

PARTICIPANT ID <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div>	REVIEW DATE <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> / <div style="border: 1px solid black; width: 20px; height: 20px;"></div> / <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	REVIEWER'S ID <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div>
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HEART AND SOUL STUDY

OUTCOME EVENT - MORBIDITY REVIEW FORM

ADMISSION DATE: /
 /

 DISCHARGE DATE: /
 /

RECORDS FROM: Hospitalization ER

Please check all that may apply:

- Myocardial Infarction —————> *Pages 2, 3, Question 1-4*
- Angina —————> *Pages 2, 4, Question 1-3, 5*
- Congestive Heart Failure (CHF) —————> *Pages 5, Question 6*
- Stroke —————> *Page 6, Question 7*
- TIA —————> *Page 7, Question 8*
- Carotid Artery Disease —————> *Page 8, Question 9*
- Peripheral Arterial Disease —————> *Page 9, Question 10*
- Coronary Artery Revascularization —————> *Page 10, Question 11*
- Catheterization Without Revascularization —————> *Page 10, Question 12*
- Severe Cardiac Dysrhythmia —————> *Page 10, Question 13*
- AICD Placement —————> *Page 10, Question 13.1*
- Psychiatric Disorder —————> *Page 11, Question 14*
- Other hospitalization, specify diagnosis:

Fill out only those pages corresponding to diagnoses checked above.

Four empty boxes for participant ID

Three empty boxes for admission date, separated by slashes

1. ECG pattern: (Mark the one category that best applies.)

- Four checkboxes with labels: Evolving diagnostic: New diagnostic Q wave, Positive: New ST elevation or New LBBB, Nonspecific: New ST depression or New T wave inversion, Normal or other ECG findings: All other findings, ECG not available

2. Cardiac enzyme information available?

- Two checkboxes: No (with arrow to 'Go to Question 3'), Yes

2.1. Serum CKMB:

- Four checkboxes with labels: CKMB diagnostic, CKMB equivocal, CKMB normal, CKMB 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.):

- Five checkboxes with labels: Troponin C, Troponin I, Troponin T, Troponin, not specified, Troponin not available (with arrow to 'Go to Question 2.3 below'). A vertical line with a downward arrow connects the checkboxes to the 2.2.1 box.

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

- Three checkboxes with labels: Troponin diagnostic, Troponin equivocal, Troponin normal

2.3. "Other" cardiac-specific lab (specify):

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

- Four checkboxes with labels: Diagnostic, Equivocal, Normal, Other (specify): followed by a row of 15 empty boxes.

3. Cardiac pain present? (Mark one.)

- Three checkboxes with labels: No, Yes, Unknown/Not recorded

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4. Myocardial infarction (MI): *(Mark one.)*

Please refer to classification of MI on page 12

- No
- Definite
- Probable
- Possible
- Aborted

4.1. MI during or resulting from a procedure? *(Mark one.)*

- No
- Yes
- Unknown/Not sure

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

- No
- Yes
- Unknown



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

4.2.2. Was the MI aborted? *(Diagnosis of an aborted MI requires: symptoms and ECG evidence for acute MI at presentation; intervention [thrombolytic therapy or a procedure] followed by resolution of ECG changes; and all cardiac enzymes within normal limits.)*

- No
- Yes
- Unknown

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5. Angina Pectoris (including unstable angina; in the ABSENCE of myocardial infarction): (Mark one.)

Angina Pectoris:

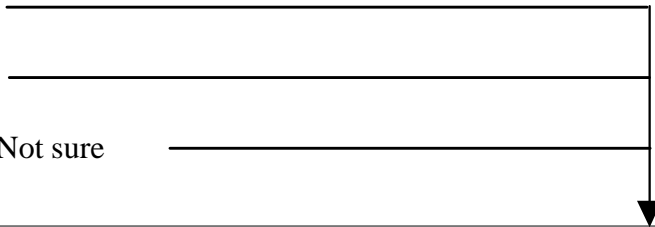
Chest pain, tightness or shortness of breath produced by myocardial ischemia that does not result in infarction (usually caused by coronary insufficiency).

No

Definite

Probable

Unknown/Not sure



5.1. Angina pectoris (including unstable angina) is based on: (Mark all that apply.)

Symptoms consistent with angina

Final physician diagnosis of angina

Receiving medical treatment for angina on this admission (e.g. nitrate, beta-blocker or calcium channel blocker)

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

CABG surgery or other revascularization procedure on this admission

70% or greater obstruction of any coronary artery on angiography on this admission

Horizontal or down-sloping ST-segment depression or abnormal ST elevation ≥ 1 mm on exercise or pharmacological stress testing with pain on this admission

Scintigraphic or echocardiographic stress test positive for ischemia on this admission


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

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6. Congestive Heart Failure (CHF): (Mark one.)

Physician diagnosis of congestive heart failure exacerbation on this admission.

- No
 - Definite _____
 - Probable _____
 - Unknown/Not sure _____
- 

6.1. MESA/CARDIA CHF criteria: (Mark all that apply.)

- Final diagnosis of CHF exacerbation by physician
- Receiving medical treatment for CHF (e.g., diuretics, digitalis, vasodilators, beta-blockers, or ACE inhibitors)
- Systolic or diastolic dysfunction by current or past echocardiography, contrast ventriculography, radionuclide ventriculogram or multigated acquisition (MUGA) scan

6.1.1 Framingham CHF criteria: (Mark all that apply.)

Symptoms

- Paroxysmal nocturnal dyspnea*
- Orthopnea*
- Dyspnea on exertion
- Night cough
- Weight loss ≥ 4.5 kg in 5 days, related to change in CHF therapy*
- Weight loss ≥ 4.5 kg in 5 days, not related to change in CHF therapy

Diagnosis of CHF requires 2 major* or 1 major* plus 2 minor criteria

Signs of CHF on this admission

- Elevated JVP*
- Pulmonary rales*
- Third heart sound*
- Peripheral edema
- Hepatomegaly
- Heart rate > 120 /min

CXR on this admission

- Pulmonary edema*
- Cardiomegaly*
- Pleural effusion

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7. Stroke: (Mark one.)

Stroke:
Deficit is not known to be secondary to brain trauma, tumor, infection or other non-ischemic cause.

- No
Definite
Probable
Unknown/Not sure

7.1. Diagnosis: (Mark the one category that best applies.)

- Subarachnoid hemorrhage not resulting from a procedure
Intracerebral hemorrhage not resulting from a procedure
Other or unspecified nontraumatic epidural or subdural hemorrhage not resulting from a procedure
Acute, but ill-defined, cerebrovascular disease not resulting from a procedure
Central nervous system complications during or resulting from a procedure
Occlusion of cerebral or precerebral arteries with infarction not resulting from a procedure:
cerebral thrombosis cerebral embolism lacunar infarction

7.2. Stroke diagnosis based on: (Mark all that apply.)

- Physician diagnosis of stroke
CT or MRI scan shows acute focal brain lesion without evidence of blood
Neurological deficit with duration >= 24 hours
Rapid onset of neurological deficit
Surgical evidence of ischemic infarction of brain
CT or MRI findings of blood in subarachnoid space or intra-parenchymal hemorrhage
Positive lumbar puncture (for subarachnoid hemorrhage)
Surgical evidence of ischemic infarction of brain
Other known causes of deficit ruled out
Other (specify):

Grid of 25 empty boxes for specifying other causes

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8. Transient Ischemic Attack (TIA): *(Mark one.)*

Transient Ischemic Attack:

One or more episodes of a focal neurologic deficit lasting more than 30 seconds and no longer than 24 hours. Rapid evolution of the symptoms to the maximal deficit in less than 5 minutes., with subsequent complete resolution. No head trauma occurring immediately before onset of the neurological event.

- No
 - Definite
 - Probable
 - Unknown/Not sure
-

8.1. Diagnosis of TIA based on: *(Mark all that apply.)*

- Episode of focal neurologic deficit
- Episode lasting more than 30 seconds, but no longer than 24 hours
- Rapid evolution of symptoms (maximum < 5 minutes)
- Complete resolution
- Other causes ruled out
- No evidence of clonic jerking, conjugate eye deviation, prolonged Jacksonian march, scintillating scotoma or headache with nausea and vomiting

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9. Carotid Artery Disease: (*Mark one.*)

Carotid Artery Disease:

Disease must be symptomatic and/or requiring intervention (e.g. vascular or surgical procedure).

No

Definite _____

Probable _____

Unknown/Not sure _____



9.1. Diagnosis: (*Mark one.*)

Carotid artery occlusion and stenosis without documentation of cerebral infarction

Carotid artery occlusion and stenosis with written documentation of cerebral infarction

9.2. Carotid artery disease based on: (*Mark all that apply.*)

Symptomatic disease with carotid artery disease listed on the hospital discharge summary

Abnormal findings ($\geq 50\%$ stenosis) on carotid angiogram or doppler flow study

Vascular or surgical procedure to improve flow to ipsilateral brain

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10. Peripheral Arterial Disease (aorta, iliac arteries or below): (Mark one.)

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.

- No
- Definite _____
- Probable _____
- Unknown/Not sure _____

10.1. Diagnosis: (Mark the one category that best applies.)

- Lower extremity claudication
- Atherosclerosis of arteries of the lower extremities
- Arterial embolism and/or thrombosis
- Abdominal aortic aneurysm

10.2. Peripheral arterial disease diagnosis based on: (Mark all that apply.)

- Final physician diagnosis of peripheral arterial disease during hospitalization
- Ultrasonographically/angiographically demonstrated obstruction or ulcerated plaque ($\geq 50\%$ of the diameter or $\geq 75\%$ of the x-sectional area) of the renal artery or of the iliac arteries or below
- Absence of pulse by doppler in any major vessel of lower extremities
- Exercise test that is positive for lower extremity claudication
- Surgery, angioplasty or thrombolysis for peripheral arterial disease
- Amputation of one or more toes of the lower extremity because of ischemia or gangrene
- Exertional leg pain relieved by rest
- Ankle-arm systolic blood pressure ratio ≤ 0.8
- Radiologically demonstrated abdominal aortic aneurysm
- Surgical or vascular procedure for abdominal aortic aneurysm


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11. Coronary Artery Revascularization: (Mark one.)

Coronary Artery Revascularization:

Coronary artery revascularization consisting of coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA) with or without placement of an intracoronary stent or coronary artery atherectomy but will not include treatment with a fibrinolytic agent.

- No
 - Definite _____
 - Probable _____
 - Unknown/Not sure _____
- 

11.1. Diagnosis: (Mark all that applies.)

- Coronary artery bypass grafting (CABG)
- Percutaneous transluminal coronary angioplasty (PTCA) without placement of stent
- PTCA with placement of stent
- Atherectomy
- Other (specify):

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12. Catheterization Without Revascularization: (Mark one.)

- No
- Yes

13. Severe Cardiac Dysrhythmia Requiring External Defibrillation, Ablation, Pacemaker or AICD placement: (Mark one.)

- No
- Yes

13.1. AICD placement for other reasons: (Mark one.)

- No
- Yes

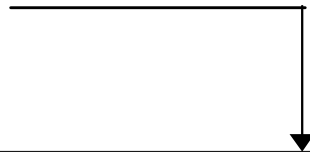
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14. Psychiatric Disorder: (Mark one.)

No

Yes



14.1. Diagnosis: (Mark all that apply.)

Major Depression

- Definite
- Probable
- Unknown/Not sure

Post traumatic stress disorder

- Definite
- Probable
- Unknown/Not sure

Substance abuse

- Definite
- Probable
- Unknown/Not sure

Schizophrenia/psychosis

- Definite
- Probable
- Unknown/Not sure

Generalized anxiety disorder

- Definite
- Probable
- Unknown/Not sure

Obsessive compulsive disorder

- Definite
- Probable
- Unknown/Not sure

Personality disorder, specify type:

Row of 15 empty boxes for specifying personality disorder type

- Definite
- Probable
- Unknown/Not sure

Other, specify:

Row of 15 empty boxes for specifying other disorder

- Definite
- Probable
- Unknown/Not sure

CLASSIFICATION OF MI

Diagnosis of MI based on symptoms, enzymes and ECG as follows:

CARDIAC SYMPTOMS OR SIGNS PRESENT	CARDIAC ENZYMES			
	<i>Diagnostic</i>	<i>Equivocal</i>	<i>Missing</i>	<i>Normal</i>
ECG PRESENT				
<i>Evolving Diagnostic</i>	Definite MI	Definite MI	Definite MI	Definite MI
<i>Positive</i>	Definite MI	Probable MI	Probable MI	No MI
<i>Nonspecific</i>	Definite MI	Possible MI	No MI	No MI
<i>Normal or other ECG findings</i>	Definite MI	Possible MI	No MI	No MI

CARDIAC SYMPTOMS OR SIGNS ABSENT	CARDIAC ENZYMES			
	<i>Diagnostic</i>	<i>Equivocal</i>	<i>Missing</i>	<i>Normal</i>
ECG PRESENT				
<i>Evolving Diagnostic</i>	Definite MI	Definite MI	Definite MI	Definite MI
<i>Positive</i>	Definite MI	Probable MI	Possible MI	No MI
<i>Nonspecific</i>	Definite MI*	Possible MI	No MI	No MI
<i>Normal or other ECG findings</i>	Definite MI*	No MI	No MI	No MI

*In absence of diagnostic troponin, downgrade to possible

ECG	Enzymes
Evolving diagnostic: New Diagnostic Q wave	Diagnostic: positive biomarker <u>and</u> rising or falling pattern in setting of clinical cardiac ischemia
Positive: New ST elevation <u>or</u> New LBBB	Equivocal: one positive biomarker <u>or</u> rising or falling pattern not in setting of clinical cardiac ischemia
Nonspecific: New ST depression <u>or</u> New T wave inversion	Missing: biomarker not measured
Normal: All other findings	Normal: no positive biomarker

Positive biomarker=exceeding 99th percentile of the distribution in healthy populations

At VA:

Troponin: 95% of normal subjects have troponin values <0.05. The recommended threshold for acute MI is >0.40. Values between 0.06 and 0.40 should be interpreted in the context of the patient's clinical presentation.

CKMB: Reference range 0 - 7. Values >7 consistent with MI. However, CKMB also found in skeletal muscle; interpret results in clinical context.