Question by Question (QXQ) Instructions for the HCHS/SOL
Myocardial Infarction Diagnosis Form (MID)

A myocardial diagnosis (MID) Form is filled out by the reviewer for all case packets that are sent to them for review by the CSCC. Initially, events will be classified independently by 2 reviewers with disagreements classified by an adjudicator. Review materials per case will include medical records and an Event Summary Form (ESF). The ESF is a 2 page summary of information abstracted from the medical records (i.e. a subset of information from the HF abstraction form). It also contains selected information from the participants' study visit (s).
A requirement of the MI classification in SOL is that at a minimum we need to be comparable with the classification done in MESA (the Multiethnic Study of Atherosclerosis). In SOL, reviewers will be asked to interpret electrocardiograms (when available) as part of the classification. There will not be a reading center review of medical record electrocardiograms. In some cases, reviewers will have to rely on the ECG interpretation available in the medical record if an ECG image is not included as part of the record.

The first section of the form is called administrative information (0A-0D). When in electronic form, parts of this will be filled out by the CSCC. For training, please fill this out.

A0. Enter date that you (the reviewer) completed the form.

B0. Enter your staff or reviewer ID number. It is 3 digits.

C0. Event ID. This number is assigned by the CSCC. It will start with a letter representing the HCHS/SOL field center site. It is stamped on the top of the medical record.

D0. Event Date. Enter the date of arrival or the earliest date on the medical record.

Answer all questions by selecting one choice from the options provided.

1. Evidence of cardiac pain (e.g., jaw, arm, chest) associated with this event?

Cardiac pain is defined as an episode of pain, tightness, pressure or discomfort in the chest, arm or jaw. If there is a clear non-cardiac cause, chest pain is considered to be absent. Duration of pain is not a part of the chest pain criterion. Other atypical pain which is deemed to be due to coronary ischemia may qualify here also. Assess for the presence of chest pain documented around the time of the potential MI. For events where the MI occurs after admission, chest pain at the actual time of the acute event being adjudicated is relevant (rather than, for example, chest pain prior to admission).

2. Describe the level of cardiac biomarkers:

1= Abnormal (at least one value at 2 X the upper limit normal)
2= Equivocal (> normal, but < 2X the upper limit normal)
3= Incomplete
4= Normal
5= None recorded

In the event that the actual laboratory values are not included in the medical record then biomarker results reported in physician notes are acceptable, as long as actual values are reported. Reports of biomarkers being "positive" or "negative" will not be sufficient.

Use Table 1 to aid in classifying cardiac biomarkers. These criteria shown in Table 1, apply as long as the patient has not had Coronary Artery Bypass Surgery (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) in the previous 24 hours. In that case, see foot notes to classify.

To summarize Table 1, equivocal biomarkers are between "above normal" and twice the Upper Limit of Normal (ULN), whereas "abnormal" biomarkers are greater than twice the upper limit of normal.

When there has been muscle trauma, liver trauma, or hemolysis then positive CPK enzymes are downgraded to equivocal.

Elevated troponins may also be considered equivocal when under the following co-morbid conditions:
myocarditis/pericarditis/endocarditis, cardiac contusion/trauma/CPR/debrillation, cardiac surgery, aortic dissection, pulmonary embolism, stroke (ischemic or hemorrhagic), chronic severe heart failure, cardiac arrhythmias, sepsis/critical illness, renal failure, hypertrophic obstructive cardiomyopathy (HOCM), takotsubo cardiomyopathy, burns, extreme exertion, infiltrative cardiac diseases such as amyloidosis. Reviewers should use their judgment as to whether they think these factors may have contributed to the elevation in troponin.

Documentation may be incomplete for cardiac biomarkers, however complete enough to decide whether they were abnormal or not. For example, incomplete documentation may include troponins may be missing as to the units or the type of troponin (I or T), and/or its upper limit of normal. You may choose "3=incomplete", however in some circumstances incomplete data may be still be useful depending the information available and the value of the biomarker. Consider the following in deciding when documentation is incomplete. There are two types of clinically used troponins, troponin I and troponin T. Currently, troponin T has a fairly uniform upper limit of normal of 0.01 ng/ml. There are many assays used troponin I, with varying upper limits of normal that range from 0.01-0.4. Currently, the highest upper limit of normal for troponin I is 0.5 ng/ml. If the incomplete data provide enough information to choose one of the other categories, for reasons such as the value was obviously high or obviously low value, then choose a category more informative than "incomplete".

Table 1. Algorithm to classify cardiac enzymes as abnormal, equivocal, normal, or incomplete

Biomarker Value	If: a) no known muscle trauma or hemolysis, and 2) no PTCA or CABG in previous 48 hours*	If secondary cause of elevated enzymes exists then:
CK-MB = "present", where only present or absent provided	Abnormal	Equivocal
CK-MB ≥ 2X ULN (upper limit of normal)	Abnormal	Equivocal
CK-MB** ≥ 10% Total CK, if no ULN is given	Abnormal	Equivocal
Total CK ≥ 2X ULN and LDH ≥ 2X ULN	Abnormal	Equivocal
LDH1: LDH2>1	Abnormal	Equivocal
LDH1 ≥ 2X ULN if LDH2 is missing	Abnormal	Equivocal
Total CK ≥ 2X ULN or LDH ≥ 2X ULN	Equivocal	Normal
Normal < Total CK < 2X ULN and Normal < LDH < 2X ULN	Equivocal	Normal
5% Total CK < CK-MB** < 9 % Total CK or CK-MB "weakly present"	Equivocal	Equivocal
Normal < CK-MB < 2X ULN	Equivocal	Equivocal
Normal < LDH1 < 2X ULN	Equivocal	Equivocal
Data present, but insufficient for criteria	*Incomplete*	*Incomplete*
Normal< Troponins < 2X ULN	Equivocal	Equivocal
Troponins > 2X ULN	Abnormal	Abnormal/Equivocal
Troponins < ULN	Normal	Normal
CK-MB < ULN	Normal	Normal
All other results	Normal	Normal

*If PTCA then **abnormal** in first 48 hours if Troponins or LDH1 or CK or CK-MB>3X ULN; **equivocal** if 1-3X ULN. If CABG then **abnormal** in first 48 hours if troponins or LDH1 or CK-MB>5X ULN; **equivocal** if 1-5X ULN.
**CK and CK-MB must be in same units for this criterion

3. Based on the evidence in the medical record, provide your interpretation of ECGs:
   1= Evolution of Major Q-Wave
   2= Evolution of ST-T Elevation with or without Q-Wave
   3= New LBBB
   4= Evolution of ST-Depression/T wave inversion alone
   5= Evolution of Minor Q-Wave alone
   6= Single ECG with Major Q-wave
   7= Single ECG with LBBB, described as new
   8= Absent, Uncodable or Other ECG

The ECG criteria for SOL are based on the Minnesota Code system of classification which is outlined in the Minnesota Code ECG Criteria. When available, reviewers ideally will interpret serial tracings; when available from the medical record, the following ECG tracings will be identified for this purpose: the first, second, third and last ECGs obtained from the hospital admission. In coding ECGs, you can take into account comments from physicians that have looked at an old ECG, even if the old ECG is not included in the record. For example, if the physician reviews an old ECG and states that the LBBB is new, AND you agree that the ECG from the current hospitalization has LBBB, THEN you may select '3' for question 3, for new LBBB.

The evolution of ECG findings may be demonstrated (1) between the ECG(s) associated with the event or (2) between a previously recorded ECG and the event ECG(s). In cases in which only a single event ECG is available, an evolving diagnostic ECG pattern cannot be recorded. When available, reviewers will review the copies of actual ECGs submitted in the case packet and will make a clinical reading of the ECG pattern, using the Minnesota Code as a guide.

In the case that no ECG images are available, then well documented readings of ECG can be considered in the place of the ECG. This should be at the reviewers discretion to use a reading without an image or select "8= Absent, Uncodable or Other ECG". Consider the person reading the ECG with a cardiologist as the highest level of reader.

Definitions of Terms
EVOLVING Q WAVE PATTERNS

Evolving Q1: No Q-code in prior study ECG or first ECG in event set of ECG(s) followed by a record with a diagnostic Q-code (Minnesota Code 1-1-1 through 1-2-5 plus1.2-7) OR any code 1-3-X or 1-2-6 in baseline ECG followed by a record with any code 1-1-X.

Evolving Q2: An equivocal Q-code (Minnesota Code 1-2-8 or any 1-3 code) and no major ST-segment depression in prior study ECG or first ECG in event set of ECG(s) followed by a record with a diagnostic Q-code PLUS a major ST-segment depression (Minnesota code 4-1-X or 4-2) and 100% increase in ST depression

Evolving Q3: An equivocal Q-code (Minnesota Code 1-2-8 or any 1-3 code) and no major ST-segment depression in prior study ECG or first ECG in event set of ECG(s) followed by a record with a Diagnostic Q-code PLUS a major T-wave inversion (Minnesota Code 5-1 or 5-2) and 100% increase in T-wave inversion

Evolving Q4: An equivocal Q-code and no ST-segment elevation in prior study ECG or first ECG in event set of ECG(s) followed by a record with a diagnostic Q-code PLUS ST-segment elevation (Minnesota code 9-2) and 100% increase in STE

Evolving Q5: No Q-code and neither 4-1-X nor 4-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS 4-1-X or 4-2 and 100% increase in ST depression

Evolving Q6: No Q-code and neither 5-1 or 5-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS a 5-1 or 5-2 100% increase in T-wave inversion

Evolving Q7: No Q-code and no 9-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS a 9-2 and a100% increase in STE.

Evolving Q8 Evolving Q5: No Q-code and neither 4-1-X nor 4-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS 4-1-X or 4-2 and 100% increase in ST depression

EVOLVING LBBB

New left bundle branch block (code 7-1-1, with the QRS duration increasing by at least 20 ms from less than 120 ms to ≥ 120ms.)

EVOLVING ST ELEVATION

Evolving STE 1: No 9.2 in prior ECG or first ECG in event set of ECG(s) and 9-2 in at least 2 leads of a following event ECG with 100% increase in STE in both leads

Evolving STE 2: 9-2 in prior ECG or first ECG in event set of ECG(s) with a 100% increase in STE in at least 2 leads.

Evolving STE 3: 9-2 and no 5-1 or 5-2 in prior ECG in first ECG in event set of ECGs and

appearance of 5-1 or 5-2 with 100% increase in T-wave inversions. in at least 2 leads.

Evolving STE R1: Reversal of evolving STE 1.

Evolving STE R2: Reversal of evolving STE 2.

EVOLVING ST-T DEPRESSION/INVERSION

Evolving ST-T1: Either 4-0 (no 4-code), 4-4 or 4-3 in prior ECG or first ECG in event set of ECG(s) followed by a record with 4-2 or 4-1-2 or 4-1-1 and 100% increase in ST segment depression.

Evolving ST-T2: Either 4-2 or 4-1-2 in prior ECG or first ECG in event set of ECG(s) followed by a record with 4-1-1 and 100% increase in ST segment depression

Evolving ST-T3: Either 5-0, 5-4 or 5-3 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-2 or 5-1 and 100% increase in T-wave inversion.

Evolving ST-T4: Code 5-2 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-1 and 100% increase in T-wave inversion

Evolving ST-T5: Code 4-1-1 in prior ECG or first ECG in event set of ECG(s) followed by a record with 4-1-1 and 100% increase in ST depression.

Evolving ST-T6: Code 5-1 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-1 with 100% increase in T wave inversion.

Evolving ST-T7: Code 5-2 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-2 with 100% increase in T wave inversion.

Evolving ST-T R1 through ST-T R7 = the reverse of ST-T1 to ST-T7, respectively.

ECG Pattern	Minnesota Codes
Evolution of Major Q-Wave	Q1, Q4, Q7
Evolution of ST Elevation with or without Q-wave	Q2, Q3, Q5, Q6, or STE1, STE2, STE3, STE R1 or STE R2
New LBBB	
Evolution of ST-T Depression/inversion alone	ST-T1, through ST-T7, or R1ST-T through R7 ST-T
Evolution of Minor Q-waves alone	Q8
Single ECG with Major Q-Wave	MC 1.1.x or 1.2.x [except 1.2.6 or 1.2.8]
Single ECG with LBBB, described as new	MC 7.1.1 for LBBB
Normal, Absent, Uncodable, other	

See next page for Question 4 instructions

4. Myocardial infarction classification (using MI algorithm):

Question 4 is the primary question which will classify the event, and will be adjudicated when needed. The table below is meant to serve as a guide to go along with the reviewer's judgement. The criteria for myocardial infarction (MI) include information about chest pain, cardiac enzymes, and ECGs. The SOL MI criteria have been adapted from MESA which was adapted from the Atherosclerosis Risk in Communities (ARIC) Study.

MI Criteria: Table 3 shows the diagnostic categories of MI according to the ECG criteria, enzyme categories, and chest-pain history.

In the case that there is a cardiac catheterization or stress test that shows an obvious new MI, and details are missing such as specific biomarker values or images of MI, you may override the algorithm in Table 3 to call this a definite MI.

Table 3 SOL Diagnostic Criteria for Hospitalized MI, adapted from MESA

ECG Pattern *	Abnormal enzymes	Equivocal enzymes	Incomplete enzymes	Normal enzymes
Chest Pain PRESENT:				
Evolution of Major Q-Wave	Definite MI	Definite MI	Definite MI	Definite MI
Evolution of ST Elevation with or without Q-wave Or New LBBB	Definite MI	Probable MI	Probable MI	No MI
Evolution of ST-T Depression/inversion alone Or Evolution of Minor Q-waves alone	Definite MI	Probable MI	No MI	No MI
Single ECG with Major Q-Wave Or Single ECG with LBBB, described as new	Definite MI	Probable MI	No MI	No MI
Normal, Absent, Uncodable, other	Probable MI	No MI	No MI	No MI
Chest Pain ABSENT:				
Evolution of Major Q-Wave	Definite MI	Definite MI	Definite MI	Definite MI
Evolution of ST Elevation with or without Q-wave Or New LBBB	Definite MI	Probable MI	No MI	No MI
Evolution of ST-T Depression/inversion alone Or Evolution of Minor Q-waves alone	Probable MI	No MI	No MI	No MI
Single ECG with Major Q-Wave Or Single ECG with LBBB, described as new	Probable MI	No MI	No MI	No MI
Normal, Absent, Uncodable, other	Probable MI	No MI	No MI	No MI

If 'Definite' or 'Probable' MI then answer the following questions 4a-4d, otherwise skip to question #5:

4.a. Type of MI?
For definite or probable MI, record TRANSMURAL if there is ST elevation or a resulting Q wave note on the ECG. Record SUBENDOCARDIAL if there is not ST elevation or a resulting Q wave. If it not clear whether there was ST elevation or a Q wave then record UNSURE/UNKNOWN.

4.b. Location of MI?
1=Anterior	3=Inferior	5=Septal	9=unable to determine
2=Posterior	4=Lateral	6=More than one areas	

Based on your interpretation of the available ECGs, select the location of MI that best describes this event. General guidelines for defining MI location will be those outlined in AHA/ACCF/HRS recommendations for standardized interpretation of ECG (Wagner et al JACC, 2009;53:1003-1011). Use your judgment and clinical experience to record location of MI. If MI location includes multiple areas, such as anterolateral or anteriorseptal then classify the MI location as having more than one area. In most cases, try NOT to determine MI location from ECHO findings, but rather use the ECG to determine MI location. For this question, if there is not an ECG image available then choose "9=unable to determine".

In general, MI locations are defined by the following ECG changes and coronary artery occlusions

MI location	ECG findings	Usually due to occlusion of:
Inferior MI	ST elevation, Q wave in II, II, and AVF	right or left coronary, depends on which coronary supplies the base of the heart
Lateral MI	ST elevation, Q wave in I and AVL	Circumflex branch of L coronary
Anterior MI	ST elevation, Q wave in V1-V4	Anterior descending branch of L coronary
Posterior MI	"opposite" of anterior MI, ST depression, R wave in V1, V2	R. coronary or one of its branches

4.c. Was the MI procedure-related?

Cardiac events up to 28 days after a medical procedure or surgery that meet the criteria for definite, or probable MI described above will be assessed for whether they were procedure-related. If the medical procedure was performed for the treatment of <u>acute</u> ischemia (e.g., angioplasty following the presentation of acute coronary syndrome), that event should *not* be considered procedure-related (Luepker, et al, 2003). The procedure-related MI category is intended to identify MIs that occurred during or after the procedure, and <u>were not already in evolution prior to the procedure</u>. In determining whether the MI was procedure related, answer YES (and choose cardiovascular or non-cardiovascular procedure) if you think it is unlikely this

MI would have occurred had the procedure <u>not</u> been performed. Answer YES, CARDIOVASCULAR PROCEDURE if the MI occurred within 28 days of a cardiovascular procedure or surgery AND in your judgment the MI was a complication (or related to) the procedure. Cardiovascular procedures include: CABG, valve replacement, AICD or pacemaker placement, PTCI, etc. Answer YES, NON-CARDIOVASCULAR PROCEDURE if the MI occurred within 28 days of a non-cardiovascular procedure or surgery AND in your judgment the MI was a complication (or related to) the procedure. Non-cardiovascular procedures include all procedures or surgeries that are not cardiovascular. Answer UNKNOWN/UNSURE if you are not certain as to whether the MI was procedure related or not.

4.d. What was the subclass of MI? Choose 'Unsure' if there is not enough information to reasonably determine subclass. Please use the table below as guidance in determining subclass. Please use your clinical judgment in choosing subclasses. It is unlikely that you will definitely know subclass and will need to take an educated guess based on the information in the record. These subclasses and definitions are from the third universal definition of MI (Thygesen K, Alpert J.S., Jaffe A.S. et al. The Third Universal Definition of MI. JACC, 2012, vol. 60, No. 16.)

Universal Classification of Myocardial Infarction from Thygesen K, Alpert J.S., Jaffe A.S. et al. The Third Universal Definition of MI. JACC, 2012, vol. 60, No. 16., p. 1587
Type 1: Spontaneous myocardial infarction
"Spontaneous myocardial infarction related to atherosclerotic plaque rupture, ulceration, erosion, or dissection with resulting intraluminal thrombus in one or more of the coronary arteries leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. The patient may have underlying severe CAD but on occasion non-obstructive or no CAD."
Type 2: Myocardial infarction secondary to an ischemic imbalance
"In instances of myocardial injury with necrosis where a condition other than CAD contributes to an imbalance between myocardial oxygen supply and/or demand, e.g. coronary endothelial

dysfunction, coronary artery spasm, coronary embolism, tachy-/brady-arrhythmias, anemia, respiratory failure, hypotension, and hypertension with or without LVH."
Type 3: Myocardial infarction resulting in death when biomarker values are unavailable
"Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB, but death occurring before blood samples could be obtained, before cardiac biomarker could rise, or in rare cases cardiac biomarkers were not collected."
Type 4a: Myocardial infarction related to percutaneous coronary intervention (PCI)
"Myocardial infarction associated with PCI is arbitrarily defined by elevation of cTn values >5 x 99th percentile URL in patients with normal baseline values (<99th percentile URL) or a rise of cTn values >20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial ischemia, or (ii) new ischemic ECG changes or new LBBB, or (iii) angiographic loss of patency of a major coronary artery or a side branch or persistent slow- or no-flow or embolization, or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required."
Type 4b: Myocardial infarction related to stent thrombosis
"Myocardial infarction associated with stent thrombosis is detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/ or fall of cardiac biomarkers values with at least one value above the 99th percentile URL."
Type 5: Myocardial infarction related to coronary artery bypass grafting (CABG)
"Myocardial infarction associated with CABG is arbitrarily defined by elevation of cardiac biomarker values >10 x 99th percentile URL in patients with normal baseline cTn values (<99th percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality."

[As of 2018, skip Question 5 and go to Question 6 to enter any comments]

5. Was this presentation consistent with an "aborted MI" due to quick medical intervention?

Please state if, in your judgement, a possible MI was "aborted" due to quick medical intervention by a procedure (PTCA or CABG), or thrombolysis. In this case, usually there is an abnormal ECG leading to quick treatment (usually administered within one-two hours of symptom onset) that limits detection of myocardial necrosis with cardiac enzymes. Record YES, if consistent with "aborted MI".

6. Comments_____