECG pattern change meets JHS criteria for an interim MI.

6.5.2 Definitions

A determination that a JHS participant has had an MI, either prior to the initial clinic visit or between visits, can be made on ECG evidence alone, using the following criteria:

6.5.2.1 Prevalent MI at Baseline

Baseline ECG (initial cohort visit) coded:

a) Any 1-1-X code

OR

b) Any 1-2-X and 4-1-1 or 4-1-2 or 4-2 or 5-1 or 5-2

6.5.2.2 Interim MI between Cohort Visits

This is an Evolving Diagnostic ECG Pattern (ED1 through ED7) between the baseline ECG (initial cohort visit) and an ECG from a later cohort visit. An “unrecognized MI” or “silent MI” can be said to have occurred in the interval between visits if such ECG evidence of MI was found and there was no clinically recognized MI event picked up by the hospitals during follow-up. More information on the determination of unrecognized MI can be found in Borland 2002.

7.0 COHORT MORBIDITY AND MORTALITY FOR STROKE

7.1 Introduction

Potential clinical stroke events are identified and then validated for cohort participants. The procedure for identification, investigation, and classification of these events is outlined below. More information on the stroke classification system can be found in Rosamond, 1999.

7.2 Identification of Stroke Events

There are two ways of identifying cohort stroke events. The abstractors review the CEL forms; identify those cohorts with a stroke code listed on their hospital discharge form and/or one of the following keywords listed in their discharge summary or mentioned during the admission: stroke, TIA, cerebrovascular disease, cerebral hemorrhage, cerebral infarction, subarachnoid hemorrhage, cerebral embolus, paralysis, aphasia, diplopia, lacunar (syndrome infarction), dysarthria, cerebral angiography, carotid endarterectomy, CT/MRI scan showing cerebrovascular findings, or Neuro ICU care. Death certificates listings are also reviewed for the presence of an underlying cause of death suggestive of stroke (ICD10 code: I60-69). Stroke deaths without additional hospitalization data will not be investigated. Classification of non-linked stroke deaths (not linked to a hospitalization within 28 days) is classified on the basis of underlying cause of death code.

7.3 Investigation

If a cohort event meets the above criteria, a specially trained abstractor then reviews these records and completes the Stroke Form (STR, Appendix VI). Approximately every month, these data are sent to the Coordinating Center and run through a series of data check programs.

7.4 Diagnosis

All potential stroke hospitalizations are automatically assigned a stroke diagnosis by the computerized stroke algorithm (Appendix III). The computerized stroke algorithm classifies stroke events based on the data from the STR form and the DTH form if the event is a death. The possible computer stroke classifications are as follows: definite or probable subarachnoid hemorrhage (SAH); definite or probable brain hemorrhage (IPH); definite or probable brain infarction, thrombotic (TIB); definite or probable brain infarction, non-carotid embolic (EIB); possible stroke of undetermined type; undocumented fatal stroke; out of hospital death stroke; or no stroke. Undocumented fatal strokes and out of hospital death strokes do not require a STR form. In the rare case where a stroke event meets the criteria for two different diagnoses, the following hierarchy is used:

Definite IPH
 Definite SAH
 Definite EIB
 Definite TIB
 Probable IPH
 Probable SAH
 Probable EIB
 Probable TIB
 Possible stroke of undetermined type

A Stroke Event Summary Form (S-ESF) is produced for each stroke event that include information on number of major/minor symptoms, procedures, discharge diagnosis codes, and the computer classification of the event. The S-ESF and all hospital materials for the stroke event are sent to one member of the Stroke-Mortality and Morbidity Classification Committee (S-MMCC) for classification. The S-MMCC reviewer fills out a Stroke Final Diagnosis Form (SDX). The S-MMCC reviewer can either cite exclusionary conditions such as major head trauma, neoplasm, CNS infection, etc., or classify the stroke event in one of the following categories: definite or probable subarachnoid hemorrhage (SAH); definite or probable brain hemorrhage (IPH); definite or probable brain infarction,

thrombotic (TIB); definite or probable brain infarction, non-cardio embolic (EIB); possible stroke of undetermined type; or other (no stroke) if no exclusionary conditions were met. Event summary forms (S-ESF) are not produced for the following three event types: 1) Events where the STR form indicates that neurological symptoms did not last more than 24 hours or there were no new neurological symptoms prior to or during the hospital admission; 2) Out of hospital stroke deaths not linked to a hospitalization; or 3) hospitalized events with no medical chart available. These events are automatically classified without physician review as “no stroke”.

7.5 Classification

The one S-MMCC reviewer and the computer algorithm determine final classification of stroke events. If there are discrepancies between these two sources, the final event classification is determined by a second reviewer (stroke –adjudicator). An event is considered classified if one of the following situations occurs:

1. If the reviewer has not cited any exclusionary conditions and the computer algorithm diagnosis agrees with the reviewer's diagnosis, the event is classified as such.
2. If the reviewer does cite exclusionary conditions and the computer algorithm diagnosis is no stroke, the event is classified as no stroke.

If the S-MMCC reviewer and the computer algorithm disagree, the adjudicator's classification is taken as the final classification.

Table 7.1. Matching ICD-9 with ICD-10 for Underlying Cause of Death Codes related to STROKE

ICD-9 Code	ICD-9 Classification	ICD-10 Code	ICD-10 Classification
430	Subarachnoid hemorrhage	I60	Subarachnoid hemorrhage
431	Intracerebral hemorrhage	I61	Intracerebral hemorrhage
432	Other intracerebral hemorrhage	I62	Other nontraumatic intracranial hemorrhage
433	Occlusion of precerebral arteries	I63	Cerebral infarction
434	Occlusion of cerebral arteries	I63	Cerebral infarction
		I65	Occlusion of precerebral arteries not resulting in infarction
		I66	Occlusion and stenosis of cerebral arteries not resulting in infarction
435	Transient ischemic attack	G45	Transient cerebral ischemic attacks and related syndromes (Not relevant death classification. Do not include in algorithm)
436	Acute, ill-defined CVD	n/a	n/a
437	Other ill-defined CVD	I64	Stroke, not specified as hemorrhage or infarction
		I67	Other CVD
438	Late effects of CVD	I69	Sequel of CVD

Important Notes:

I63 includes occlusion and stenosis of cerebral and precerebral arteries resulting in infarction.

I65 includes embolism and narrowing not resulting in infarction

Excluded is ICD-10 code I68, cerebrovascular disease in diseases classified elsewhere (cerebral amyloid angiopathy, cerebral arteritis in infectious and parasitic diseases)

Comparability ratio for ICD-9 cerebrovascular disease 430-434, 436-438 and ICD-10 I60-I69 reported to be 1.04

8.0 COHORT MORBIDITY AND MORTALITY FOR CONGESTIVE HEART FAILURE

8.1 Inpatient

8.1.1. Introduction

At the time of this printing the protocol for identifying and classifying heart failure events among cohort participants has not been finalized. Below is a summary of the preliminary approach to heart failure classification.

8.1.2. Identification of CHF Events

Definition: Congestive Heart Failure is defined as a constellation of various symptoms and physical signs that occur in a participant whose cardiac output cannot match metabolic need despite adequate filling pressure as a result of various disease processes.

8.1.33 Classification of CHF Events

Definite

Discharge Diagnosis of 428 and/or underlying cause of death I50
 AND
 Radiographic findings consistent with CHF or increased venous pressure >16 or Dilated ventricle/left ventricular function <40% by echo/MUGA scan
 OR
 Autopsy finding of pulmonary edema/CHF

Probable

Discharge Diagnosis of 428 and/or underlying cause of death I50
 AND
 Any 3 findings from CHF criteria (list below)

- Paroxysmal nocturnal dyspnea
- Orthopnea
- Distended neck veins/jugular venous distention
- Dyspnea on exertion
- Shortness of breath (dyspnea at rest)
- Night Cough
- S3
- Rales
- Hepatojugular reflux
- Hepatomegaly
- Bilateral lower extremity edema
- Tachycardia (120+)
- Decrease in vital capacity by 1/3

COHORT MORBIDITY AND MORTALITY FOR CONGESTIVE HEART FAILURE

8.2 Outpatient

8.2.1. Introduction

At the time of this printing the protocol for identifying and classifying heart failure events among cohort participants has not been finalized. Below is a summary of the preliminary approach to heart failure classification.

8.2.2. Identification of CHF Events

Definition: Congestive Heart Failure is defined as a constellation of various symptoms and physical signs that occur in a participant whose cardiac output cannot match metabolic need despite adequate filling pressure as a result of various disease processes.

8.2.3 Classification of CHF Events

Definite:

(1) Outpatient diagnosis of ICD 428 and/or underlying cause of death 150 (out of hospital)

AND

(2) Outpatient diagnosis of ICD 428 and CXR findings consistent with pleural effusion/pulmonary edema/cephalization of vessels/cardiomegaly (1 and 2)

OR

(3) Outpatient diagnosis of ICD 428 and echo consistent with dilated ventricle/left ventricular function < 40% (1 and 3)

OR

(4) Outpatient diagnosis of ICD 428 and any 3 findings from CHF criteria within 2 weeks of our patient visit (1 and 4)

Paroxysmal nocturnal dyspnea

Orthopnea

Distended neck veins/jugular venous distention

Dyspnea on exertion

Shortness of breath (dyspnea at rest)

Night Cough

S3

Rales

Hepatojugular reflux

Hepatomegaly

Bilateral lower edema

Tachycardia (120+)

Decrease in vital capacity by 1/3

Probable

Outpatient diagnosis of ICD 428 and/or underlying cause of death 150

OR

ICD 425.4 or ICD 518.4 with 1 or 2 of the symptoms listed below

AND

At least 1 but less than 3 findings from CHF criteria (list below):

Paroxysmal nocturnal dyspnea

Orthopnea

Distended neck veins/jugular venous distention

Dyspnea on exertion
 Shortness of breath (Dyspnea at rest)
 Night Cough
 S3
 Rales
 Hepatojugular reflux
 Hepatomegaly
 Bilateral lower extremity edema
 Tachycardia (120+)
 Decrease in vital capacity by /3

Unvalidated (underlying cause of death fatal heart failure-out-of hospital)

9.0 PROCEDURES FOR PREPARING MORBIDITY AND MORTALITY CLASSIFICATION COMMITTEE (MMCC)

9.1 CHD Reviews Specific to Cohort morbidity and mortality

The JHSCC generates the MMCC Event Summary Forms (ESFs) in the Data Management Program (MGP) as well as Annual Follow-up Events (AFUs). The steps taken at JHS in processing MMCC materials are to:

- A. **Separate and Organize ID Listings and Event Summary Forms (ESFs):** Job 20: Each Cohort AFU, usually one page, must be placed first when all the materials are collated with the ESFs of that event. Job 16: Linked Non-Fatal Hospitalizations (NFH-L), In-Hospital Deaths (IHD), and Linked In-Hospital Deaths (IHD-L). Job 17: Non-Linked Non-Fatal Hospitalizations (NFH). Job 18: Out-of Hospital Deaths (OHD). Job 19: Linked Out-of-Hospital Deaths (OHD-L). The number of events in Jobs 16, 17, 18, and 19 are recorded in a table, "Current Status of JHS Cohort morbidity and mortality Reviews", for monitoring purposes.
- B. **Collect All Needed ID Medical Records:** Procedures for obtaining materials are the same as for Community Events. There will be no materials at the Examination Center for Job 18.
- C. **Collate and Copy Materials for Each Event for Review:** The pages of all events to be reviewed must have the AFU sheet(s) first with the EFSs next; linked events follow, in reverse chronological order. Job 17 must be copied once. Unless events go to special view, Jobs 16, 18, and 19 need to be copied twice. The original set is placed in the event folder behind the medical record. The medical records, received in duplicate from the Examination Center, are copied once for Job 16, 18, and 19. The AFUs and ESFs are stapled to the event for review and the linked events are stapled with the ESFs and record; OHD events have none, as will others, and are stapled together. Each event is clipped together with a prepared CDX Form on top.
- D. **Prepare the Events for Reviewers:** The IDs to be sent to a reviewer are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded for Jobs 16, 17, 18, and 19.
 1. **Non-fatal Hospitalizations (NFH):** (Job 17) The Cohort morbidity and mortality CDX Form is prepared for a single reviewer using the Sequence Number X1 and Parts A and B of the Form with the Type of Review in Question 1.b. as "O" and the Code Number of the intended reviewer. (Prior to 1995 two reviewers diagnosed the non-linked NFH events.)

2. **Linked Non-fatal Hospitalizations (NFH-L) and In-hospital Deaths, Non-linked and Linked (IHD and IHD-L):** (Job 16) The CDX Form is usually prepared for two reviewers using Sequence Numbers X1 and X2 with the Type of Review in Question 1.b. as “O” and the Code Numbers of the intended reviewers. The events that are NFH-L require Parts A and B completed and IHD and IHD-L require Parts A, B, and C completed by both reviewers.
3. **Special Linked Non-fatal Hospitalizations (NFH-L) and In-hospital Deaths, Non-linked and Linked (IHD and IHD-L):** (Job 16) The Sequence Number is listed on the ESF for the event with X5, as spanning >28 days. The CDX Form is prepared for a special reviewer with the Type of Review in Question 1.b. as “G” and the Code Number of the special reviewer. The events that are NFH-L require Parts A and B completed and IHD and IHD-L require Parts A, B, and C completed.
4. **Non-linked Out-of-hospital Deaths (OHD):** (Job 18) Two CDX Forms are prepared.
5. **Linked Out-of-hospital Deaths (OHD-L):** (Job 19) The CDX Form is usually prepared for two reviewers using Sequence Numbers X1 and X2 with the Type of Review in Question 1.b. as “O” and the Code Numbers of the intended reviewers. These Cohort events require Parts A, B, and C to be completed by both reviewers. Rarely is there a special review generated for an event with Sequence X5, spanning >28 days; the CDX Form prepared for the special reviewer has the Type of Review in Question 1.b. as “G”.

9.2 Adjudication of CHD Reviews

In Cohort morbidity and mortality, adjudication is necessary when the preferred classification (CDX Questions 7B, 14B) or the algorithm classification (Questions 6, 13), if there is no preferred classification, disagrees between two reviewers. For Non-fatal Hospitalizations in Job 17, if the one reviewer disagrees with the JHS algorithm (Question 7.a. is “No”), then adjudication is necessary for Question 7.b. Special reviews (Sequences X4 and X5) do not require adjudication. Adjudication is required only for the most current data if there were data changes initiating a new review.

Copy the completed CDX Forms that were returned by the original reviewers and the ESFs with the medical records that were sent to the original reviewers. The CDX Forms are prepared for the adjudicator using Sequence Number X3, as “Adjudication”, with Type of Review marked in Question 1.b. as “A”. These events require the same Parts completed as the original review and have the same IDs and Batch Number as the original reviews. Clip the adjudicator’s new CDX Form on top of the packet of each event to adjudicate. Community events for adjudication are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded. Follow the same procedures for shipping the adjudications as those for original reviews.

9.3 Monitoring Return of CDX Forms

Reviewers who do not meet expected deadlines are reminded. If forms are found to be incomplete, they are returned to the reviewer prior to data entry. The DES and MGP also check for incompleteness of forms with inconsistent answers; forms with these problems are returned to the original reviewers for resolution.

9.4 Monitoring Consistencies of New Reviewers

When new reviewers have been certified and are ready to begin reviewing cases, the number of CHD events is kept low; the type of reviews best suited to them are OHD, then IHD, and later linked events. As original reviewers, they are paired with experienced reviewers. Feedback to the new reviewers on the cases needing adjudication is helpful. A new reviewer, still requiring training, can be given the same set of events to review as two original reviewers with Sequence Numbers 0X or 1X, which are checked by hand, until the accuracy on the CDX Forms is acceptable for events to be entered into the DES.

9.5 Filing and Storing Completed CHD Reviews in Event_ID Labelled Folders

Verified CDX Forms are placed in the front of the Event_ID folder and filed in numeric order in secured CSCC file cabinets; any linked IDs are filed independently in numeric order at the same time.

Folders with CHD events *over 5 years old*, as determined from the MGP, can be removed from the secured JHS CHD file cabinets to secured off-site storage.

9.6 Stroke Reviews Specific to Cohort morbidity and mortality

All eligible Cohort events (those that have charts and neurological signs and symptoms) are reviewed for a stroke classification. The Stroke Data Management Program (MGP) generates the MMCC Event Summary Forms (ESFs) and lists for both original reviews and required adjudications for the classification of stroke.

The procedures taken at CSCC in processing Stroke MMCC reviews is similar, but less complicated than CHD reviews. The steps are to:

- A. Organize ID Listings and Collect ID Medical Records:** Upon notification that the Stroke MGP is ready, print out the 3 listings of Job 06. The stroke records are prepared and shipped by a special abstractor on a regular basis. If an event has not yet been sent to CSCC when the Stroke MGP generates a case for review, then it must be requested. ID-labeled file folders to contain the records sent must be prepared at CSCC; they are stored in file cabinets separately from the CHD records.
- B. Copy Medical Records and Sorted EFSs:** Both the original review and adjudication are sent to one reviewer; one set of materials is copied for each event. The ESFs are stapled to the specific record. The packets are prepared similarly to reviews for CHD events: each SDX Form is clipped to the packet of the EFS sheet(s) stapled to the record of the event.
- C. Prepare the Events for Reviewers:** Each 7-digit Event_ID is written in the set of boxes on the Stroke SDX Form. The original review is prepared for a single reviewer using the Sequence Number X1, the Batch Number from the MGP, the Type of Review in Question 1.b. as "O", and the Code Number of the intended reviewer. The SDX Form for the adjudicator is prepared with Sequence Number X3, the Batch Number from the MGP, the Type of Review in Question 1.b. as "A" and the Code Number of the intended reviewer. The IDs sent to a reviewer are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded for the reviews. The packet shipped, usually by Federal Express, contains a memo describing the cases, a copy of the log sheet, and the sets of reviews in numerical order. The memo states the date that the reviews are expected to be returned to CSCC, usually a period of 3 to 4 weeks, and requests that the reviewer notify CSCC if the reviewer will be unable to complete reviews for an extended time in the future.

- D. Adjudicate Stroke Events:** Adjudication is required if the original reviewer disagrees with the computer diagnosis (variable called “COMPDIAG”, listed on the sheet “Listing of ESF for Original Review”). When the original reviewer’s SDX Forms are returned and checked for completeness, the diagnosis should be compared with the “COMPDIAG”; if there is a disagreement, then the event can be sent for adjudication prior to the next stroke retrieval. The event for adjudication is sent to the stroke adjudicator with sequence number X3.
- E. Monitor Return of Stroke Reviews:** As reviewers return their SDX Forms, they are checked for completeness and then entered into the data entry system (DES) and stamped “keyed”. Each form is “verified” by a second individual entering the same data. The number of stroke cases under original review and adjudication are recorded in a table, “Current Status of JHS Cohort morbidity and mortality Reviews”.
- F. File and Store Completed Stroke Reviews in Event-ID Labelled Folders:** Verified SDX Forms are placed in the front of the Event_ID folder and filed in numeric order in designated secure Stroke file cabinets at CSCC.

9.7 Summary of the JHS MMCC Processing Procedures*

COHORT CHD: COMPLETION OF CDX FORM (Job 16-20)						
Type	MGP Job #	Seq #	MI DX ^a (part B)	Death DX ^a (part C)	Reviewer	Items to check for Adjudications ^b
NH ^a , Unlinked, >=1995 ^c	17,20	*1*	Yes	No	Anyone	Q7a
NH ^a , Linked	16,20	*1, *2	Yes	No	Anyone	Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank
IHD ^a , Linked & Unlinked	16,20	*1, *2	Yes	Yes	Anyone	<u>MI:</u> Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank <u>Death:</u> Q14b vs Q14b if both Q14b not blank Q14b vs Q13 if one Q14b is blank Q13 vs Q13 if both Q14b are blank
OHD ^a , Unlinked	18,20	*1, *2	No	Yes	Anyone	Q14b vs Q14b if both Q14b not blank Q14b vs Q13 if one Q14b is blank Q13 vs Q13 if both Q14b are blank
OHD ^a , Linked	19,20	*1, *2	Yes	Yes	Anyone	<u>MI:</u> Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank <u>Death:</u> Q14b vs Q14b if both Q14b not blank

						Q14b vs Q13 if one Q14b is blank Q13 vs Q13 if both Q14b are blank
Special Deaths	16	*5	Yes	Yes	Folsom	
Adjudication		*3	Same as Originals	Same as Originals	Conwill	
COHORT STROKE: COMPLETION OF SDX FORM						
Type	MGP job #	Seq #	Stroke DX^a (part B)	Stroke CL^a (part C)	Reviewer	Items to check for Adjudications
Original	06	01	Yes	If Q5=C or G	Shahar	Computer DX
Adjudication		03	Yes	If Q5=C or G	Cooper Folsom	

♣ Determination of possible linkages for events occurring > 28 days (from MGP Job 04) is not included in this summary table.

◆ * =0, 1, 2, depending on the number of times that an event was reviewed. If an event is reviewed for the first time, *=0. If an event is reviewed for the second time due to data changes, *=1, etc.

a) Abbreviations:

CL = Classification DX = Diagnosis
 NH = Non-fatal Hospitalizations IHD = In-Hospital Deaths
 OHD = Out-of-Hospital Deaths L-IHD = Linked IHD

b) Criteria for adjudication:

- Cohort with 1 review: compare preferred DX with computer DX (if Q7a is 'N', need adjudication).
- Cohort with 2 reviews: compare preferred DX between reviewers. That is, compare Q7b vs Q7b if both Q7b are not blank, Q7b vs Q6 if one Q7b is blank, Q6 vs Q6 if both Q7b are blank, Similarly for Death Dx (Q13 & Q14b)

NOTE: the comparison listed above is under the assumption that the CDX form is complete (no incomplete items), and Q6(determined by Q3-Q5. See Table 2 in the next page) and Q13 (determined by Q8-12 of the CDX form) are answered correctly. If Q6 and/or Q13 are answered incorrectly, data checks will be generated and the review is considered incomplete.

- Reviews with sequence numbers *3, *4 or *5 do not require adjudication.
- Cases needing adjudication should be processed right after receiving the reviews from reviewers.
MGP Job 05 (cohort morbidity and mortality) check the cases still needing adjudication.

- c) In ARIC before 1995, Unlinked Non-fatal Hospitalizations in cohort morbidity and mortality were reviewed by 2 reviewers with sequence number *1 & *2.
- d) MGP job 04.OUT is to be sent to Folsom for > 28 days linkage review. Feedback will be passed to the Statistician for the next MGP.
- e) MI diagnosis for unlinked Non-fatal Hospitalizations and linked out-of-hospital deaths are automatically classified by computers.
- f) Linked IHD cases: if MI is computer-classified, but not death, will require 2 reviewers (unless it's >28 death event). If both MI & Death require a manual review, a special review with seq # *4 will be assigned.
- g) MI diagnosis for linked out-of-hospital deaths is mostly automatically classified by computers. However, a portion of events which linked to >=2 hospitalizations require 2 reviews.

9.8 Procedures for Hospital Records Sent to the Coordinating Center

For the following type of events, Examination Center should deliver the duplicated material to the CC on a regular basis (without CC's request):

- All hospitalized cohorts that are non-skip-outs
- All who transferred with ICD-9 code 410 or 411 or ICD-10 code I20-24
- All deaths in Cohort

For each of these events, a manila right tab file folder is prepared with the event ID label affixed to the top with the added notation if the patient is a Cohort. Included in the file folder is one of the following, ranked in priority:

- Discharge summary
- Progress note of last physician and cardiac consultation
- Progress note of last physician and history and physical

Each page should have the ID label affixed (over the patient's name) and all caregivers' and patient's names *blinded with a black china marker*. These materials are duplicated and placed in the folder behind the completed "Checklist for Hospital Event Materials. Note that death certificates are no longer sent because the DTH form has been entered into the data entry system.

When a significant number of medical records have been prepared, they are put in numeric order and shipped to CC with JHS SHIPPING FORM and a DUPLICATED MATERIALS FOR MMCC SHIPPING INVENTORY sheet (see Appendix V. Duplicate Materials Shipping Forms) with places to fix event ID labels.

If CC requires hospital records for materials not sent for a particular patient's event, such as cases of hospitalizations to determine possible linkages, these are also prepared and sent in a similar fashion.

10.0 QUALITY CONTROL

Each year, the CC generates a set of Cohort morbidity and mortality QC report. In addition, central training for abstractors and MMCC reviewers are held once every 1-3 years to assure data quality.

10.1 Quality Control for Medical Record Abstractions

In JHS Cohort morbidity and mortality, hospital medical records for cohort participants with discharge ICD-9 code 410 or 411 are re-abstracted; 12 per abstractor per calendar year and event year. Each year, items in the re-abstracted HRA were compared to their original abstraction to compute the percentage of disagreement.

10.2 Quality Control for the Out-of-hospital Death Investigation

For OHD events, information from informants, patient's physicians and coroner/medical examiner need to be abstracted. Up to 3 Informant interviews (IFI) and 2 physician questionnaires (PHQ) may be collected. Each year, the percentage of completeness of the abstractions for OHD is computed.

10.3 Quality Control for the MMCC Reviews

Linked or fatal events require either 1 review by a special reviewer or 2 original reviews to determine their MI and/or fatal CHD classification. For events reviewed by 2 original reviewers, if their MI classification and/or death classification disagreed, that event was sent to an adjudicator for adjudication.

10.4 Summary of the Annual Cohort morbidity and mortality QC Report

Each year, the CC generates a QC report includes the following items:

- HRA QC
 - disagreement rates in repeat abstraction, by year and center;
 - % of missing data or unknown responses for HRA items, by year and center
 - % of missing charts, % of MI/death unclassifiable events, by year and center
- Completeness of event investigation for OHD
- MMCC QC
 - disagreement rates for MI/Death classification between 2 original reviewers, by year
 - % of original reviews disagreed with Adjudicators for MI classification, by reviewers
 - % of original reviews disagreed with Adjudicators for Death classification, by reviewers
 - % of dirty data (inconsistent answers among Q3-Q6) for MI classification, by year & reviewers
 - % of dirty data (inconsistent answers among Q8-Q13) for Death classification, by year & reviewers

10.5 Certification Procedures

10.5.1 Certification for Medical Records Abstraction

Medical record abstractors are re-certified every three years during a central (face to face) training session. Generally, these training sessions are conducted over a period of 2 days. The agenda of the training sessions include detail discussions of changes or updates to the data entry systems, updates to question by question instructions for each data collection form, review of ongoing quality control reports. A key feature of the training is the re-certification process. As a part of that process, each abstractor receives a packet of 4 medical records. Each abstractor completes a full hospital record abstraction (HRA) for each record and sends it in electronic form to the Coordinating Center. Answers from each abstractor for every item on the HRA form are compared and a printout generated. This is reviewed in detail during the training session, with discussion lead by the senior abstractor supervisor. Discrepancies between reviewers on any items are discussed in detail. Items with significant disagreement are identified and the appropriate sections of the question-by-question

instructions and protocols discussed. In addition, each center prepares and presents four cases for review and discussion by the group. An abstractor must successfully complete these exercises in order to be re-certified. The senior abstractor supervisor in consultation with the Chair of the Events Monitoring Committee makes the decision of re-certification.

10.5.2 Certification for Informants Interview

Staffs responsible for conducting informant interviews are also re-certified every three years at the central training. During the training session, the protocol and question-by-question instructions for completing the informant interview form (IFI) are reviewed in detail. A main focus of the informant interview re-certification is review of the informant narrative. Examples (n=40) of informant narratives from all Examination Center are read out loud during the session and critiqued by the interviewers and the supervisors. Successful completion of these exercises is required to be re-certified as an informant interviewer.

10.5.3 Certification for MMCC review

On an approximate annual basis the MMCC meets either in person or by conference call to conduct its training sessions. Topics for discussion during these training sessions include update on changes in ICD coding rules, innovations in diagnostic testing (e.g. incorporation of cardiac troponins), review of quality control data, update on form changes, group discussion of informant interviews and detailed discussion of changes to case law. A main feature of the training session is the re-certification process. As a part of recertification, a standard set of cases (a variety of types including linked and non-linked nonfatal hospitalizations, in-hospital deaths, out of hospital deaths) from cohort morbidity and mortality are distributed to all members prior to the meeting. Committee members are asked to complete the appropriate CDX form as they normally would do and send them to the coordinating center. The data from the CDX forms are summarized in table form and distributed for discussion during the re-certification process. Each case is reviewed in detail with special discussion among the group on any disagreement in diagnosis. This session is lead by the chair of the MMCC. In addition, special cases selected by the chair of the MMCC are presented and discussed in detail. Successful completion of these exercises, as determined by the chair of the MMCC is required for individuals to be re-certified.

11.0 CONFIDENTIALITY

Several procedures are in place to protect the security of the personal identifying information obtained from medical records. Personal identifiers (name, social security number, date of birth, gender, and race) are abstracted from the medical record for the purpose of linkage to the National Death Index. This information is used to determine vital status of Cohort participants who are lost to follow-up. For cohort morbidity and mortality cases, personal identifiers are used to determine long-term case-fatality of validated myocardial infarction events by either linkage with death certificate data provided by the state health departments or with the National Death Index. Except for the purposes of this linkage, all personal identifiers are removed from distributed datasets. Raw data files residing at the CC are password protected. Personal identifiers are "blacked out" on any paper copy of medical records sent to the CC and these copies are stored in locked secure rooms. Study personnel involved in medical record abstraction and handling of these data have been trained on the protection of human subjects in research.

12.0 REFERENCES

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Appendix I. ICD10 Codes for Identifying Cohort morbidity and mortality Events

ICD10 Codes for the Identification of Fatal CHD

(January 1, 1999 and beyond)

<u>Code</u>	<u>Title</u>
E10-14	Diabetes Mellitus
I10	Essential Hypertension
I11	Hypertensive Heart Disease
I20	Unstable Angina, angina pectoris
I21-23	Acute Myocardial Infarction
I24	Other Acute IHD
I25	Chronic IHD (including old MI)
I46	Cardiac Arrest
I47	Paroxysmal Tachycardia
I48	Atrial Fibrillation
I49	Other cardiac arrhythmias
I50	Heart Failure
I51	Ill-defined heart disease
I70	Atherosclerosis
I97(not I97.2)	Postprocedural disorder of circulatory system
J81	Pulmonary Edema
J96	Respiratory Failure
R96	Other Sudden Death
R98	Unattended Death
R99	Other ill-defined cause

I.2 ICD9 Codes for the Identification of Hospitalized Myocardial Infarction

<u>Code</u>	<u>Title</u>
402	Hypertensive Heart Disease
410	Acute Myocardial Infarction
411	Other Acute and Sub-acute Ischemic Heart Disease
412	Old Myocardial Infarction
413	Angina Pectoris
414	Other Chronic Ischemic Heart Disease
427	Cardiac Dysrhythmias
428	Heart Failure
518.4	Acute Edema of Lung, Unspecified

Appendix II. Form Letters**Format 1-A: Sample Letter to Informant: Known Telephone Number**

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study, a project of (name of institution) designed to measure the rates of heart disease in (name of state or area), to ask for your help. Your name is listed on the death certificate of (name) who passed away on (date). In a few days (name), a member of my staff, will be calling to explain further about the project and seek your permission to ask a few medical questions. Of course, your participation is entirely voluntary.

The information we need will be used for statistical purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Thank you very much in advance for your help in this important study.

Sincerely,

JHS Principal Investigator
(Name of Institution)

Appendix II. Form Letters

Format 1-B: Sample Letter to Informant: Known Telephone Number

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study, a project of (name of institution) designed to measure the rates of heart disease in (name of state or area), to ask for your help. Your name is listed on the death certificate of (name) who passed away on (date). In a few days (name), a member of my staff, will be calling to explain further about the project and seek your permission to ask a few medical questions. Of course, your participation is entirely voluntary.

The information we need will be used for statistical purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Thank you very much in advance for your help in this important study.

Sincerely,

JHS Principal Investigator
(Name of Institution)

ARIC Principle Investigator
(Name of Institution)

Format 2-A: Sample Letter to Informant: Unknown Telephone Number

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study, a project of (name of institution), designed to measure the rates of heart disease in (name of state or area), to ask for your help. Your name is listed on the death certificate of (name) who passed away on (date). We would like to call you to explain more about the project and to ask a few medical questions, but have been unable to find your telephone number.

Could you take a few moments to fill out and mail the enclosed postcard? The information we will be calling about will be used for statistical purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary. Thank you very much in advance for your help in the important study.

Sincerely,

JHS Principal Investigator
(Name of Institution)

(ENCLOSE POSTCARD, RETURN ADDRESSED AND STAMPED. SEE FORMAT 3.)

Format 2-B: Sample Letter to Informant: Unknown Telephone Number

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study, a project of (name of institution), designed to measure the rates of heart disease in (name of state or area), to ask for your help. Your name is listed on the death certificate of (name) who passed away on (date). We would like to call you to explain more about the project and to ask a few medical questions, but have been unable to find your telephone number.

Could you take a few moments to fill out and mail the enclosed postcard? The information we will be calling about will be used for statistical purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary. Thank you very much in advance for your help in the important study.

Sincerely,

JHS Principal Investigator
(Name of Institution)

ARIC Principle Investigator
(Name of Institution)

(ENCLOSE POSTCARD, RETURN ADDRESSED AND STAMPED. SEE FORMAT 3.)

Format 3-A: Replay Postcard From Informant With Telephone Number

FORMS SHOULD BE RETURN-ADDRESSED TO JACKSON HEART STUDY AND STAMPED.

Dear (Name of Cohort morbidity and mortality Supervisor):

I will be able to help with the Jackson Heart Study.

I do have a telephone number which is () _____. The best times to reach me are _____ or _____.

An alternative telephone number is: () _____. The best times to reach me at this number are _____ or _____.

I do not have a telephone number, but I agree to be interviewed in person, and will be calling your staff to set up a time and a place for the interview.

Sincerely,

Print Name of Informant

Format 4-A: Sample Letter to a Neighbor RE: Location of Informant

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study, a project of (name of institution) designed to measure the rates of heart disease in (name of state or area), to ask for your help. As you may know, (name of decedent) passed away on (date). As part of the study, we are systematically attempting to contact a next-of-kin or another person who lived with the decedent, in order to obtain some medical information that would help us to find out whether (name of decedent) died from a heart attack. Since we have not been able to locate such a person and since you were (name of decedent's) neighbor, we believe that you may be able to help us.

Could you take a few moments to fill out and mail the enclosed postcard? The information we wish to obtain from a next-of-kin or another person who lived with (name of decedent) will be used for research purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary.

If you have any questions, please feel free to call me collect at () _____. Thank you very much in advance for your help in this important study.

Sincerely,

JHS Principal Investigator

(ENCLOSE POSTCARD, RETURN-ADDRESSED AND STAMPED. SEE FORMAT 5)

Format 4-B: Sample Letter to a Neighbor RE: Location of Informant

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Jackson Heart Study, a project of (name of institution) designed to measure the rates of heart disease in (name of state or area), to ask for your help. As you may know, (name of decedent) passed away on (date). As part of the study, we are systematically attempting to contact a next-of-kin or another person who lived with the decedent, in order to obtain some medical information that would help us to find out whether (name of decedent) died from a heart attack. Since we have not been able to locate such a person and since you were (name of decedent's) neighbor, we believe that you may be able to help us.

Could you take a few moments to fill out and mail the enclosed postcard? The information we wish to obtain from a next-of-kin or another person who lived with (name of decedent) will be used for research purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary.

If you have any questions, please feel free to call me collect at () _____. Thank you very much in advance for your help in this important study.

Sincerely,

JHS Principal Investigator

ARIC Principal Investigator

(ENCLOSE POSTCARD, RETURN-ADDRESSED AND STAMPED. SEE FORMAT 5)

Format 5-A: Reply Form on the Location of Informant

POSTCARD SHOULD BE RETURN-ADDRESSED TO JACKSON HEART STUDY AND STAMPED.

Dear (Name of Cohort morbidity and mortality Supervisor):

The following individual(s) was (were) living with (name of decedent) at the time of his/her death:

Name	Relationship to Deceased	Present Address	Present Telephone Number
_____	_____	_____	
_____	_____	_____	
_____	_____	_____	
_____	_____	_____	

I do not have any information on persons who were living with (name of the decedent) at the time of his/her death.

Sincerely,

(Print Name of Neighbor)

Format 6: Informant Release of Information Form: Nursing Home

I hereby authorize and request _____ to furnish to the Jackson Heart Study the medical records on (name of the decedent). These records will be reviewed only for research purposes and none of the information will be released to any individual other than the research team. Any costs for reproduction of records will be covered by the study.

Date: _____ Signed:

(Relationship to the Deceased)

Witness:

Format 7-A: Letter to Physician Signing Death Certificate

Dear Doctor _____,

I am writing on behalf of the Jackson Heart Study, an epidemiologic project of (name of institutions). The survey is assessing incidence of myocardial infarctions, congestive heart failure and coronary death in three counties in Mississippi. We need some information concerning (name of the decedent), whose death certificate you signed on (date). The information is needed to supplement the death certificate in assigning a cause of death. Could your nurse or you take a few moments to provide the answers to the questions on the enclosed form from your records?

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call me collect at (____)_____. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

JHS Principal Investigator

Enclosure: Physician Questionnaire

Format 7-B: Letter to Physician Signing Death Certificate

Dear Doctor _____,

I am writing on behalf of the Jackson Heart Study, an epidemiologic project of (name of institutions). The survey is assessing incidence of myocardial infarctions, congestive heart failure and coronary death in three counties in Mississippi. We need some information concerning (name of the decedent), whose death certificate you signed on (date). The information is needed to supplement the death certificate in assigning a cause of death. Could your nurse or you take a few moments to provide the answers to the questions on the enclosed form from your records?

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call me collect at (____)_____. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

JHS Principal Investigator

ARIC Principal Investigator

Enclosure: Physician Questionnaire

Format 8-A: Letter to Attending Physician of Decedent

Dear Doctor _____,

I am writing on behalf of the Jackson Heart Study, an epidemiologic project of (name of institutions). The survey is assessing incidence of myocardial infarctions and coronary death in Hinds, Madison, and Rankin counties in Mississippi. We need some information concerning (name of decedent), who, according to the family, was your patient. The information is needed to supplement the death certificate in assigning a cause of death. Could your nurse or you take a few moments to provide the answers to the questions on the enclosed form from your records?

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call me collect at (____)_____. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

JHS Principal Investigator

Enclosure: Physician Questionnaire

Format 8-B: Letter to Attending Physician of Decedent

Dear Doctor _____,

I am writing on behalf of the Jackson Heart Study, an epidemiologic project of (name of institutions). The survey is assessing incidence of myocardial infarctions and coronary death in Hinds, Madison, and Rankin counties in Mississippi. We need some information concerning (name of decedent), who, according to the family, was your patient. The information is needed to supplement the death certificate in assigning a cause of death. Could your nurse or you take a few moments to provide the answers to the questions on the enclosed form from your records?

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call me collect at (____)_____. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

JHS Principal Investigator

ARIC Principal Investigator

Enclosure: Physician Questionnaire

Format 9: Informant Release of Information: Physician

Physician:

The above named physician has my permission to release medical information to the Jackson Heart Study. This information will be used for statistical purposes only, and will remain strictly confidential.

Decedent's name:

My name:

Address:

Relationship to Decedent:

Date: _____ Signed:

Witness:

Format 10: Informant Release of Information: Out-of-Area Hospital

TO:

(Name of Hospital)

The above named hospital has my permission to release medical information to the Jackson Heart Study. This information will be used for statistical purposes only, and will remain strictly confidential.

Decedent's Name:

My Name:

Address:

Relationship to Decedent:

Date: _____ Signed:

Relationship to Decedent:

Witness:

Appendix III. Computerized Stroke Classification Algorithm

I. Subarachnoid Hemorrhage (SAH)

JHS Definition of Definite SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the four below:

1. Meets criteria (a) and (b) below:
 - a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
 - b. Bloody (not traumatic) tap or xanthochromic spinal fluid, OR
2. Demonstration by CT or MRI of a blood clot in Fissure of Sylvius, between the frontal lobes, in basal cisterns or within a ventricle with no associated intraparenchymal hematoma, OR
3. Demonstration at surgery of bleeding saccular aneurysm, OR
4. Demonstration at autopsy of recent bleeding of a saccular aneurysm

JHS Definition of Probable SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet either criterion (1) or criteria (2) and (3) below:

1. a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
 - b. Spinal tap was either not done or was traumatic, or missing, OR
2. One or more of the following symptoms or signs occurred within minutes or a few hours after onset:
 - a. Severe headache at onset, or severe headache when first conscious after hospital admission;
 - b. Depression of state of consciousness;
 - c. Evidence of meningeal irritation;
 - d. Retinal (subhyaloid) hemorrhages; AND
3. Bloody (not traumatic) tap or xanthochromic spinal fluid.

II. Brain Hemorrhage (IPH)

JHS Definition of Definite IPH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the three below:

1. Demonstration of definite intracerebral hematoma by CT or MRI, e.g. an area of increased density, such as seen with blood, OR
2. Demonstration at autopsy or surgery of intracerebral hemorrhage, OR
3. Evidence in the patient's clinical record that meet criteria (a), (b), (c), and (d) below:
 - a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:
 - Major:
 - hemiparesis involving two or more body parts
 - homonymous hemianopia
 - aphasia

Minor:

- diplopia
 - vertigo or gait disturbance
 - dysarthria or dysphagia or dysphonia
 - unilateral numbness involving two or more body parts, AND
- b. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND
 - c. Cerebral angiography demonstrates an avascular mass effect and no evidence of aneurysm or arteriovenous malformation, AND
 - d. No CT / MRI was performed or the CT / MRI was technically inadequate.

JHS Definition of Probable IPH: Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #3 that lasted at least 24 hours or until the patient died, AND
2. Decreased level of consciousness or coma that lasted at least 24 hours or until the patient died, AND
3. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND
3. No CT / MRI was performed or the CT / MRI was technically inadequate.

III. Thrombotic Brain Infarction (TIB)JHS Definition of Definite TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of nonhemorrhagic infarct in brain, OR
2. Evidence in the patient's clinical record that meet criteria (a) and (b) below:
 - a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

Major:

- hemiparesis involving two or more body parts
- homonymous hemianopia
- aphasia

Minor:

- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts, AND

- b. CT or MRI shows i nfarct or an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage.

JHS Definition of Probable TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND
2. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
3. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

IV. Noncarotid Embolic Brain Infarction (EIB)

JHS Definition of Definite EIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of:
 - a. An infarcted area (bland or hemorrhagic) in the brain, AND
 - b. A source of emboli in a vessel of any organ, or an embolus in the brain, OR
2. Evidence in the patient's clinical record that meet criteria (a), (b), and (c) below:
 - a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:
 - Major:
 - hemiparesis involving two or more body parts
 - homonymous hemianopia
 - aphasia
 - Minor:
 - diplopia
 - vertigo or gait disturbance
 - dysarthria or dysphagia or dysphonia
 - unilateral numbness involving two or more body parts, AND
 - b. Establishment of a likely source for cerebral embolus, e.g.: valvular heart disease (including prosthetic heart valve), atrial fibrillation or flutter, MI, cardiac or arterial operation or procedure, cardiac myxoma, bacterial endocarditis, AND
 - c. CT or MRI shows an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage

JHS Definition of Probable EIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND
2. An identifiable source for the cerebral embolus as specified in definite #2b, AND
3. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
4. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

V. Possible Stroke of Undetermined Type

JHS Definition:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus one major or two minor neurological signs listed below:

Major:

- hemiparesis involving two or more body parts
- homonymous hemianopia
- aphasia

Minor:

- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts
- severe headache at onset or severe headache when first conscious after hospital admit
- depression of state of consciousness
- evidence of meningeal irritation
- retinal (subhyaloid) hemorrhages
- palsy of the iii cranial nerve, AND

Clinical history, signs, symptoms, and findings from diagnostic tests and / or autopsy are not sufficient to meet the criteria for classifying the case as a "definite" or "probable" case of one of the four specific diagnostic categories of stroke.

Appendix IV. ECG Shipping Form

**JHS
ECG Shipping Form**

To: Sean Thomas
ECG Coding Center
University of Minnesota
Division of Epidemiology
Suite 300
1300 South Second St
Minneapolis, MN 55454-1015

From: JHS Examination Center _____ Date: _____ Time: _____

JHS Batch Number A R _____

Reporting Period:

Starting Date:

Ending Date:

Total Number of Specimens Enclosed:

Number of Contents Pages Attached:

Other remarks concerning shipment contents:

Initials _____

Arrive at Laboratory

Date: _____ Time: _____

Contents on condition of total shipment on arrival

Initials _____

Appendix V. Duplicate Materials Shipping Forms

**JHS SHIPPING FORM
DUPLICATED MATERIALS FOR MMCC REVIEWERS**

TO: Central Receiving
Climmon Walker

FROM:

DATE:

BATCH NUMBER:

REMARKS: _____

INITIALS:

**JHS COHORT MORBIDITY AND MORTALITY SHIPPING INVENTORY
DUPLICATED MATERIALS FOR MMCC REVIEWERS**

CENTER _____ **BATCH** _____ **DATE** _____ **TYPE** _____

Event ID #	Event ID #
1.	16.
2.	17.
3.	18.
4.	19.
5.	20.
6.	21.
7.	22.
8.	23.
9.	24.
10.	25.
11.	26.
12.	27.
13.	28.
14.	29.
15.	30.

REMARKS: _____