Question by Question (QXQ) Instructions for the HCHS/SOL
Heart Failure Diagnosis Form (HFD)

A Heart Failure Diagnosis (HFD) Form is filled out by the reviewer for all case packets that are sent to them for review by the CSCC. Initially, events will be classified independently by 2 reviewers with disagreements classified by an adjudicator. Case packets will include a set of medical records and an Event Summary Form (ESF). The ESF is a 1-2 page summary of pertinent information from the HCHS/SOL baseline study visit and of information abstracted from the medical records (i.e. a subset of information from the HF abstraction form). In general, HF diagnoses should be more specific rather than overly sensitive. An additional requirement of the HF classification in SOL is that at a minimum we need to be comparable with the HF classification done in the Multiethnic Study of Atherosclerosis (MESA).

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

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

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

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

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

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

1. History of HF? Review the physician's history and physical note, relevant consult notes, and discharge summary for evidence of prior history of a heart failure diagnosis. This could include a diagnosis or treatment of heart failure in an outpatient or inpatient setting. To answer YES to this question, there needs to be evidence a simple unsubstantiated note of "CHF" or "HF" as a past medical history. This evidence could include: specific type of HF described, or evidence of treatment for HF (medications, or AICD), although the prior treatment needs to be for HF rather than some other indication. Record NO if it is stated that the patient does not have a prior history of HF or if a past medical history is included in the record and HF is not mentioned. Record UNKNOWN if it is not recorded as to whether the patient did or did not have a prior history of HF, and there is no past medical history included in the record (or you suspect the past medical history is likely incomplete). Also if there is contradictory information about prior HF history then record UNKNOWN.

2. Was ADHF diagnosed by provider AND HF treatment provided?

This is a two part question of which both parts need to be present to answer YES. This is part of criteria used in the MESA study. For the first part of the question to be YES then there needs to be evidence in the providers note that acute decompensated heart failure (ADHF) or symptomatic HF was diagnosed by a physician during this visit. This could be an old or new diagnosis, but it must be symptomatic or decompensated. The ADHF could be mild, moderate,

or severe decompensated HF. This does not include heart failure that is currently stable and does not require further treatment to manage signs or symptoms. If stable HF is present then answer NO and go to the next question.

If the first part of the question is YES, then look for the answer to the 2nd part of the question. For the second part of the question to be YES, then look for evidence of treatment for heart failure during this admission. Examples of treatment could include medications and/or devices or procedures for HF as described below. Generally, treatment will be intravenous or increased diuretics, and occasionally hemofiltration or dialysis. In addition, medications for HF could also include an increase in regular medications for HF or the addition of a medication for the treatment of HF. Heart failure medications may include diuretics, angiotensin converting enzyme inhibitors (ACE inhibitors), angiotensin II receptor blockers (ARBs), beta-blockers, digitalis, aldosterone blockers, hydralazine, nitrates, intravenous inotropes (dobutamine, dopamine, milrinone), intravenous vasodilators (e.g., nitroglycerin, nitroprusside, nesiritide), anticoagulants; Since some drugs may be given for various conditions (e.g. diuretics for hypertension), look for HF as the stated indication. Devices that might be used to manage ADHF or end stage HF include intra-aortic balloon pump (IABP), left ventricular assist device (LVAD), ventricular assist device (VAD), biventricular assist device (BiVAD), implantable cardiac defibrillators (AICD) or hemofiltration. If, after reviewing the medical record, it is unclear as to whether there was a diagnosis of HF AND treatment for heart failure during this admission then, record NO.

3. Is there evidence of pulmonary edema/congestion on Chest X-ray?

Did this patient have pulmonary edema or congestion on Chest X-ray during this admission? Include all chest x-rays available, performed anytime during the course of the hospitalization, whether before or immediately after the HF diagnosis. This includes chest x-rays that may have preceded the onset of the event if the event occurred during the hospitalization (but after the admission date). However, if the hospitalization for HF decompensation/progression was longer than 7 days, limit your review of the total number of chest x-rays to those obtained during the first 7 chest x-rays before HF decompensation/progression. The official CXR report takes precedence over any non-radiology MD notes. Preceding adjectives such as “suggestive”, “suggesting”, and “concerning for” are synonyms for YES.

Record YES if “alveolar edema”, “pulmonary edema”, “alveolar pulmonary edema”, “failure”, “congestive heart failure”, or “volume or fluid overload” is described on chest x-ray report. Include both unilateral and bilateral alveolar or pulmonary edema. Do NOT include “interstitial edema”.

Questions 4 through 7 are aimed at imaging (usually ECHO) findings either historical or current. Only select one answer, consider current imaging to out rank a historical finding.

4. Dilated ventricle?

Record ‘YES, CURRENT IMAGING’ if there is evidence of either a dilated left or right ventricle (even if mildly dilated) noted on any imaging study performed during this admission. A dilated ventricle may also be described as enlarged. Record ‘YES, HISTORY’ if there is a

reported history of or prior imaging study showing a dilated left or right ventricle. This could be summarized in a physician's note or the actual historical imaging report. Record NO if there were imaging studies performed, but there was no evidence of dilated ventricles. Record 'NO' if you have the imaging report and dilated ventricles are not mentioned. Record UNKNOWN if there is no mention of dilated ventricles or no imaging study performed, or no report available.

5. Impaired LV function

Record 'YES, CURRENT IMAGING' if there is evidence from an imaging study from this admission of either reduced left ventricular function (EF <50) or left ventricular wall motion abnormalities. Synonyms for LV systolic function include "LV function", "LV contraction", "LV contractile performance", "LV contractile function". Synonyms for impaired LV systolic function include "LV dysfunction", "LV systolic dysfunction", "decreased LV contraction (or contractile performance)", "decreased LV ejection fraction (LVEF)", "depressed LVEF", and "impaired LVEF". Record NO if there was an imaging study but no evidence of poor LV function. Record YES if there is a history of reduced ejection fraction or impaired LV function that is mentioned in a physicians note. Answer 'YES, HISTORY' if a physician reports LV dysfunction. Record UNKNOWN if there no was no imaging study performed, or there is no report, or physician summary of the report, in the record.

Regional wall motion abnormalities are usually reported in the qualitative part of the report under 'left ventricle' and/or in the conclusions. Record 'YES, CURRENT IMAGING' if regional wall motion abnormality (ies) are described from an imaging study from this visit. Record 'YES, HISTORY' if it is reported from a study prior to this admission. Synonyms for regional wall motion abnormality include "regional WMA", "segmental WMA", "segmental LV contractile dysfunction". Frequently, specific segments are described with abnormal motion without mention of the overall description of regional wall motion abnormality; for example, specific regions of the LV include anterior, anteroseptal, septal, inferoseptal, inferior, inferoposterior, posterior, posterolateral, lateral, anterolateral, apical, basal, and mid-portions of the LV walls. Record YES if certain parts of the wall have "hypokinesis", "akinesis", "dyskinesis", or "abnormal wall motion", regardless of severity (mild, moderate, severe). Record "NO" if a report states that there are no regional wall motion abnormalities. Report UNKNOWN if it is unclear based on the report whether a regional wall motion abnormality is present OR if there is no current imaging available.

6. Impaired RV function

Record 'YES, CURRENT IMAGING' if there is evidence from an imaging study from this visit of reduced or impaired right ventricular function. Record 'YES, HISTORY' if there is a history of impaired RV function. Synonyms for RV systolic function include "RV function", "RV contraction", "RV contractile performance", "RV contractile function". Synonyms for impaired RV systolic function include "RV dysfunction", "RV systolic dysfunction", or "decreased RV contraction (or contractile performance)". Record YES for any level of severity, including mild. Record NO if there was an imaging study but no evidence of impaired RV function. Record UNKNOWN if there no was no imaging study.

7. Diastolic dysfunction [CARLOS TO ADD CRITERIA]

Record 'YES, IMAGING' if there is evidence from an imaging study from this admission of left ventricular diastolic dysfunction. Diastolic dysfunction will most likely be noted from a TTE (transthoracic ECHO), rather than a TEE (transesophageal ECHO). Record 'YES, HISTORY' if there is a history of diastolic dysfunction, or even suspected or possible diastolic dysfunction. Synonyms for diastolic dysfunction include "diastolic LV dysfunction", "impaired LV relaxation", "impaired LV compliance", "impaired LV diastolic filling", "reversed E-A ratio", "late diastolic filling", "stiff ventricle", "abnormal mitral annulus tissue Doppler signal", "pseudonormalization of transmitral Doppler flow", "restrictive filling pattern", "Grade 1 diastolic dysfunction", "Grade 2 diastolic dysfunction", and "Grade 3 diastolic dysfunction". Record YES if diastolic dysfunction is described of any severity. Record "NO" if LV diastolic function/compliance/filling is described as normal. Record UNKNOWN if it is unclear based on the report whether diastolic dysfunction was present or if there was no imaging studied at all. Record NO if there was a TTE performed but no evidence of LV diastolic dysfunction.

8. Quantitative EF during this hospitalization (or within 3 months)

Report ejection fraction (EF) if measured during this hospitalization; or if no EF measured during this hospitalization then, if available, report EF within 3 months before the hospitalization. Use the actual imaging report when available, rather than the medical doctors summary of the imaging study that is often provided in a note. If imaging report not available then could use an EF that is summarized in a physician's note as long as it is from this admission (or within 3 months). The most recent imaging study with the lowest LVEF (from this hospitalization) should be used in making this assessment. In general, the worst LVEF related to this hospitalization is, in your judgment, the LVEF that should be noted in this item. This can include LVEF documented within the previous 3 months without any intervening event that could have altered that LVEF assessment. If there is a discrepancy within the available documentation, use clinical judgment to determine which is most accurate. If a range of value is given, such as 15-20% then consider, the EF to be the lowest of the range (15). If "<" a certain number is described then consider the EF to be one under the value provided, such that <20% would actually be an EF of 19. If an ECHO was performed but EF only reported as normal without a number provided, then check ≥50, rather than unknown.

9. Does this patient have acute decompensated heart failure (ADHF)?

This question is asking about the certainty of the diagnosis of ADHF, regardless of severity of the exacerbation. This means that the main goal is the certainty that decompensation is currently present, although for answer 'c' we do want to capture those with chronic stable HF. DEFINITE ADHF should be clearly present based on the available information. PROBABLE ADHF is probably decompensated but not definitively present. Consider your answers to questions 1-3, and along with your interpretation of the BNP or pro-BNP levels, if available. Interpret BNP and pro-BNP levels in light of renal function. If renal function is decreased then mild elevations in these biomarkers may be spurious, although if they are really high then they are less likely to be spurious. When BNP levels are in the normal range then a HF exacerbation is unlikely. Answer NO, CHRONIC HF in cases in which it is clear that HF is present but not currently decompensated. To answer Chronic HF you should have some additional evidence of HF beyond just a history, such as history of type of HF, or prior LV dysfunction, or current outpatient medications that are likely for HF (such as, coreg, or ACEI). Answer NO, UNLIKELY if on review of the medical record, it seems unlikely that HF is present. Answer

NO, UNCLASSIFIABLE, if there is conflicting evidence or such limited information that you cannot confirm the presence/absence of HF. UNCLASSIFIABLE should be an uncommon response. In answering this questions, consider your clinical judgment along with the suggested guidelines in table 1. NOTE if you answer DEFINITE OR PROBABLE ADHF then you will answer questions 9-10 and SKIP question 11. IF you answer "NO, CHRONIC HF", or "NO, HF UNLIKELY", or "UNCLASSIFIABLE" then skip questions 9 and 10, and answer question 11.

A typical case of "probable" rather than "definite" would be due to the presence of co-morbidity that could also account for the acute symptoms (COPD exacerbation, for example). In some cases of chronic CHF, it may be difficult to tell whether the patient's status matches the baseline CHF status or indicates some deterioration. If in doubt, record "probable decompensated HF". In general, prefer "probable" whenever the evidence for decompensation (symptoms, signs, imaging, biomarkers) is subtle. Also, take the *totality* of the evidence provided in the medical record. For example, a case of probable decompensated HF may be one that has a known history of CHF who has chest x-rays showing "active CHF", description of diuretic therapy, and an ICD-9 codes of 428, but there is no specific statement about decompensated heart failure in the discharge summary. (However, if a patient has such documentation with documentation of decompensated HF with treatment by a physician, then the patient most likely has "definite decompensated heart failure").

Guidelines to aid in the classification of HF. Consider the '+' as may be present, and the '-' as unlikely to be present. Use your judgment and the number of signs/symptoms and other findings that are present or absent to classify events within these categories.

	Definite	Probable	Chronic HF	HF unlikely	Unclassifiable
Past History					
Heart failure noted in Past History	+	+	+	-	
Outpatient medications possibly for treatment of HF (ACE Inh, or coreg) or prior treatment for HF noted	+	+	+	-	
Diagnosis, treatment, findings from the current hospitalization					
MD diagnosis of HF exacerbation	+	+	-	-	
MD treatment provided for HF exacerbation	+	+	-	-	
Pulmonary edema on Cxray	+	+	-	-	
Cardiomegaly on Cxray	+	+	+	-	
Signs/symptoms improved with treatment for exacerbation	+	+	-	-	
ECHO/imaging					
Ejection fraction < 50 %	+	+	+	-	
ECHO evidence of diastolic dysfunction	+	+	+	-	
BNP or proBNP levels					
Mildly or moderately elevated BNP, with normal renal function	+	+	-	-	
Severely elevated BNP, with normal renal function	+	+	-	-	
Mildly or moderately elevated BNP, with abnormal renal function	-	+	-	-	

Severely elevated BNP, with abnormal renal function	-	+	-	-	
Comorbidity					
Comorbidity, such as Renal failure, COPD, or pneumonia that may be causing symptoms rather than HF	-	+	+/-	+	

Distinguish definite from probable by the number of criteria that are present.

9.a. Classify the severity of the exacerbation?

Answer only if you answered DEFINIE or PROBABLE ADHF is present. This question is asking about the severity of the exacerbation for those with definite or probable ADHF. Classify the event as SEVERE if treatment with mechanical ventilation, non-rebreather mask, noninvasive positive pressure ventilation (NPPV) which can be delivered in similar modes as mechanical ventilation (CPAP or BIPAP or AC for assist control), hemofiltration, intra-aortic 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.

9.b. Was ADHF predominantly right-sided HF (absence of LV dysfunction or valvular disease)?

Answer only if DEFINITE or PROBABLE ADHF is present. Answer NO if the patient has diastolic dysfunction, systolic dysfunction, or valvular disease. Valvular disease here is defined as at moderate to severe abnormality on ECHO (2+ or greater). Answer YES if the patient had right-sided heart failure symptoms of lower extremity edema, possibly ascites, and elevated liver function tests. 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.

10. Were any of the following problems present as active co-morbid conditions and/or possible precipitating factors for this event?

Answer only if DEFINITE or PROBABLE ADHF is present. For question 1-14a, indicate all co-morbid conditions that were active during this hospitalization. Active means that the patiently currently takes treatment for the condition or currently has the condition, regardless of whether it is causing a problem during this admission. For example, answer YES for these items if they are listed in the past medical history or noted as new during this hospitalization: coronary disease, hypertension, valvular disease, pulmonary disease, renal disease, pulmonary embolus, other arrhythmias, valvular disease or past history of toxins or chemo that may cause HF. NOTE, valvular abnormalities must be at least moderate or 2+ or higher to answer YES for valvular disease. Answer YES to fluid or volume overload if this is indicated during this admission only. Answer YES for noncompliance if medication or dietary noncompliance were mentioned as a problem during this admission. Answer YES for pulmonary infection if the patient had a pulmonary infection during this admission. Answer YES regarding cardiovascular and noncardiovascular procedures/surgery if he had one during this admission.

Only answer questions 1-14b about whether the condition may have precipitated the event, if you classified the event as definite or probable decompensated HF AND you answer YES for the (a) part of that question. In considering whether the condition may have precipitated the event, the temporal association between the condition and the HF exacerbation should make sense. For example, if the patient came in for knee surgery and had an exacerbation of HF immediately following surgery then check YES to noncardiovascular surgery precipitated the event. If the same patient then had a complicated coarse and developed a pulmonary embolus many days after the heart failure exacerbation then check YES for pulmonary embolus as an active problem (question a), but NO/NR that PE did NOT precipitate the HF exacerbation. 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 as an active problem (a) and YES for possibly precipitated the event (b).

a.1. Coronary disease refers to prior history or a new condition during this admission of coronary artery disease, prior coronary artery bypass surgery, angina, or myocardial infarction.

a.2. Hypertension – this includes history of hypertension, or on treatment for hypertension, or hypertensive level blood pressures on admission (SBP > 140 and DBP >85).

a.3. Atrial fibrillation or atrial flutter – include only active paroxysmal or chronic atrial fibrillation or atrial flutter. IF Atrial fibrillation/flutter occurred during this admission then answer YES. IF not, then for a prior history of atrial fibrillation or flutter include it if it is still a problem that the person was in/out of AF in the last few months. For example, do not include temporary atrial flutter that was converted and has not returned, or AF that has been managed with an ablation procedure.

a.4. Other arrhythmia – answer YES if any other arrhythmias (such as ventricular tachycardia, supraventricular tachycardias, AV block, etc…) was active in the last few months.

a.5. Valvular disease – Answer YES if the patient has valvular heart disease, or has had surgery in the past to repair valvular disease. Valvular abnormalities on ECHO need to have been at least moderate or 2+ or greater to answer YES here.

a.6. Fluid or volume overload- this refers to either iatrogenic fluid overload, excessive drinking of fluids causing fluid overload. Answer YES if any of those are present. Most HF patients will be volume overloaded, however this question is looking for the specific potential causes listed above (IV fluids, or drinking too much fluid). Answer NO if the patient is volume overloaded but the etiology is not from too much fluid intake. If volume overload is from missed dialysis or renal failure then answer NO here and YES to 10.a.8 for renal failure.

a.7. Medication or dietary 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.

a.8. Renal insufficiency or failure – Answer YES if renal failure is mentioned during this hospitalization as a current problem. If volume overload is from missed dialysis or renal failure then answer YES here.

a.9. Cardiovascular procedure/surgery – Answer YES if a cardiovascular procedure (CABG, valve surgery, PTCI, etc...) was performed during this hospitalization.

a.10. Noncardiovascular procedure/surgery – Answer YES if a noncardiovascular procedure or surgery was performed.

a.11. Pulmonary disease – Answer YES if the patient has pulmonary disease that requires treatment, such as COPD, sarcoidosis, interstitial lung disease, pulmonary fibrosis etc…Do not include mild asthma that does not require regular treatment. Do not include a pulmonary nodule or other minor abnormalities noted on chest x-ray but not likely causing symptoms.

a.12. Pulmonary infection – Answer YES if during this hospitalization the patient had a pulmonary infection, namely pneumonia. IF pneumonia was only part of the differential diagnosis but later determined to be heart failure then answer NO.

a.13. Pulmonary embolus (PE) – Answer YES if during this hospitalization the patient had a PE.

d.14. Toxins or chemo-induced. High doses of daunorubicin and doxorubicin are known to cause LV dysfunction. Other toxins may include radiation for treatment of cancer, or alcohol. Answer YES if it is noted that the patient was exposed to a potential cardiac toxin.

10. Does this patient have asymptomatic LV dysfunction (EF <50%)?

Record YES if this patient had a documented ejection fraction < 50%, but had not previously or during this admission had signs or symptoms of HF. Record NO if the patient either did not have a low EF or did previously have symptoms from HF. Record UNKNOWN, if it is not clear what the patients EF was or whether they had prior or current symptoms.

11. Reviewer comments: Add any brief comment(s) about this review. These comments will be made available to the adjudicator.