

QUESTION-BY-QUESTION INSTRUCTIONS FOR MMCC HEART FAILURE FINAL DIAGNOSIS FORM (HDX)

HDX, Version A, 09-10-2009
HDX QxQ

An MMCC Heart Failure Diagnosis Form (HDX) is completed for each ARIC Heart Failure hospitalization that is sent to you as a MMCC Heart Failure (HF) reviewer. The goal of this review is to be **specific** rather than too sensitive. Please refer, as needed, to the MMCC Case Law Document (Section 5.3 Manual 3a) when completing this form.

When you get your case materials, check to see that all available information is included. Events will be hospital events only. The HDX form will be accompanied by an Event Summary Form (ESF) and copies of specific documents from the medical record. Medical record documents may include a discharge summary, echocardiogram reports, nuclear imaging reports, and catheterization reports as available.

Complete only one HDX for each event.

There are two sections to the HDX form. **Part A** contains administrative information and the Coordinating Center (CC) will provide some of the information for this section. **Part B** is to be completed by a MMCC reviewer based on the information provided. All cases will be reviewed by 2 MMCC members independently, with disagreements adjudicated by a third reviewer (events occurring in 2005).

The EVENT_ID NUMBER listed at the top of the HDX form is also included in the upper left hand side of the ESF, Section A, "ARIC Identifiers" and should also appear on the second item, and on the accompanying documents from the medical record.

The CC will provide a memo with a list of the EVENT_ID NUMBERS representing the cases that are sent to reviewers. The memo will also include the CONTACT NUMBER related to each EVENT_ID NUMBER.

The CC will specify the time period for completion and/or making changes to HDX.

Instructions for Data Entry Key Field Screen

The web Data Management System (DMS) ID screen will require the EVENT_ID NUMBER as ID, "HDX" as form, and a CONTACT NUMBER. Specific instructions for using the web DMS are detailed in the DMS User Manual.

Instructions for Part A. Administrative Information

- 1.a. The Batch Number and letter for this case will be assigned by the CC. Refer to the CC memo sent with the cases being reviewed for this number and letter. 'H' indicates a Heart Failure event.

- b. The CC will indicate the type of review. See memo accompanying your set of cases. The letter “O” indicates an original review, the letter “A” indicates an adjudication, and the letter “S” indicates a special review.
 - c. Fill in the date of HDX completion.
2. Record the assigned code number of this reviewer. Your reviewer code number will be printed on the cover memo

Instructions for Part B. Review of HF Diagnosis

Items 3-8 are to be completed on your review of the ESF and medical record documents. For each, enter the letter that correctly characterizes the case under review.

3. Does this event meet criteria for complete chart abstraction? Review information provided on the ESF and materials copied from the medical record to determine if this event meets criteria for complete abstraction of the Heart Failure Record Abstraction Form (HFA). Refer to Item 1, Section C of the ESF and the medical record documents. These criteria include evidence of the presence of new or decompensated/exacerbated heart failure (HFA items 1 through 2). Evidence of symptoms and signs that may indicate new or decompensated heart failure include evidence of increasing or new onset shortness of breath, increasing or new onset edema, increasing or new onset paroxysmal nocturnal dyspnea, increasing or new onset orthopnea, increasing or new onset hypoxia; evidence in the doctor's notes that the reason for this hospitalization was heart failure. Select “Y”(Yes), “N” (No), or “U”(Unknown). If this is a cohort member but no other items suggesting decompensation (HFA items 1 through 2), then select “N” (No).

- 4a-4c. Is there evidence of (past or present): (a.) Abnormal LV systolic function? (b.) Abnormal RV systolic function? (c.) LV diastolic dysfunction? Based on your review of the ESF and the medical record documents provided, indicate either “Y”(Yes) if documentation indicates less than normal, “N” (No) if documentation indicates normal, or “U”(Unknown) if no data is available (i.e., not recorded). In general, use medical record documents related to that hospitalization as the first reference; however, records included by the abstractor that pre-date the hospitalization can be used to answer these items if there are no current related documents for that hospitalization.

4a. A dilated left ventricle alone is not sufficient to select “Y”(YES)”. An estimated LVEF of < 50% is sufficient to define LV systolic dysfunction. However, if the abstractor has recorded a specific LV ejection fraction (LVEF) on the ESF, but there are no supporting documents, then record “U”(Unknown); the rationale for this is that confirmation for LV systolic dysfunction should be documented by an official report to differentiate a historical diagnosis versus an objectively documented diagnosis (both types will be captured on the ESF).

4b. A dilated right ventricle alone is not sufficient to select “Y”(YES)”.

4c. Diastolic dysfunction must be explicitly described or documented in order to select “Y”(YES)”. Synonyms 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”. If left ventricular compliance or relaxation is normal, code “N (No)” for diastolic dysfunction (4c). An echo report or other imaging report that describes diastolic function outranks a clinical description of diastolic dysfunction.

5. Estimated LVEF (worst; related to this hospitalization): Review the data for Ejection Fraction in Item 3, Section C of the ESF and the accompanying medical record documents. If there is a discrepancy within the available documentation, use clinical judgment to determine which is most accurate (e.g., description of abnormal LVEF (<50%) by history which is not confirmed by objective testing but an echocardiogram report documents normal LVEF ($\geq 50\%$) in a patient with no symptoms of heart failure, most likely LVEF is $\geq 50\%$). The most current echocardiogram with the lowest LVEF (from the hospitalization) should be used in making this assessment. For example, if there are records documenting different estimates of LVEF, take the most recent lowest LVEF (e.g., if old LVEF prior to that hospitalization is 10% but *current* hospitalization describes *lowest* LVEF is 40%, record the *lowest current* LVEF = 40%). However, if the abstractor has recorded a specific LV ejection fraction (LVEF) on the ESF, e.g., from the notes (patient with history of LVEF x%), but there are no supporting documents, then record “d”(Unknown). The rationale for this is that confirmation for an estimated LVEF should be documented by an official report to differentiate a historical LVEF versus an objectively documented LVEF (both types will be captured on the ESF). In general, the worst LVEF related to this hospitalization is, in your judgement, the LVEF that is related to this event/hospitalization. This can include LVEF documented within the previous 3 months without any intervening event that could have altered that LVEF assessment.

Indicate either A ($\geq 50\%$), B (35-49%), C (<35%) or D (Unknown). If LVEF is described as “normal”, and no percentage is given, record A ($\geq 50\%$).

6. Assign an overall heart failure diagnosis based on your clinical judgment (select only one). Review carefully the medical record documents provided and the event summary form pertinent to this event and select a diagnosis based on your clinical judgment. Refer to Manual 3a, Section 5.0 for a guide to ARIC HF diagnosis. Select only one of the following letters:

“A” (definite decompensated heart failure), i.e., decompensation clearly present based on available data (satisfies criteria for decompensation).

“B” (possible decompensated heart failure), i.e., decompensation possibly but not definitively present. A typical case of “possible” rather than “definite” would be due to the presence of co-morbidity that could 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 “possible decompensated HF”. In general, prefer “possible” whenever the evidence for decompensation (symptoms, signs, imaging) is subtle. Also, take the *totality* of the evidence provided. For example, a case of possible 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 statement about decompensated heart failure in the discharge summary. (However, if a patient has such documentation with no known history of CHF, then the patient most likely has “definite decompensated heart failure” [“A”]). If there is scant documentation and you are choosing between “A” and “B”, rely more on the ESF than the provided records; e.g., records do not confirm definite decompensated heart failure but “MD notes suggest reason for hospitalization is HF = yes”, then choose “A”.

“C” (chronic stable heart failure) i.e., no decompensation but patient has chronic heart failure. “Stable” also denotes “compensated” heart failure (not necessarily asymptomatic, but that patient’s chronic HF symptoms are controlled with therapy and there is no evidence in augmentation of therapy for worsening HF during the hospitalization.) Note: This includes patients with asymptomatic heart failure (evidence of LV systolic dysfunction, i.e., EF < 50%, and no heart failure symptoms). Do NOT include: a history of transient LV/RV dysfunction if heart function is currently normal; or asymptomatic diastolic dysfunction alone.

“D” (heart failure unlikely), i.e., there is no HF, heart function is normal based on available documentation. Ideally, there should be some mention of normal heart function, but “heart failure unlikely” may be selected if there is sufficient data to make that inference in the absence of clear documentation.

“E” (unclassifiable), i.e., medical record documentation is missing; or there is no decompensated HF AND cannot differentiate between “chronic stable heart failure” and “heart failure unlikely”. In general, this classification should be used sparingly (least frequently).

Note: If there are symptoms of heart failure only in the setting of a fatal cardiac arrest not due to an acute myocardial infarction, and the patient otherwise was not hospitalized for a heart failure exacerbation, do not count as “decompensated heart failure” (“A” or “B”). Instead, classify the case as “chronic stable heart failure” (“C”) *if* the patient had known history of heart failure but was not hospitalized with decompensated heart failure except at time of arrest (e.g., patient with metastatic cancer who had known LVEF 15% from ischemic cardiomyopathy, but had an arrest while being evaluated for failure to thrive because of the cancer). If the patient has no history of heart failure, consider classifying the case as “D” or “E”.

Some general guidelines:

(1) If debating between the following answers -

- If choosing between “B” (possible decompensated HF) and “C” (chronic stable HF), favor “B”.
- If choosing between “A” (definite decompensated HF) and “B”, favor B.
- If choosing between “B” and “E” (unclassifiable), favor “E”.
- If choosing between “B” and “D”, favor “E”.
- If choosing between “C” and “D” (HF unlikely) [and “E”], favor “E”.

(2) Not all disagreements are equally important.

- Disagreement between “D” and “E” is not that important.
- Disagreement between “C” and “B” is very important.
- Disagreement between “C” and “A” is very important.
- Disagreement between “A” and “B” is very important.

(3) The distinction between “C” and “D” (or “C” and “E”) is important only for the Cohort (since "chronic stable HF" will not be counted in community analysis). Therefore, do not agonize about this choice unless the case is a cohort member.

If “A” or “B”, is selected, answer item 6.a. If “C”, “D” or “E” is selected, skip to item 8.

- a. Was definite or possible decompensated heart failure present at admission? After review of the medical record documents pertinent to this event, indicate if there was decompensated heart failure at admission. Indicate either “Y”(Yes), “N” (No) or “U”(Unknown).
7. Was this event fatal? After review of the medical record documents provided, indicate either “Y”(Yes), or “N” (No). If “Y” is selected, answer Item 7a. If “N” (no) is selected skip to Item 8.
- a. Was decompensated heart failure the primary cause of death? After review of the medical record documents provided, indicate either “Y”(Yes), “N” (No) or “U”(Unknown). Note that “primary” in this context is not synonymous with underlying cause from a nosologist’s point of view. Primary cause of death for the purpose of item 7a is a decision based on your clinical review of the provided materials that heart failure was the most important, or the principal, chief, crucial, or primary factor leading to death. To answer “Yes” (decompensated HF was the primary cause of death), you need to have the following idea in mind: the patient would not have died if decompensated HF were absent. If so, record “Y” (Yes) to item 7a. If it is clear that the person died and also had heart failure but heart failure was not a principal or primary factor in causing death record “N” (No). If not sure, record “U” (Unknown).

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