

# HOPE

## Event Adjudication Definitions

### Primary Outcomes

#### 1.0 Cardiovascular Death

1.11 Unexpected Death: Unexpected death presumed to be due to ischemic cardiovascular disease, occurring within 24 hours of the onset of symptoms without confirmation of cardiovascular disease, and without clinical or post mortem evidence of other etiology.

1.12 Fatal myocardial infarction (MI): death within 7 days of the onset of documented MI (see 2.0).

1.13 Congestive heart failure (CHF): death due to clinical, radiological or postmortem evidence of CHF without clinical or postmortem evidence of an acute ischemic event (cardiogenic shock to be included).

1.14 Post cardiovascular invasive interventions: death associated with the intervention: within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, or angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions.

1.15 Documented arrhythmia: death due to bradyarrhythmias or tachyarrhythmias not induced by an acute ischemic heart disease (IHD) event

1.16 Death following non-cardiovascular surgery: death due to cardiovascular causes as defined in 1.11-1.15, 1.17-1.18 and within 30 days of surgery.

1.17 Stroke: death due to stroke occurring within 7 days of the signs and symptoms of a stroke (see 3.0).

1.18 Other cardiovascular diseases: death due to other vascular diseases including pulmonary emboli, abdominal aortic aneurysm rupture, ...

1.19 Presumed Cardiovascular Death: Suspicion of cardiovascular death with clinically supporting evidence which may not fulfill criteria otherwise stated. Example: Patient admitted with typical chest pain of 3 hours duration and treated as an MI, but without ECG and enzymatic documentation to meet normal criteria.

NB Accidental Death: Qualifies as a cardiovascular event unless clear evidence of extraneous disease is known.

NB Cardiac transplantation is not a cardiac death.

## 2.0 Myocardial Infarction

2.1 Q-Wave MI: in comparison to the last ECG, presence of at least one new significant Q-wave on the standard 12-lead ECG as described in the Minnesota Code

1.1.1. appendix A, and at least one of:

1. Typical symptoms (e.g. typical ischemic chest pain >20 min).  
and/or
2. Significant elevation of serum enzymes - presence of any one of the following criteria:
  - a) elevation of CK-MB to twice the upper limit of normal for the laboratory that performed the test.
  - b) CK total at least twice the upper limit of normal for the laboratory that performed the test.
  - c) SGOT, LDH, or other cardiac enzymes at least twice the upper limit of normal for the laboratory that performed the test with a characteristic pattern.

2.2 Non Q-wave MI: defined as patient with significant elevation of cardiac enzymes (at least twice the upper limit of normal) with or without characteristic pain in absence of new significant Q wave.

2.3 Probable non Q-wave MI: presence of new and persistent ST-T changes (>24 hours in duration) on the ECG with characteristic symptoms of ischemic chest pain without documentation of enzyme elevation.

2.4 Silent MI: development of new significant Q waves (as per the Minnesota Code 1.1.1) in at least 2 adjacent leads in the absence of any other evidence of myocardial infarction (note that the date of event will be assessed as halfway between the date of discovery and last normal ECG).

2.5 Non-fatal MI post cardiovascular invasive interventions: MI (as defined in 2.1, 2.2, 2.3 or 2.4) associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, or angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions.

2.6 Non-fatal MI post non-cardiovascular surgery: MI (as defined in 2.1, 2.2, 2.3 or 2.4) occurring within 30 days of non-cardiovascular surgery.

## 3.0 Stroke

3.1 Definite ischemic stroke: CT or MRI scan within 14 days of onset of a definite stroke (focal neurological deficit greater than 24 hours) with evidence of infarction, or autopsy confirmation

3.2 Definite hemorrhagic stroke (primary intracerebral, subarachnoid, or secondary to cerebral infarction): confirmation with CT or MRI scan within 14 days of stroke, or at autopsy or by lumbar puncture

3.3 Stroke of unknown etiology: Definite stroke of unknown etiology when CT, MRI or autopsy are not done.

3.4 Non-fatal stroke post cardiovascular invasive interventions: stroke (as defined in 3.1-3.3) associated to the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, or angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions.

3.5 Non-fatal stroke post non-cardiovascular surgery: Stroke (as defined in 3.1-3.3) occurring within 30 days of non-cardiovascular surgery.

## Secondary Outcomes

4.1 Unstable angina: unstable angina requiring hospitalization because of increased frequency or severity of angina. **Note: If the unstable angina was not the reason for hospitalization then the unstable angina is coded as 411.9.**

4.2 All cardiovascular revascularization procedures to include CABG surgery, coronary interventions, carotid endarterectomy (for stenosis of carotid luminal wall, transient ischemic attacks or stroke), peripheral cardiovascular surgery or angioplasty (for limb ischemia) or limb amputation.

4.21 PTCA

4.22 CABG

4.23 Peripheral Angioplasty

4.24 Peripheral vascular Surgery

4.25 Carotid Endarterectomy

4.26 Limb Amputation: Including partial or digit amputation due to cardiovascular disease.

4.3 Total Mortality. All non-cardiovascular deaths

4.361 Cancer Death: Primary site of cancer is gastrointestinal.

4.362 Cancer Death: Primary site of cancer is lung.

4.363 Cancer Death: Primary site of cancer is breast.

4.364 Cancer Death: Primary site of cancer is prostate.

4.365 Cancer Death: Primary site of cancer is brain.

4.366 Cancer Death: Primary site of cancer is 'other'

4.367 Cancer Death: Primary site of cancer is multi site.

4.368 Cancer Death: Primary site of cancer is genito-urinary.

4.4 Development of overt diabetic nephropathy if one of the following criteria are met:

- a) A 24 hour urine protein greater than or equal to 500 mg.
- b) A 24 hour urine albumin greater than or equal to 300 mg.
- c) A timed albumin excretion rate greater than or equal to 200 microgram/min.

4.5 Hospitalization for congestive heart failure with documented clinical and radiological evidence. **Note: If CHF was not the reason for hospitalization then the CHF is coded as 428.**

4.6 Cancer or other malignancy by site and morphology.

- 4.61 Cancer gastrointestinal
- 4.62 Cancer lung
- 4.63 Cancer breast
- 4.64 Cancer prostate
- 4.65 Cancer brain
- 4.66 Cancer other site
- 4.67 Cancer multi site
- 4.68 Cancer genito-urinary