

HCHS/SOL Question by Question Instructions Myocardial Infarction Abstraction Form (MIF) Question by Question Instructions

General Instructions

The HCHS/SOL Myocardial Infarction Abstraction Form (MIF) is completed for each HCHS/SOL cardiac-related hospitalization, out-of hospital cardiac death and nonfatal outpatient cardiac event that is considered eligible per the HCHS/SOL Event Eligibility Form (EEF). The abstractor should be familiar with the document titled "General Instructions for Completing Paper Forms" prior to completing this form. Staff ID number and date the abstraction was completed as well as event ID Number and event date should be completed in the form header section.

The Myocardial Infarction Abstraction Form captures the specific reasons for cardiac-related hospitalizations and the use of various procedures and diagnostic evaluations.

The purpose of these instructions is to make sure all HCHS/SOL medical record abstractors are collecting information in the same way. The more specific information one has about each item on the form--and the more one knows regarding where to find the "answers" as well as how to record them--the more uniform and useful the HCHS/SOL data will be. Although one may have ample experience in medical record abstraction and medical terminology, these instructions provide definitions that will help ensure that everyone is using the same "tools" to describe an event.

For each item on the form, the instructions will tell you where in the medical record, and in what order, to look for the required information. When consulting several sections of the medical record, you may find that they provide different or even contradictory information. It is, therefore, very important to consult all listed sections of the medical record for a given item on the form. Ideally, the information needed to complete an item on the form will be found in one or more of the medical record sections listed. However, other parts of the medical record may need to be searched for an answer. If the information needed is still unable to be found, mark "No" for items in which "unknown" is not an available option.

If an item on the form is unable to be completed because of missing or contradictory information in the medical record, the Principal Investigator (P.I.) or physician reviewer should be consulted for advice.

ER Visits and Transfers: Separate admissions (e.g., b/c of transfers) are abstracted on separate Myocardial Infarction Abstraction forms, even though both abstractions can be scanned into a single HCHS/SOL investigation at the judgment of the Events staff. Since an ER visit alone is not an actual admission, there is no need to do two separate abstractions in a situation where a participant has an ER visit at one hospital but is then admitted at a different hospital. In such a situation, the records of the ER visit should be abstracted as part of the admission at the second hospitalization.

Multiple Care Locations: In general, there are three different options to make sure everything is abstracted when care is received in two locations:

(a) Two entirely separate investigations, each with its own abstraction form. (Use this method for two events separated by 24 hours, though the Events staff has the option of collapsing events

into a single investigation if conditions are directly related and admissions are within 30-day span).

- (b) One investigation with two or more abstraction forms. (Use for single event involving two admissions linked by a transfer.)
- (c) One investigation with one abstraction form, even though care was received in two locations. (Use for one event that involves multiple locations but only one actual admission, such as ER visit at one hospital followed by admission to a different hospital.)

Sections and Content of the Medical Record Used for Abstraction

You need to consult all of the following sections of the medical record, as appropriate, in order to gather adequate information to complete the form. If the entire chart is available, these sections should be reviewed first. It is a good idea to read through these sections (and others, if possible), before you begin recording information on the form, in order to familiarize yourself with the course of events that occurred from admission to discharge.

Although the instructions for each individual form item sometimes list the **most likely** sources for finding the information sought by that particular question, you can use documentation from anywhere in the chart if these sources do not provide the information you need. Although keep in mind questions related to the time of event.

The **Face Sheet** provides participant demographic information and admission and discharge information (dates, treating physician(s), discharge diagnosis(es), and ICD-9-CM codes). It also contains charges for certain medications, and tests.

The Emergency Department (ED) Record and Emergency Medical Technician (EMT) or Ambulance Report describe symptoms, dates and times of symptoms, vital signs, initial treatment during transportation to the hospital, ED treatment, response, and disposition. In the ED there will be a triage note from initial assessment of the patient, then notes from the nurse and a note from the physician. The triage note is particularly valuable for initial vital signs.

The **Admission History and Physical Exam** (H&P) is a detailed description of symptoms leading to admission, condition of participant on admission, current medication use, and past medical history; it also includes a physical exam, results of tests and procedures done in the ER or upon admission, provisional diagnosis(es), and treatment plan. Hospital visits of patients who stay in the hospital for < 24 hours may be designated as **observation care** which is considered outpatient care even though it may be overnight in the hospital. For these stays, you may only see a short stay note which is the admission note and discharge note combined.

The **Discharge Summary** summarizes the entire hospitalization, including admission and discharge dates, treating physician(s), admission H&P, hospital course, treatments and procedures, and discharge disposition. If the hospitalization is prolonged or if residents or

attending physicians rotate while a participant is admitted, there may also be an **interim summary** (which would not include the hospital course section). When there is an interim summary the discharge summary is still expected to be completed.

The **Death Summary** may replace or augment the discharge summary, in the event of a participant's death. It may contain, or be attached to, autopsy information or an autopsy report.

The **Consults** section contains typed or handwritten notes made by specialists (e.g., infectious disease, rehabilitation medicine) consulted while the participant was hospitalized. Handwritten consults may also be found in the physician progress notes section.

Laboratory Results. This section will contain chemistries including cardiac enzyme levels.

ECG Reports. In chronological order, the first, second, third and last ECG reports from the hospitalization are of interest.

The **Radiology** (or diagnostic tests) **section** contains reports of chest x-rays, echocardiograms, CTs, angiograms, cardiac catheterizations, VQ scans, thallium stress tests and other imaging procedures.

The **Operative** section contains operative and pathology reports and may contain autopsy reports.

Outpatient Records, if available, may be used if they can provide more information about the event in question. If within a week of the ED or hospital visit, outpatient records may help to confirm recent signs and symptoms of specific conditions.

Rules on hierarchy and use of qualitative reports: The underlying purpose of these rules is to capture information rather than to miss it, as long as the information appears accurate.

If there are conflicting sources of information, take information in this priority: the cardiologist (any type of note), the attending physician (any type of note) the resident, ED physician, and nurse. However, if there is disagreement regarding diagnosis between physicians, the subspecialist for that diagnosis takes superiority. For example, for a pulmonary issue, the pulmonologist is considered more correct, but for a cardiac issue, the cardiologist should be more correct than the non-cardiologist.

Rules for Physical Exam and Symptoms:

In general the goal is to capture any presence of an abnormal exam finding. For signs and symptoms, any documented description of an abnormal finding by any physician is sufficient unless stated otherwise in the QXQ at the time of event. In the case where an exam finding is

specifically requested for any one point in time and there is disagreement about the presence of that physical finding at that specific time point (e.g., at the time of the event), take information in this priority: the cardiologist (any type of note), the attending physician (any type of note) the resident, ED physician, and nurse. If there is disagreement between subspecialists, the subspecialist for that diagnosis takes superiority. Time of event is meant to include approximately 24 hours after time of arrival or event onset if happened after arrival.

Please avoid using the following secondary sources to gather information, unless primary sources are incomplete or unavailable: physician orders, nurse's or multidisciplinary notes, vital sign logs, or physician progress notes, unless there is **no other way** to reconstruct the event.

Rules for Vital Signs at Time of Admission:

Use the first in time for admissions and the last in time for discharge (not necessarily the H&P) to complete Section B - Presenting Signs and Symptoms.

Rules for Diagnostic Tests: Qualitative vs Quantitative reports

Generally, physician's qualitative data take precedence over quantitative (technician's) data. If there is a discrepancy between data in the qualitative description and data in the conclusion, use data in the qualitative section (i.e. go with text not test). If reviewing an actual report, the physician's qualitative interpretation takes precedence over the quantitative test result or any other physician's comments pertaining to the original interpretation. History and physical notes rank higher than emergency room notes.

Definitions of Terms

Some questions have response categories of 'Yes,' 'No,' and 'Not Recorded'. If nothing is written down that definitely answers the question, 'Not Recorded' should be chosen. Be sure to follow the correct skip patterns, i.e.: follow form logic! The following table lists terms you may encounter in the medical record that, when in doubt, should be recorded on the form as Yes, No, or NR (not recorded - unknown). Obviously, the entire content of the event should be considered as well.

Yes	No	Unknown
Present	Not present	Rule out (R/O)
		Cannot Rule Out
Likely	Low probability	Suggestive
Apparent	Unlikely	Equivocal
Consistent with		Suspicious
Compatible with		Questionable

Definite	Possible
Probable	Uncertain
Highly suspicious	Reportedly
Presumed	Perhaps
Borderline	Could be
Thought to be	Might be
Minimal	May be
Representing	May represent
Mild or trace	
Scant	

The table below contains time-of-day and length-of-time terms that you may encounter in the medical record and how they should be interpreted and/or recorded on the form. (Use 12-hour clock, not 24-hour clock).

If the medical record says this	You record this
[If no time is listed]	12:00p.m.
Middle of the night	1:00 a.m.
Early morning	6:00 a.m.
Morning	8:00 a.m.
Late morning	10:00 a.m.
Mid-day or noon	12:00 p.m.
Early afternoon	2:00 p.m.
Afternoon or mid-afternoon	3:00 p.m.
Late afternoon	4:00 p.m.
Early evening	7:00 p.m.
Late evening	11:00 p.m.
Midnight	12:00 a.m.
Several days	>3 days
A few days	\geq 2 but \leq 4 days
Several hours	\geq 4 but < 6 hours
A few hours	\geq 2 but < 4 hours

Other specific definitions are included in the instructions for each item on the individual abstraction form.

Cardiovascular Events: Synonyms and Descriptions

Myocardial Infarction (**MI**) refers to the death of a certain segment of the heart muscle (myocardium), usually the result of a focal complete blockage in one of the main coronary arteries (or a branch thereof), resulting in the deprivation of necessary oxygen-supplying blood which in turn causes injury or death to the tissue in that part of the heart.

The main cause of myocardial infarction is atherosclerosis in the coronary arteries. Atherosclerosis is a specific type of arteriosclerosis, but the terms are sometimes used interchangeably.

Arteriosclerosis occurs when the blood vessels that carry oxygen and nutrients from your heart to the rest of your body (arteries) become thick and stiff — sometimes restricting blood flow to your organs and tissues. Healthy arteries are flexible and elastic, but over time, the walls in your arteries can harden, a condition commonly called hardening of the arteries.

Atherosclerosis refers to the buildup of fats, cholesterol and other substances in and on your artery walls (plaques), which can restrict blood flow. This process can lead to events which can result in impaired contractility of the heart muscle within seconds, initially restricted to the affected segment.

Angina is a squeezing or crushing pain, pressure or discomfort that usually starts in the center of the chest behind the breastbone and may spread to the arms, neck, jaw or back. The pain can be mild, moderate or severe. It is caused by reduced oxygen to the heart, usually from poor blood supply. The pain of angina is usually brief. It often, though not always, appears when participants are physically active or emotionally stressed and is relieved in a few minutes with rest. Angina may be accompanied by shortness of breath, sweating, nausea and dizziness.

Acute Cardiac Symptoms which may be caused by coronary heart disease (CHD) or acute coronary syndrome (ACS) events such as non-fatal myocardial infarction (MI) or coronary heart disease death include: chest pain, a collapse, syncope, shortness of breath, gastrointestinal symptoms such as nausea, palpitations, throat tightness, pain in the neck, left arm, and sternum and sudden death. Chest tightness, pressure, discomfort, squeezing or heaviness is equivalent to chest pain. Marked fatigue and shortness of breath may be considered acute cardiac symptoms if the chart seems to indicate this. Some symptoms include one of these but are obviously noncardiac (e.g. chest pain from pneumonia, nausea from pancreatitis), In this case, answers to questions regarding acute CHD events or symptoms would be answered in the negative. For example: If a patient came in for a scheduled procedure (such as pacer battery replacement), but reported acute cardiac symptoms prior to arrival, then the symptoms should be considered acute symptoms. In cases where a patient collapses during a stay and had no other acute cardiac symptoms, consider the collapse a symptom and treat it as an in-hospital event. Additionally, if the patient never reported pain or discomfort before the collapse and did not recover, there is not enough information and questions regarding the event should be answered as unknown. Neurological syncope or dizziness is not considered a CHD-related symptom.

SPECIFIC ITEMS

Once 'Completion Date' (the date of abstraction) and 'Staff ID' have been entered on the Events Eligibility (EEF) Form they can be duplicated in the corresponding fields on the MIF using the "dup key" feature (or F2) in the HCHS/SOL data management system (DMS) if the forms have been entered in the same data session. 'Event ID' should be carefully checked for accuracy when entered into the DMS. 'Event Date' is the date of the hospital admission or Emergency Room (ER) visit. Event ID and event date should also be used to assist the abstractor in confirming the medical record being abstracted matches the EEF form

ITEM BY ITEM INSTRUCTIONS

SECTION A: GENERAL INFORMATION

Item 1. Choose one. Enter "1" if the event was in hospital only without a visit to the same hospital's ED, "2" if ED visit only, or "3" for both ED visit followed by a hospitalization.

<u>Item 2.</u> Record the date of arrival at the hospital; if includes an ED visit then it would be date of arrival at ED or the first date recorded for this visit. Enter as mm/dd/yyyy.

<u>Item 2a.</u> Record the time of arrival at the emergency department or hospital. If time provided in military time then convert to time in AM or PM and then choose '1' for AM or '2' for PM. If uncertain of time of arrival, provide closest time available on the day of arrival. ED triage would likely be the earliest time. Other places to consider looking for the earliest time could be the RN notes, or time of 1st lab work. If no time available from the day of arrival, then give "=" across all blanks.

<u>Item 2b.</u> Record the date of admission to the hospital. This should be on the admission history and physical and the discharge summary as the "date of admission". If date not available or this is an ED visit only, then give "=" across all blanks. Look for validation that the date of admission is correct on the H and P, especially on handwritten notes in which the admission date is not automatically filled in. Admission date may also be on the face sheet.

Be aware that the admission date may be different (e.g., the following day) from the ER date.

• Sources: Face Sheet, discharge summary.

<u>Item 3.</u> Record the date of discharge (or date of death). Enter as mm/dd/yyyy. If the participant was transferred to a rehabilitation center, chronic care facility (or chronic care in the same hospital), the discharge date is the date of transfer. If the patient died, then record the date of death.

• Sources: Discharge or death summary; autopsy report.

<u>Item 3a</u>. Record the time of discharge (or date of death). If time provided in military time then convert to time in AM or PM and then choose '1' for AM or '2' for PM. If uncertain of time of

discharge, then provide closest time available on the day of discharge. RN discharge note would likely be the latest and most accurate time. If no time IS available from the day of discharge, then give "=" across all blanks. Do not use time from the physicians discharge note as this is likely the time the doctor dictated the note.

• Sources: Discharge or death summary or autopsy report.

For questions 4 and 5, you will be entering an ICD code. All ICD-9 diagnosis codes use a minimum of 3 digits, max. of 5 digits with a decimal point after the third digit so if there is no decimal then add one after the first 3 places. ICD-9 procedure codes use 3 or 4 numeric digits (except for supplementary codes – V and E codes). ICD-10 diagnosis codes use 3-7 alphanumeric, all codes using an alpha lead character (V and E codes have been incorporated into the main code set) and a decimal point after the third character as in the ICD-9 format. ICD-10 procedure codes use 7 alpha or numeric digits.

Item 4. Primary admitting diagnosis code: Enter the primary admitting diagnosis code. This is the ICD-9 code assigned to the main reason for the hospital admission or ED visit however, once admitted and tested the original diagnosis may change or be ruled out. It may be the same as the primary discharge diagnosis code, but not always. ED visits that do not result in admission will only have discharge codes, since the patient was not admitted. If this is an ED visit only, then give "=" across all blanks. Be sure to list the admitting diagnosis code from the face sheet. If there is not a face sheet or formal ICD-9 coding summary then you may see an assigned ICD code on the ED report, H&P or other sources listed below. Note: DO NOT assign an ICD code to the admitting diagnosis, if there is no ICD code assigned already then enter "=". Do NOT use the codes listed on the 2nd page of the HCHS/SOL Medical Records Documents Shipping Cover Form.

• Sources: Face sheet, ED report, H&P, hospital transfer documents, physicians' notes.

Item 5. Primary discharge diagnosis code. This is the ICD-9 or 10 code assigned to the main reason determined for the admission, usually found on the ICD coding summary page for every hospital admission. In the absence of an ICD coding summary page, refer to the discharge report. The admission diagnosis and discharge diagnosis may not be the same. The primary discharge diagnosis will be conclusive, based on all testing and treatment per admission or ED visit. Be sure to list the discharge diagnosis code from the face sheet. Occasionally if there is not a face sheet or formal ICD coding summary then you may use an assigned ICD code if there is one on the discharge summary or other sources listed below. If there is no actual ICD-9 code present then do not code diagnoses yourself, instead put '='. Do NOT use the codes listed on the 2nd page of the HCHS/SOL Medical Records Documents Shipping Cover Form.

• Sources: ICD summary page, Face sheet, ED report, hospital transfer documents, physicians' notes.

<u>Item 6.</u> Did an emergency medical service (EMS) unit transport the patient to this hospital? Record Yes (Y) or (N/NR) if the information is not specified in the documentation provided.

Note: A participant may travel to the hospital for an elective admission by ambulance because of a pre-existing condition or disability that requires special transportation (so the answer here is "Y"). An EMS unit may be public or private and staffed by EMTs or Paramedics. ("EMS Unit" includes helicopters but excludes private vehicle or taxi.)

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P

Item 7. Was the participant transferred to this hospital from another hospital, or from this hospital to another? Record Yes (Y), No (N/NR) if the information is not specified in the documentation provided. "Another hospital" means an acute-care facility to which the participant had been admitted. If the participant was transferred from a nursing home, skilled care facility, rehabilitation center, or another hospital's ER or outpatient clinic, answer "No" to this question. If you answer "Yes" to this question, complete another HCHS/SOL MIF form for the other hospitalization if the participant was admitted to the other hospital for a cardiac event or suffered such an event while in the other hospital.

• Sources: EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physician's and/or nurses' notes.

Item 8. Ever a "no-code" or "DNR" (do not resuscitate)? "Ever" means either in the ED or at anytime during the admission for this visit only. "No code" means that no cardioversion, intubation, or mechanical ventilation will be used in a life-threatening emergency. If the face sheet reports that there are no advance directives, then No can be reported here if you do not see latter evidence of DNR. If the MD's note states "Disposition: FC" then can record NO as FC stands for "Full Code". Synonyms include: Supportive care only, DNR (do not resuscitate), comfort measures only, palliative measures only, chemical care only, or "no extreme or heroic efforts". This is often a required administrative question that is asked of everyone admitted to the hospital so it may be in the admitting nurse's note or ED Triage page. If no mention of it, choose NR.

• Sources: Discharge or death summary, ED report, H&P, physician orders or notes.

Item 9. Was the patient alive at discharge? If No (0) complete 9a-c. If Yes (1) skip to Item 10.

Items 9a-c. Record the patient's vital status on arrival at the hospital (9a) or if the patient died in the emergency department (9b). If dead on arrival (DOA) or died in the emergency department record whether or not an autopsy was performed (Item 9c). If admitted to the floor, CCU, or ICU, record "No".

NOTE: If a patient is DOA (dead on arrival), an ER death (no matter what the circumstances or how long the patient was in the ER), or hospitalized with no vital signs and dies within 24 hours of admission, s/he is treated as an *out-of-hospital death*.

• Sources: ER report (if participant died in ER), discharge or death summary, autopsy report.

SECTION B: PRESENTING SIGNS AND SYMPTOMS

Items 10-16. refer to signs and symptoms (S/S) and the timing of such that are either increasing in severity or are new, not chronic stable conditions. In most situations, if a S/S is the primary reason for the ED or hospital visit then it is likely new and/or increasing. For example, if the medical record indicates the patient reports fatigue as a secondary problem but that it was not increasing (within the past 2 months) or new record No to Item 15. However, record Yes if there was worsening of symptoms even if it happened after admission. For example, a patient might have been brought to the ER complaining of shortness of breath then developed fatigue after hospital admission. In summary, items regarding "increasing or new onset" all follow the same rule: we are interested in new onset or increasing symptoms either before admission or at any time during the hospitalization. For the purpose of items 10-16., Record Yes if increased or new onset of S/S of acute condition is reported in the medical record at time of ED, hospital arrival or at an earlier evaluation immediately preceding admission (e.g. a note from a physician's office prior to a direct admit to the hospital), or anytime during the hospitalization. If the EMS report states signs and symptoms and they are not contraindicated in the E.R. report, use the EMS S/S. Record No if there is clear indication that a particular condition being questioned was NOT present on physical exam. Record NR (not recorded) if there is no documentation in the medical records for the item or if it is unclear based on the medical record that a condition was or wasn't present. In general, any documented description by any physician, nurse or emergency services personnel of an abnormal finding at the time of the event (although it needs to be new or increasing) for items 10-16 is sufficient to record Yes (hierarchy rules do not apply here). 'At the time of event' should generally be within approximately 1 day of presentation. If not sure of the timing of the S/S then use your judgment as to whether you think the S/S were temporally related to the event.

Item 10. Did the onset of the acute episode occur prior to admission (i.e.: arrival at the ER or before)? Answer No (0), Yes (1) or NR (9).

Item 10a. Choose the box that best corresponds to evidence in the medical record that estimates time from onset of symptoms of the acute condition to arrival at the hospital. If record states "for 24 hrs." choose \ge 24 hrs.'

• Sources: EMT/ambulance report, ER report, discharge or death summary, H&P, consult; physicians' or nurses' notes.

Item 11. Was there mention in the documentation for this admission of an acute CHD event (refer to definition of terms, pg. 6) with onset after arrival at the hospital? Answer No (0), Yes (1) or NR (9). For the purpose of this question, ER visits should be considered as in-hospital events (i.e.: if the participant experienced an acute CHD event after arriving at the E.R. but before admission, record Yes here).

• Sources: EMT/ambulance report, ER report, discharge or death summary, H&P, consult; physicians' or nurses' notes.

Item 12. Was there an acute episode(s) of pain or discomfort (e.g.: pressure, tightness, heaviness) anywhere in the chest, arm, shoulder, throat or jaw either within 72 hours prior to arrival at the hospital, or in conjunction with the in-hospital CHD event? This would include cardiac as well as non-cardiac chest discomfort. If chart says "no symptoms", or if there was a sudden collapse, record 'No'. If uncertain whether chest pain or discomfort is new, then assume that it is new since most acute pain or discomfort will be. Answer No (0), Yes (1) or NR (9). If N or NR, *skip to Item 13*.

- "Chest pain" synonyms are angina; chest tightness, pressure, discomfort or heaviness, or ischemic pain.
- This may be difficult to determine, if an exact time of pain onset is not recorded in the medical record. If time is not totally clear, follow standard procedures for recording "unknown" or estimated data.
- See "Definition of Terms," in document for details. If chart says "no symptoms," no S/S were documented by others witnessing the event or if there was a sudden collapse, record "No".
 - Sources: EMT/ambulance report, ER report, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

<u>Item 12a</u>. Record Yes if new onset or an increase in chest pain, ischemic pain or discomfort (e.g.: chest pressure, tightness, heaviness,) is recorded or if the medical record mentions any of the following: pleuritic chest pain, musculoskeletal chest pain, angina, angina pectoris, crescendo angina, unstable angina or angina-like pain within 72 hours prior to arrival at the hospital or in conjunction with the in-hospital CHD event. Chest pain may be recorded as "CP" in the medical record. For this to be Yes (or 1), the patient must have complained of chest pain. Do not include angina that presents with symptoms other than chest pain. Do not include epigastric pain. (If No or NR, *skip to Item 13*).

<u>Item 12b.</u> Pain get worse (crescendo) over time? Record Yes if the medical record mentions any worsening (crescendo) of the new onset or an increase in chest discomfort (as described in Item 12a) over time once symptoms were determined (for example: patient self-report, physical assessment, mention of crescendo angina).

<u>Item 12c.</u> Was the pain or discomfort diagnosed as having a non-cardiac origin? Possible non-cardiac sources include musculoskeletal pain, pleuritic (lung) pain, pericarditis, gastroesophageal reflux disease (GERD), esophageal spasm, etc. Answer Yes only if there is a definite, final conclusion that the pain was non-cardiac in nature.

• Sources: Discharge or death summary, consult; physician notes.

<u>Item 13.</u> Nausea? Record Yes if evidence in the medical record of new onset or progression of

nausea associated with this event of chest pain or discomfort otherwise record No or NR.

<u>Item 14.</u> Diaphoresis? Record Yes if evidence in the medical record of new onset or progression of diaphoresis with this event of chest pain or discomfort otherwise record No or NR.

<u>Item 15.</u> Fatigue or Malaise? Record Yes if evidence in the medical record of new onset or progression of fatigue or general feeling of malaise with this event of chest pain or discomfort otherwise record No or NR.

<u>Item 16a-16b.</u> Record the blood pressure and heart rate at arrival to hospital (or event onset) and not during CPR. If no values for either blood pressure or heart rate are found, enter (===),

• Sources: EMT/Ambulance report, ED triage or report, physician notes.

SECTION C. MEDICAL HISTORY

The purpose of this section is to record relevant past medical history (hx.) items. "History of' (H/O) is synonymous with a documented history of the disease that was present as a "pre-event" diagnosis prior to the hospitalization, e.g., most often listed under past medical history (PMH) section of the history & physical (H & P) note. History is defined as more than one month prior to the event. So for example, if the record indicates that the only previous event was within one month, this would not be considered a history. The patient's past history may be found in the physician's history and physical section, the admission note, the discharge report, or the ED report of the medical record. Conditions noted as newly present with the current hospitalization for which there was not a prior diagnosis should not be considered historical diagnosis and should not be counted in this section.

Item 17a. Was there a history of myocardial infarction prior to the onset of this event? Answer No/NR (0) or Yes (1). If No or NR, skip to Item 17b.

Synonyms or terms that describe myocardial infarction (MI) include:

acute myocardial infarction (AMI)
acute coronary syndrome (ACS)
heart attack
cardiac infarction
coronary artery embolism, occlusion, or rupture
sub-endocardial infarction
coronary occlusion
infarction of any wall segment of the heart
microinfarct of the heart
STEMI – ST segment elevation MI

Record Yes if the patient has a history of myocardial infarction (MI). Take information from the cardiologist (any type of note), the attending physician (any type of note) the resident, ED physician, and nurse in that order. If the patient has a transplanted heart, use the history of the individual (heart transplant recipient) not the history of the heart. For the purpose of this item, information that states previous silent MI, borderline heart attack, history of aborted MI, non-Q wave MI, and history of primary (emergent) angioplasty, thrombolytic therapy, or PCI should be considered as Yes. An abnormal ECG or angiogram evidence alone, stating old MI or MI whose "age is undetermined" cannot be used to determine history of MI unless verified by the physician that patient had or probably had a MI. However, a nuclear stress test or MRI scan that demonstrates an old myocardial infarction in a patient with known CHD *can be used* to document a historical diagnosis of MI (record Yes). Statements such as no cardiac problems, no adult illness, previously well, no previous history of heart disease, essentially unremarkable history are sufficient to record No.

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

<u>Item 17a1.</u> If Yes was recorded for Item 17a, is there evidence in the medical record of an MI occurring within four weeks of this current event/episode? Answer No/NR (0) or Yes (1).

Item 17b. Was there a history of angina pectoris or coronary insufficiency (insufficient blood flow through one or more of the coronary arteries)? Answer No/NR (0) or Yes (1). Record Yes if the medical record mentions any of the following:

angina angina, NOS angina pectoris stable angina unstable angina crescendo angina atypical angina anginal equivalent angina-type pain angina-like pain angina syndrome syndrome X pre-infarction angina microvascular angina nocturnal (also called variant or Prinzmetal) angina, which occurs when a person is at rest, usually at night, and is associated with acute myocardial infarction, severe arrhythmias, and sudden death chronic ischemic heart disease coronary insufficiency

sub-endocardial ischemia impending infarction acute coronary syndrome (ACS) arteriosclerotic heart disease chronic coronary artery insufficiency chronic myocardial ischemia chronic ischemic heart disease ischemic heart disease, NOS

If the patient is currently taking nitroglycerin (NTG) or calcium channel blockers <u>for chest pain</u> record Yes. Additional statements in the medical record that should be considered as Yes to this item include: substernal pressure, pain, tightness or burning, distress precipitated by exercise or excitement and/or relieved by rest or nitroglycerin (NTG). Statements such as "no history of angina" or "no history of heart disease" should be considered as No. "Chest pain" (CP) not otherwise specified is not sufficient (record No).

Item 17c. Hx. of PCI prior to this event? Percutaneous Coronary Intervention (PCI) or Coronary Artery Angioplasty is a procedure that uses an inflated balloon to compress plaque against the walls of the coronary artery, thereby widening the channel through which blood can flow. (A laser may also be used to perform coronary artery angioplasty, but this is rare.) This procedure is also called balloon angioplasty, balloon dilation, or percutaneous transluminal coronary angioplasty (PCTA). PTCA is always preceded by cardiac catheterization. Coronary stents are often used in PCI procedures following balloon angioplasty. Coronary stent placement is the placement of a wire mesh tube (stent) to hold open an artery during and/or after angioplasty or coronary bypass surgery. The stent is collapsed to a small diameter, placed over an angioplasty balloon catheter and moved into the area of the blockage. When the balloon is inflated, the stent expands, locks in place and forms a scaffold that holds the artery open. Different types of stents may be used and include, but are not limited to, mesh stents, slotted-tube stents, coil stents, multidesign stents, and bioabsorbable stents. Record Yes if there is evidence in the medical record of history of PTCA or No or NR if there is no mention of this procedure or there is not enough evidence.

Item 17d. History of CABG prior to this event? Coronary artery bypass surgery (also called coronary artery bypass grafting, or CABG) is heart surgery in which a blood vessel or a section of blood vessel is grafted onto one of the coronary arteries and connected to the ascending aorta to bypass a narrowing of, or blockage in a coronary artery. Record No/NR or Yes. If there is evidence in the medical record of history of CABG prior to this event. Synonyms for CABG: coronary bypass, coronary artery bypass graft. Bypass grafts usually include saphenous veins (SVG), internal mammary arteries (left = LIMA, right = RIMA), radial arteries, etc.

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

Item 17e. Is there a history of other chronic ischemic heart disease? Record No/NR or Yes. This refers to coronary artery disease (CAD) or ischemic heart disease (IHD) not specified as angina or MI - includes CHF described as due to coronary disease or ASHD (Atherosclerotic Heart Disease). Record No if a history of CAD, CHD, or IHD is ruled out. Record No if patient only has heart murmur. CHF due to hypertension or other reasons is "No". Arrhythmias are "No." Terms to look for include:

Angina

Angina pectoris

Crescendo angina Atherosclerotic cardiovascular disease

Atherosclerotic heart disease

Coronary atherosclerosis

Coronary insufficiency

Myocardial infarction (MI), (AMI)

Nonobstructive coronary atherosclerosis

Coronary artery bypass graft (CABG) surgery

Percutaneous transluminal coronary angioplasty (PTCA)

Coronary angioplasty

Directional coronary angioplasty (DCA)

Percutaneous coronary Intervention (PCI)

Coronary atherectomy

Prinzmetal angina

Stable or chronic angina

Unstable angina

Variant angina

Anginal equivalent

Acute coronary syndrome (ACS)

Syndrome X (clinical syndrome with angina-like chest pain on exertion, ECG evidence of ST segment depression on treadmill exercise testing but normal coronary angiography w. no coronary artery spasm with pharmacological stress testing).

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

<u>Item 17.f.</u> Heart failure. Congestive heart failure is a condition in which the heart cannot maintain the blood supply required by tissues for oxygenation leading to a back-up of blood in vessels and accumulation of fluid in the body tissues, including the lungs. If pulmonary edema is unequivocally due to malignancy, or if it is referred to as "minimal," answer "No."

Synonyms or terms that describe congestive heart failure (CHF) include:

Congestive cardiomyopathy Congestive heart disease Right heart failure Right heart failure, secondary to left heart failure Left heart failure Left ventricular failure Heart/cardiac/myocardial failure, NOS Low cardiac output Pulmonary edema

Review the physician's notes, history and physical, and the discharge summary for evidence of a prior diagnosis of heart failure. "Prior" refers to a physician's diagnosis prior to the onset or worsening of symptoms that brought the patient to the hospital. For the purpose of this question, a mention that the patient has a history of heart failure diagnosed and treated as an out-patient is sufficient evidence to record Yes to Item 17f. In the case of patients developing symptoms in the hospital, "prior" refers to prior to this hospitalization in which the symptoms developed. Evidence of a prior physician diagnosis of heart failure is required to record Yes to item 17f. Record No if the patient does not have a history of heart failure. If there was no mention of previous heart failure in the medical record, indicate this as not recorded (NR). History is defined as more than 1 month prior to the event. If the record indicates that the only previous heart failure was within 1 month, this would not be considered as a history of heart failure. If, after reviewing the medical record, it is unclear as to whether there was a history of heart failure or there is contradictory evidence, record No/NR.

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

<u>Item 17.g</u>. Arrhythmia. Review the medical record for evidence of a history of any of the following forms of cardiac arrhythmias. IF Yes, specify type of arrhythmia.

Item 17.g.1. Arial Fibrillation/Flutter. Record Yes if evidence of history of Atrial Fibrillation or Atrial Flutter ("A-fib") is a condition of rapid, uncoordinated contractions (350–600/minute) of the muscles in the atria. Atrial flutter ("a flutter" or "AF") is a condition of organized, rapid contractions (200–400/minutes) of the atria. An ECG may be read as showing flutter waves (having a sawtooth appearance) which is adequate to record Yes. AF (referring to both conditions) may be persistent or intermittent and may be symptomatic or asymptomatic. Record Yes if there is evidence of history in the medical record of either atrial fibrillation ("A fib") or atrial flutter ("A flutter"). Include here "supraventricular tachycardia (SVT)", "atrial tachycardia (AT)", and "paroxysmal atrial tachycardia (PAT)". If no evidence of such arrhythmias, then record No or N/R.

Note: Record Yes if evidence of history of ablation procedure/s to treat atrial arrhythmias. Otherwise record No or NR. Ablation may be a surgery or non-surgery in which something is destroyed, however here record Yes for a heart-related ablation which is used to treat arrhythmias (specifically atrial fibrillation/flutter). It is used to treat many different types of arrhythmias by "disconnecting" the pathway of the abnormal rhythm. It may be referred to as a radiofrequency ablation. The surgical procedure for ablation is called MAZE procedure, modified MAZE procedure, or minimally invasive surgical ablation.

<u>Item 17.g.2.</u> Record Yes if evidence of history of Ventricular Fibrillation/Tachycardia.

Ventricular tachycardia (VT) is an abnormal rapid ventricular rhythm with aberrant ventricular excitation, usually above 150 beats per minute, generated within the ventricle, and most often associated with atrioventricular (AV) dissociation. Ventricular fibrillation (VF) is a chaotic rhythm, often leading quickly to death. In both conditions, the QRS duration is prolonged (>120 msec). Other ventricular rhythm abnormalities that should be considered as Yes to item 17.g.2. include wide complex tachycardia (but not "supraventricular tachycardia (SVT) with aberrancy"), Torsades de pointes, monomorphic VT or polymorphic VT. Asystole is the sudden and complete cessation of cardiac function. Cardiac arrest is the cessation of heart pumping due to arrhythmia, most commonly ventricular fibrillation. If there is evidence of history of asystole, cardiac arrest. If the medical record shows evidence of history of asystole, cardiac arrest, 'resuscitated cardiac arrest' record Yes to Item 17.g.2. If the record mentions a history of "sinus asystole" or "sinus pause," this is NOT asystole. Asystole as part of a surgical protocol should be answered No. If the medical record shows no evidence of such arrhythmias such as those described above then record No or N/R.

Item 17.g.3. Other arrhythmia – Record Yes if there is evidence in the medical record of history of heart block, other bradycardia or other arrhythmias. Bradycardia is defined as heart rate < 60 bpm, although elite athletes can have normal heart rates as low as 30 bpm. A mention in the medical record by the physician of heart block, high degree atrioventricular (AV) block, severe bradycardia, or severe sinus bradycardia (heart rate <40 bpm) is required to record Yes to 17.g.3. Other terms if found in the patient's history, that are sufficient to record Yes to this item include third-degree AV block, complete heart block, second-degree AV block, Type I second-degree AV block (Wenckebach/Mobitz I), Type II second-degree AV block (Mobitz II), AV block with low ventricular response, sick sinus syndrome (SSS), and tachybrady (tachycardia-bradycardia) syndrome . Record No if the only bradycardia that is mentioned is sinus bradycardia of 40-60 bpm.

Left bundle branch block is an abnormality in the conduction pattern of the QRS complex which is characterized by a prolonged QRS duration (>120 msec). Do NOT include "incomplete LBBB", "right bundle branch block (RBBB)", "nonspecific interventricular conduction delay (IVCD)", "bifascicular block", "trifascicular block", or "hemiblock". Record Yes if there is evidence of left bundle branch block (LBBB).

Supraventricular tachycardia (SVT) or multifocal atrial tachycardia (MAT) includes all forms of tachycardia that either arise above the bifurcation of or are dependent on the bundle of HIS. Record Yes if there is evidence of "supraventricular tachycardia (SVT)", "atrial tachycardia (AT)", and "paroxysmal atrial tachycardia (PAT)", supraventricular tachycardia (SVT) or paroxysmal supraventricular tachycardia (PSVT). This will have to have been read from a 12-lead ECG by a trained health care provider or diagnosed by a physician that reviewed telemetry tracings. If there is evidence of no history of these or other arrhythmias, record No or N/R.

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

D. ACTIVE OR CURRENT MEDICAL PROBLEMS (DURING THIS HOSPITALIZATION)

<u>Item 18</u>. Physician's indication of any of these conditions as being present <u>during</u> the hospitalization? This section is to identify current or active problems anytime during this visit to the ED or hospital. If there is a prior history, but it is not an active problem then record No/NR. If there is a prior history and you are not sure if the condition is currently active then record No/NR.

• Sources: Face sheet, EMT/ambulance report, ER record, discharge or death summary, H&P, hospital transfer documents, physicians' and/or nurses' notes.

Item 18a. Angina. Record Yes if the medical record mentions any of the following: angina, angina pectoris, crescendo angina, atypical angina, anginal equivalent, unstable angina, anginatype pain, angina like pain, or syndrome x as having occurred during this visit to the ED or hospital (or any additional terms listed in item 17b). If the patient was given nitroglycerin (NTG) or calcium channel blockers for chest pain while at the ED or hospital record Yes. Additional statements in the medical record that should be considered as Yes to this item include: substernal pressure, pain, tightness or burning distress precipitated by exercise or excitement and/or relieved by rest or nitroglycerin (NTG). Statements such as "no history of angina" or "no history of heart disease" should be considered as No. "Chest pain" not otherwise specified is not sufficient (record No).

<u>Item 18b</u>. Acute Myocardial Infarction. Record Yes if the medical record mentions any of the following:

Synonyms or terms that describe myocardial infarction (MI) include:

- acute myocardial infarction (AMI)
- acute coronary syndrome (ACS)
- heart attack
- cardiac infarction
- coronary artery embolism, occlusion, or rupture
- sub-endocardial infarction
- coronary occlusion
- infarction of any wall segment of the heart
- microinfarct of the heart
- STEMI S-T segment elevation MI
- NSTEMI non S-T segment elevation MI

Item 18.c. ST elevation > 1mm with pain that is not present on ECG without pain. ST elevation on an ECG often means cardiac ischemia, especially if anginal pain is present. However, sometimes ST elevation may be present continuously and not indicative of ischemia. If the MD clearly states the presence of ST elevation >1mm with pain that is not present on ECG without pain, record Yes. If ST elevation is absent, or if ST elevation seems to persist even when pain is gone, record "No." If the MD describes ST segment elevation during pain, but does not describe the ST segments without pain, you may also answer "Yes." Obviously, ECG descriptions may be incomplete and you must use your best judgment, in some cases recording N/R.

<u>Item 18.d.</u> Congestive heart failure (CHF) exacerbation or pulmonary edema. When the heart cannot maintain the blood supply required by tissues for oxygenation, it leads to a backup of

blood in vessels and accumulation of fluid in the body tissues, including the lungs. If there is evidence in the medical record of CHF or pulmonary edema, record Yes. If pulmonary edema is unequivocally due to malignancy, or if it is referred to as "minimal," answer No. If there is not enough evidence to make an accurate judgment of the presence of the condition during this hospital visit, record N/R.

Synonyms or terms that describe congestive heart failure (CHF) include:

congestive cardiomyopathy
congestive heart disease
right heart failure
right heart failure, secondary to left heart failure
left heart failure
left ventricular failure
heart/cardiac/myocardial failure, NOS (not otherwise specified)
low cardiac output
pulmonary edema

<u>Item 18.d.1</u>. If the answer to Item 18d. is Yes, does the medical record show that either or both of these conditions occurred within 24 hours of the onset of the event? If so, record Yes, otherwise record No or N/R.

<u>Item 18.e.</u> Shock or cardiogenic shock is the failure of the heart to maintain blood supply to the circulatory system and tissues because of inadequate output.

Synonyms or terms that describe shock or cardiogenic shock include:

severe pump failure cardiac shock

If there is evidence in the medical record of this condition, record Yes. If the term "septic shock" is used, answer "No."

<u>Item 18.e.1</u>. If the answer to Item 18e. is Yes, does the medical record show that shock or cardiogenic shock occurred within 24 hours of the onset of the event? If so, record Yes, otherwise record No or N/R.

<u>Item 18.f.</u> Ventricular fibrillation, cardiac arrest or asystole. Ventricular fibrillation is a condition in which disordered electrical activity causes the ventricles to contract in a rapid, unsynchronized, uncoordinated fashion. When this occurs, little or no blood is pumped from the heart. Cardiac arrest is the cessation of heart pumping due to arrhythmia, most commonly ventricular fibrillation. Asystole is the sudden and complete cessation of cardiac function. If there is evidence in the medical record of any of these conditions record Yes. Otherwise record No or N/R. If the participant has "sinus asystole," "sinus pause," this is not asystole. Asystole as part of a surgical protocol should be answered "No."

<u>Item 18.f.1</u>. If Yes, did ventricular fibrillation occur within 24 hrs. of event onset? If the answer to Item 18f. is Yes, does the medical record show that ventricular fibrillation, cardiac arrest or

asystole occurred within 24 hours of the onset of the event? If so, record Yes, otherwise record No or N/R.

<u>Item 18.g.</u> Ventricular Tachycardia is orderly rapid ventricular beating. If there is any evidence in the medical record of this condition record Yes. Otherwise record No or N/R.

<u>Item 18.h.</u> Atrial Fibrillation or atrial flutter. Atrial fibrillation (AF or A-fib) is a condition of rapid, uncoordinated contractions (350–600/minute) of the muscles in the atria. Atrial flutter (AF) is a condition of organized, rapid contractions (200–400/minutes) of the atria. AF may be persistent or intermittent and may be symptomatic or asymptomatic. If there is evidence in the medical record of either or both of these conditions record Yes. Otherwise record NO or N/R.

E. BIOMARKERS

Item 19. Were any cardiac enzymes reported within days 1-4 after arrival at the hospital or after the in-hospital CHD event? Answer No or not recorded (0) or Yes (1). If No or NR, <u>skip to Item</u> 30.

Cardiac enzymes are intracellular proteins that are released into the blood stream when there is damage to the cells of the heart muscle. They may include:

- creatinine phosphokinase (CPK) or creatinine kinase (CK) Synonyms: Total CPK, CPK, creatine phosphokinase, CK, creatine kinase, CKI. Total CK has heart (MB), skeletal muscle (MM) and brain (BB) fractions. If MB, MM and BB are given separately, add them to obtain Total CK.
- creatine phosphokinase isoenzymes (CK-MB) Synonyms: CPK-MB, CK-heart fraction
- Total LDH lactate dehydrogenase (LD or LDH)
- LDH1 and LDH2 fractions of LDH. Synonym for LDH1 is heat stable LDH (There are three other fractions of LDH, 3–5, which are not of interest at this time)
- troponins (T or cTNT; I or cTNI & High Sensitivity Troponin (HS))

<u>Creatine phosphokinase (CPK)</u> is an organ-specific enzyme found mainly in the heart, brain, and skeletal muscle which catalyzes the transfer of a phosphate group from phosphocreatine to ATP. It has three isoenzymes: CK_1 , found primarily in the brain; CK_2 , found in the myocardium; and CK_3 , found in both skeletal muscle and the myocardium. In humans, the presence of CK_2 in the blood is useful in diagnosing a recent myocardial infarction, but in animals CK_3 is most commonly increased related to muscle damage. Also called creatine phosphokinase, and Lohmann's enzyme.

<u>Total CK</u> - *Synonyms:* creatinine kinase (CK), creatinine phosphokinase (CPK), Total CPK Total CK has heart (MB), skeletal muscle (MM) and brain (BB) fractions. If MB, MM and BB are given separately, add them to obtain Total CK.

<u>CK-MB</u> - Synonyms: creatine phosphokinase isoenzymes (CPK-MB), CK-heart fraction

Possible units are: Units/ml or I.U. Special units may include: negative/positive, absent/present, normal/abnormal, negative/weak, positive/positive, absent/weak, present or trace/present, normal/high normal/abnormal, absent/small/moderate/large.

The result may also be reported as a percent or decimal proportion of total CK.

<u>Lactate dehydrogenase</u>: (LD or LDH) An enzyme that catalyzes the conversion of lactate to pyruvate. This is an important step in energy production in cells. Many different types of cells in the body contain this enzyme. Some of the organs relatively rich in LDH are the heart, kidney, liver, and muscle. As cells die, their LDH is released and finds its way into the blood.

<u>Total LDH</u> - Synonyms: Lactate dehydrogenase, (LD or LDH)

Possible units are: Units/l or I.U.

<u>LDH1</u> and <u>LDH2</u> – These are fractions of LDH. - Synonym for LDH1 is heat stable LDH

Possible units are: Units/l or I.U.

The results may also be reported as a percent or decimal proportion of total LDH.

Troponins (I or cTNI; and T or cTNT):

<u>Troponin I (ng/mL)</u>. Troponin (Tn I) is a complex muscle protein, which when combined with Calcium ions influences the contraction of heart muscle. It is normally not found in blood. Its detection in the circulation is a marker for myocardial cell damage. Record the value of troponin I (as ng/mL) reported in the medical record. Record NR (enter ===), if a value for troponin I was not available or performed during the course of this hospitalization. Record the upper limit of normal from the hospital record in item 42.c. If the upper limit of normal is described as "less than" a value, record the '<' sign). When numbers are preceded by a greater-than (">") sign, use the highest value recorded. Reference levels: 0.01-0.5 ng/mL. but can vary by assay used.

Troponin T (ng/mL). Troponin (TnT) is a complex muscle protein, which when combined with Calcium ions influences the contraction of heart muscle. It is normally not found in blood. Its detection in the circulation is a marker for myocardial cell damage. Record the value of troponin T (as ng/mL) reported in the medical record. Record as missing (enter ===) if a value for troponin T was not available or performed during the course of this hospitalization. Record the upper limit of normal from the hospital record in items 20f1. and 21f1. If the troponin value is described as "less than" a value, choose '1' for the '<' sign or '0' if no "less than" sign is present for items 22f – 29f. When numbers are preceded by a greater-than (">") sign, use the highest value recorded. Reference level: <0.029 ng/mL. but can vary by assay used.

<u>High Sensitivity Troponin (HS).</u> While there are no FDA-approved high-sensitive assays, there are many in development and being used for research use only. Their use has been shown to diagnose MI earlier and provide greater prediction of death or future MI as well as an improvement in risk stratification. It should be noted that the improvement in sensitivity is at the expense of specificity.

• Sources: Lab report. Record only cardiac enzyme results from the first four days after

Use the lab report as your primary source; if this document is not available, use results described in consults, discharge or death summary, or H&P only if the actual results cannot be located (unlikely).

For Items 20-21: Record ONLY the upper limit of normal (ULN) range on the lines for Range Set 1 **Biomarker Laboratory Standards**. *Units may be expressed as 1, 2 or 3 (i.e.: 1 = ng/mL, 2 = Units/L or $3 = \mu g/L$) When more than one upper limit of normal range is given, record those on the lines for Range Set 2 **Biomarker Laboratory Standards** in Item 21, again using the digits 1-3 as described above to discern the type of units expressed. ULNs are used to compute abnormal and borderline results.

Daily Biomarker Measurements

Items 22-29. Record serial cardiac enzymes in chronological order, days 1 through 4 of hospital admission.

For items 22 and 23: Record the actual laboratory values for the 1st and second set (if available) of cardiac enzymes drawn on Day 1 of arrival at the hospital. Repeat for Day 2 of arrival at the hospital (Items 24 & 25), Day 3 of arrival at the hospital (Items 26 & 27) and Day 4 of arrival at the hospital (Items 28 & 29). Remember to use the digit representing the *type of units* the value was expressed in as 1(ng/mL), 2 (Units/L) or 3 (μ g/L) as well as the correct digit to represent the range set pertaining to those values (choose either the digit 1 for the range set in Item 20 or the digit 2 for the range set in Item 21).

Note: When a value is recorded using words rather than numerals, use the following codes to record the value: absent/negative/normal = 1, trace/weak positive = 2, present/positive/abnormal = 3.

Recording Procedure

Occasionally, there may be more than one method used by a hospital to measure a particular enzyme, (e.g., a total LDH, may be done as part of the admission battery and also as part of the cardiac enzyme routine), with differing normal ranges with each test. List them as indicated and use the second range set. If enzymes are available in both units and percentages, <u>units are</u> preferred.

If an enzyme is not measured, leave the corresponding blocks blank. If Troponin value is greater than 100, enter 100.

You do not need to zero fill. Leading and trailing zeroes can be omitted.

Record <0.1 as 0.1. If no '<' symbol is present or can be verified (as in a handwritten notation) then it should be considered missing (= on the form, 0 in the DMS).

In cases where an enzyme (LDH or CPK) is reported both as an SMAC profile (Sequential Multiple Analysis – a somewhat outdated term) ¹ and as part of a specific isoenzyme battery, record the latter value for the total enzyme.

Record the highest patient values for each enzyme in chronological order. (The sequential acquisition number often stamped on the lab reports may be useful in clarifying order.) If no time is listed, follow standard procedures for recording "unknown" or estimated data.

Note: For f.4. of each Item 22-29, indicate what type of Troponin it was:

- 1. Troponin, type not specified
- 2. Troponin I
- 3. Troponin T
- 4. High Sensitivity Troponin (HS)
- 5. or Unsure

Item 30a-g. Is there mention of the patient having either trauma, a surgical procedure, or rhabdomyolysis, within one week prior to measurement of biomarkers? Answer No/NR (0) or Yes (1). If N or NR, *skip to Item 32*.

The intent of this question is to determine if there has been damage to muscle. "Measurement of the cardiac enzymes" refers to any of the biomarkers that are listed in Section E. Answer "Yes" even if the participant was already hospitalized, then experienced a trauma and within one week had his/her cardiac enzymes measured. Add the date of the trauma or muscle damage or enter (===) if date is not available.

"Trauma and surgical (invasive, cutting) procedures" include:

- major surgery
- cardioversion
- CPR
- coronary artery bypass graft (CABG)
- defibrillation
- crushing injury
- extensive bruising
- electrical injury
- seizure
- muscle-penetrating laceration
- cardiac catheterization/PTCA/stent placement (if all of these were done as part of a single procedure, record as a single procedure)

Answer "Yes" for CPR or BLS only if compressions were included.

"Rhabdomyolysis" is the destruction of skeletal muscle cells, often the result of electrical injury, alcoholism, injury (or lying in one position for an extended period of time), drug side effects, toxins or hypothermia.

Answer "No" for the following:

- intramuscular (IM) injections
- insertion of a Swan-Ganz catheter or pacer (may be found on anesthesia record or CXR)
- minor trauma such as scrapes, cuts, nicks
- psychological trauma
- dialysis

- dental surgery
- lumbar puncture (LP)

If Yes, specify the type of trauma or procedure in the text box(es) and the date(s) of occurrence in items 30a.–g.

• Sources: ER report, discharge or death summary, consult, H&P, autopsy report.

Item 31. Enter the item number from the biomarkers section of this form (items 22-29) corresponding to the first biomarker measurement performed after the trauma, cardiac procedure or rhabdomyolysis (including when a participant was already hospitalized, then experienced a trauma and within one week had his/her cardiac enzymes measured). Enter (===) if not known.

Item 32. Is there evidence of hemolytic disease during the hospitalization? Answer No/NR (0) or Yes (1).

• Sources: Discharge or death summary, consult, H&P, autopsy report.

"Hemolytic disease" includes or may be described as:

- hemolytic anemia
- disseminated intravascular coagulation (DIC)
- myelophthisic anemia

"Hemolytic disease" does *not* include:

- pernicious anemia
- macrocytic anemia
- normocytic anemia
- microcytic anemia
- chronic simple anemia
- anemia due to chronic renal failure (CRF)

<u>Item 33</u>. Did the participant have any active liver disease (cirrhosis, hepatitis, liver cancer, etc.)? Answer No/NR (0) or Yes (1).

"Active liver (hepatic) disease" includes or may be described as:

- cirrhosis
- Laennec's cirrhosis
- alcoholic liver disease
- acute or chronic hepatitis
- liver cancer or carcinoma
- hepatoma
- liver metastasis(es)

Sources: ER report, discharge or death summary, consult, H&P, autopsy report.

F. ELECTROCARDIOGRAPHY

Item 34a-g. Were any 12 lead ECGs taken during this admission? Answer No (0), Yes (1) or NR (9). If N skip to Item 35. If you answer "Yes" to this question, enter the corresponding dates the

ECGs were recorded and if a copy of the tracings were available in the case materials. (If this is an in-hospital event, then the first ECG is at time of event). ECG history is across the hospitalization. Record Yes if an electrocardiogram (ECG or EKG) was performed since hospital arrival or the onset of an in-hospital event up to the time of hospital discharge date and include the first, second, third and last ECGs taken in order (record dates), with the first ECG at time of event. This includes 12 lead ECGs or rhythm strips, but does not include telemetry monitoring without a paper tracing unless confirmed by a physician. Record No if no ECGs are found in the medical record.

- *Sources: ECG report(s).*
 - Good copies of ECGs will be needed. Note the dates and the chronological order in which each was done (e.g., first, #2, #3, last.
 - If a procedure or test was performed as part of the person's participation in a medical study, the results of that procedure/test should still be abstracted for HCHS/SOL. For example, if a participant is admitted to the hospital for a cardiac-related event and while there is asked to join a medical study and undergo a test for that study, then the results should be abstracted, even if the reason for the test was unrelated to the original reason for admission.
 - Ideally the chart contains de-identified copies of the FIRST (Item 34a.), SECOND (Item 34c.) and THIRD (Item 34e.) ECG tracings closest to the event. These should be attached later to the physician reviewer's summary report.
 - If three or fewer tracings were made, include all tracings. When there are only three ECGs, list the two tracings closest to the event in date/time order in Items 34a and 34c. If the third ECG was taken within 24 hours of the event, list it in Item 34e. If the third tracing was taken later than 24 hours after the event, Item 34e should remain blank (enter = signs in the field) and the third ECG listed in Item 34g 'Last ECG'.
 - If more than three tracings were made:
 - 1. In Items 34a, 34c and 34e, list the first three tracings starting at the time of the event and taken at the hospital or in the ED.
 - 2. List the last tracing prior to discharge or death in Item 34g.

If the participant is readmitted (transferred) to the ICU/CCU because of a new episode of chest pain, the first ECG tracing may be included in the physician reviewer's summary report.

• Even though only a maximum of four ECGs can be listed on the abstraction form, additional significant ECGs may be included in the physician reviewer's summary report.

Record Yes if there is evidence of 12-Lead ECGs being taken even if not included in the chart

G. PROCEDURES AND DIAGNOSTICS

Were any of the following special procedures or operations performed during this hospitalization? Answer No/NR (0) or Yes (1) - mark all that apply for items 35. - 38.

Item 35 - Transthoracic echocardiogram (TTE, cardiac ultrasound, echocardiography) and Item 35a. LV Ejection fraction: LV: % . A transthoracic echocardiogram (echo, TTE) is an ultrasound test of the heart where images are obtained through the chest wall. The results of this study describe the structures of the heart and the function of the ventricles (systolic or contractile function, diastolic function or relaxation) and of the valves. Record Yes if a TTE was performed during this hospitalization, otherwise record "No/NR" and skip to Item 36. If more than one TTE study is documented in the medical record, complete the following information based on the TTE study with the worst finding (defined as the echo study with the lowest LVEF) performed after the onset or progression of the event. Record NR (enter ===) if LVEF is not available. However, if the physician's interpretation states "normal" and a normal range is indicated on the report, record the lowest value of the normal range (e.g., if the normal range is between 55-90%, record "55").

If there is only one TTE study which was performed during this hospitalization before the onset or progression of heart failure, record Yes and the LVEF. An official echo report is one signed (electronically or in ink) by an MD. If there is <u>no</u> official echo report available, record the lowest EF and the worst findings based on whatever information you have; however, if there is a disagreement that looks significant (e.g., a difference of EF by 10% or more, no regurgitation versus severe), a cardiologist's interpretation in the notes is superior to any other interpretation by a non-cardiologist.

<u>Item 36</u> - Nuclear Medicine - also called radionuclide ventriculography cardiac blood pooling imaging (RVG or RNV), nuclear heart scan, **multi-gated acquisition (MUGA)** scan, (or SPECT) is a nuclear medicine imaging procedure done to evaluate cardiac function.

A cardiac radionuclide ventriculogram (RNV or RVG) is a noninvasive nuclear medicine test of the heart where a radionuclide is injected into a patient's vein to obtain an exact measurement of the left and right ventricular ejection fraction. Synonyms for this test include "multiple gated blood pool acquisition scan", "MUGA", or "MUGA scan" (A cardiac PET scan does not count as an a RNV). Record Yes if an RNV or RVG was performed during this hospitalization. Record No/NR if there was no mention of this study *and skip to Item 37*.

<u>Item 36 a & b.</u> Record the estimated left ventricular (LV) ejection fraction and right ventricular (RV) ejection fraction in %. In general, an exact number will be provided. However, if a range or multiple values are given, use the lowest (i.e., worst) value (e.g., if "30-35%", record "30"). Enter equal signs (===) if EF is not available.

<u>Item 36c</u>. Stress test positive for ischemia? Record Yes, No or N/R. 1 mm or more of ST depression on the ECG is the usual criterion for a positive test. Record "Yes" if present or if test result is "positive," "ischemic ECG changes," "abnormal," "significant ST depression," etc. Note, however, that a stress test for ischemia can be negative per ECG but be positive per imaging. Record "Yes" if the participant had an imaging procedure (i.e., nuclear medicine) performed and the imaging revealed "abnormality consistent with ischemia," etc., even if the

ECG did not show ischemic changes. Item 37. A stress test is a noninvasive cardiac test to assess for active coronary ischemia or coronary blockages by stressing the heart using either exercise (exercise stress test) or medications (pharmacological stress test. Stress tests can be done using echocardiography ("stress echo", "dobutamine stress echo"), nuclear imaging ("nuclear stress test"), or cardiac MRI ("cardiac MR stress test"). An exercise (treadmill) stress test is a test of heart function with a stationary bike, treadmill or handgrip while monitoring electrocardiogram. This sometimes includes an injection of thallium, a radioactive agent that indicates adequacy of blood flow to heart muscle with and without exercise (also called stress test, treadmill or stress thallium). Record Yes if any stress test (treadmill, pharmacologic, or nuclear medicine) was performed during this hospitalization. Include thallium exercise test in Item 37. Record No/NR if there is no mention of this type of study *and skip to Item 38*. Note: MUGA or RNV is not a nuclear stress test. If two stress tests were performed, use the one that gives the most information.

<u>Item 37a</u>. Record the left ventricular ejection fraction in % if stress test was performed.

Item 37b. If stress test, was it positive for ischemia? Record Yes, No or N/R.

<u>Item 37c</u>. Record whether there was greater than or equal to 1mm ST depression or elevation on ECG during stress test.

Item 37d. Record Yes, No or N/R if ischemic pain or equivalent occurred during stress test.

Item 38. - Coronary angiography (also called angiography of the heart, cardiac angiography, and coronary arteriography)— an invasive procedure of the heart where a catheter is inserted into an artery and advanced to the coronary arteries to assess for coronary blockages. The catheters can be used to measure pressures in, and the function of, the left ventricle (during a "left ventriculogram" or "left ventriculography"), the pressures in the aorta (during an "aortogram" or "aortography"), as well as to assess the function of mitral and aortic valves. Synonyms for coronary angiography include "left heart catheterization (cath)", "coronary catheterization", and "coronary arteriography". This test is usually performed in a cardiac catheterization laboratory ('cath. lab'), and there will be a separate report that describes this procedure and the results. Both actual coronary catheterization reports and descriptions of left heart catheterization reports are sources for this section; but if both are present, the actual report should be used. If a person had a percutaneous coronary intervention (PCI, PTCA, coronary stent) during the hospitalization, record Yes. If more than one coronary angiography procedure is performed during this hospitalization (e.g., there is both a diagnostic procedure followed by an interventional procedure like percutaneous coronary intervention, PCI), record most of the items from the first, diagnostic one. Record "No/NR" if there is no mention of this procedure, and skip to Item 39. *Note:* do not include CT angiography.

<u>Item 38a</u>. Date - Record the date the coronary angiogram or left heart catheterization (LHC) was performed.

Item 38b. Ejection fraction - This refers to the left ventricular ejection fraction (LVEF) assessed

during the "left ventriculogram" or "left ventriculography" part of the LHC. Record the EF in percent (%) in the space provided. If a range or multiple values are given, record the lowest (i.e., worst) value (e.g., if "30-35%", record "30"). If "greater than (>)" or "less than (<)" description is used, record the next numeric value (e.g., if ">55%", record 56; if "<20%", record "19"). Enter equal signs (===) if EF is not available. If the physician's interpretation states "normal" and a normal range is indicated on the report, record the lowest value of the normal range (e.g., if the normal range is between 55-90%, record "55"). If the ejection fraction is described as "low" with no quantitative estimate, enter equal signs (===).

Item 38c. Record Yes, No or N/R if 70% or greater obstruction is documented for any coronary artery. Coronary stenosis refers to the amount of blockage, organized in terms of each of the major coronary arteries and their related branches. In general, look for the documented % stenosis within the given categories whenever possible, whether it is located in the quantitative portion or the text portion of the report. Of note, a "stump" is synonymous with occluded (100%). If there are multiple stenoses described for the same artery and its related branches, use the highest (i.e., worst) stenosis grade to choose the category (0%, 1-24%, 25-49%, 5074%, 75-94%, 95-99%, 100%, NR). If there is more than one report, record the highest blockage among the reports. If the coronary artery or its branches are described as "normal" or "no significant disease", record "0%". If a coronary artery or its branches are described as diseased (stenotic) in terms of severity, but no exact % stenosis is given, record the % stenosis according to the following grading system:

- "normal or none" = 0%
- "mild" = 1-24%
- "mild-to-moderate" or "intermediate" = 25-49%
- "moderate" = 50-74%
- "severe" = 75-94%
- "subtotal" = 95-99%
- "occluded" = 100%.

If a coronary artery is described as "diffusely diseased" but no further specifics are provided (e.g., no exact % stenosis), record the % stenosis according to the following grading system:

- "Unspecified or "mildly diffusely diseased" = 1-24%
- "Moderately diffusedly diseased" = 50-74%
- "Severely diffusedly diseased" = 75-94%
- "Widely patent" = 0%.

If specific coronary arteries are not individually described but there is an overall description about them (e.g., all coronaries were widely patent or diffusely diseased), use the above grading system for each coronary artery. Record NR if there is no mention of an artery and its anatomy.

<u>Item 38d.</u> Coronary bypass grafts present? This refers to the surgical coronary artery bypass grafts that are evaluated during coronary angiography in patients who have undergone coronary artery bypass grafting surgery (CABG). Bypass grafts include arterial bypass grafts (e.g., left internal mammary artery [LIMA], right internal mammary artery [RIMA], radial arteries,

gastroepiploic artery), as well as saphenous vein grafts (SVG). Record Yes if grafts were assessed during the procedure. Record No/NR if there are no bypass grafts (in a patient who has never undergone CABG) or if bypass grafts were not assessed during the procedure.

Item 38d.1 If Yes, record the number of occluded bypass grafts (100% stenosis) assessed during the procedure in a patient who has had CABG. Record NR if it is unclear whether any bypass grafts are considered occluded or if the bypass grafts were not assessed during the procedure. Do not include bypass grafts with stenosis of 99% or less. Record the number of occluded grafts. For example, if the patient had 2 grafts and one was 100% occluded, record 1. If there is a discrepancy, use details in the body of the report instead of the conclusions.

H. TREATMENT

<u>Item 39.</u> Was coronary reperfusion (CABG, PCI, thrombolysis) attempted? Record "No/NR" if there is no mention of the type of treatments or interventions described below and <u>skip to Item 40.</u>

Coronary Artery Bypass Graft (CABG) refers to cardiac surgery performed in an operating room by cardiac surgeons where bypass grafts are placed to bypass coronary blockages. Record Yes if the patient underwent CABG during this hospitalization. Record Yes if patient had CABG even if it was not successful (e.g., patient died and never got off the heart-lung bypass pump).

Percutaneous Coronary Intervention (PCI)/stent refers to an invasive cardiac procedure performed in a cardiac catheterization laboratory by cardiologists where catheters are used to treat an intracoronary lesion (plaque, thrombus, blockage). It always involves coronary catheterization which also includes balloon angioplasty with or without intracoronary stent placement, or laser, or a cutting balloon (atherectomy). This interventional procedure is often performed during an acute myocardial infarction or performed electively when the presence of severe coronary blockages need to be treated. Synonyms for percutaneous coronary intervention (PCI) include "percutaneous transluminal coronary angioplasty (PTCA)", percutaneous coronary angioplasty (PCA), directional coronary angioplasty (DCA), "PCI/stent", "PTCA/stent", "percutaneous coronary atherectomy", "percutaneous coronary rotoblader", "balloon angioplasty", and "stenting". Record Yes if the patient underwent some type of PCI during this hospitalization, whether successful or not. Record No/NR if there is no mention of this type of treatment. Also record "No/NR" if percutaneous myocardial revascularization (PMR) and transmural myocardial revascularization (TMR) are the only interventions mentioned because these are not a coronary revascularization procedures. Beware of reports that may be labeled as "PCI Report" but where no PCI was actually performed or attempted. Record Yes if the patient underwent PCI during this hospitalization. Record "No/NR" if there is no mention of this type of procedure.

Thrombolytic therapy has been a major advance in the management of acute myocardial infarction and works by lysing infarct artery thrombi and achieving reperfusion, thereby reducing infarct size, preserving left ventricular function, and improving survival. It is possible for effective thrombolytic regimens to achieve infarct-artery patency in some patients within 90 minutes. The standard thrombolytic drug currently used is tissue-type plasminogen activator (tPA), also called alteplase (Activase®). Other thrombolytics used include reteplase (Retavase®), urokinase (Abbokinase®), streptokinase (Kabikinase®, Streptase®),

Lanoteplase®, Anistreplase® and Tenectaplase® (the newest drug of this class). Record Yes if the patient underwent thrombolytic therapy during this hospitalization. Record "No/NR" if there is no mention of this type of procedure.

<u>Item 39a</u>. If Yes was recorded for coronary reperfusion (CABG, PCI, thrombolysis), choose the box which most closely represents the approximate time period from the onset of the event to reperfusion.

Item 40. Were any of the following treatments given during this hospitalization? If Yes, record the date, time (and specify a.m. or p.m.) of any of the following treatments that were given for Items 40a-j.

<u>Item 40a1-a3</u>. Coronary artery bypass graft surgery (CABG) – cardiac surgery performed in an operating room by cardiac surgeons where bypass grafts are placed to bypass coronary blockages.

<u>Item 40b1-b3</u>. Coronary atherectomy (<u>coronary endarterectomy</u>) - a catheter-based procedure intended to remove calcified (hardened) plaque that is blocking an artery and blood supply to the heart. A thin, soft, flexible tube carrying a special cutting or grinding device clears the blockage. Specific names for this procedure, which depend on the type of device used, include rotational atherectomy, dissectional atherectomy, transluminal extraction catheter (TEC) atherectomy, directional coronary atherectomy (DCA), or RotablatorTM atherectomy (RCA). Atherectomy may be followed by angioplasty, which is used to compress any remaining plaque against the artery wall.

<u>Item 40c1-c3.</u> Record Yes or No/NR regarding whether Intra-arterial (IA) or intravenous (IV) thrombolytic therapy was used during this hospitalization.

<u>Item 40d1-d3</u>. Coronary angioplasty without stent – Coronary artery angioplasty is the procedure that uses an inflated balloon to compress plaque against the walls of the coronary artery, thereby widening the channel through which blood can flow (also called balloon angioplasty, balloon dilation, or percutaneous transluminal coronary angioplasty or PCTA). PTCA is always preceded by cardiac cath. Stent placement often accompanies or follows this procedure but for Item 40d, PTCA should be recorded separately from stent placement. Record Yes if coronary artery angioplasty was performed without stent placement, otherwise record No/NR

<u>Item 40e1-e3</u>. Record Yes if coronary artery angioplasty was performed WITH stent placement, otherwise record No/NR

<u>Item 40f1-f3</u>. Valve surgery (Valve replacement/repair) - This refers to cardiac surgery performed in an operating room by cardiac surgeons where heart valves are either replaced with prosthetic valve (mechanical or bioprosthetic) or repaired. Record Yes if the patient underwent valve replacement or repair surgery during this hospitalization. Record "No/NR" if there is no mention of this type of surgery.

<u>Item 40g1-g3</u>. Record Yes if the patient has non-cardiac surgery during this visit. Surgery does not include procedures, such as catheter placement or biopsy drainage, unless it was performed in an operating room under anesthesia.

Item 40h1-h3. Aortic balloon pump - Intraaortic balloon pump (IABP),), counterpulsation pump, balloon counterpulsation pump, or intra-aortic pump. This refers to a balloon-based mechanical cardiac support device that is implanted by a cardiologist either in the cardiac catheterization lab or at the patient's bedside in the intensive care unit when emergent. They support the heart function as VADs do, but this is only temporary support. Record Yes if the patient underwent insertion of IABP support. Record No/NR if there is no mention of this therapy.

<u>Item 40i1-i3</u>. Pacemaker placement (temporary or permanent) - This refers to implantation of either a permanent pacemaker or a temporary transvenous pacemaker (TVP) wire for treating severe bradycardia or bradyarrhythmias resulting from sinus node dysfunction, heart block, carotid sinus hypersensitivity, or arrhythmias secondary to ablation. They may be single-chamber (single-lead) or dual chamber (dual-lead).

The placement of a permanent pacemaker usually takes place in the electrophysiology (EP) laboratory and has an accompanying report to document this procedure. Pacer pads may be placed in the ER. A temporary pacemaker is usually performed in the catheterization laboratory, electrophysiology (EP) laboratory, in the operating room during heart surgery (see OR sheet), or in the coronary care unit (CCU). There is usually an accompanying report to document this procedure; this report is a separate report if pacemaker was placed in a laboratory, or it is documented in physician notes if it was placed in the CCU. Record Yes if the patient received a pacemaker, whether temporary or permanent, during this hospitalization. However, record No if pacing catheters were used during a diagnostic EP study; only temporary pacemaker wires or catheters used for *therapy* should be included. Do NOT include biventricular pacemakers (cardiac resynchronization therapy) here. Also, do NOT include automatic implantable cardioverter defibrillator-only (AICD) devices even though AICD devices all have backup pacemaker capabilities. Record "No/NR" if there is no mention of this type of treatment.

Item 40j. Cardioversion or defibrillation - This refers to treatment of either atrial or ventricular arrhythmias using electrical cardioversion (DC cardioversion or DC CDV) or medications (pharmacological cardioversion) to convert the rhythm back to normal sinus rhythm. This includes an emergency cardioversion (e.g., during a cardiac arrest) and AICD firings that occur during the hospitalization. This may be performed either in the electrophysiology (EP) laboratory or in the patient's hospital room. Record Yes if the patient underwent an electrical or pharmacological cardioversion therapy during this hospitalization. There may or may not be an accompanying report to document this procedure. However, do NOT include cardioversion used as part of routine procedure during cardiac surgery that uses cardiopulmonary bypass; one shock is considered a normal part of the CABG procedure (record No), but if a second shock is required, then record Yes for cardioversion. Record "No/NR" if there is no mention of this type of treatment or if cardioversion was performed in response to induced arrhythmia. Record Yes if a cardioversion was attempted but was not successful in converting the rhythm back to normal or baseline rhythm. Items 40j1, 40j2, 40j3 – as with the other items, record the date, time and a.m., or p.m. of the cardioversion or defibrillation.

<u>Item 40j4</u>. If cardioversion took place after arrival at the hospital, what rhythm(s) were present prior to cardioversion? Record No/NR (0) or Yes (1) for any of the following ECG rhythms listed in Items 40j4a-j4f Ventricular Fibrillation (V-Fib.), Ventricular Flutter, Ventricular

Tachycardia (VT), Asystole, Complete AV Block (3 HB), Atrial Fibrillation (A-Fib.), Atrial Flutter, Pulseless Electrical Activity (PEA).

Item 41. Were any of the following medications received by the participant either during the hospitalization ('Admission Meds') or at discharge ('Discharge Meds')? Record Yes (1) for Admission AND Discharge for each of the medication categories listed, Items 41a – 41i, record No/NR (0) if there is no mention of the drug/s. If the participant is known to be noncompliant with medication, still record the prescribed list of medications during hospitalization or at discharge. If the patient is transferred out to another hospitalization, and no discharge summary is available, record the medications that were listed on day of discharge, which may be found on the medication administration sheets. If the patient died during the hospitalization, record No/NR for all drugs in the 'Discharge Meds' category.

• Sources for abstracting medications include medication administration records (MAR), physician notes, and orders. If possible, the medications should be confirmed as being given; if that is not possible, use your best judgment. Note that in MARs, nursing notation of a circle (with or without an "H" sign) around a time indicates that the medication was held during that time; a documented subsequent time indicates that the medication was given at that later time.

Some of the trade names contain medications that belong to two classes. For example, Accuretic is a combination of an ACE inhibitor and a diuretic. If so, record such medications in both classes if applicable. Such medications are marked with '+' followed by an abbreviation for the other class involved. (The following abbreviations are used: AAR = Antiarrhythmic, ACE = ACE inhibitor, ARBAngiotensin II receptor blocker, BB=beta blocker, CCB = calcium channel blocker, D=Diuretic).

Item 41a. Nitroglycerin (Nitrates) - Nitrates are vasodilators used to treat angina, hypertension, and heart failure. A listing of nitrates follows:

Generic Trade Isosorbide dinitrate Anginabid

Isosorbide mononitrate Bidil (+ hydralazine)

Nitrates Cardilate

Nitrites Deponit NTG Film

Nitroglycerin Dilatrate

NTG Trinitroglycerine Imdur I.S.D

Duotrate Ismo Isochron Isosorbdin Isosorbide Isosorb mono Iso-Bid Isordil **Isotrate** Mi-trates

Minitran Monoket N.T.S. Nitrek Nitro **NitroBid** Nitrocap Nitrocine Nitrocot **Nitrodisc** NitroDur **Nitrogard** Nitroglyn Nitrol Nitrolin Nitrolingual Nitronal **Nitrong** Nitro-par Nitroquick Nitrorex Nitrospan **Nitrostat** Nitrotab Nitro-time Nitro-transderm Nitrotransdermal NTG-spray Pentylan Peritrate

<u>Item 41b</u>. Beta-blockers (BB) – This category of drugs block beta-adrenergic receptors, thereby decreasing the stress on the heart. They are used to treat arrhythmias, hypertension, and heart failure. However, do not include beta-blocker eyedrops (e.g., record "No/NR" for Timolol eye drops). A listing of Beta Blockers follows:

Transdermal NTG

Sorbitrate Transderm

Tridil

<u>Generic</u> <u>Trade</u> Acebutolol Betachron

Atenolol Betapace (*AAR)

Betaxolol Bisoprol
Bisoprol Bisoprol
Carteolol Blocadren

Carvedilol Brevibloc (*AAR)

Esmolol (*AAR) Cartrol

LabetalolCoregMetoprololCorgardNadololCorzide (+ D)PenbutololInderal

Pindolol Inderide (+ D)
Propranolol Innopran XL

Sotalol (*AAR) Kerlone
Timolol Levatol

Lopressor or Lopressor HCT (+ D)

Normodyne Normozide Sectral

Tenoretic (+ D)
Tenormin
Timolide (+ D)
Toprol XL
Trandate
Visken
Zebeta

Ziac (+ D)

<u>Item 41c.</u> Calcium Channel Blockers (CCB) – These drugs block calcium channels in the heart and arteries which results in vasodilation. They are used to treat hypertension, arrhythmias, and angina.

GenericTradeAmlodipineAdalatBepridilAfeditabDiltiazem (**AAR only if indicated)Amlod

Felodipine Caduet (+ statin)

Isradipine Calan Mibefradil Cardene

Nicardipine Cardizem (**AAR only if indicated)

Nifedipine Covera-HS
Nimodipine Cartia XT
Nisoldipine Dilacor XR
Verapamil (**AAR only if indicated) Diltia XT
DynaCirc

DynaCirc Isoptin

Lexxel (+ ACE) Lotrel (+ ACE) Nifedical XL Nimotop Norvasc Plendil Posicor Procardia Sular Tarka (+ ACE) Taztia XT

Teczem (+ ACE)

Tiamate Tiazac Vascor

Verelan (**AAR only if indicated)

<u>Item 41d</u>. ACE Inhibitor (or ARB - Angiotensin II receptor blocker)

ACE (angiotensin-converting enzyme) inhibitors are vasodilators that lower blood pressure and can improve the pumping action of the heart in those with heart failure. They are used for hypertension (especially those with diabetes) and heart failure.

Generic Trade
Benazepril Accupril
Captopril Accuretic (+ D)

Enalapril Aceon
Enalaprilat Altace
Fosinapril Capoten
Lisinopril Capozide (+ D)
Moexipril Lexxel (+CCB)

Perindopril Lotensin

Quinapril Lotensin HCT (+ D)
Ramipril Lotrel (+ CCB)

Trandolapril Mavik

Monopril

Monopril HCT (+ D)

Prinivil

Prinzide (+ D) Tarka (+ CCB) Teczem (+ CCB) Uniretic (+ D)

Univasc

Vaseretic (+ D)

Vasotec

Zestoretic (+ D)

Zestril

<u>Item 41e</u>. Scheduled Aspirin (not PRN) – Anti-platelet agents affect platelets such that they are less likely to form a clot. Aspirin is an analgesic, but its main use is to prevent heart attack and stroke. For these indications, usually a low-dose aspirin is given. Record aspirin under Item 41e. separately from other anti-platelet agents.

Generic Trade

Acetylsalicylic Acid Aggrenox (+ other anti-platelet)

Aspirin Alka-Seltzer

ASA Anacin

Cilostazol Arthritis Pain Formula

A.S.A. Enseals

Ascriptin Aspergum Baby Aspirin Bayer (Aspirin) Buffaprin

Buffered Aspirin

Bufferin Buffex Buffinol

CAMA Arthritis Pain Reliever

Easprin
Ecotrin
Empirin
Excedrin
Gelpirin
Genprin
Halfprin
Magnaprin
Measurin
Norwich
Pletal

Pravigard PAC (+ statin)

St. Joseph Verin

Wesprin Buffered

ZORprin

<u>Item 41f.</u> Heparin or Enoxaparin - Anticoagulants are drugs given to prevent blood from clotting or prevent existing clots from becoming larger. They can keep harmful clots from forming in your heart, veins and arteries. Record Yes if there is evidence in the medical record of Heparin or Enoxaparin being given during this hospitalization or at discharge. Otherwise record No/NR

<u>Item 41g</u>. Record Yes if there is evidence in the medical record of any of the following anticoagulants being given during this hospitalization or at discharge, otherwise record No/NR:

<u>Generic</u> <u>Trade</u> Warfarin Coumadin

Panwarfarin Dicumarol

Item 41h. Anti-platelet agents (non-aspirin)

Generic Trade Investigational

Abciximab Aggrastat Orofiban

Clopidogrel Aggrenox (+ Aspirin)

Dipyridamol Flolan
Epoprostenol Integrilin
Eptifibatide Persantine
Ticlopidine Plavix
Tirofiban ReoPro
Xemilofiban Ticlid

Item 41i. Statin.

GenericTradeAtorvastatinAdvicorFluvastatinAltocor

Lovastatin Caduet (+ CCB)

Pravastatin Crestor
Rosuvastatin Lescol
Simvastatin Lipitor

Mevacor Pravachol

Pravigard PAC (+ aspirin)
Vytorin (+ other lipid lowering)

Zocor

<u>Item 42</u>. Was the participant treated with any of the medications in the categories listed in Items 42a, 42b, or 42c during this hospitalization? Record Yes (1) or No/NR (0) if no medications in a category are mentioned.

<u>Item 42a</u>. IV pressors - <u>Pressor</u>, <u>vasoconstrictive</u>, <u>vasoconstrictor</u> - terminology used to describe agents that produce vasoconstriction and a rise in blood pressure (usually understood as increased arterial pressure). In other words a vasoconstrictor could be any agent that causes a narrowing of an opening of a blood vessel i.e.: cold or stress, nicotine, epinephrine or norepinephrine, angiotensin, vasopressin or certain drugs which can either maintain or increase blood pressure. Vasopressor drugs are useful for resuscitation of seriously ill patients, and for the treatment of hypotension (in surgery for example). All of these drugs act directly or indirectly on the SNS, but the effect of each varies according to which sympathetic receptor the drug has greatest affinity for. The duration of action also varies. Direct acting drugs act by stimulating the SNS receptor whereas indirect acting drugs cause the release of noradrenaline from the receptor which produces the effect. Some drugs have a mixed effect.

Generic Trade

Epinephrine Adrenalin Chloride

Norepinephrine Levarterenol Phenylephrine Levophed

Dopamine HCL, Intropin

Dobutamine Dobutrex Metaraminol Aramine Item 42b. IV nitroglycerin is used to treat several conditions including increased blood pressure around the time of surgery, unpredictable severe constricting chest pain, dysfunction of left ventricle of the heart following heart attack. It may also be used to treat severe uncontrolled high blood pressure, heart attack, acute syndrome of the heart and suddenly serious symptoms of heart failure. Record Yes if the medical record shows evidence of IV nitroglycerin being used during this hospitalization otherwise record No/NR

Item 42c. IIb./IIIa. inhibitors or thrombin inhibitors is a class of antiplatelet agents. Glycoprotein IIb/IIIa inhibitors are frequently used during percutaneous coronary interventions (angioplasty with or without intracoronary stent placement). They work by preventing platelet aggregation and thrombus formation. They do so by inhibition of the GpIIb/IIIa receptor on the surface of the platelets. They may also be used to treat acute coronary syndromes, without percutaneous coronary intervention, depending on TIMI risk and should be given intravenously. Examples of Glycoprotein IIb/IIIa inhibitors include:

GenericTradeabciximabReoProeptifibatideIntegrilintirofibanAggrastat

These procedures are always in the following order when PTCA or PTCA/stent done:

- 1. Catheterization
- 2. Angiography
- 3. PTCA
- 4. Stent
 - Record CABG time as the time the person went on bypass.
 - If CABG is recorded, always answer "No" for defibrillation "unless defibbed more than once"
 - If a participant received intra-arterial or intravenous thrombolytic therapy as part of a separate blinded (placebo vs. active drug) study, answer "Yes".
 - If a thrombolytic medication is given for a stroke cause, it should still be recorded on the cardiac abstract.
 - If a medication is not listed, or if it was ordered but never given, answer "no."
 - Answer "no" to heparin if it was used only to maintain an open intravenous line ("heplock," hepflush, or heparin TKO) or given only in conjunction with a procedure.
 - Record coronary artery angioplasty as time when the balloon is over the lesion and inflated.
 - If stent placement is attempted but unsuccessful, answer "no" for coronary stent placement.

- Record coronary stent placement as the time the stent was deployed.
- If the procedure time is unclear, follow standard procedures for recording "unknown" or estimated data. (Refer to General instructions and definitions of terms for completion of form for details). If time is unclear or not recorded, use 12:00 p.m.
- Synonyms for cardioversion include:
 - DC countershock
 - defibrillation
 - electric countershock of heart
 - external electrode stimulation
 - carotid sinus stimulation
 - electrocardioversion
 - Might be recorded on sheet in "joules."
- Include cardioversion given immediately before (e.g., by paramedics during transport) or at any time during hospitalization.
- Answer "no" for cardioversion after CABG, unless done more than once.
- Answer "no" for medication or chemical cardioversion, i.e. adenosine.

If a test was done, abstractors should attempt to assign a Yes/no to the categories based on the procedure report. The abstractor can certainly record clear cut normal and abnormal results. However, if there are unfamiliar words in the report, or you are otherwise uncertain regarding how to interpret a particular result, consult an HCHS/SOL colleague, physician consultant or principal investigator.

Upon Completion of Form:

Review the form for completeness and accuracy and resolve any discrepancies/questions, consulting with your colleagues, HCHS/SOL physician consultant or principal investigator as needed. Enter and save the abstracted data in the Data Management System (DMS).