

**HEALTH ABC**  
**DEATH ADJUDICATION PROTOCOL**  
(REVISED MAY 2009)

**I. Definitions**

1) Death

- Absence of life-sustaining heart rhythm, i.e., ventricular fibrillation, asystole
- Failure to breathe on own
- Failure to regain consciousness
- Without vital signs (no heart rate and no systolic blood pressure, or on a respirator with no pulse rate or systolic blood pressure at any time off the respirator).

2) Fatal event

A clinical event such as a heart attack or a stroke that results in the death of a participant. This may be synonymous with the onset of acute symptoms if the participant dies when the event begins (or, death may follow the acute symptoms by several hours or days.)

3) In-hospital death

A death that occurs during the course of a hospital admission.

4) Out-of-hospital death

- Deaths occurring outside of regular acute-care hospitals
- Deaths occurring in hospital emergency rooms or outpatient departments
- Participants dead on arrival
- Participants admitted without vital signs, that is persons:
  - with no heart rate and no systolic blood pressure, or
  - on a respirator with no pulse or systolic blood pressure at any time off the respirator.

5) Hospital admission

A hospital admission occurs when the attending physician admits a participant to an acute-care hospital. An overnight stay is required to meet the definition of a hospital admission.

**II. Ascertainment of Deaths during Surveillance**

1) Semi annual telephone interview-proxy

2) Annual clinic visit-proxy

3) Scheduling of annual clinic visits-proxy

4) Proxy, spouse, relative, or friends contact field center to report hospitalization

5) Hospital medical records from later event indicate a death occurred.

- 6) HCFA tape review
- 7) Obituary
- 8) National Death Index search

### **III. Health ABC Data Collection Forms to be Completed by Examiners and Events Coordinators (or their designates) at the Field Centers**

- 1) Data collection forms required for all deaths
  - a) Health ABC Event Form
  - b) Report of Death
  - c) Decedent Proxy Interview
  - d) Final Death Adjudication Report (at central adjudication)
- 2) Data collection forms also required for in-hospital deaths
  - a) Discharge Abstract Form
  - b) Local Adjudication Report
  - c) As appropriate:
    - Cancer Adjudication Report
    - Cardiovascular Disease Adjudication Report
    - Fracture Adjudication Report

An in-hospital death, in which a participant is actually admitted to the hospital, not just from the ER, should be adjudicated with Discharge Abstract Form and Local Adjudication Report, even if the stay is not overnight.

- 3) Data collection forms also required for out-of-hospital deaths
  - a) Informant Interview for Out-of-Hospital Deaths
  - b) As appropriate:
    - Cancer Adjudication Report
    - Cardiovascular Disease Adjudication Report
    - Fracture Adjudication Report

### **IV. Documentation to be Requested for Deaths by Events Coordinator (or their designates)**

- 1) Death certificate (for ALL deaths)
- 2) Coroner's/medical examiner's investigative report (if death certified by a coroner or medical examiner)
- 3) Autopsy results (if autopsy performed)
- 4) Face sheet or physician attestation with ICD codes and Discharge summary (if in-hospital death)
- 5) Event-specific documentation may include:
  - History and physical exam
  - ECG
  - Cardiac enzymes

- Cardiac catheterization
- Stress test
- Echocardiography
- Carotid dopplers
- Carotid angiogram
- Lower extremity doppler
- Lower extremity angiography
- Exercise test
- CT head
- MRI brain
- Neurology consult
- Chest x-ray report
- Arterial blood gases report
- Pulmonary function test results
- Microbiology report of blood culture, sputum culture, transtracheal aspirate, bronchial brushing, or biopsy
- Endoscopy report
- Upper GI report
- Angiography report
- Barium enema/lower GI report
- Radiology report
- Pathology report

## **V) Procedures**

Once the Health ABC field center is notified of the death of a participant, the following protocol should be followed:

- 1) An Event Form is completed by examiner or Event Coordinator at the local field center once notified of death.
- 2) The completed Event Form is scanned into data system.
- 3) A copy of the Event Form is forwarded to the Event Coordinator at the local field center.
- 4) The Event Coordinator enters tracking information into the web-based D and D tracking system.
- 5) An interviewer from the clinic calls the designated proxy or next of kin to complete the Decedent Proxy Interview. After interviewing the designated proxy or next of kin and completing the Decedent Proxy Interview, the interviewer determines whether the death was an in-hospital or out-of-hospital death. If the interviewer determines that the event was an out-of-hospital death, the Informant Interview for Out-of-Hospital Deaths will be completed at this time. If the interviewer determines that the event was an in-hospital death, then the interviewer would attempt to obtain a release for the deceased participant's medical records.
- 6) Once completed, the Decedent Proxy Interview form is scanned into data system.
- 7) Event Coordinator requests:
  - a) Death certificate

- b) Coroner's/medical examiner's investigative report (if death certified by a coroner or medical examiner)
  - c) Autopsy results (if autopsy performed)
  - d) Face sheet or physician attestation with ICD codes and Discharge summary (if in-hospital death)
  - e) Event-specific documentation (refer to Section IV.5 above)
- 8) The Event Coordinator notes first request for documentation in the D and D tracking system.
  - 9) If necessary, the Event Coordinator makes second request for documentation.
  - 10) The Event Coordinator notes second (and all additional) requests for documentation in the D and D tracking system.
  - 11) All documentation received is noted in the D and D tracking system.
  - 12) Once all documentation is received, the appropriate data collection forms, depending on whether death was an in-hospital or out-of-hospital death and what events preceded the death (refer to Section III) are completed.
  - 13) Event Coordinator notes the date the event packet is complete (documentation received and all appropriate data collection forms filled out) in the D and D tracking system.
  - 14) Deaths are centrally adjudicated by the Disease and Diagnosis Ascertainment Adjudication Subcommittee (refer to Section VIII for description of adjudication process).
  - 15) Once death is centrally adjudicated, all data collection forms are entered into the data system.
  - 16) The final status of the adjudicated death is entered into the D and D tracking system. The death is officially closed.

## **VI) Completing the Report of Death form**

Question #1: Record the Health ABC Event Form reference number from the lower left-hand corner of the Event Form.

Question #2: Record the date of death that is in Section IV of the Health ABC Event Form. Note that this date may simply be the best guess of the person reporting the event.

Question #3: Record the date of death that is on the death certificate.

Question #4: Record the location of the death as noted on the death certificate. If the death is an in-hospital death, indicate whether a Discharge Abstract Form and the Location Adjudication Report are attached to the Report of Death form. Do not staple the Discharge Abstract Form and the Location Adjudication Report to the Report of Death form, since this may interfere with the scanning of the data forms. Note that the actual adjudicated location of death is recorded in Question #8.

Question #5: Indicate whether a copy of the death certificate is attached to the Report of Death form. If a copy of the death certificate is attached, indicate whether the death certificate was certified by a coroner/medical examiner.

Do not staple the death certificate or the coroner's/medical examiner's investigative report to the Report of Death form, since this may interfere with the scanning of the data forms.

Question #6: Indicate whether an autopsy was performed. If available, do not staple the autopsy results to the Report of Death form, since this may interfere with the scanning of the data forms.

Question #7: Write in both the immediate and underlying cause of death as recorded on the death certificate in the space provided. Be sure to print clearly. Refer to list of sanctioned abbreviations.

Question #8: Mark the actual adjudicated location of the death, indicating whether the death occurred in a hospital (inpatient death), emergency room, nursing home, hospice (not within a hospital), residence, or other location. If the location is unknown, indicate that by filling in the appropriate bubble. The Event Coordinator can answer this question before the Disease and Diagnosis Ascertainment Adjudication Subcommittee meets to adjudicate death events. If, however, the Subcommittee disagrees with the location of death recorded by the local Event Coordinator, the local Event Coordinator is responsible for changing the answer recorded on the form to reflect the adjudicated location.

Question #9: Indicate whether the death was witnessed. A "witnessed" death is any death in a private residence or non-medical location in which someone else is present in the building, whether or not anyone actually sees the person dying. Often a family member hears a person fall, or a family member is sleeping in the house when a person dies in his sleep. These cases are considered witnessed deaths. All deaths that are inpatient, or in a nursing home or hospice are considered witnessed.

Question #10: Write in a description of the events surrounding the death. Be as detailed as possible. Be sure to print clearly. Refer to list of sanctioned abbreviations.

Question #11: Mark ONE classification of the underlying cause of death. Refer to the decision rules in Section VII, if necessary. The response to this question will be considered the adjudicated cause of death and will be used in analyses.

The Event Coordinator can answer this question before the Disease and Diagnosis Ascertainment Adjudication Subcommittee meets to adjudicate death events. If, however, the Subcommittee disagrees with the classification of the underlying cause of death recorded by the local Event Coordinator, the local Event Coordinator is responsible for changing the answer recorded on the form to reflect the adjudicated underlying cause of death.

Question #12: Indicate whether the death was procedure related.

## **VII. Adjudication of Deaths**

- 1) Deaths are centrally adjudicated by the Disease and Diagnosis Ascertainment Adjudication Subcommittee. Representatives from both field centers, the NIA Project Office, and the UCSF Coordinating Center are represented on this Subcommittee.
- 2) The central adjudication of deaths involves agreement of the Subcommittee concerning the location of the death (inpatient hospital, emergency room, nursing home, hospice – not within a hospital, residence, or some other location) and the classification of the underlying cause of death.
- 3) Complete packets consisting of copies of the following are forwarded by the Event Coordinators at the field centers to the UCSF Coordinating Center:
  - Report of Death
  - Decedent Proxy Interview
  - Informant Interview for Out-of-Hospital Deaths (if applicable)
  - Event-specific documentation (refer to Section IV, #5 above)
  - Discharge Abstract Form (if applicable)
  - Local Adjudication Report (if applicable)
  - Cancer Adjudication Report (if applicable)
  - Cardiovascular Disease Adjudication Report (if applicable)
  - Fracture Adjudication Report (if applicable)
  - Medical Record and Death Certificate documentation appropriate for the case

The complete packets are sent by express mail to the Coordinating Center a minimum of 2 weeks before Disease and Diagnosis Ascertainment Adjudication Subcommittee meeting (whether the adjudication meeting occurs by phone or face-to-face). A specific timeline for the receipt of completed packets will be provided by the Coordinating Center.

- 4) The Coordinating Center will make copies of each packet documenting a death for every member on the Disease and Diagnosis Ascertainment Adjudication Subcommittee.
- 5) The Coordinating Center will distribute copies of each packet to the Subcommittee members at least 2 weeks prior to an adjudication meeting.
- 6) The Disease and Diagnosis Ascertainment Adjudication Subcommittee reviews the documentation for each death event prior to the adjudication meetings. Upon central adjudication, the Event Coordinator at the field center where the event occurred thoroughly completes the Death Adjudication Report, ensuring that the final resolution of the immediate and underlying cause of death are accurately recorded on the form (question #2 and #3, respectively). If the classification of the immediate and underlying cause of death that were recorded on the Report of Death form differ from what is ultimately recorded on the Death Adjudication Report, the Report of Death form does NOT need to be changed so that the responses on both forms are consistent.
- 7) The Event Coordinator closes out the death in D and D tracking system.

## VIII. Completing the Death Adjudication Report

The Death Adjudication Report is completed when the Disease and Diagnosis Ascertainment Adjudication Subcommittee meets to centrally adjudicate death events.

Question #1: Record the Health ABC Event Form reference number from the lower left-hand corner of the Event Form.

Question #2: After the death has been reviewed and adjudicated by the D and D Ascertainment Adjudication Subcommittee, mark the ONE classification for the immediate cause of death. Refer to the decision rules in Section VIII, if necessary. The response to this question will be considered the adjudicated immediate cause of death and will be used in analyses.

Question #3: After the death has been reviewed and adjudicated by the D and D Ascertainment Adjudication Subcommittee, mark the ONE classification for the underlying cause of death. Refer to the decision rules in Section VIII, if necessary. The response to this question will be considered the adjudicated underlying cause of death and will be used in analyses.

Question #4: Indicate whether the death (either the immediate or underlying cause) was procedure-related.

Question #5: Indicate whether the death (either the immediate or underlying cause) was fall-related.

Question #6: Indicate whether there was any mention of dementia in the death packet.

Question #7: Indicate whether the final adjudication decision concerning the immediate and underlying cause of death was unanimous. If there was any disagreement among the members of the D and D Ascertainment Adjudication Subcommittee regarding the immediate and/or underlying causes of death, mark that the final adjudication was NOT unanimous.

## IX. Decision Rules

### ***General***

- 1) The coroner's report is not required for death adjudication.
- 2) Each death event will be categorized as to the immediate and the underlying cause. For example, if a participant was seriously ill with cancer and died of renal failure caused by their cancer, the immediate cause of death would be renal failure and the underlying cause of death would be cancer. The D and D Ascertainment Adjudication Subcommittee will make a final decision regarding the each immediate and underlying cause of death.

For deaths that occur in persons with underlying chronic conditions, but no specific cause of death can be determined (e.g., death in a hospice or under hospice care), then the underlying, chronic condition will be considered to be the cause of death. If a participant has an underlying chronic condition, and an unrelated event occurs that is likely to have caused their death, then the unrelated event would be the cause of death.

- 3) Do not code a *procedure* as an underlying cause of death.
- 4) If a participant is admitted to hospital and dies within 24 hours of admission, a Discharge Abstract Form and Local Adjudicator Report should be completed for that admission.
- 5) If a participant is 'hospitalized' as either admitted overnight, or admitted but died that day, a Local Adjudicator Report should be completed.
- 6) If a participant dies out of the hospital and is brought to the hospital to be pronounced dead, or if a person is brought to the hospital and dies in the ER, they are never admitted (being in the ER is not considered 'admitted'); do NOT complete a Discharge Abstract Form or Local Adjudicator Report.
- 7) In-hospital deaths, in which a participant is actually admitted to the hospital, not just the ER, should be adjudicated with a Discharge Abstract Form and Local Adjudicator Report, even if the stay is not overnight.

#### ***Location of Death / Witnessed Deaths***

- 1) For actual adjudicated location of death -- A participant, who has been treated in a hospital and moved to a hospice or skilled nursing facility located within the hospital (or which is a part of the hospital) and then dies, is considered to have had an inpatient or in-hospital death. If the death occurs outside of an acute care hospital on the same day that the participant was discharged from the acute care hospital, then the hospitalization and death should be treated as one event. If the death occurs on a different day from the discharge from an acute care hospital, then the hospitalization and death should be treated as two events.
- 2) If the participant is brought to the emergency room but has no vital signs at any point during the resuscitation efforts, the death is 'out of hospital'. If resuscitation is still being attempted in the emergency room and there are vital signs at any time during that effort (pulse, respirations, heart rhythm), then the place of death is the emergency room.
- 3) A "witnessed" death is any death in a private residence in which someone else is present in the residence, whether or not anyone actually sees the person dying. Often a family member hears a person fall, or a family member is sleeping in the house when a person dies in his sleep. These cases are considered witnessed deaths.
- 4) All deaths in a health care facility including hospitals, nursing homes, SNFs etc. are considered 'witnessed'.

## **Cancer**

- 1) For cancer deaths, include the Cancer Adjudication Report from the incident cancer diagnosis, and the associated source documents such as the pathology report(s), and/or diagnoses.
- 2) A cancer death requires pathological confirmation of the cancer, or radiologic confirmation without evidence of other cause of death. The cancer adjudication form is completed as a part of the death packet only if the cancer was first diagnosed during this death event. If the cancer was diagnosed during an earlier hospitalization or outpatient event, the cancer form should be completed for that earlier event.
- 3) *Cancer* as underlying cause of death includes:
  - a) end stage cancer with metastasis and hospice care;
  - b) death due to complications of immediate cancer treatment including surgical resection, radiation, or chemotherapy.
- 4) When the underlying cause is a *cancer* and the death is out of the hospital, the immediate cause should be *unknown*.
- 5) When the underlying cause is a *cancer* and the death is in the hospital, the immediate cause should be the same *cancer* unless there is a specific additional mechanism to which the immediate cause can be attributed (i.e., multisystem failure).

## **Cardiovascular**

- 1) Deaths due to small bowel/colon infarct, abdominal or thoracic aortic aneurysm should be categorized as deaths due to *Atherosclerotic Disease, Other than Coronary or Cerebrovascular* in Question #11 on the Report of Death form.
- 2) Deaths due to pulmonary embolism should be categorized as *Other Cardiovascular Disease, Other* in Question #11 on the Report of Death form.
- 3) For deaths in which both a stroke and myocardial infarction are simultaneously clinically diagnosed, but it is not possible to determine which occurred first, *stroke* should be considered as the primary cause of death.
- 4) When the underlying cause is *CHD (definite fatal MI, definite fatal CHD or possible fatal CHD)* and the death occurred out of the hospital, the immediate cause should be the same *CHD* as the underlying cause.
- 5) When the underlying cause is *CHD (definite fatal MI, definite fatal CHD or possible fatal CHD)* and the death occurred in the hospital, the immediate cause should be the same *CHD* as the underlying cause unless there is a specific additional mechanism to which the immediate cause can be attributed.
- 6) When the underlying cause is *stroke* and the death occurred out of the hospital, the immediate cause should be the *stroke*.
- 7) When the underlying cause is *stroke* and the death occurred in the hospital, the immediate cause should be *stroke* unless there is a specific additional mechanism to which the immediate cause can be attributed.
- 8) Do not use *cardiorespiratory arrest* as an immediate or underlying cause of death.

- 9) If cognitive decline appears to be initiated from one or more discreet clinically recognized disabling strokes that lead to a picture of end stage disability/dementia/death, we will call the death a *stroke* death.

### ***Cognitive Decline/Dementia***

- 1) *Dementia* as underlying cause of death includes:
  - a) complications of end stage dementia, defined as unable to walk, difficulty swallowing, or dependent in all ADL's with aspiration pneumonia, dehydration, urosepsis, sepsis from decubitus ulcer, or malnutrition;
  - b) dementia is so advanced that treatment is refused or is not feasible regarding dialysis, surgery, antibiotics, IV fluids.
  - c) The cognitive decline must clearly have been observed for six months or more.
- 2) If the cognitive decline appears to be initiated from one or more discreet clinically recognized disabling strokes that lead to a picture of end stage disability/dementia/death, we will call the death a *stroke* death.
- 3) If the dementia was advanced and the diagnosis of stroke was made only from a scan, and this leads to end stage dementia death, we will call it a *dementia* death.
- 4) If the cognitive decline is directly associated with progressive *Parkinson's disease*, then we will call the death a *Parkinson's disease* death.

### ***Gastrointestinal***

- 1) When the underlying cause is *small bowel infarction*, the immediate cause should be the same unless an additional mechanism occurred.
- 2) When the underlying cause is *small bowel obstruction*, the immediate cause should be a more proximal condition or complication (i.e., sepsis).
- 3) Deaths due to small bowel/colon infarct, abdominal or thoracic aortic aneurysm should be categorized as deaths due to *Atherosclerotic Disease, Other than Coronary or Cerebrovascular* in Question #11 on the Report of Death form.

### ***Procedure-related***

- 1) A death will be considered procedure-related if the majority of the Disease and Diagnosis Ascertainment Committee agrees that the procedure is likely to have caused the death.
- 2) If the death is an immediate complication of the procedure, then the box "procedure-related" should be checked.
- 3) If the patient would have died without attempting the procedure, then death should not be called procedure-related.
- 4) If the death is a complication of a procedure from years ago that was initially successful, then death is not procedure-related. For example, previous abdominal surgery with death much later related to adhesions is not procedure-related. This is because the procedure-related code is primarily meant to capture iatrogenic illness.

- 5) A death might be noted as procedure-related, but, in the same case, an MI might not be noted as procedure-related on the Cardiovascular Disease Adjudication Report form.

### ***Pulmonary/Respiratory***

- 1) When the underlying cause is *COPD*, *pulmonary fibrosis* or another chronic lung condition, the immediate cause should be *respiratory failure* unless there is a specific additional mechanism to which the immediate cause can be attributed. In addition to chronic lung disease, *respiratory failure* should be used as the immediate cause when it is the consequence of a non-pulmonary underlying cause resulting in the subject developing ARDS and/or becoming ventilator dependent.
- 2) When the underlying cause is *pneumonia*, the immediate cause should also be coded as *pneumonia* in order to reflect the acute condition without additional mechanisms or complications.
- 3) When the immediate cause is *pulmonary embolism*, and there is no known condition that caused the PE, then the underlying cause should also be *pulmonary embolism*. When the cause of the PE is a known medical condition (not a procedure), then the medical condition should be the underlying cause of death. (e.g., Cancer/coagulopathy/PE)
- 4) Deaths due to pulmonary embolism should be categorized as *Other Cardiovascular Disease, Other* in Question #11 on the Report of Death form.
- 5) Do not use *cardiorespiratory arrest* as an immediate or underlying cause of death.

### ***Renal Failure***

- 1) When the underlying cause is *renal failure*, the immediate cause should also be *renal failure* unless there is a specific additional mechanism to which the immediate cause can be attributed. If the renal failure was a complication of another underlying condition identified during the same hospitalization, and the renal failure resulted in the death, *renal failure* should be the immediate cause and the condition causing the renal failure should be the underlying cause.
- 2) *Renal failure* as an underlying cause of death includes:
  - a) an inability to tolerate dialysis due to poor or infected access or refusal of dialysis;
  - b) when it is the predominant failing organ;
  - c) If the *renal failure* is caused by end stage CHD-CHF, multiple myeloma, or sepsis, then *renal failure* is the immediate not underlying cause.

### ***Sudden Death***

- 1) Classification of sudden death (includes "found dead"):  
To determine whether or not the participant had a history of CHD, refer to Questions #93 and #94 in the Baseline Questionnaire (pages 49 and 50).

The subclasses of fatal coronary heart disease are as follows:

- a) Definite fatal MI: no known non-atherosclerotic cause, and definite MI within 4 weeks of death.
- b) Definite fatal CHD: no known non-atherosclerotic cause, and one or both of the following: chest pain within 72 hours of death or a history of chronic ischemic heart disease in the absence of valvular heart disease or non-ischemic cardiomyopathy.
- c) Possible fatal CHD: no known non-atherosclerotic cause, and death certificate consistent with underlying cause. Do not count other vascular conditions (CVA, PVD, etc.) or procedures such as fem-pop bypass or carotid endarterectomy as CHD history equivalent. Must have history of CHD (in the heart) including MI, angina, CABG, or PTCA.