Outcomes Documentation Form Instructions
OUT Version A: 12/4/2002
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I. GENERAL INSTRUCTIONS

Before completing the Outcomes Documentation Form (OUT), it is essential that you read chapter 10, Endpoints. Chapter 10 provides information regarding how to assign an EPID number, what events will be adjudicated, what source documents are required, how to assign contact occasion and sequence numbers and how and when to complete a physician's narrative.

The Outcomes Documentation Form (OUT) should be completed when a participant is reported as deceased, or as required due to data in a Hospitalization Form (HOS) or Informant Interview Form (INF) indicating myocardial infarction (MI), unstable angina (USA), stroke, resuscitated sudden death (RSD), or urgent revascularization procedures occurred.

If more than one non-fatal event of the same type is suspected to have occurred during one hospitalization (i.e., the patient is suspected to have had two strokes during one hospitalization), complete a second OUT, incrementing the sequence number. Otherwise, use this form to capture all applicable events that may have occurred during one hospitalization. The sequence number for the OUT will often differ from that for the HOS to which it is linked. However, the Event Packet ID number (EPID) entered in each will be the same, and will be used to link all the forms associated with events within one hospitalization (including hospitalization transfers).

Prior to completing the OUT data collectors or abstractors must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTION

A. Administration Information

1. Record the Event Packet ID (EPID). The EPID number was assigned on the corresponding HOS or INF form. The same EPID should be used on all forms relating to one hospitalization or transfer. Record this OUT along with its contact occasion and sequence number on the EPID log sheet.

   Each OUT form can record up to one occurrence of each type of event (death, MI, RSD, stroke). If one type of event occurs more than once in a hospitalization, then additional OUT form(s) will be required. Increment the sequence number for each additional OUT, but use the same EPID for all forms related to one hospitalization (hospitalization transfers are considered one hospitalization and share EPID numbers, if needed.)

B. Death Event

2. Record "Y" if a death is being documented. If a death is not being reported on this form, record "N" then skip to item 18.

3. Record the date of death.

4. Record the FAVORIT investigator's assessment of the primary cause of death, indicating only one response.
   Record "A" if the primary cause of death is atherosclerotic coronary heart disease.
   Record "B" if the primary cause of death is atherosclerotic vascular disease, excluding coronary disease, then skip to item 6.
   Record "C" if the primary cause of death is other cardiovascular disease (non-atherosclerotic), then skip to item 7.
   Record "D" if the primary cause of death is non-cardiovascular, then skip to item 8.
   Record "E" if the primary cause of death is unknown, then skip to item 9.

5. Record the description of the primary atherosclerotic coronary heart disease cause of death, indicating only one response then skip to item 9.
   A. Participant dying from documented acute MI.
   B. Participant dying unexpectedly who was seen alive within 24 hours prior to discovery of death.
   C. Participant dying with signs or symptoms or augmentation of therapy for worsening CV condition; for example, participant who dies from progressive heart failure.
   D. Participant with documented CAD dying unexpectedly but not seen alive for 24 hours prior to discovery of death.
   E. Participant dying after a coronary artery procedure (e.g. PCI, CABG) whose death can be related temporally to the procedure or related to a documented complication of the procedure.

6. Record the description of the primary atherosclerotic vascular disease, excluding coronary disease, cause of death, indicating only one response then skip to item 9.
   A. Participant dying from cerebrovascular disease, including stoke and hemorrhage.
   B. Participant dying from aortic, mesenteric, renal vascular or peripheral vascular disease.
   C. Participant dying from procedural 9related to vascular procedures, please specify.
   D. Participant dying from other types of atherosclerotic vascular disease, please specify.

7. Record the description of the primary "other cardiovascular disease", non-atherosclerotic, cause of death, indicating only one response then skip to item 9.
   A. Participant dying from pulmonary embolism.
   B. Participant dying from endocarditis.
   C. Participant dying from valvular disease.
   D. Participant dying from procedural, please specify.

E. Participant dying from other cardiovascular disease, please specify.

8. Record the description of the primary non-cardiovascular cause of death, indicating only one response.
   A. Participant dying from infection.
   B. Participant dying from malignancy.
   C. Participant dying from pulmonary.
   D. Participant dying from gastrointestinal.
   E. Participant dying from accidental.
   F. Participant dying from suicide.
   G. Participant dying from diabetes
   H. Participant dying from renal, please specify.
   I. Participant dying from other unwitnessed non-cardiovascular causes, please specify.

9. Record "Y" if participant was hospitalized at the time of death. Record "N" if participant was not hospitalized at the time of death and skip to item 11. If the participant died in or in route to the Emergency Room then record "N".

10. Source documentation is required. Record the status of the hospital death/discharge summary, which is required to be sent to the DCC, if available. If it is available, accurate, and complete in terms of describing the participant's death, and is being sent to the DCC, record "Y", and go to item 12. If a hospital death/discharge summary is being sent to the DCC but is not complete and a physician narrative is being sent in addition record "S". If a hospital death/discharge summary is not available and cannot be obtained by the site record "N. Please record the reason why source documents are not available in a notelog.

11. If an accurate and complete hospital death/discharge summary is not available, the physician narrative should support the reasons for the death classification. This narrative should be complete and concise, and should contain all the relevant information of the participant's status/clinical course before the death.

    Examples of what to consider when completing physician narrative:

    - Did the death occur shortly after an important medical event? If so, did that non-fatal event contribute to, or directly cause the patient's death?
    - Was the patient expected to die? Describe the patient's condition in detail, prior to death (i.e. If the patient had been failing or had a poor prognosis prior to death, please explain).
    - If the patient had been stable or out of the hospital, support your cause of death and describe the circumstances by which the patient was found to have died.
    - Key autopsy findings, if performed, when report cannot be obtained.

    Record whether a physician narrative is being sent to the DCC. If a narrative is not being sent, specify the reason in a notelog.

12. Record whether an autopsy was performed. If an autopsy was not performed or if this information is unknown then skip to item 14a.

13. Record status of autopsy report. If a copy of the autopsy report is available, record "A" and send a copy to the DCC. If the report is unavailable, record "B" and send physician narrative. Record "C" if the autopsy report findings are unavailable and the investigator is unaware of any principal findings. Please record in a notelog how you reached the decision of "C" unknown if an autopsy was performed.

14a-b. Record the date and value of the last known creatinine measurement

15. Record whether the participant's death was clinically expected.

16. Record whether the participant had a recurrence of renal failure prior to death. Skip to item 18 if there was no recurrence or if this information is unknown

17a-f. Record information about the participant's acute renal failure, related complications and procedures. Complications may include, but are not limited to, increased risk of infection, gastrointestinal loss of blood, chronic renal failure, end-stage renal disease, damage to the heart or nervous system, and hypertension

17a. Record the date the participant was found to have renal failure.

17b. If there were complications of acute renal failure persent a the time of death record "Y" and specify complications.

17c. Record "Y" if the participant refusual to reinitite dialysis contributed to their death. Record "U" if this is unknown.

17d. Record "Y" if the participant died from complications related to a procedure to treat renal failure. If they did not die from complications related to a procdure to treate renal failure of if this is unknown then skip to item 18.

17e. Record the type of renal failure procedure with which participant had complications related to death
   A. Dialysis procedure
   B. Dialysis access procedure
   C. Renal re-transplation
   D. Other, please specify

17f. Record the date of the procedure.

C. Other Cardiovascular Outcomes

18. Record whether events other than death (i.e., MI, USA, Stroke, RSD, Urgent Non-CABG Coronary Revascularization or an Urgent CABG) are being recorded on this OUT. If no other events are being recorded, then skip to item 45.

19. Record date of hospital admission for the non-death events recorded on the OUT. The date of admission at the hospital may be different from the date of arrival. For example, a patient may first be taken to the emergency room (arrival at the hospital), but may not be admitted for several hours. In this case, record date of admission, which is generally recorded explicitly in the chart.

20. Source documentation is required. Record the status of the discharge summary to be sent to the DCC.

Avoid CEC queries: please review the discharge summary carefully to be sure it provides an accurate and complete description of each event reported during the hospitalization. If the requested information, as detailed in the following items for each event type, is not contained in the discharge summary, the CEC may need to query your site for more information.

If the discharge summary is incomplete or unavailable, you will need to send a physician narrative containing general information not present on the discharge summary such as admit and discharge dates, diagnoses, clinical symptoms, physical findings, relevant tests and principal findings. In addition, the narrative should give a complete description of each separate event reported on the OUT. For example, if an MI, stroke and death are reported on the OUT, the Narrative would include pertinent details related to MI (symptoms, ECGs, cardiac markers), Stroke (neurological deficits, consult/imaging results), and Death.

Complete 21a-44b for all events being reported for this hospitalization.

Items 21a – 25h document MI.

21a-c. Record whether a non-fatal MI is being reported. If an MI occurred immediately prior to death then consider this to be a non-fatal MI and record all information below. If a non-fatal MI occurred then record "Y", also record the event number and date as recorded in the HOS, items 15c-e. If multiple non-fatal MI events are recorded in the HOS, then multiple OUT forms are needed; one event per OUT. For each such additional OUT, increment the sequence number in the form header by one. If an MI is not being documented then skip to item 26a.

Examples of how MI's might be recorded in the medical records

Term
MI extension
Evolving MI
Acute MI
Aborted MI
Heart attack

22. Record whether the non-fatal MI occurred within the setting of a coronary revascularization.

23. Record whether there were ischemic symptoms (pain, dyspnea, or pressure) at rest or accelerated ischemic symptoms, lasting at least 10 minutes and secondary to ischemia (per site investigator). Please be sure to include event source documentation as requested above in Item 20.

24a-b. Record whether cardiac markers were drawn in association with this event and, if yes, record whether lab reports of the peak values of all cardiac markers (CK, CKMB, Troponin I/T) drawn are being sent to the DCC. (Lab report must include ULN and be labeled with a date and time. If CK was the only marker obtained, please provide all CK values in order to establish serial change. If Troponin was drawn and the results are given in ranges, please be sure and provide all reference range values). If markers are not being sent to the DCC please specify why then skip to item 25a

25a-c. Record whether an ECG was performed in association with this event. If yes, record whether, in the opinion of the investigator, there are new ECG changes consistent with infarction documented in association with this event. Also record the date of the ECG consistent with infarction.

25d-h. In the opinion of the investigator (not using results printed on the ECGs), record the presence of ECG changes consistent with infarction (new ST segment elevations or depressions, new Q waves, new T wave inversions, etc.).

Items 26a – 29h document unstable angina (USA).

26a-c. Record whether a USA event is being reported. If yes, also record event number and date as recorded in the HOS, items 16c-e. If multiple USA events are recorded in the HOS, then multiple OUT forms are needed, one event per OUT. For each such additional OUT, increment the sequence number in the form header by one. If an USA is not being reported, then skip to item 30a

Examples of how USA's might be recorded in the medical records

Term	Comments
Ischemic pain	
Substernal pain	Only if due to myocardial ischemia
Chest tightness	Only if due to myocardial ischemia

27. Record whether there were ischemic symptoms (pain, dyspnea, or pressure) at rest or accelerated ischemic symptoms, lasting at least 10 minutes and secondary to ischemia (per site investigator). Please be sure to include event source documentation as requested above in Item 20.

28a-b. Record whether cardiac markers were drawn in association with this event and, if yes, record whether lab reports of the peak values of all cardiac markers (CK, CKMB, Troponin I/T) drawn are being sent to the DCC. (Lab report must include ULN and be labeled with a date and time. If CK was the only marker obtained, please provide all CK values in order to establish serial change. If Troponin was drawn and the results are given in ranges, please be sure and provide all reference range values). If markers are not being sent to the DCC please specify why then skip to item 30a

29a-c. Record whether an ECG was performed in association with this event. If yes, record whether, in the opinion of the investigator, there are new ECG changes consistent with ischemia documented in association with this event. Also record the date of the ECG consistent with ischemia. If no, skip to item 30a.

29d-h. In the opinion of the investigator (not using results printed on the ECGs), record the presence of ECG changes (e.g. new and dynamic ST segment elevations or depressions, new T wave inversions, etc.).

Items 30 – 34b document non-fatal stroke.

30a-c. Record whether a non-fatal stroke is being reported. If a stroke occurred immediately prior to death then consider this to be a non-fatal stroke and record all information below. If a non-fatal stroke occurred record "Y", also record event number and date as recorded in the HOS, items 17c-e. If multiple non-fatal stroke events are recorded in the HOS, then multiple OUT forms are needed, one event per OUT. For each such additional OUT, increment the sequence number in the form header by one. If a non-fatal stroke is not being reported then skip to item 35a.

Examples of how Stroke's might be recorded in the medical records

Term	Comments
Cortical infarction	Only if symptoms persist for 24 hours
Intracranial hemorrhage	Only if symptoms persist for 24 hours
Cerebral thrombosis	Only if symptoms persist for 24 hours
Cerebral artery occlusion	Only if symptoms persist for 24 hours
Cerebral infarction	Only if symptoms persist for 24 hours
Subarachnoid hemorrhage	Only if symptoms persist for 24 hours
Brain attach	Only if symptoms persist for 24 hours
Cerebral vascular incident	Only if symptoms persist for 24 hours
Apoplexy	Only if symptoms persist for 24 hours
Cerebrovascular accident (CVA)	Only if symptoms persist for 24 hours

31. Record whether the participant suffered a neurological deficit (e.g. aphasia, dysarthria, localized motor weakness, localized sensory alterations etc.) of sudden onset (not attributed to a readily identifiable cause such as brain tumor or trauma). Please be sure to include event source documentation as requested above in Item 20. If the participant did not suffer a neurological deficit of sudden onset or if this information is unknown then skip to item 35a.

32. Record whether the neurological deficit was reversible within 24 hours.

33a. Record whether a neurology consult was performed in association with this event. If no, skip to item 34a.

33b. Record "Y" if report is being sent to the DCC; record "N" if you are unable to obtain a copy of this report but a physician narrative of the principal findings is being sent to the DCC; record "F" if you are unable to report on any findings of the neurology consult.

34a. Record whether imaging studies were performed in association with the reported event. If imaging studies were not performed or if this information is unknown then skip to item 35a

34b. Record "Y" if report is being sent to the DCC; record "N" if you are unable to obtain a copy of this report but a physician narrative of the principal findings is being sent to the DCC; record "F" if you are unable to report on any findings of the imaging studies.

Items 35a – 38 document resuscitated sudden death (RSD).

35a-c. Record whether RSD is being reported. If yes, also record event number and date as recorded in the HOS, items 18c-e. If multiple RSD events are recorded in the HOS, then multiple OUT forms are needed, one event per OUT. For each such additional OUT, increment the sequence number in the form header by one. If an RSD is not being reported then skip to item 39

Examples of how RSD's might be recorded in the medical records.

Term	Comments
Cardiopulmonary resuscitation	
Closed chest massage	
Cardioversion	But **not** as part of CABG or EP studies

36. Record whether the patient suffered a loss of consciousness due to cardiac arrest, excluding transient losses of consciousness due to seizure or vasovagal episodes

37a-d. Record the resuscitative means used in association with this event.

38. Record the patient's status after resuscitation. Record "A" if the patient was resuscitated but then later died in the setting of this acute event; record "B" if the patient was resuscitated (i.e. circulation restored) but did not regain consciousness (i.e. patient was intubated as a result of the event); record "C" if the patient was resuscitated and was able to regain consciousness after the event (i.e. patient survived the event and may have later been discharged after suffering cardiac arrest); record "D" if unknown.

Items 39 – 41b document urgent non-CABG coronary revascularization.

39. Record whether an urgent non-CABG coronary revascularization procedure occurred (PCI, laser rotational/directional/extraction atherectomy, stent implants, Vineberg). If no, skip to item 42.

40a. Record whether there were pathologic Q waves or other wall-motion abnormalities identified peri-operatively. If yes, provide documentation of this (i.e., two comparative ECGs documenting new Q waves or echo report documenting wall-motion abnormality). If no, skip to item 41a

40b. Record whether the ECG or echo report is being sent to the DCC. Record "Y" if report is being sent to the DCC; record "N" if you are unable to obtain a copy of this report but a physician narrative of the principal findings is being sent to the DCC; record "F" if you are unable to report on any findings of the ECG or echo.

41a. Record whether there were cardiac marker elevations $\geq$ 3 time the ULN and $\geq$ 50% above last measurement, if last measure was $\geq$ ULN. If yes, provide cardiac marker documentation of all markers drawn before and within 24 hours of procedure. If no, skip to item 42.

41b. Record whether the Lab Report documenting all cardiac markers drawn is being sent to the DCC. Record "Y" if report is being sent to the DCC. If the lab report documents only some of the cardiac markers that were drawn please explain this in the physicians narrative. Record "N" if you are unable to obtain a copy of this report but a physician narrative of the principal findings is being sent to the DCC. Record "F" if you are unable to report on any findings of the cardiac markers.

Items 42 – 44b document urgent CABG revascularization

42. Record whether urgent CABG revascularization is being reported. If an urgent CABG Revascularization is not being reported then skip to item 45

43a. Record whether there were new pathologic Q waves or other wall-motion abnormalities identified peri-operatively. If yes, provide documentation of this (i.e., two comparative ECGs documenting new Q waves or echo report documenting wall-motion abnormality). If no, skip to item 44a

43b. Record whether the ECG or an echo report is being sent to the DCC. Record "Y" if report is being sent to the DCC; record "N" if you are unable to obtain a copy of this report but a physician narrative of the principal findings is being sent to the DCC; record "F" if you are unable to report on any findings of the ECG or echo.

44a. Record whether there were cardiac marker elevations $\geq$ 5 times the ULN and $\geq$ 50% above last measurement, if last measure was $\geq$ ULN. If yes, provide cardiac marker documentation of all markers drawn before and within 24 hours of procedure. If no, then skip to item 45.

44b. Record whether the Lab Report documenting all cardiac markers drawn is being sent to the DCC. Record "Y" if report is being sent to the DCC. If the lab report documents only some of the cardiac markers that were drawn please explain this in the physicians narrative. Record "N" if you are unable to obtain a copy of this report but a physician narrative of the principal findings is being sent to the DCC. Record "F" if you are unable to report on any findings of the cardiac markers.

D. Sign off

45. Record your certified initials.

46. Record the date of data collection.

47. Site investigator should sign form and print name. If you entered this OUT directly into the DMS without entering it on a paper form then please print a copy of this OUT from the DMS and have the site investigator sign the DMS copy. This signed copy is to be placed in the participant's folder. It does NOT need to be sent to the DCC.

48. Record the date signed by site investigator.