

CHAPTER 28

Outcome Events Adjudication

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28.1 Ascertainment of Outcome Events (Overview)

In addition to reducing the primary LIFE Study endpoint, of major mobility disability, the study's physical activity intervention is also hypothesized to affect the frequency of serious fall injuries, combined cardiovascular events, and pulmonary disease events. Total death, combined with the primary endpoint, is also a secondary outcome.

Documents verifying the occurrence of these events are obtained by identifying and obtaining information on overnight hospitalizations, fall-related fractures, outpatient coronary and lower extremity revascularizations (including abdominal aortic aneurysm repair or rupture), other hospitalizations for lower extremity peripheral arterial disease, and deaths. This chapter describes the process involved in adjudicating these events in a standardized and unbiased manner.

Note: An overnight hospitalization requires an admission to the hospital. Even if it spans two days, e.g. 9 pm on one day to 9 am the next day, a visit to an emergency department is not considered an overnight hospitalization if it does not result in a hospital admission. For billing purposes, some hospital admissions may be classified as "hospital outpatient" or "observation care". These should be considered as overnight hospitalizations, as long as the discharge date is different from the admission date.

The secondary and tertiary hypotheses that relate to these outcomes are:

- **Secondary:** Compared with SA, the PA program
 - Reduces the risk of serious fall injuries;
 - Reduces the risk of persistent major mobility disability and of the combined outcome of major mobility disability or death;
- **Tertiary:** Compared with SA, the PA program
 - Reduces the risk of hospital admissions for exacerbation of airway disease (asthma, bronchitis, emphysema, and/or COPD) or pneumonia.
 - Reduces the risk of combined cardiovascular events, including
 - Myocardial infarction (MI),
 - Angina requiring hospitalization,
 - Any stroke (ischemic or hemorrhagic),
 - Transitory ischemic attack (TIA) requiring hospitalization,
 - Hospitalization for carotid artery disease,
 - Hospitalization for congestive heart failure (CHF),
 - Hospitalization for peripheral artery disease (PAD) or outpatient revascularization for PAD,
 - Ruptured abdominal aortic aneurysm (AAA), and
 - CVD death.

28.2 Health Outcomes

The following events are LIFE outcomes, which can be tracked by the LIFE website through use of an outcome interface. The outcome interface will register each outcome reported and will enable field centers and the DMAQC to track the outcomes as they

move through the process of outcome reporting and adjudication. The final classification of LIFE Health Outcomes is made by the central adjudication committee based on satisfaction of the diagnostic criteria described below. (See Section 28.3 for operational details for central adjudication.)

28.2.1 Death

The confirmation and date of death are confirmed by death certificate. Cause of death is determined from hospital records and death certificate and coded into fall-related injury, cardiovascular categories, pulmonary disease categories, and other causes of death. If hospital records are not available, information regarding medications and medical history will be obtained from the most recent clinic assessment visit.

28.2.2 Serious Fall Injuries

Serious fall injuries include (1) fall-related fractures and/or (2) other fall-related injuries that lead to hospitalization or death. Criteria for serious fall injuries do not include other adverse consequences of falls, e.g., restricted activity, fear of falling, non-fracture injuries that do not lead to hospitalization. Fall-related fractures are defined as those due to falls and do not include non-fall related fractures such as vertebral (i.e. compression) fractures, stress fractures, or fractures from excessive trauma (e.g. MVA or fall from height > 3 feet).

Definition of DEFINITE serious fall injury

The criteria for injurious fractures must meet all of these below:

- Radiologic evidence of non-vertebral, non-stress fracture
- Report of fall within 1 week of diagnosis of injury.
- Absence of major trauma (MVA or fall from height > 3 feet) or peri-prosthetic fracture, i.e. fracture around a joint replacement prosthesis.
- No evidence of pathologic fracture (malignancy, osteoporosis is not considered pathologic)

A participant is considered to have a serious fall injury if any of these four criteria are met:

- Fracture as per criteria above

Hospitalized for and/or died from one of the following three conditions:

- Non-Fracture head injury with loss of consciousness, subdural or other intracranial hematoma by MRI or CT, facial trauma requiring sutures, traumatic vision loss with report of visual function, or other similar head injury sequela.
- Consequences of long lie such as rhabdomyolysis, with increases in muscle enzymes, dehydration/volume depletion with use of parental fluid replacement,

decreased blood pressure, increase BUN and /or sodium level, or hypothermia (rectal temp < 36° C).

- Other injury attributed to a fall such as burns with report of burn severity and extent, severe sprains with description of swelling, pain and change in motion, visceral injury with radiologic confirmation of blood collection or change in organ features, internal bleeding with report of hematoma or need for surgery, or acute peripheral nerve damage with neurological description of acute deficit.

If a participant is hospitalized for a fall, but does not meet one of the aforementioned criteria, the event should not be classified as a serious fall injury.

Definition of PROBABLE serious fall injury

Does not meet the criteria above, but there is sufficient evidence based on the clinical findings that a serious fall injury occurred.

28.2.3 Pulmonary Disease Outcomes

Pulmonary outcomes to be assessed include hospital admissions for exacerbation of airway disease and for pneumonia.

A. The criteria for exacerbation of airway disease are two-fold:

1. A diagnosis of airway disease, including asthma, chronic bronchitis, emphysema, or COPD, as recorded at discharge; and
 2. At least one of the following cardinal symptoms, as recorded at admission: *
- An acute increase in sputum volume
 - An acute increase in sputum purulence
 - An acute increase in dyspnea

* Clinical judgment is required. Meaning, the clinical setting is consistent with airway disease being a significant contributor to the cardinal symptom AND the timeline for the cardinal symptom should reflect an acute change (i.e. usually over days), rather than progression of chronic disease (i.e. usually over weeks to months).

In addition, must also have at least one of the following, at admission or during hospitalization:

- Diagnosis of a recent upper respiratory tract infection (URI), occurring within 5 days prior to the admission
- Symptoms of cough or fever
- Physical examination consistent with wheezing
- Severe respiratory impairment (FEV1 < 1.2 liters, PaO2 < 60, SaO2 < 90%, or a PaCO2 > 44 with a pH < 7.36)

- Treatment with bronchodilators, corticosteroids, antibiotics, or oxygen in a pattern that represents a change from baseline (e.g. increased dose or frequency of use or a new prescription)

NOTE: In the absence of a prior diagnosis of chronic airway disease, a distinction should be made between an exacerbation of newly diagnosed airway disease (a LIFE outcome) versus an episode of acute bronchitis (not a LIFE outcome). Such a distinction requires clinical judgment, including ascertaining the severity of symptoms (i.e. severe wheezing or dyspnea) and/or the use of systemic steroids or oxygen supplementation, which would both support the diagnosis of airway disease.

B. The criteria for pneumonia include the following:

- Symptoms of cough, fever, or sputum production or exam finding of rales and/or dullness to percussion;
- Chest radiograph (including CT imaging, when available) showing new or progressive infiltrate, consolidation, cavitation, or pleural effusion

Definite pneumonia requires the presence of symptoms AND chest radiographic findings (including CT findings, when available), as noted above.

Probable pneumonia may be considered when the chest radiograph (including CT imaging, when available) is non-diagnostic (e.g. poor quality) but symptoms and clinical presentation are otherwise consistent with pneumonia, and vice-versa.

The **subtype of pneumonia** is defined by a 48-hour window at admission and patient population:

- Healthcare-associated pneumonia: symptoms and chest X-ray findings are recorded during the first 48-hours of the admission, specific to patients who 1) attended a hemodialysis clinic or received cancer chemotherapy in the 30 days prior to the current pneumonia admission; or 2) were admitted to an acute care hospital for at least 2 days or resided in a nursing home or long-term care facility in the 90 days prior to the current pneumonia admission.

NOTE: In most cases, it will be obvious that the pneumonia is healthcare associated, e.g. participant was admitted directly to the hospital from a nursing home with pneumonia. Since the hospital records should include information about hemodialysis and cancer chemotherapy, their absence from the records should lead to a NO response to Q4a. DMAQC will try to provide information about prior hospitalizations within the 90-day window. If there is still uncertainty about the healthcare exposures or the time-intervals of 30- and 90-days, indicate don't know/not enough information to Q4a and/or Q4b and subsequently in Section 3.

- Community-acquired pneumonia: symptoms and chest X-ray findings are recorded during the first 48-hours of the admission and patients do not otherwise meet criteria for healthcare-associated pneumonia.

- Hospital-acquired pneumonia: symptoms and chest X-ray findings are recorded only after the first 48-hours of the admission.

NOTE: Although hospital-acquired pneumonia will be recorded, it will not be considered as a LIFE pneumonia outcome.

28.2.4 Cardiovascular Disease Outcomes

Cardiopulmonary events to be assessed as tertiary outcomes include:

- Myocardial infarction (MI),
- Angina requiring hospitalization,
- Any stroke (ischemic or hemorrhagic),
- Transitory ischemic attack (TIA) requiring hospitalization,
- Hospitalization for carotid artery disease,
- Hospitalization for congestive heart failure (CHF),
- Hospitalization for peripheral artery disease (PAD) or outpatient revascularization for PAD,
- Ruptured abdominal aortic aneurism (AAA), and
- CVD death.

Criteria for DEFINITE and PROBABLE adjudication criteria are supplied. The composite outcomes will include only definite cases. Assigning “probable” cases allows sensitively analysis, but should not be used for the main analysis.

28.2.4.1 Myocardial Infarction (MI)

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. Myocardial infarction in LIFE must result in an overnight hospitalization. The algorithm for classifying myocardial infarction includes elements of the medical history, results of the cardiac injury biomarkers, and electrocardiogram readings.

LIFE has adopted the ARIC criteria for myocardial infarction but this has been updated by the LIFE outcomes adjudication committee based on new criteria to evaluate troponin levels proposed by investigators from the REGARDS (Monika Safford) and SPRINT (Beth Lewis) studies and supported by their publication (under review) .

For classification as a DEFINITE myocardial infarction, the participant must have ONE of the following:

- An evolving diagnostic ECG pattern (evolving localized Q wave MI pattern or evolving profound ST-T abnormalities)
- An ECG pattern of either evolving Q wave, evolving major ST-T abnormalities, or new LBBB, and abnormal biomarkers

- Cardiac pain and abnormal biomarkers and either an evolving ST-T pattern or a non-evolving ECG pattern (non-evolving major or minor Q-waves or non-evolving major or minor ST-T abnormalities)
- In the absence of cardiac pain, abnormal biomarkers and abnormal ECG with clinical indication consistent with MI.

Definition of terms used in these criteria and the criteria for probable and suspected myocardial infarction are found in Appendix A. It is **essential** to refer to Appendix A Tables to adjudicate MI. The definition of myocardial infarction includes events that occurred during surgery or angioplasty. The final classification of myocardial infarction is made by the Adjudication Committee based on satisfaction of the appropriate algorithm.

Biomarkers

Biomarkers to consider include CPK and Troponin, and in some cases may still include LDH. An 'Adequate' set of biomarkers are at least 2 measurements of the same marker taken at least 6 hours apart. 'Positive' biomarkers include at least 1 value which is at least twice the upper limit of normal.

Biomarker criteria:

- Diagnostic biomarkers: At least 1 'positive' biomarker in an 'Adequate' set of biomarkers showing a rising or falling pattern in the setting of clinical cardiac ischemia and the absence of noncardiac causes of biomarkers elevation (see Figure 1 and examples in Table 2 for Troponin, and Table 3 for CK, CK-MB or LDH).
- Equivocal biomarkers: Only 1 available measurement that is 'positive' or a rising or falling pattern not in the setting of clinical cardiac ischemia or in the presence of nonischemic causes of biomarker elevation.
- Missing biomarkers: Biomarkers not measured.
- Normal biomarkers: Measured biomarkers do not meet the criteria for a 'positive' biomarker.

Despite presenting evidence of worse prognosis with mild elevations following CABG, the Universal Definition of MI guideline (Thygesen, 2007) statement recommends using 5x the usual decision threshold to define MI following CABG and 3X following angioplasty, noting that "scant literature exists concerning the use of biomarkers for defining myocardial infarction in the setting of CABG." LIFE will follow these recommendations and define as **positive** levels of CK- MB or troponin above 3 times the ULN within 48 hours of PTCA or similar procedure, and above 5 times the ULN within 48 hours of CABG.

Note that biomarker elevations can also occur in the setting of ablation for arrhythmia or myocardial contusion from trauma. Elevations beyond 5 times normal should be carefully reviewed for the possibility of concurrent MI, though final call will by necessity be based on consensus clinical judgment.

The Universal Definition of MI guidelines also state that "myocardial infarction does not include...myocardial necrosis due to miscellaneous causes, e.g. renal failure".

Therefore patients with end-stage renal disease and positive biomarkers without a rising and falling pattern, and no symptoms of MI or ischemic ECG changes, will not be considered as having MI.

Note that it is possible to adjudicate a definite MI without diagnostic biomarkers. This could happen in cases of rapid onset of cardiac death prior to a blood draw with other convincing evidence of MI (e.g. with diagnostic ST elevations on ECG), or a similar catastrophic event.

PROBABLE MI is based on specific combinations of symptoms, enzyme elevations or ECG changes that do not meet criteria for DEFINITE MI.

Other abnormal ECG would include abnormalities other than infarct or ischemia patterns in the previous categories. Other abnormalities would include atrial fibrillation, pacemaker pattern, other arrhythmias including heart block, low amplitude of waveforms or patterns of atrial or ventricular hypertrophy. Some of these abnormalities could potentially obscure ischemia or infarction patterns. Not diagnostic ECG is equivalent to a normal ECG.

28.2.4.2 Hospitalized for Angina Pectoris/Symptomatic Coronary Artery Disease (CAD), not MI

Hospitalized angina pectoris/symptomatic coronary artery disease is defined as overnight hospitalization for symptoms, such as chest pain, chest tightness, or shortness of breath, produced by myocardial ischemia that do not result in myocardial infarction, but are treated medically or surgically during an overnight stay. The symptoms generally last less than 20 minutes, and may have occurred prior to the admission. Outpatient diagnosis or medical treatment of angina/symptomatic CAD will not be tracked as an outcome in the LIFE study. Furthermore, a positive diagnostic test alone without a history of symptoms or subsequent treatment does not qualify as angina/symptomatic CAD.

LIFE criteria for DEFINITE hospitalized angina/symptomatic coronary artery disease require:

- Admission overnight to a hospital for report of symptoms, such as chest pain, chest tightness, or shortness of breath, or for the diagnosis of angina/symptomatic CAD from a physician based on history and a positive diagnostic test,

AND

- Be under medical treatment for angina or be treated with coronary artery bypass graft surgery or angioplasty (with or without stent).

Treatment may be defined as medication or a therapeutic coronary revascularization procedure, but all must be associated with symptoms. These definitions allow for including subjects with symptoms as outpatients who are hospitalized for treatment and/or therapeutic procedures without actually having the symptoms in the hospital.

PROBABLE angina/symptomatic coronary artery disease is defined as being strongly suspect as meeting criteria for angina/symptomatic CAD, but falling short of documenting the criteria.

Medical treatment for angina includes a current prescription for any of the following medicines:

- nitroglycerine (oral or sublingual), or
- beta blocker, or
- calcium channel blocker

Medical treatment for angina does not require an acute response to nitroglycerin or a change in the medical regimen during hospitalization.

Positive diagnostic tests include

- Coronary angiography showing more than 70% obstruction of any coronary artery, or
- ST-depression of more than 1 mm on exercise stress testing with symptoms of chest pain or an angina equivalent, resulting in an overnight hospitalization for treatment. In other words, the evaluation for the symptoms can occur prior to the hospitalization, but the treatment occurs as part of an overnight hospitalization even if the actual symptoms occurred prior to the admission.
- Positive stress perfusion scan.
- Positive stress echocardiogram.

28.2.4.3 Coronary Revascularizations

Coronary revascularizations are defined as therapeutic procedures for symptoms, including coronary artery bypass graft surgery or angioplasty (with or without stent). Therapeutic procedures without symptoms – such as coronary artery bypass graft surgery or angioplasty (with or without stent) performed for reasons of prevention based on incidental findings- will be tallied as separate outcomes and will count towards the total cardiovascular disease outcome, but NOT as angina/symptomatic coronary disease. This will allow for future evaluation of a hierarchy of cardiovascular disease endpoints, with procedures alone being considered as “softer” outcomes.

There is no ‘probable’ category for coronary revascularizations. ‘Definite’ is defined as having documentation of the procedure, while ‘not’ is defined as having documentation that the procedure did not occur. The last category should be used if there is inadequate documentation or no information about whether the procedure was performed.

28.2.4.4 Stroke

Stroke in LIFE requires an overnight hospitalization.

Definition of DEFINITE stroke diagnosis requires that three (3) criteria listed below are met:

- Rapid onset of neurologic deficit attributed to obstruction or rupture of an artery
- No evidence of cause due to tumor, trauma, infection or other non-ischemic cause

AND

- Deficit lasting greater than 24 hours (unless death intervenes)
OR
- New CT/MRI lesion consistent with clinical presentation

Definition of PROBABLE stroke diagnosis:

- Does not meet the criteria above, but there is sufficient evidence based on the clinical findings that a stroke occurred.

28.2.4.5 Transient Ischemic Attack

TIA in LIFE requires an overnight hospitalization.

Definition of DEFINITE TIA diagnosis requires all the following criteria are met:

- Any episode of transient neurologic dysfunction, defined here as lasting less than 24 hours, attributable to focal brain or retinal vascular territory ischemia.
- No objective evidence of acute infarction (i.e., from review of neuroimaging studies) matching the neurological dysfunction.
- Absence of the following etiologies that could present as focal neurological dysfunction:
 - Seizures
 - Orthostatic hypotension
 - Migraine equivalents/variants
 - Meniere disease
 - Multiple sclerosis
 - Encephalopathies from hepatic, renal or pulmonary etiologies
 - Electrolyte metabolic disturbances such as hyponatremia, hypoglycemia

Definition of PROBABLE TIA diagnosis: Does not meet the criteria above, but there is sufficient evidence based on the clinical finding that a TIA occurred.

NOTE:

Transient neurological dysfunction that resolves AND there is evidence of focal acute infarction (i.e., from review of neuroimaging studies) that matches the presenting neurological symptom(s) should be adjudicated as DEFINITE stroke.

In addition, if any acute ischemic/hemorrhagic lesion on neuroimaging investigations does not match the presenting symptom(s), this should be adjudicated as PROBABLE stroke.

28.2.4.6 Carotid Artery Revascularization

Definition of carotid artery revascularization

The carotid revascularization procedure must be therapeutic, i.e. the indication must be the treatment of cerebrovascular symptoms. This definition allows for including subjects with symptoms as outpatients who are hospitalized for treatment and/or therapeutic procedures without actually having the symptoms in the hospital. Therapeutic procedures for carotid artery disease include hospitalization for carotid endarterectomy or angioplasty (with or without stent).

28.2.4.7 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 need despite adequate filling pressures. Only CHF events found during an inpatient hospitalization will be reviewed as outcomes.

Definition of DEFINITE Congestive Heart Failure

LIFE criteria for hospitalized congestive heart failure require that the participant must have:

- Symptoms (shortness of breath, fatigue, orthopnea, or paroxysmal nocturnal dyspnea) and physical signs (such as edema, rales, tachycardia, a gallop rhythm, or a displaced PMI),

AND

- Be under medical treatment for congestive heart failure.
 - Medical treatment is defined as a current prescription for BOTH of the following:
 - a diuretic, and
 - beta blocker or a vasodilator (e.g. ARB or angiotensin converting enzyme [ACE] inhibitor)

NOTE: If participant has HF with preserved EF, then treatment with a diuretic would be sufficient to meet this criterion.

Signs and symptoms should be suggestive of an acute decompensated state (worse than patient's baseline). Although not required, additional supporting evidence can include:

- 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

OR

- Elevation of NT-Pro BNP of 2X the upper level of normal

Definition of PROBABLE Congestive Heart Failure

- Does not meet criteria for signs and symptoms plus medical therapy above, but there is substantial evidence based on all of the available clinical information that congestive heart failure has occurred.

Note that the syndrome of heart failure with preserved left ventricular function or heart failure due to valvular disease or hypertrophy would be captured by the above criteria.

The committee will record the condition(s) underlying the heart failure diagnosis based on the hospital record (Congestive Heart Failure Report Form, Q1aj.). Underlying acute or chronic conditions that contribute to the heart failure diagnosis should be recorded. For example, arrhythmia or hypertension can be checked if they are mentioned in the record as contributing to the heart failure. Simple history alone should not be checked if there is no relationship to the heart failure diagnosis.

The central adjudication committee will also determine whether a specific procedure, such as surgery, blood transfusion, or IV fluids precipitated the exacerbation of the symptoms (Congestive Heart Failure Report Form, Q3b).

28.2.4.8 Lower Extremity Peripheral Arterial Disease.

The outcome of peripheral arterial disease is defined as lower extremity revascularization, lower extremity amputation because of peripheral arterial disease, or other hospitalization for peripheral arterial disease (PAD).

Definition of DEFINITE Peripheral Arterial Disease (PAD)

- Lower extremity revascularization (surgical revascularization, lower extremity angioplasty with or without stent placement, and thrombolysis). Lower extremity revascularization can be inpatient or outpatient.
- Lower extremity amputation because of PAD (can include toe amputations, below knee amputation, or above knee amputation). Lower extremity amputation may be performed as an inpatient or outpatient.
- Hospitalization overnight for PAD other than for lower extremity revascularization or lower extremity amputation. For example, this may consist of hospitalization for critical limb ischemia that is not accompanied by lower extremity revascularization or amputation, for example. This outcome must include a primary discharge diagnosis of peripheral arterial disease along with evidence of lower extremity ischemia, as measured by angiography or non-invasive testing in a non-invasive vascular laboratory.

28.2.4.9 Abdominal Aortic Aneurysm Outcome

The outcome of abdominal aortic aneurysm is defined as rupture of abdominal aortic aneurysm (AAA) or AAA repair.

Definition of DEFINITE AAA

- AAA repair. This may be performed as an inpatient or outpatient and includes open repair and endovascular repair. AAA repair may or may not be performed in response to screening for AAA.
- AAA rupture.

28.2.4.10 Cardiovascular Death

Cardiovascular deaths include fatal events for which the underlying cause of death is Atherosclerotic due to Peripheral Vascular Disease, Cerebrovascular Disease, or Coronary Heart Disease, or Non-Atherosclerotic Other Cardiovascular Disease. The underlying cause of death is defined as the pathologic or pathophysiologic condition which initiated the train of events resulting in death.

In cases of death where no medical records are available, information regarding medical history and medications will be obtained from the most recent clinic assessment visit.

Criteria for Peripheral Vascular Disease (PVD) death include complications of abdominal aortic aneurysms and lower extremity arterial disease (must meet PVD criteria as defined in Sections 28.2.4.6 and 28.2.4.7).

Criteria for Cerebrovascular death include acute and late effects of stroke (must meet criteria for stroke as defined in Section 28.2.4.3).

Criteria for Coronary Heart Disease (CHD) death include at least one of the following:

- Hospitalization for MI within 28 days of death
- Previous angina or MI and no known potentially lethal non-CHD process
- CHD diagnosed as cause of death at post-mortem examination
- Death resulting from a CHD-related procedure such as CABG or PTCA

In addition, fatal CHD must be subclassified by one of the following categories:

- *Definite Fatal MI* (no known non-atherosclerotic cause, and definite MI within 4 weeks of death)
- *Definite Fatal CHD* (no known non-atherosclerotic cause, and one or both of the following: chest pain within 72 hours of death, or a history of chronic ischemic heart disease in the absence of valvular heart disease or non-ischemic cardiomyopathy)
- *Possible Fatal CHD* (no known non-atherosclerotic cause, and death certificate consistent with underlying cause)

Finally, CHD death must be classified according to timing from onset of symptoms to death in the following categories:

- *Sudden death* (death occurring within an hour of symptom onset or after the participant was last seen without symptoms, and death occurs in the absence of potentially lethal non-coronary disease process,
- *Rapid Death* (death occurs within 1-24 hours of symptom onset)
- *Other Coronary Death* (does not fulfill criteria for sudden or rapid coronary death)

Criteria for Non-Atherosclerotic Other Cardiovascular Disease includes not meeting criteria for PVD, cerebrovascular disease or CHD, and does include valvular heart disease, pulmonary embolism, pericarditis and endocarditis.

28.3 Central Adjudication

The posted outcome packets with linked forms will be assigned to two central adjudicators (central adjudicators from sites will not be assigned outcomes from their site). Via the outcome interface, the central adjudicators will access and review the outcome packet and linked forms. After review of the outcome packet, the central adjudicators will submit an adjudication status (ex. Definite MI, Probable MI, Not an MI, not enough information to classify) for each outcome assigned in the outcome interface.

Please note that if records are inadequate the adjudicator can request additional records through the DMAQC. If adjudication of the outcome is questionable and the adjudicator wishes to consult with the committee they can mark the outcome for "COMMITTEE ADJUDICATION".

After the adjudicators submit their adjudication status of the assigned outcomes the DMAQC PM will then compare the submitted adjudication statuses. If the 2 adjudications MATCH, the DMAQC PM will "CONFIRM Adjudication" and final adjudication status is confirmed. After confirmation of final adjudication status the outcome is closed and the outcome report form is "locked". If the 2 adjudications DON'T MATCH, the DMAQC PM will mark the outcome for "COMMITTEE ADJUDICATION".

28.3.1 Additional Outcome Identification

If the adjudicator, while adjudicating an outcome, identifies additional outcomes the adjudicator can indicate in the Outcome Interface that a possible additional outcome has been identified. The DMAQC PM will investigate in order to ascertain whether the identified outcome has been reported or not. If the identified outcome has not already been reported the DMAQC PM will notify the site and they will be instructed to complete the Additional Outcome Identification Form and to obtain appropriate medical records for the event. If the identified outcome has already been reported the DMAQC PM will denote this in the Outcome Interface.

28.3.2 Committee Adjudication

If an outcome is assigned an adjudication status of “COMMITTEE ADJUDICATION” or if the two adjudication statuses DON’T MATCH, at the next Adjudication Committee call, the outcome will be viewable to all committee members for committee review and adjudication (committee members from sites will not be able to view outcomes from their site).

The 2 central adjudicators will present the outcomes to the committee. The Adjudication Committee will discuss the outcome in order to reach consensus on adjudication. After consensus, the adjudication status will be centrally modified by the DMAQC PM (based on the decision of the committee) and final adjudication status is confirmed. After confirmation of final adjudication status the outcome is closed and the outcome report form is “locked”.

28.4 Hierarchical Adjudication of Major Mobility Disability Outcome

Definite: ANY of the Following

(1) PRIMARY

Unable to complete 400-meter walk in 15 minutes. This includes participants who return to the clinic with a walker or comparable device (e.g. quad cane, crutch, hemiwalker, etc.) and indicate that they are unwilling to try the walk without the assistive device.

(2) ALTERNATIVE (IN HOME OR CLINIC)

Unable to walk 4 meters without assistance of another person, a walker or comparable device (only a single straight cane is allowed) OR Unable to complete 4-meter walk test in 10 seconds or less, i.e. gait speed less than 0.4 meter/sec

If an alternate course for the 400 m walk test is used for a visit completed outside of the clinic, the following adjudication criteria will be utilized:

- If the participant is able to walk less than 200 m on the alternate course, they will be considered to have major mobility disability.
- If the participant is able to walk 200-399 m on the alternate course, they will be classified as indeterminant because it is not clear if they could have been successful on a course with fewer turns.
- If the participant is able to complete the full 400 m, they will be designated as having no major mobility disability.

(3) ALTERNATIVE (TELEPHONE OR IN HOME)

(a) Self report of inability to walk across a room (12 ft) without the assistance of another person

Operationally, this criterion is met based on an affirmative response to one or more of the following 2 questions:

(i) respondent answers “unable to do” when asked, “During the past month, how much difficulty have you had walking across a small room because of your health?”

(ii) respondent answers “Yes” to “Do you usually receive help from another person when you walk across a small room”;

OR

(b) Proxy report of inability to walk across a room (12 ft) without the assistance of another person

Operationally, this criterion is met based on an affirmative response to the following question:

(i) proxy answers “Yes” to “Does (participant) usually receive help from another person when he/she walks across a small room”;

(4) ALTERNATIVE (MEDICAL RECORD)

Documentation of inability to walk across a room (12 ft) without the assistance of another person, a walker or comparable device (only a single straight cane is allowed); example of descriptors include: bed-bound or wheelchair-bound, obtunded or moribund, etc.

Only the 4th criterion (alternative medical record) requires central adjudication, as described in Section 28.3.

28.4.1 Collection of Records for Hierarchical Alternative 4 (Medical Records)

To facilitate adjudication of major mobility disability through medical records in the absence of documentation from assessment forms (as outlined in Section 28.4), the DMAQC will provide the clinical sites with a report of all hospitalizations within the expected visit window (i.e. expected visit date +/- 4 weeks). Sites will be expected to collect any Physical Therapy reports/records for these hospitalizations to be used in the adjudication of the major mobility disability outcome.

During outcome ascertainment at each follow-up visit, sites/assessors can proceed with obtaining Physical Therapy reports/records for any hospitalizations they are notified of that occur 4 weeks prior to the target date of the current follow-up visit or in the 4 weeks following the previous follow-up visit target date. This will alleviate the site from having to obtain the information later.

At all follow-up visits, the Outcome Events Questionnaire is a priority form to be obtained in order to capture all relevant study outcome information. If, at the current visit, a participant did not attempt the 400m walk or the SPPB (in clinic or at home) and neither the Disability Questionnaire nor the Proxy ADL Questionnaire is obtained, then the site must obtain the Physical Therapy reports/records for the any hospitalizations that occurred in the 4 weeks prior to the target date of the visit. Also, any Physical

Therapy reports/records for hospitalization that occurred in the 4 weeks following the target date of the previous visit must be obtained.

28.4.2 Use of Hospital Records to Adjudicate Major Mobility Disability

Among Decedents

When participants die between clinic visits, an Outcome Events Questionnaire should be completed by a Proxy informant. If the participant had been hospitalized between the time of the last clinic visit and the time of death, the hospital records should be obtained and used to adjudicate for possible major mobility disability.

In some cases, the hospital records will indicate that the participant was nonambulatory or unable to walk a short distance, i.e. across a room, without the use of a walker or the help of another person prior to the hospital admission. These cases should be adjudicated as major mobility disability.

If the participant died during the hospitalization and did not meet criteria for major mobility disability prior to their admission, the case should be adjudicated as indeterminant. Some catastrophic events, e.g. severe stroke, ruptured aortic aneurysm, will lead to death over a short period of time, i.e. days. We will consider these cases to be similar to “sudden death”, which is not adjudicated as major mobility disability. Rather than establish a set number of days to death, we will adjudicate participants who sustained a severe debilitating event as major mobility disability if they are discharged from the hospital alive, but subsequently die. The date of major mobility disability should be assigned as the date of hospital discharge.

Among Non-Decedents

Hospital records may also be used to adjudicate cases when insufficient information is available to assign as major mobility disability, using Criterion 1, 2 or 3. If the hospital records indicate that the participant was nonambulatory or unable to walk a short distance, i.e. across a room, without the use of a walker or the help of another person prior to the admission, the case should be adjudicated as major mobility disability. When there is no evidence that the participant had major mobility disability prior to their admission, the participant should be adjudicated as having major mobility disability only if: (1) there is documentation in the hospital record of inability to walk across a room (12 ft) without the assistance of another person, a walker or comparable device (only a single straight cane is allowed); and (2) this disability is likely to persist for at least two weeks following hospital discharge. The date of major mobility disability should be assigned as the date of hospital discharge. A short term limitation that is a direct result of an acute illness or surgery, e.g. bunionectomy, should not be adjudicated as major mobility disability.

APPENDIX A
Table 1
Diagnostic Criteria for MI

Cardiac Pain Present	Cardiac Biomarker Level and Pattern			
ECG Pattern	<u>Diagnostic</u>	<u>Equivocal</u>	<u>Missing</u>	<u>Normal</u>
Evolving localized Q wave MI pattern or evolving profound ST-T abnormalities	Definite MI	Definite MI	Definite MI	Definite MI
Evolving Q wave or evolving major ST-T abnormalities or new LBBB	Definite MI	Definite MI	Probable MI	No MI
Non-evolving major or minor Q-waves or non-evolving major or minor ST-T abnormalities	Definite MI	Probable MI	No MI	No MI
Other ECG, not diagnostic ECG, ECG absent or uncodable	Definite MI	No MI	No MI	No MI

Cardiac Pain Absent	Cardiac Biomarker Level and Pattern			
ECG Pattern	<u>Diagnostic</u>	<u>Equivocal</u>	<u>Missing</u>	<u>Normal</u>
Evolving localized Q wave MI pattern or evolving profound ST-T abnormalities	Definite MI	Definite MI	Definite MI	Probable MI
Evolving Q wave or evolving major ST-T abnormalities or new LBBB	Definite MI	Probable MI	No MI	No MI
Non-evolving major or minor Q-waves or non-evolving major or minor ST-T abnormalities	Definite MI	No MI	No MI	No MI
Other ECG, not diagnostic ECG, ECG absent or uncodable	No MI	No MI	No MI	No MI

Figure 1. The approach to determining decision thresholds for troponin (I or not specified) in SPRINT and adopted by the LIFE study (Use troponin T cut point below if troponin T clearly indicated in lab results.)

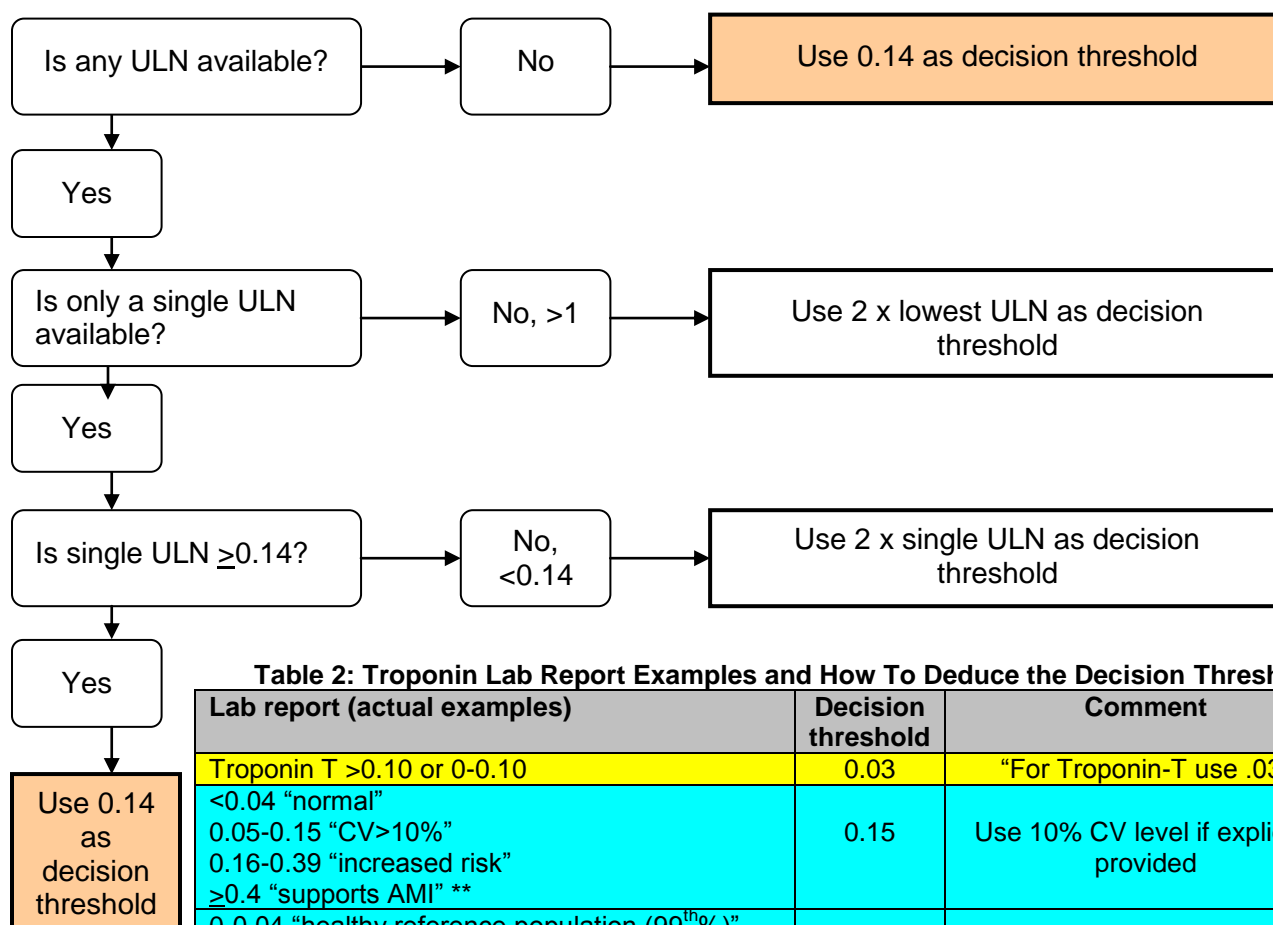


Table 2: Troponin Lab Report Examples and How To Deduce the Decision Threshold.

Lab report (actual examples)	Decision threshold	Comment
Troponin T >0.10 or 0-0.10	0.03	"For Troponin-T use .03"
<0.04 "normal" 0.05-0.15 "CV>10%" 0.16-0.39 "increased risk" ≥0.4 "supports AMI" **	0.15	Use 10% CV level if explicitly provided
0-0.04 "healthy reference population (99 th)" 0.05-0.15 "indeterminate (method CV>10%)" 0.16-0.39 "borderline (possible Minor Myocardial Damage "MMD")" 0.4 "suggestive of Myocardial Injury" **	0.15	Use 10% CV level if explicitly provided
No upper limit	0.14	Use 0.14 when no ULN
<0.1 nl 0.1-0.59 "indeterminant" (sic) 0.6-1.5 "further eval" >1.5 "cardiac damage"	0.2	Double the lowest threshold if two thresholds are given
0.04-1.6 (range of 2 non-zero values)	0.08	Double the lowest threshold if two thresholds are given
0-0.15 "normal range" 0.6-1.5 "consistent with WHO criteria for AMI"	0.3	Double the lowest threshold if two thresholds are given
0-0.04 (range with one value=0, i.e., single ULN)	0.08	For single ULN <0.14, use 2x single ULN
0-0.6 (range with one value=0, i.e., single ULN)	0.14	For single ULN ≥0.14, use 0.14

Table 3: CK, CK-MB and LDH Biomarkers (Based on CHS)

	There is no known Cardiac Surgery or Muscle Trauma	Muscle Trauma or Cardiac Surgery Exists
CK-MB \geq Upper limit of normal or present	Abnormal	Normal
CK-MB \geq 10% Total CK, if no upper limit is given	Abnormal	Normal
Total CK \geq 2x Upper Limit of Normal And LDH \geq 2x Upper Limit of Normal	Abnormal	Normal
LDH1 : LDH2 > 1	Abnormal	Normal
LDH1 \geq 2x Upper limit of normal if LDH2 is missing	Abnormal	Normal
Total CK \geq 2x Upper limit of normal Or LDH \geq 2x Upper limit of normal	Equivocal	Normal
Normal < Total CK < 2x Upper limit of normal And Normal < LDH < 2x Upper limit of normal	Equivocal	Normal
5% Total CK < CK-MB < 9% Total CK or “weakly present”	Equivocal	Normal
Normal < CK-MB < 2x Upper limit of normal	Equivocal	Normal
Normal < LDH1 < 2x Upper limit of normal	Equivocal	Normal

Appendix B

Outcome Report Form Completion Instructions

Outcome Report Forms are completed by adjudicator to indicate the details of the outcome cases and to indicate the adjudicator's choice for final adjudication status.

As with all LIFE forms, the header information is standardized for each of the outcome report forms. The PID and Acrostic will be pre-filled by the Outcome Management Tool Adjudication system. The date that the form is completed should be supplied by the adjudicator in the space provided. In addition, the 5-digit staff ID of the adjudicator should be supplied in the "Completed by" space.

Instructions for Entering the Death Report Form

For reported death outcomes, the Death Report form will be assigned.

Date of Death – fill in the date provided in the documentation as the date of death.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding the death.

Q1 – Review the death certificate and indicate whether the cause of death is listed. If listed, provide the underlying cause in the specify area in Q1a.

Q2 – Review the death certificate and indicate whether there were contributory causes of death listed. If listed, provide the contributory in the space provided (maximum three contributory causes).

Q3 – Review the death certificate and indicate whether an immediate cause of death was specified. If specified, indicate the cause in the space provided.

Q4 – Indicate whether an autopsy was performed or not.

The purpose of Section 2 is to indicate the sub-classification of the cause of death.

Indicate whether the death was due to: a) fall related injury, b) pulmonary disease, c) cardiovascular disease, or d) other cause of death. Only one choice can be made.

The purpose of Section 3 is to indicate the type of fall related injury (if applicable).

The purpose of Section 4 is to indicate whether the pulmonary disease death was due to COPD/Asthma or Pneumonia.

The purpose of Section 5 is to indicate the type of cardiovascular disease (peripheral vascular disease, cerebrovascular, coronary heart disease, or other cardiovascular). If cerebrovascular or coronary heart disease, further information is collected.

Q5b1A – indicate whether the cerebrovascular death was an acute CVA

Q5b1B – indicate whether the cerebrovascular death was due to the late effect of a stroke; if it was, then the date of stroke should be entered.

Q5c1A-E – indicate the coronary death criteria; more than one entry from A to D may be marked as “yes”, but E should only be “yes” if A-D are all “no”

Q5c2A-C – indicate the sub-classification of the coronary death marking only one of A-C as “yes”

Q5c3A-C – indicate timing of the coronary death marking only one of A-C as “yes”

The purpose of Section 6 is to indicate an other cause of death (meaning it was not any of the other classifications)

Q6a – indicate whether the cause of death was specified in the medical records and if specified provide the other cause.

Q6b – indicate whether the cause of death was unknown

Section 7 is to indicate the adjudicator’s choice for final adjudication status for a cardiovascular death outcome.

Instructions for Entering the Injurious Fall and/or Fracture Report Form

For reported serious fall injury outcomes, the Injurious Fall and/or Fracture Report form will be assigned.

Date of Fall/Fracture – fill in the date provided in the documentation as the date of the fall.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding the injurious fall or fracture
Q1a-b – review the medical record and mark “yes” if the injurious fall or fracture resulted in an overnight hospitalization and provide the date of hospital admission.

Q2a-h – review the medical record and indicate which of the criteria for injurious falls and/or fractures (from a to g) were met by marking “yes”. (Q2h should not be “yes” unless Q2a-g are all marked as “no”.)

Q3a – If Q2a-d were ALL marked as “Yes”, then indicate “yes” and continue to 3b to confirm documentation of the fracture. If Q2a-d were not all “yes”, then indicate “no” and go to Section 2.

Q3b – indicate how the fracture was confirmed by selecting one of the 4 choices

Q4a – indicate whether there was more than one fracture reported in the medical records

Q4b – indicate the fracture site. If there was only one fracture, only mark one site. If there were multiple fractures, then more than one site can be selected.

The purpose of Section 2 is to indicate the adjudicator’s choice for final adjudication status for a serious fall injury outcome.

Instructions for Entering the Exacerbation of Airways Disease Report

For reported exacerbation of airway disease (asthma, bronchitis, emphysema, and/or COPD) outcomes, the Exacerbation of Airways Disease Report form will be assigned.

Date of Hospitalization – fill in the date of admission provided in the documentation as the date of the hospitalization for exacerbation of airways disease. Hospitalization is a requirement for an exacerbation of airways disease to be adjudicated as an outcome. OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding the exacerbation of airway disease.

Q1 – review the medical records and indicate which of the listed diagnoses were recorded at discharge.

Q2a-h – review the medical records and indicate whether any of the criteria were present at admission. If Q2a-c are ALL “no” then Q2d-h are not required to be answered, skip to Q3a.

Q3a – confirm your criteria responses by selecting “yes” if any of Q2a-c were “yes”. If not, mark “no” and skip to Section 2. If yes, continue to 3b.

Q3b – confirm your criteria responses for Q2d-h and indicate whether any of them were “yes” by selecting “yes”.

The purpose of Section 2 is to indicate the adjudicator’s choice for final adjudication status for an exacerbation of airways disease outcome.

Instructions for Entering the Community Acquired Pneumonia Report

For reported pneumonia outcomes, the Community Acquired Pneumonia Report form will be assigned.

Date of Hospitalization – fill in the date of admission provided in the documentation as the date of the hospitalization for pneumonia. Hospitalization is a requirement for community acquired pneumonia be adjudicated as an outcomes.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding the pneumonia.

Q1 – review the medical records and indicate whether there was a diagnosis of pneumonia recorded at discharge.

Q2a-b – review the medical records and indicate whether any of the criteria were present at admission or during the first 48 hours of hospitalization.

Q3a – confirm your criteria responses by selecting “yes” if both Q2a-b were “yes”. If not, mark “no” and skip to Section 2. If yes, continue to 3b.

Q3b – review the medical records and indicate whether an organism was identified as the cause of pneumonia. If yes, specify the organism in Q3c.

The purpose of Section 2 is to indicate the adjudicator’s choice for final adjudication status for a community acquired pneumonia outcome.

The purpose of Section 3 is to classify the subtype of pneumonia.

Instructions for Entering the Myocardial Infarction (MI) & Symptomatic Coronary Artery Disease Report form

For reported MI or Symptomatic CAD outcomes, the Myocardial Infarction (MI) & Symptomatic Coronary Artery Disease Report form will be assigned.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to indicate the type of criteria present for the case
Q1-3 – review the medical records and indicate the presence/absence of the criteria listed (use the appendix in MOP chapter 28 for the algorithm to classify the biomarkers of MI).

The purpose of Section 2 is to indicate the adjudicator's choice for final adjudication status for the MI outcome. Note: if the case is adjudicated as Definitely or Probably an MI, Section 3 is completed and Sections 4-6 are skipped, but if it is adjudicated as Not an MI or Don't Know/Not Enough Information, then section 3 is skipped and Sections 4-6 should be completed.

The purpose of Section 3 is to provide information regarding an MI

Q1 – If the participant is hospitalized, provide the date of admission for the MI hospitalization

Q2 – provide the date of the MI

Q3 – indicate whether there was a resuscitated cardiac arrest

Q4 – indicate whether the MI was related to a procedure. If yes, specify the procedure.

(If Section 3 is completed, skip Sections 4-6)

The purpose of Section 4 is to provide information regarding symptomatic coronary artery disease (CAD) when no MI is present

Q1-2 – review the medical record and if the participant was hospitalized for CAD symptoms mark “yes” and provide the date of hospital admission in Q2

Q3 – review the medical record and record whether the criteria listed were met.

The purpose of Section 5 is to provide information regarding treatment of Symptomatic CAD

Q1 – review medical record and indicate whether there was treatment for symptoms

Q2 – review medical record and indicate whether there was a procedure for symptoms, if so continue to Q2a, otherwise skip to Section 6.

Q2a – indicate whether the procedure was completed as an outpatient or inpatient

Q2b – indicate the date of the procedure (either outpatient or inpatient)

Q2c – if it was an inpatient procedure, indicate the date of hospitalization admission for the procedure

The purpose of Section 6 is to indicate the adjudicator's choice for final adjudication status for a Symptomatic CAD outcome. "Definitely" should be selected only if Q1 or Q3 in Section 4 was marked as "yes" AND if Q1 or Q3 in Section 5 was marked as "yes".

Instructions for Entering the Coronary Revascularization Report Form

For reported coronary revascularization outcomes, the Coronary Revascularization Report form will be assigned.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding a reported coronary revascularization procedure

Q1 – review medical record and indicate whether there was a coronary revascularization procedure. If no, skip to Section 2.

Q2 – review medical record and indicate the type of procedure

Q3 – indicate whether the procedure was completed as an outpatient or inpatient

Q4 – indicate the date of the procedure (either outpatient or inpatient)

Q5 – if it was an inpatient procedure, indicate the date of hospitalization admission for the procedure

The purpose of Section 2 is to indicate the adjudicator's choice for final adjudication status for a coronary revascularization procedure outcome.

Instructions for Entering the Carotid Artery Revascularization Report Form

For reported carotid artery revascularization outcomes, the Carotid Revascularization Report form will be assigned.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding a reported carotid revascularization procedure

Q1 – review medical record and indicate whether there was a carotid revascularization procedure. If no, skip to Section 2.

Q2 – review medical record and indicate the type of procedure

Q3 – indicate whether the procedure was completed as an outpatient or inpatient

Q4 – indicate the date of the procedure (either outpatient or inpatient)

Q5 – if it was an inpatient procedure, indicate the date of hospitalization admission for the procedure

The purpose of Section 2 is to indicate the adjudicator's choice for final adjudication status for a carotid revascularization procedure outcome.

Instructions for Entering the Stroke Report

For reported stroke outcomes, the Stroke Report form will be assigned.

Date of Hospitalization – fill in the date of admission provided in the documentation as the date of the hospitalization for stroke. Hospitalization is a requirement for stroke to be adjudicated as an outcome.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information regarding the reported stroke.

Q1a-d – review the medical records and indicate whether any of the listed criteria were present. If part A and B, and C or D are marked as “yes”, then continue to Q2, if not, skip to Section 2.

Q2a – review the medical records and indicate the brain image findings

Q2b – review the medical records and indicate the stroke type

Q2c – indicate the date of the stroke event

Q2d – indicated whether the stroke was related to a procedure. If yes, specify the procedure.

The purpose of Section 2 is to indicate the adjudicator’s choice for final adjudication status for a stroke outcome.

The purpose of Section 3 is to provide information regarding the reported TIA.

Q1a-e – review the medical records and indicate whether the criteria listed were present.

Q2a-c – review the responses in Q1 to determine if the event meets the criteria for TIA for the LIFE Study.

The purpose of Section 4 is to indicate the adjudicator’s choice for final adjudication status for a TIA outcome.

Section 5- indicate the date of the TIA event

Instructions for Entering the Congestive Heart Failure Report Form

For reported congestive heart failure outcomes, the Congestive Heart Failure Report form will be assigned.

Date of Hospitalization – fill in the date of admission provided in the documentation as the date of the hospitalization for CHF. There must be a hospitalization in order to be adjudicated as a CHF outcome.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information about the reported CHF

Q1 – review the medical records and indicate the conditions at presentation (mark all that apply)

Q2 – review the medical records and indicate whether any of the listed criteria were present or not.

Q3 – review of the medical records and indicate whether the reported CHF was related to a procedure. If yes, specify the procedure.

The purpose of Section 2 is to indicate the adjudicator's choice for final adjudication status for a CHF outcome.

Instructions for Entering the Abdominal Aortic Aneurysm (AAA) Report Form

For reported abdominal aortic aneurysm rupture or repair, the Abdominal Aortic Aneurysm (AAA) Report form will be assigned.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information about the reported AAA rupture or repair.

Q1 – review the medical records and indicate whether the participant had an AAA rupture. If “no”, skip to Q2. If “yes”, complete Q1a and Q1b by providing the date of the rupture and date of hospitalization for the rupture and then complete Q2.

Q2 – review the medical records and indicate whether the participant had an AAA repair. If “no”, skip to Section 2. If “yes”, complete Q2a-d.

Q2a – indicate whether the participant had the AAA repair as a response to screening

Q2b – indicate whether the procedure was completed as an outpatient or inpatient

Q2c – indicate the date of the procedure (either outpatient or inpatient), if outpatient, enter the date of the procedure and skip to Section 2)

Q2d – if it was an inpatient procedure, indicate the date of hospitalization for the procedure

The purpose of Section 2 is to indicate the adjudicator's choice for final adjudication status for an Abdominal Aortic Aneurysm (AAA) outcome.

Instructions for Entering the Peripheral Vascular Disease Report Form

For reported symptomatic peripheral artery disease (PAD) outcomes, the Peripheral Vascular Disease Report form will be assigned.

OID – will be pre-filled by the system but should match the OID indicated on the medical records

The purpose of Section 1 is to provide information about the reported lower extremity peripheral artery disease (PAD).

Q1 – indicate whether the participant was hospitalized for lower extremity PAD. If yes, indicate the date of hospitalization and go to Section 2. If no, go to Section 2.

The purpose of Section 2 is to provide information regarding possible lower extremity revascularization.

Q1 – indicate whether the participant had lower extremity revascularization. If no, go to Section 3. If yes, go to Q1a.

Q1a – indicate whether the procedure was completed as an outpatient or inpatient

Q1b – indicate the date of the procedure (either outpatient or inpatient), if outpatient, enter date and skip to Section 5, if inpatient, continue to Q1c.

Q1c – if it was an inpatient procedure, indicate the date of hospitalization for the procedure. Continue to Section 5.

The purpose of Section 3 is to provide information regarding possible lower extremity amputation.

Q1 – indicate whether the participant had a lower extremity amputation. If no, go to Section 4. If yes, go to Q1a.

Q1a – indicate whether the procedure was completed as an outpatient or inpatient

Q1b – indicate the date of the procedure (either outpatient or inpatient), if outpatient enter date and skip to Section 5, if inpatient, continue to Q1c.

Q1c – if it was an inpatient procedure, indicate the date of hospitalization for the procedure. Continue to Section 5.

The purpose of Section 4 is to provide information regarding PAD hospitalizations not related to revascularization or amputation.

Q1 – indicate whether the participant was hospitalized for a condition other than lower extremity revascularization or amputation. If yes, specify the condition and go to Section 5. If no, go to Section 5

The purpose of Section 5 is to indicate the adjudicator's choice for final adjudication status for symptomatic peripheral artery disease.