## ­­­­­D.3 Events Eligibility

### D.3.1 Introduction

After a possible event of interest to MESA is identified, an *Initial Notification of Potential Event/Death* form is completed and submitted, in order to trigger the next step in events collection at the field center and notify the Coordinating Center of the potential event. Field center staff then commence the process of events data collection, which varies according to the type of event reported (see details in the table below).

To complete the *Events Eligibility* form, the following initial information should be collected for various types of reported events:

|  |  |
| --- | --- |
| **Type of Event** | **Data Collected** |
| Hospitalized cardiac/PVD event | Discharge ICD-9-CM or ICD-10-CM codes and discharge summary or the last physician’s progress note if discharge summary was not done or is unavailable |
| Hospitalized cerebrovascular event | Discharge ICD-9-CM or ICD-10-CM codes and discharge summary or the last physician’s progress note if discharge summary was not done or is unavailable |
| Other hospitalizations | Discharge ICD-9-CM or ICD-10-CM codes and discharge summary or the last physician’s progress note if discharge summary was not done or is unavailable |
| Cardiac/Cerebrovascular death | Death certificate with cause of death ICD-10 codes and any in-patient records, ER/EMS notes, nursing home and/or hospice progress notes |
| Outpatient cardiac/PVD nonfatal event | Physician office notes/procedure reports, possibly PQ |
| Outpatient cerebrovascular nonfatal event | Physician office notes/procedure reports, possibly PQ |
| Ineligible death | Death certificate with cause of death ICD-10 codes and date of death records (discharge summary, ER/EMS, nursing home, hospice notes.) |

After this information is obtained, the Field Center Abstractor abstracts and enters the necessary information from the medical record to complete an *Events Eligibility* form. While the EDC will determine event eligibility depending on the ICD codes entered, it is essential for the abstractor to carefully read the discharge summary, review the diagnostic and procedure information found there, and confirm the eligibility of the event based on the language in addition to the codes.

Whenever possible, the Field Center Abstractor should be the staff member who completes the *Events Eligibility* form.

ICD-10 codes will be requested from the provider of the medical records (ICD-9 codes are acceptable.) In the event the ICD codes cannot be obtained from the hospital, any alternative ICD coding must be performed by a nosologist professionally certified in the specific coding system in use (ICD-9 and ICD-10 require separate certifications). Coding by uncertified but experienced staff members is not acceptable. For a hospitalization to be coded by an outside nosologist both the discharge summary and the history and physical must be sent. The code sheet must be signed and dated by the nosologist.

No ICD codes found in any hospital record other than the discharge summary or the code sheet may be used.

**Transfers**: If the event under investigation involves a hospital transfer, complete a separate *Events Eligibility* form for each hospitalization using the "*Click here to enter a NEW Eligibility*" option in the Event EDC. Only the ICD codes from over-night hospitalizations are entered; ER, clinic, and same-day procedure visits, even if coded, are not entered.

### D.3.2 Item-by-Item Instructions

##### Investigation ID

The Investigation ID is pre-entered in the EDC when an *Events Eligibility* form is opened. It corresponds to the Investigation ID on the *Initial Notification of Potential Event/Death* form for the same investigation.

#### D.3.2.1 Setting of Event/Death

(Question 1) Record the setting at which the event occurred:

* "In Hospital" is used if the patient was **admitted**to a hospital and stayed overnight, which must always indicate a change of date, even if less than 24 hours. (Emergency Room-only, dead-on-arrival, or other medical settings are recorded under separate categories.) If the participant experiences an event outside the hospital (e.g., suffers a myocardial infarction at home) but is transported to and admitted to the hospital, “Hospital” is the appropriate setting to select.
* "Physician Office/Clinic" is used for an event occurring at any outpatient medical facility. For example, this setting would be chosen for an incidence of angina diagnosed in the physician’s office, or a cardiac/PAD/PVD procedure done in a clinic or same-day surgery/specialty center. (If a participant is admitted to a hospital directly from such a procedure, the event is recorded as occurring in Hospital, and abstracted from arrival at the procedure through discharge from the hospital.)
* "Emergency Room" is used if the participant is seen in the emergency room (ER), is alive at discharge, and is **not**admitted to the hospital. If the participant experiences an event outside the ER (e.g., suffers a myocardial infarction at home) but is transported to the ER, not admitted to the hospital, and discharged alive, this is the appropriate setting to select.

**NOTE**: If a participant is transported to the ER but is dead-on-arrival (DOA), do not choose this category. In this case, the category corresponding to the setting where the death occurred should be selected (example: “Home or Public Place”).

* "Nursing Home/Skilled Nursing Facility" is used if an event occurred at a nursing home, skilled nursing facility (SNF), transitional care facility, long-term care facility, rehab facility, or hospice residence, and the participant is **not**transported to an ER/hospital (e.g., a resident of such a facility dies in his/her sleep there).
* "Home or Public Place" is used if an event occurred at the participant’s home, another private residence, or a public location, and the participant is *not* transported to an ER/hospital.
* "Other" is used if none of the above categories is appropriate. It is expected this will be the case only in rare instances. Record the location in the box specified.

This is the category to choose in the case of a Non-Event. For example, the participant reported a hospital stay but none could be found after investigation. See Appendix D.14, Question 3. The reason for this category selection should be entered in the box specified.

**NOTE:** If a participant dies at *home* under hospice care, the category to select is “Home or Public Place.” If the participant dies in an *out-patient hospice facility* the correct category is “Nursing Home /Skilled Nursing Facility.” If the participant dies in hospice care while still *in the hospital*, the correct category is “In Hospital.” Always be guided by the location of death on the death certificate.

**NOTE:** If the event under investigation is a hospitalized event, continue to Question 2. Questions 2–10 are completed only for hospitalized events. For out-of-hospital events (including ER and DOA), skip to Question 11.

#### D.3.2.2 Hospitalized Events

If the event under investigation involves a hospital transfer, complete a separate *Events Eligibility* form for each hospitalization using the "*Click here to enter a NEW Eligibility*" option in the Event EDC. Only the ICD codes from over-night hospitalizations are entered; ER, clinic, and same-day procedure visits, even if coded, are not entered.

**(Question 2) Admission Date**

Enter the hospital admission date from the face sheet or discharge summary. If the participant was transferred to a second facility, record the admit date from the first hospital. The admit information for the transfer admission should be entered on a second eligibility form.

**NOTE:** The participant may have arrived at the hospital on one day, but not have been admitted to the hospital until the next day. Record the day of actual admission, but remember that hospital care begins in the ambulance or ER, and abstract the record accordingly. Thus lab results, ECGs, etc. from the ambulance or the ER, prior to admission, will be abstracted as part of the hospitalized event.

##### (Question 3) Discharge Date/Date of Death

Enter the hospital discharge date or date of death from the face sheet or discharge summary. If the participant was transferred to a second facility, record the discharge date from the first hospital. The discharge information for the transfer admission should be entered on a second Eligibility form.

If the participant is discharged from acute care and transferred to in-hospital hospice care or in-hospital rehab during the same hospitalization, then survives to discharge, the date of admission to hospice or rehab is the date of discharge for the acute event. The hospice or rehab care is not included in abstraction *unless* an event of interest occurs in the hospice or rehab setting and the participant is readmitted to acute care. If uncertain, check with the Central Abstractor for determination of event abstraction procedure.

If the participant dies while in in-patient hospice or in-patient rehab care, the date of discharge is the date of death, and the entire hospitalization is abstracted as one event, with the ICD codes from acute care being the ones chosen to enter into the EDC.

##### (Question 4) Vital Status at Discharge

Enter the participant’s vital status at the time of discharge from the face sheet or discharge summary. If the participant was transferred to a second facility, record the vital status at the time of discharge from the first hospital. The discharge information for the transfer admission should be entered on a second eligibility form.

##### (Question 5) Hospital MESA ID Code

Record the four-digit hospital code for the institution at which the event occurred. If the participant was transferred to a second facility, record the hospital code for the first known hospital. The hospital code for the transfer admission should be entered on a second eligibility form.

**NOTE:** Prior to the start-up of events data collection, each MESA field center provided the Coordinating Center with a list of area hospitals and other health care institutions where their participants are likely to be having overnight stays. The Coordinating Center assigned each of these institutions with a four-digit MESA Hospital Code. This is the value that is entered in the “Hospital Code” field. If a participant reports a stay at a hospital that has not been assigned hospital code, the MESA database allows you to enter a new institution name, which will be automatically assigned the next (sequentially) available MESA Hospital Code.

##### (Questions 6 and 7) Hospital Discharge Summary ICD Diagnosis Codes

##### NOTE: ICD codes may be found in the hospital and other records for ER, rehab, nursing home, clinic visits, and in-patient consults. MESA is only interested in the in-hospital discharge summary codes/billing codes for determining eligibility for cardiac, peripheral arterial disease and cerebrovascular events.

##### NOTE: Requesting the Discharge Summary Diagnostic and Procedure ICD-10 codes is standard, although some hospitals may send ICD-9 for more remote admissions, which is acceptable.

Record either the ICD-10-CM or ICD-9-CM diagnosis codes documented on the hospital discharge summary code sheet, physician’s attestation, or face sheet, **exactly**as they are written and **in the order listed,** including any duplicate codes.Be sure to include the primary diagnosis as well as all secondary diagnoses, but **exclude** the admitting diagnosis.

* If only discharge diagnoses but no ICD codes are available, nosologist coding may be required. See D.3.1 for specific instructions.
* Do not use ICD codes embedded in narrative reports (e.g. HISPHY, CARNOT, etc.)
* It is acceptable to record only the diagnostic codes if the procedure codes were not sent by the hospital, although they should always be requested from both hospital and outside nosologist.
* The EDC can accept any number of ICD codes found in the record. If the participant was transferred to a second facility, record only the ICD codes from the initial hospitalization here. The ICD codes from the transfer facility should be entered on another Events Eligibility form.

**Instructions for Data Entry of ICD Diagnostic Codes**

1. Click on “ICD Code”.
2. When the dialog box appears, click on the ICD version desired, either 9 or 10.
3. Enter the entire code. The code description will appear in the box – verify that it matches the code description on the hospital code sheet. If it matches, click “Save.”
4. Continue entering all codes provided in the hospital record. When all have been entered, click on “Next Page” to enter the procedure codes.

##### (Questions 8 and 9) ICD Hospital Procedure Codes

* Record the ICD-9 or -10 procedure codes documented on the hospital discharge summary code sheet, physician’s attestation, or face sheet **exactly** as they are written and **in the order listed,** including any duplicate codes.If no procedures were listed, leave the question blank and proceed to Question 10.
* The EDC can accept any number of procedure codes

**Instructions for Data Entry of ICD Procedure Codes**

1. Click on “ICDval.”
2. When the dialog box appears, click on the ICD version desired, either 9 or 10.
3. For both ICD-9 and -10, enter the code exactly as written on the code sheet.
4. Verify that the code description in the dialog box matches that found on the hospital code sheet, then click “Save.”
5. When all codes have been entered, click on “Next Page” to continue to Question 10.

##### (Question 10) Inpatient Event Eligibility Determination

The EDC will determine eligibility based on the ICD codes entered. However, special care must be taken to review the discharge summary/last progress note narrative in case the EDC fails to capture a diagnosis/procedure code of interest (as described in Questions 10.B and 10.D) to the MESA Study. If an eligible diagnosis or procedure is discovered that was not captured by the EDC, notify the Coordinating Center.

NOTE: The hospitalization MUST contain either primary or secondary eligible codes to be eligible for review. All events with eligible cardiac/PAD/cerebrovascular diagnostic codes will be sent for abstraction to the Central Abstractors.

**Q10**. Are the discharge summary diagnostic and procedure codes ICD-9-CM? Yes No

 If Yes, proceed to Q10.A.l. ICD-9-CM Discharge Summary Codes

 If No, proceed to Q10.A.2. ICD-10-CM Discharge Summary Codes

*Regarding ICD-10 codes: If an ICD-10 code is found that begins as described below but has more numbers or letters appended, consider the longer code eligible also. For example, I21 is an eligible code, so I21.19 would also be eligible*.

**ICD-9 ELIGIBILITY CODES** (Questions 10.A.1 - 10.D.1.)

**(Question 10A.1.)** The event is eligible for cardiac or peripheral arterial disease (PAD/PVD) investigation if one of the ICD-9-CM diagnosis codes listed below is present in any of the hospitalizations:

402, 410–414, 425, 427.5, 427.9, 428-429, 440, 441, 443.8, 443.9, 518.4

If the three-digit body of any code is one of those listed above, regardless of whether a fourth/fifth digit appears after the decimal (*except* for 427.5, 427.9, 443.8, 443.9, or 518.4, which must appear exactly), record "Yes," the event is eligible for further investigation.

If the case is eligible based on the presence of one or more of these codes, select “yes” and continue at **Question 10C.1.**

If none of the listed codes is present, fill in the circle corresponding to “no” and continue**.**

**(Question 10B.1.)** The event is eligible for cardiac or peripheral arterial disease (PAD/PVD) investigation if one of the diagnosis codes listed below is present *AND* at least one of the listed diagnoses or procedures is indicated in the discharge summary/last progress note:

Diagnoses: 35, 250, 390–459, 745-747, 794.3, 798, 799;

Procedures: 00.66, 36–37 (with any post-decimal digits), 38–39 (cardiac/PAD/PVD-related only—not venous) 84.1, 88.5

 AND the following words/phrases:

MI, angina, ischemic heart disease, CHD, unstable angina, coronary insufficiency, cardiac arrest, atherosclerotic heart disease, CHF, heart failure, cardiomyopathy, atherosclerosis, PAD/PVD (must be arterial—not venous), claudication, acute pulmonary edema, aortic aneurysm

CABG, coronary stent, elevated CK-MB, cardiac angioplasty, atherectomy, leg amputation, leg angioplasty, other leg revascularization

Procedure codes 38 (Incision, excision, and occlusion of blood vessels) and 39 (Other operations on blood vessels) include many organ systems, and we are interested only if the procedure involves an artery of the heart or leg or the abdominal aorta. Do not include vein procedures. Also, do not include 39.95 (hemodialysis).

As in Question 10A.1., unless the fourth/fifth digit of the ICD-9-CM diagnosis code is specified, presence of the code makes the case “eligible” (assuming a required key word is also present), regardless of code’s fourth/fifth digit.

If the case is eligible based on the presence of one or more of these codes *and* one or more of these words/phrases, fill in the circle corresponding to “yes” and continue with Question 10C.1

OR

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no” and continue with Question 10C.1

**(Question 10C.1.)** The event is eligible for cerebrovascular disease investigation if one of the diagnosis codes listed below is present:

430–436

If the three-digit body of any code is as indicated, regardless of whether a fourth/fifth digit appears after the decimal, record "Yes," the event is eligible for further investigation.

If the case is eligible based on the presence of one or more of these codes, fill in the circle corresponding to “yes” and continue at Question 13.

If none of the listed codes is present, fill in the circle corresponding to “no” and

**Continue with**

**(Question 10D.1.)** The event is eligible for cerebrovascular disease investigation if one of the diagnosis codes listed below is present **and**at least one of the listed diagnoses or procedures is indicated in the discharge summary.

Make sure any listed diagnosis is specified as being**new** or **acute,**as MESA is interested in ascertaining new diagnoses only.

Diagnoses: 35, 250, 390–459, 745–747, 794.3, 798, 799; Procedures: 38–39 (cerebrovascular-related only)

AND the following words/phrases:

Stroke, TIA, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar syndrome or infarction, cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis.

During this admission: Carotid endarterectomy, CT/MRI showing new cerebrovascular findings.

**NOTE:** Procedure codes 38 (Incision, excision, and occlusion of blood vessels) and 39 (Other operations on blood vessels) include many organ systems, and we are interested only if the procedure involves the arteries of the neck, head, or brain.

As in Question 10C.1., unless the fourth/fifth digit of the ICD-9-CM diagnosis code is specified, presence of the code makes the case “eligible” (assuming a required key word is also present), regardless of code’s fourth/fifth digit.

If the case is eligible based on the presence of one or more of these codes **and** one or more of these words/phrases, fill in the circle corresponding to “yes.”

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no.”

**ICD-10 CODES** (Questions 10.A.2 – 10.D.2.)

**(Question 10.A.2.)** The EDC will automatically capture eligible ICD-10-CM codes entered for a cardiac or peripheral arterial disease (PAD/PVD) investigation. Watch for the following diagnostic codes and descriptions that may indicate eligibility:

I11 – Hypertensive heart disease

I20 – Angina pectoris

I21 – Acute myocardial infarction

I24 – Other ischemic heart disease

I25 – Other chronic ischemic heart disease

I25.2 – Old myocardial infarction

I42 – Cardiomyopathy

I46 – Cardiac arrest

I49 – Cardiac dysrhythmia

I50 – Heart failure

I51-52 – Other heart disease and complications

I70 – Atherosclerosis

I71 – Aortic aneurysm/dissection

I73 – Peripheral vascular disease

I79 – Other peripheral vascular disease

J81 – Acute pulmonary edema

If the case is eligible as determined by the EDC, select “yes” and continue at **Question 10C.2.**

If none of the listed codes is present, fill in the circle corresponding to “no” and continue**.**

**(Question 10.B.2)**

The event is eligible for a cardiac or peripheral arterial disease (PAD/PVD) investigation if the EDC captures one of the eligible secondary codes *AND* at least one of the listed diagnoses or procedures is indicated in the discharge summary/last progress note.

Watch for the following secondary ICD-10-CM diagnosis or procedure codes that may indicate conditional eligibility:

 E10-13 – Diabetes mellitus

 I00-02 – Acute rheumatic fever

 I05-09 – Chronic rheumatic heart disease

 I10-15 – Hypertensive disease

 I20-25 – Ischemic heart disease

 I26-28 – Disease of pulmonary circulation

 I30-52 – Other forms of heart disease

 I70-79 – Disease of arteries, arterioles, and capillaries

I80-89 – Diseases of veins, lymphatics, and other diseases of the

 circulatory system

Q21.8 – Bulbus cordis anomalies

Q21.9 – Anomalies of cardiac septal closure

Q24.8 – Other congenital anomalies of heart

Q28.9 – Other congenital anomalies of circulatory system

R94.30 – Abnormal cardiovascular function study, unspecified

R99 – Sudden death, cause unknown, and other ill-defined and unknown

 causes of morbidity and mortality

 *The event is also eligible if certain procedure codes are present.*

AND the following words/phrases:

MI, angina, ischemic heart disease, CHD, unstable angina, coronary insufficiency, cardiac arrest, atherosclerotic heart disease, CHF, heart failure, cardiomyopathy, atherosclerosis, PAD/PVD, claudication, acute pulmonary edema, aortic aneurysm

CABG, coronary stent, elevated CK-MB. cardiac angioplasty, atherectomy, leg amputation, leg angioplasty, other leg revascularization

**NOTE** *that the eligible ICD-10 procedure codes for cardiac/PVD/PAD events are too complex to enumerate (see Appendix H, “MESA Eligible ICD-10 codes.xlsx” for specific correspondences between eligible ICD-9 and ICD-10 codes.)*

If the case is eligible based on the presence of one or more of the EDC-selected codes *and* one or more of these words/phrases, fill in the circle corresponding to “yes” and continue with Question 10C.2.

OR

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no” and continue with Question 10C.2.

**(Question 10C.2.)**

The EDC will automatically capture eligible ICD-10-CM diagnostic codes entered for a cerebrovascular event investigation. Watch for the following codes that may indicate eligibility:

 G45 – Transient cerebral ischemia

I60 – Subarachnoid hemorrhage (SAH)

I61 – Intracerebral hemorrhage

I62 – Other intracranial hemorrhage

I63 – Cerebral infarction

I65 – Occlusion/stenosis of pre-cerebral arteries

I66 – Occlusion of cerebral arteries

I67 – Acute cerebrovascular disease

If the case is eligible based on the presence of one or more of these codes, fill in the circle corresponding to “yes” and continue at Question 13.

If none of the listed codes is present, fill in the circle corresponding to “no” and

**Continue with**

**(Question 10D.2.)**

The EDC will automatically capture eligible secondary ICD-10-CM codes entered for a cerebrovascular investigation.

Watch for the following secondary ICD-10 codes that may indicate conditional eligibility:

 E10-13 – Diabetes mellitus

 I00-99 – Diseases of the circulatory system

 Q20-28 – Congenital anomalies of the circulatory system

 R94.30 – Nonspecific abnormal results of function study of cardiovascular system

 R99 – Sudden death cause unknown, unknown causes of morbidity and mortality

*The event is also eligible if certain procedure codes are present.*

AND the following words/phrases:

Stroke, TIA, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar syndrome or infarction, cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis.

During this admission: Carotid endarterectomy, CT/MRI showing new cerebrovascular findings.

Make sure any listed diagnosis is specified as being**new** or **acute,**as MESA is interested in ascertaining new diagnoses only.

**NOTE** *that the eligible ICD-10 procedure codes for cardiac/PVD/PAD events are too complex to enumerate (see Appendix H, “MESA Eligible ICD-10 codes.xlsx” for specific correspondences between eligible ICD-9 and ICD-10 codes.)*

If the case is eligible based on the presence of one or more of the EDC-selected codes *and* one or more of these words/phrases, fill in the circle corresponding to “yes” and

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no” and

**Continue at Question 13.**

* If Question 10A or 10B is answered “yes,” the case is investigated as a **Hospitalized Cardiac or Peripheral Arterial Event**, and the relevant documents are prepared for the Central CVD Abstractor for abstraction.
* If Question 10C or 10D is answered “yes,” the case is investigated as a **Hospitalized Cerebrovascular Event**, and the relevant documents are prepared for the Central Stroke Abstractor for abstraction.
* A case could be investigated as both a **Hospitalized Cardiac or PVD Event and Hospitalized Cerebrovascular Event.**
* If Questions 10A, 10B, 10C, and 10D are all answered “no,” the case is a non-cardiovascular event. No additional investigation is required. Scan the records collected (e.g., discharge summary/last progress note) and complete a *Final Notification of Events/Death* form to close out the investigation.
* See Section D.3.3, “Action Required After This Form,” for more information on the next steps to take upon completion of this form.

#### D.3.2.3 Nonfatal Outpatient Events Eligibility Determination

To complete the questions in this section, “Nonfatal Outpatient Events,” you need to review the available supporting documentation for all potential events and determine if, based on this information, an event of interest to MESA did occur. If review of this documentation indicates the event is eligible for further investigation by field center surveillance staff and ultimately for review by MESA physician reviewers (or if there is not enough information contained in the records), the Field Center may attempt to obtain a *Physician Questionnaire*. See Section D.7, *“*Physician Questionnaire: Cardiac/PVD,’ and Section D.8, “Physician Questionnaire: Stroke/TIA,”for information about completing these forms.

##### (Question 11) Outpatient Events

This includes all potential events that did not involve an admission to a hospital. This includes ER, DOA, Clinic Visits, Same-Day Procedures, Nursing Homes, Hospice, etc.

##### (Question 11A)Nonfatal outpatient event

If this is **not**a nonfatal, outpatient/out-of-hospital event, record "no" and skip to **Question 13.** If this is an event of interest, record “yes” and continue with **Question 11B.**

**(Question 11B) Cardiac/PVD outpatient event**

Review all available supporting documentation (records plus any available PQ’s) for references to one or more of the following diagnoses/procedures:

**Diagnoses:** **New**myocardial infarction, MI, angina, ischemic heart disease, CHD, angina pectoris, unstable angina, coronary insufficiency, cardiac arrest, CHF, heart failure, cardiomyopathy, PAD/PVD, claudication, acute pulmonary edema, aortic aneurysm

**Procedures:** Coronary revascularization, peripheral vascular surgery, leg angioplasty or revascularization procedure

NOTE:**These terms are intended as guidelines only.** It is possible that diagnoses/procedures not listed here could be indicative of an outpatient cardiovascular event. If you are uncertain if a case is eligible, check with the Central Abstractor or cardiac physician/reviewer. Also, there may be a cardiac procedure performed as part of a routine work-up. **NOTE**: If there is a routine procedure that is negative, and there is no mention of a cardiovascular diagnosis, then select ‘no’.

If the event is eligible based on documentation of a listed or other relevant diagnosis/procedure, fill in the circle corresponding to “yes.”

If there is no documentation of a relevant diagnosis/procedure, fill in the circle corresponding to “no.”

**Continue at Question 11C.**

##### (Question 11C) Cerebrovascular outpatient event

Review all available supporting documentation for references to one or more of the following diagnoses/procedures:

**Diagnoses:** Stroke, TIA, mini-stroke, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar syndrome or infarction, cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis

**Procedure:** Carotid endarterectomy

NOTE:**These terms are intended as guidelines only.**It is possible that diagnoses/procedures not listed here could be indicative of an outpatient cerebrovascular event. If you are uncertain if a case is eligible, check with the Central Abstractor or cerebrovascular physician/reviewer.

If the event is eligible based on documentation of a listed or other relevant diagnosis/procedure, fill in the circle corresponding to “yes.”

If there is no documentation of a relevant diagnosis/procedure, fill in the circle corresponding to “no.”

**Continue at Question 12.**

**Summary Notes:**

* If Question 11B is answered “yes,” the event is investigated as a **Non-Hospitalized Cardiac or PVD Event.**
* If Question 11C is answered “yes,” the event is investigated as a **Non-Hospitalized Cerebrovascular Event.**
* It is possible a single investigation might be investigated as **both cardiac/PVD and cerebrovascular.**
* If both Question 11B and 11C are answered “no,” the event is a non-cardiovascular event. No further investigation is required, but a *Final Notice of Event/Death* form must be entered to close out the event.
* If the out-patient event leads directly to a hospitalization, then the out-patient records are included in the records for the in-hospital abstraction and physician review, and are considered part of the same event. For example, a participant has an out-patient angiogram that reveals serious coronary disease, and is transported immediately to a hospital for additional procedures. Or, a participant has an ecg as an out-patient that reveals him/her to be experiencing a myocardial infarction, and is transported emergently to a hospital.

See Section D.3.4, “Action Required After This Form,” for more information on the next steps to take upon completion of this form.

##### (Question 12) Date of Event

Record the date of the out-of-hospital/outpatient event from the relevant records or the *Physician Questionnaire*.

If there are multiple events, e.g. clinic visit, followed by procedure, etc., assign the event date according to the following priority: Date of death, date of clinic visit, date of procedure.

Scan the records collected and enter a *Final Notification of Events/Death* form to complete the investigation. Enter this information into the Events Data Management Software.

#### D.3.2.4 Deaths

##### (Question 13) Is Event a Death?

Indicate if the event is a (hospitalized or out-of-hospital) death.

If “yes,” continue to **Question 14.** If “no,” skip to the end of the form.

##### (Questions 14-19) Death Certificate Information

In order to complete **Questions 14–19,** the death certificate must be obtained. The information documented here (including the date of death, time of death, death certificate number, whether or not an autopsy was performed, whether or not the death was confirmed by a Coroner/Medical Examiner, the cause of death, and the interval between onset and death) is found on all U.S. death certificates and should be abstracted from there and recorded verbatim.

#####  (Question 20) ICD-10 Code for *Underlying* Cause of Death

ICD-10 codes might be recorded on the death certificate, or they may need to be obtained from your local Health Department. Each field center is responsible for determining how ICD-10 codes are determined within their municipality and working out a system for obtaining those codes. Under rare circumstances, MESA may need to have an ICD-10 -certified nosologist code the cause. Under no circumstances should field center staff members code the deaths themselves.

The underlying cause is an official designation of the cause most central to the death. Obtain and record this ICD-10 code, which may be listed on the death certificate as the “UL” code.

##### (Question 21) Other ICD-10 Codes

Record the ICD-10 codes corresponding to all the other causes associated with the death. The underlying cause should not be repeated here. Only the ICD-10 codes found on the death certificate should be entered.

##### (Question 22) Death Events Eligibility Determination

To complete **Question 22,** “Determine if event is eligible,” you need to review the underlying and supporting ICD-10 codes listed in **Questions 20 and 21,** respectively, and determine if, based on this information, a death event of interest to MESA did occur. In this case, the event is eligible for further investigation by the Central Abstractor and ultimately for review by MESA physician reviewers.

**(Question 22A)**  The event is eligible for cardiac death investigation if one of the ICD-10 codes listed below has been indicated as the underlying cause of death in **Question 20:**

I\*\* (**except** I60–I69), E10–E13, J81, R07, R96, R98, R99

If the case is eligible based on one of these ICD-10 codes being indicated as the underlying cause of death, fill in the circle corresponding to “yes.”

If none of the listed codes is indicated as the underlying cause of death, fill in the circle corresponding to “no.”

Continue at **Question 22B.**

**(Question 22B)** The event is eligible for cardiac death investigation if one of the ICD-10 codes listed below has been indicated as an “other” cause of death in Question 21:I20–I23

If the case is eligible based on one of these ICD-10 codes being indicated as another cause of death, fill in the circle corresponding to “yes.”

If none of the listed codes is indicated as other cause of death, fill in the circle corresponding to “no.”

Continue at**Question 22C.**

**(Question 22C)** The event is eligible for cerebrovascular death investigation if one of the ICD-10 codes is listed as the “underlying” or “other” cause of death in Question 20:I60–I67, G45–G46

If the case is eligible based on one of these ICD-10 codes being indicated as the “underlying” or “other” cause of death, fill in the circle corresponding to “yes.”

If none of the listed codes is indicated as the “underlying” or “other” cause of death, fill in the circle corresponding to “no.”

Summary Notes:

If **Question 22A** is answered “yes,” case is investigated as a **Cardiac-Eligible Death.**

NOTE: Cardiac death has an ICD code that relates to heart disease death. The Cardiac eligible codes include a lot of other codes that do not appear to be cardiac, but upon investigation could harbor cardiac deaths.

* If **Question 22B** is answered “yes”, the case is investigated as a **Cardiac Death.**
* If **Question 22C** is answered “yes,” the case is investigated as a **Cerebrovascular Death.**
* A case could be investigated as both a **Cardiac and Cerebrovascular Death.**
* If **Questions 22A, 22B and 22C,** are all answered “no,” the case is a non-cardiovascular death.

**NOTE**: An in-hospital death may have eligible cardiac, PAD/PVD, or cerebrovascular codes which make the event eligible for review even if the death codes do not. Investigate the event according to the codes which would make it eligible, either hospital or death certificate.

### D.3.3 Additional Form Information

Review the form for completeness and accuracy. Enter the date abstraction was completed and your Abstractor ID in the boxes at the bottom of the final page of the form.

### D.3.4 Action Required After Form is Complete

**D.3.4.1 Ineligible Events**

An event under investigation may be ineligible for further investigation (i.e., beyond completion of the *Events Eligibility* form) for any of the following reasons:

* The event is a non-cardiovascular morbid (nonfatal) event or death
* The event is prevalent (i.e. defined as an event that occurred prior to the participant’s MESA enrollment date)
* There is insufficient information
* There was no event (i.e. nothing happened)

In each of these instances, no **additional**documentation (i.e. the information displayed in **Table D.3.2)**need be obtained. However, to close the investigation you must complete a *Final Notification of Events/Death* form. (See Section D.3.14, “Final Notice of Event/Death.”)

The Discharge Summary (or Last Physician’s Progress Note) must be de-identified and scanned into the EDC. See the Privacy Act De-identification guidelines list in Appendix D.5.3.

#### D.3.4.2 Eligible Events

If it is determined that the event under current investigation is eligible for further investigation, the following specific additional documentation required. *Table D.3.2* shows the documentation that needs to be obtained for each event type. (See also Section 3, page 4 Flow Chart).

***Table D.3.2
Documentation Required to Complete Events Investigation***

|  |  |
| --- | --- |
| **Type of Eligible Event** | **Additional Documentation Required** |
| Hospitalized Cardiac/PVD non-fatal | *Hospital Abstraction: Cardiac/PAD/PVD medical records\*\*\*Cardiac Interview* (if needed) |
| Hospitalized Cardiac/PVD or Cardiac-Eligible death\*\* | *Hospital Abstraction: Cardiac/PAD/PVD medical records\*\*\*Informant Interview* (if needed), *Death Certificate* |
| Hospitalized Cerebrovascular non-fatal | *Hospital Abstraction: Stroke/TIA medical records\*\*\*Stroke/TIA Interview* (if needed) |
| Hospitalized Cerebrovascular death\*\* | *Hospital Abstraction: Stroke/TIA medical records\*\*\***Stroke/TIA Narrative* (if needed), *Death Certificate* |
| Out-of-hospital Cardiac/PVD non-fatal | *Clinic/Procedure Notes, Physician Questionnaire: Cardiac/PVD*\*(if needed*)Cardiac Interview* (if needed) |
| Out-of-hospital Cardiac or Cardiac-Eligible death\*\* | *EMS/ER/NH/Hospice Notes, Physician Questionnaire: Cardiovascular Death* (if needed)*Informant Interview, Death Certificate* |
| Out-of-hospital Cerebrovascular non-fatal | *Clinic/Procedure Notes, Physician Questionnaire: Stroke/TIA\** (if needed)*Stroke/TIA Interview or Stroke Narrative*  |
| Out-of-hospital Cerebrovascular death\*\* | *EMS/ER/NH/Hospice Notes, Physician Questionnaire: Stroke/TIA\** (if needed)*Stroke/TIA Narrative, Death Certificate*  |

\*In some cases, the *Physician Questionnaire* will already have been obtained for the purpose of completing the *Events Eligibility* form.

The Field Center will request records first, and will only request a *Physician Questionnaire: Cardiac/PVD* if the information in the records is not sufficient.

In most cases, a *Physician Questionnaire* will not be needed for hospitalized events. However, if the field center determines the hospital record is lacking vital information that a physician knowledgeable about the participant’s case/death might be able to provide, a *Physician Questionnaire* may be sent.

\*\*If the case is a death and an autopsy or coroner investigation occurred, obtain the appropriate reports.

\*\*\* If a hospital transfer is involved, complete a hospital abstraction form for *each* hospitalization. Despite using separate abstraction forms for each hospital when a transfer is involved, the same investigation ID should be used on the transfer hospital abstraction forms as they are considered part of the same events investigation.

If the event being investigated is a death and a *Follow-Up* form was not just recently completed, surveillance staff should attempt to complete one by proxy as soon as possible or appropriate.

**D.3.4.3 Eligible Out-of-Hospital Events: Requested Records**

Eligible out-of-hospital events may be found in clinic, nursing home and other care facility, hospice, and same-day procedure records. Out-of-hospital events of interest include *new* diagnoses of:

* MI
* Angina
* CHF
* PAD/PVD
* Stroke
* TIA
* Deaths due to cardiovascular/peripheral arterial diseases.
* Deaths due to cerebrovascular diseases.

Procedures of interest include:

* Revascularization by angioplasty and bypass grafts of coronary and lower extremity arteries.
* Revascularization by endarterectomy/angioplasty of pre-cerebral/cerebral arteries

(See Overview Section 1, Page 1.) Requests for these types of records should include a date range more inclusive than that reported by the participant.

**D.3.4.4 Eligible Hospitalized Events: Requested Records**

When an eligible hospitalized cardiac/PAD/PVD/cerebrovascular event is identified, the following records *only* should be requested based on the type of event:

CARDIOVASCULAR and PERIPHERAL VASCULAR DOCUMENTS:

* **Discharge Summary ICD Diagnostic and Procedure Codes**
* **Physician’s Discharge Summary** (or last Physician’s Progress Note if necessary)
* **History and Physical** (including out-patient pre-operative if available)
* **Emergency Physician’s Notes**, and **EMS Report** with **12-Lead ECGs** tracings
* **Physician’s Consults**
* **Physician’s Progress Notes**
* **Laboratory Report** with Patient Values, Normal Ranges, and Collection Times
* **Imaging Reports** including:
	+ Chest X-rays
	+ CT/MRI/MRA
	+ Ultrasounds (including Doppler)
	+ Echocardiograms
* **Cardiac and Vascular Procedures** including:
	+ 12-Lead ECG Tracing Images
	+ CABG (Coronary Artery Bypass Graft) Report with Hemodynamic/Procedure Log
	+ Cardiac/Arterial Vascular Surgical Report Summary with Hemodynamic/

Procedure Log

* + Angiogram/Angioplasty/PTCA/PCI Reports with Hemodynamic/Procedure Log
	+ Cardiac Stress TestsNarrative Summary (such as Myocardial Perfusion, Bruce Protocol, Nuclear, Cardiolite) No stress ECGs or worksheets are required.
	+ ABI (Ankle-Brachial-Arm Index) Report
* **Autopsy/Coroner Report**

**CEREBROVASCULAR DOCUMENTS:**

* **Discharge Summary ICD Diagnostic and Procedure Codes**
* **Physician’s Discharge Summary** (or last Physician’s Progress Note if necessary)
* **History and Physical** (including out-patient pre-operative if available)
* **Emergency Physician’s Notes** with **EMS Report** and **12-Lead** **ECGs** tracings
* **Physician’s Consults**
* **PMR/PT/OT/Rehab/Speech Initial Assessments**
* **Physician’s Progress Notes**
* **Imaging Reports** including:
* CT/MRI/MRA/Angiograms (head and neck)
* Ultrasounds (including Doppler)
* Echocardiograms
* EEG
* **12-Lead ECG Tracing Images**
* **Lumbar Puncture Report**
* **Head and Neck Surgical Reports**
* **Autopsy/Coroner Report**

**D.3.4.5 Central Abstraction**

Upon the receipt of the requested medical records, eligible events will be prepared for the Central Abstractor as follows:

* Medical records received from the provider will be carefully reviewed for completeness and appropriateness. Inappropriate records (not found on the request guideline list) should be purged.
* Requested records found to be noted in the record, but missing, will be re-requested from the record provider. It is helpful to review the Discharge Procedure codes, as well as the Discharge Summary, ER Notes, H and P, etc., to determine which procedures should be found in the record, such as ECGs, CXRs, Echos, etc.
* If the provided record is complete and appropriate, the documents are scanned into the EDC in the order noted on the FINAL form if found as individual reports, **or** in the hospital page order if the reports are run-together, with the exception that the ICD Code sheet should be scanned first following the Coversheet.
* If the event involves a transfer of overnight care, as per item D.3.1, prepare a coversheet for each set of individual hospital records, and scan together in order of hospitalization.
* DO NOT SCAN THE RECORD UNTIL IT IS COMPLETE. If there are records that are unobtainable even though mentioned in the record, wrote a “Note for Abstractor” on the Coversheet.













