CARDIA Endpoint Events
Manual of Operations
# Table of Contents

1. Introduction ............................................................................................................................................. 1

2. Organization and Goals of the Endpoints Surveillance and Adjudication Subcommittee ....................... 2

3. Mortality Events ....................................................................................................................................... 2
   3.1. Data Collection and Data Entry ...................................................................................................... 2
   3.2. Criteria for Mortality Events .......................................................................................................... 3
       3.2.1. Fatal Atherosclerotic Coronary Heart Disease ................................................................ 3
       3.2.2. Fatal Stroke ...................................................................................................................... 4
       3.2.3. Fatal Atherosclerotic Disease Other than Coronary or Stroke ........................................ 4
       3.2.4. Fatal Non-Atherosclerotic Cardiac Disease ..................................................................... 4
       3.2.5. Fatal Pulmonary Embolism .............................................................................................. 4
       3.2.6. Fatal Non-Cardiovascular Disease and Other Reasons of Death ..................................... 5
       3.2.7. Procedure-Related Death ................................................................................................ 5
   3.3. Protocol for National Death Index (NDI) Matching for Cause of Death ......................................... 5

4. Morbidity Events ...................................................................................................................................... 6
   4.1. Criteria for Morbidity Events .......................................................................................................... 7
       4.1.1. Myocardial Infarction ...................................................................................................... 7
       4.1.2. Non-MI ACS .................................................................................................................... 10
       4.1.3. Coronary Revascularization ........................................................................................... 11
       4.1.4. Congestive Heart Failure ............................................................................................... 12
       4.1.5. Stroke ..................................................................................................................................... 15
       4.1.6. Transient Ischemic Attack .............................................................................................. 17
       4.1.7. Carotid Artery Disease ................................................................................................... 18
       4.1.8. Peripheral Arterial Disease ............................................................................................ 18
       4.1.9. Deep Venous Thrombosis ................................................................................................. 19
       4.1.10. Pulmonary Embolus ....................................................................................................... 19
       4.1.11. Diabetes Mellitus .......................................................................................................... 20
       4.1.12. Asthma/COPD .............................................................................................................. 20
       4.1.13. Hypertension .................................................................................................................. 21
       4.1.14. End Stage Renal Disease ............................................................................................... 21
4.1.15. Atrial Fibrillation/Flutter

Appendix 1. CARDIA Mortality Record Acquisition and Review Process Flow Chart

Appendix 2. Decision Matrix for Forms to be obtained when Participant Dies

Appendix 3. Mortality Review Forms (Form 33A, B, C, F)

Appendix 4. CARDIA Morbidity Record Acquisition and Review Process Flow Chart

Appendix 5. CARDIA Morbidity Triage Form (M-0)

Appendix 6. CARDIA Morbidity Review/Adjudication Form (M-1)

Appendix 7. Medical Documentation Requirements for CARDIA Endpoints

Appendix 8. Step-by-Step Instructions for Personnel on How to Manage Medical Records

Appendix 9. Heart Failure Case Law

Appendix 10. Endpoint Abstraction Forms

References

Appendix 11. CARDIA Endpoints Tracking Reports Instructions
1. Introduction

The CARDIA Study was designed to look at the evolutions of cardiovascular disease (CVD) risk factors and their determinants in young adults. The original study design did not consider disease endpoints, with the exception of the high-risk state/disease entities such as hypertension, and hypercholesterolemia. As the participants have grown older and begun to develop cardiovascular and other disease endpoints of interest, a Mortality and Morbidity Committee was established to define endpoints of interest to the study and to determine what information related to these endpoints should be collected. Once the endpoints were established, the need was recognized for an Endpoints Committee to identify the criteria for an endpoint and to adjudicate whether a particular episode of care met the established criteria. Subsequently, the Endpoints Surveillance and Adjudication Subcommittee (ESAS) was formed to oversee refinements in the collection process and to adjudicate outcomes, subsuming the previous two-committee functions.

The CARDIA Manual of Operations for Endpoints Events includes events protocols, summarizes the ESAS procedures, and provides detailed data collection guidelines for completing the mortality review forms.

The ESAS established the following definitions of mortality and morbidity endpoints that could be revised and modified to meet study goals:

**CARDIA mortality** endpoints—ALL cases of death occurring in CARDIA participants

**CARDIA morbidity** endpoint—an incident event in a CARDIA participant resulting in a minimum 24-hour hospitalization for:

- Myocardial infarction (MI)
- Coronary revascularization
- Non MI acute coronary syndrome
- Congestive heart failure (CHF)
- Stroke
- Transient ischemic attack (TIA)
- Carotid artery disease (CAD)
- Peripheral arterial disease (PAD)
- Deep venous thrombosis (DVT)
- Pulmonary embolism (PE)
- End stage renal disease (ESRD)
- Diabetes mellitus (DM)*
- Asthma* / Chronic obstructive pulmonary disease (COPD)*
- Hypertension (HTN)*
- Atrial fibrillation/flutter

*only if primary reason for hospitalization or outpatient admission

Event identification occurs during exams and annual follow-up of cohort members. The ESAS evaluates only incident events, except in the case of MI and stroke, where there were different classification of stroke (hemorrhagic, ischemic, or unknown) reported at different times.

The ESAS recommended a redesign of the outcomes data collection protocol to be implemented beginning with the 288-Month follow-up annual contact in April 2009. The new system includes a
triage step and protocols using a nurse reviewer/abstractor, so that cases clearly without a potential event will not slow down the final physician adjudication processes. This will entail collection of the discharge summary and ICD codes for many hospital stays; admissions for specific non-CVD procedures will be exempt from collection if length of stay is short. Specific documents for specific types of cases (i.e., collect ECG, cardiac enzymes, etc. for chest pain and possible MI) will continue to be collected. Sleep studies and bariatric surgery were added to the 288 and year 25 contact period to the cases for which records will be collected. These cases are of potential interest to CARDIA.

2. Organization and Goals of the Endpoints Surveillance and Adjudication Subcommittee

The Subcommittee consists of clinicians from the participating CARDIA centers. The Chair and members are appointed by the Steering Committee. A recording of the decisions will be provided by the Coordinating Center. Meetings are open to invitees. If neurologic expertise is not present on the subcommittee, it may be added. All decisions are made by majority vote, preferably by consensus.

The goals of the Subcommittee are to:
- Classify the cause of death, including cardiovascular and cerebrovascular specific subtypes; and
- Classify specific morbidity endpoint events using pre-established criteria.

The Subcommittee reviews the process of events investigation in other large cohort studies and assesses the appropriateness of the criteria used to determine the eligibility of medical records retrieving. The Subcommittee oversees the tracking process of medical records and works on increasing the percent of obtained medical records.

3. Mortality Events

3.1. Data Collection and Data Entry

The CARDIA Study will collect data for each participant death that occurs during the study. The CARDIA Mortality Record Acquisition and Review Process Flow Chart (Appendix 1) depicts the processes employed for tracking, data collection, data entry and adjudication of a discovered/reported participant death. The forms to be completed vary, depending upon the cause of death and whether the participant was hospitalized at the time of death. A decision matrix describes which forms require completion/collection when a death occurs (Appendix 2). Data collection begins when field center staff first learn of a death. The Initial Notification of Death Form (Form 33A) is to be completed and sent to the coordinating center within 48 hours of first knowledge of a death. Required forms are completed, reviewed, and sent to the Coordinating Center within 90 days of first knowledge of a death. Forms not submitted within the specified time due to inavailability of necessary information, will be submitted once information become available and they can be completed. All mortality review forms (Form 33A – Form 33F) are included in Appendix 3.

Instructions for processing mortality records are detailed in the document titled Step-by-Step Instructions for Personnel on How to Manage Medical Records found in Appendix 8.

Forms Required to be Completed for All Death Cases

Initial Notification of Death Form (F33A)—Completed form to be submitted to the coordinating center within 48 hours of first learning of the death.
Final Report of Death Form (F33B)—The form is completed by field center staff. A review of all forms and attachments is conducted for completeness and accuracy. All relevant forms and materials are attached and sent to the Coordinating Center within 90 days of first knowledge of a death, with additional material submitted as it becomes available.

CARDIA Mortality Review/Adjudication Form (F33F)—This form is completed by two CARDIA endpoint reviewers. The final decision as a result of adjudication is recorded on this form by the Coordinating Center designee.

Forms Required to be Completed for Possible Cardiovascular and Unclear Out-of-Hospital Deaths
The clinical center representative or PI initially determines the adequacy of information and necessity for additional questionnaires, although the ESAS may request it.

CARDIA Interviews with Witness or Next of Kin Form (F33C)—There may be instances in which there is insufficient documentation to adjudicate the cause of death. When this appears to be the case, the field center staff member should consult with their PI to determine whether or not an interview should be conducted with a member of the decedent's family, a friend, or other person present when the participant died. Additional interviews may be appropriate when additional information regarding the circumstances surrounding the death is required.

CARDIA Interview with Participant’s Physician Form (F33D)—was discontinued and no longer in use.

3.2. Criteria for Mortality Events

3.2.1. Fatal Atherosclerotic Coronary Heart Disease
The definitions consider location of death (in or out of the hospital), presumptive cause, and timing. Cause of death is hierarchical (Luepker, Apple, Christenson, Crow, Fortmann, Goff et al., 2003).

DEFINITE Fatal Myocardial Infarction
Definite Myocardial Infarction within 28 days of death with no evidence of a non-atherosclerotic cause of death.

DEFINITE Fatal CHD
Must lack sufficient evidence to diagnose Definite Fatal MI and meet BOTH of the following criteria:
• No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal AND
• Presence of one OR both of the following findings:
  o Chest pain within 72 hours of death
  o A history of ever having had chronic ischemic heart disease (such as definite or possible MI, coronary insufficiency or angina pectoris) in the absence of valvular heart disease or non-ischemic cardiomyopathy

POSSIBLE Fatal CHD
Must lack sufficient evidence to diagnose Definite Fatal MI or Definite Fatal CHD and meet BOTH of the following criteria:
• No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal AND
• Death certificate with consistent underlying cause, i.e. ICD9-CM codes 410-414, 427.5, 429.2 and/or 799

Subclassification of Deaths Due to CHD
Chronology of Death (if died out of hospital)—All CHD deaths are classified, where possible, according to time interval from onset of acute symptoms to time of death as 1 hour or less; 1-24 hours; more than 24 hours; unknown.

Presence of cardiac symptoms (if died out of hospital)
All CHD death cases are classified as with chest pain within 72 hours of death or unknown (cannot determine).

3.2.2. Fatal Stroke
DEFINITE
Death due to definite stroke (hemorrhagic, ischemic, unknown) with consistent imaging, surgical, or autopsy evidence.

POSSIBLE
Death due to presumed stroke (hemorrhagic, ischemic, unknown) that did not meet criteria for definite stroke and death certificate consistent with stroke without other underlying or immediate cause.

Subclassification of Deaths Due to Stroke
Chronology of Death—All stroke deaths are classified, where possible, according to time interval from onset of acute symptoms to time of death as less than 5 minutes; 5 minutes – 59 minutes; 1 hour – 23 hours; 1 day – 6 days; 1 week – 1 month; longer than 1 month.

3.2.3. Fatal Atherosclerotic Disease Other than Coronary or Stroke
DEFINITE
Consistent imaging, surgical, or autopsy evidence

POSSIBLE
Death due to presumed other atherosclerotic disease that did not meet criteria for definite one and death certificate consistent with atherosclerotic disease without other underlying or immediate cause

3.2.4. Fatal Non-Atherosclerotic Cardiac Disease
Non-ischemic cardiomyopathy (e.g., Hypertrophic obstructive cardiomyopathy (HOCM), alcoholic, idiopathic/unknown)

3.2.5. Fatal Pulmonary Embolism
DEFINITE
Death due to definite pulmonary embolism with consistent imaging, surgical, or autopsy evidence

POSSIBLE
Death due to presumed pulmonary embolism that did not meet criteria for definite one and death certificate consistent with pulmonary embolism without other underlying or immediate cause
3.2.6. **Fatal Non-Cardiovascular Disease and Other Reasons of Death**

Fatal non-cardiovascular diseases and other reasons of death were defined as follows: AIDS; cancer; diabetes; kidney disease; liver disease; asthma; other lung disease; homicide; suicide; unintentional injury; other.

3.2.7. **Procedure-Related Death**

**Cardiovascular Intervention**

Death within 28 days of cardiovascular surgery or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment, or other invasive coronary vascular intervention

**Non-cardiovascular Intervention**

Cardiac death occurred within 28 days of surgery or other invasive procedure

**Mechanisms of Cardiovascular Disease Death**

Participants with CVD death, excluding those with death from stroke, are subsequently classified according to mechanism of death into the following groups:

- Primary arrhythmic (death within 5 minutes in otherwise asymptomatic individual);
- Secondary arrhythmic/mechanical (death with preceding symptoms of heart disease, but no evidence of chronic myocardial pump failure);
- Congestive heart failure (death due to shock or low output syndrome);
- Cardiac procedure (death related to coronary artery bypass grafting [CABG] or angioplasty);
- Multiple mechanism (death in an individual with severe chronic heart failure who died from ventricular arrhythmia); and
- Hemorrhage from thrombolytic therapy.

3.3. **Protocol for National Death Index (NDI) Matching for Cause of Death**

If death certificates will not be ordered for each decedent participant, the following protocol is suggested by the Northwestern group, based on experience matching large numbers of participants from a 40,000 person cohort.

Given the small number of deaths expected for the near term in CARDIA, the reports from the NDI are easily reviewable to determine whether the decedent is a match. An exact match is necessary on social security number (SSN) to get a cause of death from NDI-Plus. Thus, it is recommend that there should be a match on SSN, last and first name, sex, and two of three birthdate items (month/day, month/year, or day/year). A participant meeting these criteria would be determined to be a match, and cause of death assigned.

If a record does not meet the above criteria, but it is believed that the record is a potential match, then an independent verification, such as the Social Security Death Index (SSDI) or a report from a relative, is required to accept the death. In these few cases, cause of death is not obtained from NDI-Plus, so it should be coded as cause unknown or the death certificate obtained.

If death certificates are requested, it is recommended that anyone who matches with at least 5 digits on the SSN, and at least 3 of last name, first name, month of birth, day of birth, and year of birth be requested, then make a determination based on visual examination of the certificate.

We have a SAS program for our large datasets that implements a version of the criteria stated above. It
accepts either 8+ matching SSN digits or 12 matching NDI elements plus a match on sex, month of birth, and year of birth. When there were 7+ matching SSN digits or 10 matching NDI elements and a match on sex, the record was put aside for manual verification in the SSDI. A very small number of these close matches were verified this way and coded as unknown causes. However, this should really only be needed when there are very large numbers of deaths that are being screened for.

4. Morbidity Events

CARDIA collects data from exams and interim contacts to identify the following possible endpoints:
- Myocardial infarction
- Non MI acute coronary syndrome
- Congestive heart failure
- Stroke
- Transient ischemic attack
- Carotid artery disease
- Peripheral arterial disease
- Deep venous thrombosis
- Pulmonary embolism
- Diabetes
- Asthma / Chronic Obstructive Pulmonary Disease
- Hypertension
- End Stage Renal Disease
- Coronary Revascularization

In-depth data collection is focused on incident CARDIA endpoint events. Limited data are collected for recurrent endpoint events and events and conditions not included as CARDIA endpoints. The CARDIA Morbidity Record Acquisition and Review Process Flow Chart (Appendix 4) depicts the process for morbidity identification, tracking, data collection, decision activities, and data entry. Medical records are collected on all relevant hospitalizations and outpatient episodes of care to determine the degree to which the Study is interested in the episode(s) of care. The ESAS identified the list of required medical documentation that should be obtained for the specified CARDIA endpoints to assure the high quality of review and adjudication process (Appendix 7).

Instructions for processing morbidity records are detailed in the document titled Step-by-Step Instructions for Personnel on How to Manage Medical Records found in Appendix 8.

Beginning with the Year 20 Exam, records are also requested on all reported outpatient coronary catheterizations, angiograms, procedures to open blocked arteries and initial kidney dialysis.

The Medical History Questionnaire (Form 8) administered during each exam visit, and the annual follow-up form administered at annual follow-up contacts is used to determine whether participants have been assigned a diagnosis and/or treatment for most CARDIA endpoints. No endpoint event is defined solely on the basis of self-report of diagnosis.

For hypertension, and diabetes mellitus, CARDIA exam measurements (blood pressure and glucose) may be sufficient to establish that an endpoint has occurred. Where the criteria for the endpoint event are met from exam measurements alone, these events are not submitted to the ESAS for review. Similarly,
where two self-report criteria are met for event designation, i.e. self-report of angina and self-report of anti-anginal medication, these events are also not submitted to the ESAS for review.

Once the data is available at the coordinating center, the coordinating center designee will complete Form M-0—CARDIA Morbidity Triage Form (Appendix 5). If the event is determined, during triage, as not meeting criteria for an endpoint event, no further action is necessary. These decisions are evaluated by submitting a 10% sample of triaged events to the ESAS or to a designated member of the ESAS for quality control purposes. If the event meets the criteria for a potential endpoint, Form M-1—CARDIA Morbidity Review/Adjudication Form (Appendix 6) and appropriate medical records will be forwarded to two CARDIA endpoint reviewers who will review the episode of care and complete relevant section(s) of Form M-1. Minor disagreements can be adjudicated by the Chair of the Subcommittee or designee. If there is major disagreement, the entire ESAS membership will review the event. Results of adjudication will be recorded on Form M-1.

4.1. Criteria for Morbidity Events
To assure comparability with other epidemiologic studies, CARDIA has adopted events criteria used by previous studies, as appropriate. For cardiovascular and cerebrovascular disease, CARDIA uses criteria comparable to those of the Cardiovascular Health Study (CHS) which are also comparable to those of the Atherosclerosis Risk in Communities (ARIC) and Women’s Health Initiative (WHI) studies.

4.1.1. Myocardial Infarction
Myocardial infarction is defined as the death of part of the myocardium due to an occlusion of a coronary artery from any cause, including spasm, embolus, thrombosis, or the rupture of a plaque. The CARDIA algorithm for classifying myocardial infarction includes elements of the medical history, results of enzyme determinations, and electrocardiogram readings.

CARDIA originally adopted the CHS criteria for myocardial infarction and updated them subsequently. Troponin and myoglobin are added to the list, and LDH (Lactate dehydrogenase) is removed from the list of enzymes to be evaluated (Table 1). In addition, a new category, Aborted Myocardial Infarction, is included in Form M-1 (criteria included).

Table 1. Summary of Diagnostic Criteria for Myocardial Infarction

<table>
<thead>
<tr>
<th>ECG FINDINGS</th>
<th>CARDIAC ENZYME LEVELS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac symptoms or signs present</td>
<td></td>
</tr>
<tr>
<td>Evolving diagnostic</td>
<td>Definite Definite Definite Definite</td>
</tr>
<tr>
<td>Positive</td>
<td>Definite Probable Probable No</td>
</tr>
<tr>
<td>Nonspecific</td>
<td>Definite Possible No No</td>
</tr>
<tr>
<td>Normal or other ECG</td>
<td>Definite Possible No No</td>
</tr>
<tr>
<td>Cardiac symptoms or signs absent</td>
<td></td>
</tr>
<tr>
<td>Evolving diagnostic</td>
<td>Definite Definite Definite Definite</td>
</tr>
<tr>
<td>Positive</td>
<td>Definite Probable Possible No</td>
</tr>
<tr>
<td>Nonspecific</td>
<td>Definite* Possible No No</td>
</tr>
<tr>
<td>Normal or other ECG</td>
<td>Definite* No No No</td>
</tr>
</tbody>
</table>

*in absence of diagnostic troponin, downgrade to Possible
Source for Table: (Luepker, Apple, Christenson, Crow, Fortmann, Goff et al., 2003)

Aggressive treatment of signs and symptoms of impending myocardial infarction, such as angioplasty,
coronary artery bypass graft, or thrombolysis, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately.

For classification as **ABORTED Myocardial Infarction**, the event must meet all of the following criteria:
- symptoms and ECG evidence for acute MI at presentation
- intervention (e.g., thrombolytic therapy procedure) is followed by resolution of ECG changes
- all cardiac enzymes are within normal limits

**CARDIA Criteria to Define Myocardial Infarction:**

**Electrocardiographic Criteria**
Where possible, the following ECG tracings are identified from the hospital record:
- The first ECG recorded after admission;
- The last ECG recorded before discharge;
- The last ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event;
- The first ECG following a recurring episode of chest pain during a prolonged stay in the ICU/CCU, or the first ECG following transfer back to the ICU/CCU because of a new episode of chest pain.

**Cardiac Enzyme Criteria**
Pertinent enzyme results recorded in the hospital chart for days 1 through 4 after hospital admission, or days 1 though 4 after an in-hospital CHD event are used. Information on non-ischemic cause for elevation of enzymes should be made exclusively from the discharge summary or lab report on the medical chart. Table 2 includes a summary of the criteria.

Table 2. Algorithm for Enzyme Diagnostic Criteria

<table>
<thead>
<tr>
<th>ENZYME</th>
<th>ENZYME LEVELS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine Kinase MB fraction (CK-MB)</td>
<td>Abnormal</td>
</tr>
<tr>
<td></td>
<td>- &gt;2x ULN or 10% of total CK or &quot;present&quot; without quantification</td>
</tr>
<tr>
<td></td>
<td>- &gt;3x ULN during 48 hrs after PTCA</td>
</tr>
<tr>
<td></td>
<td>- &gt;5x ULN during 48 hrs after CABG</td>
</tr>
<tr>
<td>Myoglobin</td>
<td>&gt;2x ULN</td>
</tr>
<tr>
<td></td>
<td>1-2x ULN</td>
</tr>
<tr>
<td>Troponin (C, I, or T)</td>
<td>1-2x ULN</td>
</tr>
<tr>
<td></td>
<td>1-2x ULN</td>
</tr>
<tr>
<td></td>
<td>2x ULN</td>
</tr>
<tr>
<td></td>
<td>3x ULN during 48 hrs after PTCA</td>
</tr>
<tr>
<td></td>
<td>5x ULN during 48 hrs after CABG</td>
</tr>
<tr>
<td>Total Creatinine Kinase (CK)</td>
<td>&gt;2x ULN</td>
</tr>
<tr>
<td></td>
<td>1-2x ULN and Troponin 1-2x ULN</td>
</tr>
</tbody>
</table>

ULN = Upper Limit of Normal
WNL = Within Normal Limit

**Abnormal Cardiac Enzymes**
Must meet one of the following criteria:
- Either Creatinine Kinase (CK)-MB (heart fraction) is > 2x upper limit of normal (ULN) or 10% of the total CK value or. CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a numerical value); and there is no known non-ischemic cause (cardiac surgery, severe
muscle trauma, rhabdomyolysis) of the elevation enzyme value.

- CK-MB is > twice the upper limit of normal for that hospital lab.
- Total CK and troponin are both at least twice the upper limit of normal (not necessarily on the same day) and there is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis).
- Troponin is > twice the upper limit of normal for that hospital laboratory.
- Myoglobin or other Cardiac specific enzyme is ≥ 2x ULN.

Abnormal Cardiac Enzymes following the surgical procedure
Cardiac enzymes collected within the 48 hours after CABG or percutaneous transluminal coronary angioplasty (PTCA) will be classified as follows:

- PTCA—levels of CK-MB and troponin above three times the upper limit of normal will be categorized as abnormal
- CABG—levels of CK-MB and troponin above five times the upper limit of normal will be categorized as abnormal

These abnormal enzymes would not be “downgraded to equivocal” on the basis of surgical procedure and the standard enzyme criteria would apply after 48 hours again. Total CK will not be used for post CABG enzymes. Troponin should take precedence over CK-MB according to current guidelines.

Equivocal Cardiac Enzymes
Do not meet criteria for abnormal enzymes and meet one of the following criteria:

- Total CK or Troponin is at least twice the upper limit of normal.
- Both total CK and Troponin are between the upper limit of normal and twice the upper limit of normal (not necessarily on the same day).
- CK-MB = 5 - 9% of total CK or "weakly present" or greater than the upper limit of normal but less than twice the upper limit of normal.
- Troponin is greater than the upper limit of normal but less than twice the upper limit of normal.

A summary of the enzyme diagnostic criteria as related to Troponin and CK is provided in Table 2.

CARDIA aims for a well-standardized process for events identification of acute MI, allowing for valid inter-community and longitudinal comparisons, as well as the examination of associations with risk factors.

Cardiac Signs/Smptoms of Ischemia Criteria
Possible ischemic symptoms include various combinations of chest, upper extremity, mandibular or epigastric discomfort (with exertion or at rest [Thygesen K, et al. European Heart Journal 2012; Luepker RV et al. Circulation. 2003]). The discomfort associated with acute MI usually lasts >20 min. Symptoms should not have an apparent noncardiac source, such as gastroesophageal reflux. Often, the discomfort is diffuse—not localized, nor positional, nor affected by movement of the region—and it may be accompanied by diaphoresis, nausea or syncope. However, these symptoms are not specific for myocardial ischemia. Atypical symptoms, such as fatigue, nausea, vomiting, diaphoresis, faintness, and back pain, should not be used as a diagnostic criterion, but may accompany more specific symptoms (eg, chest pain with diaphoresis). Cardiac signs include acute congestive heart failure or cardiogenic shock in the absence of non-CHD causes.
MI references


4.1.2. Non-MI ACS -Revised by ESAS 06.19.2014

Defined as an unscheduled admission for hospitalization, or at least an overnight observation stay, for evaluation and treatment of an accelerating or new symptom pattern consistent with coronary artery ischemia leading to an evaluation that rules out MI (See CARDIA MI Definition pages for evaluation criteria), but is nevertheless thought to be due to coronary ischemia upon completion of the evaluation. The admission for rule out MI evaluation is necessary, but not sufficient, for the diagnosis of non-MI ACS. Elective admission for a procedure (e.g. cardiac catheterization with PCI) will not be adjudicated as non-MI ACS, since an unscheduled admission for treatment/evaluation of acute ischemic symptoms is required.

The unscheduled hospital admission must have begun within 24 hours of the most recent symptoms. Escalation of pharmacotherapysuch as intravenous nitrates or increasing dosages of β-blockers, should be considered supportive but not diagnostic of non-MI ACS.

If a participant is admitted with suspected unstable angina/ACS, and subsequent testing reveals a non-cardiac or non-ischemic etiology, this event should not be recorded as hospitalization for non-MI ACS.

Rehospitalization of a participant meeting the criteria for non-MI ACS who was stabilized, discharged, and subsequently readmitted for planned revascularization, does not constitute a second hospitalization for non-MI ACS.
Hospitalization of a participant with stable exertional angina for coronary angiography and PCI that is prompted by a positive outpatient stress test should not be considered hospitalization for non-MI ACS.

**Definite Non-MI ACS** in CARDIA will require

- physician diagnosis of acute coronary syndrome/unstable angina and receiving medical treatment for angina (e.g., nitrates, beta-blockers, or calcium-channel blockers) and requires new chest pain or changing symptom pattern consistent with cardiac ischemia

Non-MI ACS will also require objective findings of coronary artery disease/ischemia, AND includes one or more of the following:

- Significant (> 70% obstructive lesion(s) on coronary catheterization during index hospitalization and/or an intervention for revascularization;
  and/or
- Ischemic ECG changes or imaging findings on exercise or pharmacologic stress testing associated with the index hospitalization;
  and/or
- Resting ECG findings consistent with ischemia occurring with symptoms during the index hospitalization

There also should be no other explanation or cause for the presenting symptoms, such as GERD. The diagnosis of definite non-MI ACS should preferentially be based upon the discharge diagnosis/summary rather than on the admission diagnosis.

**Probable non-MI ACS** will be defined as hospitalization for evaluation and treatment of an accelerating or new symptom pattern consistent with coronary artery ischemia leading to an evaluation that rules out MI in patients without the objective findings required above. Participants with a prior history of CAD but who do not have the objective findings of coronary artery disease/ischemia as defined above are also included here. Participants must have a diagnosis of non-MI ACS or equivalent on the discharge summary and no other explanation or cause for the presenting symptoms. A discharge diagnosis of “chest pain” or similar non-specific diagnosis is not sufficient. The diagnosis of both definite and probable non-MI ACS should preferentially be based upon the discharge diagnosis/summary rather than on the admission diagnosis.

All of the following guidelines below should be followed:

a. Clear and thorough documentation of symptoms is needed to identify an event as “non-MI ACS.” Even if a test such as an exercise stress test lists “Angina” or chest pain” as its indication, non-MI ACS should not be ruled unless there is additional, explicit information from the physician regarding symptoms.

b. Only code an event as non-MI ACS if it is distinct from an MI. Reviewers should not code non-MI ACS as part of pain symptoms of an MI. If a participant is admitted for non-MI ACS and undergoes a procedure with a subsequent MI, both non MI ACS and MI can be adjudicated in the same hospital admission.

**4.1.3. Coronary Revascularization (CARDIA Endpoint beginning with YR20 Exam)**

Coronary revascularization procedures are defined as CABG, PTCA, coronary stent, or coronary atherectomy. Review criteria are included on Form M-1 Item 6.
4.1.4. **Congestive Heart Failure**

Congestive heart failure is defined as a constellation of symptoms and physical signs that occur in a participant whose cardiac output cannot match metabolic needs despite adequate filling pressures. In CARDIA, only a hospitalization for CHF will be a CARDIA outcome. Thus, diagnosis and treatment of CHF by a physician or other provider in the office or clinic setting or ER without hospital admission will not be considered a CARDIA outcome.

CARDIA is gathering information adequate to use published criteria for congestive heart failure. The goal is to be specific rather than too sensitive. An overall heart failure diagnosis must be assigned based on the adjudicator’s clinical judgment after careful review of the medical record documents provided and the Event Summary Form (ESF) pertinent to this event. The information on the ESF is derived from the Hospital Records Abstraction Form completed by the abstractors (Appendix 10).

**Question 7.** Only one option should be selected to indicate, based on clinical judgment, whether the participant had definite or possible decompensated heart failure, chronic stable heart failure, heart failure was unlikely, or the case is unclassifiable. Evidence of signs and symptoms that may indicate new or decompensated heart failure include evidence of increasing or new onset shortness of breath, increasing or new onset edema, increasing or new onset paroxysmal nocturnal dyspnea, increasing or new onset orthopnea, increasing or new onset hypoxia, and evidence in the doctor’s notes that the reason for this hospitalization was heart failure.

**Option 1** (heart failure unlikely)—there is no HF, heart function is normal based on available documentation. Ideally, there should be some mention of normal heart function, but “heart failure unlikely” may be selected if there is sufficient data to make that inference in the absence of clear documentation.

**Option 2** (definite decompensated heart failure)—decompensation clearly present based on available data (satisfies criteria for decompensation).

**Option 3** (possible decompensated heart failure)—decompensation possibly but not definitively present. A typical case of “possible” rather than “definite” would be due to the presence of co-morbidity that could account for the acute symptoms (COPD exacerbation, for example). In some cases of chronic CHF, it may be difficult to tell whether the patient’s status matches the baseline CHF status or indicates some deterioration. If in doubt, record “possible decompensated HF.” In general, prefer “possible” whenever the evidence for decompensation (symptoms, signs, imaging) is subtle. Also, take the totality of the evidence provided. For example, a case of possible decompensated HF may be one that has a known history of CHF who has chest x-rays showing “active CHF,” description of diuretic therapy, and an ICD-9 codes of 428, but there is no statement about decompensated heart failure in the discharge summary. (However, if a patient has such documentation with no known history of CHF, then the patient most likely has “definite decompensated heart failure” [”2”]). If there is scant documentation and you are choosing between “2” and “3”, rely more on the ESF than the provided records; e.g., records do not confirm definite decompensated heart failure but “MD notes suggest reason for hospitalization is HF = yes,” then choose “2”.

**Option 4** (chronic stable heart failure)—no decompensation but patient has chronic heart failure. “Stable” also denotes “compensated” heart failure (not necessarily asymptomatic, but that patient’s chronic HF symptoms are controlled with therapy and there is no evidence of augmentation of therapy for worsening HF during the hospitalization.)
NOTE: This includes patients with asymptomatic heart failure (evidence of LV systolic dysfunction, i.e., EF < 50%, and no heart failure symptoms). Do NOT include: a history of transient LV/RV dysfunction if heart function is currently normal; or asymptomatic diastolic dysfunction alone.

Option 8 (unclassifiable)—medical record documentation is missing; or there is no decompensated HF AND cannot differentiate between “chronic stable heart failure” and “heart failure unlikely.” In general, this classification should be used sparingly (least frequently).

NOTE: If there are symptoms of heart failure only in the setting of a fatal cardiac arrest not due to an acute myocardial infarction, and the patient otherwise was not hospitalized for a heart failure exacerbation, do not count as “decompensated heart failure” (“2” or “3”). Instead, classify the case as “chronic stable heart failure” (“4”) if the patient had known history of heart failure but was not hospitalized with decompensated heart failure except at time of arrest (e.g., patient with metastatic cancer who had known LVEF 15% from ischemic cardiomyopathy, but had an arrest while being evaluated for failure to thrive because of the cancer). If the patient has no history of heart failure, consider classifying the case as “1” or “8”.

General Guidelines:
• If debating between...
  o Option 3 (possible decompensated HF) and Option 4 (chronic stable HF), then favor Option 3.
  o Option 2 (definite decompensated HF) and Option 3 (possible decompensated HF), then favor Option 3.
  o Option 3 (possible decompensated HF) and Option 8 (unclassifiable), then favor Option 8.
  o Option 3 (possible decompensated HF) and Option 1 (HF unlikely), then favor Option 8.
  o Option 4 (chronic stable HF) and Option 1 (HF unlikely) [and Option 8], then favor Option 8.

• Not all disagreements are equally important.
  o Disagreement between “1” and “8” is NOT very important.
  o Disagreement between “4” and “3” is very important.
  o Disagreement between “4” and “2” is very important.
  o Disagreement between “2” and “2” is very important.
  o Disagreement between “4” and “1” (or “4” and “8”) is important.

Question 7.1
(If option “2” or “3”, is selected, answer item 7.1. If “1”, “4” or “8”, is selected, skip to item 7.2.
Question 7.1 “Was definite or possible decompensated heart failure present at admission?” After review of the medical record documents pertinent to this event, indicate if there was decompensated heart failure at admission. Indicate either “Yes” or “No.”

Question 7.2
Based on your review of the Event Summary Form (ESF) and the medical record documents provided, record in question 7.2 whether there is evidence of (past or present) systolic or diastolic dysfunction as: Abnormal LV systolic function (7.2.1); abnormal RV systolic function ; (7.2.2); or LV diastolic dysfunction (7.2.3). For each, select “Yes” if the documentation indicates less than normal, “No,” if the documentation indicates normal, or “unknown” if no data is available (i.e., not recorded). If there is no specific information in the documentation, do not assume that the value is normal, but record as “unknown.” For example, record unknown if there is no specific mention of left ventricular diastolic dysfunction; do not assume that no mention means that the left ventricular function is normal. Do not
record that diastolic dysfunction is present if the report mentions only left ventricular hypertrophy. Use only medical record documents related to that hospitalization to answer these items; do not use historical information (e.g., note that the EF was x% 6 months prior to current hospitalization). Information should be specific, preferably from a specific report of the test results (e.g., echo report). Specific information in a progress report or other note, such as recording of a specific value of EF in the cardiology consult note from the current admission, is acceptable if no other documentation is provided. Historical information will be captured in the abstraction.

A dilated left ventricle alone is not sufficient to indicate that abnormal LV systolic function is present. An estimated LVEF of < 50% is sufficient to define LV systolic dysfunction. However, if the abstractor has recorded a specific LV ejection fraction (LVEF) on the ESF, but there are no supporting documents from the current hospitalization, then record Unknown.

A dilated right ventricle alone is not sufficient to indicate that abnormal RV systolic function is present.

Diastolic dysfunction must be explicitly described or documented in order to select “Y”(YES”). Synonyms include “diastolic LV dysfunction”, “impaired LV relaxation”, “impaired LV compliance”, “impaired LV diastolic filling”, “reversed E-A ratio”, “late diastolic filling”, “stiff ventricle”, “abnormal mitral annulus tissue Doppler signal”, “pseudonormalization of transmitral Doppler flow”, “restrictive filling pattern”, “Grade 1 diastolic dysfunction”, “Grade 2 diastolic dysfunction”, and “Grade 3 diastolic dysfunction”. If left ventricular compliance or relaxation is normal, code “N (No)” for diastolic dysfunction. An echo report or other imaging report that describes diastolic function outranks other documentation of diastolic dysfunction.

Question 7.3
Record in question 7.3 the estimated LVEF (worst; related to this hospitalization). Review the data for Ejection Fraction in the ESF and the accompanying medical record documents. If there is a discrepancy within the available documentation, use clinical judgment to determine which is most accurate (e.g., description of abnormal LVEF (<50%) by history which is not confirmed by objective testing but an echocardiogram report documents normal LVEF (≥50%) in a patient with no symptoms of heart failure, most likely LVEF is ≥50%). The most current echocardiogram or other imaging procedure (e.g., contrast ventriculogram) with the lowest LVEF (from the hospitalization) should be used in making this assessment. For example, if there are records documenting different estimates of LVEF, take the most recent lowest LVEF (e.g., current hospitalization describes lowest LVEF is 40%, record the lowest current LVEF = 40%). However, if the abstractor has recorded a specific LV ejection fraction (LVEF) on the ESF, e.g., from the notes (patient with history of LVEF x%), but there are no supporting documents, then record unknown. The rationale for this is that confirmation for an estimated LVEF should be documented by an official report to differentiate a historical LVEF versus an objectively documented LVEF. Both types will be captured on the ESF, but adjudicators should only record specific information from the current hospitalization. In general, the worst LVEF related to this hospitalization is, in your judgment, the LVEF that is related to this event/hospitalization. Indicate either 1 (≥ 50 %), 2 (35-49%), 3 (<35%) or 4 (Unknown/not sure). If LVEF is described as “normal” in the report, and no percentage is given, record A (≥50%).

Incident vs. Recurrent CHF Cases
Although CARDIA is interested in incident CHF cases, and does not ordinarily adjudicate recurrent cases of CHF for the same participant, the reviewers will receive recurrent cases until criteria are met for a diagnosis of DEFINITE Decompensated Heart Failure.

CARDIA Endpoint Events Manual of Operations v02/14/2017 14
NOTE: Refer to Heart Failure Case Law from the ARIC Study while reviewing each CHF case (Appendix 9).

4.1.5. Stroke
CARDIA has adopted the TOAST criteria for ischemic stroke (Madden, Karanjia, Adams, Clark and the TOAST Investigators, 1995). Stroke is defined as the rapid onset of a headache, meningsmus, or a persistent neurologic deficit attributable to an obstruction or rupture of the arterial system (including stroke occurring during a procedure such as angiography or surgery). Deficit is not known to be secondary to brain trauma, infection, or other non-ischemic cause. Deficit must last more than 24 hours, unless death supervenes or there is a demonstrable lesion compatible with acute stroke on CT or MRI scan.

The definition of a stroke excludes:
• Headache alone and no demonstrated blood by LP, CT, or MRI scan;
• Bell’s palsy or labyrintheine disease;
• Metabolic problems (such as diabetic, uremic, or hepatic coma) as a cause of altered consciousness;
• Brain tumor as found by hospital course, CT or MRI scan, angiography, biopsy, or autopsy;
• Trauma by history, CT or MRI scan, or angiography
• Infection (encephalitis, abscess) by CT or MRI scan, LP, or absence of fever;
• Old stroke by CT or MRI scan. This is usually diagnosed if the location of the infarct is inappropriate to explain the findings or when there is nearby focal ventricular enlargement. Recent infarcts often have edema or show distortion of the brain, are enhanceable, or show progression between CT or MRI scans;
• Seizures with status and post-ictal paralysis (Todd’s) by history or observation and history of past seizures. Sometimes when a stroke causes seizure, CT or MRI scan or angiogram can confirm the stroke;
• Venous infarcts and subdural hematomas; or
• Hysteria, which can usually be differentiated by inconsistencies on examination and evidence of secondary gain.

The assessment of DEFINITE stroke will be made based on 1) the final physician diagnosis that a stroke has occurred, and 2) the satisfaction of the appropriate algorithms. It will include strokes occurring during surgery. If only a physician diagnosis of stroke and algorithms are not satisfied, it is a PROBABLE stroke. The algorithm is by branching logic.

Stroke Subtypes:

Hemorrhagic Stroke
Must meet one or more of the following criteria:
• Blood in subarachnoid space or intraparenchymal hemorrhage by CT or MRI scan. If intraparenchymal, blood must be dense and not mottled (mixed hyperdensity and hypodensity).
• Bloody spinal fluid by lumbar puncture plus neurologic signs and symptoms consistent with stroke.
• Death from stroke within 24 hours of onset and no LP, CT, MRI or autopsy. (Death within 24 hours of stroke is nearly always due to hemorrhage.)
• Surgical or autopsy evidence of hemorrhage as a cause of clinical syndrome.

Hemorrhagic Stroke Subtypes
Subarachnoid Hemorrhage Stroke
Must meet one or more of the following criteria:
- Headache or coma or combination with possibly some focal deficit and CT or MRI shows subarachnoid blood in basal cistern, tissues, convexity, or blood clots in these locations; may also see aneurysm or arteriovenous malformation with enhancement.
- Similar clinical picture with bloody CSF. Headaches, stiffness and coma outweighs focal deficit; may have subhyloid hemorrhage, 3rd nerve palsy.
- Autopsy evidence of subarachnoid hemorrhage.

Intraparenchymal Hemorrhage Stroke
Must meet one or more of the following criteria:
- CT or MRI shows intraparenchymal increased density (not mottled); location is compatible with deficit.
- Bloody CSF with progressive focal deficit.
- Autopsy evidence of intraparenchymal hemorrhage.

Indeterminate Type Hemorrhage Stroke
Must meet one or both of the following criteria:
- Death within 24 hours of onset without evidence by CT or MRI, or surgery, or autopsy of location of blood.
- Bloody LP but no definite clinical picture compatible with either subarachnoid or intraparenchymal hemorrhage.

Ischemic Stroke
Must meet one or more of the following criteria:
- Focal brain deficit without CT, MRI, or LP evidence of blood.
- CT or MRI with mottled cerebral pattern or showing decreased density in a compatible location with reported symptoms and signs.
- Surgical or autopsy evidence of ischemic infarction.

Ischemic Stroke Subtypes
Lacunar Stroke
Must meet one or both of the following criteria:
- Angiogram, if done, shows evidence of adjacent major artery occlusion or severe stenosis and one of the following is present:
  - CT or MRI shows a deep area of decreased density less than 2 cm in maximum length in a location compatible with the clinical picture
  - normal CT or MRI with clinical syndrome of pure motor hemiparesis, pure sensory stroke, ataxia hemiparesis and dysarthria clumsy hand syndrome
  - autopsy evidence of lacunar stroke due to small vessel disease

Embolic Stroke
Must meet one or more of the following criteria:
- Cerebral hemisphere infarction with a recognized source for emboli or systemic emboli (including atrial fibrillation, endocarditis, mitral valve disease, clot in the heart by echocardiogram, CT or MRI, recent cardiac surgery or trauma, myocardial infarction).
- No lacunae by CT or MRI compatible with the clinical picture.
- Hemorrhagic infarction (mottled) by CT or MRI.
- CT or MRI showing small <1/2 lobe cortical infarction compatible with clinical findings, and no prior TIAs in the same territory.
- Autopsy shows area of infarction thought to be due to embolus.

**Atherosclerotic Infarction**
Must meet one or both of the following criteria:
- Focal infarct in the setting of evidence for large vessel disease, with no evidence of lacunar, mottled infarction, or small cortical infarct by CT or MRI and no sources of emboli and one of the following:
  - preceding TIAs in the same vascular territory
  - carotid artery bruit over the proximate artery
  - internal carotid bifurcation if compatible
- Autopsy evidence of infarction caused by atherosclerosis.

**Unknown Type Stroke**
Satisfies the criteria for stroke; inadequate information to categorize as hemorrhagic or ischemic.

**Other/Unknown Infarction**
Includes:
- All cases not classified by the above rules for lacunar, embolic or atherosclerotic infarction;
- All cases that could be classified in more than one of the above categories; and
- All cases attributed to arteritis or dissection of the arterial wall.

**STROKE References**


**4.1.6. Transient Ischemic Attack**
Transient ischemic attack is defined as a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction (Easton et al., 2009). A definite diagnosis will depend on the extent of evaluation the participant receives.

Hemiparesis is defined as weakness of the face, arm, and/or leg; hemiparesis of two or more body parts would refer to ipsilateral face and arm, or arm and leg. Much less common, but perhaps worth noting, brainstem strokes can present with crossed weakness - that is, the face on one side and contralateral arm +/- leg.

A participant has a DEFINITE diagnosis of TIA if he/she has one or more episodes of a focal neurologic deficit involving ONE major neurologic symptom or TWO minor neurologic symptoms with no head trauma occurring immediately before the onset of the neurological event. If deficits resolve, but imaging is negative, this is consistent with TIA. A DEFINITE diagnosis cannot be assigned without brain imaging. There should be no evidence of clonic jerking, conjugate eye deviation, prolonged Jacksonian
march, scintillating scotoma, or headache with nausea, and vomiting. Conditions to be ruled out include seizures, hypoglycemia, migraine, drug intoxication, tumor, infection, orthostatic hypotension, and generalized cerebral ischemia. Discovery of an infarct by CT or MRI scan in a location compatible with the symptoms, even if the symptoms cleared in less than 24 hours, shall be diagnosed as a stroke, not a TIA.

If other conditions have not been adequately ruled out or if brain imaging was not done, it should be defined as a PROBABLE TIA.

The reviewer may assign an overall diagnosis based on clinical judgment. It is possible to downgrade the diagnosis based on the medical history evidence (eg, weak documentation, atypical symptoms) regardless of parenthetical criteria.

TIA Reference

4.1.7. Carotid Artery Disease
A CARDIA diagnosis of DEFINITE carotid artery disease requires:
- Hospitalization with mention of carotid artery disease as a final diagnosis AND
- Angiographic or carotid ultrasound evidence of > 50% stenosis of one or both carotid arteries OR
- Surgical or diagnostic procedure (including atherectomy, angioplasty, surgery or angiogram)

A CARDIA diagnosis of PROBABLE carotid artery disease requires:
- Hospitalization with mention of carotid artery disease as a final diagnosis

4.1.8. Peripheral Arterial Disease
PAD is defined as leg pain, usually exertional, produced by ischemia from peripheral arterial disease or hospitalization for positive diagnostic test results or surgical intervention for lower extremity arterial occlusion or abdominal aortic aneurysm. The CARDIA criteria for PAD rely on the angiographically or ultrasound- demonstrated obstruction of the iliac arteries or below, surgical procedures for the obstruction or for treatment of an abdominal aortic aneurysm, exertional leg pain history, the ratio of the ankle-arm blood pressures, absence of pulse by Doppler in a major lower extremity vessel, and physician diagnosis. In case of existing lower extremity claudication and atherosclerosis of arteries of the lower extremities at the same time, the preferred option is atherosclerosis of arteries of the lower extremities as a diagnosis while lower extremity claudication is a symptom.

To classify a CARDIA outcome as DEFINITE PAD, the following criteria must be met:
• Angiographically-demonstrated obstruction, or ulcerated plaque (≥50% of the diameter or ≥75% of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below. (11.2.2) OR
• Surgery, angioplasty, or thrombolysis for PAD (11.2.5) OR
• Surgical or vascular procedure for abdominal aortic aneurysm (11.2.9).

To classify a CARDIA outcome as PROBABLE PAD, the following criteria must be met:

• Exertional leg pain relieved by rest (11.2.7) AND
• Ankle-arm systolic blood pressure ratio < 0.8 (11.2.8) OR
• Final diagnosis of PAD during hospitalization by treating physician (11.2.1) AND
• Any one of the following:
  o Absence of pulse by Doppler in any major vessel of lower extremities (11.2.3);
  o Exercise test that is positive for lower extremity claudication (11.2.4);
  o Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene (11.2.6);
  o Exertional leg pain relieved by rest (11.2.7);
  o Ankle-arm systolic blood pressure ratio ≤0.8.

If only physician diagnosis is present, define as PROBABLE PAD.

The final classification of PAD is made by the ESAS based on agreement that the criteria included in the appropriate algorithm are met.

4.1.9. **Deep Venous Thrombosis**

In order to be labeled DEFINITE, DVT requires hospital discharge summary or physicians notes with a diagnosis of DVT in combination with at least one of the following diagnostic criteria:

• Positive venographic study
• Positive impedance plethysmography study
• Positive findings on Doppler duplex, ultrasound, sonogram, or other non-invasive test
• Positive isotope scan

Reported DVT documented by positive impedance plethysmography or Doppler exam or radioisotope scan only are considered PROBABLE (modified from WHI).

4.1.10. **Pulmonary Embolism**

In order to be labeled DEFINITE, PE requires:

• Diagnostic (reported as definite) pulmonary arteriogram or contrast-enhanced CT pulmonary angiogram (13.2.3) OR
• Diagnostic spiral CT scan with contrast (not a dedicated contrast-enhanced CT pulmonary angiogram).

PE will be defined as PROBABLE if any of the following combinations of criteria are marked:

• Hospital discharge summary with a diagnosis of pulmonary embolism (13.2.1) and High probability positive ventilation-perfusion lung (13.2.2) OR
• High probability positive ventilation-perfusion lung scan (13.2.2) and Diagnosis of DVT based on >1 DVT criterion in 12.2 plus signs and symptoms suggestive of PE (e.g. acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest x-ray findings suggestive of PE) OR
• Hospital discharge summary with a diagnosis of PE (13.2.1) and Finding from contrast enhanced CT scan reported as probable of possible PE (13.2.6) OR
• Diagnosis of DVT based on >1 DVT criterion in 12.2 plus signs and symptoms suggestive of PE (13.2.5) and Finding from contrast-enhanced CT scan reported as probable or possible PE (13.2.6).

4.1.11. Diabetes Mellitus
Diabetes mellitus will be adjudicated as an endpoint only if it is the primary reason for the hospitalization. If the participant is hospitalized primarily because of a stroke, angina or MI, or congestive heart failure, diabetes will not be considered an endpoint, even if it is a contributing factor in the principal condition.

The following are the criteria for DEFINITE diabetes mellitus:
• Physician diagnosis of diabetes and on diabetes medication OR
• Self report or physician diagnosis of diabetes and a fasting and/or random blood glucose ≥ 126mg/dl* (*:Individual investigators may choose to use other cut points) at a CARDIA exam OR
• Abnormal OGTT at a CARDIA exam [must be abnormal fasting (≥126mg/dl) and any other measure >200mg/dl] OR
• Measure of fasting blood glucose >126mg/dl during at least two CARDIA exams

If only one criterion is met in each, the case is termed PROBABLE diabetes mellitus.

4.1.12. Asthma/COPD (revised by ESAS 08/21/2014)
Asthma/COPD will be adjudicated as an endpoint only if it is the primary reason for the hospitalization. If the participant is hospitalized primarily because of a stroke, angina or MI, or congestive heart failure, asthma/COPD will not be considered an endpoint, even if it is a contributing factor in the principal condition.

CARDIA will only adjudicate hospitalized Asthma/COPD, the definition is based on that of “Global Initiative for Chronic Obstructive Lung Disease (GOLD), 2005 Update,” as we anticipate there will be no cases of chronic stable Asthma/ COPD as a primary reason for admission to a hospital. According to GOLD, an exacerbation is an “acute, sustained worsening of the patient’s condition from stable state and beyond normal day-to-day variation.” The GOLD report notes that most studies define exacerbation on the basis of an increase in symptoms, requiring patient perception and reaction to this perception. The typical presentation is increased breathlessness with or without cough, changes in sputum volume or purulence, wheezing, and chest tightness.

Objective measures of severity according to GOLD include symptoms, change in volume and color of sputum (increased volume, purulence), and blood gases. A severe exacerbation may be accompanied by acute respiratory failure, defined by GOLD as decreased PaO2 (<60 mm Hg on room air) with or without increased PaCO2 (>50 mm Hg; O2 saturation by pulse oximetry less accurate). Acute respiratory failure is perceived by the patient as severe dyspnea, often with agitation, confusion, tachycardia, sweating. In general, a peak expiratory flow (PEF) less that 100 L/min indicates severe exacerbation. Other markers of severity include use of supplemental O2, noninvasive positive pressure ventilation (NIPPV), or mechanical ventilation.

Dual diagnoses do exist: clearly some people had asthma as a child, it probably was not very active as an adult, but they smoked and eventually developed chronic lung disease with cough and sputum.
production. So they seem to have both and may be more responsive to bronchodilators than typical patients with COPD. It is difficult to tell if either of the specific diagnoses is acutely exacerbated.

The major drugs used for exacerbation are the same:
- corticosteroids - #1 drug to use for both; 2) β2 agonist 3) anticholinergics 4) Xanthines
- Chromolyn is not used much and has limited availability
- Anti-IgE therapy is not used commonly but is specific for asthma. It is not used for acute exacerbation. Anti-leukotrienes are sometimes used in COPD.

Assigning definite or probable will depend on the type and quality of documentation available to the reviewer.

CARDIA criteria to allow investigators to determine the severity of an exacerbation:
(Reviewers should mark each indicator that is present.)
- Presence of acute respiratory failure defined as decreased PaO2 (<60 mm Hg on room air) or O2 saturation (<88%) with or without increased PaCO2
- Report of severe dyspnea with or without agitation, confusion, tachycardia, or sweating
- Treatment with supplemental O2 or increased O2 if on chronic supplemental O2
- Treatment with noninvasive positive pressure ventilation (NIPPV)
- Intubated and treated with mechanical ventilation
- PEF <100 L/min
- None of the above

4.1.13. Hypertension
Hypertension will be adjudicated as an endpoint only if it is the primary reason for the hospitalization. If the participant is hospitalized primarily because of a stroke, angina or MI, or congestive heart failure, hypertension will not be considered an endpoint, even if it is a contributing factor in the principal condition.

The following are criteria for DEFINITE hypertension:
- Physician diagnosis of hypertension and on blood pressure lowering medication(s) OR
- Systolic blood pressure is greater than 140 mmHg AND/OR diastolic blood pressure is greater than 90 mmHg on more than one occasion

The following are criteria for PROBABLE hypertension:
- Only one measure of systolic blood pressure is greater than 140 mmHg AND/OR diastolic blood pressure is greater than 90 mmHg AND
- Not on blood pressure lowering medication(s) AND/OR
- Physician diagnosis is not clearly defined

4.1.14. End Stage Renal Disease (CARDIA Endpoint beginning with YR20 Exam)
The following are criteria for DEFINITE end stage renal disease:
- Physician diagnosis of end stage renal disease OR
- Chronic dialysis OR
- Kidney transplantation

4.1.15. Atrial Fibrillation/Flutter (Added 09.06.2011) (Revised by ESAS 02.20.2014)
Atrial fibrillation or flutter cases will be identified based on the current hospitalization using a combination of physician documentation of atrial fibrillation or flutter, EKG tracings and reports, cardioversion attempts, documentation of appropriate anti-arrhythmic medication use in setting of an arrhythmia history and documentation of appropriate procedure such as ablation in setting of arrhythmia history. Atrial fibrillation/flutter does not have to be the primary reason for admission. Based on the adjudicator’s clinical judgment and the criteria below, each atrial fibrillation/flutter case will be grouped in one of the following categories:

1. **DEFINITE** cases must meet one of the following criteria or combinations of criteria:
   - Documentation of atrial fibrillation/flutter as present during this hospitalization in a physician note such as the ER note, admission and physical, cardiology consult or discharge summary. Do not include atrial fibrillation if present only in the acute setting of EP study, e.g. only present when induced by the EP study
   
   **AND**
   
   A computer-based reading of the 12-lead ECG from the current admission that says atrial fibrillation/flutter

   - A computer-based reading of the 12-lead ECG from the current admission that says atrial fibrillation/flutter
   
   **AND**
   
   Documented history of atrial fibrillation/flutter with use of an appropriate anti-arrhythmic medication **OR** Documented history of atrial fibrillation/flutter and procedure to treat atrial fibrillation/flutter (e.g. ablation).

   - Adjudicator diagnosis of atrial fibrillation/flutter on 12-lead ECG or rhythm strip from this admission. The rhythm strip must be at least 10 seconds

   - Documented cardioversion attempt (chemical or electrical) for atrial fibrillation/flutter during the current admission

2. **PROBABLE** cases must meet one of the following criteria:
   - Documentation of atrial fibrillation/flutter as present during this hospitalization in a physician note such as the ER note, admission and physical, cardiology consult or discharge summary. Do not include atrial fibrillation if present only in the acute setting of EP study, e.g. only present when induced by the EP study
   
   - A computer-based reading of the 12-lead ECG from the current admission that says atrial fibrillation/flutter
   
   - Documentation of history of atrial fibrillation/flutter with use of an appropriate anti-arrhythmic medication
   
   - Documentation of atrial fibrillation/flutter as present during this hospitalization in a physician note such as the ER note, admission and physical, cardiology consult or discharge
summary. Do not include atrial fibrillation if present only in the acute setting of EP study, e.g. only present when induced by the EP study

AND
Documentation of history of atrial fibrillation/flutter with use of an appropriate anti-arrhythmic medication

Adjudicators will also determine whether the atrial fibrillation/flutter is presented in the post-CABG setting. The post-CABG setting would be defined as any point following a coronary bypass surgery in the same hospitalization.

Finally, adjudicators will report whether atrial fibrillation or flutter was present on discharge. Cases warranting a **YES** response to this item could include those with:

- specific mention or EKG documentation of atrial fibrillation/flutter or at discharge
- Specific mention or EKG documentation of atrial fibrillation/flutter prior to discharge without intervening evidence of conversion to normal sinus rhythm or some other rhythm prior to discharge

Conversely, cases warranting a **NO** would include

- Specific mention or EKG documentation of normal sinus rhythm or another rhythm distinct from atrial fibrillation/flutter at discharge
- Specific mention or EKG documentation of normal sinus rhythm or another rhythm distinct from atrial fibrillation/flutter prior to discharge without intervening evidence of reversion back to atrial fibrillation/flutter prior to discharge
- Reporting of successful cardioversion (chemical or electrical) without intervening evidence of reversion back to atrial fibrillation/flutter prior to discharge

Cases warranting an **UNKNOWN** would include

- those with intermittent or paroxysmal atrial fibrillation/flutter early in the hospitalization without a specific mention or EKG documentation of a particular rhythm at discharge
Appendix 1
CARDIA Mortality Record Acquisition and Review Process Flow Chart
CARDIA MORTALITY RECORD ACQUISITION AND REVIEW PROCESS

Death is discovered / reported

FC requests Death Certificate

Death certificate received by FC

No

FC requests additional information (ER records, hospital records, next of kin, autopsy report, MD report: coroner’s report)

Information available

Yes

Start searching National Death Index and other eligible Internet resources

Data from NDI and Internet resources available

No

FC forwards Death certificate to CC

Yes

FC forwards Death certificate to CC

FC collects all relevant death related records following the decision matrix and sends it to CC

FC forwards information to CC

STOP!

FC by MD

CC enters Forms 33C and 33D into the M&M database

All available death related documents and forms forwarded to 2 reviewers

Complete two Form 33E (mortality review/adjudication form)

Endpoints reviewers agree?

Yes

Adjudicated by MD at CC

No

Forward to Endpoints Committee for adjudication

CC enters ICD-9 codes into the M&M database

CC enters Form 33E into the M&M database

CC enters Forms 33A and 33B into the M&M database and maintains other death related records

CC stores Forms 33A-E and all death related documents

XX – finalized complete

CC updates tracking codes in the M&M database
### Appendix 2

**Decision Matrix for Forms to be obtained when Participant Dies**

<table>
<thead>
<tr>
<th>CAUSE OF DEATH</th>
<th>FORM 33</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>HR</td>
<td>AU</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Sudden Death</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Stroke/Cerebrovascular</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Hypertension</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Renovascular (Kidney)</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Cancer</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Infection</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Influenza</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>AIDS</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injury-unintentional</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homicide</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suicide</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Other</td>
<td>*</td>
<td>*</td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Ambiguous</td>
<td>*</td>
<td>*</td>
<td>(*)</td>
<td></td>
<td>*</td>
</tr>
</tbody>
</table>

**Legend**

- **Form 33A**: Initial Notification of Death Form
- **Form 33B**: Final Report of Death Form
- **Form 33C**: Next of Kin/Witness (when indicated)
- **HR**: Hospital record (all admitting medical history and physical exam; daily lab work; ECG tracings; chest x-ray reports; results of all special procedures performed; e.g., scans, any other angiographic reports, graded exercise test, MRI; face sheet; discharge summary)
- **AU**: Autopsy record (if autopsy was performed)/coroner's report
INITIAL NOTIFICATION OF DEATH FORM
FORM 33A

P ID

Date Completed

This form should be completed and a copy mailed to Coordinating Center within 48 hours after CARDIA learned of the death of any participant. The Final Report of Death Form should be completed and sent as soon as possible to the Coordinating Center with appropriate materials attached.

1) Date of Death

2) Date CARDIA Learned of Death

3) Place of Death (geography)

4) Place of death (type of location)

5) Was the participant hospitalized around the time of death? (If answer to Q4, is 2-4, this is definitely “yes.” Otherwise, answer will depend on the specific circumstances.)

1 No

2 Yes

8 Unknown at this time

Version: 03/01/2015

Page 1 of 2
6) Was the participant hospitalized for any reason since [last date of contact]? (Record any additional hospitalizations here.)

<table>
<thead>
<tr>
<th>Number</th>
<th>Yes/No</th>
<th>Date of Admission</th>
<th>Date of Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Unknown at this time</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7) According to the information you have now, what was the cause of death?

- 01 Accident
- 02 Homicide
- 03 Suicide
- 04 AIDS
- 05 Heart Attack, Coronary Heart Disease, Other Cardiovascular Disease
- 06 Cardiac Arrest
- 07 Cerebrovascular (e.g. stroke /transient ischemic attack)
- 08 Cancer
- 09 Kidney Disease
- 10 Liver Disease
- 11 Diabetes
- 12 Lung Disease
- 13 Other, Specify: ________________________________
- 14 Unknown

8) Was the participant under a physician’s care for the condition that led to his/her death?

<table>
<thead>
<tr>
<th>Number</th>
<th>Yes/No</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Unknown at this time</td>
<td></td>
</tr>
</tbody>
</table>
**FINAL REPORT OF DEATH FORM**

**FORM 33B**

<table>
<thead>
<tr>
<th>PID</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date Completed</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>Day</td>
<td>Year</td>
<td></td>
</tr>
</tbody>
</table>

This form is to be completed and forwarded to the Coordinating Center. Copies of other appropriate documents noted below should accompany this form. Each of the documents should be carefully reviewed for completeness prior to being forwarded to the Coordinating Center.

1) **Date of Death**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>Day</td>
<td>Year</td>
</tr>
</tbody>
</table>

2) **Time of Death**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th>AM</th>
<th></th>
<th>PM</th>
<th></th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td>2</td>
<td></td>
<td>8</td>
</tr>
</tbody>
</table>

3) **Was an autopsy performed?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Has a copy been made of the autopsy report and enclosed with this form?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

4) **Was the participant hospitalized or seen in the ER around the time of death?** *(i.e., immediately prior to death or as part of the circumstances that led to the participant’s death)*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

8 Unable to determine

The following potential sources of available information about circumstances leading up to the terminal event should be consulted according to the decision matrix and where available, copies should be made and sent to the Coordinating Center.

5) **According to the decision matrix (insert location) should a medical record be obtained?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

End of questionnaire; go to CARDIA Staff ID.

6) **Were medical records requested?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No, Unable to locate NOK</td>
<td>No, Refusal by NOK</td>
</tr>
<tr>
<td>No, Refusal by facility</td>
<td>Yes, Requested from facility</td>
</tr>
</tbody>
</table>

Version: 03/01/2015
7) Please indicate the status of records below by marking (V, X) the appropriate box for each line item.

<table>
<thead>
<tr>
<th>DOCUMENT</th>
<th>Copy enclosed</th>
<th>Original does not exist</th>
<th>Original exists; no copy available</th>
<th>If no copy, explain</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Form 33A</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>B. Form 33B</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>C. Death Certificate</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>D. Form 33C (if required)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>E. Autopsy Report</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>F. Emergency Room/Dept</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>G. Hospital Inpatient</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

Go to 7H.

Go to 7H.

i. Discharge summary       | 1             | 2                       | 3                                 |                     |
ii. Discharge diagnosis    | 1             | 2                       | 3                                 |                     |
iii. ECGs (12 lead)        | 1             | 2                       | 3                                 |                     |
iv. Procedure/Operative Reports | 1         | 2                       | 3                                 |                     |
v. Lab reports             | 1             | 2                       | 3                                 |                     |
vi. X-rays, CAT scans, angiography reports | 1        | 2                       | 3                                 |                     |
vii. Surgical pathology report | 1       | 2                       | 3                                 |                     |

Go to Question 8.

H. Ambulance/EMS            | 1             | 2                       | 3                                 |                     |
I. Coroner’s Report         | 1             | 2                       | 3                                 |                     |
J. Other                    | 1             | 2                       | 3                                 |                     |

8) According to the decision matrix, should Form 33C be completed?

1 No ➔ End of questionnaire; go to CARDIA Staff ID.

2 Yes ➔ Has/have a copy/copies been made and enclosed with this form?
   1 Yes, copy/copies enclosed
   2 No, Explain:

__________________________________________________________

CARDIA Staff ID [ ] [ ]
INTERVIEW WITH WITNESS/NEXT OF KIN
FORM 33C

PID

Date of Interview

Month / Day / Year

These interviews should be carried out where appropriate, according to the decision matrix. The interviews can usually be done by telephone, and should follow the specified sequence (e.g., using open-ended questions first). More than one form may be completed if several relevant interviews were done.

1) Ask the respondent for his/her contact information. Record it in Question 7 on Page 3.

2) Was the respondent with the participant when he/she died?
   1 No
   2 Yes

   When was the death discovered?
   Date
   Month / Day / Year
   Time
   1 AM 2 PM

   GO TO QUESTION 3.

   When did the death occur?
   Date
   Month / Day / Year
   Time
   1 AM 2 PM

   GO TO QUESTION 4.

3) When was the participant last seen alive?

   Date
   Month / Day / Year
   Time
   1 AM 2 PM

4) Where did the death occur?
   01 Home 04 Hospital, Palliative Care 07 Rehabilitation Facility
   02 Hospital 05 Nursing Home 08 Other, Specify: __________
   03 ER/ED 06 Hospice 09 Unknown
5) Ask the respondent: Can you tell me what happened?
   Let the respondent describe the situation in their own words. Make note of everything. Listen for points of interest, and probe for more if not given in their initial response. Attach additional pages if needed.
   Some questions you may use to probe if applicable:
   - What was the participant's health like that day?
   - Did you observe any symptoms? What were they? How long did they last?
     Symptoms of special interest: increased fatigue or weakness; pain or discomfort in chest, left arm/shoulder, jaw; shortness of breath; dizziness; palpitations or irregular heart beat; indigestion, nausea, or vomiting; sudden numbness or weakness on one side of the body, sudden changes in vision; sudden paralysis; sudden loss of speech or the ability to understand speech
   - What was he/she doing at the time of death?
   - Did you notice any changes in his/her abilities?
   - Had the participant complained of anything related to his/her health in the weeks before?
   - To the best of your knowledge, what was the cause of death?
6) **Was the participant hospitalized for any reason since [last date of contact]? (Record any additional hospitalizations here.)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

**Hospitalization 1**

<table>
<thead>
<tr>
<th>Date of Admission</th>
<th>Date of Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Department Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Street Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hospitalization 2**

<table>
<thead>
<tr>
<th>Date of Admission</th>
<th>Date of Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Department Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Street Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hospitalization 3**

<table>
<thead>
<tr>
<th>Date of Admission</th>
<th>Date of Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Department Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Street Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7) Ask the respondent: Is there anyone else who might have more information about the circumstances surrounding the death?

1 □ No → Be sure information in Question 7 is complete, and thank the respondent.
   End of questionnaire.

2 □ Yes

   Contact One
   Contact Name (First, M/L, Last)
   Street Address
   Street Address
   City State Zip
   Telephone
   Relationship to Participant

   Contact Two
   Contact Name (First, M/L, Last)
   Street Address
   Street Address
   City State Zip
   Telephone
   Relationship to Participant

8) Enter the respondent’s contact information here:

   Respondent
   Respondent’s Name (First, M/L, Last)
   Street Address
   Street Address
   City State Zip
   Telephone
   Relationship to Participant

DO NOT SEND THIS PAGE TO COORDINATING CENTER
Form 33E
CARDIA ID: __________ __________

CARDIA MORTALITY REVIEW/ADJUDICATION FORM

1 □ 1st Review  2 □ 2nd Review  3 □ CC Adjudication  4 □ ESAS Adjudication

Date of review/adjudication: ______ / ______ / ______  Date of death: ______ / ______ / ______

Reviewer ID ______ (BL-601; KBD-605; DLL-606; SS-608; CI-612; RC-616; GW-618; RD-619; HL-620; SH-621; DL-622)

1. Location of death: (CHECK ONE)
   1 □ out of hospital/DOA (not nursing home)
   2 □ emergency room
   3 □ in hospital
   4 □ nursing home, skilled nursing, extended care facility
   0 □ unknown/unable to determine

2. Reviewer’s Classification of death: (CHECK ONE)
   1 □ Atherosclerotic coronary heart disease - GO TO QUESTION 2.A
   2 □ Stroke - GO TO QUESTION 2.B
   3 □ Atherosclerotic disease other than coronary or stroke - GO TO QUESTION 2.C
   4 □ Non-atherosclerotic cardiovascular disease - GO TO QUESTION 2.D
   5 □ Pulmonary Embolus - GO TO QUESTION 2.E
   6 □ Non-cardiovascular disease - GO TO QUESTION 2.F
   7 □ Unknown - GO TO QUESTION 4

2a Atherosclerotic coronary heart disease

1 □ Definite fatal MI (no known non-atherosclerotic cause, definite MI w/in 4 weeks of death)
2 □ Definite fatal CHD (no known non-atherosclerotic cause, one or both of the following: 1) chest pain within 72 hours of death or 2) a history of chronic ischemic heart disease in the absence of valvular heart disease or non-ischemic cardiomyopathy)
3 □ Possible fatal CHD (compatible underlying cause of death ICD9 410-14, 427.5, 429.2 and/or 799 and no known non-atherosclerotic cause)

2a1 Mechanism of death

1 □ Primary arrhythmic death (death within 5 minutes in otherwise asymptomatic individual);
2 □ Secondary arrhythmic/mechanical death mechanical (death with preceding symptoms of heart disease, but no evidence of chronic myocardial pump failure);
3 □ Congestive heart failure (death due to shock or low output syndrome);
4 □ Cardiac procedure (death related to CABG or angioplasty);
5 □ Unknown/cannot determine

2a2 Timing of death (if died out of hospital)

CARDIA Form 33E ver. 09/13/2012
2a3 Presence of cardiac symptoms (if died out of hospital):
1  □ Cardiac chest pain within 72 hours of death
8  □ Unknown or cannot determine

2b Stroke:
1  □ Definite (Death due to definite stroke with consistent imaging, surgical, or autopsy evidence)
   1  □ Hemorrhagic
   2  □ Ischemic
   8  □ Unknown
2  □ Possible (Death due to presumed stroke that did not meet criteria for definite stroke and death certificate consistent with stroke without other underlying or immediate cause)
   1  □ Hemorrhagic
   2  □ Ischemic
   8  □ Unknown
3  □ Estimated time between onset of acute stroke symptoms and death
   1  □ Less than 5 minutes
   2  □ 5 minutes to 1 hour
   3  □ 1 hour to 24 hours
   4  □ 1 day to 1 week
   5  □ 1 week to 1 month
   6  □ Longer than one month

2c Atherosclerotic disease other than coronary or stroke (e.g. abdominal aortic aneurism; complications of peripheral arterial disease):

Specify ________________________________

1  □ Definite (Consistent imaging, surgical, or autopsy evidence)
2  □ Possible (Death due to presumed other atherosclerotic disease that did not meet criteria for definite one and death certificate consistent with atherosclerotic disease without other underlying or immediate cause)

2d Non-atherosclerotic cardiac disease

1  □ Non-ischemic cardiomyopathy
   Type (e.g., Hypertrophic obstructive cardiomyopathy (HOCM), alcoholic, idiopathic/unknown) ________________________________

2  □ Other (describe): ________________________________

2d1 Mechanism of death

CARDIA Form 33E ver. 09/13/2012
1  □  Primary arrhythmic death (death within 5 minutes in otherwise asymptomatic individual);
2  □  Secondary arrhythmic/mechanical death mechanical (death with preceding symptoms of heart disease, but no evidence of chronic myocardial pump failure);
3  □  Congestive heart failure (death due to shock or low output syndrome);
4  □  Cardiac procedure (death related to CABG or angioplasty);
5  □  Unknown/cannot determine

2c  Pulmonary Embolus

1  □  Definite (Death due to definite pulmonary embolism with consistent imaging, surgical, or autopsy evidence)
2  □  Possible (Death due to presumed pulmonary embolism that did not meet criteria for definite one and death certificate consistent with pulmonary embolism without other underlying or immediate cause)

2f  Non-cardiovascular disease

01  □  AIDS
02  □  Cancer, specify type
03  □  Diabetes, specify type
04  □  Homicide
05  □  Kidney Disease, specify type
06  □  Liver Disease, specify type
07  □  Asthma
08  □  Other Lung Disease, specify type
09  □  Suicide
10  □  Unintentional Injury
11  □  Sepsis
12  □  Other: __________________________

3.  Procedure related death

1  □  Yes
1  □  Death after invasive cardiovascular intervention. Death within 28 days of cardiovascular surgery or within 7 days of cardiac cath, arrhythmia ablation, angioplasty, atherectomy, stent deployment, or other invasive coronary vascular intervention
2  □  Cardiac death after noncardiovascular intervention occurred within 28 days of surgery or other invasive procedure.
2  □  No

4.  Documentation used for death adjudication: (MARK ALL THAT APPLY)

1  □  Medical records documentation  6  □  Informant interview
2  □  Report of autopsy findings  7  □  Initial death notification form (33A)
3  □  Death certificate  8  □  Final death notification form (33B)
4  □  ER record  9  □  Coroner’s report
5  □  EMS report  10  □  Other (specify) __________________________

CARDIA Form 33E ver. 09/13/2012  3
Appendix 4
CARDIA Morbidity Record Acquisition and Review Process Flow Chart

CARDIA MORBIDITY RECORD ACQUISITION AND REVIEW PROCESS

Hospitalization or outpatient procedure reported (Form 31 or Interim Contact Questionnaire)
  Scanning Form 31; Follow-up forms,
  CARDIA codes assigned at FC; Forms B and C filled out
  Possible endpoint
    Yes
    FC obtains informed consent for medical record retrieval and review
      Yes
      Medical record requested
      No
      Medical record received
        No
        Search remains active?
          No
          STOP!
          Yes
          Medical record complete
          No
          Request missing documents (EKG, lab, etc.)
            No
            STOP!
          Yes
          Medical record de-identified and forwarded to CC

IT updating M&M database (import new reported admissions)

MORBIDITY AND MORTALITY DATABASE

CC enters ICD-9 codes and tracking codes

ICD-9 Coding done by CC coder

Complete Form M0 (Triage form)
  Triaged by MD
    No
    STOP!
    Yes
    Meets study criteria?
      No
      STOP!
      Yes
      Forwarded to 2 endpoints reviewers

Complete two Forms M1 (morbidity review/adjudication form)
  Endpoints reviewers agree?
    No
    STOP!
    Yes
    Complete one Form M1 (morbidity review/adjudication form)

Finalized complete
  Yes
  Discrepancy resolved?
    Yes
    Forward to Endpoints Committee for resolution
    No
  No
  Adjutation by MD at CC
CARDIA Endpoint Events Manual of Operations v02/14/2017

39

### Appendix 5

CARDIA Morbidity Triage Form (M-0)

<table>
<thead>
<tr>
<th>Form M-0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CARDIA MORBIDITY TRIAGE FORM</strong></td>
</tr>
<tr>
<td><strong>CARDIA ID:</strong> ___________________________  Contact Period: __________</td>
</tr>
<tr>
<td>Admission Date: __________ / __________ / __________  Hospitalization Number: __________</td>
</tr>
<tr>
<td><strong>Month</strong> / <strong>Day</strong> / <strong>Year</strong>  (Note: If admission date not available, enter 'M' for missing value)</td>
</tr>
<tr>
<td><strong>Review Date:</strong> __________ / __________ / __________  Reviewer ID __________</td>
</tr>
<tr>
<td><strong>Month</strong> / <strong>Day</strong> / <strong>Year</strong></td>
</tr>
<tr>
<td><strong>COMMENTS</strong>  (Please include any other information you deem important here):</td>
</tr>
</tbody>
</table>

1. Do the Discharge Diagnoses include any ICD-9 codes of 410-414, mention **Myocardial Infarction**, **Angina, coronary revascularization**, or is any serum enzyme level above the normal limit?  
   - 1  No
   - 2  Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Questions 1-6

2. Does the Discharge Diagnosis mention **Congestive Heart Failure** (ICD-9 - 428)?  
   - 1  No
   - 2  Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Questions 1-3, 7

3. Does the Discharge Diagnosis include any ICD-9 codes of 430-436, 437.0, 437.1 or does the Discharge Diagnosis mention **Stroke or TIA**?  
   - 1  No
   - 2  Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Questions 8-9

4. Does the Discharge Diagnosis mention **Carotid Artery Disease** (ICD-9 codes – 433.1; 443.21)?  
   - 1  No
   - 2  Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 10
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
</table>
| 5 | Does the Discharge Diagnosis mention **Peripheral Arterial Disease or Abdominal Aorta Aneurism** (ICD-9 codes 441.3; 441.4; 443-445)?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 11 |
| 6 | Does the Discharge Diagnosis include any ICD-9 codes of 325, 415.1, 437.6, 444, 451, 453, 639.6, 673.2 or does the Discharge Summary mention **Venous Thrombosis or Pulmonary Embolism**?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Questions 12-13 |
| 7 | Does the Discharge Diagnosis mention **Diabetes Mellitus** as a primary reason (ICD-9 codes - 250)?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 14 |
| 8 | Does the Discharge Diagnosis mention **Asthma** as a primary reason (ICD-9 codes - 493)?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 15 |
| 9 | Does the Discharge Diagnosis mention **Hypertension** as a primary reason (ICD-9 codes - 401)?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 16 |
| 10 | Does the Discharge Summary mention **End-stage Renal Disease** (ICD-9 code - 585.6)?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 17 |
| 11 | Does the Discharge Summary mention **Chronic Obstructive Pulmonary Disease** as a primary reason (ICD-9 codes - 490-492; 494; 496)?  
1. No  
2. Yes -- Complete Form M-1 CARDIA Morbidity Review/Adjudication Form Question 18 |
Form M-0

12 Is **Atrial fibrillation or atrial flutter** mentioned as present during this hospitalization, or is **atrial fibrillation or atrial flutter** among the first three ICD-9 codes listed (ICD-9 code – 427.31 or 427.32)?

1 □ No

2 □ Yes -- Complete Form **M-1** CARDIA Morbidity Review/Adjudication Form Question 19
Appendix 6
CARDIA MORBIDITY REVIEW / ADJUDICATION FORM (Form M-1)

Form M-1

MORBIDITY REVIEW / ADJUDICATION FORM

☐ 1st Review  ☐ 2nd Review  ☐ CC Adjudication  ☐ ESAS Adjudication

CARDIA PID: ___________ ___________ ___________ ___________ ___________ Contact Period: ___________

Admission Date: _______ / _______ / _______ Hospitalization/Event Number: ___________

Month  Day  Year

Did the participant die during this admission?
1  ☐ No
2  ☐ Yes → complete Form 33F - Mortality Review/Adjudication Form

Reviewer/Adjudicator ID: _______ (BL-601; BS-602; CI-612; GW-618; RD-619; HK-620; SS-621; DL-622; DD-623; SG-624)

Review/Adjudication Date: _______ / _______ / _______

Month  Day  Year

Please review/adjudicate for the endpoints marked below. If additional endpoints are identified during the review/adjudication process, please mark them and record any comments in the space provided below.

☐ Myocardial Infarction (MI)  Question No.  Questions 1-4
☐ Non-MI Acute Coronary Syndrome (previously termed “angina”)  Questions 1-3, 5
☐ Coronary Revascularization  Question 6
☐ Congestive Heart Failure (CHF)  Questions 1-3, 7
☐ Stroke  Question 8
☐ Transient Ischemic Attack (TIA)  Question 9
☐ Carotid Artery Disease (CAD)  Question 10
☐ Peripheral Arterial Disease (PAD)  Question 11
☐ Deep Venous Thrombosis (DVT)  Question 12
☐ Pulmonary Embolism (PE)  Question 13
☐ Diabetes Mellitus (DM)  Question 14
☐ Asthma/ Chronic Obstructive Pulmonary Disease (COPD)  Question 15
☐ Hypertension  Question 16
☐ End Stage Renal Disease (ESRD)  Question 17
☐ Atrial Fibrillation/ Atrial Flutter  Question 18

COMMENTS (Please include any other information you deem important here):
1. **ECG Pattern**  
   (Mark the one category that best applies.)  
   - 1  ☐ Evolving diagnostic ECG (e.g. new diagnostic Q wave)  
   - 2  ☐ Positive ECG (e.g. evolving ST elevation or new LBBB)  
   - 3  ☐ Non-specific ECG (e.g. evolving non-ST elevation, non-Q wave pattern)  
   - 4  ☐ ECG negative for ischemia  
   - 5  ☐ ECG not available  

2. **Is cardiac enzyme information available?**  
   (At least two measurements of same marker taken at least six hours apart)  
   - 1  ☐ No → Go to Question 3  
   - 2  ☐ Yes—adequate (see Table 2 “Algorithm for enzyme diagnostic criteria of MI”)  
   - 3  ☐ Yes—inadequate  

2.1. **Serum creatine kinase (CK)**  
   (Always record % or index if available.)  
   **If CK-MB available:**  
   2.1a. **CK-MB expressed as a % or index** (Record peak results only.)  
      - 5  ☐ CK-MB at least 5x ULN for % or index  
      - 4  ☐ CK-MB at least 3x ULN but less than 5x ULN  
      - 1  ☐ CK-MB at least 2x ULN but less than 3x ULN  
      - 2  ☐ CK-MB greater than ULN but less than 2x ULN  
      - 3  ☐ CK-MB within normal limits for % or index  
   2.1b. **CK-MB expressed in units (usually ng/ml)** (Record peak results only.)  
      - 5  ☐ CK-MB at least 5x ULN for units  
      - 4  ☐ CK-MB at least 3x ULN but less than 5x ULN  
      - 1  ☐ CK-MB at least 2x ULN but less than 3x ULN  
      - 2  ☐ CK-MB greater than ULN but less than 2x ULN  
      - 3  ☐ CK-MB within normal limits for units  
   2.1c. **No units or % index given for CK-MB**  
      - 1  ☐ CK-MB reported as “present” without quantification  
      - 2  ☐ CK-MB reported as “weakly present” without quantification  
   2.1d. **If CK-MB not available**  
   (Mark the one category that best applies.)  
      - 1  ☐ Total CK at least 2x ULN  
      - 2  ☐ Total CK greater than ULN but less than 2x ULN  
      - 3  ☐ Total CK within normal limits  
      - 4  ☐ CK result not available
2.2. Troponin lab test
(Mark the one category that best applies. If more than one test was conducted, record the type with the most elevated lab result.)

1 □ Troponin C → Go to Question 2.2.1
2 □ Troponin I → Go to Question 2.2.1
3 □ Troponin T → Go to Question 2.2.1
4 □ Troponin, not specified → Go to Question 2.2.1
5 □ Troponin not available → Go to Question 2.3

2.2.1. Results
(Mark the one category that best applies.)

5 □ Troponin at least 5x ULN
6 □ Troponin at least 3x ULN but less than 5x ULN
1 □ Troponin at least 2x ULN but less than 3x ULN
2 □ Troponin greater than ULN but less than 2x ULN
3 □ Troponin within normal limits
4 □ Other

2.3. Myoglobin

1 □ At least 2x ULN
2 □ Greater than ULN but less than 2x ULN
3 □ Within normal limits
4 □ Other (specify): __________________________

2.4. “Other” Cardiac-Specific Lab (specify): ________________________

Results
(Mark the one category that best applies.)

1 □ At least 2x ULN
2 □ Greater than ULN but less than 2x ULN
3 □ Within normal limits
4 □ Other (specify): __________________________

3. Were there cardiac signs or symptoms of ischemia on admission or within 24 hours of the event?

1 □ No
2 □ Yes
8 □ Unknown/Not Recorded

Cardiac Symptoms:
Presence of acute chest, epigastric, neck, jaw or arm pain or discomfort or pressure without apparent non-cardiac cause
4. **Myocardial Infarction (MI)**

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>□</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>□</td>
<td>Definite (see Table 1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>□</td>
<td>Probable (see Table 1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>□</td>
<td>Possible (see Table 1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>□</td>
<td>Aborted (see Table 1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>□</td>
<td>Unknown/Not Sure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.1. **Was the MI during, or resulting from, a procedure?**

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>□</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>□</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>□</td>
<td>Unknown/Not Sure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2. **Was a thrombolytic agent (e.g. TPA, streptokinase, urokinase) or procedure (e.g. angioplasty) administered?**

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>□</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>□</td>
<td>Yes → [Go to Question 4.2.1]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>□</td>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2.1. **Type of procedure on this admission**

(Mark all that apply.)

- □ Coronary artery bypass graft (CABG)
- □ Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy
- □ Thrombolytic agent

5. **Non-MI Acute Coronary Syndrome (previously termed “angina”)**

Definite requires evaluation to rule MI, including collection of cardiac biomarkers (e.g. cardiac enzymes). Favor the discharge summary/discharge diagnoses over the admitting note, admitting diagnosis, differential diagnosis. Non-MI ACS must be distinct from MI.

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>□</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>□</td>
<td>Definite (5.1.1 and 5.1.2) AND (at least one criterion of 5.1.3 – 5.1.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>□</td>
<td>Probable (5.1.1 and 5.1.2) OR (5.1.1 and 5.1.3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>□</td>
<td>Unknown/Not Sure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.1. **Non-MI ACS is based on:** (Mark all that apply.)

5.1.1 □ New chest pain or changing symptom pattern consistent with cardiac ischemia prompting admission

5.1.2 □ Final physician diagnosis of Non-MI ACS by treating physician and receiving medical treatment on this admission (e.g. nitrate, beta blocker or calcium channel blocker.)

5.1.3 □ Current medical record documenting a history of coronary heart disease by previous catheterization or revascularization procedure

5.1.4 □ CABG surgery or other revascularization procedure on this admission

5.1.5 □ ≥ 70% obstruction of any coronary artery on angiography on this admission

5.1.6 □ Horizontal or down-sloping ST-segment depression or abnormal ST elevation ≥ 1 mm on exercise or pharmacological stress testing with pain on this admission or immediately preceding and leading to this admission

5.1.7 □ Scintigraphic or echocardiographic stress test positive for ischemia on this admission or immediately preceding and leading to this admission

5.1.8 □ Resting ECG shows horizontal or down-sloping ST depression or abnormal ST elevation ≥ 1 mm with pain that is not present on ECG without pain on this admission
6. **Coronary revascularization during this episode of care**
   1. No
   2. Yes → Go to Questions 6a. & 6b.

6a. **Type of procedure:** Any one of the following procedures aimed at improving cardiac status.
   (Mark all that apply.)
   - Coronary artery bypass graft (CABG)
   - Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy

6b. **Second myocardial infarction (MI) (e.g. second MI not already reported in Question 4, occurring as a result of, or during the, revascularization procedure)**
   1. No
   2. Yes

7. **Congestive Heart Failure (CHF)**
   Assign an overall heart failure diagnosis based on your clinical judgment (select only one). Historical information can be considered when assigning this diagnosis. However imaging results recorded no this form should be from this admission only.
   1. Heart failure unlikely → Skip to Item 7.2
   2. Definite decompensated heart failure
   3. Possible decompensated heart failure
   4. Chronic stable heart failure → Skip to Item 7.2
   8. Unclassifiable → Skip to Item 7.2

7.1. **Was definite or possible decompensated heart failure present at admission?**
   1. No
   2. Yes

7.2. **Is there evidence of:**
   (Please record findings present during current admission only.)
<table>
<thead>
<tr>
<th>Abnormal LV systolic function</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal RV systolic function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LV diastolic dysfunction</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7.3. **Estimated LVEF (worst):**
   (Mark the one category that best applies. If reported as “normal” record as ≥50%,
   Please record findings present during current admission only.)
   1. ≥50%
   2. 35-49%
   3. <35%
   8. Unknown/Not Sure
8. Stroke
Rapid onset of headache, meningismus or a persistent neurologic deficit attributable to an obstruction or rupture of the arterial system (including stroke occurring during a procedure such as angiography or surgery). Deficit is not known to be a secondary to brain trauma, infection, or other non-ischemic cause. Deficit must last more than 24 hours, unless death supervenes or there is a demonstrable lesion compatible with acute stroke on CT or MRI scan.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Definite (8.2.1 OR 8.2.4 OR 8.2.5 OR 8.2.6 OR 8.2.8)</td>
</tr>
<tr>
<td>3</td>
<td>Probable (8.2.2 OR 8.2.3 OR 8.2.9)</td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Unknown/Not Sure</td>
</tr>
</tbody>
</table>

8.1. Final stroke diagnosis (Mark the one category that best applies.)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Definite ischemic stroke (confirmed by CT, MRI, or autopsy)</td>
</tr>
<tr>
<td>2</td>
<td>Large artery atherosclerosis</td>
</tr>
<tr>
<td>3</td>
<td>Cardioembolic (high, medium, or low risk source – if more than one is present, mark the highest risk only)</td>
</tr>
</tbody>
</table>

**High Risk Source (Mark all that apply.)**

- Mechanical prosthetic valve(s)
- Mitral stenosis with atrial fibrillation
- Atrial fibrillation
- Left ventricular or left atrial appendage thrombus
- Sick sinus syndrome
- MI within 4 weeks
- Dilated cardiomyopathy
- Akinetic left ventricular segment
- Atrial myxoma
- Infective endocarditis

**Medium Risk Source (Mark all that apply.)**

- Mitral valve prolapse
- Mitral annulus calcification
- Mitral stenosis without atrial fibrillation
- Left atrial turbulence
- Atrial septal aneurysm
- Patent foramen ovale
- Atrial flutter
- Bioprosthetic cardiac valve
- Nonbacterial thrombotic endocarditis
- Congestive heart failure
- Hypokinetiic left ventricular segment
- MI more than 4 weeks but less than 6 months before onset

**Low Risk Source**

- Lone atrial fibrillation

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Small vessel occlusion (lacunar)</td>
</tr>
<tr>
<td>4</td>
<td>Stroke of other determined etiology (Mark all that apply.)</td>
</tr>
<tr>
<td>4</td>
<td>Vasculitis</td>
</tr>
<tr>
<td>4</td>
<td>Noninflammatory vasculopathy</td>
</tr>
<tr>
<td>4</td>
<td>Hypercoagulable state</td>
</tr>
<tr>
<td>4</td>
<td>Other</td>
</tr>
<tr>
<td>5</td>
<td>Stroke of indeterminate etiology</td>
</tr>
</tbody>
</table>
2  Probable ischemic stroke (negative or nonspecific CT or MRI performed within 48 hours of onset)
3  Definite primary intracerebral hemorrhage (confirmed by CT, MRI, or autopsy)
4  Probable intracerebral hemorrhage (decreased consciousness for at least 24 hours with bloody or xanthochromic CSF and no CT)
5  Subarachnoid hemorrhage
6  Possible subarachnoid hemorrhage
7  Stroke of unknown type (CT, MRI, or autopsy not done)

8.2. Stroke diagnosis was based on:
   (Mark the one category that best applies.)

   8.2.1  Rapid onset of neurological deficit and CT or MRI scan shows acute focal brain lesion consistent with neurological deficit and without evidence of blood (except mottled cerebral pattern)
   8.2.2  Rapid onset of localizing neurological deficit with duration ≥ 24 hours but imaging studies are not available
   8.2.3  Rapid onset of neurological deficit with duration ≥ 24 hours and the only available CT or MRI scan was done early and shows no acute lesion consistent with the neurological deficit
   8.2.4  Surgical evidence of ischemic infarction of brain
   8.2.5  CT or MRI findings of blood in subarachnoid space
   8.2.6  Intra-parenchymal hemorrhage, consistent with neurological signs or symptoms
   8.2.7  Positive lumbar puncture (for subarachnoid hemorrhage)
   8.2.8  Surgical evidence of subarachnoid or intra-parenchymal hemorrhage as the cause of a clinical syndrome consistent with stroke
   8.2.9  None of the above (e.g. fatal strokes where no imaging studies or clinical evidence are available)
9. Transient Ischemic Attack (TIA)
Assign an overall diagnosis based on clinical judgment. It is possible to downgrade the diagnosis based on the medical history evidence (e.g., weak documentation, symptoms atypical) regardless of parenthetical criteria. (select only one)
1  No
2  Definite (9.1.1 or 9.1.2; and 9.1.3)
3  Probable (9.1.1 or 9.1.2; and 9.1.4) or (9.1.3 and 9.1.5)
8  Unknown/Not Sure

Transient Ischemic Attack:
One or more episodes of the sudden onset of a focal neurologic deficit involving ONE major neurologic symptom or TWO minor neurologic symptoms. No head trauma occurring immediately before the onset of the neurologic event. If deficits resolve, but imaging is negative, consistent with TIA.

9.1. Diagnosis of TIA based on:
(Mark all that apply.)
9.1.1  Transient episode involving ONE major neurologic symptom (hemiparesis of two or more body parts, homonymous hemianopia, amaurosis fugax, speech disturbance)
9.1.2  Transient episode of TWO minor neurologic symptoms (diplopia, vertigo, plus gait disturbance, dysphagia, dysphonia, or unilateral numbness of one or more body parts)
9.1.3  No clinically relevant lesion on brain imaging
9.1.4  Brain imaging not done (cannot be definite without brain imaging)
9.1.5  Non-focal symptoms, such as headache (if present without 1 or 2 could not be definite)

10. Carotid Artery Disease (CAD)
1  No
2  Definite (10.2.1 AND 10.2.2 or 10.2.3)
3  Probable (10.2.1)
8  Unknown/Not Sure

10.1. Diagnosis
(Mark the one category that best applies.)
1  Carotid artery occlusion and stenosis without documentation of cerebral infarction
2  Carotid artery occlusion and stenosis with written documentation of cerebral infarction

10.2. Carotid artery disease based on:
(Mark all that apply.)
10.2.1  Symptomatic disease with carotid artery disease listed on the hospital discharge summary
10.2.2  Abnormal findings (>50% stenosis) on carotid angiogram or Doppler flow study
10.2.3  Vascular or surgical procedure to improve flow to the ipsilateral brain
11. Peripheral Arterial Disease (PAD) (aorta, iliac arteries, or below)

1. No
2. Definite (11.2.2 or 11.2.5 or 11.2.9)
3. Probable (11.2.7 AND 11.2.8) or (11.2.1 AND any one of 11.2.3, 11.2.4, 11.2.6, 11.2.7, or 11.2.8)
4. Unknown/Not Sure

Peripheral Arterial Disease:
Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene.
Disease must be symptomatic and/or requiring intervention (e.g. vascular or surgical procedure for arterial insufficiency in the lower extremities or abdominal aortic aneurysm).

11.1. Diagnosis
(Mark the one category that best applies.)

1. Lower extremity claudication
2. Atherosclerosis of arteries of the lower extremities
3. Arterial embolism and/or thrombosis of the lower extremities
4. Abdominal aortic aneurysm (AAA)

11.2. Diagnosis specified in 11.1 based on:
(Mark all that apply.)

11.2.1 Final diagnosis of PAD during hospitalization by treating physician
11.2.2 Angiographically-demonstrated obstruction, or ulcerated plaque (> 50% of the diameter or ≥ 75% of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below
11.2.3 Absence of pulse by Doppler in any major vessel of lower extremities
11.2.4 Exercise test that is positive for lower extremity claudication
11.2.5 Surgery, angioplasty, or thrombolysis for PAD
11.2.6 Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene
11.2.7 Exertional leg pain relieved by rest
11.2.8 Ankle-arm systolic blood pressure ratio ≤ 0.8
11.2.9 Surgical or vascular procedure for abdominal aortic aneurysm
12. Deep Venous Thrombosis (DVT)

1  □ No
2  □ Definite (12.2.1 AND at least one criterion of 12.2.2-.12.2.5)
3  □ Probable (12.2.3 AND/OR 12.2.4 AND/OR 12.2.5)
8  □ Unknown/Not Sure

12.1. Diagnosis for Deep Venous Thrombosis (DVT)
(Mark the one category that best applies.)

1  □ Deep venous thrombosis of lower extremities not resulting from a procedure within 60 days
2  □ Deep venous thrombosis of lower extremities during or following a procedure within 60 days

12.2. Diagnosis of deep venous thrombosis is based on:
(Mark all that apply.)

12.2.1 □ Hospital discharge summary or physician’s note with a diagnosis of deep venous thrombosis
12.2.2 □ Positive findings on a venogram
12.2.3 □ Positive findings using impedance plethysmography
12.2.4 □ Positive findings on Doppler duplex, ultrasound, sonogram, or other non-invasive test examination
12.2.5 □ Positive findings on isotope scan

12.3. Was a work-up for pulmonary embolism performed?

1  □ No
2  □ Yes
8  □ Unknown/Not sure
13. Pulmonary Embolism

1  No
2  Definite (13.2.3) OR (13.2.4)
3  Probable (13.2.1 and 13.2.2) OR (13.2.2 and 13.2.5) OR (13.2.1 and 13.2.6) OR (13.2.5 and 13.2.6)
8  Unknown/Not sure

13.1. Diagnosis for Pulmonary Embolism (PE)
(Mark the one category that best applies.)

1  Pulmonary embolism not resulting from a procedure within 60 days
2  Pulmonary embolism during or following a procedure within 60 days

13.2. Diagnosis of pulmonary embolism is based on:
(Mark all that apply.)

13.2.1 Hospital discharge summary with a diagnosis of pulmonary embolism
13.2.2 High probability positive ventilation-perfusion lung scan
13.2.3 Diagnostic (reported as definite) pulmonary arteriogram or contrast-enhanced CT pulmonary angiogram
13.2.4 Diagnostic spiral CT scan with contrast (not a dedicated contrast-enhanced CT pulmonary angiogram)
13.2.5 Diagnosis of deep venous thrombosis (DVT) based on > 1 DVT criterion in 12.2 plus signs and symptoms suggestive of PE (e.g. acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest x-ray findings suggestive of PE)
13.2.6 Finding from contrast enhanced CT scan reported as probable or possible PE
13.2.7 Autopsy
14. Diabetes Mellitus (DM) is the primary reason for the hospitalization

1. No
2. Definite (14.1.1 AND 14.1.2 OR 14.1.3 OR 14.1.4 OR 14.1.5)
3. Probable (only one criterion of 14.1.1 OR 14.1.3 OR 14.1.4 OR 14.1.5)
4. Unknown/Not Sure

14.1. Diagnosis of diabetes is based on:
(Mark all that apply.)

14.1.1 Diagnosis of diabetes by treating physician
14.1.2 Receiving medications for diabetes (e.g. insulin, oral agent)
14.1.3 Fasting blood sugar ≥ 126 mg/dl (7 mmol/l)
14.1.4 Abnormal Oral Glucose Tolerance Test (OGTT) at this admission (fasting ≥ 126 mg/dl and 2 hour ≥ 200, mg/dl [11.1 mmol/l])
14.1.5 For any other glucose measurement >200 mg/dl (11.1 mmol/l)

14.2.a Highest glucose level
(Record Lab measure if possible. Do not use minimally elevated or borderline glucometer readings for determining diabetes)

<table>
<thead>
<tr>
<th>Glucometer</th>
<th>Lab Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Fasting blood sugar _____ _____ _____ _____ mg/dl</td>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>[ ] Other blood sugar _____ _____ _____ _____ mg/dl</td>
<td>[ ] [ ]</td>
</tr>
</tbody>
</table>

14.2.b HbA1c (enter the value from the medical record)
[ ] _____ : _____ %

14.3. Type of diabetes mellitus
(Mark the one category that best applies.)
1. Type I
2. Type II
3. Unknown/Not Sure

15. Asthma or COPD exacerbation is the primary reason for the hospitalization

1. No
2. Definite asthma
3. Probable asthma
4. Definite COPD
5. Probable COPD
6. Asthma/COPD indeterminate

15.1. Diagnosis is based on:
(Mark all that apply.)

15.1.1 Hospital discharge diagnosis of asthma or asthma exacerbation as the
primary reason for hospitalization
15.1.2 Hospital discharge diagnosis of COPD or COPD exacerbation as
the primary reason for the hospitalization
15.1.3 Documentation of prescription of specific asthma medication as an
outpatient (anti IgE [Omalizumab])
15.1.4 Treatment during admission with medication for acute exacerbation of

Form M-1 rev 09/15/2014
COPD or asthma (β₂ agonist (e.g., albuterol), anticholinergics (e.g., ipratropium), or corticosteroids, xanthines [e.g., theophylline])

15.1.5 Other (specify): ________________________________

15.2. Severity of exacerbation is based on: (Mark all that apply.)

15.2.1 Presence of acute respiratory failure defined as decreased PaO₂ (<80 mm Hg on room air) or O₂ saturation (<88%) with or without increased PaCO₂
15.2.2 Report of severe dyspnea with or without agitation, confusion, tachycardia, or sweating
15.2.3 Treatment with supplemental O₂ or increased O₂ if on chronic supplemental O₂
15.2.4 Treatment with noninvasive positive pressure ventilation (NIPPV)
15.2.5 Intubated and treated with mechanical ventilation
15.2.6 PEF <100 L/min
15.2.7 None of the above

16. Hypertension is the primary reason for the hospitalization
   1. No
   2. Definite (see definition below)
   3. Probable (see definition below)
   8. Unknown/Not Sure

Definite Hypertension:
1. Physician diagnosis of hypertension and on blood pressure lowering medication(s); OR
2. Systolic blood pressure is greater than 140 mmHg AND/OR diastolic blood pressure is greater than 90 mmHg on more than one occasion.

Probable Hypertension:
1. Only one measure of systolic blood pressure is greater than 140 mmHg AND/OR diastolic blood pressure is greater than 90 mmHg, AND
2. Not on blood pressure lowering medication(s), AND/OR
3. Physician diagnosis is not clearly defined.

16.1. Diagnosis of hypertension is based on: (Mark all that apply.)

- Final diagnosis of hypertension by treating physician
- On blood pressure lowering medication(s) (e.g., diuretic, beta-blocker, ACE-inhibitor, calcium channel blocker, vasodilator)
- Systolic blood pressure is greater than 140 mmHg
- Diastolic blood pressure is greater than 90 mmHg

16.2. Type of hypertension:
   1. Primary
   2. Secondary
   8. Unknown/Not Sure

17. End stage renal disease (ESRD)
   1. No
2  □  Definite (17.1.1 OR 17.1.2 OR 17.1.3)
3  □  Probable
8  □  Unknown/Not Sure

17.1. Diagnosis of end stage renal disease is based on:
(Mark all that apply.)
17.1.1  □  Physician diagnosis of ESRD
17.1.2  □  Is undergoing chronic dialysis
17.1.3  □  Has had (or is undergoing) renal transplant

18. Atrial Fibrillation (A-fib) / Atrial Flutter
Assign an overall diagnosis based on your clinical judgment (select only one). Do not assign definite or probable diagnosis if atrial fibrillation was only induced during EP study.

1  □  No
2  □  Definite (18.1.1 AND 18.1.2) OR (18.1.2 AND 18.1.3) OR (18.1.4) OR (18.1.5) OR (18.1.1 and 18.1.6)
3  □  Probable (18.1.1) OR (18.1.2) OR (18.1.3) OR (18.1.1 AND 18.1.3) OR (18.1.6)
8  □  Unknown/Not Sure

18.1. Diagnosis of Atrial fibrillation / Atrial flutter based on:
(Mark all that apply.)

18.1.1  □  Documentation of atrial fibrillation/flutter as present during this hospitalization in a physician note such as the ER note, admission and physical, cardiology consult or discharge summary. Do not include atrial fibrillation if present only in the acute setting of EP study, e.g. only present when induced by the EP study.
18.1.2  □  A computer-based reading of the 12-lead ECG from this admission that says atrial fibrillation/flutter
18.1.3  □  Documentation of history of atrial fibrillation/flutter with use of an appropriate antiarrhythmic medication
18.1.4  □  Adjudicator diagnosis of atrial fibrillation/flutter on 12-lead ECG or rhythm strip from this admission. The rhythm strip must be at least 10 seconds.
18.1.5  □  Documented cardioversion attempt (chemical or electrical) for atrial fibrillation/flutter during this admission. Do not select if A-fib was induced during EP study.
18.1.6  □  Documented procedure to treat atrial fibrillation/flutter (e.g. ablation) and documentation of atrial fibrillation/flutter history

18.2. If atrial fibrillation/flutter is found, is it present only in the post-CABG setting?
1  □  No
2  □  Yes
8  □  Unknown

18.3. Was the participant discharged in atrial fibrillation/flutter?
1  □  No
2  □  Yes
8  □  Unknown
TABLE 1. SUMMARY OF DIAGNOSTIC CRITERIA FOR MYOCARDIAL INFARCTION

<table>
<thead>
<tr>
<th>ECG FINDINGS</th>
<th>CARDIAC ENZYME LEVELS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diagnostic</td>
</tr>
<tr>
<td><strong>Cardiac symptoms or signs present</strong></td>
<td></td>
</tr>
<tr>
<td>Evolving diagnostic</td>
<td>Definite</td>
</tr>
<tr>
<td>Positive</td>
<td>Definite</td>
</tr>
<tr>
<td>Nonspecific</td>
<td>Definite</td>
</tr>
<tr>
<td>Normal or other ECG</td>
<td>Definite</td>
</tr>
<tr>
<td><strong>Cardiac symptoms or signs absent</strong></td>
<td></td>
</tr>
<tr>
<td>Evolving diagnostic</td>
<td>Definite</td>
</tr>
<tr>
<td>Positive</td>
<td>Definite</td>
</tr>
<tr>
<td>Nonspecific</td>
<td>Definite*</td>
</tr>
<tr>
<td>Normal or other ECG</td>
<td>Definite*</td>
</tr>
</tbody>
</table>

*In absence of diagnostic troponin, downgrade to possible

TABLE 2. ALGORITHM FOR ENZYME DIAGNOSTIC CRITERIA OF MI

<table>
<thead>
<tr>
<th>ENZYME LEVELS</th>
<th>ENZYME LEVELS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal</td>
<td>Equivocal</td>
</tr>
<tr>
<td>Creatine Kinase MB fraction (CK-MB)</td>
<td>&gt;2x ULN or 10% of total CK or &quot;present&quot; without quantification</td>
</tr>
<tr>
<td></td>
<td>&gt;3x ULN during 48 hrs after PTCA</td>
</tr>
<tr>
<td>Myoglobin</td>
<td>&gt;2x ULN</td>
</tr>
<tr>
<td>Troponin (C, I, or T)</td>
<td>2x ULN</td>
</tr>
<tr>
<td></td>
<td>3x ULN during 48 hrs after PTCA</td>
</tr>
<tr>
<td>Total Creatinine Kinase (CK)</td>
<td>&gt;2x ULN</td>
</tr>
</tbody>
</table>

ULN = Upper Limit of Normal; WNL = Within Normal Limit

DEFINITION OF ABORTED MYOCARDIAL INFARCTION

For classification as ABORTED Myocardial Infarction, the event must meet all of the following criteria:
- symptoms and ECG evidence for acute MI at presentation
- intervention (e.g. thrombolytic therapy procedure) is followed by resolution of ECG changes
- all cardiac enzymes are within normal limits
Appendix 7
Medical Documentation Requirements for CARDIA Endpoints

Medical Documentation Requirements for CARDIA Endpoints

***PLEASE REMEMBER TO DE-IDENTIFY THE MEDICAL RECORDS BEFORE YOU SEND TO THE COORDINATING CENTER***

Coronary Heart Disease (CAD, CHD, MI, Angina): Revascularization
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER reports
5. Consultation reports
7. 12-lead EKG/ECGs: ALL. Ensure date and time is on tracing.
8. Diagnostic procedures, scans: Echocardiogram, stress test, perfusion scintography report, Chest X-ray, MUGA or RVG
9. Catheterization report (angiogram/ arteriogram, contrast ventriculogram)
10. Operative or procedural report (PTCA/PCI (angioplasty or stent) or CABG); coronary atherectomy; thrombolytic therapy

Congestive Heart Failure (CHF)
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER reports
5. 12-lead EKG/ECGs
6. Labs: Cardiac Enzymes; BNP or Pro-BNP (Brain-type natriuretic peptide)
7. Chest X-ray; Chest CT; magnetic resonance imaging (MRI)
8. Diagnostic procedures, scans: Echocardiogram; radionuclide ventriculography (RVG); multigated acquisition (MUGA); contrast ventriculography
9. Cardiac catheterization

Stroke/TIA
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER reports
5. Physician notes/ Consultation reports/nursing notes
6. Diagnostic procedures, scans: CT scan; CT angiography, MRI, MRA, Echocardiogram, Transesophageal echocardiogram (TEE), Duplex ultrasound, angiography, Lumbar puncture, Carotid Doppler ultrasound
7. Thrombolytic therapy
8. Surgery (operative) reports, carotid angioplasty and stenting
9. EKG/ECGs, rhythm strips

**Carotid Artery Disease**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Diagnostic procedures: Duplex ultrasound; Doppler flow study; CT angiography; Magnetic Resonance Angiography (MRA); arteriogram
5. Operative reports: carotid endarterectomy, carotid angioplasty and stenting
6. Physicians notes /Consultation reports

**Peripheral Artery Disease**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Angiogram/ arteriogram report; MRA; CT angiography
5. RE reports
6. Doppler flow studies/ultrasound
7. Operative or procedural report: angioplasty or stent; bypass surgery; Abdominal aortic aneurysm repair; amputation for ischecmia
8. Exercise test for lower extremity claudification
9. Thrombolytic therapy
10. Ankle-arm systolic pressure ratio

**Deep Vein Thrombosis**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician notes/Consultation reports
6. Pulmonary arteriogram/CT angiogram/spiral CT scan,
7. Ventilation-perfusion lung scan report
8. Diagnostic procedures: Venogram; Impedance plethysmography, isotope scan, Doppler flow study
9. IVC filters, thrombolytic therapy
10. Operative and procedure reports for extracting embolus

**Pulmonary Embolism**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician/Consultation reports
6. Pulmonary arteriogram/CT angiogram/spiral CT scan, venogram, isotope scan
7. Ventilation-perfusion lung scan report, Impedance plethysmography, Doppler flow study
8. Operative and procedure reports for extracting embolus,
9. Thrombolytic therapy,
10. Vena cava filter

**Diabetes Mellitus**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician/Consultation reports
6. Lab reports: blood glucose (fasting; other); HbA1c
7. Oral glucose tolerance test (OGTT)

**Asthma**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Chest X-ray
6. Physician/Consultation reports
7. Spirometry

**Hypertension**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Notes
5. Labs: chemistries, including creatinine, electrolytes

**End-Stage Renal Disease**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Procedure reports, including dialysis initiation; catheter insertion or AV fistula or graft access
5. Operative reports, including kidney transplant, fistula or graft placement
6. Labs: chemistries, including creatinine, electrolytes
7. Inpatient or outpatient physician notes with start dates
**Chronic obstructive pulmonary disease (COPD)**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 codes diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. ER Reports
5. Physician/Consultation reports
6. Imaging: Chest x-ray; chest CT
7. Spirometry

**Other Hospitalizations**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Physician/Consultation reports
5. ER reports
6. Reports of all diagnostic procedures, including scans, x-rays
7. Operative reports
8. 12-lead EKG/ECG
9. Labs, including pathology reports

**Weight Loss Surgery**
1. Face Sheet physician attestation statement with ICD-9 or ICD-10 diagnosis and procedure codes
2. Discharge Summary (for short stays, may substitute final progress note)
3. Admission History and Physical (dictated or handwritten)
4. Operative report(s)

**Sleep Apnea**
1. Report of sleep study
2. Clinic progress note
Appendix 8

Step-by-Step Instructions for Personnel on How to Manage Medical Records

Step-by-Step Instructions for Personnel on How to Manage Medical Records

Mortality Endpoints Checklist (For Death Records)

- Complete Form 33A – Initial Notification of Death.
- Send 33A to coordinating center within 1-2 days of discovery of the event, even if the information is incomplete.
- Enter death into the Mortality Tracking System.
- Record death in Follow-Up system under currently open window.
- Request Death Certificate.
- Log date of Death Certificate request into Mortality Tracking System.
- Process Received Death Certificate:
  - Stamp or write participant ID onto Death Certificate.
  - Copy Death Certificate.
  - De-Identify copy, completely blacking out all protected health information (PHI) except date of death.
  - Send de-identified copy to coordinating center.
- Check Death Certificate for Hospitalization information.
- Review “Decision matrix for Forms to be Obtained When Participant Dies,” to see if hospital records are needed.
- Request records from hospital/MD office, if applicable.
  - Use Medical Release already signed by participant, AND/OR
  - Use letter explaining why Medical Release not needed for research records of deceased participants, and include copy of Death Certificate, OR
  - Request signed Medical Release from Next of Kin:
    - Call to verify receipt of Medical Release request (1-2 weeks)
    - Repeat at intervals as needed until signed Medical Release is received or Next of Kin refuses.
  - Log date Hospital Record requested into Mortality Tracking System.
  - Call to verify receipt of request if hospital record is not received in 1-2 weeks.
  - Repeat at intervals as needed until hospital record is received.
- Process received hospital record
  - Review for completeness.
  - Re-request any missing documents which are needed.
  - Call to verify receipt of re-request if not received within 1-2 weeks.

1 of 3
- Log date hospital record received into the Mortality Tracking system.
- Stamp or write participant ID on each page of completed Hospital record.
- Copy records.
- De-Identify the copy, completely marking out all PHI.
  - Review “Decision matrix for Forms to be Obtained When Participant Dies” to see if Form 33C – CARDIA Interviews with Witness or Next of Kin - is needed.
  - Complete Form(s) 33C for Next of Kin and/or as many witnesses to death as have information which may aid in adjudication of the records.
    - Copy 33C
    - Black out all the Next of Kin PHI on the copy.
  - Complete Form 33B – Final Report of Death.
    - Attach a copy of the de-identified hospital record.
    - Attach a copy of all the Forms 33C.
    - Attach death certificate.
    - Attach autopsy report, if applicable.
    - Send to the Endpoints Coordinator at the coordinating center.
  - Log date sent to the coordinating center in the Mortality Tracking System.

**Hospital/Outpatient Records**
- Review participant questionnaire for endpoints or other events requiring record retrieval.
- Code hospitalizations. (requires certification in CARDIA codes)
- Scan completed form(s) to coordinating center.
- Enter each event into the M&M Tracking System.
- Request signed Medical Release from participant.
- Log date of Medical Release request into M&M system
- Call to verify receipt of Medical Release request (1-2 weeks).
- Repeat at intervals as needed until signed Medical Release is received or participant refuses
- Log date Medical Release received into M&M system.
- Request records from hospital/MD office using signed Medical Release. Refer to list of required documents for each event.
- Log date hospital record requested into M&M system.
- Call to verify receipt of request if records are not received in 1-2 weeks.
- Repeat at intervals as needed until record is received.
- Review medical record for completeness.
- Re-request any missing documents which are needed.
- Call to verify receipt of re-request if not received within 1-2 weeks.
- Log date medical record is received into the M&M system.
- Stamp or write CARDIA ID on each page of completed hospital record.
- Copy Hospital Record.
- De-identify the copy, completely marking out ALL PHI.
- Attach a copy of the questionnaire page that is relevant to the particular hospitalization/outpatient procedure.
- Send complete package of questionnaire and copied, de-identified medical record to the coordinating center.
- Log date the endpoint package was sent to the coordinating center in the M&M system.
- Interviewers at the field centers will identify hospitalizations or outpatient procedures at interim contacts or at clinic visits. Using the Follow-up Contact Forms or Form 31 enter CARDIA codes, complete the Follow-up forms B and C relating to hospitalizations or procedures, making sure that each event has been captured. Following the algorithms on Forms B and/or C ascertain whether records need to be requested, or if they are not relevant to CARDIA. Scan all completed forms to the coordinating center.

After receiving notification of an event and determining that records should be retrieved, the field center will request written permission to obtain medical records from the participant. Using the list of records needed to adjudicate events in the appendix, request medical records from the health care facility.

When the records are received, review the records for completeness and for discovered events. In the event of incomplete records, e.g., no ECG or cardiac enzymes in a heart-related event, ask for additional records. In the event of a discovered event that was sent to the field center but for about which the field center has no prior knowledge, contact the participant and ask for permission to have the records. If permission is denied, shred the documents that do not relate. If permission is granted, amend the Follow-up form and rescan the corrected form to add additional events.

Copy records and remove all PHI using a grease pencil prior to scanning the records to the coordinating center. Along with the records, scan the appropriate Follow-up form that matches the event. A date that is incorrect on the Follow-up Form, because of a misreport by the participant, does not need to be corrected.
Appendix 9
Heart Failure Case Law
(Updated 9/10/2009)

1. If there is no evidence of exacerbation or decompensation until a fatal cardiac arrest and there is no other evidence of heart failure, then there is not sufficient evidence for a diagnosis of definite decompensated HF (option 2) or possible decompensated HF (option 2).

2. If there is no history of symptoms or evidence from echocardiography or other imaging to suggest LV systolic or diastolic dysfunction, then there is not sufficient evidence for a classification of chronic stable Heart Failure (option 4).

3. Assign a classification of unclassifiable (option 8) if you can’t decide between chronic Heart Failure (option 4) and HF unlikely (option 1). Do not use “unclassifiable” if you are uncertain between “definite decompensated HF” and “possible decompensated HF”; in such a case, record “possible decompensated HF” (option 3).

4. In the context of an acute exacerbation of COPD with symptoms of heart failure but with no direct or clear evidence of right or left ventricular dysfunction from imaging, then classify as unclassifiable (option 8).

5. When deciding between Heart Failure unlikely (option 1) and unclassifiable (option 8) consider the completeness or sufficiency of the evidence. If there is sufficient or substantial amount of information provided in the reports to suggest that the patient did not have heart failure, choose HF unlikely (option 1). Use unclassifiable (option 8) in the cases where the level or amount of documentation is simply insufficient to make a clear diagnosis (whether heart failure is present versus absent).

6. Evidence of dilated ventricle alone is not sufficient to record abnormal LV/RV dysfunction.

7. Use all of the data available which is provided by the field center for your diagnosis in question 7, even it is seems old, because it is relevant to the case/admission under review. However, for recording LVEF or LV/RV/Diastolic dysfunction, use only the documentation related to the current hospitalization rather than records that pre-date the hospitalization.

8. Do not put too much weight on one piece of evidence. For example, when the discharge summary appears inconsistent with a HF diagnosis (i.e., does not list HF as a problem/diagnosis when there was an obvious problem of heart failure based on other documents like chest x-rays or description of treatment), make sure to weigh the totality of the evidence in the chart in order to classify the case.

9. If left ventricular compliance is normal, record no for 7.2.3.

10. If the event summary form indicates an ejection fraction was recorded, but there is no supporting information provided in the materials included in the case, record Unknown for 7.3.

11. If there are multiple echocardiography reports containing ejection fraction from old admissions and current admissions, make sure to use the lowest ejection fraction from the CURRENT admission.
12. For patients with specific types of cardiomyopathies that are not described as heart failure, (e.g., hypertrophic cardiomyopathy/IHSS), use supporting evidence to determine that the condition exists (either as a chronic stable type of heart failure or a decompensated state). If the available evidence (e.g., treatment, past history) does not confirm that this condition exists as a “heart failure” condition, and you are trying to choose among “chronic stable HF,” “HF unlikely,” and “unclassifiable,” then choose “unclassifiable”.

13. When deciding between “chronic stable HF,” “HF unlikely,” and “unclassifiable”: if the record only mentions history of HF, and there is no other information to substantiate the diagnosis, choose “unclassifiable” (not “chronic stable HF”). However, in order to choose “chronic stable HF”, there must be no contradictory evidence AND some kind of supporting information; for example, a statement about previous hospitalization for HF, low ejection fraction, medications specifically for heart failure, or X-ray finding like cardiomegaly. The ESF can be used to provide this supporting evidence, but a previous diagnosis alone may not be sufficient. Evidence of HF treatment should come from the medical record (sole mention of treatment in the ESF is not sufficient). (This case law is a similar but an expanded version of Case Law #2.)

14. When patients with severe or late stage kidney disease that are not currently on dialysis and no history of clinical HF have symptoms/signs of pulmonary edema which respond to specific heart failure treatment then choose “3” (Possible decompensated heart failure) rather than “2” (Definite decompensated heart failure) because of the confounding comorbidity of renal failure. However, “1” (HF unlikely) should generally be chosen if the patient is on chronic dialysis and symptoms are due to inadequate dialysis finding like cardiomegaly: however evidence of cardiac systolic or diastolic dysfunction or history of clinical heart failure. Patients with ESRD on dialysis may be classified as “3” (or possibly “2”) when there is appropriate supporting evidence for heart failure and the primary cause of the exacerbation is unlikely due to inadequate or missed dialysis. Patients with ESRD and low LVEF who had inadequate dialysis as the cause of volume overload should be classified as “1”. The following hierarchy of supporting evidence can be used to determine the “diagnosis”:

- Heart Function including past or present systolic and diastolic measurements;
- Therapy for chronic or acute heart failure;
- Chest x-ray that shows pulmonary edema or cardiomegaly (pulmonary vascular congestion is not sufficient);
- Totality of evidence.

15. RV strain noted in the case materials is insufficient to consider it RV dysfunction unless there are further details suggesting RV dysfunction. If only RV strain is present, abnormal RV systolic function is unknown.

16. If a patient has an acute pulmonary embolus resulting in right ventricular dysfunction, but is without signs or symptoms, the patient does not have heart failure; the reviewer should choose “1” (heart failure unlikely).

17. Patients with obvious HF signs and symptoms secondary to arrhythmia (e.g. atrial fibrillation) severe valvular disease, or cor pulmonale, and with no documented evidence of diastolic or systolic dysfunction, may still be classified as “2” (definite decompensated HF) is there is clear evidence for right- or left-sided heart failure.

CARDIA Endpoint Events Manual of Operations v02/14/2017
65
# Appendix 10  Endpoint Abstraction Forms
## Heart Failure

For CC use only

<table>
<thead>
<tr>
<th>CARDIA PID: <strong>-</strong> __ __ __ -__ __ __ __ __ __</th>
<th>Contact Period: __________</th>
<th>Hosp. No: ________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Date: ____ / ____ / _______</td>
<td>Discharge Date: ____ / ____ / _______</td>
<td></td>
</tr>
<tr>
<td>Did the participant die during this admission? □ No □ Yes</td>
<td>Date sent to abstractor: ____ / ____ / _______</td>
<td></td>
</tr>
<tr>
<td>Date received at CC: ____ / ____ / _______</td>
<td>Date entered at CC: ____ / ____ / _______</td>
<td></td>
</tr>
</tbody>
</table>

**Abstractor ID:** ______  **Abstraction Date:** ____ / ____ / _______  **Abstraction Date:** ____ / ____ / _______

### General Information

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>DK/NR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the patient have new onset or progressive symptoms/signs of heart failure at the time of admission to the hospitalization?</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

### History of Heart Failure

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>DK/NR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Is the diagnosis “heart failure with preserved ejection fraction?” Preserved EF ( \geq 45% ) or qualitative description of systolic function. <em>If No or DK/NR, GO TO Q3</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a. Hypertensive</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2b. Ischemic</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2c. Other</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2c1. Specify: ______________________________________</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3. Is the diagnosis “heart failure with reduced ejection fraction?” (Base only on EF) <em>If No or DK/NR, GO TO Q4</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a. Ischemic cardiomyopathy</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3b. Idiopathic/dilated cardiomyopathy</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3c. Other cardiomyopathy/heart failure (specify) ______________________</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>4. Did the patient have an automatic implantable cardioverter defibrillator (AICD) prior to admission?</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

### Comorbid Conditions on Admission or During Hospitalization

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Anemia</td>
<td>□</td>
</tr>
<tr>
<td>6. Respiratory</td>
<td></td>
</tr>
<tr>
<td>5a. Asthma</td>
<td>□</td>
</tr>
<tr>
<td>5b. Chronic bronchitis/chronic obstructive pulmonary disease</td>
<td>□</td>
</tr>
<tr>
<td>5c. Other chronic lung disease</td>
<td>□</td>
</tr>
<tr>
<td>5d. Pulmonary embolus</td>
<td>□</td>
</tr>
</tbody>
</table>
5e. Sleep apnea

7. Cardiovascular
   7a. Arrhythmia [If No, GO TO Q7b]
       7a1. Atrial fibrillation / atrial flutter
       7a2. Heart block or other symptomatic bradycardia
       7a3. Ventricular fibrillation or tachycardia

<table>
<thead>
<tr>
<th>Comorbid Conditions on Admission or During Hospitalization (continued)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7b. Cardiac procedures during hospitalization [If No, GO TO 7c]</td>
</tr>
<tr>
<td>7b1. Coronary artery bypass grafting</td>
</tr>
<tr>
<td>7b2. Percutaneous coronary intervention</td>
</tr>
<tr>
<td>7b3. Valve surgery</td>
</tr>
<tr>
<td>7b4. Pacemaker</td>
</tr>
<tr>
<td>7b5. Defibrillator</td>
</tr>
<tr>
<td>7c. Coronary heart disease history</td>
</tr>
<tr>
<td>7d. Hypertension</td>
</tr>
<tr>
<td>7e. Myocardial infarction or unstable angina (during hospitalization)</td>
</tr>
<tr>
<td>7f. Pulmonary hypertension history</td>
</tr>
<tr>
<td>7g. Peripheral vascular disease history</td>
</tr>
<tr>
<td>7h. Valvular heart disease history</td>
</tr>
</tbody>
</table>

8. Endocrine/Renal
   8a. History of Diabetes |
   8b. History of Chronic kidney disease (GFR < 60 ml/min/1.73 m^2) |
   8c. Dialysis

9. Neurology/Psychiatry
   9a. History of Stroke/transient ischemic attack |
   9b. History of Depression

10. Did the patient have any of the following **GENERAL signs**, at admission or anytime during the hospitalization?
    10a. Lower extremity edema |
    10b. Jugular venous distension |
    10c. Hepatomegaly |
    10d. Hepatomegaly |
    10e. Rales

11. Did the patient have any of the following **symptoms**, at admission or anytime during the hospitalization?
    11a. Dyspnea/shortness of breath |
    11b. Paroxysmal nocturnal dyspnea |
    11c. Orthopnea

**Diagnostic Tests**
12. Are chest x-ray findings noted during this hospitalization? [If No, GO TO Q13]  

13. Did the patient have any of the following signs on chest X-ray, at admission or anytime during the hospitalization? (When available, prioritize official read in radiology report.)
   13a. Pulmonary edema/Vascular congestion  
   13b. Cardiomegaly  
   13c. Any effusion

14. In the assessment of LV function during this admission, how was the EF reported or characterized? (Mark only one.)
   - Specific value of EF reported. Please record value below. (If a range is provided on a single imaging study, report the lowest end of the range.) [If checked, complete 14a. -14b.]
     14a. EF (%) ______________ (Please enter one value)
     14b. Please check the modality below. (Mark only one)
       - Echocardiogram  
       - Gated SPECT (e.g. thallium, cardiolite)  
       - Multigated acquisition (MUGA)  
       - Contrast ventriculography  
       - Other: ______________________________

   - Qualitative description only (no mention of specific numerical value for EF) of normal LV systolic function.  
   - Qualitative description only (no mention of specific numerical value for EF) of abnormal LV systolic function.  
   - No assessment of LV function during this admission

15. Was a heart catheterization performed, at admission or anytime during the hospitalization? [If No, GO TO Q18]
   15a. Date performed: ______ / _____ / _______

---

### Biochemical Analyses

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DK/NR</td>
<td>DK/NR</td>
<td>DK/NR</td>
<td>DK/NR</td>
</tr>
<tr>
<td><strong>16. BNP (pg/mL)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>_____</td>
<td>_____</td>
<td>_____</td>
<td>_____</td>
</tr>
<tr>
<td><strong>17. ProBNP (pg/mL)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>_____</td>
<td>_____</td>
<td>_____</td>
<td>_____</td>
</tr>
</tbody>
</table>

---

### Medications

<table>
<thead>
<tr>
<th></th>
<th>Prior to hospitalization</th>
<th>At hospital discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>19. ACE inhibitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Angiotensin II receptor blockers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Beta blockers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Digitalis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>23.</td>
<td>Diuretics</td>
<td></td>
</tr>
<tr>
<td>24.</td>
<td>Aldosterone blocker</td>
<td></td>
</tr>
<tr>
<td>25.</td>
<td>Nitrates</td>
<td></td>
</tr>
<tr>
<td>26.</td>
<td>Hydralazine</td>
<td></td>
</tr>
<tr>
<td>27.</td>
<td>IV drugs during this hospitalization</td>
<td>Yes</td>
</tr>
<tr>
<td>27a.</td>
<td>IV ionotropes</td>
<td></td>
</tr>
<tr>
<td>27b.</td>
<td>IV diuretics</td>
<td></td>
</tr>
<tr>
<td>27c.</td>
<td>IV vasodilators</td>
<td></td>
</tr>
</tbody>
</table>
CHD

To be filled out at CC

CARDIA PID: __-__ __ __ __ -__ __ __ _ __ __  Contact Period: _________  Hosp. No: ______
Admission Date: ____ / ____ / _______  Discharge Date: ____ / ____ / _______
Did the participant die during this admission? 1 □ No 2 □ Yes  Date sent to abstractor: ____ / ____ / ____
Date received at CC: _____ / ____ / _______  Date entered at CC: _____ / ____ / _____

Endpoint being abstracted (Mark all that apply.):

2 □ Non-MI ACS  2 □ MI  2 □ Coronary Revascularization

Abstractor ID: ____________  Abstraction Date: __ / ___ / __________

1. Are cardiac enzymes available?
   □  1 No → Skip to Question 5.
   □  2 Yes

2. Are enzymes uninterpretable due to CPR, rhabdomyolysis, or other reason?
   □  1 No → Skip to Question 4.
   □  2 Yes

3. Reason enzymes are uninterpretable: _________________________ → Skip to Question 5.

4. Complete the following table for all available cardiac enzyme results. (Use supplemental page
   for additional collection points.)

<table>
<thead>
<tr>
<th>Enzyme Type</th>
<th>Troponin</th>
<th>CK-MB</th>
<th>CK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Given ULN</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collection Point 1</th>
<th>Collection Point 2</th>
<th>Collection Point 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Time</td>
<td>Value</td>
</tr>
<tr>
<td>-------</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collection Point 4</th>
<th>Collection Point 5</th>
<th>Collection Point 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Time</td>
<td>Value</td>
</tr>
<tr>
<td>-------</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. Was any imaging done within 30 days prior OR during this admission?
   □ 1 No → Skip to Question 8.
   □ 2 Yes

6. What imaging was done? Mark all that apply.
   □ 2 Cardiac cath without LVgram
   □ 2 Cardiac cath with LV gram
   □ 2 Intravascular ultrasound
   □ 2 Nuclear stress test
   □ 2 Nuclear study without stress
   □ 2 Echo resting
   □ 2 Echo stress
   □ 2 PET
   □ 2 MRI

7. What were the findings of the imaging? Mark all that apply and the result.
   _____ 7.a. 2 Wall motion abnormality(ies)
      Result:
      □ 1 Not assessed
      □ 2 Assessed but negative
      □ 3 Assessed and present
   _____ 7.b. 2 Nonviable areas
      Result:
      □ 1 Not assessed
      □ 2 Assessed but negative
      □ 3 Assessed and present
   _____ 7.c. 2 Scar
      Result:
      □ 1 Not assessed
      □ 2 Assessed but negative
      □ 3 Assessed and present
   _____ 7.d. 2 Intracoronary thrombosis
      Result:
7.e. 2 Ulcerated (hazy) plaque

Result:
- 1 Not assessed
- 2 Assessed but negative
- 3 Assessed and present

7.f. 2 Apical ballooning

Result:
- 1 Not assessed
- 2 Assessed but negative
- 3 Assessed and present

7.g. 2 In stent restenosis

Result:
- 1 Not assessed
- 2 Assessed but negative
- 3 Assessed and present

8. Mention of use of cocaine or amphetamines/stimulants in the past?

- 1 No → Skip to Question 9.
- 2 Yes

8.a. Cocaine?

- 1 No
- 2 Yes
- 8 Don’t Know/Not Recorded

8.b. Amphetamines or other stimulants (including prescription)?

- 1 No
- 2 Yes
- 8 Don’t Know/Not Recorded

9. Mention of use of cocaine or amphetamines/stimulants in the 3 days prior to the event?

- 1 No → Skip to Question 10.
- 2 Yes

9.a. Cocaine?

- 1 No
- 2 Yes
- 8 Don’t Know/Not Recorded

9.b. Amphetamines or other stimulants (including prescription)?

- 1 No
10. Was a drug/toxicology screen performed during this admission?

☐ 1 No → Skip to Question 11.
☐ 2 Yes → Complete the table below.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Positive</th>
<th>Negative</th>
<th>DK/N R</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.a. Barbiturate</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.b. Buprenorphine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.c. Cocaine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.d. Amphetamine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.e. Methadone</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.f. Propoxyphene</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.g. Phencyclidine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.h. Opiate</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.i. Tricyclics</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.j. Cannabinoids</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.k. Oxycodone</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.l. Methamphetamine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10.m. Benzodiazepine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

11. Did the participant die as a result of the endpoint(s)?

☐ 1 No
☐ 2 Yes

End of Form if Non-MI ACS and/or Coronary Revascularization Endpoint

If MI Endpoint, continue.
12. Select the one MI Subtype.

- **2 Type 1 MI** (Definition: spontaneous MI related to atherosclerotic plaque rupture, ulceration, fissuring, erosion or dissection with resulting intraluminal thrombus in one or more of the coronary arteries leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. The patient may have underlying severe CAD, but on occasion non-obstructive or no CAD.)  
  
  → **End of Form**

- **2 Type 2 MI** (Definition: in instances of myocardial injury with necrosis where a condition other than CAD contributes to an imbalance between myocardial oxygen supply and/or demand)  
  
  → **Skip to 13.**

- **2 Type 3 MI** (admission to the hospital, followed by death within a few hours – Specific Definition: cardiac death with symptoms suggestive of MI and presumed new ischemic ECG changes or new LBBB, but death occurring before blood samples could be obtained, before cardiac biomarker could rise, before biomarkers collected, or biomarkers were obtained but uninterpretable due to resuscitation efforts including CPR.)  
  
  → **End of Form**

- **2 Unusual MI Type** Does not fit in one of the above categories.  
  
  → **Skip to 14.**

13. For Type 2 MI, record the cause of the supply/demand imbalance relating in the myocardial injury/ischemia. (Check all that apply.)

- 2 Tachyarrhythmia (e.g. atrial fibrillation with rapid ventricular response)
- 2 Brady arrhythmia
- 2 Aortic dissection or severe aortic valve disease
- 2 Cardiogenic, hypovolemic, or septic shock
- 2 Severe respiratory failure
- 2 Severe anemia
- 2 Hypertension with or without LVH
- 2 Coronary spasm
- 2 Coronary embolism or vasculitis
- 2 Other (e.g. coronary endothelial dysfunction without significant CAD)

  Describe: __________________________________________________________

14. For unusual types of MIs, select or specify the type below.

- 2 Takotsubo
- 2 Other, Specify: ____________________________________________________

**End of Form**
Stroke/TIA

To be filled out at CC

CARDIA PID: ___________ Contact Period: _______ Hosp. No: ______

Admission Date: ____ / ____ / _______ Discharge Date: ____ / ____ / _______

Did the participant die during this admission? Yes

Date to abstractor: ____ / ____ / ______

Date received at CC: _____ / _____ / _______ Date entered at CC: _____ / _____ / _______

Abstractor ID: Abstraction Date: / /

Medical History

1. Mark all of the following that apply to this participant:
   - Current Smoker
   - History of hypertension
   - History of diabetes
   - History of alcoholism, heavy or binge drinking

2. Does the participant have a history of stroke?
   - No/Not Specified → GO TO Q3
   - Yes

   2.1 What is the approximate date of the past stroke? _____ / _____ / ________

3. Does the participant have a history of blood coagulation disorder?
   - No/Not Specified → GO TO Q4
   - Yes

   3.1 Mark if present (Mark all that apply.)
   - Factor V Leiden (activated protein C resistance)
   - Prothrombin gene mutation (G20210A)
   - Antithrombin deficiency
   - Protein C deficiency
   - Protein S deficiency
   - Other (specify) ____________________________

4. Does the participant have a clinical history of transient ischemic attacks?
   - No/Not Specified → GO TO Q5
4.1 What is the approximate date of (only or last) TIA? _____ / _____ / _________  Unknown

5. Does the participant have a history of atrial fibrillation/atrial flutter?
   - No/Not Specified → GO TO Q6
   - Yes

5.1 Was atrial fibrillation confirmed by ECG or Echo?
   - No
   - Yes
   - Unknown

6. Has the participant been treated for cancer of blood (leukemia/lymphoma) within past 12 months?
   - No/Not Specified
   - Yes

7. Has the participant had polycythemia vera or an admission hematocrit greater than 60% within past 12 months?
   - No/Not Specified
   - Yes

8. Has the participant had any brain tumor treatment within past 12 months?
   - No/Not Specified
   - Yes

9. Does the participant have suspected metastasis of cancer to brain?
   - No/Not Specified
   - Yes

10. Does the participant have any history of a valve replacement (any time in the past)?
    - No/Not Specified
    - Yes

Current Stroke/TIA (this event only)

11. Did this event occur in the setting of a procedure?
    - No/Not Specified → GO TO Q12
    - Yes

11.1 Mark the type of procedure during which the event occurred. (Mark all that apply.)
    - Cardiac surgery
    - Angiogram
12. Did this event occur during a pregnancy or up to 6 weeks post-partum?
   - Male, Not Applicable → GO TO Q13
   - No/Not Specified
   - Yes

13. At the onset of this event, were any of the following symptoms present? Mark all that apply.
   - Severe headache
   - Vomiting
   - Seizures
   - Decreased consciousness or coma
   - Paralysis or weakness in the face, arm, or leg
   - None

### Neurologic Examination

14. Was the neurologic examination done by a neurologist?
   - No/Not Specified
   - Yes

15. Was the patient alert during the exam?
   - No/Not Specified
   - Yes → GO TO Q16

15.1 Mark the best description of the participant’s state during the exam.
   - Lethargic, drowsy, or stupor
   - Coma

16. Was the neurologic exam normal?
   - No
   - Not Specified
   - Yes

### Diagnostic Procedures  (Use definitive diagnostic reports to complete sub-questions.)

17. Was a CT scan of the head performed?
   - No/Not Specified → GO TO Q18
17.1 Mark the items that describe the CT scan. (Mark all that apply.)
- Within 48 hours of event onset
- Subarachnoid hemorrhage (old)
- Subarachnoid hemorrhage (new)
- Intraparenchymal hemorrhage (old)
- Intraparenchymal hemorrhage (new)
- Chronic ischemic changes
- Infarct (old)
- Infarct (new)

17.1a How would you describe the new infarct? (Mark all that apply.)
- Hemorrhagic conversion of infarction
- Cerebral cortical infarct
- Small deep infarct
- Brain stem infarct
- Cerebellar infarct

18. Was an MRI scan of the head performed?
- No/Not Specified → GO TO Q19
- Yes

18.1 Mark the items that describe the MRI scan. (Mark all that apply.)
- Within 48 hours of event onset
- Subarachnoid hemorrhage (old)
- Subarachnoid hemorrhage (new)
- Intraparenchymal hemorrhage (old)
- Intraparenchymal hemorrhage (new)
- Chronic ischemic changes
- Infarct (old)
- Infarct (new)

18.1a How would you describe the new infarct? (Mark all that apply.)
- Hemorrhagic conversion of infarction
- Cerebral cortical infarct
- Small deep infarct
- Brain stem infarct
- Cerebellar infarct
19. Was a Carotid Doppler done?
   - No/Not Specified  ➔ GO TO Q20
   - Yes

19.1 Mark the items that describe the Doppler results. (Mark all that apply.)
   - Normal or less than 50% stenosis
   - Greater than or equal to 50% stenosis or occlusion on right side
   - Greater than or equal to 50% stenosis or occlusion on left side
   - Vertebral artery abnormality

20. Was a Transcranial Doppler done?
   - No/Not Specified  ➔ GO TO Q21
   - Yes

20.1 Mark the items that describe the Doppler results. (Mark all that apply.)
   - Intracranial artery abnormality
   - Extracranial artery abnormality

21. Was an angiogram done (includes MRA, CTA)?
   - No/Not Specified  ➔ GO TO Q22
   - Yes

21.1 Was there stenosis or occlusion greater than or equal to 50%?
   - No/Not Specified  ➔ GO TO Q21.2
   - Yes

21.1a Mark the affected artery (arteries)? (Mark all that apply.)
   - Right carotid artery
   - Left carotid artery
   - Extracranial Vertebral artery
   - Major cerebral stem artery (MCA, ICA, ACA, PCA)
   - Intracranial vertebral artery
   - Intracranial basilar artery

21.2 Was there arteriovenous malformation (AVM)?
   - No/Not Specified
   - Yes

21.3 Was there intracranial aneurysm?
   - No/Not Specified
   - Yes
21.4 Was there dissection?

- No/Not Specified
- Yes

21.5 Was there arteritis or vasculitis?

- No/Not Specified
- Yes

22. Was a transthoracic or transesophageal echocardiography done?

- No/Not Specified → GO TO Q23
- Yes

22.1 Mark the items that describe the transesophageal echocardiography results. (Mark all that apply.)

- Intracardiac thrombus
- Valvular heart disease (moderate or severe)
- Dilated ventricle or poor ventricular function
- Aortic arch atheroma
- Atrioseptal aneurysm
- Patent foramen ovale (PFO)
- Valve vegetations
- Artificial valve (specify) _____________________________
- None

23. Was an initial ECG done?

- No/Not Specified → GO TO Q24
- Yes

23.1 Did the ECG show atrial fibrillation or flutter?

- No/Not Specified
- Yes

**Medications**

24. Was the patient using a hormonal contraceptive at the time symptoms/signs were first noted?

- Male, Not Applicable → GO TO Q26
- No/Not Specified
- Yes

25. Was the patient on post-menopausal hormone therapy/hormone replacement/SERM??

- No/Not Specified
26. Was the patient using testosterone?
   - No/Not Specified
   - Yes

27. Was the patient using erythropoietin stimulating agents?
   - No/Not Specified
   - Yes

### Drug Abuse/Use

28. Is there mention of use of cocaine, amphetamines, or other stimulants **in the past**?
   - No → GO TO Q29
   - Unknown → GO TO Q29
   - Yes

28.1 Was there mention of use of cocaine in the past?
   - No
   - Unknown
   - Yes

28.2 Was there mention of use of amphetamines in the past?
   - No
   - Unknown
   - Yes

28.3 Was there mention of use of other stimulants (including prescriptions) in the past?
   - No
   - Unknown
   - Yes

29. Is there mention of use of cocaine or stimulants **in the 3 days prior to the event**?
   - No → GO TO Q30
   - Unknown → GO TO Q30
   - Yes

29.1 Was there mention of use of cocaine in the 3 days prior to the event?
   - No
   - Unknown
   - Yes
29.2 Was there mention of use of amphetamines (including prescriptions) in the 3 days prior to the event?
   - No
   - Unknown
   - Yes

29.3 Was there mention of use of other stimulants in the 3 days prior to the event?
   - No
   - Unknown
   - Yes

30. Was a drug/toxicology screen performed during admission for stroke?
   - No ➔ GO TO Q31
   - Unknown ➔ GO TO Q31
   - Yes ➔ Complete the following table based on the drug/toxicology screen.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Positive</th>
<th>Negative</th>
<th>Don't Know/Not Recorded</th>
</tr>
</thead>
<tbody>
<tr>
<td>30.1 Barbiturate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.2 Buprenorphine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.3 Cocaine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.4 Amphetamine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.5 Methadone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.6 Propoxyphene</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.7 Phencyclidine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.8 Opiate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.9 Tricyclics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.10 Cannabinoids</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.11 Oxycodone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.12 Methamphetamine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30.13 Benzodiazepine</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

31. What was the participant’s functional status at the time of discharge (from ED, hospital, or physician’s office)? **Mark the ONE category that applies best.** [Glasgow Outcome Scale]
   - Good recovery – patient can lead a full and independent life with or without minimal neurological deficit
- **Moderately disabled** – patient has neurological or intellectual impairment but is independent
- **Severely disabled** – patient conscious but dependent on others to get through daily activities
- **Vegetative survival** – has no obvious cortical functioning
- **Dead**
- **Unable to categorize** stroke based on available documentation (This is for very limited cases when abstractor is unable to categorize in one of the above.)
References


Appendix 11
CARDIA Endpoints Tracking Reports Instructions
CARDIA COORDINATING CENTER MORBIDITY & MORTALITY SYSTEM — REPORTS OPTION

1. Log-in Instructions

Step 1. There should be a CARDIA dashboard shortcut on your desktop. Double click on the shortcut and then single click on “Remote application gateway” on this screen.

![CARDIA Dashboard](image)

Step 2. There is a strong possibility that you may get a certificate security warning as in this screenshot. Click on the “Continue to this website (not recommended)”
Step 3. Enter your CARDIA user name and password

Step 4. Click on “Endpoints - PRODUCTION” icon
Step 5. If you get this screen, then click on “Connect” button

Step 6. To run the report of ALL reported admissions for a particular participant ID go to “Forms” tab and click on “Reported Morbidity Admissions” and type in or select ID needed.
Step 7. You’ll see the report that has the following information: ID, FU period, Admission number (1-20 are inpatient and 21 and more are outpatient), Date of admission, Reported reason for admission, Date medical records received at CC, and Tracking code in the Endpoints system.

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>FU Period</th>
<th>Admission Number</th>
<th>Admission Date</th>
<th>Reason for Admission</th>
<th>Date Records Received at CC</th>
<th>Tracking Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-0400-61-103200</td>
<td>HF103</td>
<td>1 02/25/1999</td>
<td>OTHER</td>
<td>02/27/1999</td>
<td>112</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE104</td>
<td>1 03/17/2007</td>
<td>HEART PROBLEM KNOWN AS AFIB</td>
<td>03/27/2007</td>
<td>132</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE104</td>
<td>2 03/30/2007</td>
<td></td>
<td></td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE103</td>
<td>1 05/01/2013</td>
<td>AFIB</td>
<td>05/01/2013</td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE104</td>
<td>21 08/08/2014</td>
<td>CARDIOVERSION</td>
<td>08/14/2014</td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE104</td>
<td>22 08/08/2014</td>
<td>A-PO</td>
<td>08/14/2014</td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE103</td>
<td>1 09/12/2017</td>
<td>Appendicitis</td>
<td>09/12/2017</td>
<td>113</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE104</td>
<td>2 09/12/2017</td>
<td>complications from appendicitis, abscessed ilac</td>
<td>09/12/2017</td>
<td>113</td>
<td></td>
</tr>
<tr>
<td>3-0400-61-103200</td>
<td>RE104</td>
<td>21 09/03/2017</td>
<td>CARDIOVERSION TO TREAT ATRIAL FIBRILLATION</td>
<td>09/03/2017</td>
<td>102</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>CC - record received at CC, not marked</td>
</tr>
<tr>
<td>101</td>
<td>CC - record received, coded, and scanned at CC</td>
</tr>
<tr>
<td>102</td>
<td>CC - failed to print</td>
</tr>
<tr>
<td>103</td>
<td>CC - data entry performed but not reported</td>
</tr>
<tr>
<td>104</td>
<td>CC - data entry performed and reported</td>
</tr>
<tr>
<td>105</td>
<td>CC - data entry performed and not reported</td>
</tr>
<tr>
<td>106</td>
<td>GP - duplicate record report</td>
</tr>
<tr>
<td>107</td>
<td>GP - record not according to medical record</td>
</tr>
<tr>
<td>108</td>
<td>GP - record not according to medical record, not marked</td>
</tr>
<tr>
<td>109</td>
<td>GP - record not according to medical record, marked</td>
</tr>
<tr>
<td>110</td>
<td>GP - record not according to medical record, not marked</td>
</tr>
<tr>
<td>111</td>
<td>GP - record not according to medical record, marked</td>
</tr>
<tr>
<td>112</td>
<td>GP - record not according to medical record, not marked</td>
</tr>
<tr>
<td>113</td>
<td>GP - record not according to medical record, marked</td>
</tr>
<tr>
<td>114</td>
<td>GP - record not according to medical record, not marked</td>
</tr>
</tbody>
</table>

Page 1 of 1

Version 10/09/2017
Step 8. In the **Morbidity & Mortality window**, click on the **Reports tab** which contains M&M TABLES and **TRACKING REPORTS**.

![Image of Morbidity & Mortality window]

2. **Tracking Reports**

2.1. **Mortality Cases**

2.1.1. **Mortality Tracking Reports**

- **Report 1. Death Cases – All**: reported/known death cases with current case status
- **Report 2. Death Cases – In Process**: currently-open death cases
- **Report 3. Death Cases – Closed**: processed/closed death cases

2.1.2. **Running Mortality Tracking Reports**

Ver. 10/09/2017
To generate Mortality Tracking Reports, within the Reports tab under the Tracking Reports section and Mortality Cases subsection click one of the 1, – 3, radio buttons (see screenshot above).

2.1.3. Mortality Tracking Report Contents

NOTE: Data in all mortality reports is sorted in ascending order by participant ID. Field centers are specified in subheadings.

- **ID**: participant CARDIA identification number
- **Date of Death**: date of participant’s death
- **Date CARDIA Learned of Death**: date when the FC the first time knew about participant’s death
- **ICD-9 Coded**: YES (ICD-9 coded) and NO (ICD-9 not coded) options
- **Death Certificate**: tracking status using tracking codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF</td>
<td>Default - new record</td>
</tr>
<tr>
<td>IN</td>
<td>Received but incomplete</td>
</tr>
<tr>
<td>NA</td>
<td>Requested but not available</td>
</tr>
<tr>
<td>NC</td>
<td>Received but not coded by nosologist</td>
</tr>
<tr>
<td>NS</td>
<td>Semi to nosologist</td>
</tr>
<tr>
<td>PN</td>
<td>Pending</td>
</tr>
<tr>
<td>RR</td>
<td>Request refused</td>
</tr>
<tr>
<td>RV</td>
<td>Coded awaiting review</td>
</tr>
<tr>
<td>XX</td>
<td>Finalized</td>
</tr>
</tbody>
</table>

- **Autopsy Report**: tracking status using tracking codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF</td>
<td>Default - new record</td>
</tr>
<tr>
<td>NA</td>
<td>Requested but not available</td>
</tr>
<tr>
<td>ND</td>
<td>Autopsy not done</td>
</tr>
<tr>
<td>PN</td>
<td>Pending</td>
</tr>
<tr>
<td>RR</td>
<td>Request refused</td>
</tr>
<tr>
<td>XX</td>
<td>Finalized</td>
</tr>
</tbody>
</table>

- **Form Z33A**: received at CC?; YES (received at CC) or blank (not received at CC)
- **Form Z33B**: received at CC?; YES (received at CC) or blank (not received at CC)
- **Form Z33C**: received at CC?; YES (received at CC) or blank (not received at CC)
- **Adjudication Done?**: death case review/adjudication status with options YES (reviewed/adjudicated) or blank (not reviewed/adjudicated)
- **Overall Death Case Status**: tracking status using tracking codes

<table>
<thead>
<tr>
<th>Overall Death Case Status Tracking</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF</td>
</tr>
<tr>
<td>NA</td>
</tr>
<tr>
<td>ND</td>
</tr>
<tr>
<td>PN</td>
</tr>
<tr>
<td>RR</td>
</tr>
<tr>
<td>XX</td>
</tr>
</tbody>
</table>
2.2. Morbidity Cases

2.2.1. Morbidity Tracking Reports

<table>
<thead>
<tr>
<th>Code</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF</td>
<td>Default - new record</td>
</tr>
<tr>
<td>EC</td>
<td>Sent to Endpoints Surveillance &amp; Adjudication Subcommittee</td>
</tr>
<tr>
<td>PN</td>
<td>Pending</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control</td>
</tr>
<tr>
<td>RC</td>
<td>All documents received at QC</td>
</tr>
<tr>
<td>RR</td>
<td>Request refused</td>
</tr>
<tr>
<td>XX</td>
<td>Finalized</td>
</tr>
</tbody>
</table>

**Morbidity Cases**

- Report 6. Morbidity Tracking Detail: all reported inpatient and outpatient admissions and their current status for specified follow-up period and field center
- Report 7. Morbidity Tracking Summary: Overall: summary data for morbidity cases for the specified follow-up period broken down by field center
- Report 8. MR - Pending Release: lists all cases awaiting participant consent status. The report is sorted by field center and participant
- Report 9. MR - Requested, Not Received by FC: shows medical records requested from the hospital, but not yet received at the field center
- Report 10. MR - Received at FC, Not Sent to CC: shows the list of medical records that are currently processed by the field center and not yet sent to the coordinating center
- Report 11. MR - Sent to CC: shows the list of medical records processed at field center and sent to coordinating center
- Report 12. MR - Received at CC, Not Sent to Adjudicator: lists medical records that have been received at coordinating center and not sent to reviewers because: 1) currently being ICD-coded, 2) currently being QC-ed, or 3) case already triaged and determined not to be an endpoint
- Report 13. MR - Sent to Adjudicator: shows medical records sent for review and adjudication

Ver. 10/09/2017
Report 15. MR – Closed: lists all morbidity cases that are closed/finalized. All medical records with tracking codes XX “Finalized (reviewed and adjudicated)” may be destroyed by the field center.

2.2.2. Running Morbidity Tracking Reports

To generate Morbidity Tracking Reports, within the Reports tab under the Tracking Reports section and Morbidity Cases subsection...


Click the 6. Morbidity Tracking Detail radio button (see screenshot above). In the ReportOptions window, select the follow-up period(s) and field center(s) of interest from the menus provided. Click Create Report button.

![Report 6 screenshot]

Report 7.

Click the 7. Morbidity Tracking Summary: Overall radio button. In the Follow-Up Period window, select the follow-up period from the drop down menu and then click OK button.

![Follow-Up Period window]

Reports 8-15.

Click one of the 8. – 15. radio buttons.
2.2.3. Morbidity Tracking Report Contents

<table>
<thead>
<tr>
<th>ID</th>
<th>Admission Date</th>
<th>Direct Discovery</th>
<th>Date Code Received</th>
<th>Potential Endpoint?</th>
<th>Date Identified</th>
<th>Discharge Date</th>
<th>Date Code Received</th>
<th>Date Code Received</th>
<th>Date Records Received</th>
<th>Date Records Received</th>
<th>Date MR Sent to CC</th>
<th>Date MR Received by CC</th>
<th>Tracking Code by CC</th>
</tr>
</thead>
</table>

- **ID:** participant CARDIA identification number
- **Admission Number:** has codes from 1 through 20 for inpatient admissions and starting with 21 for outpatient admissions
- **Date of Discovery:** date when the field center learned about this admission
- **Date Coded by FC:** date when CARDIA codes assigned by field center
- **Potential Endpoint?:** endpoint status with options YES and NO. The field center defines whether or not this admission is a potential endpoint based on criteria developed by the Endpoints Surveillance & Adjudication Subcommittee [CARDIA XXX-Month Follow-up Questionnaire; Hospitalizations Checksheet (Form XXXB) and Procedures Checksheet (Form XXXC)].
- **Date Endpoint Identified:** date when the field center identified an endpoint
- **Admission Date:** admission date reported by a participant and verified from the medical record
- **Discharge Date:** discharge date identified from the medical record
- **Date Consent Requested:** date when participant’s consent was requested by field center
- **Date Consent Received:** date when participant’s consent was received by field center
- **Date Records Requested:** date when medical record was requested by field center
- **Date Records Received:** date when medical record was received by field center
- **Date MR Sent to CC:** date medical record sent to coordinating center by field center
- **Date MR Received by CC:** date when medical record received by coordinating center
- **Tracking Code by CC:** overall tracking code assigned by coordinating center

<table>
<thead>
<tr>
<th>Code</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI</td>
<td>Awaiting CARDIA coding</td>
</tr>
<tr>
<td>AR</td>
<td>Ambulance record</td>
</tr>
<tr>
<td>CC</td>
<td>Record received at coordinating center, not coded</td>
</tr>
<tr>
<td>CD</td>
<td>Record received, coded, and reviewed at coordinating center</td>
</tr>
<tr>
<td>DE</td>
<td>Data entry error - no participant report</td>
</tr>
<tr>
<td>DF</td>
<td>Default - new record</td>
</tr>
<tr>
<td>DR</td>
<td>Duplicate record/report</td>
</tr>
<tr>
<td>EC</td>
<td>Record sent to Endpoints Surveillance &amp; Adjudication Subcommittee</td>
</tr>
<tr>
<td>ER</td>
<td>Emergency room visit</td>
</tr>
<tr>
<td>HR</td>
<td>Hospital refused permission</td>
</tr>
<tr>
<td>HI</td>
<td>Insufficient information from participant to find record</td>
</tr>
<tr>
<td>KR</td>
<td>Next of kin refused permission</td>
</tr>
<tr>
<td>LR</td>
<td>Lost record (received at coordinating center)</td>
</tr>
<tr>
<td>NI</td>
<td>Not interested (not a tracked reason)</td>
</tr>
</tbody>
</table>
3. Tracking Report Functions

**Export**. To export a report, click the Export Report icon . In the Export Report window, type the file name in the File name field and select the file format from the drop down menu in the Save as type field. Note: the default format is Crystal Reports.
**Print.** To print a report, click the **Print Report icon**. From the **Print window**, select a printer, page range, and number of copies. Click **Print button**.

**Toggle Group Tree.** To go directly to a specific part of a report, click the **Toggle Group Tree icon**. Then select the report section you want to access.

**Go to Next Page.** To view a report page-by-page, click the **Go to Next Page icon**. The current page number and total number of pages are shown at the bottom of the **Report window**.

**Go to Page.** To access a specific page of a report, click the **Go to Page icon**. Enter the page number in the **Go to Page window** and click **OK button**.

**Find Text.** To search for specific text or numeric entry, click the **Find Text icon**. Enter the text or numeric entry into the **Find Text window** and click **Find Next button**.
**Zoom.** To zoom in on a report image, click the **Zoom icon** and select percent of zoom from the drop down menu.