

**HEALTH ABC  
CARDIOVASCULAR ADJUDICATION PROTOCOL  
(Revised November 2005)**

**I. Definitions**

- 1) Cardiovascular Endpoint: An acute myocardial infarction, angina pectoris, or congestive heart failure resulting in symptoms and/or treatment. The event must result in an overnight hospitalization.
- 2) Incident, first episode, and recurrent CHD endpoint: Health ABC will investigate all overnight hospitalizations from CHD. The Cardiovascular Adjudication Form must be completed for:
  - ✓ The first episode of acute myocardial infarction, angina, and/or congestive heart failure after study enrollment (baseline clinic visit), regardless of whether the condition was prevalent at baseline.
  - ✓ Inpatient death due to CHD or with an acute CHD event.
- 3) Myocardial Infarction: Myocardial infarction (MI) is defined as the death of part of the myocardium due to occlusion of a coronary artery from any cause, including spasm, embolus, thrombosis, or the rupture of a plaque. The Health ABC algorithm for classifying MI includes elements of the medical history, cardiac enzymes, and ECG readings.

Criteria for definite MI must include at least ONE of the following:

- ✓ Evolving diagnostic ECG pattern
- ✓ Diagnostic ECG pattern AND abnormal enzymes
- ✓ Cardiac pain OR ischemic symptoms AND either an evolving ST-T pattern OR an equivocal ECG pattern.

- 4) Angina Pectoris: Angina pectoris is defined as symptoms, such as chest pain, chest tightness, or shortness of breath, produced by myocardial ischemia that do not result in infarction. The symptoms generally last less than 20 minutes.

Criteria for definite angina must have ALL of the following:

- ✓ Symptoms such as chest pain, chest tightness, shortness of breath.
- ✓ Diagnosis of angina from a physician.
- ✓ Be under medical treatment for angina including nitroglycerine, beta-blocker, or calcium channel blocker.

In addition, the following are sufficient but not necessary to confirm angina IF the participant has also reported symptoms:

- ✓ Coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA), or other coronary revascularization procedure
- ✓ Coronary angiography showing >70% obstruction of any coronary artery.
- ✓ ST depression of more than 1 mm on exercise stress testing.

- 5) Congestive Heart Failure: Congestive heart failure (CHF) is defined as a constellation of symptoms (such as shortness of breath, fatigue, orthopnea, and paroxysmal nocturnal dyspnea) and physical signs (such as edema, rales, tachycardia, a gallop rhythm, and a displaced PMI) that occur in a participant whose cardiac output cannot match metabolic need despite adequate filling pressures.

Criteria for definite CHF require that the participant must have BOTH of the following:

- ✓ Diagnosis of CHF from a physician,
- ✓ Be under medical treatment for CHF including BOTH of the following:
  - ✓ A diuretic AND
  - ✓ Digitalis OR a vasodilator (nitroglycerine, apresoline, angiotensin converting inhibitor)

In addition, the following are sufficient but not necessary to validate CHF:

- ✓ Presence of cardiomegaly and pulmonary edema on chest x-ray OR
- ✓ Evidence of a dilated ventricle and global or segmental wall motion abnormalities with decreased systolic function either by echocardiography or contrast ventriculography.

## **II. Ascertainment of CHD**

- 1) Semi annual telephone interview
- 2) Annual clinic visit
- 3) Scheduling of annual clinic visit
- 4) Proxy, spouse, relative, or friend contacts field center to report hospitalization
- 5) Hospital medical records from later event indicate a hospitalized CHD event occurred.
- 6) HCFA tape review
- 7) Obituary

## **III. Data Collection Forms to be Completed by Field Centers**

- 1) Data collection forms required for all inpatient (overnight) CHD events, both incident and recurrent:
  - a. Health ABC Event Form
  - b. Discharge Abstract Form

c. Local Adjudication Report

- 2) Data collection forms also required for incident/first episode of acute MI, angina and/or CHF
  - a. Cardiovascular Disease Adjudication Report
- 3) Data collection forms also required for CHD event resulting in an inpatient death, or CHD contributing to an inpatient death
  - a. Cardiovascular Disease Adjudication Report
  - b. Report of Death Form
  - c. Decedent Proxy Interview (narrative not necessary)
  - d. Final Death Adjudication Report (at central adjudication)

**IV. Documentation to be requested**

- 1) For all CHD inpatient events
  - a. Face sheet or physician attestation with ICD codes
  - b. Discharge summary
- 2) In addition, for all first episodes of MI, angina, and/or CHF after Health ABC enrollment, when available/applicable:
  - a. History and physical exam
  - b. Cardiac enzyme lab report
  - c. ECG tracings
  - d. Echocardiography report or MUGA scan report
  - e. Stress test report
  - f. Cardiac angiography/catheterization report
  - g. Operative report
  - h. Chest x-ray report
  - i. Cardiology consult
  - j. Emergency room report
- 3) In addition, for all inpatient deaths related to CHD
  - a. Death certificate
  - b. Autopsy report, if done.

**V. Procedures**

Once the Health ABC field center is notified of a CHD inpatient event, the following protocol should be followed:

- 1) A Health ABC Event Form is completed by examiner or Event Coordinator at the local field center once notified of CHD event. Check the appropriate box under Section I: Overnight Hospitalization, and the text field indicates a CHD event may have occurred.
- 2) The completed Event Form scanned into data system.
- 3) A copy of the Event Form is forwarded to the Event Coordinator at the local field center.

- 4) The Event Coordinator enters tracking information into the web-based D and D tracking system.
- 5) Event Coordinator requests the event-specific documentation (refer to Section IV above)
- 6) The Event Coordinator notes first request for documentation in the D and D tracking system.
- 7) If necessary, the Event Coordinator makes second request for documentation.
- 8) The Event Coordinator notes second (and all additional) requests for documentation in the D and D tracking system.
- 9) All documentation received is noted in the D and D tracking system.
- 10) Once all documentation is received, the appropriate data collection forms, depending on whether the CHD event was the first after enrollment, or if a CHD-related death occurred (refer to Section III), are completed.
- 11) Event Coordinator notes the date the event packet is complete (documentation received and all appropriate data collection forms filled out) in the D and D tracking system.
- 12) Any unclear or difficult cases are sent to the other field center for review.

## **VI. Completing the Cardiovascular Disease Adjudication Report**

Question 1: Record the Health ABC Event Form reference number from the lower left corner of the Event Form.

Question 2: Record the date that the participant was admitted to the hospital as stated on the face sheet or discharge summary.

Question 3: Record the date that the participant was discharged from the hospital as stated on the face sheet or discharge summary.

Question 4: Record if there were any angina symptoms such as chest pain or other anginal equivalent, as described in the discharge summary, emergency room record, history and physical exam, or cardiology consult. Symptoms may occur on admission, or any time during the hospitalization. For 4a, if 'yes,' indicate if the participant received any nitrates or nitroglycerin, either prior to or during the hospitalization, for these symptoms. If 'yes,' indicate the treatment response. For 4b, indicate if there was any indication that the symptoms lasted for 20 minutes or longer.

Question 5: Based on the history and physical exam, discharge summary, consults, emergency room report, or other notes, record all symptoms listed in a. through h.

Question 6: Based on the history and physical exam, discharge summary, consults, emergency room report, or other notes, record all symptoms listed in a. through j.

Question 7: If any chest x-rays were done during the hospitalization, mark 'yes.' Record any findings from the radiology reports in a. through h. If the radiology reports are not available, record any findings from chest x-rays as listed in other documents such as history and physical exam, discharge summary, emergency room report, or consult.

Question 8: Record any of the listed medications used to treat the participant any time during the hospitalization, as indicated in the discharge summary, history and physical exam, emergency room record, or consult.

Question 9: Based on the lab reports, indicate if any of the cardiac enzymes were reported. If total CK, CK-MB, LDH, LD-1, LD-2, and/or Troponin were reported, mark a. through d. Use the peak (highest) value for each enzyme value and mark the appropriate range for each value based on the hospital normal ranges.

- 9a. If total CK was reported, use the highest value and compare it to the lab high normal.
- 9bi. If CK-MB was reported, use the highest value and compare it to the lab high normal. CK-MB may be reported in units or percent.
- 9bii. Record the CK-MB value relative to the total CK peak value.
- 9ci. If LDH was reported, use the highest value and compare to the lab high normal.
- 9cii. If LD-1 was reported, use the highest value and compare to the lab high normal. LD-1 may be reported in units or percent.
- 9ciii. If LD-2 was reported, determine its relative value compared to the LD-1.
- 9di. If Troponin was reported, determine if it was Troponin C, I or T. If this is not indicated on the lab report, call the hospital's lab and ask.
- 9dii. Use the highest Troponin value and compare it to the lab high normal.

Question 10: If any ECG tracings were done any time during the hospitalization, mark 'yes' and attach the tracings to the record. If the hospital did not send tracings, but interpretations are mentioned in any other part of the record, contact the hospital and request the tracings.

Question 11: Mark any/all of the three criteria for MI if they are present. If at least one of the criteria is marked, indicate 'yes' on the Local Adjudication Report next to 'myocardial infarction.' If none of the criteria are present, but evidence exists to indicate an MI may have occurred, mark 'possible' on the Local Adjudication Report. For example, if the enzymes are elevated but the participant was comatose and could not report symptoms, or no ECGs were done, mark 'possible' on the Local Adjudication Report.

If the ECGs reflect Q-waves were present, mark 'yes.'

If the MI occurred during or shortly after a procedure, regardless of whether the procedure was cardiac or not, mark 'yes.'

Question 12: Mark any/all of the four criteria for angina if they are present. If at least one of the criteria is marked, indicate 'yes' on the Local Adjudication Report next to 'angina.' If none of the criteria are present, but evidence exists to indicate angina may have been present, mark 'possible' on the Local Adjudication Report.

Question 13: Mark any/all of the three criteria for congestive heart failure if they are present. If at least one of the criteria is marked, indicate 'yes' on the Local Adjudication Report next to 'CHF.' If none of the criteria are present, but evidence exists to indicate CHF may have been present, mark 'possible' on the Local Adjudication Report.

If a left ventricular ejection fraction from this hospitalization was noted in the echocardiography report, MUGA report, cardiac catheterization report, or anywhere in the discharge summary or other source document, record it. If more than one ejection fraction was documented during the hospitalization, record the lowest. Indicate the diagnostic test used to determine the ejection fraction.

- 13a. Based on the discharge summary or procedure reports, indicate if the CHF was procedure related.
- 13b. Based on the diagnostic test reports or discharge summary, indicate if the heart failure was due to systolic dysfunction, diastolic dysfunction, both or unknown.
- 13c. Indicate the primary underlying cause of the CHF and up to five other causes of the CHF, using codes 1 through 12. In order to apply a cause code, evidence of the underlying disease must be present. For example, code 5 cannot be used if one of the pulmonary conditions listed was not present during the hospitalization.

## **VII. Decision Rules**

- 1) There is no outer time limit set to consider an MI procedure related, as long as the MI occurs during the same hospitalization as the procedure.
- 2) If the CHD event meets the criteria for MI, then angina should NOT be marked on the Local Adjudication Report unless:
  - a. There is at least one episode of post infarction angina.
  - b. The participant is admitted for angina and rules out for MI but subsequently has an MI (ex. Post CABG MI).
- 3) If the participant is admitted with a symptomatic condition that also results in symptomatic CHF, then both the admitting condition and the CHF should be marked on the local adjudicator form, and the primary reason for hospitalization should be the *cause* of the CHF. Ex. Admission for chest pain

diagnosed as atrial fibrillation or COPD exacerbation with CHF, the primary reason would be the atrial fibrillation or COPD.

- 4) If the participant is admitted with symptoms specific to CHF, then the CHF is the primary reason for admission, and the other conditions contributing to the CHF would be marked on the local adjudicator form.
- 5) If the participant undergoes a cardiac catheterization showing >70% of a vessel and has a revascularization procedure, or has a stress test positive for ischemia, but NO symptoms, then do not mark 'angina' on the CHD form. Do mark 'yes' for the coronary insufficiency/ischemic heart disease on the local adjudicator form.
- 6) For hospitalizations involving coronary revascularizations in a participant with a prior CVD form for incident angina, and therefore not requiring a CVD form, code the revascularization in text field on page 2 of the Local Adjudication Report (question 4u) with code 15 representing coronary revascularization.