
GRACE STANDARD DIAGNOSIS

STEMI New or presumed new ST-elevation >1 mm seen in any location on the index ECG or on any subsequent ECG, together with one or more positive enzymes, based on laboratory ranges in use at each hospital.

Non-STEMI No new ST-elevation seen on the index or on any subsequent ECG, with one or more positive cardiac enzymes, based on laboratory ranges in use at each hospital.

Unstable angina Negative enzyme findings, CRF discharge diagnosis of ACS.

**Other cardiac/
non-cardiac** Cases where these were the only discharge diagnoses.

ENROLLMENT CRITERIA

Patients must meet the following criteria:

- Must have one of the Acute Coronary Syndromes as a presumptive diagnosis
- Must be ≥ 18 years old.
- Must be alive at the time of hospital presentation.
- The qualifying acute coronary syndrome must not have been precipitated or accompanied by a significant co-morbidity such as a motor vehicle accident, trauma, severe gastrointestinal bleeding, operation or procedure. Inpatients who develop ACS symptoms while hospitalized for any reason are not eligible for enrollment in GRACE.
- Patients transferred into or out of a registry hospital can be enrolled regardless of the time spent at the transferring hospital.
- For patients transferred out of a registry hospital, data collection for the Initial CRF will end with the transfer and indication of purpose of transfer.
- Patients may be re-enrolled in GRACE provided that ≥ 6 months has passed since their prior enrollment. When a patient is re-enrolled, a new patient number must be assigned.
- The criteria for ACS as defined below must be met, with one exception:
- Patients hospitalized for < 1 day that die and do not meet the criteria may be enrolled provided that the cause of death is confirmed to be due to ACS.
- Patients who meet eligibility criteria and who die shortly after admission e.g. in the emergency room should also be included.

Acute Coronary Syndromes

(Including Unstable or Intermediate Coronary Syndromes AND/OR Acute Myocardial Infarction):

Eligible patients should have symptoms considered as consistent with acute cardiac ischemia within 24 hours of hospital presentation.

They should also have at least one of the following:

• **ECG Changes**

- Transient ST segment elevations of ≥ 1 mm*
- ST segment depressions of ≥ 1 mm
- New T wave inversions of ≥ 1 mm*
- Pseudo-normalization of previously inverted T waves*
- New Q-waves (1/3 the height of the R wave or ≥ 0.04 seconds)*
- New R wave > S wave in lead V₁ (posterior MI)
- New left bundle branch block

* Changes should be seen in two or more contiguous leads.

• **Documentation of Coronary Artery Disease**

- History of MI, angina, CHF felt to be due to ischemia or resuscitated sudden cardiac death
- History of, or new positive stress test, with or without imaging
- Prior, or new, cardiac catheterization documenting coronary artery disease
- Prior, or new, percutaneous coronary intervention or coronary artery bypass surgery

• **Increase in Cardiac Enzymes**

- CK-MB > 2x upper limit of the hospital's normal range or if no CK-MB available, then total CPK > 2x upper limit of the hospital's normal range.
- Positive troponin I
- Positive troponin T

NOTE: Patients with unstable or intermediate coronary syndromes who are hospitalized for < 1 day cannot qualify for GRACE based on symptoms and history alone (i.e., they must have one of the ECG changes or new documentation of CAD as listed above).

MEDICAL HISTORY - SELECTED DEFINITIONS

Smoker

History of cigarette smoking (pipe and cigar smoking is excluded).

Smoker Codes

- Former smoker – defined as previous smoker who reports having quit smoking cigarettes >1 month prior to admission.
- Current smoker – defined as person who reports active smoking of cigarettes within one month prior to this admission.
- Smoking status not recorded i.e. no information in case notes available on the patient's smoking status.

Diabetes

Previous diagnosis of diabetes mellitus regardless of duration of disease or need for anti-diabetic agents. Patient may have been treated with diet, oral hypoglycemic agents or insulin at any time prior to hospitalization. Record

the patient's *current treatment at presentation* using the following treatment types:

Diabetes Treatment Types

- Diet controlled
 - Oral hypoglycemics
 - Insulin-dependent
 - No treatment or diet regimen being used
 - Type not recorded
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Renal Insufficiency

Any documented history of renal compromise.

MEDICATION CONTRAINDICATIONS

ASA

- patients with true allergy to aspirin
 - patient with active bleeding on admission
 - patient admitted on warfarin (coumadin)
 - patient refuses aspirin
 - taking other antiplatelet medication
 - taking nonsteroidal anti-inflammatory agents (NSAID)
 - other documented reason
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Beta Blockers

- allergy or intolerance to beta blockers
 - bradycardia (heart rate < 60 bpm) while not on a beta blocker
 - symptomatic heart failure
 - systolic blood pressure less than 100mmHg
 - PR intervals greater than 0.24 seconds on electrocardiogram (ECG)
 - second or third degree heart block on ECG
 - asthma
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ACE Inhibitors

- allergy or intolerance to ACE Inhibitors
 - patients on an angiotensin receptor blocking agent (ARB)
 - moderate or severe aortic stenosis
 - bilateral renal artery stenosis
 - history of angioedema, hives, or rash with ACEI use other reasons, such as hyperkalemia, symptomatic hypotension, severe renal dysfunction
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ARB

- allergy or intolerance to ARB
 - patients on ACE Inhibitors
 - bilateral renal artery stenosis
 - severe CHF
 - hepatic insufficiency
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Statins	<ul style="list-style-type: none"> • acute liver disease • hypersensitivity to HMG-CoA reductase inhibitors • alcohol abuse • history of, or suspected rhabdomyolysis
LMWH	<ul style="list-style-type: none"> • major bleeding disorders • thrombocytopenia • active gastric or duodenal ulceration • recent ischemic CVA • any patient with increased risk of hemorrhage • uncontrolled severe hypertension • hypersensitivity to LMWH
Unfractionated Heparin	<ul style="list-style-type: none"> • major bleeding disorders • thrombocytopenia • peptic ulcer • recent cerebral hemorrhage • severe hypertension • severe liver disease • renal failure • recent trauma (including surgery) • hypersensitivity to heparin
IN-HOSPITAL EVENTS	
CHF/Pulmonary Edema	Criteria same as Killip Class II: Bibasilar rales in 50% or less of lung fields, or an S3 heart sound.
CHF=Congestive Heart Failure.	Pulmonary Edema = Criteria same as Killip Class III: Bibasilar rales in more than 50% of lung fields.
Cardiogenic Shock	Criteria same as Killip Class IV : Pulmonary edema and hypo perfusion characterized by systolic BP < 80mmHg.
Cardiac Arrest/VF (after presentation)	Ventricular Fibrillation, Rapid ventricular tachycardia with hemodynamic instability, asystole, or EMD (Electrical-Mechanical Dissociation) requiring CPR.
Atrial Fib/Flutter	Documented in physician's note or by ECG documentation.
Sustained VT (after presentation)	<i>Sustained</i> VT (Ventricular Tachycardia): Documented in physician's note or by ECG documentation and requiring intervention.
Thrombocytopenia	Thrombocytopenia - any etiology. Defined as documented platelet levels < the lower limit of normal for the local laboratory.

HIT	<p>HIT = Heparin Induced Thrombocytopenia defined as Thrombocytopenia occurring \geq to 4 days post initiation of heparin with platelets $<$ 100,000 or \geq 50% drop from baseline AND one of the (HIT) following:</p> <ol style="list-style-type: none"> 1. Associated with venous or arterial thrombotic event, OR 2. Positive assay for heparin associated antibodies (C-serotonin, ELISA, platelet aggregation study, etc.) OR 3. If only clinical diagnosis of HIT, thrombocytopenia prompting discontinuation of heparin product.
Venous Thrombo-embolism	Any documented evidence of acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE) during index hospitalization.
Acute Renal Failure	Acute renal failure with oliguria and elevation of creatinine $>$ 2.0 mg/dl or 177 μ mol/l.
AV Block (Mobitz II, 3rd degree)	<p>Atrio-ventricular block: as shown on ECG:</p> <p>Mobitz II 2 degree (second degree), 3 degree (third degree) or complete AV block.</p>
Mechanical Complication	<p>Ventricular Septal Defect</p> <p>Mitral Regurgitation</p> <p>Free Wall Rupture</p>
MI $>$ 24 hours after hospital presentation/ Re-infarction	<p>MI is documented by positive markers with the time of the first positive marker determining the time of diagnosis.</p> <ol style="list-style-type: none"> 1. Patients with an admission diagnosis of unstable angina who develop an MI $>$ 24 hours after presentation. Note: The biomarker (troponin, CPK or CKMB) confirming the MI should be drawn beyond the first 24 hours of presentation to hospital. 2. Patients who are diagnosed with an MI after CABG or a PCI (and $>$ 24 hours after presentation) as long as they qualified for GRACE prior to the CABG or PCI. <p>Post CABG or PCI Myocardial Infarction Criteria</p> <ul style="list-style-type: none"> • Following PCI, CK-MB (or CPK) elevation must be $>$ 3 X ULN • Following CABG, CK-MB (or CPK) must be $>$ 5 X ULN <ol style="list-style-type: none"> 3. Patients who are diagnosed as having had a recurrent MI confirmed by ECG changes or elevation of cardiac markers. <p>Criteria for patients with an initial diagnosis of MI as the qualifying event who subsequently reinfarct.</p>

In patients with acute MI as the qualifying event, marker criteria for recurrent infarction are:

- A. *re-elevation* of the CK-MB to above the ULN and increased by at least 50% over the previous value.
- B. If CK-MB is not available, then *re-elevation* of total CPK must be either > 2 X ULN and increased by 25% over the previous value, or > 1.5 X ULN and increased by at least 50% over the previous value.
- C. Following PCI, CK-MB (or CK) elevation must be > 3 X ULN and increased by at least 50% over previous value.
- D. Following CABG, the criteria for recurrent infarction require *both enzyme criteria in C. above and ECG changes consistent with MI.*

Stroke	Stroke-related neurological signs or symptoms, e.g., loss or slurring of speech, altered state of consciousness. Confirmed by either computed tomography or magnetic resonance imaging. Stroke type: Embolc/Ischemic Embolc w/Hemorrhagic Conversion Hemorrhagic/ Subdural Hematoma Other
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Major Bleeding (except hemorrhagic stroke)	Life-threatening bleeding requiring a transfusion of 2 or more units of packed red cells or resulting in an absolute decrease in Hematocrit of $\geq 10\%$ or resulting in death. (Excludes bleeding post CABG surgery)
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OUTCOMES (6-MONTH FOLLOW-UP)

Death	Record No , if the patient was alive at the time of the 6-month follow-up. Record Yes , if the patient died during the 6 months following discharge from the hospital. If Yes , record the day, month, and year that the patient died. If you are unable to determine the exact day of death, please report the approximate day or even just the month and year of death. Indicate the main cause of death as one of the following: Cardiac Trauma Suicide Pulmonary Embolism Other Non-Cardiac If the patient died in the 6-month follow-up period, please endeavor to complete all information on unscheduled re-hospitalization, MI, stroke and procedures.
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MI

Record **Yes**, if a Myocardial Infarction was diagnosed (or if the patient reported that an MI was diagnosed) at any time during period post discharge up to 6-month follow-up point. **If a patient was re-admitted into the hospital with a clinical syndrome of suspected acute ischemia, with a positive rise in troponin, or CKMB, then record this event as a Myocardial Infarction even if the discharge diagnosis in the patient chart was either unstable angina, or acute coronary syndrome. (This is based on the current ACC/ESC guidelines regarding the definition of MI).** If Myocardial Infarction was reported as **Yes**, record date of myocardial infarction. If more than one myocardial infarction occurred, record the date of the first myocardial infarction. Record **No**, if no Myocardial Infarction was diagnosed.
