Tracking of Revisions to HCHS/SOL V3 MOP #15

[Previous Manual, Date, Version]	Date(s) of Revisions; source	Approved by, Date	Revisions	Previous Page #s section changed etc.	Distribution Date
Version 1.2	7/3/2014	LL, AS, MY	New section on pregnancy related complications	New section #6	pending
Version 1.4	5/23/2023	JS, WR	Revised sections 7.0 & 8.0 Fatal Events and Classification (Figure 4 added)		To IRB 6/1/2023 (?).
Version 1.5	2/23/2024	JS	Added HCHS/SOL Death Investigation Process Flow Chart In top of Section 7.1.1 – death Investigation Data Collection Process Addition to section 7.1.1 – regarding addition of 2nd GHE for prompt death investigation Addition to section 7.6 Out-of-Hospital Deaths (OOHs) – regarding data from any hospitalization or E.D. visits within 30 days of an OOH death will be included in the info. sent to the death investigation committee for classification of cause of death	Flow Chart under Section 7.1.1 Addition to 1st pp in section 7.1.1 Addition to 2nd pp in section 7.6	Pending submission for IRB approval
Version 1.6	9/92024	JS	Addition of Section 7.1.2 Out of Country Death Investigation Data Collection Process – regarding each field center following its own protocol for collecting data for an out-of-country fatal event and ideas for new incentives to be submitted for IRB approval. Same materials collected for deaths in the U.S. will pertain to out-of-country deaths. The CSCC will provide instruction and be responsible for reporting the ongoing status of fatal event data collected at each center. Addition of HCHS/SOL Death Investigation Form (DTH Version 3) under Appendix C. Data Collection	Addition of Section 7.1.2 on pp. 37-38 Addition of DTH V.3 – pp. 64-67 Addition of MOR V.1 pp. 119-121	Still pending submission for IRB approval as of 12/10/2024

[Previous Manual, Date, Version]	Date(s) of Revisions; source	Approved by, Date	Revisions	Previous Page #s section changed etc.	Distribution Date
			Forms Required for Assessing Endpoints Addition of Mortality Reviewer form (MOR Version 1) Under Appendix E. Reviewer Forms		

Updated 1/22/2025 3:52 PM

HCHS/SOL Manual 15
Endpoint Ascertainment Procedures

Sept. 9, 2024 - Version 1.6

Prepared by the HCHS/SOL Endpoints Subcommittee

Study website - http://www.cscc.unc.edu/hchs/

Endpoint Ascertainment Procedures
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1.0 Endpoint Ascertainment Procedures

1.1 Overview.

The mission of the Endpoints Ascertainment and Classification Committee is to design and implement a system for event ascertainment, including review and validation of a variety of endpoints to facilitate the classification of specific clinically recognized events occurring among the Hispanic Community Health Study / Study of Latinos (HCHS/SOL) cohort participants. The specific objectives of the endpoints procedure manual are to clearly describe how the HCHS/SOL will:

- identify acute myocardial infarction, stroke, heart failure, asthma and chronic obstructive pulmonary disease (COPD) events that have required hospitalization following the initial examination;
- identify acute exacerbations of asthma or COPD requiring emergency department (ED) care; and
- review and evaluate clinical diagnostic information collected from medical records from hospitals and emergency departments to classify each event type.

The identification and classification of clinical events in the HCHS/SOL outlined in this manual follows standard principles of population-based cohort surveillance. These principles include ascertaining potential events, gathering medical information about these events, and conduction physican review of collected data to validate the types of events of interest. The aim of surveillance of the HCHS/SOL cohort is to identify all hospitalizations and emergency department visits for each cohort participant (regardless of reason) and validate the diagnosis of all potential coronary, stroke and pulmonary disease events and key pregnancy related complications (PRC) that occur between baseline exam and the subsequent follow up. We will also investigate deaths (in hospital and out of hospital deaths) to validate cause of death. The general approach to defining endpoints of interest, ascertainment of potential cases, gathering medical information, and review/validation of events is outlined below. Details of each of these steps are provided in the proceeding chapters of this manual.

1.2 Specific Disease Endpoints.

The specific cardiovascular and respiratory disease endpoints of primary consideration in HCHS/SOL are: 1) hospitalizations for myocardial infarction, stroke, heart failure, COPD, gestational diabetes mellitus, pre-eclampsia, eclampsia, and asthma, and 2) emergency department visits for COPD and asthma exacerbations. The cause of death of any cohort participant will also be established and is a primary endpoint. Available information on deaths occurring among cohort participants will be reviewed and fatal events will be classified as death due to cardiovascular disase, pulmonary disease, or other.

1.3 Ascertaining Potential Events.

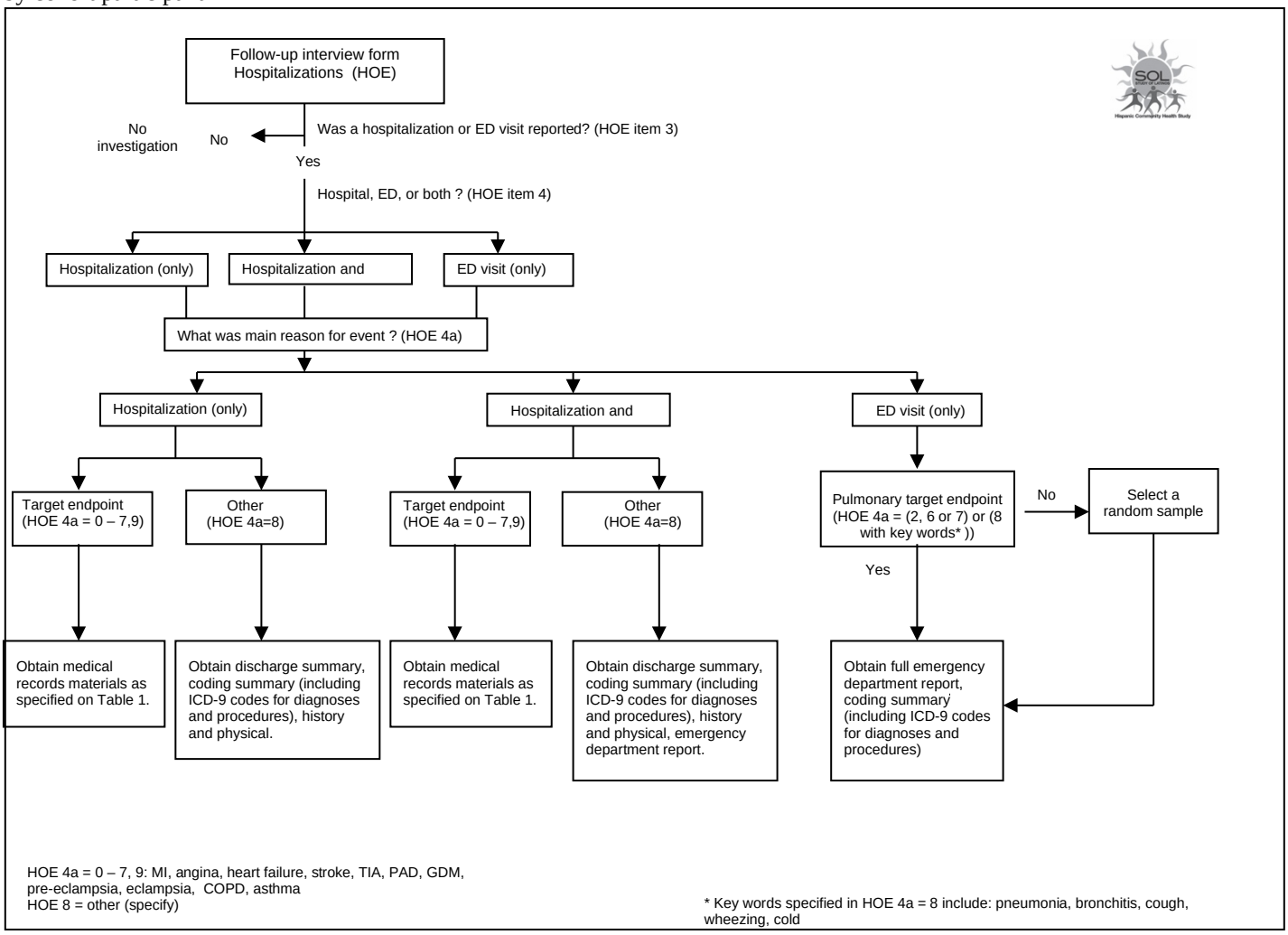
Event surveillance of the cohort uses information obtained from the annual phone follow-up interview. When the annual follow-up interview indicates that the participant has either died, been admitted to a hospital, or been seen in an emergency department, mechanisms to obtain the appropriate medical records or death certificate are initiated. Hospital admissions may be identified initially through review of hospital discharge indexes or information elicited during the cohort follow-up interviews. However, the protocol sent to hospital administrators emphasizes the fact that, for cohort members, HCHS/SOL obtains signed hospital record release forms. Hospital admissions are therefore able to be identified via a retrospective review of admission dates in electronic medical records (EMR). In addition to acquiring information from death certificates, fatal events are also ascertained from review of vital statistics lists and obituaries for the date in which the community is located.

In the HCHS/SOL study, a hospitalization will be defined as admission into an acute care hospital, i.e. a facility which has an ambulance bay and an emergency department (ED). Hospitalization can be either by direct admit from a doctor's office or clinic or via ED arrival and subsequent admission to an inpatient

acute care unit. Direct admission to an inpatient acute care unit for overnight stay following planned surgery will also be considered a hospitalization. Admission to inpatient rehabilitation or hospice units, outpatient rehabilitation, hospice, or skilled nursing facilities, psychiatric hospitals or any other type of care facility that does not have an ambulance bay and ED department will not be considered a hospitalization. ED observation or declared observation stays will be considered an ED visit. Treatment received in a doctor's office, walk-in clinic, and outpatient/day surgery will not be investigated.

The HCHS/SOL records the occurrence of all hospitalizations and all emergency department visits and captures the discharge diagnosis and procedure codes (ICD-9 and ICD-10 codes) but only conducts detailed investigations for the selected kinds of medical events noted above. Detailed investigation of recalled hospitalized and emergency department events will be triggered initially by the reported reason for the event but verified by the presence of certain discharge diagnoses or procedure codes (see Figure 1 below). Presence of certain presenting symptoms will trigger investigation of emergency department or emergency medical services (EMS) records. Death investigation will be triggered by certain underlying cause of death codes (ICD-10 codes) on the death certificate; and investigation of out-of-hospital deaths will include interviews with next of kin and mailed questionnaires to appropriate physicians, medical examiners or coroners and review of EMR for discharge summaries. Emergency department admissions and death on arrival to the E.D. are treated as out-of-hospital deaths. . See Chapter 7 for surveillance of fatal events.

Figure 1. Summary of event investigation based on initial reason for hospitalization or emergency department visit as reported by cohort participant



1.4 Collection and Abstraction of Medical Information.

A detailed abstraction form specific to the type of event will be used by trained staff at the coordinating center to collect relevant data from medical records of eligible events. Copies of discharge summaries, history and physical, electrocardiograms, echocardiography reports, neuro-imaging reports, consult reports and other pertinent documents will be obtained by field center staff and sent to the coordinating center for abstraction. The type of records from the medical chart to be sought, copied, and sent to the coordinating center is summarized in Table 1. Abstractors follow detailed question by question instructions (QXQ) for the standardized abstraction of medical record information to a database. Abstractors are trained and certified. A brief summary (1-2 pages) of information abstracted from these materials (the Event Summary Form or ESF) will be provided to the Event Classification Committee (ECC) for their review when classifying the event. In addition, copies of selected portions of the materials from the medical record will be provided to the Events Classification Committee members for their use in determining the final event classification of each event.

Table 1. Documents requested for endpoint classification by type of endpoint, determined by responses to self report by cohort participants on annual follow up phone interviews (Annual follow up form item HOE4a)

Medical Record Materials	MI (HOE4a=0)	Chest pain (HOE4a=1)	Heart failure (HOE4a=2)	Stroke (HOE4a=3)	COPD (HOE4a=6)	Asthma (HOE4a=7)	PRC (HOE4a=9)	Other (HOE4a=8) HOSP only or plus ED
Coding summary with ICD-9-CM codes	√	√	√	√	√	√	√	√
Discharge summary	√	√	√	√	√	√	√	√
History and physical	√	√	√	√	√	√	√	√
Vital signs, weight							√	
12 lead ECG reports (all)	√	√	√	√	√	√		
Cardiac biomarker report	√	√	√		√	√		
Emergency Department report	√	√	√	√	√	√	√	
Cardiac catheterization report	√	√	√					
Arteriogram reports	√	√	√	√				
Stress test report	√	√	√					
Procedure report, delivery or operating room notes	√	√	√	√	√	√	√	
Spirometry report					√	√		
Pulse oximetry report					√	√		
Arterial blood gas report					√	√		
Discharge medication report				√	√	√	√	
Laboratory report	√	√	√	√	√	√	√	
Chest X-ray report			√		√	√		
CT scan report				√	√	√		
Echocardiology report	√	√	√	√	√	√		
RVG or MUGA report	√	√	√		√	√		
Nuclear studies report				√				
MRI report				√				
Lumbar puncture report				√				
Ultrasound report (other than echocardiogram)				√				
Doppler flow study report					√	√		
Carotid studies report				√				
Pulmonary angiography					√	√		
Isotope scan								
Lung scan					√	√		
Autopsy or Medical examiner report	√	√	√	√	√	√	√	

1.5 Death Investigations.

A death certificate form will be completed for all fatal events. For in-hospital deaths, data collected on the death certificate form and the hospital abstraction form will be combined for use by the ECC for review and event classification.

Deaths occurring outside the regular acute care hospital are categorized as out of hospital deaths. This includes persons dead on arrival at acute care hospitals, and those dying in outpatient departments or emergency rooms, or admitted without vital signs. For out of hospital deaths meeting underlying cause of death code criteria, information is sought from the decedent's family and physician within 6 months after death. The former is contacted by telephone and the latter by mailed questionnaire. Often the informant is the spouse or other family member of the decedent. Information provided by the informant and the physician is combined for use by the ECC for review and event classification.

1.6 Review and Validation.

Diagnostic information obtained through abstraction of the medical record combined with documents copied from the medical records are de-identified and prepared for review by members of the ECC. Cause of death ICD-10 codes obtained through abstraction of the death certificate are combined with supplemental information from informants (in the case of out of hospital deaths) and prepared for review by members of the ECC. ECC members complete an fatal event classification form where the indicates a classification as to the cause of death. ECC reviewers are trained and certified to follow standardized rules and case laws when determining the final event classification of each case. Out of hospital deaths are reviewed and cause of death classified independently by two physicians with difference adjudicated by a third reviewer.

1.7 Clinical Site Procedures for Identifying and Processing Events for Endpoint Classification

Annual Follow-Up Form (AFU) (See Manual 16 and study web site for example and QxQ)

During the completion of the annual follow-up interview (contact year 1), field center staff will ask the participant whether they had been admitted to a hospital or seen in an emergency department (ED), at any time since their last HCHS/SOL center visit (HOEA item 3). If no events are reported (HOEA item 1 = 'no' or 'unsure') there will be no events to be investigated. If participants respond 'Yes' to HOEA item 1 then they are asked to identify the type of event in HOEA item 4. HOEA item 4 identifies whether the event was a visit to the ED or an admission to the hospital, or both. This information on event type appears on the Event Tracking Report and can be useful in field center efforts to obtain medical records.

Item 4a on the HOEA form asks: *What was the main reason for going to the (insert emergency room or hospital) that day?* The discharge summary, history and physical and associated summary of all discharge diagnosis and procedure codes are important parts of the record that will always be obtained for all hospitalized or emergency department events. Events reported during the annual follow up interview that involve an emergency department visit without subsequent hospital admission (a stand-alone ED visit) are selected for further investigation as shown Figure 1 above. Emergency department visits without a subsequent hospitalization are investigated if they are suspected to be for COPD or asthma based on the self-reported reason for the visit (from item 4a of the HOEA form).

<u>Event Identification (ID) Numbers</u>

When an event eligible for investigation is reported during an Annual Follow Up interview and the data is entered into the data management system, a unique event ID number is assigned to each reported event by the endpoints management system. This event ID is derived from the cohort ID number and the reported hospitalization by computer algorithm. If more than one eligible event is reported during an annual follow interview for an individual, then the data management system creates new event IDs for each reported

event. For example, for a given cohort ID number there may be several event IDs. Information about the reported event and the associated event ID is automatically imported into the Event Tracking Table (ETT). An example of the ETT is shown in Table 2.

Table 2. HCHS/SOL Event Tracking Table

Event ID	Cohort name	Date of event	Event type	Medical facility/location	Main reason	Event status tracking	Data status	Comment
X60000130102	Doe, J.	03/04/2008	ED only	Memorial Medical Center	Asthma	Requested	02/01/2009	Pending
X60000130101	Doe, J.	03/01/2008	Hospital	Mercy Medical Center	Heart Failure	Requested	02/01/2009	Release requested

The event ID is composed of the participant's 8 digit study ID number, followed by 4 digits. The first two digits indicate the year of follow-up (re: 01, 02) the last two digits indicate the sequentially numbered events. (re: 01, 02, 03, 04, etc.)
Examples:

Year one follow-up event labeling for San Diego participant id S8XXXXXX:
S8XXXXXX0101, S8XXXXXX0102, S8XXXXXX0103, S8XXXXXX0104

Year two follow-up event labeling for San Diego participant id S8XXXXXX:
S8XXXXXX0201, S8XXXXXX0202, S8XXXXXX0203, S8XXXXXX0204

Event Tracking Table/Status Report (DMS generated)

The Event Tracking Table/Status Report stores key ascertainment data abstracted from the AFU interview. Field site Endpoint Ascertainment staff have password protected access to this report, and have the option of allowing access to the Annual Follow-up Interviewer(s) for ease in confirming changes to the AFU, based on record ascertainment. See the study Data Management system User Guide to create password protected access for selected staff.

The table/report has two drop-down menus in the header section of the screen.

1. Select Event Status: lists all open or closed events
2. Sort By: Sorts by event id, event type or event status

The table/report consists of nine (9) columns. The first 6 columns are auto-populated by DMS

Column 1: Event ID
Column 2: Name
Column 3: Event Date—Item 4b from HOE
Column 4: Event Type—Item 4 from HOE
Column 5: Medical Facility/Location—Item 4c from HOE
Column 6: Main Reason—Item 4a from HOE

Column 7—9 require manual entry by the Endpoint Ascertainment Staff.

Column 7: Event Status (Click for ETR form)

Event Tracking Report Form (ETR) (See appendix XX for example and QxQ).
This record will be used to track the site efforts on obtaining, processing and shipping the medical records for an event under investigation.
Once an event has been listed on the Event Tracking Status Report in DMS, the staff will create an ETR by clicking on *"No ETR"* under column 7.
In order for the ETR form to auto-save in the system you must completely enter the form. (Event ID and Event Date are pre-populated).

This form should be updated as record acquisition work progresses through "pending records request" to "shipping records to the Coordinating Center".
Study reports developed will use the ETR to give the field centers and steering committee feedback on the progress of end points investigation activities at each site.

All "closed events" (with terminating/final codes: 4, 5 or 9) will be auto-stored in the Closed Event Table, which is accessed by the "Select Event Status" menu on the Event Tracking Table/Status Report.

Column 8: Status Date--Auto populates once the ETR form is entered.

Column 9: Click for VER Form

Verification Form (VERA) (See appendix C4 for example)
When medical records of interest are received for an event, enter the ICD-9 codes appearing on the discharge summary page into the verification form (VERA) by clicking on the equal sign (=) in the last column for the event.
Once the ICD-9 codes have been entered, the DMS will list the medical record materials expected for this event. For each listing, code whether the document of interest was:
1=received, 2=pending, 3=not available
Successful verification of the discharge codes will produce a face sheet for the materials being transferred to the coordinating center. Table 3 which follows on the next page shows the linkage between the ICD-9 code keyed from the face sheet of the medical record on the VERA form and all of the expected medical record information required to adjudicate the event.

Print the VER form and face sheet to send with the documents. Please note, if the face sheet is not pre-populated with the Subject ID, Date of Event and Event ID—contact the DCC and the staff will assist you.

Table 3. Medical Record Materials Required for HCHS/SOL Endpoint Validation of Hospitalized Events* by ICD-9-CM Diagnosis Code

	Hospital discharge diagnosis codes or procedure codes (ICD-9-CM)						
Documents requested for HCHS/SOL Endpoints	**MI** (402.xx, 410-414, 427, 428, 518.4, 00.50-00.54, 00.61-00.66, 35-39, 88.5, 89.49, 99.10)	**Heart failure** (398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0 425.4, 428, 518.4, 786.0x, 786.2)	**Stroke** (430-438)	**COPD** (491.0, 491.2, 491.9, 491.22, 492.0, 492.8, 493.0, 493.1, 493.2, 493.9, 496, 786.2, 30.3-30.4, 31.1-31.29, 33.20-33.24, 33.26, 33.27, 33.29, 33.72, 33.99, 89.37, 89.38, 93.90-93.99, 96.01-96.05, 96.7, 96.71-96.72)	**Asthma** (493, 493.X)	**PRC** (642.0x 642.1x, 642.2x, 642.3x, 642.4x, 642.5x, 642.6x, 642.7x, 642.8x, 648.0x, 648.8x)	**Other** discharge or procedure codes
Coding summary with ICD-9-CM codes	√	√	√	√	√	√	√
Discharge summary	√	√	√	√	√	√	√
History and physical	√	√	√	√	√	√	√
Vital signs, weights						√	
12 lead ECG reports (all)	√	√	√	√	√		
Cardiac biomarker report	√	√		√	√		
Emergency Department report	√	√	√	√	√	√	
Cardiac catheterization report	√	√					
Arteriogram reports	√	√	√				
Stress test report	√	√					
Procedure report, delivery or operating room notes	√	√	√	√	√	√	
Spirometry report				√	√		
Pulse oximetry report		√		√	√		
Arterial blood gas report				√	√		
Discharge medication report	√	√	√	√	√	√	
Laboratory report	√	√	√	√	√	√	√
Chest X-ray report		√		√	√		
CT scan report			√	√	√		
Echocardiology report	√	√	√	√	√		
RVG or MUGA report	√	√		√	√		
Nuclear studies report			√				
MRI report			√				
Lumbar puncture report			√				

Ultrasound report (other than echocardiogram)			√				
Doppler flow study report				√	√		
Carotid studies report			√				
Pulmonary angiography				√	√		
Isotope scan							
Lung scan				√	√		
Autopsy or Medical examiner report	√	√	√	√	√	√	

* For emergency department only events selected for investigation, request only the ICD-9-CM coding summary and emergency department report
MI = myocardial infarction
PRC = pregnancy related complications of gestational diabetes, , pre-eclampsia, eclampsia
COPD = chronic obstructive pulmonary disease including emphysema, chronic bronchitis

Table 3a. Medical Record Materials Required for HCHS/SOL Endpoint Validation of Hospitalized Events* by ICD-10-CM Discharge Diagnosis Code

	Hospital discharge diagnosis codes or procedure codes (ICD-9-CM)						
Documents requested for HCHS/SOL Endpoints	**MI** (402.xx, 410-414, 427, 428, 518.4, 00.50-00.54, 00.61-00.66, 35-39, 88.5, 89.49, 99.10)	**Heart failure** (398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0 425.4, 428, 518.4, 786.0x, 786.2)	**Stroke** (430-438)	**COPD** (491.0, 491.2, 491.9, 491.22, 492.0, 492.8, 493.0, 493.1, 493.2, 493.9, 496, 786.2, 30.3-30.4, 31.1-31.29, 33.20-33.24, 33.26, 33.27, 33.29, 33.72, 33.99, 89.37, 89.38, 93.90-93.99, 96.01-96.05, 96.7, 96.71-96.72)	**Asthma** (493, 493.X)	**PRC** (642.0x 642.1x, 642.2x, 642.3x, 642.4x, 642.5x, 642.6x, 642.7x, 642.8x, 648.0x, 648.8x)	**Other** discharge or procedure codes
Coding summary with ICD-9-CM codes	√	√	√	√	√	√	√
Discharge summary	√	√	√	√	√	√	√
History and physical	√	√	√	√	√	√	√
Vital signs, weights						√	
12 lead ECG reports (all)	√	√	√	√	√		
Cardiac biomarker report	√	√		√	√		
Emergency Department report	√	√	√	√	√	√	
Cardiac catheterization report	√	√					
Arteriogram reports	√	√	√				
Stress test report	√	√					
Procedure report, delivery or operating room notes	√	√	√	√	√	√	
Spirometry report				√	√		
Pulse oximetry report		√		√	√		
Arterial blood gas report				√	√		
Discharge medication report	√	√	√	√	√	√	
Laboratory report	√	√	√	√	√	√	√
Chest X-ray report		√		√	√		
CT scan report			√	√	√		
Echocardiology report	√	√	√	√	√		
RVG or MUGA report	√	√		√	√		
Nuclear studies report			√				
MRI report			√				
Lumbar puncture report			√				

Ultrasound report (other than echocardiogram)			√				
Doppler flow study report				√	√		
Carotid studies report			√				
Pulmonary angiography				√	√		
Isotope scan							
Lung scan				√	√		
Autopsy or Medical examiner report	√	√	√	√	√	√	

* For emergency department only events selected for investigation, request only the ICD-9-CM coding summary and emergency department report
MI = myocardial infarction
PRC = pregnancy related complications of gestational diabetes, , pre-eclampsia, eclampsia
COPD = chronic obstructive pulmonary disease including emphysema, chronic bronchitis

Updating Events

There may be instances when the participant has reported an incorrect or incomplete event date, which is discovered when the medical records are obtained. The AFU or Data Management (DM) staff can correct the appropriate HOEA by line number for the event. It is very important to select and update the precise HOE record of interest by going to the existing entry for the case, and not creating a new entry (which is default for entering HOE forms).

To do this, right click on the "page" icon just to the left of the participant's HOE form on the menu on the left side of the DMS screen. Use the "jump to" sub-menu to select the appropriate line.

The program that creates the endpoints workflow table incorporates changes to items on the related HOE form overnight. Corrected information should appear once the CHANGE transaction has cleared the processing system.

Events Not Reported During Annual Follow-up Interviews

Additional events, not self-reported at annual follow-up may be identified when medical records are obtained for a self-reported event. These newly discovered events must be assigned event IDs and must be distinguished from the self-reported events on the HOEA form for the contact year in which it took place.

To correctly capture this information: 1) "jump to" the last HOEA line in the sequence, 2) tab to question 4f, and change that from a "No" to a "Yes" which will bring up a blank HOE form to complete, 3) enter the information for the newly discovered event, 4) Create a note log for HOE item 4b, Date of Event, that says: ***"Detected after AFU interview"***, and 5) Save the changes. If the newly discovered event is eligible for investigation, it will appear in the work panel as a new entry after the system updates the tracking table overnight.

Numbering Events

If a participant has an ED or hospitalized event where he/she was transferred ***directly*** to another facility, this is considered one (1) event only and documentation from both facilities should be sought to complete event processing. If a participant has discrete admission and discharge dates that are not continuous (with intervening time of any amount not in the hospital, or intervening time not on an acute care inpatient unit), these are considered two (2) events. For example, if a patient is seen in the ED and discharged home, then returns to the ED on the same day (even 5 minutes later), this would constitute two (2) events. Another

example is if the patient is transferred *within the same facility* from an acute care unit to an inpatient rehabilitation unit or inpatient hospice unit and then returned back to an acute care unit for worsening condition, this would constitute two (2) events, with the time spend on the non-acute care unit disregarded.

1.8 Medical Records Processing

Medical Record Release Forms and Cover Sheet (See appendix XX for example)

In order to obtain medical records for a specific event, a current and signed medical record release form will need to be sent to each medical facility identified (as indicated on the Event Tracking Status Report) for each event. Medical record release forms are valid for 90 days from the time the patient signs and dates the form. Keeping in mind that a patient may have more than one event or may have been seen in more than one institution; it may be helpful to have the participant sign several release forms at one time, or to sign one and leave the date blank. Alternatively, some institutions may release medical records with a copy of the participant's signed HIPAA consent form.

The medical records release form must include the specific dates of the event and the name of the healthcare provider requesting the records. A cover sheet with auto-populated demographics and participant's self-reported reason for event from the AFU will accompany each request for medical records.

When records are received, the field center (FC) determines if the records are sufficient to ascertain the event. The first step is to directly compare what was received to what was requested.

ICD Codes (International Classification of Diseases)

Obtaining discharge diagnosis and procedure ICD codes for all events is critical for the standardized ascertainment of potential events. Originally constructed to provide comparable international data on causes of death, today it is used in many countries for coding hospital discharge diagnoses for billing purposes. For both hospitalizations and ED visits, an ICD code is assigned for each diagnosis. Usually there is one *primary* discharge diagnosis/ICD Code for each hospitalization/ED visit, but there may be several *secondary* diagnoses listed as well. The secondary diagnoses may include old and new diagnoses. Usually, an ICD summary page is included in medical records for any event, and this is often on the face page. If this is not received for a specific event, the FC will need to follow-up with the medical records department to obtain it before the event can be sent to abstraction and processed further classification. It is necessary to obtain and send the ICD summary page to the Data Coordinating Center (DCC) as part of the medical records package for each identified event. If the ICD-9/ICD-10 summary is not available after exhausting efforts at the medical records department, an attempt to obtain it through the hospital's billing department should then be pursued. Only nosologist-generated codes are acceptable.

If the field center is coding diagnoses without the summary page from medical records, the coder should indicate such on the VER form, Item 2, by entering "3" (unavailable).

De-Identifying and Labeling Medical Records

In order to comply with the de-identification rules for research conducted under HIPAA, field centers are to mask or de-identify the following items on the medical records.

Each page of medical records received must be checked and the following de-identified:

- ✓ Participant name and/or initials
- ✓ Hospital name and street address

- ✓ Institutional letterheads and/or logos
- ✓ Names of everyone (keep degrees or titles)
- ✓ Telephone numbers
- ✓ Medical record numbers
- ✓ Health plan ID numbers
- ✓ Account numbers
- ✓ Social security number
- ✓ Electronic mail addresses
- ✓ Web addresses or URLs, IP addresses

Prior to de-identifying, each page of the medical record must be labeled with the event ID and the date of the event. This may be done by placing a pre-printed label on each page, or writing the information on each page. Blinded materials should be scanned using the document scanner provided for HCHS study use. Scanned medical records should be output from your scanner or workstation to the network server. Use output file type options for a OCR text formatted PDF file that would be named using the event ID of the case (e.g. B12345670201.PDF)

De-identification of hardcopies may be done using a regular point black Sharpie or similar marker. If masking is performed on electronic records, then use Adobe Acrobat to redact text of PDFs using a light gray colored overlay (not white, or deep black).

Transfer of Electronic Medical Records to the Data Coordinating Center

Scanned endpoints materials should be uploaded weekly to the HCHS coordinating center. More than one event may be batched in an upload with each of the separate PDF files uniquely named using the event ID of the case. The face sheet from the VER should be appended electronically in front of the first page of the scanned medical records. Weekly secure FTP upload requests for endpoints materials will be made by CC staff. Never email medical records to the CC, always use the secure FTP transfer mode instead. Electronic transfer is always preferred to postal mail delivery.

Shipping Printed Materials to the Data Coordinating Center

If hardcopy of records needs to be transmitted, then bundle materials for each participant event separately. The face sheet printed from the VER form must appear as the first page for each event packet. More than one event may be shipped together as long as each event has been accurately labeled. All medical records must be shipped by a service providing a tracking mechanism, such as Federal Express. Medical records may be shipped using 2nd or 3rd day delivery option. Next day delivery is not necessary and is more expensive. Remember to maintain the tracking number of the package(s) until notification of receipt by the Data Coordinating Center has been emailed to you.

Please mail medical record packet(s) to:

Allison McGee
(phone: (919) 966-6005 or (919) 667-3513~~962-3092~~)
HCHS/SOL Event Receiving
Collaborative Studies Coordinating Center
123 West Franklin St.Suite 450
Campus Box 8030
Chapel Hill, NC 27516

In the event that a record received at the CSCC has not been de-identified, the FC will be notified of this error, the record at the CSCC will be appropriately destroyed and a de-identified copy will need to be sent from the FC.

2.0 Endpoint Surveillance for Hospitalized Acute Myocardial Infarction

2.1 Introduction

The aim of surveillance of the HCHS/SOL cohort in regard to acute myocardial infarction is to identify all hospitalizations for each participant and validate the diagnosis of all potential coronary events. The criteria outlined below were created to be comparable to that used by MESA. Ascertainment and validation of all out-of-hospital fatal events that are potentially cardiac-related are also completed (see Endpoint surveillance of fatal events, Section 7 of this manual).

2.2 Event Identification

If a participant reports any hospitalization, field center staff requests the discharge summary, discharge diagnoses an associated ICD-9-CM or ICD-10-CM codes, and any related test results and progress notes from the hospital (see Table 1). A recent signed consent is required by most hospitals in order to release records (see earlier in this section for more information about consents). Once the record is received, field center staff matches the reported hospitalization to the actual record and, if discrepancies are found, re-contacts the participant to resolve these differences. If the event involved a transfer to another hospital or other health-care facility, field center staff obtain all pertinent records from all institutions. Transfers are considered together as one potential investigation.

Endpoints staff at the Coordinating Center reviews the ICD-9-CM or ICD-10-CM codes and, if necessary, the discharge summary, to complete the Events Eligibility form, which determines whether the hospitalization is eligible for further detailed record abstraction. (Please see Table 3.1 for a list of eligible ICD codes.) Pertinent parts of the hospital medical record will be copied and sent to the coordinating center for central abstraction. Components of the chart are scanned at the coordinating center and stored for use by the Endpoints Review committee.

2.3 Screening Codes

Events with CPT procedure code 35, ICD-9 discharge diagnosis codes 250, 390–459, 745–747, 794.3, 798-799 or ICD-10 codes (to be completed once CMS publishes its mapping from ICD-9 CM to IC-10 CM codes) are eligible for detailed abstraction by coordinating center staff for myocardial infarction. Events without these target codes, yet upon review the discharge summary by coordinating center abstractors contain evidence of eligible conditions an acute myocardial infarction event are also eligible for detailed abstraction.

2.4 Diagnostic Criteria

2.4.1 Myocardial Infarction. Myocardial infarction is defined as the death of part of the myocardium due to an occlusion of a coronary artery from any cause, including spasm, embolus, thrombus or rupture of a plaque. The algorithm for classifying MI includes history of chest pain, evidence from cardiac biomarkers, and ECGs. The criteria to be used in HCHS/SOL was designed to be comparable with that used in the MESA Study. Additional event classification elements (e.g. anatomical location of MI) not available in MESA were also incorporated into the HCHS/SOL MI validation process.

The definition includes MI that occurred during surgery/procedure and MI aborted by thrombolytic therapy or procedure. The differentiation of definite vs. probable MI will be made based on the criteria described below. These criteria are summarized in Table 4.

Table 4. HCHS/SOL Diagnostic Criteria for Hospitalized MI, adapted from MESA

ECG Pattern*	Abnormal	Equivocal	Incomplete	Normal

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

* ECG categories are listed in Appendix 6. Definite indicates definite MI; Probable, probable MI; and No, no MI. Classification of case is at highest level allowed by combinations of 3 characteristics (cardiac signs and symptoms, ECG findings, biomarkers).
** Abnormal and Diagnostic = Adequate set and ≥2xULN. Adequate are two sets at least 6 days apart at the time of the event.
Equivocal = Present but not diagnostic.
Incomplete = Not available for the time of the event.

2.5 Cardiac Symptoms and Signs

2.5.1 Chest Pain. Chest pain is defined as an episode of pain, tightness, pressure or discomfort in the chest, arm or jaw. If there is a clear non-cardiac cause, chest pain is considered to be absent. Duration of pain is not a part of the chest pain criterion. Adjudicators will assess for the presence of chest pain documented around the time of the potential MI. For events where the MI occurs after admission, chest pain at the actual time of the acute event being adjudicated is relevant (rather than, for example, chest pain prior to admission).

2.5.2 Cardiac Biomarker Criteria. The 2003 AHA Scientific Statement defined positive biomarkers as "the 99th percentile of the distribution in healthy populations or the lowest level at which a 10% coefficient of variation can be demonstrated for that laboratory." However, as of fall, 2004, this recommendation has not been consistently implemented by manufacturers and upper limits of normal range from the 95th percentile to the 99th percentile, with coefficients of variation difficult to ascertain at these levels. Many manufacturers continue to include an "indeterminate" range, often from the upper limit of normal to some higher value. This indeterminate range is not recommended to be of interest for determination of MI in epidemiologic studies according to the 2003 Position Statement, and will not be of interest to HCHS/SOL. Because of the continued inconsistency of reporting of the 99th percentile and the 10% coefficient of variation, HCHS/SOL will follow the practice of the MESA summarized in Table 3.

In the event that the actual laboratory values are not included in the medical record then biomarker results reported in physician notes are acceptable, as long as actual values are reported. Reports of biomarkers being "positive" or "negative" will not be sufficient. Use Table 1 to classify cardiac biomarkers. To summarize Table 1, equivocal biomarkers are between "above normal" and twice the Upper Limit of Normal (ULN), whereas "abnormal" biomarkers are greater than twice the upper limit of normal. When there has been muscle trauma, liver trauma, or hemolysis then positive enzymes are downgraded to equivocal. These criteria apply as long as the patient has not had Coronary Artery Bypass Surgery (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) in the previous 24 hours. In that case, see foot notes to classify.

Table 5. Algorithm to classify cardiac enzymes as abnormal, equivocal, or normal

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

*If PTCA then **abnormal** in first 48 hours if Troponins or LDH1 or CK or CK-MB>3X ULN; **equivocal** if 1-3X ULN. If CABG then **abnormal** in first 48 hours if troponins or LDH1 or CK-MB>5X ULN; **equivocal** if 1-5X ULN.

**CK and CK-MB must be in same units for this criterion

2.5.3 ECG Criteria. The ECG criteria for HCHS/SOL are based on the Minnesota Code system of classification which is outlined in the Minnesota Code ECG Criteria shown in the appendix. This is also the same criteria used in MESA. The reviewers will interpret serial tracings; the following ECG tracings are identified and provided for this purpose: the first, second, third and last ECGs obtained from the hospital admission.

The evolution of ECG findings may be demonstrated (1) between the ECG(s) associated with the event or (2) between a previously recorded ECG and the event ECG(s). In cases in which only a single event ECG is available, an evolving diagnostic ECG pattern cannot be recorded. In order to ascertain MI by ECG, precise guidelines to determine wave duration and voltage will be determined following the Minnesota Code. HCHS/SOL reviewers will consider the copies of actual ECGs submitted in the case packet and will make a clinical reading of the ECG pattern, using the Minnesota Code as a guide. The categories of ECG are: a) Evolution of Major Q-Wave, b) Evolution of ST-T Elevation with or without Q-Wave, c) New LBBB, d) Evolution of ST-Depression/T wave inversion alone, e) Evolution of Minor Q-Wave alone, f) Single ECG with Major Q-wave, g) Single ECG with LBBB, described as new, and h) Absent, Uncodable or Other ECG.

2.5.4 Subclassification of definite or probable MI: How to define MI type, location, and whether related to a procedure

MI type: For events classified as definite or probable MI, describe the type of MI as either transmural or subendocardial or undetermined (unsure). Record TRANSMURAL if there is ST elevation or a resulting Q wave note on the ECG. Record SUBENDOCARDIAL if there is no evidence of ST elevation or a resulting Q wave on the ECGs provided.

MI location: Based on your interpretation of the available ECGs, select the location of MI that best describes this event. General guidelines for defining MI location will be those outlined in AHA/ACCF/HRS recommendations for standardized interpretation of ECG (Wagner et al JACC, 2009;53:1003-1011). This will be discussed and revised further at the reviewer training and this manual modified accordingly. Reviewers are asked to classify the MI location for definite or probable MIs as either: 1) Anterior, 2) Posterior, 3) Inferior, 4) Lateral, 5) Septal, 6) Anteroseptal, 7) Anterolateral, or 9) Unable to determine.

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

Procedure-related MI: Cases classified as either definite or probable MI will be further assessed as to whether or not they are related to a procedure. Cardiac events up to 28 days after a medical procedure or surgery may meet criteria for being procedure-related. If the medical procedure was performed for the treatment of acute ischemia (e.g., angioplasty following the presentation of acute coronary syndrome), that event should *not* be considered procedure-related (Luepker, et al, 2003). The procedure-related MI

category is intended to identify MIs that occurred only after the procedure, and were not already in evolution prior to the procedure. In determining whether the MI was procedure related, answer YES (and choose whether it was a cardiovascular or non-cardiovascular procedure) if you think it is unlikely this MI would have occurred had the procedure not been performed. Answer YES, CARDIOVASCULAR PROCEDURE if the MI occurred within 28 days of a cardiovascular procedure or surgery AND in your judgment the MI was a complication (or related to) the procedure. Cardiovascular procedures include: CABG, valve replacement, AICD or pacemaker placement, PTCI, etc. Answer YES, NON-CARDIOVASCULAR PROCEDURE if the MI occurred within 28 days of a non-cardiovascular procedure or surgery AND in your judgment the MI was a complication (or related to) the procedure. Non-cardiovascular procedures include all procedures or surgeries that are not cardiovascular. Answer UNKNOWN/UNSURE if you are not certain as to whether the MI was procedure related or not.

2.5.5 Angina For events reviewed that are classified as "no MI" or "unclassifiable, then as a secondary endpoint reviewers are asked to state whether angina was present. Angina is a symptomatic event generally involving ischemic chest, left arm, or jaw pain, though the symptoms may be "atypical." Atypical anginal symptoms can include shortness of breath, exertional dyspnea, epigastric discomfort, and back pain, in addition to pain that is isolated to the arm or the jaw. HCHS/SOL endpoint reviewers categorize angina events as "definite," "probable," and "no Angina" based on their clinical judgment in light of the following criteria from the MESA study in answering this question:

a. Physician diagnosis of angina and receiving medical treatment for angina (e.g., nitrates, beta-blockers, or calcium-channel blockers)

b. CABG surgery or other revascularization procedure

c. 70% or greater obstruction of any coronary artery per angiography

d. Horizontal or down-sloping ST-segment depression or abnormal ST elevation of $\geq$1 mm on exercise or pharmacological stress testing with pain

e. Scintigraphic or echocardiographic stress test positive for ischemia

f. Resting ECG shows horizontal or down-sloping ST depression or abnormal ST elevation $\geq$1 mm with pain that is not present on ECG without pain

Given the difficultly in the diagnosis of angina yet the need to standardize its classification as much as possible, HCHS/SOL endpoint reviewers are instructed to follow the guidelines a-d below when recording their answer.

a. Clear and thorough documentation of symptoms is needed to identify an event as "definite angina." Even if a test such as an ETT lists "angina" or "chest pain" as its indication, angina should not be ruled as being present unless there is additional, explicit information from the physician regarding symptoms. Likewise, a test showing positive ischemia or the performance of a further procedure (e.g., catheterization) is not enough to rule for angina if other HCHS/SOL criteria are not met.

b. Only classify an event as angina if it is distinct from an MI.

c. Reviewers should not classify angina as part of pain symptoms of an MI.

d. Angina will require clinical symptoms. If there is only a physician diagnosis/treatment, then the diagnosis cannot be 'definite.' If there is more than just a physician diagnosis, then the reviewer can assign 'definite" instead of 'probable.'

2.5.6 Revascularization procedure interrupting an MI. Revascularization procedures occurring during the course of hospitalization in general will be documented by the abstractors. However,

HCHS/SOL endpoint reviewers are asked to record whether in their judgement an intervention performed early in the clinical presentation of a potential MI may have prevented an MI. In cases where revascularization was performed without clinical symptoms, HCHS/SOL endpoint reviewers will record NO to this item. Reviewers should record YES, if on presentation with chest pain or other MI symptoms, the patient is immediately received a revascularization procedure.

3.0 Endpoint Surveillance for Hospitalized Heart Failure

3.1 Introduction

All cases of hospitalized heart failure among HCHS/SOL participants will be identified through the annual follow up call. All eligible hospitalization will be investigated and processed through the HCHS/SOL Event Classification Committee. Heart failure events resulting in outpatient diagnosis and treatment without hospitalization will not be identified and reviewed by HCHS/SOL event reviewers. See nonfatal outpatient event surveillance for details.

3.2 Event Identification

Events to be investigated for hospitalized heart failure include those with the following target ICD-9 discharge diagnosis codes: 402, 404, 415, 416, 425, 428, 518.4, and 786. Equivalent ICD-10 codes mapped from ICD-9 codes for heart failure will also be investigated. Specified components of the medical record from eligible events will be copied and sent to the coordinating center for processing. Data from the medical record of hospitalizations with these discharge diagnosis codes will be abstracted using the HCHS/SOL heart failure abstraction form. Materials from the medical record to be copied and provided to the HCHS/SOL event reviewers include: the first three (3) chest X-ray reports, echocardiography reports, cardiology consult report, discharge summary, and cardiac catheterization report.

3.3 Diagnostic Criteria for Acute Decompensated Heart Failure

The HCHS/SOL criteria for heart failure were adapted from the MESA and the Atherosclerosis Risk in Communities study. HCHS/SOL physician reviewers will determine if the event has a heart failure diagnosis from the provider and whether the patient was treated for heart failure. The reviewer will also determine if there is sufficient evidence to indicate the patient has history of heart failure and whether there was X-ray pulmonary edema or congestion. Evaluation of these items follow MESA guidelines and allow for comparability of heart failure diagnosis between MESA and HCHS/SOL. (See Heart Failure Diagnosis (HFD) Form)

In addition HCHS/SOL physician reviewers categorize acute decompensated HF (ADHF) events as “definite,” “probable,” “no ADHF”, and “unknown” in a manner adapted from the ARIC classification scheme for heart failure.. (See Heart Failure Diagnosis (HFD) Form).

Specifically the HCHS/SOL reviewers are asked to evaluate the evidence for the following items:

a. Heart failure diagnosed by physician, and treatment provided for heart failure,
b. Acute decompensated heart failure,
c. Pulmonary edema/congestion by chest X-ray,
d. Cardiac imaging study results, (Each of these questions is asked separately and if present then specify, as to whether the finding was by history, or by current imaging.)
    1. Dilated ventricle or
    2. Poor left ventricular function (e.g., low ejection fraction or wall motion abnormalities),
    3. Poor right ventricular function, or
    4. Left ventricular diastolic dysfunction.

5. If available, the quantitative ejection fraction is specifically provided within a range of choices of ≥ 50, 40-49, 30-39, 20-29, <20 or unknown.

This approach has the advantage of easily permitting a range of analyses based on definitions of heart failure that include "soft" criteria or various types of "hard" criteria.

In general, the reviewer should examine the original report of a procedure rather than accept references to results of the diagnostic or therapeutic procedures in discharge summaries. If an original full report is not available, a convincing reference to the procedure results in the discharge summary is acceptable.

In addition, HCHS/SOL reviewers evaluate the evidence or against history of heart failure, severity of heart failure and presence of right-sided heart failure, comorbid conditions, and asymptomatic ventricular dysfunction. These are described in more detail below.

3.3.1 Prior history of heart failure. Reviewers are asked to classify the event to whether participant had a prior history of HF or not. Prior history is relevant as the evaluation of a patient with an established history of HF may be more limited as compared to a patient with a new diagnosis of heart failure. This also allows the HCHS/SOL to classify those with chronic stable heart failure if the answer is YES to prior history of HF and NO for the classification of ADHF.

3.3.2 Severity of the heart failure exacerbation. Reviewers classify the severity of the HF exacerbation for those classified as probable or definite ADHF. Classify the event as SEVERE if treatment with mechanical ventilation, non-rebreather mask, CPAP, hemofiltration, intraortic balloon pump, or thoracentesis was required for management of HF exacerbation. Classify event as MODERATE, if it is clear the event was neither SEVERE nor MILD. Classify event as MILD if this exacerbation could have been managed in the outpatient setting had the patient been an outpatient. In these cases, the primary reason for being hospitalized will likely be something other than HF. If it is unclear as to the severity of the event then classify as UNKNOWN.

3.3.3 Predominantly right-sided heart failure. The most common presentation for ADHF is left sided HF which is dyspnea and pulmonary edema, however symptoms of pure right sided HF do not include dyspnea. In the future when considering criteria for the diagnosis of HF, it may be necessary to differentiate left and right sided HF. Answer YES if the patient had right-sided heart failure symptoms only of lower extremity edema and possible ascites and a normal LV ejection fraction. Answer NO/NR if the patient had both right-sided and left-sided signs/symptoms, or if it is clearly not right sided HF, or it is unclear whether the patient had predominantly right sided failure.

3.3.4 Co-morbid and potentially precipitating factors to ADHF. Acute decompensated HF may be precipitated by multiple conditions. In addition, many of the listed comorbid condition may be caused by the exacerbation. As a result, it can be difficult to tell whether the condition precipitated the event or not. Here we ask reviewers to consider the timeline of occurrence of the condition with the HF exacerbation and based on their judgment state as to whether the condition may have precipitated the HF exacerbation. As stated in the question by question instructions for the HFD form, reviewers indicate all co-morbid conditions that were active during this hospitalization AND may have precipitated the event. The temporal association of between the event and the HF exacerbation should make sense. For example, if the patient came in for surgery and had an exacerbation of HF immediately following surgery due to fluid overload then check YES to fluid overload. If the same patient then had a complicated coarse and developed a PE many days later then check NO/NR for PE, if it temporal association with the HF exacerbation is not correct. If a patient presents to the hospital with heart failure AND one of these diagnosis that is active then check YES. For example, if presents with both HF and atrial fibrillation the

check YES for atrial fibrillation. Reviewers answer No/Not recorded or YES to all of the following: 1) Myocardial infarction, 2) Atrial fibrillation or atrial flutter, 3) Other arrhythmia, 4) Fluid overload or volume overload- this refers only to either iatrogenic fluid overload OR to excessive drinking of fluids, or renal failure due to missed or inadequate hemodialysis, 5) Medication noncompliance – Medication noncompliance would include refusal of medications for patients in the hospital, but more commonly this would be outpatient noncompliance. Noncompliance includes those patients who did not get their medications due to lack of funds, 6) Pulmonary embolus, 7) Renal insufficiency or failure – use your judgement as to whether renal failure was of a severity that it may have contributed to the HF. This would likely be those who are approaching dialysis and are less responsive to diuretics, 8) Cardiovascular procedure/surgery, 9) Non-cardiovascular procedure/surgery, 10) Pulmonary disease, and 11) Uncontrolled Hypertension – systolic blood pressure >180 at the time of the event.

3.3.5 Asymptomatic left ventricular dysfunction. The focus of the primary outcome in HCHS/SOL is classification of acute decompensated heart failure (adapted from ARIC criteria) and the MESA definition of physician diagnosed and treated heart failure. In addition, for those events that are not classified as "definite" or "probable" ADHF then we ask reviewers to identify those with asymptomatic left ventricular dysfunction, defined here as documented ejection fraction < 50%, but no HF symptoms previously or during this admission.

4.0 Endpoint Surveillance for Stroke and Transient Ischemic Attacks

4.1 Event Identification

A hospitalization is eligible for stroke evaluation and classification by the HCHS/SOL reviewers if it has an ICD-9 procedure code 38-39 or discharge diagnosis codes for cerebrovascular (ICD-9-CM 430-438, and equivalent ICD-10 CM codes mapped from ICD-9 codes for stroke.). If a hospitalization meets procedure or discharge code criteria for stroke or transient ischemic attack (TIA,) the medical records obtained by field center staff and sent to the coordinating center for detailed abstraction using the HCHS/SOL stroke abstraction form. These data will be summarized and made available to the stroke group of the Event Classification Committee. Copies of specific portions of the medial record are also provided to the HCHS/SOL reviewers. The reviewers will follow the criteria below in making a final event classification.

4.2 Diagnostic Criteria

The classification criteria for stroke and TIA for HCHS/SOL were adapted from MESA.

4.3 Definitions of TIA and Stroke

4.3.1 Transient Ischemic Attack (TIA) Transient ischemic attack is a temporary stroke-like event that lasts for only a short time and is caused by temporarily blocked blood vessels to part of the brain. For the purposes of HCHS/SOL classification of TIA, a TIA includes one or more episodes of [acute] focal neurologic deficit, lasting more than 30 seconds, with complete resolution of focal neurologic deficit within 24 hours. It must have no clinically relevant lesion on brain imaging (or brain imaging not done). In order for an event to be classified as TIA it must NOT have any of the following features: clonic jerking, conjugate eye deviation, prolonged focal seizure with spread, scintillating scotoma, headache with nausea and vomiting, or immediately-preceding head trauma.

A clinically relevant lesion on brain imaging includes finding judged to be consistent with signs and symptoms regardless of timing of brain imaging (i.e., less or greater than 24 hours), regardless of stroke type (i.e., with or without blood), and regardless of imaging technique (i.e., cranial competed tomography [CT scan] or cranial magnetic resonance imaging [MRI]). If an event under review is determined by the

reviewer to classified as a TIA, this is indicated on the stroke reviewer diagnosis form and no further subtyping or detailed review is required.

4.3.2 Stroke A stroke is defined as loss of muscle function, vision, sensation or speech resulting from brain cell damage caused by an insufficient supply of blood to part of the brain. Synonyms for stroke include apoplexy, cerebrovascular accident, or cerebral vascular accident. For the purpose of HCHS/SOL classification of stroke, a stroke involves rapid onset of neurologic deficit, headache, or meningismus and neurologic deficits not secondary to brain trauma (closed head injury), tumor, infection (e.g., encephalitis or meningitis), or other non-vascular cause. Clinical evidence or suspicion of embolic stroke secondary to SBE is counted as stroke. Classification of stroke requires either clinically relevant lesion on brain imaging∗, or duration of symptoms greater than 24 hours, or death within 24 hours of symptoms.

4.4 Definitions of stroke subtypes

4.4.1 Subarachnoid hemorrhage (SAH): A subarachnoid hemorrhage has a clinical presentation of sudden onset of headache, meningismus, loss of consciousness, or coma. Focal neurologic deficit may also be present. Classification of SAH also requires consistent imaging findings with blood mainly in the subarachnoid space (basal cistern or convexity) or isolated intraventricular hemorrhage, or cerebral fluid bloody or xanthochromic on direct non-traumatic examination. Surgical or autopsy evidence of subarachnoid hemorrhage is sufficient for a classification of SAH.

4.4.2. Intraparenchymal hemorrhage (IPH): A intraparenchymal hemorrhage has a clinical presentation of focal neurologic deficit, coma as a possible accompanying condition. Classification of IPH requires consistent imaging findings with mainly intraparenchymal, dense hemorrhage, or if there is no imaging available, cerebral spinal fluid bloody or xanthochromic on direct non-traumatic examination or surgical or autopsy evidence of intraparenchymal hemorrhage is sufficient for a classification of IPH.

4.4.3. Other hemorrhage (OH): If there is insufficient data to classify subarachnoid or intraparencymal hemorrhage, and imaging shows blood in the parenchyma, subarachnoid space, or both then a classification of other hemorrhage is made. Cerebrospinal fluid bloody or xanthochromic on direct non-traumatic examination, or surgical or autopsy evidence of blood in parenchyma, subarachnoid space, or both in the absence of a classification of SAH or IPH is sufficient for a classification of other hemorrhage.

4.4.4. Brain infarction (ischemic stroke) (INF): If a case does not meet criteria for SAH, IPH, or OH and there is a clinical presentation of focal neurologic deficit (with or without coma present) and there is consistent imaging findings without clinically relevant lesion or with clinically relevant mainly non-hemorrhagic lesion or hemorrhagic lesion indicating a hemorrhagic infarction a classification of INF can be made. Surgical or autopsy evidence of brain infarction is also sufficient for a classification of INF.

4.4.5. Other stroke types (OS): If a case does not meet criteria for SAH, IPH, OH, or INF and there is a clinical presentation of focal neurologic deficit it may be classified as OS. Examples include venous thrombosis with bleed and arterial dissection.

4.4.6. Unknown stroke type: If a case does not meet criteria for SAH, IPH, OH, INF, or OS and there is a clinical presentation of focal neurologic deficit it may be classified as UNK. Examples includes evidence of symptoms but no work-up was done. A classification of NO stroke is made if the case meets none of the criteria above.

4.5 Ischemic Stroke Classification

Ischemic Stroke Classification (modified TOAST criteria utilizing findings of Neuroimaging, especially MRI and MRA) Hospitalizations classified by HCHS/SOL reviewers as ischemic strokes (INF) are further classified by reviewers using the following sub-classification criteria.

4.5.1. Cardioembolic stroke: Symptoms consistent with brain infarction (see general definition of brain infarction); and acute or subacute appearing, cortical or cerebellar infarcts and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on neuroimaging (CT or MRI), either in one or multiple vascular territories; and evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence); and no supportive evidence by vascular imaging for a stenosis of greater than 50% of the appropriate extracranial artery proximal to the infarct (diagnosed either by ultrasound studies, CTA, MRA, or conventional DSA); and no laboratory abnormality suggestive for non-cardiac, non-lacunar, or non-athero thromboembolic cause (for example nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.5.2 Extracranial large-artery atherosclerosis: Symptoms consistent with brain infarction (see general definition of brain infarction); and acute or subacute appearing, cortical or cerebellar infarcts and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on neuroimaging (CT or MRI); and supportive evidence by vascular imaging of a stenosis of greater than 50% of the appropriate extracranial artery proximal to the infarct (diagnosed either by ultrasound studies, CTA, MRA, or conventional DSA); and no evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence); and no laboratory abnormality suggestive for non-cardiac, non-lacunar, or non-athero thromboembolic cause (for example nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.5.3. Intracranial large-artery atherosclerosis: Symptoms consistent with brain infarction (see general definition of brain infarction); and acute or subacute appearing, cortical or cerebellar infarcts and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on neuroimaging (CT or MRI); and supportive evidence by vascular imaging of a stenosis of greater than 50% of the appropriate intracranial artery proximal to the infarct (diagnosed either by ultrasound studies, CTA, MRA, or conventional DSA); and no evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence); and no laboratory abnormality suggestive for non-cardiac, non-lacunar, or non-athero thromboembolic cause (for example nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.5.4. Lacunar stroke: Symptoms consistent with brain infarction (see general definition of brain infarction); and symptoms consistent with a lacunar stroke syndrome (i.e. pure motor, pure sensory, mixed sensorimotor syndrome without cortical signs, ataxic hemiparesis, dysarthria-clumsy hand syndrome); acute or subacute appearing infarct <1.5 cm in diameter in a subcortical structure or brainstem in the territory of a small penetrating artery on neuroimaging (CT or MRI): Infarct should be smaller than 1.5 cm (or described as ‘small’ or ‘lacunar’). Typical subcortical locations include corona radiata, internal capsule, external capsule, basal ganglia, thalamus. Lesions may also be in the pons or medulla. Reviewers may score this response if ANY one of multiple new lacunar infarcts is appropriate for symptoms. Reviewers may also be scored if there is a clinically appropriate lesion of undetermined age. Do not score if the patient is described as having ‘Binswanger’s disease (encephalopathy)’ unless there is a discrete new lesion appropriate for symptoms; and no evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence); and no evidence for intra- or extracranial large artery stenosis in the artery proximal to the infarct (by CTA, MRA, or conventional angiography); and no laboratory abnormality suggestive for non-cardiac, non-lacunar, or non-athero thromboembolic cause (for example nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.5.5. Other determined etiology: Symptoms consistent with brain infarction (see general definition of brain infarction); and acute or subacute appearing infarct of any size in diameter either in cortical or subcortical structure or brainstem on neuroimaging (CT or MRI); and no evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence); and no evidence for intra- or extracranial large artery stenosis in the artery proximal to the infarct (by CTA, MRA, or conventional angiography); and laboratory abnormality suggestive for non-cardiac, non-lacunar, or non-athero thromboembolic cause (for example nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.5.6. Undetermined etiology, complete: Symptoms consistent with brain infarction (see general definition of brain infarction) ; and acute or subacute appearing, cortical or cerebellar infarcts and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on neuroimaging (CT or MRI); and no supportive evidence by vascular imaging of a stenosis of greater than 50% of the appropriate intra- or extracranial artery proximal to the infarct (diagnosed either by ultrasound studies, CTA, MRA, or conventional DSA); and no evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence); and no laboratory abnormality suggestive for non-cardiac, non-lacunar, or n non-athero thromboembolic cause (for nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.5.7. Undetermined etiology, incomplete evaluation: Symptoms consistent with brain infarction (see general definition of brain infarction); and incomplete cardiac evaluation (EKG or transthoracic echocardiography not performed); or incomplete evaluation of extra- or intracranial arteries (carotid ultrasound, CTA or MRA not performed).

4.5.8. Multiple possible etiologies: Symptoms consistent with brain infarction (see general definition of brain infarction); and a combination of at least 2 or more of the following:

- Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on neuroimaging (CT or MRI)
- Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts less or equal than 1.5 cm in diameter on neuroimaging (CT or MRI)
- supportive evidence by vascular imaging of a stenosis of greater than 50% of the appropriate extracranial artery proximal to the infarct (diagnosed either by ultrasound studies, CTA, MRA, or conventional DSA).
- supportive evidence by vascular imaging of a stenosis of greater than 50% of the appropriate intracranial artery proximal to the infarct (diagnosed either by ultrasound studies, CTA, MRA, or conventional DSA).
- evidence suggestive for high-risk or medium-risk cardiac source for emboli (clinical and laboratory evidence)
- no laboratory abnormality suggestive for non-cardiac, non-lacunar, or non-atherothromboembolic cause (for example nonatherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders).

4.6 Ischemic Stroke Classification *Use of Probable and Possible Brain Infarct Subtype Classification* (modified TOAST criteria)

A "possible" diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype, but other studies are not done. A “probable” diagnosis is made when the clinical findings and diagnostic work-up are complete to allow classification to one of the major brain infarct subtypes. The diagnostic work-up must include clinical syndrome description, neuroimaging, intra- and extracranial vascular imaging, EKG, at least transthoracic echocardiography, and basic laboratory studies.

5.0 Endpoint Surveillance for Exacerbations due to Chronic Obstructive Pulmonary Disease or Asthma

5.1 Introduction

All cases of exacerbation due to COPD or asthma resulting in either a hospitalization or emergency room visit among HCHS/SOL participants will be identified through the annual follow up call. All eligible events will be investigated and processed through the HCHS/SOL Event Classification Committee. Self-reported COPD and asthma exacerbations resulting in outpatient diagnosis and treatment without hospitalization or emergency department visits will also be identified through the annual follow up call. However, the outpatient records will not be obtained for verification.

COPD and asthma are the most common chronic lung diseases in adults. Patients with asthma have intermittent airway obstruction while those with COPD have irreversible airway obstruction (90% due to smoking). The distinction between asthma and COPD in adults has become blurred during the past five years, as the term COPD has been advertised to primary care physicians and the general public. Industry-sponsored COPD guidelines cause many adults with asthma (even never-smokers) to be falsely labeled as COPD. Asthma can begin at any age (even after age 75). Only half of asthma in adults is associated with or triggered by allergies (extrinsic asthma). There is some overlap between COPD and asthma.

By definition, GOLD criteria classify a non-smoking asthmatic that develops irreversible changes as COPD, although this type of case would be clarified clinically as COPD secondary to asthma. About half of adults with asthma are smokers. Both asthma and COPD are under-diagnosed and over-diagnosed, so self-reports and physician diagnoses are unreliable. Misclassification rates are high because objective test results are often not obtained or are incorrectly interpreted. In particular, pulmonary function tests are not generally obtained at the time of a respiratory exacerbation. About half of those with asthma or COPD in general population samples have not been diagnosed. On the other hand, some patients who have been prescribed inhalers for asthma or COPD have neither asthma nor COPD.

5.2 Event Identification

Hospitalization and emergency room events to be investigated for exacerbation due to COPD should have one of the following ICD-9 codes: 490, 491 (chronic obstructive bronchitis), 492 (emphysema), 494 (bronchiectasis), 496 (chronic airway obstruction not otherwise classified), 415, and 416.9. The codes for asthma start with 493. ICD Code 518 (Respiratory Failure, secondary to COPD) will also be investigated. Hypersensitivity pneumonitis (495) will not be considered as COPD or asthma (mapped ICD-10 codes are in the process of being published).

Data from hospitalizations and emergency room visits with the above discharge codes will be abstracted using the HCHS/SOL pulmonary event abstraction form (PUL). Requests for medical records are sent to the hospital and specified components of the medical record for that visit are requested. The record is blinded at the field center site and then copied and sent to the coordinating center. For emergency room visits, this information will include discharge diagnoses, physician, triage, and nurses notes, chest X-ray

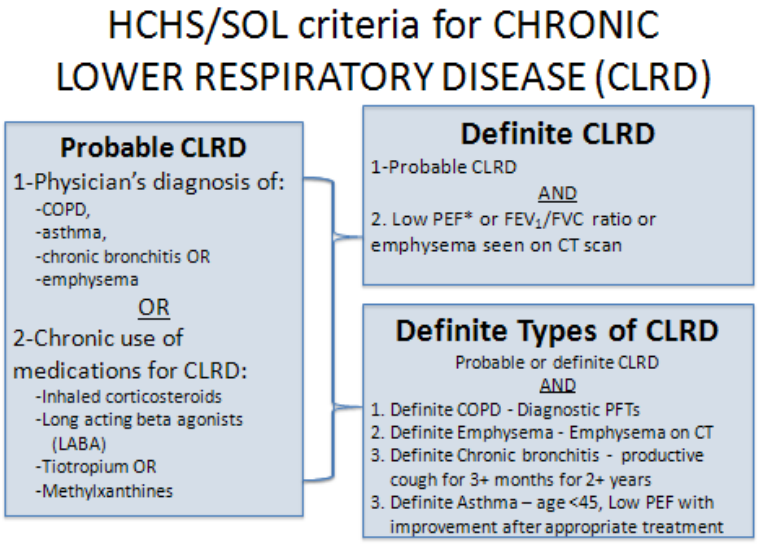
reports, blood count, temperature, oxygen saturation by pulse oximetry, spirometry or peak flow, arterial blood gases, and treatments such as bronchodilators, oxygen, and corticosteroids. For hospitalizations, the same test results will be required, and in addition, discharge medications and pulmonary function results, if performed.

Exacerbations of both asthma and COPD will be diagnosed based on chart review including the materials described above. In a patient presenting to the emergency department (ED) with an acute episode of shortness of breath, it is often difficult to distinguish between pneumonia, an asthma exacerbation, a COPD exacerbation, a pulmonary embolism, and an exacerbation of congestive heart failure (CHF). A bacterial or viral pneumonia can trigger an asthma or COPD exacerbation, but the usual cause is an upper respiratory viral infection (Fabbri L, et al, Similarities and discrepancies between exacerbations of asthma and COPD. *Thorax* 1998; 53:803). The criteria used below were created by consensus by the HCHS/SOL pulmonary endpoints committee.

5.3 Diagnostic criteria for pulmonary events

Initially reviewers will state the level of evidence for whether the participant has a *history of chronic lower respiratory disease* (CLRD) as definite, probable, probably not, definitely not, and unknown. CLRD includes COPD, emphysema, chronic bronchitis, and asthma. Our first question is broad, in case details regarding history of respiratory disease are limited. Criteria for definite and probable CLRD are shown in the figure below. Criteria for a categorization of "definite" for each type of CLRD are specified below in the figure.

Figure 2.



The peak expiratory flow (PEF) and pulmonary function tests (PFTs) referred to in the figure are those in the medical record and not from the HCHS/SOL study visit. PFTs from the study visit will not be used to classify events. *See PFT criteria page for definitions of obstruction.

Definite criteria for the diagnosis of COPD require obstruction on PFTs or a low peak expiratory flow, both defined in the PFTs section. Definite emphysema must be confirmed on chest CT. Definite chronic bronchitis is only a clinical definition: cough for at least 3 months of the year for at least two years in a row. Note that you can have definite emphysema without PFTS, but this would not be definite COPD (need to confirm obstruction). The same is true for chronic bronchitis (ie, no PFTs does not confirm COPD)

Definite asthma is defined by low peak flow with improvement with bronchodilators in a patient less than 45 years of age. Definite criteria for diagnosis of asthma also includes the following: positive methacholine challenge test, and reversibility on PFTs with no other obstructive lung diseases (eg CF, bronchiectasis, upper airway obstruction). See below for definition of reversibility in PFTs. In hospital and ER medical records are most likely to have PEF measures and not PFT measures.

'PROBABLE' CLRD should be selected if there is a physician diagnosis of COPD, emphysema, asthma, or chronic bronchitis OR chronic use of medications used to manage CLRD including inhaled corticosteroids (not intra-nasal), inhaled long acting beta agonists (eg, salmeterol [Serevent], formoterol [Foradil]), inhaled long acting anticholinergic (ie Spiriva or tiotriopium), or methylxanthines (eg, theophylline).

If the answer is definite or probable history of CLRD, we ask about the evidence for history of each specific type of CLRD --COPD, emphysema, chronic bronchitis, and asthma with the same categories as in the first question. These questions go beyond 'history of', include 'new onset'.

COPD. Answer DEFINITE if there is definite or probable history of CLRD and if there is evidence of obstruction from PFTs, per HCHS/SOL criteria. IF PFTs are not available and there is a history reported of COPD then answer PROBABLE. IF there is conflicting information as to whether the patient has COPD or not then answer unclassifiable. If there are normal PFTs then answer DEFINITELY NOT.

Emphysema. Answer DEFINITE if there is evidence of emphysema from a CT scan. Answer PROBABLE if there is an MD diagnosis of emphysema, but there is not imaging to support the diagnosis or if only the CXR is suggestive of emphysema. Answer DEFINITELY NOT, if there is a normal CHEST CT in which the lung parenchyma is reported as normal. IF there is conflicting information as to whether the patient has emphysema or not then answer unclassifiable.

Chronic Bronchitis. Definite chronic bronchitis is only a clinical definition. Answer DEFINITE if cough for at least 3 months of the year for at least two years in a row is reported. Answer PROBABLE, if there is a physician diagnosis of chronic bronchitis. Answer UNCLASSIFIABLE if it is not stated whether the patient has had chronic cough or not.

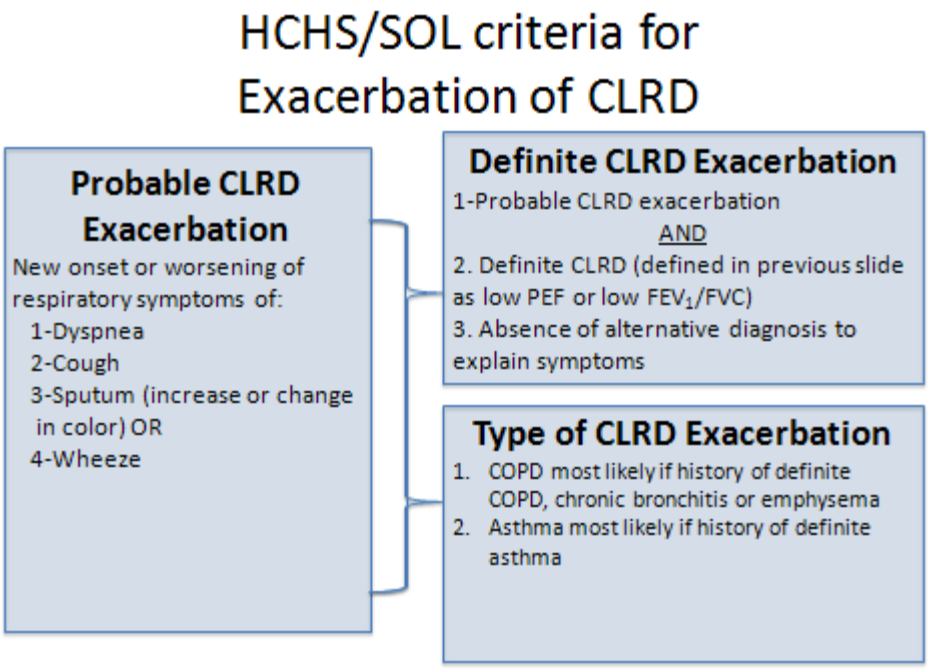
Asthma. Answer DEFINITE, if patient with a history of asthma has a low peak flow with improvement with bronchodilators AND the patient is less than 45 years of age. Definite criteria for diagnosis of asthma also includes the following: positive methacholine challenge test, and reversibility on PFTs with no other obstructive lung diseases (eg CF, bronchiectasis, upper airway obstruction). In medical records, we are most likely to have PEF measures. Answer PROBABLE, if patient has a history of asthma AND has a history of the following: age of onset of asthma under the age of 40, positive allergy testing, wheezing on exam that responds to bronchodilators.

If there is some other lung disease present, then specify the type.

Next reviewers are asked about an exacerbation of underlying chronic lower respiratory disease (CLRD). Answer PROBABLE, if the patient has new onset or worsening of respiratory symptoms which must include the following symptoms: dyspnea, cough, change in sputum color, change in sputum volume, or wheeze (either reported or on exam). If the primary reason the patient is in the ER or hospital is for one of these symptoms then assume symptoms are worse from baseline. Answer 3a.

Answer DEFINITE, if the patient has criteria for a probable CLRD exacerbation AND a low peak flow or low FEV1/FVC, AND absence of alternative diagnosis likely to cause CLRD symptoms and/or low peak flow or low FEV1/FVC. Answer DEFINITELY NOT, if the patient does not have symptoms of CLRD exacerbation and/or has a clear alternative cause of symptoms. Answer PROBABLY NOT, if there is not strong enough evidence to answer DEFINITELY NOT, but you feel it is not likely that the patient has an exacerbation of CLRD. Answer UNCLASSIFIABLE if there is inadequate information to determine if there is an exacerbation of CLRD. Skip to question 4.

Figure 3.



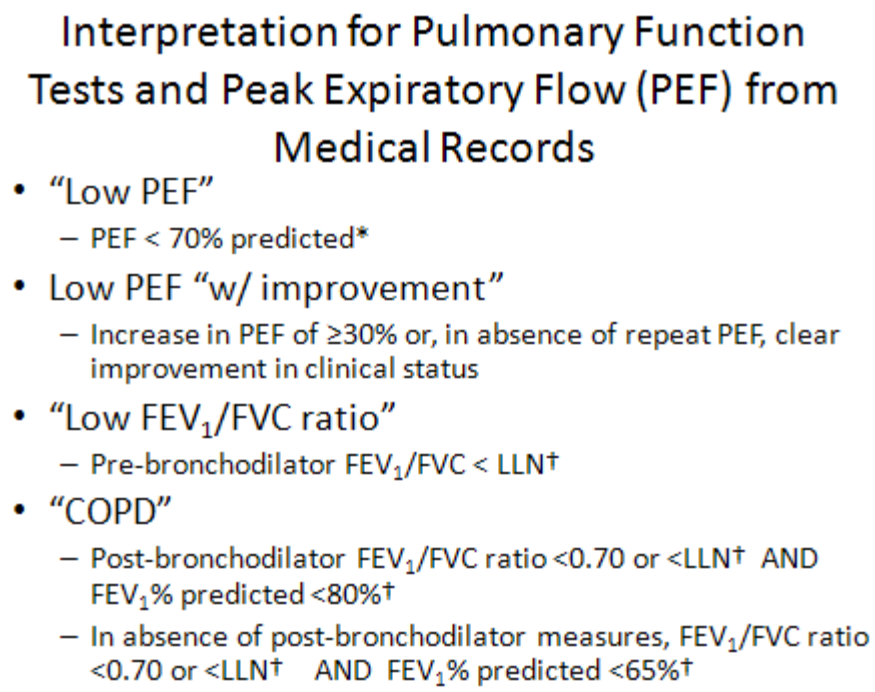
If definite or probable exacerbation, then specify which type of lung disease is likely the cause: COPD predominant, asthma predominant, either asthma or COPD or unclassifiable. Answer 'asthma predominant' if it is clear from the medical record that asthma is the cause of the exacerbation. Answer 'COPD predominant' if it is clear from the medical record that COPD is the cause of the exacerbation. Answer 'either asthma or COPD' if the physicians are not sure if the patient has asthma or COPD and/or if there is conflicting evidence as to which diagnosis that is the cause of the exacerbation. Answer UNCLASSIFIABLE if there is not adequate information to determine whether COPD or asthma was the cause of the exacerbation.

Pneumonia causes respiratory symptoms that are similar to a COPD exacerbation, it is somewhat controversial as to whether a person with COPD and pneumonia also has a COPD exacerbation, therefore reviewers need to state whether the patient had pneumonia, defined as a new infiltrate on Chest Xray or on chest CT scan. The same 5 categories from definite to unknown are available as options.

Interpretation of PFTS and Peak expiratory flow from medical records

In order to classify pulmonary events, one must have criteria for interpreting pulmonary function tests and peak expiratory flow values that are found in the medical record. Although as mentioned, it is mostly PEF

values that will be found in a medical record for a potential CLRD exacerbation. The criteria described and summarized below.



"Low PEF" is defined as PEF < 70% predicted. PEF predicted values will be based upon HCHS/SOL predicted values (currently pending) using age at time of clinical PEF measurement, gender, and measured height at HCHS/SOL exam. These 3 variables are included in the event summary form available with all medical records sent to reviewers.

Low PEF "w/ improvement" is defined as an increase in PEF of ≥30% or, in absence of repeat PEF, clear improvement in clinical status.

"Low FEV1/FVC ratio" is defined as pre-bronchodilator FEV1/FVC < LLN (lower limit of normal). The LLN for FEV1/FVC is based upon HCHS/SOL reference equations, determined on each individual patient, (currently pending) using age at time of clinical PFT measurement, gender, and measured height at HCHS/SOL exam.

"COPD" from PFT results are based ideally on post-bronchodilator PFTS; however, if not available then pre-bronchodilator PFTs are used.

The definition for COPD from post-bronchodilator PFTs is: 1) FEV1/FVC ratio <0.70 or <LLN.

In absence of post-bronchodilator measures, the definition of COPD from pre-bronchodilator PFTS is: 1) FEV1/FVC ratio <0.70 or <LLN AND 2) FEV1 percent predicted <65%.

6.0 Endpoint Surveillance for Pregnancy Related Complications

6.1 Introduction

The numerous physiological changes that occur during pregnancy stress the metabolic system and thus may reveal existing subclinical disease states as well as trigger the onset of new chronic conditions. Several studies have demonstrated that gestational diabetes (GDM) is associated with a four-fold higher risk of subsequent type 2 diabetes (T2DM). Hypertensive disorders during pregnancy are associated with subsequent high CVD risk factor status and elevated CVD risk. Offspring born to women with GDM are more likely to be overweight or develop metabolic syndrome or T2DM later in life. However, few such studies have included H/L women, and few studies have pre-pregnancy metabolic measures from a population-based sample. HCHS/SOL allows timely study of this issue, given the high prevalence of obesity (a RF for pregnancy complications) among H/L women, and the proposed collection of extensive longitudinal data on CVD RFs.

The specific endpoints of interest for pregnancy related complications (PRC) are pre-eclampsia, eclampsia, and gestational diabetes. All potential cases of one of these pregnancy related complications resulting in either a hospitalization or emergency room visit among HCHS/SOL participants will be identified through the annual follow up call, at the time of the second HCHS/SOL study visit, or through existing hospital medical records available at the CSCC. All eligible events will be investigated and processed through the HCHS/SOL Event Classification Committee. In addition, if possible, birth certificates will be requested to provide information on the child, and assure other events were not missed. Note that these three conditions will be classified by reviewing all hospitalizations or ER visit, and the birth certificate (if available), for the entire pregnancy episode, rather than by each hospitalization or ER visit.

6.2 Event Identification

Hospitalization and emergency room events to be investigated for pregnancy related complications (PRC) of interest should have one of the relevant keywords (see table) in the medical record for a pregnancy or one of the following ICD-9 or ICD-10 codes shown in the table. Since baseline, the HCHS/SOL study has collected discharge summaries and face sheets for all hospitalizations. Those hospital medical records on file at the CSCC will be used to classify PRC using an abstraction form, and a physician review panel with adjudication.

Medical records collected for all hospitalizations since baseline will be used to classify pregnancy related complications events using those existing records. In addition, we will request birth certificates for all births since the baseline visit to assess the presence of maternal pregnancy-related diagnoses of interest for each pregnancy. In addition, the event eligibility form has been updated to include the relevant keywords and ICD codes for PRC, such that current hospitalizations and ER visits that are being investigated will request additional medical records of relevance to classify the event.

Data from hospitalizations and emergency room visits with any of the below discharge codes or keywords will be abstracted using the HCHS/SOL pregnancy complications abstraction form (PCA). Requests for medical records are sent to the hospital and specified components of the medical record for that visit are requested. The record is blinded at the field center site and then copied and sent to the coordinating center.

Pregnancy related complications will be <u>diagnosed per pregnancy</u> rather than per admission or ER visit. All admissions and emergency room visits for that pregnancy will be reviewed as a single event by physicians on the pregnancy related complications review panel. Events for pregnancy related complications will be diagnosed based on chart review including the materials described above.

Table 6. Keywords and ICD codes used to identify events for abstraction as and review as a possible pregnancy related complication			
Diagnosis	**ICD9**	**ICD10**	**Keywords**
Mild or unspecified preeclampsia	642.4x	O14.0x, O14.9x	Preeclampsia, toxemia, eclampsia, PreX, PEC, PET,
Severe preeclampsia	642.5x	O14.1x O14.2x	Preeclampsia, toxemia, eclampsia, PreX, PEC, PET,
Preeclampsia superimposed on chronic HTN	642.7x	O11.x	Preeclampsia, toxemia, eclampsia, PreX, PEC, PET,
Gestational hypertension	642.3x	O13.x	PIH, pregnancy-induced hypertension, gHTN, Gestational hypertension
Eclampsia	642.6x	O15.x	Seizure, eclampsia,
Pregestational hypertension	642.0x 642.1x 642.2x	O10.1x O10.2x O10.3x O16.x	Chronic hypertension, pregestational hypertension, htn
Gestational Diabetes	648.8x	O24.4 O99.81	Gestational diabetes, diabetes, hyperglycemia, insulin
Pregestational Diabetes	648.0x	O24.0x O24.1x O24.3x O24.8x O24.9	Gestational diabetes, diabetes, hyperglycemia, insulin

6.3 Physician review of events

There will be a panel of physician reviewers for pregnancy related outcomes. This panel will be trained and certified to classify PRC. There will be one type of reviewer form for all PRC of interest including pre-eclampsia, eclampsia and gestational diabetes. For each potential pregnancy event, two reviewers will be assigned to review the event independently, and if needed, an adjudicator will resolve differences between reviewers to provide a final classification for the event.

6.4 Diagnostic criteria for pregnancy related complications

There are two main outcomes of interest for pregnancy related complications, which are: 1) Pre-eclampsia or eclampsia and 2) Gestational Diabetes. The diagnostic criteria that will be used to classify these events by the physician reviewer panel are discussed below. Criteria for each of these pregnancy complications will be defined based on existing diagnostic criteria, and experience from research studies. Physician reviewers are asked to use their judgment in applying these criteria after review of the available medical records.

6.4.1 Pre-eclampsia and Eclampsia

Table 7. Diagnostic criteria for definite, probable, unlikely and unclassifiable pre-eclampsia and eclampsia		
	Pre-Eclampsia	Eclampsia
Definite	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 6 hours apart) AND 2) Proteinuria by one of the following criteria one of the following: a) ≥ 0.3g / 24h urine , or b) ≥1+ urine dipstick, or c) urine protein:creatinine ratio documented as "positive" by local lab criteria	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 6 hours apart) AND 2) a grand mal seizure during pregnancy in the absence of other known causes
Probable	1) a) Mention of pre-eclampsia, or other keywords for pre-eclampsia in the medical record AND b) Mention of protein or albumin in the urine in the medical record OR 2) Documentation of intrapartum magnesium for seizure prophylaxis	A grand mal seizure during pregnancy in the absence of other known causes for seizure
Unlikely	Normal documented blood pressure, AND urine protein not documented or <1+, AND no mention of preeclampsia for this pregnancy in obstetric records in a record with reasonable documentation	No mention of seizure or eclampsia during this pregnancy, in a medical record with reasonable documentation
Unclassifiable	Contradictory information or inadequate medical record such that unable to classify as pre-eclampsia or not	Contradictory information or inadequate medical record such that unable to classify as eclampsia or not

6.4.2 Gestational Diabetes Mellitus

Table 8. Diagnostic criteria for Gestational Diabetes Mellitus (GDM)	
Definite	1) Glucose tolerance testing results not available AND documented treatment with insulin or oral hypoglycemic (ie glyburide) OR 2) Laboratory evidence of diagnostic glucose intolerance (one of a-d): a) 3 hour Oral glucose tolerance test (OGTT) with ≥2 abnormal values: fasting glucose ≥95mg/dL; 1 hour ≥180mg/dL; 2 hour ≥155mg/dL; 3 hour ≥ 140mg /dL (Carpenter-Coustan Criteria), OR b) 2 hour 75g oral glucose tolerance test exceeding any one of the following thresholds: fasting glucose ≥ 92 mg/dl, or 1 hour ≥180 mg/dl, or 2 hour ≥ 153 mg/dl (IADPSG criteria), OR c) 50g GLT exceeding 200 mg/dl, OR d) Two or more documented fasting glucoses > 125 mg/dL
Probable	1) Physician or advanced practice provider mention of current gestational diabetes in medical record
Possible	1) Laboratory evidence of abnormal but non-diagnostic glucose intolerance: a) Elevated 1-hour Glucose load testing ≥ 135 mg/dl, OR b) Other evidence of abnormal but non-diagnostic glucose tolerance: fasting glucose ≥ 105 mg/dl, or 1 hour post prandial ≥ 140 mg/dl, or 2 hour post prandial ≥ 120 mg/dl)
Unlikely	No evidence in medical record to suggest deviation from normal glucose tolerance
Unclassifiable	Contradictory information or inadequate medical record such that unable to classify as GDM or not

7.0 Endpoint Surveillance of Fatal Events

7.1 Event Identification

All deaths will be identified using several methods including questions asked during the annual follow up contact, review of vital statistics lists and obituaries from each state or matching with the National Death Index (NDI). Once a death is identified, field center staff will obtain a death certificate and send a copy to the coordinating center for processing and abstraction. All deaths will be investigated with special interest in those with the following ICD-10 underlying cause of death codes:

Table 9.

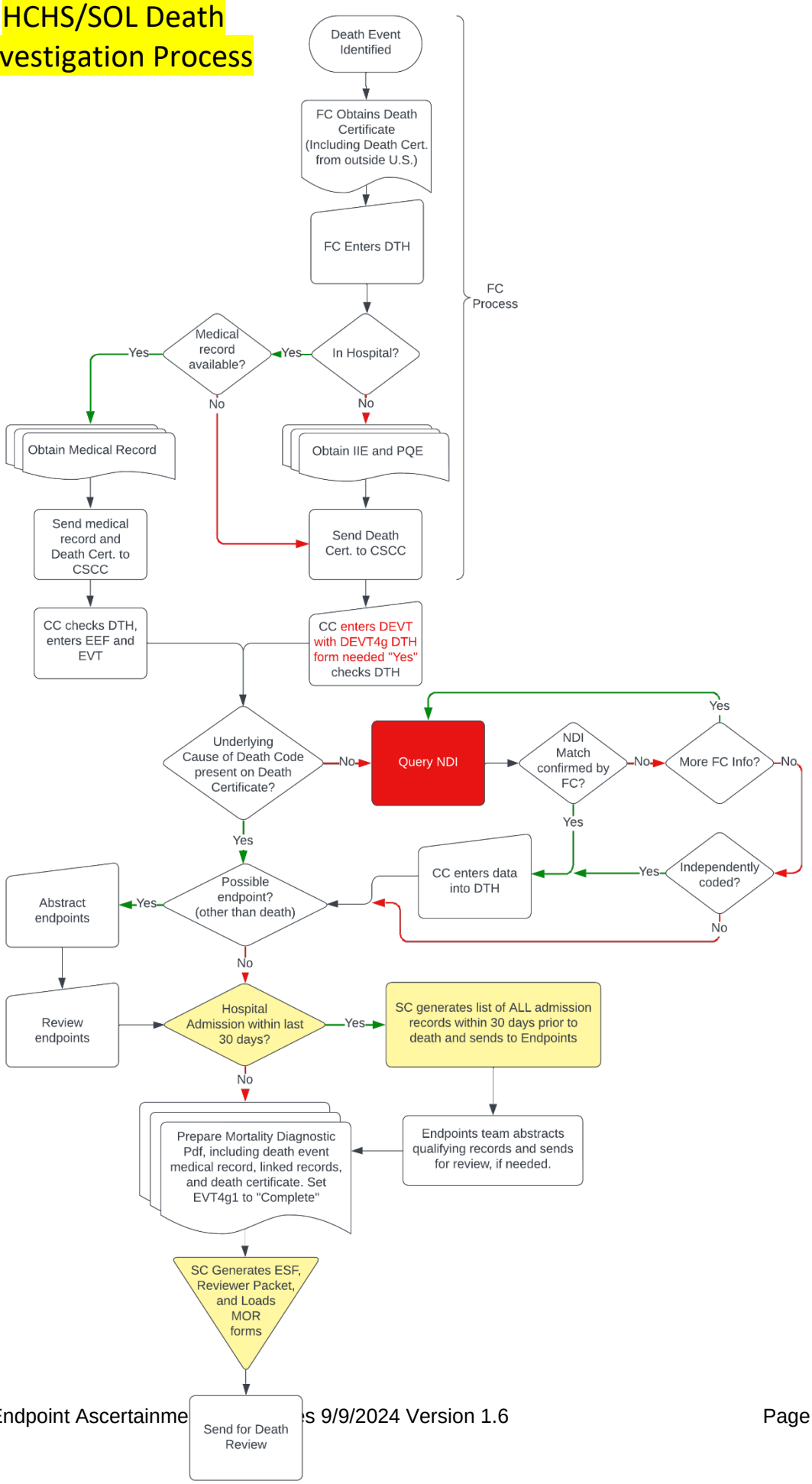
ICD-10 codes (Underlying cause of death)	Description
I00-I52, I70-I99	Cardiovascular Disease
I60-I69	Cerebrovascular Disease
G45-G46	Transient cerebral ischemic attack
E10-E14	Diabetes
J81	Pulmonary edema
R96, R98, R99	Ill-defined
R07	Chest Pain
J40-J42	Bronchitis
J43	Emphysema
J44	Other chronic obstructive pulmonary disease
J45	Asthma
J46	Status asthmaticus (acute severe asthma)
J47	Bronchiectasis

In addition to the fatal events identified by the underlying cause of death codes noted above, deaths with the following ICD-10 codes listed on the death certificate as secondary causes will also be investigated: I20-I23 (Acute CHD), I60-67, G45-G46 (Acute stroke), or J40-J47 (chronic lower respiratory disease)

Information collected on all deaths occurring among HCHS/SOL cohort participants will be reviewed and used to classify the cause of death by the Endpoints Classification Committee (ECC) physician reviewer team. Investigation of out-of-hospital deaths will include posthumous interviews with next of kin/informants and mailing questionnaires to appropriate physicians, medical examiners, or coroners listed on the death certificate. These data collected will be used by the ECC physician reviewer team, in conjunction with the underlying cause of death ICD-10 codes from the death certificate to complete out-of-hospital death investigations.

7.1.1 Death Investigation Data Collection Process

HCHS/SOL Death Investigation Process



Once a death is identified, the proper data will be completed for the HCHS/SOL Follow-up Interview Form (AFE/S). If it is learned that a death occurred after a participant has completed their most recent Annual Follow Up visit (AFU) but the next AFU year is not yet available in the CDART Data Management System (DMS), a second occurrence of the General Health (GHE/S) portion of the Annual Follow-up form is available to use for the most recent open AFU year in the DMS system. This allows site managers & staff to record the death in the current year so they may begin the death investigation without delay. Field center staff will then obtain a death certificate filled out by a physician, medical examiner, or coroner, abstract and enter the data into the HCHS/SOL online Death Investigation (DTH) form and send a copy of it with medical record (if available) to the coordinating center for processing and quality control checks. Information collected on all deaths in the HCHS/SOL cohort will be reviewed and used to classify the cause of death by an Endpoints Classification Committee physician reviewer. Because an out-of-hospital-death will have little or no related hospital data to use for classification, information from the death certificate is recorded electronically on the DTH form in an online HCHS/SOL data management system (DMS). The information provides names and addresses from the certifying physician, next of kin and other informants. UNC maintains this confidential data in an encrypted database and restricts access to it as well as protecting it by a certificate of confidentiality issued to the principal investigator responsible for the study.

According to the HIPAA Privacy Rule*, HCHS/SOL personnel are not required to obtain authorizations from deceased individuals, their personal representative or their next of kin, to request, search and/or review medical records, death certificates and electronic health data for these persons. The PHI for decedents involved must be sought solely for the purposes of approved research and must be deemed necessary for the research purposes.

Materials requested for death events include medical record documents for deaths occurring in or on arrival to an Emergency Department (ED) or during a hospitalization. If a death occurred outside a hospital admission (including DOA or death in ED), field center staff will attempt to complete an Informant Interview (IIE) with the participant's designated contact after a four to six week grieving period. They will also work to collect a Physician Questionnaire (PQE) form from the last physician to see the participant alive (or who had been involved with his/her healthcare shortly before the death occurred).

The National Death Index (NDI) will also be queried for all reported participant deaths. Records will be matched based on participant identifiers and confirmed by field center staff. These data will be included in the DTH form in place of missing or incomplete death certificate data.

Footnote: *see page 17 of source: https://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf: "To use or disclose PHI of the deceased for research, covered entities are not required to obtain Authorizations from the personal representative or next of kin, a waiver or an alteration of the Authorization, or a data use agreement."

7.1.2 Out of Country Death Investigation Data Collection Process

Out of country deaths present special challenges regarding data collection. Each HCHS/SOL field center will have experience obtaining mortality data from countries which impact their participant cohort. Since each center's location is unique, they will follow their own protocols and possibly use preferred staff members to contact family members or contacts provided by the participant to collect data for an out of country fatal event. If field centers wish to provide extra incentives or send letters to family members as

encouragement and support in the effort to collect data necessary to investigate a death, they may, informing the IRB of their intent and the procedure they plan to follow.

Materials collected for out of country deaths should be the same as for U.S. deaths, including: Death Certificates; medical records for DOA, death in ED, or inpatient deaths; and IIE and PQE for out-of-hospital deaths.

The UNC Coordinating Center staff will answer questions and provide instruction on data collection for death events for whoever may contact them. The CSCC will be responsible for reporting the ongoing status of the fatal event data collected at each of the centers.

7.2 Diagnostic Criteria for Fatal Events

The goal of the HCHS/SOL mortality review is to classify all fatal events into one of six categories:
1. Atherosclerotic coronary heart disease,
2. Stroke,
3. Atherosclerotic disease other than coronary disease or stroke,
4. Other cardiovascular disease, not defined in categories previously described
5. Respiratory disease
6. Non-cardiovascular disease or non-respiratory disease

With some modifications, HCHS/SOL classification criteria for atherosclerotic disease, stroke and other cardiovascular disease follows that used in the Multi-Ethnic Study of Atherosclerosis (MESA) study. An unwitnessed death may be classified as "Non-cardiovascular disease" if there is a history of another likely cause of death. (MESA Events Investigation – Mortality Review 3.12.2004).

7.3 Fatal Coronary Heart Disease Events

Death determined to be due to atherosclerotic coronary disease will be further classified as follows:

A. Definite fatal MI
    a. A definite hospitalized MI and death within 28 days of hospital admission or autopsy evidence of an acute MI or MI within 4 weeks, (including coronary thrombosis or myocardial necrosis),
    b. Autopsy evidence of old MI or other chronic CHD counts as evidence of a history of CHD for classification purposes.
    c. Death during thrombolysis or other direct vascular intervention also would be assigned according to the event process being treated. Ex; tPA for an MI with a hemorrhagic stroke resulting in death would be coded as a death due to MI (in its absence no stroke would have occurred).
B. Definite Fatal CHD
    a. Usually assigned when someone dies during an elective CABG as a complication of the surgery.
    b. An unwitnessed death may be classified as "definite" in cases where there is a history of CHD or chest pain.
C. Possible Fatal CHD
    a. When the death certificate is the only available document and the underlying cause ICD code is compatible with CHD (120-25, I46, 151.6, R96, or R98-99) then the classification of cause of death is usually Possible Fatal CHD.
D. Sudden Cardiac Death

a. Definite Sudden Arrhythmic Death
b. Possible Sudden Arrhythmic Death
c. Unclassifiable

As far as possible, mechanisms of deaths of participants classified as atherosclerotic coronary disease also determined as arrhythmic death, heart failure, related to cardiac procedure, or unknown will be established.

7.4 Fatal Pulmonary Events

Hospital records will be obtained when a respiratory-related death such as chronic bronchitis, COPD exacerbation or asthma exacerbation (J42, J44, J45, J46) occurred during a hospitalization, emergency room visit or when an out-of-hospital death occurred within 30 days following a hospital visit for a respiratory-related event. Out-of-hospital deaths are addressed in section 7.6.

Death determined to be due to pulmonary disease will be further classified as follows:

A. Chronic obstructive pulmonary exacerbation
B. Emphysema exacerbation
C. Bronchial asthma exacerbation
D. Other

Whenever possible, death certificates will be obtained in all cases. If a death certificate cannot be obtained, it will be stated in the documentation. If medical records are inadequate and a death certificate cannot be obtained, a cause of death will be adjudicated based on the best available evidence of record. If a probable cause cannot be adjudicated, it will be classified as “unknown”.

The primary cause of death should be attributed to the disorder that causes the patient to present for medical treatment and should be distinguished from terminal events that are the immediate cause of death.

For example, if a patient is admitted to the hospital or the emergency room with a COPD exacerbation and during the exacerbation subsequently develops complications such as pneumonia, respiratory failure, renal failure, sepsis or myocardial infarction, the primary cause of death should be attributed to COPD.

7.5 Fatal Stroke Events

Hospital records are collected when a stroke-related death such as from an ischemic or hemorrhagic stroke has occurred during a hospitalization, emergency room visit or when an out-of-hospital death occurred within 30 days following a hospital visit for a stroke-related event.

Death determined to be due to stroke will be further classified as follows:

A. Brain Infarction, Subtypes and if procedure-related
B. Subarachnoid Hemorrhage, Subtypes and if procedure-related
C. Intracerebral Hemorrhage, Subtypes and if procedure-related
D. Other Stroke Type
E. Unknown Stroke Type

Refer to section 4.0 for definitions and descriptions of stroke types.

As with other fatal events, whenever possible, death certificates will be obtained in all cases. If medical records are inadequate and a death certificate cannot be obtained, a cause of death will be adjudicated based on the best available evidence of record and the lack of data will be stated in the documentation. If a probable cause cannot be adjudicated, it will be classified as "unknown".

Classification of stroke cases follows the same process for the standardized training, certification and review process for physicians participating in stoke review.

7.6 Out-of-Hospital Deaths

Investigation of out-of-hospital deaths will include posthumous interviews with next of kin/informants as well as mailing questionnaires to appropriate physicians, medical examiners, or coroners. These data will be used by the endpoints committee physician reviewer in conjunction with the underlying cause of death ICD codes from the death certificate to complete the out-of-hospital death investigation.
.
Classifying out-of-hospital deaths will be a part of the HCHS/SOL outcomes and adjudication activities. Classification of out-of-hospital CHD death is often based on sparse data due to the frequency of unwitnessed events, low autopsy rates, limited information of medical history of the descendent and its sudden onset in many instances.

Data collected on all investigated deaths (including out of hospital deaths) include the following:

A. Location and date of death
B. Interval between onset of symptoms and death
C. All listed ICD-10 codes (including underlying cause and all listed death codes)
D. Name and address of certifying physician

For out of hospital deaths, HCHS/SOL staff members will perform a brief interview with either next-of-kin or contacts provided by the participant for this purpose using the Informant Interview form (IIE or IIS depending on the language needed). This interview will occur after a four to six week grieving period has passed out of respect for the next-of-kin. The interview is designed to gather information essential for adjudication of cause of death for each case.

Data elements to be obtained as part of the informant interview include the following (see IIE form for more details):

A. Circumstance surrounding the death.
    a. Location of death
    b. Presence of a witness
    c. Time between symptoms and death
B. Medical History
    a. Recent hospitalizations
C. Symptoms
    a. Pain or discomfort
    b. History of symptoms
    c. Duration of symptoms
    d. Shortness of breath
D. Emergency Medical Care
    a. Presence of EMS personnel
    b. Timing of EMS arrival
    c. Resuscitation attempts

8.0 Event Classification Committee

8.1 Introduction

The Event Classification Committee (ECC) is organized into four working groups consisting of a cardiac group, a pulmonary group, a stroke group and a fatal events group. See Figure 4 below. The cardiac group is responsible for reviewing hospitalized myocardial infarction, heart failure, hospitalized cardiac death, and out-of-hospital cardiac death. The stroke group is responsible for reviewing hospitalized stroke and stroke death and out-of-hospital death. The pulmonary group is responsible for reviewing hospitalized COPD and asthma events as well as emergency department-only events for exacerbations of COPD and asthma and hospitalized as well as out-of-hospital pulmonary-related deaths as data can be collected and as detailed per section 7.1 above (Event Identification). The fatal events group is responsible for reviewing all eligible fatal events occurring among cohort participants.

8.2 Review Process

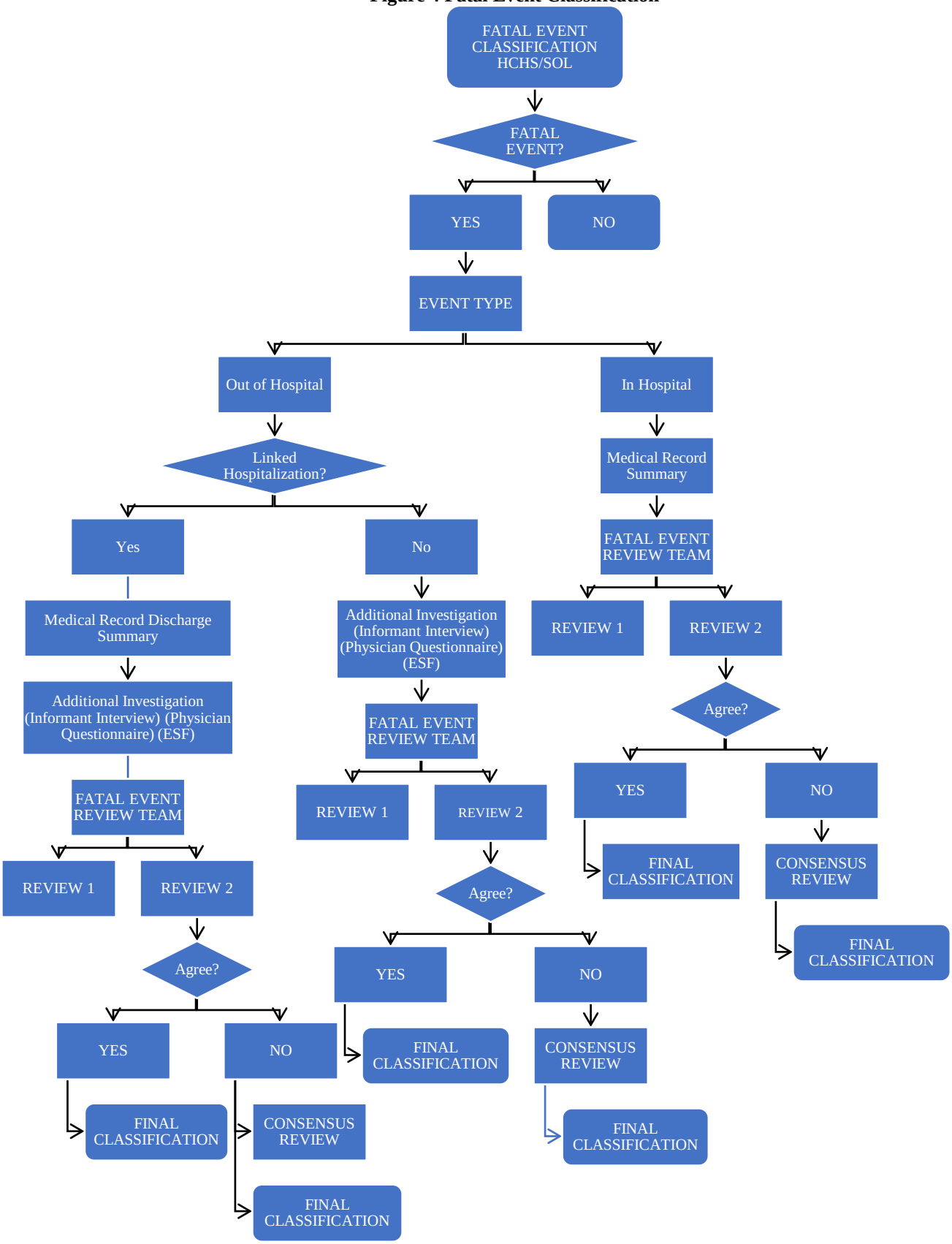
The Coordinating Center creates, assembles, and disseminates a summarized packet of materials for each eligible event of interest. This one-page packet combines critical variables abstracted from the medical record by trained professional abstractors' redacted copies of portions of the actual medical record (for hospitalized death or death with a hospitalization within 30 days). Portions of the record provided to the reviewer include the discharge summary, history, and physical notes, consult notes, laboratory values, medications and diagnostic reports. Based on information contained in this 'Event Summary Form' or ESF, the reviewer completes an approximately one-page diagnosis form specific to the type of event being reviewed in an online format available through the HCHS/SOL website. Question by question instructions for completing each diagnosis form are also provided online to the reviewers. Initial training of new reviewers is conducted with the lead reviewer facilitating case review procedures in a standardized manner across all members of the review team. Once certified, reviewers are asked to review approximately 25-50 cases per month and usually have approximately four weeks to complete a set of reviews once notified that a set of cases is ready for classification.

For out-of-hospital deaths the reviewer will be provided with an event summary form with data from the informant interview, the physician questionnaire, death certificate and any other materials available.

8.3 Reviewer Disagreement Resolution

Cases will be independently reviewed by two reviewers with disagreements adjudicated by consensus between them. The consensus reviews will be considered the final diagnostic classifications.

Figure 4 Fatal Event Classification



8.4 Confidentiality

Several procedures are in place to protect the security of the personal identifying information obtained from medical records and used in the event ascertainment process. Personal identifying information (name, SSN, date of birth, etc.) from cohort members is used for the purpose of linkage to the National Death Index. This information is needed to determine vital status of cohort participants who are lost to follow up. All personal identifiers of cohort participants', treating physicians, hospital name and location, and other identifying information are redacted on any paper copy of medical records sent to the coordinating center and doubled checked for proper deidentification prior to distribution to the ECC. ECC members are instructed in the proper confidential destruction of any medical record information they are provided. Study personnel involved in processing medical record information, from abstraction to handling of these data have been trained on the protection of human subjects in research.

References

Luepker RV, Apple FS, Christenson RH, Crow RS, Fortmann SP, Goff D, Goldberg RJ, Hand MM, Jaffe AS, Julian DG, Levy D, Manolio T, Mendis S, Mensah G, Pajak A, Prineas RJ, et al. Case definitions for acute coronary heart disease in epidemiology and clinical research studies. A statement from the AHA Council on Epidemiology and Prevention; AHA Statistics Committee, World Heart Federation Council on Epidemiology and Prevention; the European Society of Cardiology Working Group on Epidemiology and Prevention; Centers for Disease Control and Prevention; and the National Heart, Lung and Blood Institute. Circulation 2003;108:2543-2549. (McGarvey LP, et al. Ascertainment of cause-specific mortality in COPD: operations of the TORCH Clinical Endpoint Committee. Thorax 2007; 63:411).

APPENDIX A. Minnesota Code ECG Criteria

APPENDIX B. GLOSSARY of Key Event Data Collections Terms

APPENDIX C. Data Collection Forms required for assessing Endpoints:
HCHS/SOL Event Tracking Form (ETR) & QxQ
HCHS/SOL Informant Interview Form (IIE) & QxQ
HCHS/SOL Death Certificate Form (DTH) & QxQ

APPENDIX D. Abstraction Forms
Myocardial Infarction Abstraction Form (MIF)
Heart Failure Abstraction Form (HTF)
Pulmonary Abstraction Form (PUL)

APPENDIX E. Reviewer Forms for classification and adjudication
Myocardial Infarction Form (MIF)
Stroke and TIA Form
Heart Failure Exacerbations Form (HFT)
COPD and Asthma Form (PUL)

APPENDIX F. Event Summary Forms (ESF)
Myocardial Infarction Abstraction Form (MIF)
Heart Failure Abstraction Form (HTF)
Pulmonary Abstraction Form (PUL)

APPENDIX A. Minnesota Code ECG Criteria

Table 1. Evolving diagnostic ECG (any of the following Q1 through Q4)

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

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

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

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

*Note for Table 2: A significant Q-code change requires $\geq$50% increase in event Q/R ratio or $\geq$ 1 mm initial R-wave amplitude decrease in event ECG compared with corresponding lead(s) of baseline ECG.

Table 2. Positive ECG

(a) Evolving ST elevation alone

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

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

Evolving STE 3: 9-2 and no 5-1 or 5-2 in prior ECG in first ECG in event set of ECGs and appearance of 5-1 or 5-2 with 100% increase in T-wave inversions in at least 2 leads.

Evolving STE R1: Reversal of evolving STE 1.

Evolving STE R2: Reversal of evolving STE 2.

OR

b) Evolving equivocal Q-wave plus evolving ST-T depression/inversion

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

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

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

OR

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

*STE indicates ST elevation. In the case of a single ECG available only from a possible event hospital admission, a probable MI can be classified if compared with the previous study ECG, there is a new appearance of a diagnostic Q-wave (+MS 1-1-1 through 1-2-5 plus 1-2-7 or any code 1-3-X in the previous ECG and the event ECG has any code 1-1-X or presence of 9-2 in at least 2 leads).

Table 3. Nonspecific ECG: Evolution of minor ST-T depression/inversion alone, or minor Q-wave alone

(a) Evolving non-STE non–Q-wave pattern MI

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

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

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

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

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

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

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

Evolving ST-T R1 through ST-T R7_the reverse of ST-T1 to ST-T7, respectively

OR

(b) Evolving minor Q wave alone

No Q code in previous study ECG or event ECG, followed by an event ECG with an equivocal Q-code (any 1-3 code)

The ECG series is assigned the highest category for which criteria are met, i.e., evolving diagnostic > diagnostic > evolving ST-T patterns > equivocal > other.

APPENDIX B. GLOSSARY of Key Event Data Collections Terms

This section has intentionally been left blank.

APPENDIX C. Data Collection Forms Required for Assessing Endpoints:

HCHS/SOL Event Tracking Form (ETR)
HCHS/SOL Informant Interview Form (IIE)
HCHS/SOL Physician Interview Form(PQE)
HCHS/SOL Death Certificate Form (DTH)

Note that current copies of all study data collection forms and QxQs can also be found on the study web site page:
http://www.cscc.unc.edu/hchs/utilities/docfilter.php?study=hchs&filter_type=forms

HCHS / SOL Event Tracking form

PARTICIPANT ID NUMBER:									FORM CODE: ETR VERSION: A 07/01/09	Contact Occasion		SEQ #	

EVENT ID NUMBER: ☐☐☐☐☐☐☐☐☐☐☐☐ **EVENT Date:** ☐☐/☐☐/☐☐☐☐

Instructions: *This form is completed by the Outcomes Coordinators to document the stages in the hospital or Emergency Department records acquisition process. The EVENT ID and DATE of EVENT fields above are pre-filled by the Data Management System for HCHS. The form is entered into the DMS as a multi-line form with the last status being the one of record for a given event. Use as many paper forms as needed to track the progress of medical records acquisition.*

Event Records Tracking Results

1. Date (MM/DD/YYYY)	2. Notes	3.Result Code*	4. Staff Code
/ /			
/ /			
/ /			
/ /			
/ /			
/ /			
/ /			

***RESULT CODES for Records Processing**

0 Pending records request
1 Release of Information requested from Participant
2 Release of Information obtained from Participant
3 Event Record requested
4 Confirmed, No event to investigate
5 Confirmed, Records Not Available
6 Medical records received for event
7 Supplemental records requested
8 Verification of medical records to be sent [note: ICD-9 codes needed at this step]
9 Shipping medical records to Coordinating Center [cover sheet for shipping produced]

HCHS/SOL Informant Interview

ID NUMBER:									FORM CODE: IIE VERSION: A 12/02/2008	Contact Occasion	0	1	SEQ #		

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: The informant interview form is completed for each informant for an eligible death as determined by the HCHS/SOL event investigation worksheet.

Decedent's name: _____ Date of death: ☐☐/☐☐/☐☐☐☐ Age at death: ☐☐ Place of death: _____	Informant name: _____

"Hello, my name is (interviewer's name) *with the HCHS/SOL study. I'm calling regarding* (name of decedent) *involvement with the HCHS/SOL study, a medical study in which* (name of decedent) *was enrolled. I want to express our condolences for your loss. We understand that you have been identified as someone who can help us close out* (decedent name)*'s file. I need to ask you a few questions about the circumstances surrounding* (name)*'s death. Would now be a good time to talk?*

No ⟶ When would be convenient to call back? _____

Yes ⟶ Thank you. If you have any questions, please ask me.

1. *"Before we get started could you please tell me what was your relationship with the deceased?"*
(Respondent was deceased's…)

Spouse	1 ☐	
Daughter/Son	2 ☐	
Parent	3 ☐	
Friend	4 ☐	
Workmate	5 ☐	
Other relative	6 ☐	Specify: _____

Other 7 ☐ Specify: _____

"Now, I would like to ask you about the circumstances surrounding (insert decedent's name) medical history."

2. *"Please tell me about his/her general health, health on the day s/he died, and about the death itself."*

Record a brief synopsis of the events surrounding the death as related by the informant:

_____

_____

_____

_____

"Some of the remaining questions may repeat information already provided, but it helps us to ask these items specifically."

3a. Was anyone present when s/he died?

No	0 ☐
Yes	1 ☐
Unknown	9 ☐

3b Where was (insert decedent name) when s/he died (Check one)

Home	0 ☐	→ **GO TO 3c**
Work	1 ☐	
Public building	2 ☐	
Bus or public transportation	3 ☐	
In a car	4 ☐	
Nursing home	5 ☐	
In an emergency room	6 ☐	
In an ambulance	7 ☐	
In a hospital	8 ☐	
Unknown	9 ☐	
Other	10 ☐	

3c. If s/he died at home, was s/he found:

In bed	0 ☐	
In a chair	1 ☐	
On the floor	2 ☐	
Elsewhere	3 ☐	specify: _____

Unknown 9 ☐

4. Was anyone close enough to hear (insert decedent's name) if s/he had called out?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

5. How long was it between the time (insert decedent's name) was last known to be alive and the time s/he was found dead?

Less than 5 minutes 1 ☐
5 minutes to 1 hour 2 ☐
1 to 24 hours 3 ☐
Longer than 24 hours 4 ☐
Unknown 9 ☐

6. Please tell me who was present. (check all that apply)

Self 1 ☐ (skip to question 8)
Health care person(s) 2 ☐
Other person(s) 3 ☐

7. When was the last time you saw (insert decedent's name) prior to his/her death?

Less than 5 minutes 1 ☐
5 minutes to 1 hour 2 ☐
1 to 24 hours 3 ☐
Longer than 24 hours 4 ☐
Unknown 9 ☐

HISTORY

The next few questions concern (insert decedent's name) medical history.

8. Was s/he restricted to home, able to leave home only with assistance or great effort, or was his/her activity unrestricted?

Restricted to home 1 ☐
Able to leave home only with assistance or great effort 2 ☐
Unrestricted 3 ☐

9. Was s/he hospitalized within the four weeks prior to death?

No 0 ☐ Skip to question 13
Yes 1 ☐
Unknown 9 ☐ Skip to question 13

10. What was the reason for the hospitalization? (select all that apply)

Heart attack or heart disease	1 ☐	
Stroke	2 ☐	
Heart surgery	3 ☐	
Surgical procedure (other than heart)	4 ☐	
Emphysema, chronic bronchitis, or chronic obstructive pulmonary disease (COPD)	5 ☐	
Pneumonia	6 ☐	
Infection	7 ☐	
Other condition	8 ☐	specify: _____
Unknown	9 ☐	

11. What was the date of the hospitalization:

☐☐/ ☐☐/ ☐☐☐☐
Month Day Year

12. What was the name and location of the hospital?

_____

13. Was (insert decedent's name) seen by a doctor at an emergency room or in any other facility in the last four weeks prior to death?

No	0 ☐	Skip to question 15
Yes	1 ☐	
Unknown	9 ☐	Skip to question 15

13a. What was the reason for this visit to an emergency room or doctors office? (select all that apply)

Heart attack or heart disease	1 ☐	
Stroke	2 ☐	
Heart surgery	3 ☐	
Surgical procedure (other than heart)	4 ☐	
Emphysema, chronic bronchitis, or chronic obstructive pulmonary disease (COPD)	5 ☐	
Pneumonia	6 ☐	
Infection	7 ☐	
Other condition	8 ☐	specify: _____
Unknown	9 ☐	

14. What was the name and address of this physician or emergency room?

_____

_____

SYMPTOMS

"The next set of questions deals specifically with acute symptoms such as pain, discomfort that (insert decedent's name) *may have experienced at the time of his/her death."*

15. Did s/he experience pain, discomfort or tightness in the chest, left arm or jaw?

No 0 ☐ Skip to question 22
Yes 1 ☐
Unknown 9 ☐ Skip to question 22

16. Did the pain, discomfort or tightness specifically involve the chest?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

16a. Did (insert decedent's name) ever take nitroglycerin for this pain?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

17. Were these episodes new, or had they occurred previously?

New symptoms 1 ☐ Skip to question 22
Previous symptoms 2 ☐
Unknown 9 ☐

18. Were the episodes getting longer or more frequent?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

19. Were the episodes getting more severe?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

****If No or Unknown to Questions 18 and 19, skip to Question 21****

20. Over what period of time did these episodes become longer, more frequent, or more severe?

Days 1 ☐
Weeks 2 ☐
Months 3 ☐
Unknown 9 ☐

21. Did s/he experience shortness of breath?

No 0 ☐ Skip to item 22
Yes 1 ☐
Unknown 9 ☐ Skip to item 22

21a. Did s/he have shortness of breath while at rest?

No 0 ☐
Yes 1 ☐

Unknown 9 ☐

22. *"I apologize if this question sounds hard or if it makes you uncomfortable. Please be assured we respect your feelings about this unfortunate event. How long was it from* (insert decedent's name) *last episode of symptoms to the time that s/he stopped breathing on his/her own?"*

Less than 5 minutes 1 ☐
Less than 1 hour 2 ☐
Less than 24 hours 3 ☐
Greater than 24 hours 4 ☐
Unknown 9 ☐

EMERGENCY MEDICAL CARE

"The next few questions are concerned with emergency medical care (insert decedent's name) may have received prior to or at the time of death. You may have already given this information in an answer to an earlier question. Since it is important to obtain information specifically on emergency medical care, I hope you don't mind if these questions seem repetitive."

23. Was a physician, ambulance or other emergency medical team called?

No 0 ☐ Skip to question 24
Yes 1 ☐
Unknown 9 ☐ Skip to question 24

23a. How long was it from the time the last episode of symptoms started to the time that medical assistance was called for?

5 minutes or less 1 ☐
10 minutes or less 2 ☐
1 hour or less 3 ☐
6 hours or less 4 ☐
24 hours or less 5 ☐
More than 24 hours 6 ☐
Unknown 9 ☐

23b. How long was if from the time medical care was called to the time when it arrived?

5 minutes or less 1 ☐
10 minutes or less 2 ☐
1 hour or less 3 ☐
6 hours or less 4 ☐
24 hours or less 5 ☐
More than 24 hours 6 ☐
Unknown 9 ☐

24. Were resuscitation measures, such as CPR attempted?

No 0 ☐ Skip to question 25
Yes 1 ☐

Unknown 9 ☐ Skip to question 25

24a. Who started the CPR or resuscitation?

Bystander	1 ☐
Physician	2 ☐
Ambulance personnel	3 ☐
Fireman or Police	4 ☐
The informant	5 ☐
Other	6 ☐
Unknown	9 ☐

25. Was (insert decedent's name) taken to the hospital, emergency room or any other emergency care facility?

No	0 ☐
Yes	1 ☐
Unknown	9 ☐

26. Is there anyone else we could contact who might be able to provide additional information about the circumstances surrounding (insert decedent's name) death or his/her usual state of health?

No	0 ☐	Skip to Closing Script
Yes	1 ☐	
Unknown	9 ☐	Skip to Closing Script

27. How is s/he related to the deceased?

Spouse	1 ☐	
Daughter/Son	2 ☐	
Parent	3 ☐	
Friend	4 ☐	
Workmate	5 ☐	
Other relative	6 ☐	Specify: _____
Other	7 ☐	Specify: _____

28. What is the name and address of this person?

_____

_____

CLOSING SCRIPT

"Thank you very much for your assistance in this study. Do you have any questions? Thanks again for your help."

RELIABILITY
(To be completed after the interview)

29. On the basis of these questions, give your rating of reliability of the interview.

Poor	1 ☐
Fair	2 ☐
Good	3 ☐

HCHS/SOL Physician Questionnaire

ID NUMBER:								

FORM CODE: PQE
VERSION: A
12/02/2008

Contact Occasion: 0 1

SEQ #: ☐☐

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (month / may / year)

0b. Staff ID: ☐☐☐

Instructions: Please complete the following questions to the best of your ability by filling in the appropriate bubbles or writing the answer in the blank provided. Please return completed forms in the self addressed stamped envelope provided to the local HCHS/SOL field center.

DETAILS OF DEATH

1. Are you familiar with the events surrounding the decedent's death?

No 0 ☐
Yes 1 ☐

2. Did you witness the death?

No 0 ☐
Yes 1 ☐

If informant answered "Yes" *to one or both of Items 1 and 2, please skip to Item 4.*

3. If you answered "No" to both Questions, are you aware of another physician who could provide information regarding the death?

No 0 ☐ Please sign and date the bottom of this form
Yes 1 ☐

3a. Provide contact information. Please then sign and date the bottom of this form.

Name of physician: _____

Address: _____

_____

_____

CIRCUMSTANCES SURROUNDING DEATH

4. What do you believe to be the underlying cause of death?

Acute Myocardial Infarction	1 ☐	
Other Ischemic Heart Disease	2 ☐	
Cerebrovascular Disease	3 ☐	
Other Cardiovascular Disease	4 ☐	
Emphysema, chronic bronchitis or chronic obstructive pulmonary disease (COPD)	5 ☐	
Pneumonia	6 ☐	
Asthma	7 ☐	
Other Lung Disease	8 ☐	specify: _____
Non Cardio - Pulmonary Disease	9 ☐	specify: _____

5. Please specify the time between the onset of the acute episode of symptoms and death. (We are defining death as the point where spontaneous breathing ceased and the patient never recovered.) Please check the appropriate time period.

Less than 5 minutes	1 ☐
5 minutes to 1 hour	2 ☐
1 hour to 24 hours	3 ☐
More than 24 hours	4 ☐
1 day to 3 days	5 ☐
More than 3 days	6 ☐
Unknown	9 ☐

6. Was there an acute episode of pain in the chest, left arm or jaw during the last 72 hours prior to death?

No	0 ☐
Yes	1 ☐
Unknown	9 ☐

7. Was there an acute episode of shortness of breath during the 72 hours prior to death?

No	0 ☐
Yes	1 ☐
Unknown	9 ☐

8. Was there an acute episode of wheezing during the 72 hours prior to death?

No	0 ☐
Yes	1 ☐
Unknown	9 ☐

9. Did the decedent take or was s/he given nitrates or nitroglycerin at the time of the acute episode?

No	0 ☐
Yes	1 ☐
Unknown	9 ☐

MEDICAL HISTORY

10. Are you familiar with the decedent's medical history?

No	0 ☐	End questionnaire
Yes	1 ☐	

11. Did the decedent have a medical history of any of the following conditions prior to the acute event which led to death?

11a. Myocardial Infarction (MI)?

No	0 ☐	Skip to 11b
Yes	1 ☐	
Unknown	9 ☐	Skip to 11b

i. Date of most recent MI: ☐☐/ ☐☐/ ☐☐☐☐
month day year

11b. Angina Pectoris, Coronary Insufficiency or Other Chronic Ischemic Heart Disease?

No	0 ☐	Skip to 11c
Yes	1 ☐	
Unknown	9 ☐	Skip to 11c

i. Date of first diagnosis: ☐☐/ ☐☐/ ☐☐☐☐
month day year

11c. Congestive Heart Failure (CHF) or Congestive Cardiomyopathy?

No	0 ☐	Skip to 11d
Yes	1 ☐	
Unknown	9 ☐	Skip to 11d

i. Date of first exacerbation: ☐☐/ ☐☐/ ☐☐☐☐
month day year

11d. Stroke (CVA)?

No 0 ☐ Skip to 11e
Yes 1 ☐
Unknown 9 ☐ Skip to 11e

i. Date of most recent CVA: ☐☐/ ☐☐/ ☐☐☐☐
month day year

11e. Transient Ischemic Attack (TIA)?

No 0 ☐ Skip to 11f
Yes 1 ☐
Unknown 9 ☐ Skip to 11f

i. Date of first diagnosis: ☐☐/ ☐☐/ ☐☐☐☐
month day year

11f. Intermittent Claudication or Other Peripheral Arterial Disease (PAD)?

No 0 ☐ Skip to 11g
Yes 1 ☐
Unknown 9 ☐ Skip to 11g

11g. Lower Extremity Bypass, Angioplasty or Amputation Secondary to PAD?

No 0 ☐ Skip to 11h
Yes 1 ☐
Unknown 9 ☐ Skip to 11h

11h. Coronary Bypass Surgery?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

11i. Coronary Angioplasty?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

11j. Emphysema, chronic bronchitis, or Chronic Obstruction Pulmonary Disease (COPD)?

No 0 ☐ Skip to 11k
Yes 1 ☐
Unknown 9 ☐ Skip to 11k

i. Date of first exacerbation (or onset): ☐☐/ ☐☐/ ☐☐☐☐
month day year

11k. Asthma?

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

i. Approximate age asthma first started: ☐☐

12. If you saw the participant within one month of death, please fill out the following for the most recent visit:

12a. Date of visit: ☐☐/ ☐☐/ ☐☐☐☐
month day year

12b. Chief Complaint:_____

_____

12c. Primary Diagnosis:_____

_____

12d. Changes in Medical Management:_____

_____

_____

Form completed by: _____ Date: _____

HCHS/SOL Death Investigation Form
DTH version 3

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐

0d. Event Date: ☐☐/☐☐/☐☐☐☐

Instructions: The Death Investigation Form is completed for each death reported on the General Health Status Form (GHE). Complete this form with data from a Death Certificate, NDI request, or another specified source.

1. Was a death certificate obtained? No 0☐ Yes 1☐

   1a. Did the death occur outside of the U.S.? No 0☐ Yes 1☐

      1a1. Field Center evaluation of NDI quality match: No Match 0☐

      Match Confirmed 1☐

      Update Participant Information and Resubmit 2☐

   1b. Was data obtained from another source(s)? No 0☐ Yes 1☐

      1b1. Specify other source(s): _____

2. Date of death: ☐☐/☐☐/☐☐☐☐

   2a. How was date of death obtained? ***(only answer if more than one 'Yes' in Q1, 1a1, or 1b)***

   Death Certificate 1☐ NDI 2☐ Other 9☐

      2a1. Specify other date source: _____

   2b. Location of death:

      2b1. City _____

      2b2. State _____

      2b3. Country _____

   2c. How was location of death obtained? ***(only answer if more than one 'Yes' in Q1, 1a1, or 1b)***

   Death Certificate 1☐ NDI 2☐ Other 9☐

      2c1. Specify other location source: _____

(if Q1 = No, skip to Q11)

3. Time of death: ☐☐:☐☐ 3a. ☐ *1 = A.M., 2 = P.M.*

4. Did the decedent die in a hospital? No 0☐ ***Skip to 6*** Yes 1☐ Unknown 9☐

5. Was the death classified as: *(select one)* ☐

1. dead on arrival (DOA) 2. emergency dept (ED) 3. outpatient 4. inpatient
5. none of the above 6. not recorded

6. Was this a coroner's or medical examiner's case? No 0☐ ***Skip to 10*** Yes 1☐

7. Was the name and address of the coroner or medical examiner recorded?
No 0☐ ***Skip to 10*** Yes 1☐

8. Name:_____

9. Address:

9a. Street_____

9b. City_____

9b1. State_____

9b2. Zip code_____

9c. Country_____

10. Was an autopsy performed? No 0☐ Yes 1☐

11. **ICD-10 Code** for **UNDERLYING** cause of death: ☐☐☐.☐

11a. Indicate how this code was obtained, or confirm that it is missing:

Death Certificate 1☐ NDI 2☐ Study-coded 3☐ Other 9☐ Confirmed Missing 0☐

11a1. Specify other code source: _____

12. All listed **ICD-10 Codes** for death:

a. ☐☐☐.☐ e.☐☐☐.☐ i. ☐☐☐.☐ m.☐☐☐.☐ q. ☐☐☐.☐
b. ☐☐☐.☐ f. ☐☐☐.☐ j. ☐☐☐.☐ n. ☐☐☐.☐ r. ☐☐☐.☐
c. ☐☐☐.☐ g.☐☐☐.☐ k.☐☐☐.☐ o. ☐☐☐.☐ s. ☐☐☐.☐
d. ☐☐☐.☐ h.☐☐☐.☐ l. ☐☐☐.☐ p. ☐☐☐.☐ t. ☐☐☐.☐

12u. Were codes obtained from the death certificate? ***(only answer if Q1=Yes)***

No 0☐ Yes 1☐

12v. Were codes obtained from NDI? ***(only answer if Q1a1=Match Confirmed)***

No 0☐ Yes 1☐

12w. Were codes obtained from another source? ***(only answer if Q1b=Yes)***

No 0☐ Yes 1☐

12w1. Specify other code source: _____

(if Q1 = No, skip to end of form)

13. Are there causes of death recorded on the death certificate? No 0☐ ***skip to 14*** Yes 1☐

13a. Immediate cause:_____

13b. Due to or as a consequence of (1)_____

13c. Due to or as a consequence of (2)_____

13d. Due to or as a consequence of (3)_____

14. Are there other significant conditions Recorded on the death certificate?

No 0☐ ***Skip to 16*** Yes 1☐

15. Conditions:_____

16. Interval between onset and death for <u>immediate</u> cause of death: ☐

a. 1 = 5 minutes or less
b. 2 = 1 hour or less
c. 3 = 1 day or less
d. 4 = 1 week or less
5 = 1 month or less
6 = more than 1 month
7 = unknown or not recorded

17. Was the name and address of the informant recorded? No 0☐ ***Skip to 22*** Yes 1☐

18. Name:_____

19. Address:

19a. Street_____

19b. City_____

19b1. State____

19b2. Zip code_____

19c. Country_____

20. Relationship of informant to deceased: ☐ 1 = spouse, 2 = other, 3 = unknown

21. If other, specify:_____

22. Was the name and address of the certifying physician recorded? No 0☐ Yes 1 ☐

23. Name:_____

24. Address:

24a. Street_____

24b. City_____

24b1. State_____

24b2. Zip code_____

24c. Country_____

APPENDIX D. Abstraction Forms

Myocardial Infarction Abstraction Form (MIF)
Heart Failure Abstraction Form (HTF)
Pulmonary Abstraction Form (PUL)
Stroke Abstraction Form (STR)

HCHS/SOL MYOCARDIAL INFARCTION ABSTRACTION FORM (MIF)

ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: MIF VERSION: A 08/04/11 Contact Occasion ☐☐ SEQ # ☐☐

ADMINISTRATIVE INFORMATION

0A. Completion Date: ☐☐/☐☐/☐☐☐☐ Month/Day/Year

0B. Staff ID: ☐☐☐

Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ Event Date: ☐☐/☐☐/☐☐☐☐

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received (or classified as unobtainable) as indicated on the Verification of ICD Discharge Codes Form

A. GENERAL INFORMATION

1. Was the event (choose one): ☐

1= In hospital only 2= Emergency Dept. visit only(ED) 3= Both ED and in hospital

2. Date of arrival: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

a. Time of arrival ☐☐:☐☐ *1= A.M., 2 = P.M.* ☐

b. Date of admission ☐☐/☐☐/☐☐☐☐

3. Date of discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

a. Time of discharge ☐☐:☐☐ *1= A.M., 2 = P.M.* ☐

4. What was the primary admitting diagnosis code? ☐☐☐☐☐.☐☐

5. What was the primary discharge diagnosis code? ☐☐☐☐☐.☐☐

	No/NR	Yes
6. Did an emergency medical service unit transport the patient to this hospital?	0☐	1☐
7. Was the patient transferred to this hospital from another hospital?	0☐	1☐
8. Was the patient's code status ever "no-code" or "DNR" (do not resuscitate)?	0☐	1☐
9. Was the patient alive at discharge? ***If Yes, go to Item 10***	0☐	1☐

9.a. Was the patient dead on arrival? No 0☐ Yes 1☐

9.b. Did the patient die in the Emergency Department? No 0☐ Yes 1☐

9.c. Was an autopsy performed? No 0☐ Yes 1☐

B. PRESENTING SIGNS AND SYMPTOMS

	No	Yes	NR

			Not recorded
10. Did the onset of the acute episode occur prior to admission?	0☐	1☐	9☐

a. If YES, estimate the time from onset of symptoms of acute condition to arrival at the hospital

< 1hr☐ ≥ 1- < 3 hrs☐ ≥ 3 - < 6 hrs☐ Unsure ☐

≥ 6 - < 12 hrs☐ ≥ 12 - < 24 hrs☐ ≥ 24 hrs. ☐

11. Was there mention of an acute CHD event with onset after arrival at the hospital?	0☐	1☐	9☐
12. Was there an acute episode(s) of pain or discomfort (eg: tightness) anywhere in the chest, arm, shoulder throat or jaw, either within 72 hours prior to arrival to the hospital, or in conjunction with the in-hospital CHD event? **(If No or NR, go to Item 13)**	0☐	1☐	9☐
a. Did this pain or discomfort specifically involve the chest?	0☐	1☐	9☐
b. Did the pain get worse (crescendo) over time?	0☐	1☐	9☐
c. Was the pain or discomfort diagnosed as having a non-cardiac origin?	0☐	1☐	9☐
13. Was there nausea or vomiting associated with this event?	0☐	1☐	9☐
14. Was there diaphoresis associated with this event?	0☐	1☐	9☐
15. Was there fatigue or malaise associated with this event?	0☐	1☐	9☐

16. Vital Signs at arrival (or event onset) and not during CPR

a. Blood pressure ☐☐☐/☐☐☐mmHg

b. Heart rate ☐☐☐bpm

C. MEDICAL HISTORY

17. Prior to this event was there history of any of the following:	No/NR	Yes
17.a. Myocardial infarction ***If No or NR, skip to 17.b.***	0☐	1☐
1. If history of MI, then MI within 4 weeks of this event?	0☐	1☐
17.b. Angina	0☐	1☐
17.c. Percutaneous coronary intervention (PCI)	0☐	1☐
17.d. CABG	0☐	1☐
17.e. Coronary artery disease (CAD)	0☐	1☐
17.f. Heart failure	0☐	1☐
17.g. Arrhythmia		
IF YES, specify type of arrhythmia		
17.g.1 Arial Fibrillation/Flutter	0☐	1☐
17.g.2 Ventricular Fibrillation/Tachycardia	0☐	1☐
17.g.3 Other arrhythmia	0☐	1☐

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

18. Did a physician indicate any of these as being present during the hospitalization? Exclude old episodes; include only current conditions.

	No/NR	Yes
18.a. Angina	0☐	1☐
18.b. Acute myocardial Infarction	0☐	1☐
18.c. ST elevation > 1mm with pain that is not present on ECG without pain	0☐	1☐
18.d. Congestive heart failure exacerbation or pulmonary edema	0☐	1☐
1.IF YES, Did heart failure/pulmonary edema occur within 24 hours of event onset?	0☐	1☐
18.e. Shock or cardiogenic shock	0☐	1☐
1.IF YES, Did shock occur within 24 hours of event onset?	0☐	1☐
18.f. Ventricular fibrillation, cardiac arrest or asystole	0☐	1☐
1.IF YES, Did the arrest occur within 24 hours of event onset?	0☐	1☐
18.g. Ventricular Tachycardia	0☐	1☐
18.h. Atrial fibrillation or atrial flutter	0☐	1☐

E. BIOMARKERS

	No/NR	Yes
19. Were cardiac enzymes reported within days 1-4 after arrival at the hospital or after the in-hospital CHD event? **If No/NR skip to 32**	0☐	1☐

Biomarker Laboratory Standards:

Units:** **1= ng/mL** **2 = Units/L** **3 = µg/L

20. Range Set 1		Upper limit of normal (only)	Units*	N/A
a. Total CK (CPK)		a.☐☐☐☐.☐☐	b.☐	c.☐
b. CK-MB		a.☐☐☐☐.☐☐	b.☐	c.☐
c. Total LDH	☐<	a.☐☐☐☐.☐☐	b.☐	c.☐
d. LDH – 1		a.☐☐☐☐.☐☐	b.☐	c.☐
e. LDH – 2		a.☐☐☐☐.☐☐	b.☐	c.☐
f. Troponin	☐<	a.☐☐☐☐.☐☐	b.☐	c.☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

21. Range Set 2

		Upper limit of normal (only)	Units*	N/A
a. Total CK (CPK)		a.☐☐☐☐.☐☐	b.☐	c.☐
b. CK-MB		a.☐☐☐☐.☐☐	b.☐	c.☐
c. Total LDH	☐<	a.☐☐☐☐.☐☐	b.☐	c.☐
d. LDH – 1		a.☐☐☐☐.☐☐	b.☐	c.☐
e. LDH – 2		a.☐☐☐☐.☐☐	b.☐	c.☐
f. Troponin	☐<	a.☐☐☐☐.☐☐	b.☐	c.☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

Daily Biomarkers Measurements:

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***

Note: *If more than two sets pick the two with the highest values of Troponin*

22. Day 1/Set 1	Date:☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐

e. Unsure ☐

23. Day 1/Set 2	Date: ☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

24. Day 2/Set 1	Date: ☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

25. Day 2/Set 2	Date: ☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐

e. Unsure ☐

26. Day 3/Set 1	Date: ☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

27. Day 3/Set 2	Date: ☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

28. Day 4/Set 1	Date: ☐☐/☐☐/☐☐☐☐	Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐

e. Unsure ☐

29. Day 4/Set 2 Date: ☐☐/☐☐/☐☐☐☐		Units* (see pg. 3)	Range Set* (1or 2)	Words Code*
a. Total CK (CPK)	☐☐☐☐	1. ☐	2. ☐	3. ☐
b. CK-MB	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
c. Total LDH	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
d. LDH-1	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
e. LDH-2	☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐
f. Troponin	☐ < ☐☐☐☐.☐☐	1. ☐	2. ☐	3. ☐

f.1. What type of Troponin was this?

a. Troponin, type not specified ☐
b. Troponin I ☐
c. Troponin T ☐
d. High Sensitivity Troponin (HS) ☐
e. Unsure ☐

30. Is there mention of the patient having either trauma, a surgical procedure, or rhabdomyolysis, within one week prior to measurement of biomarkers? 0☐No/NR 1☐Yes **If No/NR *skip to 31***

If yes, Indicate the type of procedure or trauma:

	No	Yes	Date	
a. Cardiac procedure	0☐	1☐	☐☐/☐☐/☐☐☐☐	
b. CPR or cardioversion	0☐	1☐	☐☐/☐☐/☐☐☐☐	
c. Other cardiac trauma	0☐	1☐	☐☐/☐☐/☐☐☐☐	c1. Specify:_____
d. Rhabdomyolysis	0☐	1☐	☐☐/☐☐/☐☐☐☐	
e. Intramuscular Injection	0☐	1☐	☐☐/☐☐/☐☐☐☐	
f. Non-cardiac procedure	0☐	1☐	☐☐/☐☐/☐☐☐☐	f1. Specify:_____
g. Non-cardiac trauma	0☐	1☐	☐☐/☐☐/☐☐☐☐	

31. Enter the item number from the biomarkers section (items 22—30) of this form which corresponds to the first biomarker measurement performed after the trauma, cardiac procedure or rhabdomyolysis: ☐☐

32. Is there evidence of hemolytic disease during the hospitalization? 0☐No/NR 1☐Yes

33. Did the participant have any active liver disease (cirrhosis, hepatitis, liver cancer, etc.)? 0☐No/NR 1☐Yes

F. Electrocardiography

34. Were any 12 lead ECGs taken during this admission? 0☐No 1☐Yes 9☐NR
(If this is an in-hospital event, then first ECG is at time of event)

a. First ECG Date:☐☐/☐☐ ☐☐☐☐ b. Copy of ECG enclosed? No 0☐ Yes 1☐

c. Second ECG Date:☐☐/☐☐ ☐☐☐☐ d. Copy of ECG enclosed? No 0☐ Yes 1☐

e. Third ECG Date:☐☐/☐☐ ☐☐☐☐ f. Copy of ECG enclosed? No 0☐ Yes 1☐

g. Last ECG Date:☐☐/☐☐ ☐☐☐☐ h. Copy of ECG enclosed? No 0☐ Yes 1☐

G. Procedures and Diagnostics

Were any of the following special procedures or operations performed during this hospitalization? *(Mark all that apply)*

	No/NR	Yes
35. Transthoracic echocardiogram (TTE) performed? **If No/NR, *skip to 36***	0☐	1☐
a. LV Ejection fraction: ☐☐%		
36. Was a Nuclear Medicare Scan (MUGA, SPECT or radionuclide ventriculogram (RVG)) performed? **If No/NR, *skip to 37***	0☐	1☐
a. Ejection fraction: LV: ☐☐% b. RV: ☐☐%		
c. Stress test positive for ischemia	0☐	1☐
37. Was any stress test (treadmill, pharmacologic, or nuclear medicine) performed during this admission: **If No/NR, *skip to 38***	0☐	1☐
a. Ejection fraction: LV: ☐☐%		
b. Stress test positive for ischemia)	0☐	1☐
c. Greater than or equal to 1mm ST depression or elevation	0☐	1☐
d. Ischemic pain or equivalent occurred	0☐	1☐
38. Was a coronary angiography performed? **If No/NR, *skip to 37***	0☐	1☐
a. Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐		
b. Ejection fraction: LV: ☐☐%		

	No	Yes	NR
c. 70% or greater obstruction of any coronary artery	0☐	1☐	9☐
d. Were coronary bypass grafts present?	0☐	1☐	9☐

1. If yes, number of occluded grafts: ☐☐

H. Treatment

	No/NR	Yes
39. Was coronary reperfusion (CABG, PCI, thrombolysis) attempted? **If No/NR, *Skip to 40***	0☐	1☐

39.a. If yes, what was the approximate time from event onset to reperfusion?

☐< 2 hours ☐2-4 hours ☐4-6 hours ☐6-12 hours ☐12-24 hours ☐> 24 hours ☐ not sure

40. Where any of the following treatments given during this hospitalization?

	No/NR	Yes
a. Coronary artery bypass graft surgery (CABG)	0☐	1☐

1. If yes, Date:☐☐/☐☐ ☐☐☐☐ b. Time ☐☐:☐☐ c. ☐ 1= am, 2 = pm

b. Coronary atherectomy	0☐	1☐

1. If yes, Date:☐☐/☐☐ ☐☐☐☐ b. Time ☐☐:☐☐ c. ☐ 1= am, 2 = pm

c. Intra-arterial or intravenous thrombolytic	0☐	1☐

1. If yes, Date:☐☐/☐☐ ☐☐☐☐ b. Time ☐☐:☐☐ c. ☐ 1= am, 2 = pm

d. Coronary angioplasty without stent	0☐	1☐

1. If yes, Date:☐☐/☐☐ ☐☐☐☐ b. Time ☐☐:☐☐ c. ☐ 1= am, 2 = pm

e.Coronary angioplasty with stent placement	0☐	1☐

1. If yes, Date:☐☐/☐☐ ☐☐☐☐ b. Time ☐☐:☐☐ c. ☐ 1= am, 2 = pm

	No/NR	Yes
f. Valve surgery	0☐	1☐
g. Non-cardiac surgery	0☐	1☐
h. Aortic balloon pump	0☐	1☐
i. Pacemaker placement (temporary or permanent)	0☐	1☐

j. Cardioversion or defibrillation 0☐ 1☐

1. If yes, Date:☐☐/☐☐ ☐☐☐☐ b. Time ☐☐:☐☐ c. ☐ 1= am, 2 = pm

2. If cardioversion took place after arrival at the hospital, what rhythm(s) were present prior to cardioversion?

		No/NR	Yes
a.	Ventricular Fibrillation/Flutter	0☐	1☐
b.	Ventricular Tachycardia (VT)	0☐	1☐
c.	Asystole	0☐	1☐
d.	Complete AV Block (3 HB)	0☐	1☐
e.	Atrial Fibrillation/Flutter	0☐	1☐
f.	Pulseless Electrical Activity (PEA)	0☐	1☐

41. During the hospitalization or at discharge, did the participant receive any of the following medications?

	Admission Meds		Discharge Meds	
	No/NR	Yes	No/NR	Yes
a. Nitroglycerin	0☐	1☐	0☐	1☐
b. Beta Blockers	0☐	1☐	0☐	1☐
c. Calcium Channel Blockers	0☐	1☐	0☐	1☐
d. ACE Inhibitor or ARB	0☐	1☐	0☐	1☐
d. Scheduled aspirin (not PRN)	0☐	1☐	0☐	1☐
e. Heparin or Enoxaparin	0☐	1☐	0☐	1☐
f. Coumadin, warafin, panwafarin, dicumarol	0☐	1☐	0☐	1☐
g. Anti-platelet agents (non-aspirin)	0☐	1☐	0☐	1☐
h. Statin	0☐	1☐	0☐	1☐

42. During this hospitalization was this patient treated with:

	No/NR	Yes
a. IV pressors	0☐	1☐
b. IV nitroglycerin	0☐	1☐
c. IIb / IIIa inhibitors or thrombin inhibitors	0☐	1☐

HCHS/SOL HEART FAILURE ABSTRACTION FORM (HTF)

PARTICIPANT ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: HTF VERSION: A 7/26/11 Contact Occasion ☐☐ SEQ# ☐☐

ADMINISTRATIVE INFORMATION

0B. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0B. Staff ID: ☐☐☐

Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ Event Date: ☐☐/☐☐/☐☐☐☐

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received (or classified as unobtainable) as indicated on the Verification of ICD Discharge Codes Form

A. GENERAL INFORMATION

1. Was the event (choose one):..... ☐
   - 1= In hospital
   - 2= Emergency Dept. (ED)
   - 3= Both ED and in hospital

2. Date of arrival: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

   a. Time of arrival ☐☐:☐☐ *1 = A.M., 2 = P.M.* ☐

   b. Date of admission ☐☐/☐☐/☐☐☐☐

3. Date of discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

   a. Time of discharge ☐☐:☐☐ *1 = A.M., 2 = P.M.* ☐

4. What was the primary admitting diagnosis code? ☐☐☐☐☐.☐☐

5. What was the primary discharge diagnosis code? ☐☐☐☐☐.☐☐

	No/NR	Yes
6. Did an emergency medical service unit transport the patient to this hospital?	0☐	1☐
7. Was the patient transferred to this hospital from another hospital?	0☐	1☐
8. Was the patient's code status ever "no-code" or "DNR" (do not resuscitate)?	0☐	1☐
9. Was the patient alive at discharge?	0☐	1☐

B. SIGNS AND SYMPTOMS

I. Signs and Symptoms

10. Did the patient have any of the following signs or symptoms at the time of event ?

	No	Yes	NR Not recorded
a. An increase or new onset of paroxysmal nocturnal dyspnea (PND)	0 ☐	1 ☐	9 ☐
b. An increase or new onset of orthopnea?	0 ☐	1 ☐	9 ☐
c. An increase or new onset of shortness of breath?	0 ☐	1 ☐	9 ☐
d. An increase or new onset edema?	0 ☐	1 ☐	9 ☐
e. Hypoxia	0 ☐	1 ☐	9 ☐
f. Dyspnea (at rest) or tachypnea (RR>22)	0 ☐	1 ☐	9 ☐
g. Dyspnea (walking or on exertion)	0 ☐	1 ☐	9 ☐

II. Evidence in Physicians' Notes of Reason for Event

11. Was there evidence in the doctor's notes that the reason for this event was an exacerbation of heart failure?	0 ☐	1 ☐	9 ☐
12. Did the patient have new onset or progressive signs/symptoms of heart failure prior to presentation in ED or hospital?	0 ☐	1 ☐	9 ☐

13. Did the physician's note or discharge summary indicate the presence of any of the following specific types of heart failure? (check all that apply)

	No	Yes
a. Diastolic heart failure	0 ☐	1 ☐
b. Systolic heart failure	0 ☐	1 ☐
c. Right-sided heart failure	0 ☐	1 ☐
d. Ischemic cardiomyopathy	0 ☐	1 ☐
e. Idiopathic/dilated cardiomyopathy	0 ☐	1 ☐
f. Myocarditis	0 ☐	1 ☐
g. Peripartum cardiomyopathy	0 ☐	1 ☐
h. Other specific cardiomyopathy/heart failure	0 ☐	1 ☐

1. If other cardiomyopathy, specify type _____

III. Prior cardiac testing

14. Was cardiac imaging performed prior to this hospitalization?

No/NR 0 ☐ Yes 1 ☐
skip to 15

a. Lowest LV ejection fraction recorded: ☐☐%

b. Qualitative description of ejection fraction:☐

Normal……..…… N
Mildly reduced…….M
Decreased moderately……...D
Severely reduced……S
None of the above……..O
Unsure-Not available..……U

c. Time (months) since recording of lowest ejection fraction: ☐☐.☐ months

d. Type of Imaging from which ejection fraction was obtained: ☐
1. ECHO
2. MUGA
3. Catheterization with ventriculography
4. CT
5. MRI
6. Other
7. Unknown

C. MEDICAL HISTORY

15. Prior to this event was there a history of any of the following:	No/NR	Yes
a. Diagnosis of heart failure	0☐	1 ☐
b. Prior hospitalization for heart failure	0☐	1 ☐
c. Treatment for heart failure	0 ☐	1 ☐
d. Valvular heart disease	0 ☐	1 ☐
e. Rheumatic heart disease (RHD)	0 ☐	1 ☐
f. Congenital heart disease	0 ☐	1 ☐
g. Coronary heart disease (ever)	0 ☐	1 ☐
h. Coronary heart disease (within year)	0 ☐	1 ☐
i. Angina	0 ☐	1 ☐
j. Myocardial infarction	0 ☐	1 ☐
	No/NR	Yes
k. Atrial fibrillation/atrial flutter	0 ☐	1 ☐

l. Heart block or other bradycardia 0 ☐ 1 ☐

m. Ventricular fibrillation or tachycardia 0 ☐ 1 ☐

n. Hypertension 0 ☐ 1 ☐

o. Diabetes 0 ☐ 1 ☐

p. Chronic Obstructive Pulmonary Disease (COPD) 0 ☐ 1 ☐

q. Cor pulmonale 0 ☐ 1 ☐

r. Pulmonary hypertension 0 ☐ 1 ☐

D. SURGICAL HISTORY

16. Past cardiac procedures	No/NR	Yes
a. CABG	0 ☐	1 ☐
b. Percutaneous coronary intervention (PCI)	0 ☐	1 ☐
c. Valve surgery	0 ☐	1 ☐
d. Pacemaker	0 ☐	1 ☐
e. Automatic Internal Cardiac Defibrillator (AICD)	0 ☐	1 ☐
f. Ablation for arrhythmia	0 ☐	1 ☐
g. Cardiac transplant	0 ☐	1 ☐
h. Ventricular Assist Device (VAD)	0 ☐	1 ☐

E. HOSPITAL COURSE

17. Current or Active Problems	No/NR	Yes
a. Myocardial Infarction	0☐	1 ☐
b. Shock or Cardiogenic Shock	0☐	1 ☐
c. Ventricular Fibrillation, Cardiac Arrest or Asystole	0 ☐	1 ☐
d. Ventricular Tachycardia	0 ☐	1 ☐
e. Atrial Fibrillation/Atrial Flutter	0 ☐	1 ☐

No/NR Yes

f. COPD exacerbation 0 ☐ 1 ☐

g. Cardiac Surgery – CABG or valvular surgery 0 ☐ 1 ☐

h. Non-cardiac surgery 0 ☐ 1 ☐

i. Pulmonary Embolus 0 ☐ 1 ☐

j. Pneumonia 0 ☐ 1 ☐

F. PHYSICAL EXAM

18. Vital Signs at Admission (or at onset of event)

a. First available weight or BMI ☐☐☐ ☐ 1= weight in lbs
2= weight in Kg
3= BMI

19. Did the patient have any of the following signs?

	No	Yes	Not recorded NR
a. Jugular venous distension (JVD)	0 ☐	1 ☐	9 ☐
b. Heart/Lung sounds:	0 ☐	1 ☐	9 ☐
1. crackles or rales	0 ☐	1 ☐	9 ☐
2. wheezing	0 ☐	1 ☐	9 ☐
3. rhonchi	0 ☐	1 ☐	9 ☐
4. S3 gallop	0 ☐	1 ☐	9 ☐
c. Lower extremity edema-unilateral	0 ☐	1 ☐	9 ☐
d. Lower extremity edema-bilateral	0 ☐	1 ☐	9 ☐

G. DIAGNOSTIC TESTS

20. Was a chest X-ray performed during this event? No/NR 0 ☐ ***skip to 21*** Yes 1 ☐

21. Did the patient have any of the following signs on chest x-ray at any time during this event?

	NoNR	Yes
a. Pulmonary edema or CHF	0 ☐	1 ☐
b. Cardiomegaly or Cardiothoracic ratio $\geq$ 0.5	0 ☐	1 ☐

	No/NR	Yes

c. Pulmonary vascular congestion or Interstitial edema 0 ☐ 1 ☐

d. Bilateral or unilateral pleural effusion 0 ☐ 1 ☐

22. Was a chest/lung CT scan or CT angiogram (CTA) performed during this hospitalization? 0 ☐ 1 ☐

23. Did the patient have any of the following signs on CT scan at any time during this hospitalization?

a. Pulmonary edema or pulmonary vascular congestion 0 ☐ 1 ☐

b. Cardiomegaly 0 ☐ 1 ☐

c. Bilateral or unilateral pleural effusion 0 ☐ 1 ☐

d. Enlarged superior or inferior vena cava 0 ☐ 1 ☐

e. Enlarged Pulmonary arteries 0 ☐ 1 ☐

24. Was a transthoracic echocardiogram (TTE) performed? 0 ☐ 1 ☐
Skip to 27

First transthoracic echocardiogram performed after onset of event:

a. Date (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

b. Left Ventricular Ejection Fraction: ☐☐%

c. Record the following if present on transthoracic echocardiogram:

	None	Mild	Mod	Severe	NR
1. Left ventricular hypertrophy (LVH)	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐
2. Impaired LV systolic function	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐
3. Impaired RV systolic function	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐
4. Pulmonary hypertension	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐
5. Valvular heart disease	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐

	No/NR	Yes
6. Diastolic dysfunction	0 ☐	1 ☐
7. Stress test positive for ischemia	0 ☐	1 ☐
8. Regional wall motion abnormalities	0 ☐	1 ☐

9. Dilated left ventricle 0 ☐ 1 ☐

10. Dilated right ventricle 0 ☐ 1 ☐

25. Was a transesophageal echocardiogram (TEE) performed? 0 ☐ 1 ☐
skip to 26

First transesophageal echocardiogram performed after onset of event:

a. Date (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

b. Ejection fraction: b.1. LV☐☐% b.2. RV☐☐%

c. Record the following if present on transesophageal echocardiogram:

	None	Mild	Moderate	Severe	NR
1. Impaired LV systolic function	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐
2. Impaired RV systolic function	0 ☐	3 ☐	4 ☐	5 ☐	9 ☐

	No/NR	Yes
3. Regional wall motion abnormalities	0 ☐	1 ☐
4. Dilated left ventricle	0 ☐	1 ☐
5. Dilated right ventricle	0 ☐	1 ☐
6. Valvular heart disease	0 ☐	1 ☐

	No/NR	Yes
26. Was coronary angiography performed?	0 ☐	1 ☐

skip to 27

a. Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ b. LV Ejection fraction: ☐☐%

	No/NR	Yes
c. 70% or greater obstruction of any coronary artery	0 ☐	1 ☐

	No/NR	Yes
27. Was a cardiac multiple-gated acquisition scan (MUGA) or RVG performed?	0 ☐	1 ☐

skip to 28

a. Ejection fraction: LV: ☐☐% b. RV: ☐☐%

	No/NR	Yes

c. Dilated ventricle or impaired ventricular function 0 ☐ 1 ☐

28. Was a cardiac Magnetic Resonance Imaging (MRI) performed? 0 ☐ 1 ☐ ***skip to 29***

a. Ejection fraction: LV: ☐☐% b. RV: ☐☐%

29. Did any imaging/diagnostic test show:

a. Ejection fraction: LV: ☐☐%

	No/NR	Yes
b. Stress test positive for ischemia?	0 ☐	1 ☐
c. Dilated ventricle or impaired ventricular function	0 ☐	1 ☐
d. Left ventricular diastolic dysfunction	0 ☐	1 ☐
e. Ventricular Septal Defect (VSD)	0 ☐	1 ☐
f. Atrial Septal Defect (ASD)	0 ☐	1 ☐
g. Patent Ductus Arteriosus (PDA)	0 ☐	1 ☐
h. Artificial heart valve	0 ☐	1 ☐
i. Hypertrophic Obstructive Cardiomyopathy (HOCM)	0 ☐	1 ☐
j. Valvular Heart Disease	0 ☐	1 ☐

H. LABORATORY TESTS

	a.Worst*	**b.Last**	**c. Upper Limit Normal**
30. BNP (pg/mL)	☐☐☐☐☐.☐	☐☐☐☐☐.☐	☐☐☐☐☐.☐
31. ProBNP (pg/mL)	☐☐☐☐☐.☐	☐☐☐☐☐.☐	☐☐☐☐☐.☐

32. Troponin ☐ < a.☐☐☐☐.☐☐ c. ☐< ☐☐☐☐.☐ ☐

a. If troponin value available, then what type of Troponin was this?

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

a.Worst*

33. Sodium (mEq/L) ☐☐☐

34. Serum creatinine (mg/dL) ☐☐.☐☐

35. BUN (mg/dL) ☐☐☐

36. Hemoglobin (g/dL) ☐☐.☐

37. Hematocrit (%) ☐☐.☐

Worst = highest value with exception of hemoglobin, hematocrit and sodium. For these the worst is the lowest value

I. TREATMENTS

38. Were any of the following treatments given during this visit?	No/NR	Yes
a. Cardioversion or Defibrillation	0 ☐	1 ☐
b. Aortic balloon pump	0 ☐	1 ☐
c. Percutaneous coronary intervention (PCI)	0 ☐	1 ☐
d. CPAP or BIPAP	0 ☐	1 ☐
e. Mechanical Ventilation	0 ☐	1 ☐
f. Thoracentesis (therapeutic or diagnostic)	0 ☐	1 ☐
g. Ventricular Assist Device (VAD)	0 ☐	1 ☐
h. Heart transplant	0 ☐	1 ☐

J. MEDICATIONS

	Prior to hospitalization		**At discharge**	
	No/NR	Yes	No/NR	Yes
39. ACE inhibitors	0 ☐	1 ☐	0☐	1 ☐
40. Angiotensin II receptor Blockers	0 ☐	1 ☐	0☐	1 ☐
41. Beta blockers	0 ☐	1 ☐	0☐	1 ☐
42. Digitalis	0 ☐	1 ☐	0☐	1 ☐
43. Diuretics	0 ☐	1 ☐	0☐	1 ☐
			No/NR	Yes
44. Aldosterone blocker	0 ☐	1 ☐	0☐	1 ☐

45. Lipid lowering agents	0 ☐	1 ☐	0☐	1 ☐
46. Nitrates	0 ☐	1 ☐	0☐	1 ☐
47. Hydralazine	0 ☐	1 ☐	0☐	1 ☐

48. IV drugs during this hospitalization?

	No/NR	Yes
a. IV inotropes	0 ☐	1 ☐
b. IV diuretics	0 ☐	1 ☐

HCHS/SOL PULMONARY ABSTRACTION FORM (PUL)

PARTICIPANT ID NUMBER:									FORM CODE: PUL VERSION: A 7/26/2011	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐

0d. Event Date: ☐☐/☐☐/☐☐☐☐

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received (or classified as unobtainable) as indicated on the Verification of ICD Discharge Codes Form

A. GENERAL INFORMATION

1. Was the event (choose one): ..... ☐ →***if response is "2" skip to Item 3***
   1= In hospital only 4= Observation care only
   2= Emergency Dept. visit only(ED) 5= Both ED and observation care
   3= Both ED and in hospital

2. Was the hospital stay less than 24 hours? ..... No 0 ☐ Yes 1 ☐ Not Recorded 9 ☐

3. Date of arrival: (mm/dd/yyyy) ..... ☐☐/☐☐/☐☐☐☐

   a. Time of arrival ☐☐:☐☐ *1 = A.M., 2 = P.M.* ☐

   b. Date of admission ☐☐/☐☐/☐☐☐☐

4. Date of discharge:(mm/dd/yyyy) ..... ☐☐/☐☐/☐☐☐☐

   a. Time of discharge ☐☐:☐☐ *1 = A.M., 2 = P.M.* ☐

5. What was the primary admitting diagnosis code? ☐☐☐☐☐.☐☐

6. What was the primary discharge diagnosis code? ☐☐☐☐☐.☐☐

	No	Yes	NR
7. Did an emergency medical service unit transport the patient to this hospital?	0 ☐	1 ☐	9 ☐
8. Was the patient transferred to this hospital from another hospital?	0 ☐	1 ☐	9 ☐
9. Was the patient's code status ever "no-code" or "DNR" (do not resuscitate)?	0 ☐	1 ☐	9 ☐
10. Was the patient alive at discharge?	0 ☐	1 ☐	9 ☐

SIGNS AND SYMPTOMS

I. Signs and Symptoms

11. Did the patient have any of the following signs or symptoms at the time of the event?

Recorded	No	Yes	Not
a. New onset or increase in cough?	0 ☐	1 ☐	9 ☐
b. New onset or increase in sputum production?	0 ☐	1 ☐	9 ☐
c. New onset or increase in sputum purulence?	0 ☐	1 ☐	9 ☐
d. New onset or increase in wheezing?	0 ☐	1 ☐	9 ☐
e. New onset or increase in chest tightness or chest pain?	0 ☐	1 ☐	9 ☐
f. New onset or increase in leg edema (unilateral or bilateral)?	0 ☐	1 ☐	9 ☐
g. New onset or increase in use of rescue bronchodilator?	0 ☐	1 ☐	9 ☐
h. New onset or increase in dyspnea?	0 ☐	1 ☐	9 ☐
i. Dyspnea (at rest)?	0 ☐	1 ☐	9 ☐
j. Dyspnea (walking or on exertion)?	0 ☐	1 ☐	9 ☐
k. Woken up at night by shortness of breath?	0 ☐	1 ☐	9 ☐
l. Fever?	0 ☐	1 ☐	9 ☐
m. Delirium or altered mental status (AMS)?	0 ☐	1 ☐	9 ☐

II. Evidence in Physicians' Notes of Reason for Event

	No/NR	Yes
12. Was there evidence in the doctor's notes that the reason for this event may be an exacerbation of COPD, chronic bronchitis, or emphysema?	0 ☐	1 ☐
13. Was there evidence in the doctor's notes that the reason for this event may be an exacerbation of asthma?	0 ☐	1 ☐
14. Did the patient have new onset or progressive signs/symptoms of this exacerbation Prior to presentation in ED or hospital?	0 ☐	1 ☐

B. MEDICAL HISTORY

15. Prior to this event was there a history of any of the following:	No/NR	Yes
a. Asthma	0 ☐	1 ☐
b. Chronic bronchitis	0 ☐	1 ☐
c. Emphysema	0 ☐	1 ☐
d. Chronic obstructive pulmonary disease (COPD)	0 ☐	1 ☐
e. Pulmonary fibrosis	0 ☐	1 ☐
f. Sarcoidosis	0 ☐	1 ☐
g. Lung cancer	0 ☐	1 ☐
h. Lung resection or lobectomy	0 ☐	1 ☐

15. Prior to this event was there a history of any of the following:

		No/NR	Yes
i.	Home oxygen (do not include CPAP)	0 ☐	1 ☐
j.	Pulmonary embolus	0 ☐	1 ☐
k.	Pulmonary hypertension	0 ☐	1 ☐
l.	Cor pulmonale	0 ☐	1 ☐
m.	Obstructive Sleep Apnea (OSA)	0 ☐	1 ☐
n.	Coronary artery disease	0 ☐	1 ☐
o.	Heart failure	0 ☐	1 ☐
p.	Atrial fibrillation/atrial flutter	0 ☐	1 ☐
q.	Diabetes	0 ☐	1 ☐
r.	Pulmonary Tuberculosis	0 ☐	1 ☐
s.	Bronchiectasis	0 ☐	1 ☐

16. If prior PFT results were provided, what is percent predicted FEV1?

16.a. Pre-bronchodilator ☐☐☐.% 16.b.Post-bronchodilator ☐☐☐.%

17. What is FEV_1/FVC ratio? ☐☐☐.☐☐ units ☐ 1=proportion or decimal
2=percent (If percent, then assure not percent predicted for the ratio)

C. HOSPITAL COURSE

18. Current or Active Problems anytime during this visit

		No/NR	Yes
a.	Upper Respiratory Infection (sinusitis, nasopharyngitis, pharyngitis, epiglottitis, laryngitis, laryngotracheitis, acute bronchitis)	0 ☐	1 ☐
b.	Pneumonia	0 ☐	1 ☐
c.	Pulmonary embolus	0 ☐	1 ☐
d.	Myocardial infarction	0 ☐	1 ☐
e.	Heart failure exacerbation	0 ☐	1 ☐
f.	Atrial fibrillation/atrial flutter	0 ☐	1 ☐
g.	Supraventricular Tachycardia (SVT) or multifocal atrial tachycardia (MAT)	0 ☐	1 ☐
h.	Cardiac Surgery – CABG or Valvular Surgery	0 ☐	1 ☐
i.	Non-cardiac surgery	0 ☐	1 ☐

D. PHYSICAL EXAM

19. Vital Signs at arrival to hospital or ED (or at onset of event if began after arrival)

a. heart rate ☐☐☐ bpm

b. respiration rate ☐☐ per minute

c. Oxygen Saturation (SpO_2/pulse oximetry) ☐☐☐.%

c.1. Oxygen Sats on room air? No 0 ☐ Yes 1 ☐ ***Skip to 19d*** Unknown 9 ☐ ***Skip to 19d***

c.2. If not on room air, what level oxygen? ☐☐☐.☐ ☐ 1= Liters, 2=Percent

d. Weight ☐☐☐.☐ ☐ 1= Lbs, 2=Kg

20. Did the patient have any of the following signs (at the time of the event)?

	No	Yes	NR
a. Use of accessory muscles	0 ☐	1 ☐	9 ☐
b. Cyanosis	0 ☐	1 ☐	9 ☐
c. Clubbing	0 ☐	1 ☐	9 ☐
d. Jugular venous distention (JVD) or distended neck veins	0 ☐	1 ☐	9 ☐
e. Crackles/rales	0 ☐	1 ☐	9 ☐
f. Wheezing or rhonchi	0 ☐	1 ☐	9 ☐
g. Decreased unilateral breath sounds	0 ☐	1 ☐	9 ☐
h. Decreased bilateral breath sounds	0 ☐	1 ☐	9 ☐
i. Prolonged expiratory time	0 ☐	1 ☐	9 ☐
j. Egophony	0 ☐	1 ☐	9 ☐
k. Lower extremity edema (unilateral or bilateral)	0 ☐	1 ☐	9 ☐

E. DIAGNOSTIC TESTS

21. Was a chest X-ray performed during this event? No/NR 0 ☐ ***skip to 23*** Yes 1 ☐

22. Did the patient have any of the following signs on chest x-ray at any time during this event?

	No/NR	Yes
a. Hyperinflation	0 ☐	1 ☐
b. Flattened diaphragms	0 ☐	1 ☐
c. Consolidation or infiltrate	0 ☐	1 ☐
d. Scarring	0 ☐	1 ☐
e. Nodule(s) > 8mm	0 ☐	1 ☐
f. Mass(es) > 3cm	0 ☐	1 ☐
g. Pulmonary edema, pulmonary vascular congestion (alveolar, interstitial)	0 ☐	1 ☐
h. Bilateral pleural effusion	0 ☐	1 ☐
i. Unilateral pleural effusion	0 ☐	1 ☐
j. Emphysema	0 ☐	1 ☐
k. Cardiomegaly	0 ☐	1 ☐

23. Was a chest/lung CT scan or CT angiogram (CTA) performed during this event?

No/NR 0 ☐ ***skip to 25*** Yes 1 ☐

24. Did the patient have any of the following signs on CT scan at any time during this event?

		No/NR	Yes
a.	Emphysema	0 ☐	1 ☐
b.	Nodule(s) > 8mm	0 ☐	1 ☐
c.	Mass(es) > 3cm	0 ☐	1 ☐
d.	Lymphadenopathy	0 ☐	1 ☐
e.	Ground glass changes	0 ☐	1 ☐
f.	Pneumonia	0 ☐	1 ☐
g.	Fibrosis or honeycombing	0 ☐	1 ☐
h.	Filling defect—vascular (PE)	0 ☐	1 ☐
i.	Filling defect—mucus plug	0 ☐	1 ☐
j.	Cysts or blebs	0 ☐	1 ☐
k.	Atelectasis	0 ☐	1 ☐
l.	Calcifications	0 ☐	1 ☐
m.	Pulmonary embolus	0 ☐	1 ☐
n.	Enlarged pulmonary artery	0 ☐	1 ☐
o.	Bronchiectasis	0 ☐	1 ☐
p.	Pulmonary edema or pulmonary vascular congestion	0 ☐	1 ☐
q.	Cardiomegaly	0 ☐	1 ☐
r.	Bilateral pleural effusion	0 ☐	1 ☐
s.	Unilateral pleural effusion	0 ☐	1 ☐
t.	Airway wall thickening	0 ☐	1 ☐

25. Was spirometry (lung function testing) performed during this hospitalization?

No/NR 0 ☐ ***Skip to 26*** Yes 1 ☐

a1. FEV_1 ☐☐.☐☐ L a2. FEV_1 Percent Predicted ☐☐☐ %

b1. FVC ☐☐.☐☐ L b2. FVC Percent Predicted ☐☐☐ %

c1. FEV_1/FVC ratio ☐☐☐.☐☐ units ☐ **1=**proportion or decimal **2=**percent (If percent, then assure not percent predicted for the ratio)

26. Was post-bronchodilator spirometry measured? No/NR 0 ☐ ***Skip to 27*** Yes 1 ☐

a1. FEV_1 ☐☐.☐☐ L a2. FEV_1 Percent Predicted ☐☐☐%

b1. FVC ☐☐.☐☐ L b2. FVC Percent Predicted ☐☐☐%

c1. FEV_1/FVC ratio ☐☐☐.☐☐ units ☐

1=proportion or decimal
2=percent (If percent, then assure not percent predicted for the ratio)

27. Was peak expiratory flow rate (PEFR or PEF) obtained at the time of event?

No/NR 0 ☐ ***Skip to 28*** Yes 1 ☐

a. Date of first PEF(R) taken at time of event: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

b. First PEF recording ☐☐☐

c. Worst or lowest PEF recording (anytime during hospitalization) ☐☐☐

28. Was peak expiratory flow rate (PERF or PEF) obtained at discharge?

No/NR 0 ☐ ***Skip to 29*** Yes 1 ☐

a. Date of last PEF(R) taken at discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

b. Last PEF recording ☐☐☐

29. Was a ventilation perfusion scan (VQ Scan) done? No/NR 0 ☐ ***Skip to 30*** Yes 1 ☐

a. Ventilation perfusion scan results (record number of answer) ☐

1. High probability
2. Intermediate probability
3. Low probability
4. No evidence of Pulmonary Embolus
5. Indeterminate

30. Was an echocardiogram (TTE or TEE) performed? No/NR 0 ☐ ***Skip to 31*** Yes 1 ☐

If more than one ECHO performed, then use the worst value for each question

a. Ejection fraction: ☐☐% b. RVSP (right ventricular systolic pressure) ☐☐☐.☐☐mmHg

Record the following if present on echocardiogram:	None	Present	Mild	Mod	Severe	NR
c. Right Ventricular Hypertrophy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐
d. Impaired RV systolic function	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐
e. Pulmonary hypertension.....	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐
f. Tricuspid Regurgitation.....	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐
g. Diastolic dysfunction	0 ☐	1 ☐				9 ☐

BIOCHEMICAL TESTS

31. White Blood Cell Count ☐☐.☐

a. First (at event)

32. Hemoglobin (g/dL) ☐☐.☐
33. Hematocrit (%) ☐☐.☐
34. Sodium (mEq/L) ☐☐☐
35. Serum creatinine (mg/dL) ☐☐.☐☐
36. BUN (mg/dL) ☐☐.☐
37. Bicarbonate (total CO2) ☐☐.☐

	a.First (at event)	**b.Upper limit normal**
38. BNP (pg/mL)	a. ☐☐☐☐☐.☐	b. ☐☐☐☐☐.☐
39. ProBNP (pg/mL)	a. ☐☐☐☐☐.☐	b. ☐☐☐☐☐.☐

40. Were Arterial Blood Gases (ABGs) obtained? No/NR 0 ☐ ***Skip to 41*** Yes 1 ☐

	a.First blood gas (at time of event)	**b. Last blood gas**
pH	1.☐☐.☐☐	1.☐☐.☐☐
PaCO2	2.☐☐.☐ mmHg	2.☐☐.☐ mmHg
PaO2	3.☐☐☐.☐ mmHg	3.☐☐☐.☐ mmHg
O_2 Saturation	4.☐☐☐.☐ %	4.☐☐☐.☐ %

c. Blood gas on room air? No 0 ☐ Yes 1 ☐ ***Skip to 41*** Not Recorded 9 ☐ ***Skip to 41***

c.1. If not on room air, what level oxygen? ☐☐☐.☐ ☐ 1= Liters, 2=Percent

41. Was a sputum culture done? No/NR 0 ☐ ***Skip to 42*** Yes 1 ☐

a. Culture Results Neg 0 ☐ ***Skip to 42*** Pos 1 ☐ Not Recorded 9 ☐ ***Skip to 42***

b. If yes, were any of the following reported in the sputum culture?

	No	Yes
1. Haemophilus Influenzae	0 ☐	1 ☐
2. Moraxella Catarrhalis	0 ☐	1 ☐
3. Streptococcus pneumoniae	0 ☐	1 ☐
4. Methicillin-resistant Staphylococcus Aureus (MRSA)	0 ☐	1 ☐
5. Staphylococcus aureus (not MRSA)	0 ☐	1 ☐
6. Mycoplasma pneumoniae	0 ☐	1 ☐
7. Pseudomonas Aureginosa	0 ☐	1 ☐
8. Chlamydophila (or Chlamydia) pneumoniae	0 ☐	1 ☐
9. Oropharyngeal flora	0 ☐	1 ☐
10. Other_____		

42. Was a blood culture done? No/NR 0 ☐ ***Skip to 43*** Yes 1 ☐

a. Culture Results Neg 0 ☐ ***Skip to 43*** Pos 1 ☐ Not Recorded 9 ☐ ***Skip to 43***

b. If yes, were any of the following reported in the blood culture?

	No	Yes
1. Haemophilus Influenzae	0 ☐	1 ☐
2. Moraxella Catarrhalis	0 ☐	1 ☐
3. Streptococcus pneumoniae	0 ☐	1 ☐
4. Methicillin-resistant Staphylococcus Aureus (MRSA)	0 ☐	1 ☐
5. Staphylococcus aureus (not MRSA)	0 ☐	1 ☐
6. Other_____		

43. Influenza swab Neg 0 ☐ Pos 1 ☐ Not Recorded 9 ☐

F. TREATMENTS / MEDICATIONS

	No/NR	Yes
44. CPAP or BiPap	0 ☐	1 ☐
45. Mechanical Ventilation	0 ☐	1 ☐
46. Inhaled short-acting beta-agonists (ie,albuterol, xopenex)	0 ☐	1 ☐
47. Inhaled short-acting anticholinergics (ie, atrovent, ipratropium)	0 ☐	1 ☐
48. Nebulized Bronchodilators	0 ☐	1 ☐
49. Magnesium injections in ED	0 ☐	1 ☐
50. Oxygen (continuous or prn)	0 ☐	1 ☐
51. IV Antibiotics	0 ☐	1 ☐
52. Systemic Corticosteroid (IV or PO)	0 ☐	1 ☐
53. IV Lasix or Furosemide	0 ☐	1 ☐

	At onset of time of event			At discharge	
	No/NR	Yes		No/NR	Yes
54. Antibiotics-oral	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
55. Systemic corticosteroid (ie prednisone)	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
56. Inhaled short acting beta-agonists (ie albuterol)	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
57. Inhaled long-acting beta-agonist (ie, serevent)	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
58. Inhaled short-acting anticholinergics (ie, atrovent)	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
59. Inhaled long-acting anticholinergics	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
60. Inhaled corticosteroids	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
61. Nebulized bronchodilators	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
62. Leukotriene antagonist	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐
63. Home oxygen	a. 0 ☐	1 ☐	.....	b. 0 ☐	1 ☐

HCHS/SOL Stroke Abstraction Form (STR)

ID NUMBER:										FORM CODE: STR VERSION: 1 05/28/2020	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐

0d. Event Date: ☐☐/☐☐/☐☐☐☐

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received (or classified as unobtainable) as indicated on the Verification of ICD Discharge Codes Form

A. General Information

1. Date of arrival: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

   a. Time of arrival: ☐☐:☐☐

2. What was the primary admitting diagnosis code? ☐☐☐☐.☐☐☐☐

3. Date of discharge/death: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

4. What was the primary discharge diagnosis code? ☐☐☐☐.☐☐☐☐

5. Mode of arrival from home/scene:

   Unknown 9☐

   EMS 1☐

   Private transport/taxi/walk-in 2☐

   Transfer from another hospital 3☐

   Mobile stroke unit 4☐

6. Was the participant transferred from this hospital to another?

   No 0☐ Yes 1☐ Unknown 9☐

7. Was a DNR/DNI or Withdrawal of Care order present during this hospitalization?

   No 0☐ Yes 1☐ Unknown 9☐

B. Medical History

8. Were there new neurological signs/symptoms present upon this admission?

No 0☐ Yes 1☐ Unknown 9☐

9. Did the participant's stroke or TIA occur during this hospitalization?

No/NR 0☐ Yes 1☐

10. Did the event occur in the setting of a procedure within the last 30 days or during this hospitalization?

No/NR 0☐ ***Skip to 11*** Yes 1☐

a. If yes, what procedure? (answer 0=No/NR or 1=Yes for each procedure)

1. Cerebral Angiogram No/NR 0☐ Yes 1☐
2. Coronary Angiogram No/NR 0☐ Yes 1☐
3. Cardiac Surgery or Procedures (e.g. stenting, LVAD, TAVR, etc.) No/NR 0☐ Yes 1☐
4. Carotid Endarterectomy No/NR 0☐ Yes 1☐
5. Carotid Stenting No/NR 0☐ Yes 1☐
6. Other No/NR 0☐ Yes 1☐
   a. Specify:_____

11. Date/time of onset of current neurological symptoms:

a. Date Known? No 0☐ ***Skip to 12*** Yes 1☐

b. Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

c. Time Known? No 0☐ ***Skip to 12*** Yes 1☐

d. Time: ☐☐:☐☐

12. When was the participant last known to be free of deficits?

a. Date Known? No 0☐ ***Skip to 13*** Yes 1☐

b. Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

c. Time Known? No 0 ☐ ***Skip to 13*** Yes 1 ☐

d. Time: ☐☐:☐☐

13. Was there a history of previous stroke?

No 0 ☐ ***Skip to 14*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 14***

a. Date Known? No 0 ☐ ***Skip to 13c*** Yes 1 ☐

b. Date of most recent stroke: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

c. Type of stroke:

Unknown 9 ☐ ***Skip to 14***

Ischemic 1 ☐ ***Skip to 14***

Intracranial hemorrhage 2 ☐ ***Skip to 13c1***

Subarachnoid hemorrhage 3 ☐ ***Skip to 13c3***

1. If the participant had an ICH, was hematoma evacuation performed? No 0 ☐ Yes 1 ☐ Unknown 9 ☐
2. Did the participant receive an intra-hematoma tPA infusion? No 0 ☐ Yes 1 ☐ Unknown 9 ☐

For any answer to 13c2, skip to 14

3. If the participant had an SAH, was an aneurysm found? No 0 ☐ Yes 1 ☐ Unknown 9 ☐
4. Was aneurysm coiling performed? No 0 ☐ Yes 1 ☐ Unknown 9 ☐
5. Was aneurysm clipping performed? No 0 ☐ Yes 1 ☐ Unknown 9 ☐

14. Is there a history of previous TIA? No 0 ☐ ***Skip to 15*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 15***

a. Date Known? No 0 ☐ ***Skip to 15*** Yes 1 ☐

b. Date of most recent TIA: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

15. Does the participant have a history of coronary artery disease?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

16. Does the participant have a history of peripheral vascular disease?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

17. Does the participant have a history of carotid disease?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

18. Does the participant have end stage renal disease?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

19. Does the participant have a history of diabetes?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

20. Does the participant have a history of hypertension?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

21. Does the participant have a history of dyslipidemia or prior therapy for such?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

22. Does the participant have a history of smoking?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

23. Does the participant have a history of alcohol use disorder?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

24. Does the participant have a history of illicit stimulant use within four weeks prior to this hospitalization?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

25. Are any of the following conditions documented as having been present prior to or during this hospitalization?

	No/NR	Yes
a. Recent myocardial infarction	0 ☐	1 ☐
b. intracardiac thrombus or intracardiac tumor	0 ☐	1 ☐
c. atrial fibrillation/atrial flutter	0 ☐	1 ☐
1. Was there ≥24 hours of cardiac monitoring for this participant?	0 ☐	1 ☐
d. left-sided atrial enlargement on echocardiogram	0 ☐	1 ☐
e. rheumatic heart disease	0 ☐	1 ☐
f. systemic embolus	0 ☐	1 ☐

g. hematologic abnormality (hypercoagulable state) 0 ☐ 1 ☐

h. hematologic abnormality (hemorrhagic) 0 ☐ 1 ☐

i. migraine headaches 0 ☐ 1 ☐

j. left-sided bioprosthetic valve 0 ☐ 1 ☐

k. left-sided mechanical valve 0 ☐ 1 ☐

C. Signs and Symptoms

26. If the new neurological signs/symptoms resolved, how long did they last? ☐

1. Less than 24 hours *2. Twenty four - forty eight hours*
3. Greater than 48 hours *4. Unknown* *5. Not applicable*

27. Was an NIHSS recorded? No 0 ☐ ***Skip to 27b*** Yes 1 ☐

a. If yes, what was the score? ☐☐ ***Skip to 28***

b. If no, complete the scores in the following Items (descriptions in Question by Question Instructions - QxQ)

1. LOCa 0 ☐ 1 ☐ 2 ☐ 3 ☐
2. LOCb 0 ☐ 1 ☐ 2 ☐
3. LOCc 0 ☐ 1 ☐ 2 ☐
4. Best Gaze 0 ☐ 1 ☐ 2 ☐
5. Visual Fields 0 ☐ 1 ☐ 2 ☐ 3 ☐
6. Facial Palsy 0 ☐ 1 ☐ 2 ☐ 3 ☐
7. Motor Arm
   a. Left 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4☐
   b. Right 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4☐
8. Motor Leg
   a. Left 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4☐
   b. Right 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4☐
9. Limb Ataxia 0 ☐ 1 ☐ 2 ☐
10. Sensory 0 ☐ 1 ☐ 2 ☐

11. Best Language 0 ☐ 1 ☐ 2 ☐ 3 ☐

12. Dysarthria 0 ☐ 1 ☐ 2 ☐

13. Extinction and Inattention 0 ☐ 1 ☐ 2 ☐

14. Total Score: [save form and click arrows to calculate]

28. Was the participant asleep at the time of the event?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

29. Severe headache at onset of symptoms or on hospital admission?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

30. Vomiting? No 0 ☐ Yes 1 ☐ Unknown 9 ☐

31. Blurry Vision? No 0 ☐ Yes 1 ☐ Unknown 9 ☐

32. Diplopia? No 0 ☐ Yes 1 ☐ Unknown 9 ☐

33. Vertigo? No 0 ☐ Yes 1 ☐ ***Skip to 35*** Unknown 9 ☐

34. Dizziness? No 0 ☐ Yes 1 ☐ Unknown 9 ☐

35. Seizure? No 0 ☐ ***Skip to 36*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 36***

a. Was this the first neurological symptom?

No 0 ☐ Yes 1 ☐ Unknown 9 ☐

D. Neurological Exam *(Skip to 48 if retrospective NIHSS Q27b was completed)*

36. Level of Consciousness:

Normal 0 ☐ Abnormal 1 ☐ Unconscious 2 ☐ Unknown 9 ☐

37. Aphasia: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

38. Hemianopsia: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

39. Any abnormality of Cranial Nerves III, IV, or VI:

No 0 ☐ ***Skip to 40*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 40***

a. Location of abnormality: ☐ (1 = Left, 2 = Right, 3 = Both, 9 = NR)

40. Horizontal Gaze Palsy (Conjugate Gaze Deviation): No 0 ☐ ***Skip to 41*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 41***

a. Location of Gaze Deviation: ☐ (1 = Left, 2 = Right, 3 = Both, 9 = NR)

41. Dysphagia: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

42. Dysarthria: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

43. Weakness (paresis): No 0 ☐ ***Skip to 44*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 44***

a. Face ☐ (1 = Left, 2 = Right, 3 = Both, 4 = None, 9 = NR)

b. Arm ☐ (1 = Left, 2 = Right, 3 = Both, 4 = None, 9 = NR)

c. Leg ☐ (1 = Left, 2 = Right, 3 = Both, 4 = None, 9 = NR)

44. Sensory Deficit: No 0 ☐ ***Skip to 45*** Yes 1 ☐ Unknown 9 ☐ ***Skip to 45***

a. Face ☐ (1 = Left, 2 = Right, 3 = Both, 4 = None, 9 = NR)

b. Arm ☐ (1 = Left, 2 = Right, 3 = Both, 4 = None, 9 = NR)

c. Leg ☐ (1 = Left, 2 = Right, 3 = Both, 4 = None, 9 = NR)

45. Visual Fields Abnormality: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

46. Ataxic Gait: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

47. Hemiataxia: No 0 ☐ Yes 1 ☐ Unknown 9 ☐

E. Diagnostic Tests

48. First Recorded Blood Pressure: ☐☐☐/☐☐☐ mmHg

49. First Glucose Level: ☐☐☐☐

50. Was a Lumbar Puncture performed? No/NR 0 ☐ ***Skip to 51*** Yes 1 ☐

a. Lumbar Puncture Diagnosis: Normal 0 ☐ Abnormal 1 ☐ Unknown 9 ☐

51. Was one or more CT scan/s of the head performed during this hospitalization?

No 0 ☐ ***Skip to 52*** Yes, one CT 1 ☐ Yes, two or more CTs 2 ☐ NR 9 ☐ ***Skip to* 52**

a. If yes, date of first CT: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

b. Was acute or subacute stroke diagnosed on the first CT?

No 0☐ Yes 1☐ Unknown/NR 9☐

If only one CT was performed, skip to 52

c. If two or more were performed, date of last CT: ☐☐/☐☐/☐☐☐☐

d. Was acute or subacute stroke diagnosed on the last CT, or was any stroke identified on the last CT that was not previously identified on the first CT?

No 0☐ Yes 1☐ Unknown/NR 9☐

52. Was Magnetic Resonance Imaging (MRI) including the head performed?

No 0☐ ***Skip to 53*** Yes 1☐ Unknown/NR 9☐ ***Skip to 53***

a. Was acute or subacute stroke diagnosed on the MRI?

No 0☐ Yes 1☐ Unknown/NR 9☐

b. Was a Diffusion Weighted Imaging (DWI) study performed?

No 0☐ ***Skip to 53*** Yes 1☐ Unknown/NR 9☐ ***Skip to 53***

c. DWI Diagnosis: Normal 0☐ Abnormal 1☐ Unknown/NR 9☐

53. Was Cerebrovascular Angiography performed?

No 0☐ ***Skip to 54*** Yes 1☐ Unknown/NR 9☐ ***Skip to 54***

If yes, indicate if any of the following were done:

a. Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

b. CTA Head: No 0☐ Yes 1☐ NR 9☐

c. CTA Neck: No 0☐ Yes 1☐ NR 9☐

d. MRA Head: No 0☐ Yes 1☐ NR 9☐

e. MRA Neck: No 0☐ Yes 1☐ NR 9☐

f. Carotid Doppler: No 0 ☐ Yes 1 ☐ NR 9 ☐

g. Transcranial Doppler: No 0 ☐ Yes 1 ☐ NR 9 ☐

h. Catheter Angiogram: No 0 ☐ Yes 1 ☐ NR 9 ☐

Extracranial Studies

i. Stenosis – Right Internal Carotid Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

j. Stenosis – Left Internal Carotid Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

k. Stenosis – Right Vertebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

l. Stenosis – Left Vertebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

Intracranial Studies

m. Stenosis – Right Internal Carotid Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

n. Stenosis – Left Internal Carotid Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

o. Stenosis – Right Vertebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

p. Stenosis – Left Vertebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

q. Stenosis – Right Middle Cerebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

r. Stenosis – Left Middle Cerebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

s. Stenosis – Right Anterior Cerebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

t. Stenosis – Left Anterior Cerebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

u. Stenosis – Right Posterior Cerebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

v. Stenosis – Left Posterior Cerebral Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

w. Stenosis – Basilar Artery: No 0 ☐ Yes 1 ☐ NR 9 ☐

54. Was a transthoracic echocardiography study performed?

No/NR 0 ☐ ***Skip to 55*** Yes 1 ☐

a. If yes, what was the ejection fraction? ☐☐

55. Was a transesophageal echocardiography study performed?

No/NR 0 ☐ ***Skip to 56*** Yes 1 ☐

a. If yes, what was the ejection fraction? ☐☐

If both 54 and 55 are No/NR, skip to 57

56. Please indicate the presence on either type of echocardiogram of each of the following:

a. Intracardiac Thrombus: No 0 ☐ Yes 1 ☐ NR 9 ☐

b. Mitral Stenosis: No 0 ☐ Yes 1 ☐ NR 9 ☐

c. Mitral Regurgitation: No 0 ☐ Yes 1 ☐ NR 9 ☐

d. Aortic Stenosis: No 0 ☐ Yes 1 ☐ NR 9 ☐

e. Aortic Regurgitation: No 0 ☐ Yes 1 ☐ NR 9 ☐

f. Poor Ventricular Function: No 0 ☐ Yes 1 ☐ NR 9 ☐

g. Dilated Left Ventricle: No 0 ☐ Yes 1 ☐ NR 9 ☐

h. Ascending Aortic Arch Atheroma: No 0 ☐ Yes 1 ☐ NR 9 ☐

1. If yes: Mild 1 ☐ Moderate 2 ☐ Severe 3 ☐ NR 9 ☐

i. Atrioseptal Aneurysm: No 0 ☐ Yes 1 ☐ NR 9 ☐

j. Patent Foramen Ovale (PFO): No 0 ☐ Yes 1 ☐ NR 9 ☐

k. Valve Vegetations: No 0 ☐ Yes 1 ☐ NR 9 ☐

l. Artificial Valve: No 0 ☐ Yes 1 ☐ NR 9 ☐

m. Left Atrial Enlargement: No 0 ☐ Yes 1 ☐ NR 9 ☐

F. Laboratory Tests - First available lab values

57. Sodium (mmol/L or mEq/L): ☐☐☐

58. Serum creatinine (mg/dL): ☐☐.☐☐

59. BUN (mg/dL): ☐☐☐

60. Hemoglobin (g/dL): ☐☐.☐

61. Hematocrit (%): ☐☐.☐

62. INR: ☐☐.☐

63. PTT: ☐☐

a. Was this an activated PTT (aPTT)? No 0☐ Yes 1☐ NR 9☐

64. Platelet count (x1000): ☐☐☐☐

65. Total Cholesterol (mg/dL): ☐☐☐☐

66. LDL (mg/dL): ☐☐☐

67. HbA1c (%): ☐☐

G. Treatment

68. Did the participant receive thrombolytic treatment for stroke?

No 0☐ ***Skip to 69*** Yes 1☐ Unknown 9☐ ***Skip to 69***

a. If yes, did the participant suffer symptomatic ICH post tPA?

No 0☐ Yes 1☐ Unknown 9☐

69. Did the participant receive endovascular therapy (EVT) for ischemic stroke?

No 0☐ ***Skip to 70*** Yes 1☐ Unknown 9☐ ***Skip to 70***

a. If yes, did the participant suffer symptomatic ICH post EVT?

No 0☐ Yes 1☐ Unknown 9☐

70. Did the participant receive osmotic/hypertonic treatment?

No 0☐ Yes 1☐ Unknown 9☐

71. Was decompressive hemicraniectomy performed?

No 0☐ Yes 1☐ Unknown 9☐

H. Discharge

72. Was the participant alive at discharge? No 0 ☐ Yes 1 ☐ ***Skip to 73***

    a. If no, was an autopsy performed?

    No 0 ☐ ***Skip to 78*** Yes 1 ☐ NR 9 ☐ ***Skip to 78***

    1. Autopsy Diagnosis ☐ ***Skip to 78***
       (1 = recent bleeding of saccular aneurysm/subarachnoid hemorrhage 2 = hemorrhagic infarction of the brain, 3 = lacunar stroke, 4 = embolic stroke, 7 = other)

73. Was the participant able to ambulate independently before the current hospitalization?

    No 0 ☐ Yes 1 ☐ Unknown/NR 9 ☐

74. Was the participant able to ambulate independently at discharge?

    No 0 ☐ Yes 1 ☐ Unknown/NR 9 ☐

75. Where was the participant discharged to? ☐
    (1 = Home, 2 = Acute Rehabilitation, 3 = Skilled Nursing Facility, 4 = Assisted Living, 5 = Hospice, 6 = Other/Unknown)

76. At the time of discharge, did the participant require more help from another person for everyday activities compared to status prior to event?

    No 0 ☐ Yes 1 ☐ Unknown/NR 9 ☐

77. Was a Modified Rankin Scale done at discharge?

    No 0 ☐ ***Skip to 77b*** Yes 1 ☐ Unknown/NR 9 ☐ ***Skip to 77b***

    a. If yes, what was the score? ☐ ***Skip to 78***

    b. If no or not recorded, at discharge was the participant:

    Back to Normal 0 ☐
    Exhibiting S/S related to stroke but otherwise without disability 1 ☐
    Able to ambulate independently with some disability 2 ☐
    Dependent on others for some ADLs, but able to walk 3 ☐
    Moderately severe disability 4 ☐
    Bedridden (requires 24/7 care) 5 ☐

Unknown/NR 9☐

I. Medications

78. Prior to admission, did the participant receive any of the following medications?

a. Oral Anticoagulants No/NR 0☐ Yes 1☐
Apixaban, Rivaroxaban, Dabigatran, Edoxaban

b. Beta Blockers No/NR 0☐ Yes 1☐

c. Calcium Channel Blockers No/NR 0☐ Yes 1☐

d. ACE Inhibitor or ARB No/NR 0☐ Yes 1☐

e. Scheduled aspirin (not PRN) No/NR 0☐ Yes 1☐

f. Heparin or Enoxaparin No/NR 0☐ Yes 1☐

g. Coumadin, warfarin, panwarfarin, dicumarol No/NR 0☐ Yes 1☐

h. Anti-platelet agents (non-aspirin) No/NR 0☐ Yes 1☐

i. Statin or other lipid-lowering medication No/NR 0☐ Yes 1☐

79. During hospitalization or at discharge, did the participant receive any of the following medications?

a. Oral Anticoagulants No/NR 0☐ Yes 1☐
Apixaban, Rivaroxaban, Dabigatran, Edoxaban

b. Beta Blockers No/NR 0☐ Yes 1☐

c. Calcium Channel Blockers No/NR 0☐ Yes 1☐

d. ACE Inhibitor or ARB No/NR 0☐ Yes 1☐

e. Scheduled aspirin (not PRN) No/NR 0☐ Yes 1☐

f. Heparin or Enoxaparin No/NR 0☐ Yes 1☐

g. Coumadin, warfarin, panwarfarin, dicumarol No/NR 0☐ Yes 1☐

h. Anti-platelet agents (non-aspirin) No/NR 0☐ Yes 1☐

i. Statin or other lipid-lowering medication No/NR 0☐ Yes 1☐

APPENDIX E. Reviewer Forms

Myocardial Infarction diagnosis form (MID)
Heart Failure diagnosis form (HFD)
Pulmonary diagnosis form (PLD)
Stroke diagnosis form (STD)
Mortality Reviewer form (MOR)

HCHS/SOL MYOCARDIAL INFARCTION (MID) DIAGNOSIS FORM

ID NUMBER:									FORM CODE: MID VERSION: A 08/17/2011	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Reviewer ID: ☐☐☐

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ 0d. Event Date: ☐☐/☐☐/☐☐☐☐

1. Was there evidence of chest pain associated with this event? 0☐No 1☐Yes9☐Unknown

2. Describe the level of cardiac biomarkers:..... ☐
   - 1= Abnormal (at least one value at 2 X the upper limit normal)
   - 2= Equivocal (> normal, but < 2X the upper limit normal)
   - 3= Incomplete
   - 4= Normal
   - 5= None recorded

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

4. **Myocardial infarction classification (using MI algorithm):**

   1☐Definite 2☐Probable 3☐No MI ***(skip to 5)*** 4☐Unclassifiable***(skip to 5)***

   If 'Definite' or 'Probable' MI then answer the following questions 4a-4c:

   4.a. Type of MI? 0☐Transmural 1☐Subendocardial 9☐Unsure/unknown

   4.b. Location of MI? ..... ☐
   - 1=Anterior
   - 2=Posterior
   - 3=Inferior
   - 4=Lateral
   - 5=Septal
   - 6=Anteriorseptal
   - 7=Anteriorlateral
   - 9=Unable to determine

   4.c. Was the MI procedure-related? ***(skip to 6 after answering)***

   1☐Yes, cardiovascular procedure 2☐ Yes, non-cardiovascular procedure 3☐ No/Unsure

5. If 'No' MI or 'unclassifiable' for MI then did this patient have angina, either stable or unstable?

   1☐Definite 2☐Probable 3☐No MI 4☐Unclassifiable

6. Did this patient have a coronary revascularization procedure (PTCA, CABG, stent etc…) during this admission that likely interrupted an MI? 0☐No 1☐Yes9 ☐Unsure
7. Comments_____

HCHS/SOL HEART FAILURE (HFD) DIAGNOSIS FORM

ID NUMBER:									FORM CODE: HFD VERSION: A 8/17/2011	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Reviewer ID: ☐☐☐

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐

0d. Event Date: ☐☐/☐☐/☐☐☐☐

	No	Yes	Unknown
1. Does this patient have a history of heart failure	0☐	1☐	9☐
2. HF diagnosed by provider AND treatment provided for HF?	0☐	1☐	9☐
3. Pulmonary edema/congestion on Chest X-ray	0☐	1☐	9☐

Historical or imaging evidence of:	No	Yes, history	Yes, current imaging	Unknown
4. Dilated ventricle?	0☐	1☐	2☐	9☐
5. Poor LV function (e.g., low EF or wall motion abnormalities)	0☐	1☐	2☐	9☐
6. Poor RV function	0☐	1☐	2☐	9☐
7. Diastolic dysfunction	0☐	1☐	2☐	9☐

8. Quantitative EF during this hospitalization (or within 3 months)?

1☐≥ 50 2☐40-49 3☐ 30-30 4☐ 20-29 5☐ <20 6☐ unknown

REVIEWER CLASSIFICATION

9. Does this patient have acute decompensated heart failure (ADHF)?

1☐Definite 2☐Probable 3☐No, ***skip to 10*** 4☐Unknown, ***skip to 10***

If Definite or Probable ADHF then answer 9a-9c:

9a. How would you classify the severity of the exacerbation?

1☐Mild 2☐Moderate 3☐Severe 4☐unknown

9b. Was ADHF predominantly right-sided HF (normal LV EF)? 0☐No 1☐Yes 9☐Unknown

9c. Were any of the following problems co-morbid with this event and could have precipitated this event?

	NO/NR	YES
c.1. Myocardial infarction	0☐	1☐
c.2. Atrial fibrillation/atrial flutter	0☐	1☐
c.3. Other arrhythmia	0☐	1☐
c.4. Fluid or volume overload	0☐	1☐
c.5. Medication noncompliance	0☐	1☐
c.6. Pulmonary embolus	0☐	1☐
c.7. Renal Insufficiency or failure	0☐	1☐
c.8 Cardiovascular procedure/surgery	0☐	1☐
c.9. Non-cardiovascular procedure/surgery	0☐	1☐
c.10. Pulmonary disease	0☐	1☐
c.11.Uncontrolled Hypertension	0☐ ***skip to 11***	1☐ ***skip to 11***

10. If **not** definite or probable ADHF, then does this patient have Asymptomatic LV dysfunction (EF< 50%)?

0☐No/NR 1 ☐Yes 9☐Unknown

11. Reviewer comments: _____

HCHS/SOL PULMONARY DIAGNOSIS (PLD) FORM

ID NUMBER:									FORM CODE: PLD VERSION: A 7/20/11	Contact Occasion		SEQ #	

Administrative Information

0A. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0B. Reviewer ID: ☐☐☐

0C. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐

0D.Event Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

	Yes		No		
	Definite	Probable	Probably Not	Definitely not	Unknown
1. Does this patient meet SOL criteria for a history of chronic lower respiratory disease (CLRD)?	1 ☐	2 ☐	3 ☐ **Go to Q2**	4 ☐ **Go to Q2**	5 ☐ **Go to Q2**
If YES (definite or probable.) Does this patient have a history of any of the following?					
a. COPD	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b. Emphysema	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
c. Chronic Bronchitis	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
d. Asthma	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

2. Is there evidence of other lung disease? No=0 ☐ Yes=1 ☐

a. If yes, specify lung disease_____

	Yes		No		
	Definite	Probable	Probably Not	Definitely not	Unknown
3. Does this patient have an exacerbation of underlying chronic lower respiratory disease (CLRD)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

a. If Yes (definite or probable), then which type of CLRD is the cause of this exacerbation? (select one)

1. Asthma predominant ☐
2. COPD predominant ☐
3. Either asthma or COPD ☐
4. Unclassifiable ☐

	Yes		No		Unknown/
	Definite	Probable	Probably Not	Definitely not	unclassified
4. Did this patient have pneumonia (new infiltrate on chest imaging)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

5. Comments: _____

HCHS/SOL STROKE DIAGNOSIS FORM (STD)

ID NUMBER:									FORM CODE: STD VERSION: 1 04/17/2020	Contact Occasion		SEQ #	

Administrative Information

0A. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0B. Staff ID: ☐☐☐

0C. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ 0D. Event Date: ☐☐/☐☐/☐☐☐☐

Instructions: Answers are derived from the medical records or death certificate received. Complete this form once the physician summary packet including designated pages chosen from medical record is provided.

A. PRIMARY DIAGNOSIS

1. Diagnosis (choose one): ☐

(1) Not a TIA or stroke ***(skip to Item 12**.)*
(2) TIA *(see QxQ for definition and **skip to Item 12**.)*
(3) Stroke

B. STROKE TYPE – (for Item # 2 use codes (1) – (5) below)

2. Type ☐

CODES:

(1) Brain Infarction ***(skip to Item C3)***
(2) Subarachnoid Hemorrhage ***(skip to Item D5)***
(3) Intracerebral Hemorrhage ***(skip to Item D8)***
(4) Other Stroke Type ***(skip to 2A and specify)***
(5) Unknown Stroke Type ***(skip to 2B and specify)***

2A. Other Stroke Type Specify:_____

2B. Unknown Stroke Type Specify:_____

C. BRAIN INFARCT SUBTYPES – (for Item # 3 use codes (0) – (8) below.)

3. Choice of Subtype ☐

CODES:

(0) N/A (not applicable)
(1) Large vessel extracranial atheroembolic
(2) Large vessel intracranial atheroembolic
(3) Cardioembolic
(4) Lacunar Infarction
(5) Acute ischemic stroke of other known etiology (***specify below in 3A***)
(6) Ischemic stroke of unknown cause (no probable etiology despite complete workup)
(7) Ischemic stroke of unknown cause (more than one etiology, ***specify below in 3B***)
(8) Ischemic stroke of unknown cause (workup is incomplete)

3A. Acute ischemic stroke of other known etiology specify: _____

(Skip to item 4.)

3B. Ischemic stroke of unknown cause (more than one etiology) specify: _____

4. Was the Brain Infarction Procedure-Related? Record No (0), Yes (1), or Unknown (9) ☐
(If No (0) or Unknown (9) and event is only a brain infarction Skip to Item 12)

4A. If yes, please specify the procedure involved: _____
(If event is only a brain infarction Skip to Item 12.)

D. HEMORRHAGIC SUBTYPES

5. If the event was a Subarachnoid Hemorrhage, what was the subtype? ☐
(record using the codes below)

CODES:

(0) N/A (not applicable) ***(Skip to Item 11)***
(1) Aneurysmal
(2) Sulcal
(3) Perimesencephalic
(4) Other ***(complete Item 5a. below)***
(9) Unknown

5A. If Code 4, 'Other' is chosen, please specify:_____

6. If the event was a Subarachnoid Hemorrhage, was there an intraventricular extension? ☐
Record No(0), Yes (1), Unknown (9)

7. If the event was a Subarachnoid Hemorrhage, was there an intraparenchymal extension? ☐
Record No(0), Yes (1), Unknown (9)
(If only SAH, Skip to Item 11)

8. If the event was an Intracerebral Hemorrhage, what subtype? ☐ (Choose from the codes below)

CODES:

(0) N/A (not applicable) ***(Skip to Item 11)***
(1) Small Vessel Hypertensive Vasculopathy
(2) Cerebral Amyloid
(3) Vascular Malformation Arteriovenous
(4) Vascular Malformation Cavernous
(5) Endocarditis
(6) Primary Intraventricular Hemorrhage
(7) Other ***(complete Item 8a below)***
(9) Unknown

8A. If Code 7, 'Other' is chosen, please specify: _____

9. If the event was an Intracerebral Hemorrhage, was there an intraventricular extension? ☐

No(0), Yes (1), or Unknown (9)

10. Was the core of the hemorrhage best described as: ☐ (Choose from the codes below)

CODES:

(1) Lobar
(2) Deep
(3) Cerebellar
(9) Unknown

11. Is the Hemorrhagic Stroke Procedure-related? No or N/A (0), Yes (1), or Unknown (9) ☐
(If No, skip to Item 12. If Yes, complete Item 11a.)

11A. Please specify the procedure involved: _____

12. Reviewer Comments: _____

_____

Mortality Review Form (MOR)

ID Number: ☐☐☐☐☐☐☐☐ FORM CODE: MOR Contact ☐☐ SEQ# ☐☐
VERSION: 1 5/16/2024 Occasion

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month Day Year) 0b. Reviewer ID: ☐☐☐

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ 0d. Event Date: ☐☐/☐☐/☐☐☐☐

1. Location of Death: (choose one) ☐
   a. Out-of-Hospital
   b. Emergency Room (not Dead on Arrival)
   c. In Hospital
   d. Nursing Home, Skilled Nursing Facility, or Extended Care Facility
   e. Other

   1a. If other, specify:_____

2. Was the death witnessed? y/n/u ☐ **y = Yes, n = No, u = Unknown**

3. HCHS/SOL classification for underlying cause of death:

   3a. Stroke? y/n/u ☐
   If Yes, skip to question 9

   3b. Atherosclerotic coronary heart disease? y/n/u ☐
   If Yes, skip to question 4

   3c. Atherosclerotic disease, other than coronary disease or stroke? y/n/u ☐

   3c1. If Yes, specify and *skip to question 6* _____

   3d. Other cardiovascular disease, not defined above? y/n/u ☐

   3d1. If Yes, specify and *skip to question 6* _____

   3e. Respiratory disease? y/n/u ☐
   If Yes, skip to question 11

   3f. Non-cardiovascular disease or non-respiratory disease? y/n/ u ☐

   3f1. If Yes, specify and *skip to question 13*_____

CORONARY HEART DISEASE (CHD) DEATHS

4. Type of fatal coronary heart disease: (choose one) ☐
    a. Definite fatal MI (no known non-atherosclerotic cause and definite MI within 4 weeks of death)
    b. Definite fatal CHD (no known non-atherosclerotic cause, and one or both of the following: chest pain within 72 hours of death or a history of chronic ischemic heart disease)
    c. Possible fatal CHD (no known non-atherosclerotic cause, and death certificate underlying cause: I20-25, I46, I51.6, R96 or R98-99)

5. Estimated time between onset of acute cardiac symptoms and death: (choose one) ☐
    a. Less than 5 minutes
    b. 5 minutes to 1 hour
    c. 1 hour to 24 hours
    d. More than 24 hours
    e. Unknown

6. Sudden cardiac death? y/n/u ☐
    If No or Unknown, skip to question 7

    6a. Type of sudden cardiac death: (choose one) ☐
        a. Definite sudden arrhythmic death
        b. Possible sudden arrhythmic death
        c. Not sudden arrhythmic death
        d. Unclassifiable

CARDIOVASCULAR DEATH (INCLUDING CHD)

7. Mechanism of death in patients dying of cardiovascular causes (choose one number from below) ☐
    a. Primary arrhythmic death
    b. Secondary arrhythmic/mechanical death
    c. Heart failure
    d. Treatment or procedure related
    e. Other
    f. Unknown

    7a. If Other, please specify: _____

(if Q7 = d, complete Q8)

8. Treatment or procedure-related: (choose one) ☐
    a. Cardiac procedure such as CABG or PCI
    b. Hemorrhage from thrombolytic therapy
    c. Other Cardiovascular

    8a. If c, specify: _____

    d. Non-cardiovascular

    8b. If d, specify: _____

Skip to question 13

STROKE DEATH

9. Estimated time between onset of acute stroke symptoms and death: (choose one) ☐
    a. Less than 5 minutes
    b. 5 minutes to 1 hour
    c. 1 hour to 24 hours
    d. 1 day to 1 week
    e. 1 week to 1 month
    f. Longer than one month
    g. Unknown

10. Mechanism of stroke death (choose one) ☐
    a. Critical brain injury
    b. Infection
    c. Pulmonary Embolus
    d. Other
    e. Unknown

    10a. If Other, specify _____

    Skip to question 13

PULMONARY DEATH

11. Estimated time between the onset of symptoms and death: (choose one) ☐

    a. Less than 5 minutes
    b. 5 minutes to 1 hour
    c. 1 hour to 24 hours
    d. 1 day to 1 week
    e. 1 week to 1 month
    f. Longer than one month
    g. Unknown

12. Mechanism of death: (choose one) ☐

    a. Emphysema exacerbation
    b. Chronic Obstructive Pulmonary Disease exacerbation
    c. Bronchial asthma exacerbation
    d. Other

    12a. If other, specify:_____

13. Second Review Requested: y/n ☐

14. **Reviewer Comments**: _____
    _____
    _____

Appendix F. Event Summary Forms

Myocardial Infarction Event Summary
Heart Failure Event Summary
Pulmonary Event Summary
Stroke Event Summary

Event Summary Form (ESF) for Myocardial Infarction

EVENT ID: X050000600101

HCHS ID:	**Gende**r:	**Age at Baseline:**	**Age at Event:**
X0000060	Female	54	55

Prevalent CHD without Angina? No
Prevalent CHD with Angina? Yes

Abnormal ECG:
Prevalent MI by ECG? **No**
Prevalent Q wave? **No**

Self-report hx of:

Angina [MHEA3]	**Yes**
MI [MHEA4]	**No**
Coronary bypass, angio, or stent [MHEA9]	**No**
CHF [MHEA5]	**No**
Stroke [MHEA10]	**No**
Carotid endarterectomy, angioplasty, or surgery [MHEA12]	**No**
PAD [MHEA14]	**No**
Leg angio, stent, or amputation for vasc [MHEA15]	**No**

Event Date Date of arrival: [mm/dd/yyyy] Date of discharge: [mm/dd/yyyy]

ICD-9 Discharge Codes:

Was the patient alive at discharge?

Signs and symptoms

Acute episode(s) of pain or discomfort (eg: tightness) in the chest, arm, shoulder, throat or jaw, either within 72 hours?
Did this pain or discomfort specifically involve the chest?

Was the pain or discomfort diagnosed as having a non-cardiac origin?

Doctor's diagnosis

Did a physician indicate any of these as being present during the hospitalization?
Angina
Acute myocardial Infarction
Congestive heart failure exacerbation or pulmonary edema
Shock or cardiogenic shock
Ventricular fibrillation, cardiac arrest or asystole
ST elevation > 1mm with pain that is not present on ECG without pain

History

Prior to this event was there history of any of the following:
Myocardial infarction
MI within 4 weeks?
Angina
Percutaneous coronary intervention (PCI)
CABG
Coronary artery disease (CAD)
Heart failure

Treatment/Tests

Coronary reperfusion (CABG, PCI, thrombolysis) attempted within 24 hours?

Any of the following treatments given during this hospitalization?

Coronary artery bypass graft surgery (CABG)
Coronary atherectomy
Intra-arterial or intravenous thrombolytic
Coronary angioplasty without stent
Coronary angioplasty with stent placement
Valve surgery
Non-cardiac surgery
Aortic balloon pump
Pacemaker placement (temporary or permanent)
Cardioversion or defibrillation

Were any 12 lead ECGs taken during this admission?

First ECG	Date:	Copy enclosed?
Second ECG	Date:	Copy enclosed?
Last ECG	Date:	Copy enclosed?
Third ECG	Date:	Copy enclosed?

Biomarkers

Mention of trauma, procedure, or rhabdomyolysis, one week prior to biomarkers?

Evidence of hemolytic disease during the hospitalization?

Active liver disease?

Biomarker set	Date	Total CK	CK-MB	Troponin	Type of Troponin
1st set					
2nd set					
3rd set					
4th set					
5th set					
6th set					
Lab Standards					
Upper Limits Normal Units					

If quantitative biomarker value not available and only qualitative value then answers “A-C” are:

A = negative/absent/normal,

B = weak positive/weak present/trace/ high-normal/small,

C = present/ positive/abnormal/medium/large

Event Summary Form (ESF) for Heart Failure

EVENT ID: X00000080101

HCHS ID:	**Gender**:	**Age at Baseline:**	**Age at Event:**
X0000008	Male	57	58

Self-report hx of:

CHF [MHEA5]	**No**
Angina [MHEA3]	**No**
MI [MHEA4]	**No**
Coronary bypass, angioplasty, or stent [MHEA9]	**No**
Prevalent CHD without Angina?	**Yes**
Prevalent CHD with Angina?	**Yes**

Event Date Date of arrival: [mm/dd/yyyy] Date of discharge: [mm/dd/yyyy]

ICD-9 Discharge Codes:

Was the patient alive at discharge?

Signs and symptoms

An increase or new onset of paroxysmal nocturnal dyspnea (PND)
An increase or new onset of orthopnea
An increase or new onset of shortness of breath
An increase or new onset edema
Hypoxia
Dyspnea (at rest)
Dyspnea (walking or on exertion)
New onset or progressive signs/symptoms of HF prior to presentation?

History

Prior to this event was there a history of any of the following:
Diagnosis of heart failure
Prior hospitalization for heart failure
Treatment for heart failure

Physician Diagnosis

Evidence that event was exacerbation of HF?

Ejection Fraction

Prior to this hospitalization:
During this hospitalization:
TTE
TEE
Coronary angiography
Radionuclide ventriculogram (RVG)

Chest X-ray

Did the patient have any of the following signs on chest x-ray at any time during this event?
Pulmonary edema or pulmonary vascular congestion
Cardiomegaly or Cardiothoracic ratio $\geq$ 0.5
Bilateral pleural effusion
Unilateral pleural effusion

BNP Levels (include worst, upper limit normal)

BNP (pg/mL)

ProBNP (pg/mL)

Treatment with IV diuretic

Event Summary Form (ESF) for Pulmonary Diagnosis

EVENT ID: X000000100101

HCHS ID:	**Gender**:	**Age at Baseline:**	**Age at Event:**	**Height**	**Predicted PEF**	**BMI**
X0000010	F	55	556	161.00	27.9	

Event Date 12/28/2009 Date of arrival: [mm/dd/yyyy] Date of discharge: [mm/dd/yyyy]

ICD-9 Discharge Codes:

786.50 486 493.20 99.21

ER, hospital or observation:

Doctor's diagnosis

Reason in doctor's notes that this event may be exacerbation of COPD:
Reason in doctor's notes that event may be exacerbation of asthma:

Signs and symptoms

Any of the following signs or symptoms at the time of the event:

- New onset or increase in cough:
- New onset or increase in sputum production:
- New onset or increase in sputum purulence:
- New onset or increase in wheezing:
- New onset or increase in dyspnea:
- Crackles / rales:
- Wheezing or rhonchi:

History

History of any of the following:

- Asthma:
- Emphysema:
- Chronic obstructive pulmonary disease(COPD):

Tests

Any of the following signs on chest x-ray at any time during this event?

- Hyperinflation:
- Flattened diaphragms:
- Emphysema:
- Infiltrate/consolidation:
- Pulmonary edema:
- Pleural effusion:

Prior PFTS: Percent predicted FEV_1: FEV1/FVC:

Peak flows

Date of first PEF(R) taken after hospital/ED arrival: (mm/dd/yyyy)
First PEF recording (L/min)
Worst PEF recording (L/min) during this hospitalization

TREATMENTS / MEDICATIONS

No/NR 0 Yes 1

Inhaled short-acting beta-agonists (ie,albuterol, xopenex):
Inhaled short-acting anticholinergics (ie, atrovent, ipratropium):
Systemic corticosteroid (oral or IV):
CPAP or BiPap:
Mechanical Ventilation:

HCHS/SOL Event Summary Form (ESF) for Stroke

EVENT ID: STR0c

HCHS ID:	**Gende**r:	**Age at Baseline:**	
SUBJID	GENDER	AGE	**Age at Event:**

The data below were abstracted from the medical record for this event:

Date of Arrival: STR1 Date of Discharge: STR3

Admit Diagnosis Code: STR2 Primary Discharge Diagnosis Code: STR4

Discharge Diagnosis Codes:

EEFA5a EEFA5b EEFA5c EEFA5d EEFA5e EEFA5f EEFA5g EEFA5h EEFA5i EEFA5j EEFA5k EEFA5l EEFA5m EEFA5n EEFA5o EEFA5p EEFA5q EEFA5r EEFA5s EEFA5t

Signs and Symptoms

Date of Symptom Onset:	STR10b
Time of Symptom Onset:	STR10d
	STR22
Time Between Onset and Resolution:	
NIHSS Score:	STR27a OR STR27b14
Discharge Rankin Score:	STR77a OR STR77b

Neurological Exam

Level of Consciousness:		STR35
Aphasia:		STR36
Hemianopsia:		STR37
Abnormality of Cranial Nerves III, IV, or VI:		STR38
Location of Abnormality:		STR38a
Horizontal Gaze Palsy:		STR39
Location of Gaze Deviation:		STR39a
Dysphagia:		STR40
Dysarthria:		STR41
Weakness:		STR42
	Face:	STR42a
	Arm:	STR42b
	Leg:	STR42c
Sensory Deficit:		STR43
	Face:	STR43a
	Arm:	STR43b
	Leg:	STR43c
Visual Fields:		STR44
Gait Disturbance:		STR45
Hemiataxia:		STR46

CT

Date of First CT:	STR51a
First CT Diagnosis:	STR51b
Date of Last CT:	STR51c
Last CT Diagnosis:	STR51d