

Updated Manual 3d

This table summarizes changes of Manual 3d as of 08/19/2021

Item in Manual 3d	Description of Changes in Manual
pg. 2-3	<ul style="list-style-type: none"><li data-bbox="683 407 1333 436">• Added instructions for blinding duplicate materials



ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

Manual 3d

COVID-19 Event Ascertainment Manual of Procedures

Version 1.2
08/19/2021

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National Heart, Lung, and Blood Institute of the National Institutes of Health

1. CSCC will provide abstractors a list of self-reported COVID19 hospitalizations (per AFU or SAF or COV questionnaire) that might be COVID19 eligible, but field centers may discover some charts on their own. There is no need to pursue outpatient tests or outpatient or ER medical records.
2. Abstractors will complete a CEL for all self-reported COVID19 hospitalizations or otherwise identified COVID19 hospitalizations. If there is a CEL for simultaneous CVD eligibility determination, abstractors do not need to do another CEL.
3. If no hospitalization record can be found for a self-reported COVID19 hospitalization, abstractors follow the standard procedures for recording events not found in the CEL (CEL8B = No). If a hospitalization record is found, but there are no COVID19 ICD10 codes present, enter a CEL and set CEL2 to 'query reviewed' so that they are taken off the list described in item 1.
4. CSCC will provide abstractors with a list of all ARIC cohort COVID19 non-fatal hospitalizations, in-hospital deaths and out-of-hospital deaths based on CELs and DTHs with any of the ICD codes listed below:
 - ICD codes indicating COVID illness are sufficient to define eligibility for full abstraction.
 - U07.1, Confirmed COVID-19
 - U09.9, Post-infectious state after COVID-19
 - Z86.16, Personal History of COVID-19
 - J12.82, Pneumonia due to coronavirus disease 2019
 - J12.89, Other viral pneumonia
 - M35.81, Multisystem inflammatory syndrome associated with COVID-19
 - For events occurring prior to May 1, 2020:
 - B97.29, Other coronavirus (prior to May 1, 2020)

Note: For COVID-19 self-reported on the ARIC AFU/sAFU/COVID-19 questionnaire: abstractors still will complete the CEL form and copy medical record materials, even in the absence of COVID19 eligible ICD codes.

5. Abstractors will retrieve and save to a pdf file the required components of the chart for COVID-19 event review. **Materials must be deidentified fully and completely.** The following items should be blinded for all duplicate materials sent to the CC:
 - Names of the Patient or of the Patient's Relatives, Employers, or Household Members. (Their initials need NOT be redacted. Names/Initials of hospital/medical care personnel do NOT need to be redacted.)
 - Social Security number
 - Date of Birth
 - Street address, city county, precinct, zip code, and equivalent geocodes
 - Telephone, Fax, Drivers License or plate numbers
 - Email addresses

- Medical record number
- Health plan ID numbers
- Account numbers

Some chart materials may have been redacted and abstracted for CVD already, but should be resubmitted for COVID19 review and include all of the following:

- Discharge diagnoses and ICD codes
- Notes
 - Admission note
 - History & Physical, and HPI
 - ED notes (if available)
 - Physician consult notes (all services)
 - ICU admission note (if applicable)
 - Discharge note/summary
- Death certificate (if applicable)
- Laboratory reports:
 - Microbiology including COVID testing (PCR, antigen testing, and serology)
 - All other laboratory reports (of note, if it is possible to select only certain results: event review requires only creatinine, troponin, and arterial blood gas (ABG))
- Radiology reports:
 - Chest radiography (X-ray)
 - Chest computed tomography (CT)
 - Echocardiogram (TTE, TEE)
 - Head computed tomography (CT)
 - Brain magnetic resonance imaging (MRI)
 - Lower extremity ultrasound (Doppler/duplex)
- Medications
 - Please include home medication list (e.g., ACE inhibitors, anticoagulants)
 - Please include all hospitalization medications (those listed in the C4R event adjudication form are the key medications of interest, but if it is easier to simply include all, that is certainly acceptable)
- Vital signs (Of note, if it is possible to select only certain vital signs, event review requires only respiratory rate, O2 saturation, O2 supplementation)
- Electrocardiogram (ECG) report (Include ECG Tracings when a report is not available)

NOT NEEDED: Nurses notes, Progress notes, physical therapy notes, care planning notes

6. The Event ID for the COVID19 Event is the ARIC CEL Event ID. Abstractors will save the **deidentified** and **redacted** case materials for the COVID19 Event as a pdf with the file name being the ARIC CEL Event ID with a V added at the end of the file name. Abstractors will assign the Event ID and submit the records to CSCC via LiquidFiles.

POST-PROCESSING STEPS

7. The CSCC will save the case materials to J:\ARIC\ADMIN\SURVEILL\MMCC\MMCC Scanned Material\C4R Covid Case Materials. A SAS program will rename the case materials with the ARIC Event ID to the C4R ID, and save it to J:\ARIC\ADMIN\SURVEILL\MMCC\MMCC Scanned Material\C4R Covid Case Materials\Case Materials with C4R ID. The pdf of the case materials will then be uploaded to the secure Psychiatric Institute portal <https://attach.nyspi.org/filedrop/AkshayaKrishnaswamy> with the C4R ID + SEQNO. The SEQNO is 001 unless there is more than one event. For participants with multiple events (hospitalizations/death), those materials will be sequenced.
8. Columbia MDs will review the charts and record the C4R required information on the COVID Event Review form and COVID Event Diagnosis form.