QUESTION-BY-QUESTION INSTRUCTIONS FOR MMCC COHORT FINAL DIAGNOSIS FORM (CDX)
Cohort Surveillance Events
Version J

An MMCC Cohort Final Diagnosis Form (CDX) is completed for each ARIC event that is sent to you as an MMCC reviewer. Please refer, as needed, to the MMCC Case Law Document (Section 5.4 Manual 3) when completing this form.

When you get your case materials, check to see that all available information is included. If the event is a hospital event, a copy of the discharge summary must accompany the Event Summary Form. If the event involves a death, a copy of DTHA19-21 must be included with the Event Summary Form. For out-of hospital deaths, the availability of narratives from the IFI and COR forms is indicated on the first page of the Event Summary Form.
An autopsy report may be included for cohort surveillance cases only and the availability of this information is also indicated on the Event Summary Form.

If available materials are not included for an event, alert the MMCC coordinator at the Coordinating Center via email. The address is mmcc_aric@unc.edu. Do not attempt to fill out the CDX form with incomplete information.

There are three sections to the CDX form. **Part A** contains administrative information; most of which is already populated for you and should simply be verified. The Completion Date is the one field in the administrative section that is completed by the reviewer or adjudicator.. **Part B** is completed by two randomly assigned MMCC reviewers for cohort surveillance hospitalizations to determine the Overall MI Diagnosis. **Part C** is completed for all deaths requiring MMCC review to determine Death Classification.

Starting in 2015, the CC shifted from sending Event Summary Forms (ESFs) and case materials via secure email, and transitioned to attaching these materials as a pdf file to the CDX form in CDART in an automated fashion. The file appears at the bottom of each screen tab within the CDX, in a window labeled 'Files'. The materials are named with the 3-digit batch number, followed by '_', then the 7 digit Event ID and the letters 'CHD'. The field center staff are responsible for the case materials within the pdf. The CC generates the Event Summary Form information. The CC does not review these case materials before the automated upload occurs. If there are issues with the materials, alert the MMCC coordinator and steps can be taken to communicate with the field centers if there are repeated issues.

In some instances, there will be multiple Event Summary Forms (ESFs) and case materials in one packet. These events are referred to as "linked" events, which are hospitalizations and/or a death that occurred within 28 days of each other. When several events are so linked, EVENT_ID is the ID common to all and is used to identify that set of linked events. The common ID (EVENT_ID) is listed in the upper left hand side of each Event Summary Form. Use only one CDX Form for linked events occurring within 28 days, as these will be treated as one in analysis. The Coordinating Center (CC) will provide a CDX form for each event already labeled with the EVENT_ID and sequence number.

Instructions for Part A. Administrative Information

For most reviews, all of the administrative fields except CDX Completion Date are populated from data generated in the CC monthly management report. These variables are loaded into CDART on a monthly basis. The source of the information is denoted below.

0. This field is pre-filled with date assigned, and is assigned by the MMCC Coordinator.
1a. This field is pre-filled with batch number, and is assigned at the time the monthly management report is generated.
1b. This field is pre-filled with occurrence number and is assigned at the time the monthly management report is generated.
1c. Fill in the date of CDX completion.
2. This field is pre-filled with the reviewer code and is assigned by the MMCC Coordinator.
2a. This field is pre-filled. This variable indicates whether the event is an out of hospital death. If EVTYPE (derived variable created in the CC monthly management report) is 'O' for 'Out-of-hospital death (OHD)', then the value is 'Y'. If EVTYPE is either 'N' for 'Non-fatal hospitalization (NFH)' or 'I' for 'In-hospital death (IHD)', then the value is 'N'.
2b. This field was dropped in Version I of the CDX form.
2c. This field is pre-filled. This variable indicates whether the event has linked occurrences. If C_LINK (derived variable created in the CC monthly management report) is 1 then the value is 'Y=Yes'. If C_LINK is 0, then the value is 'N=No'.

The combination of 2a and 2c determine whether or not Part B must be completed. CDART will skip Part B for non-linked out-of-hospital deaths.

A note regarding fields 6, 13 and 15a in the CDX. These three fields are populated based on algorithms that run upon saved data by clicking the arrows  at the far left of the field. In order to run the algorithm that exists for data items 6 (ARIC MI diagnosis algorithm), 13 (ARIC Death Classification algorithm) and 15a (Time of death information needed Yes/No), the form must first be saved before clicking the arrows. Any time any data is updated in the form, you must first SAVE the form, then click the arrows to update the field. The field does not auto-populate with updated information; it only updates on saved forms, upon clicking the arrows. This save reminder is highlighted on the screen in pink for you.

Instructions for Part B. MI Diagnosis

Items 3-5 represent the elements used by the ARIC algorithm for MI diagnosis. For each, select the letter that correctly characterizes the case under review. For events with a single hospitalization, select for each of items 3-5 the letter corresponding to the pain, enzyme, or ECG diagnosis from the Event Summary Form. For linked events, the information on pain, enzymes and ECG contained in the Event Summary Forms may be mixed and matched in answering the respective questions on the CDX. Special cases where HRA question 20 triggers a skip (i.e. no pain, enzyme and ECG information) will result in '*' for pain dx, enz dx, and ecg dx in the Event Summary Form. (These cases are indicated by a footnote in the Event Summary Form.) For these cases, select 'A' for pain (CDX3), 'E' for ECG (CDX4), and 'I' for enzyme (CDX5).

3. If the Event Summary Form indicates a possible non-cardiac origin of chest pain (B.1e. =Y), the pain information will have been reviewed by an MMCC member. The pain criterion may have been downgraded after review as indicated in B.1f. Select "A" if downgraded. If not downgraded, select the letter corresponding to the pain diagnosis from the Event Summary Form(s) for Hospitalized Events. For linked events, consider pain information from all the Event Summary Forms in determining whether cardiac pain was present.

4. Transcribe the letter corresponding to the ECG diagnosis from the Event Summary Form(s) for Hospitalized Events items B.2a. to the Final Diagnosis Form. For linked events, consider ECG diagnoses from all the Event Summary Forms in arriving at the ECG Diagnosis.

5. If the Event Summary Form indicates possible spurious enzymes to be reviewed (B.3e. = Y), the enzyme information will have been reviewed by an MMCC member. The enzyme criterion may be been downgraded after review as indicated in B.3f = "ARIC enzyme diagnosis downgraded to Equivocal."

Select the letter corresponding to the downgraded enzyme criterion if it was downgraded ("E" if changed to Equivocal). If not downgraded, select the letter corresponding to the ARIC enzyme diagnosis from the Event Summary Form(s) for Hospitalized Events. For linked events, consider enzyme information from all the Event Summary Forms in determining the appropriate enzyme category.

6. Once questions 3-5 have been answered, scroll to the bottom of the screen, **save the form** and click the arrows  in Q6 to run the ARIC algorithm. The answer is automatically calculated for you. The ARIC MI Diagnosis Table is, upon which the algorithm is based, is on the last page of this QxQ, and is also available as a link from the screen in CDART. This table is Table 4.1 of ARIC Manual 3 - Surveillance Component Procedures Manual of Operations.

7a. Review carefully the discharge summary diagnoses, and other attached information to assist you in deciding on the correct MI diagnosis. You may find errors in the algorithm or in abstracted information, or you may find important clinical facts in the discharge summary. If, as a result of your review, you do not agree with the ARIC MI diagnosis assigned in Item 6, indicate this in Item 7a. Otherwise, select 'Yes' in Item 7a, and skip to 7c.

7a1. Record in detail your reasons for disagreement with the ARIC algorithm. .
7a2. If disagreeing with the ARIC algorithm, cite the relevant case law, by number, supporting your diagnosis~~.~~. If no such law exists, propose a new one to cover this and similar cases in above item 7a1. There is a link to the Case Law from the CDART screen that has numbered laws. Please click the link to access the most current case law, and then enter the Number and, if relevant, letter of the corresponding case law. For example, '17b'. For cohort specific case law in Appendix B, note 'cohort' before the case law number and letter.

7b. Indicate your preferred diagnosis after consulting the ARIC Diagnostic Criteria for Hospitalized MI table. The table is available on the last page of this QxQ as well as from a link in CDART.

7c. If an Event Summary Form indicates that this event is a death, select "Y" and proceed to Part C (Death Classification). If the event is not a death, select "N" and save and close the form.

Instructions for Part C. Death Classification

8. After review of materials pertinent to this event, if, in your opinion, there is evidence that the death was due to a non-atherosclerotic or non-cardiac atherosclerotic process, circle "Y" for "Yes". Autopsy information may be used to answer this question for cohort surveillance review. If you have responded "Yes" to this item, record the source of evidence by recording the items and forms from the Event Summary Form that provided this evidence. If the item number is not available, record briefly the item content.

9. If a diagnosis of definite MI was assigned in Section B, item 7b (or item 6 if 7b was skipped) and it occurred within 4 weeks of death, circle "Y" for this item. Use autopsy information, if available, to judge whether MI was present within 4 weeks of, or at, death. Otherwise circle "N" for No. In general, ARIC uses hospital admission date as a surrogate for date of onset of symptoms for the MI, unless the onset of symptoms is after hospital admission.

10. If the death is classified "out-of-hospital" and is not linked to another event, refer to Part B of the "Event Summary for Out-of-Hospital Deaths" and the informant narrative (if any), to determine presence of chest pain within 72 hours of death. Enter that response. If the death is classified "in-hospital", refer to the Hospital Event Summary Form(s) to determine presence of cardiac pain. If the death is classified "out-of-hospital" with linked hospitalization(s), consider the information combined in the "Event Summary Form for Out-of-Hospital Deaths", the informant narrative (if any), and information from the Hospital Event Summary Form(s) to complete this item.

11. After reviewing all available information, including Parts A-C in the Event Summary Form, Part D in the Event Summary Form for Hospitalized Events, and all special information available for cohort surveillance members, record "Y" for "Yes" if there is evidence of a history of chronic ischemic heart disease, including angina pectoris. Answer "no" for valvular heart disease or nonischemic cardiomyopathy. A history of use of medication for angina pectoris may be used as evidence of a history of angina. Autopsy reports and the additional cohort surveillance event information may be used to judge prior history of ischemic heart disease.

12. Review the underlying cause of death code in the header of the Event Summary Form for In-Hospital Events or in Section D of the Event Summary Form for Out-of-Hospital Deaths. If the code is included among the codes listed in Item 12, circle "Y" for "Yes".

13. Once questions 8-12 have been answered, scroll to the bottom of the page, **save the form** and then click the arrows  in Q13 to run the ARIC algorithm. This is automatically calculated for you.

14.a. After reviewing all the evidence, you may feel that a different classification is more appropriate than that specified in Item 13. If you do not agree with the classification assigned in Item 13, select "N" for "No".

- 14a1. Indicate your reason for disagreement in the space provided.
- 14a2. Cite the relevant case law supporting your diagnosis. If no such law exists, propose a new one to cover this and similar cases.

14b. If you circled "N" in Item 14a, record the letter from the choices in Item 13 that you consider a more appropriate classification.

15.a. **Save the form**, and then click the arrows  to populate this field. If the response to either Item 13 or Item 14b is "A" or "B" or "C", AND the type of event is an Out of Hospital Death, the field will populate with a 'Yes'. Otherwise, it will populate with 'No'.

15b. Using all pertinent information, indicate the interval of time from onset of acute symptoms to death. If time of onset of acute symptoms is unknown, indicate the time interval from point when decedent was last known to be alive and free of symptoms. Select the letter corresponding to this interval.

After saving the completed form, run the missing fields report from the link at the bottom of the last tab. This will open a report in a new tab in your browser. The report will either list any fields that were left blank that should have been filled, or will report "no missing fields". If there are missing fields listed, go back and fill in those missing items.

Table for Hospitalized MI

Cardiac Pain	ECG Finding	Enzymes	Diagnosis
Present	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
	Evolving ST-T Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
	Equivocal	Abnormal	Definite MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodable, or Other	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
Not Present, Unknown or Missing	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Evolving ST-T Pattern	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Equivocal ECG Pattern	Abnormal	Suspect MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodable, Or other	Abnormal	Suspect MI
		Equivocal	No MI
		Incomplete	No MI
		Normal	No MI