

Framingham Heart Study

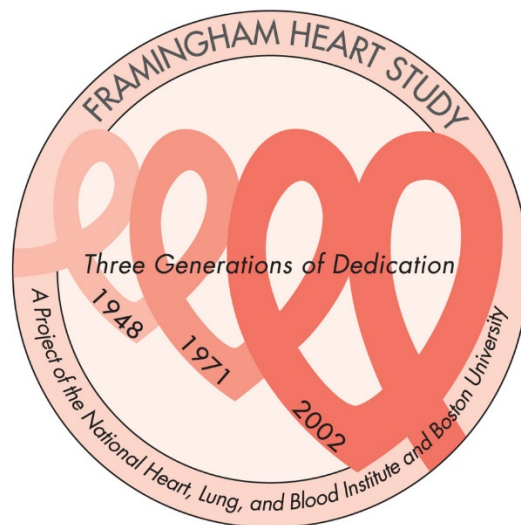
Manual of Procedures

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Endpoint Review Manual





Tracking of Revisions to this FHS Protocol MOP

Revised Section	Revision Author	Date (s) of Revisions; source	Approved by, Date	Revisions	Previous Pages #s section changed	Distribution Date
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1.0 Framingham Heart Study Endpoint Review: Overview

(last revised: 08/01/2018)

PRIOR TO REVIEW SESSIONS

The endpoint review administrator schedules review sessions with physicians trained to adjudicate cases according to Framingham Heart Study Criteria for Events. Two to three physicians are needed for cardiovascular events including death reviews, depending on the cases being presented. Two neurologists are needed for stroke reviews. Cases presented to a panel of physicians have been prepared according to standardized protocols. All pertinent information is highlighted, and all tests, procedures, labs, and imaging reports are flagged to ensure the review process moves along quickly.

AT REVIEW

The administrator presents medical records and FHS exam information in chronological order for each case and informs the physicians of the symptoms described in each medical record (e.g., chest pain, shortness of breath). One physician reads the notes or clinic exam information while the other physicians look at the ECGs. The physicians then give their independent vote as to whether a new event has occurred. They also do independent readings of the ECGs and serial readings if there is any question of an acute or remote MI. During the review session, the administrator documents all findings on evaluation forms and codes Sequence of Events forms for each new or questionable event and each cardiovascular procedure.

DEATH REVIEW

All records pertinent to a participant's death, including hospitalizations, physician visits and nursing home notes, pathology and other testing, are reviewed. An FHS Sequence of Events code is assigned for cause of death, and an SOE death form is completed listing underlying, immediate and contributing causes of death. If a subject is deceased, and information regarding the circumstances or cause of death is not available, a *Cause of Death Interview* (CODI) form, which an FHS physician has completed after speaking with the next of kin, is reviewed to ascertain cause of death.

Death certificates are requested for every participant known to be deceased. They are useful for next of kin and place/date of death information. However, the cause of death listed on death certificates is known to sometimes be inaccurate due to a lack of information at the time of death. Therefore, information on a death certificate may be considered when determining cause of death, but medical records should be the primary source of information.

All death certificates through 2001 were ICD coded and are filed in the Review Room.

VALIDATION AFTER REGULAR REVIEW

After review sessions, the date of each medical record and review findings are recorded in each participant's *Summary of Findings*. All new events are entered into the *Sequence of Events* log.

Forms are separated from medical records. If a new event has occurred, the first page of the SOE form is copied and attached to the evaluation form. Evaluation forms and SOE forms are set aside to be checked for accuracy at a later date. All entries in the SOE log are also checked.

2.0 Framingham Heart Study Criteria for Events

(last revised: 08/24/2006)

1. Cardiovascular Disease

Cardiovascular disease is considered to have developed if there was a definite manifestation of coronary heart disease, intermittent claudication, congestive heart failure, or stroke or transient ischemic attack in the absence of a previous manifestation of any of these diseases. Criteria for all these events are given below. A person having more than one cardiovascular manifestation within the follow-up period is counted as an incident case only at the time of the first event.

2. Coronary Heart Disease

Subjects are diagnosed as having developed coronary heart disease (CHD) if upon review of the case a panel of three investigators (the Framingham Endpoint Review Committee) agrees on one of the following definite manifestations of CHD: myocardial infarction, coronary insufficiency, angina pectoris, sudden death from CHD, non-sudden death from CHD. Persons with pre-existing CHD at Exam 1 are excluded from the population at risk of developing CHD but may be eligible for studies of prevalent CHD. Pre-existing CHD at Exam 1 is identified by any one of the following diagnoses at Exam 1: definite angina pectoris, definite history of myocardial infarction, definite myocardial infarction by electrocardiogram, doubtful myocardial infarction by electrocardiogram, definite coronary insufficiency by electrocardiogram and history.

The various manifestations of CHD are these:

Angina Pectoris

Brief recurrent chest discomfort of up to 15 minutes duration, precipitated by exertion or emotion and relieved by rest or by nitroglycerine is regarded as angina pectoris (AP) if two physicians interviewing the subject at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition was definitely present. This diagnosis is based solely on evaluation of subjective manifestations. Abnormality of the resting or exercise electrocardiogram is not required for this diagnosis.

Myocardial Infarction

Recent or acute myocardial infarction (MI) is designated when there were at least two of three findings:

- 1) symptoms indicative of ischemia;
- 2) changes in biomarkers of myocardial necrosis;

- 3) serial changes in the electrocardiograms indicating the evolution of an infarction, including the loss of initial QRS potentials (that is, development of “pathologic” Q-waves of 0.04 second duration or greater).

An old or remote myocardial infarction is considered to be present when the electrocardiogram shows a stable pattern including a pathologic Q-wave of 0.04 second or greater or loss of initial QRS potential R-wave in those leads in which this would not be expected to occur. Also, an interim unrecognized MI is indicated when changes from a previous tracing show development of loss of R-wave potential or appearance of pathologic Q-waves not otherwise explained, in persons in whom neither the patient nor his physician considered the possibility of MI. If the patient was asymptomatic for chest pain or upper abdominal pain during the interval at which the unrecognized MI occurred, the event is classified as silent, unrecognized. More weight is given to this finding if a T-wave abnormality is also associated with Q-wave abnormality.

An autopsy report showing an acute, new, or recent infarction of the myocardium is accepted as evidence of an incident myocardial infarction. Because it is not possible to date an old infarction found on autopsy, such evidence is not used in the clinical diagnosis of a new event, unless there was an interim clinical event suspected of being an infarction.

Coronary Insufficiency

The coronary insufficiency syndrome is designated when a history of prolonged ischemic chest pain (> 15 minutes duration) was accompanied by transient ischemic S-T segment and T-wave abnormality in the electrocardiographic tracing but not accompanied by development of Q-wave abnormality or by serum enzyme changes characteristic of myocardial necrosis.

Coronary Heart Disease Death

Death from coronary heart disease is diagnosed as either sudden or nonsudden. For a detailed description of these diagnoses, see 6 below.

3. Stroke

The diagnosis of cerebrovascular disease is based on the occurrence of a clinically evident stroke documented by clinical records reviewed by at least two neurologists. Stroke is defined as the sudden or rapid onset of a focal neurologic deficit persisting for greater than 24 hours. Stroke is further categorized into infarction or hemorrhage.

Hemorrhagic Stroke

The diagnosis of subarachnoid hemorrhage is based on a history suggestive of this process such as abrupt onset headache, with or without change in the level of

consciousness, and signs of meningeal irritation with or without other localizing neurological deficits. Intracerebral hemorrhage is diagnosed clinically by the occurrence of abrupt focal neurologic deficit, often with altered level of consciousness and symptoms of increased intracranial pressure. Hemorrhages are confirmed by imaging.

Ischemic Stroke

A diagnosis of cerebral embolism is made when an established source for embolus including atrial fibrillation, rheumatic heart disease with mitral stenosis, recent myocardial infarction, bacterial endocarditis or other known source is determined. A clinical course consistent with embolic infarction or evidence of other systemic embolism may be present. Symptoms are usually rapid with maximal severity at onset.

Antherothrombotic brain infarction is defined as the sudden onset of a focal neurologic deficit lasting longer than 24 hours, in the absence of:

- 1) known source of embolism (atrial fibrillation, rheumatic heart disease with mitral stenosis, myocardial infarction within preceding six months, bacterial endocarditis);
- 2) intracranial hemorrhage (intracerebral or subarachnoid);
- 3) known hypercoagulable states;
- 4) other disease processes causing focal neurologic deficits (brain tumor, subdural hematoma, hypoglycemia).

Confirmatory imaging supports the diagnosis.

Silent stroke may be documented at the stroke review sessions when a stroke event is determined and an incidental infarct is seen on brain imaging in the absence of a reported clinical event.

Transient ischemic attack

A transient ischemic attack is defined as a focal neurologic deficit of sudden or rapid onset that fully resolves in less than 24 hours.

Stroke Death

Death attributed to stroke is designated when a documented focal neurologic deficit of greater than 24 hours duration preceded death and was responsible for the fatality.

4. Intermittent claudication

Minimum criteria for the subjective diagnosis of intermittent claudication consists of a cramping discomfort in the calf clearly provoked by walking some distance with the pain

appearing sooner when walking quickly or uphill and being relieved within a few minutes by rest. This diagnosis is designated if two physicians at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition is definitely present. A diagnosis of intermittent claudication is based solely on evaluation of subjective manifestations.

5. Congestive heart failure

A definite diagnosis of congestive heart failure requires that a minimum of two major or one major and two minor criteria be present concurrently. The presence of other conditions capable of producing the symptoms and signs are considered in evaluating the findings.

Major Criteria:

- 1) Paroxysmal nocturnal dyspnea or orthopnea;
- 2) Distended neck veins (in other than the supine position);
- 3) Rales;
- 4) Increasing heart size by x-ray;
- 5) Acute pulmonary edema on chest x-ray;
- 6) Ventricular S(3) gallop;
- 7) Increased venous pressure > 16 cm H₂O;
- 8) Hepatojugular reflux;
- 9) Pulmonary edema, visceral congestion, cardiomegaly shown on autopsy;
- 10) Weight loss on CHF Rx: 10 lbs./5days.

Minor criteria:

- 1) Bilateral ankle edema;
- 2) Night cough;
- 3) Dyspnea on ordinary exertion;
- 4) Hepatomegaly;
- 5) Pleural effusion by x-ray;
- 6) Decrease in vital capacity by one-third from maximum record;
- 7) Tachycardia (120 beats per minute or more);
- 8) Pulmonary vascular engorgement on chest x-ray.

6. Coronary heart disease death

Death from coronary heart disease is diagnosed as either sudden or nonsudden.

Nonsudden death from CHD

If the terminal episode lasted longer than one hour, if the available information implies that the cause of death was probably CHD, and if no other cause can be ascribed, this is

called nonsudden death from CHD. In making this diagnosis, the review panel uses prior clinical information as well as information concerning the final illness.

Sudden death from coronary heart disease

If a subject, apparently well, was observed to have died within a few minutes (operationally documented as under one hour) from onset of symptoms and if the cause of death cannot reasonably be attributed on the basis of the full clinical information and the information concerning death to some potentially lethal disease other than coronary heart disease, this is called sudden death and is attributed to coronary heart disease.

7. Cardiovascular disease death

This cause of death is designated when any disease of the heart or blood vessels is considered responsible.

8. All-cause mortality

The fact of death is supported by a death certificate. Additional information is obtained from records supplied by hospital, attending physician, pathologist, medical examiner, or family. The Framingham Endpoint Review Committee reviews all evidence to arrive at the cause of death.

3.0 Chart Preparation for Endpoint Review

(last revised: 08/01/2018)

1. Evaluation Forms

Evaluation forms become part of the participant's permanent FHS record and are referred to when there is a question regarding a previous diagnosis. Therefore, it is very important for the forms to be neat and legible. Before completing an Evaluation Form for a medical encounter, check the Summary of Findings to make sure the material you are preparing has not been previously reviewed. Complete an Evaluation Form for each medical encounter as follows:

- **Name** - Use the participant's ID label for name if available and write the ID#;
- **Date** - Note the date pt. arrived at the hospital, which might not be the admit date. Check date of first ECG to confirm date;
- **Hospital** - Write name of hospital and (*transfer*) if pt. was transferred from another hospital;
- **MD visits** - Note date of visit and list M.D. or name of facility as **Other Source** Use one Evaluation Form for consecutive multiple visits to the same M.D. for the same symptoms during the same exam cycle. Note first and last dates, e.g., 1-3-09 to 4-8-09;
- **ECGS/no medical records** -Note "*ECG only*" after the name of MD or hospital in **Other Source** space when there is only an ECG with no MD or hospital notes. e.g., *Metrowest Heart Center – ECG only*;
- Beside **Notes**, list SOE procedures and dates performed if dates aren't the same as admission date;
- Write ID# on a post it and attach to Evaluation Form. On the post it, note the reason pt. sought medical attention, e.g., chest pain, SOB, CHF symptoms,,and procedures performed during admission. Do not list the discharge diagnosis;
- Initial and date upper right hand corner of evaluation sheet;
- **Death Review**
 - Note "*DOD*" and date of death under admit date;
 - Note "*Cause of death*" beside **Notes**;
 - Note "*No autopsy*", "*Autopsy shows:*" or "*Brain Autopsy Only*" above **Notes**;
 - **Other Source** – Note source of death information if there is no hospitalization, e.g.name of nursing home/hospice death facility, M.D. name, *CODI* if cause of death interview was completed. If there are no medical records available for review, note circumstances of death, e.g., *Pt. died in nursing home, unable to obtain records.*

2. Summary of Findings

- Check the SOF to make sure the material you are preparing has not been previously reviewed.
- Prepare a new SOF form if there won't be enough space on the current one to summarize the review findings.
- Previous MI: Note on post-it any previous definite MI by ECG and the FHS exam cycle during which the MI was assigned, e.g., AMI @ Exam 8. An MI is considered definite if an ECG was read serially (ser) as definite or if a definite MI by ECG was assigned without a serial reading.

3. Medical Records

- Order of Medical Information - Material within a medical encounter should be in the following order:
 - emergency room notes – highlight time participant arrived at hospital;
 - discharge summary;
 - admission notes;
 - progress notes;
 - cardiac consult, regular review - red flag and label;
 - neuro consult, stroke review - blue flag “consult”, highlight M.D. name and date of service;
 - op/procedure notes, regular review - red flag, label (e.g., cath, cabg), and highlight date;
 - op/procedure notes, stroke review - blue flag, label, and highlight date;
 - tests, regular review - red flag, label (e.g., echo, ETT), and highlight date;
 - tests, stroke review - blue flag, (e.g., CT, MRI, EEG), and highlight date;
 - xrays - in chronological order with chest xrays first, red flag “Xray”;
 - labs - in chronological order with cardiac enzymes first, red flag “Labs”, highlight cardiac enzymes (CK, CKMB, BNP and Troponins) and note positive cardiac enzymes (e.g. ↑ CKMB) on the post it you placed on the Evaluation Form;
 - ECGs - must have name and date, stapled together in chronological order, date and time highlighted, rhythm strips separate from 12 lead ECGs.

Xrays, labs and ECGs are always last in the above order.

Make sure there are no records with dates that do not coincide with the admission you are preparing.

- If there are multiple visits with the same M.D. or medical practice, highlight date of each visit.
- Look through each admission/medical encounter and highlight symptoms and pertinent information, e.g., loc, type of chest pain, length of CP, radiation of CP, time of onset, what participant was doing at time of onset, if nitro was given and if it helped. If there is a question of CHF, highlight positive and negative CHF criteria (see CHF SOE form) and list positive criteria on the post it. For Stroke

Review, highlight neurological symptoms, time of onset and whether TPA was administered, and neurological deficits and functional status at time of discharge. Do not repeatedly highlight the same information throughout the admission.

- ECGS - Check for MI and note on post-it, e.g. ? *IMI on ECG*. Shred duplicate ECGS. Make sure they are exact duplicates before shredding.
- **Atrial fibrillation/flutter**

Check SOF for history of AF. If an ECG has been reviewed as definite AFib or Aflutter, every ECG following onset must be reviewed.

 - Recurrent AF – Note *Hx AF* and date of onset on post-it
 - Onset AF – Note ? *onset AF* on post-it and highlight TSH in labs report
 - Flag discharge meds.
 - If cardioversion, note on post it and evaluation form.
 - Ask Medical Records to obtain ECGs for initial AF if they are not in the chart.
 - If there are no ECGs, highlight the ECG reading in the notes.
- Flag cancer/dementia in Review Tracking if noted in the medical records.
- Attach the group of admissions prepared for review in chronological order to the chart. Place autopsy reports behind death records.

4. SOE Forms

Clip appropriate SOE forms behind the Evaluation Form. Use participant label if available and fill in ID# and exam cycle.

See *Death Review* section for information regarding SOE Death forms.

To help determine which SOE forms are needed for Regular Review, check the Summary of Findings (SOF) for the following history:

- Previous AF: Attach an SOE AF Follow-up form.
- Previous AP: If present symptoms suggest AP, attach an SOE AP Rereview form (only one form per exam cycle unless interim CABG or PTCA).
- Previous IC: If present symptoms suggest IC with or without vascular testing, attach an SOE IC Rereview form (one form per cycle unless interim procedure).

5. Death Reviews

- If Cause of Death Interview form has been completed, make sure CODI form is noted as Source on Evaluation form;
- If pt. did not die in a hospital but had a fairly recent medical encounter, place most recent medical encounter on top of chart and flag “*Last admit*” or “*Last MD visit*”;
- Attach an SOE Death form after completing everything except cause of death. Make sure the date of death matches the date in Roster, on the Evaluation Form and on the death certificate. If only a brain autopsy was performed, circle “yes” for autopsy and note “*Brain only*”. To determine if the participant is a Brain Bank

participant, check Brain Bank status in Roster. If the participant is a Brain Bank participant and there is no neuropathology report in the chart, contact the Review Administrator.

- Note “Death Review” on post it and list cause of death, if known, and other conditions that might have contributed to death. Dementia should always be noted, if documented in participant’s records;
- Place a red flag labeled “*Death*” where the death is documented in the medical record;
- For cancer deaths, red flag pathology report or other documentation of cancer and place behind death material.

6. Framingham Heart Study Exams

If there is positive or question CHF, AP, CI, MI, TIA, CVA, IC on an FHS exam, print the corresponding exam pages. Attach a post it noting first and second examiners opinions to the appropriate SOE form and attach to exam page.

Example:

ID#
Exam #
AP 1st +, 2nd ?
+IC 1st and 2nd
+AMI on ECG

If FHS exam is being reviewed with next exam cycle medical encounters, place the exam material on top of the next cycle’s first medical record. If exam is being reviewed with the corresponding exam cycle medical records, place the exam material after the last admit of the corresponding cycle.

7. Chart Content

Check that all other admissions in the chart have been marked **R** (reviewed) or **no R** (does not require review) in upper left hand corner. If not, check SOF to see if they have been reviewed. Also, check Review Tracking to determine if record is open for other reviews. Some admissions do not need review such as cancer and fracture admissions with no AF/MI on ECG and no history of AF. Usually only cardiovascular medical encounters and deaths go to Regular Review. Neurological medical encounters go to Stroke Review. All ECGs must be checked to determine need for review; check ECGs for questions of AF, MI, or CI.

Consult with the Review Administrator if there is any question regarding a record needing review.

Contents of current chart should be in the following order:

- Death certificate, if deceased;
- Obituary, if deceased;
- Death Information Form, if deceased and completed;
- Personal Hx or admitting form;

- Summary of findings - **search the entire chart, old and new, if this is missing;**
- Condolence letter, if deceased;
- Most recent FHS exam ECG;
- Most recent FHS exam - **all** exam parts together including letters;
- Consent forms for most recent exam;
- Health updates with consent forms, most recent on top ***;
- Medical records material clipped together ***;
- Admissions, MD notes for exam cycle all marked "R" or "No R" and stapled together***;
- FHS bone density and cardiac CT reports;
- FHS MRI reports;
- FHS Neuro/Cognitive exam reports;
- Abstracts (FHS exam summaries) – **search the entire chart, old and new if these are missing.**
 *** Behind Summary of Findings if postdates most recent exam

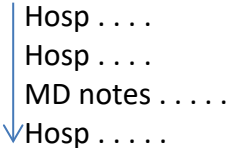
8. Additional Instructions for Stroke Review

- If there is a history/new atrial fibrillation or flutter, ECGs at the time of, and prior to, a stroke must be reviewed before stroke review;
- Clip participant's stroke card to chart. If the participant doesn't have a stroke card, prepare a new one with name on top left and ID# on top right;
- Complete the stroke review worksheet;
- Attach ID labels to the following forms and clip to stroke review worksheet:
 - 209/210 form;
 - Stroke classification form;
 - tPA form;
 - Stroke Imaging Form;
 - TIA Imaging Form;
 - Neurological Tracking Form (ICD Form).
- Flag and place dictation behind the medical records on top of chart Not all participants will have dictation;
- Gather imaging available for stroke review. MRIs & CT disks & films can be found in the disk box in Room 214.

4.0 Post Endpoint Review Procedures

(last revised: 08/01/2018)

1. Document each medical encounter reviewed in the Summary of Findings making sure entries go in the correct exam cycle space.
 - The documentation for regular review should include Hosp./M.D. visit, date of hospitalization or visit, “revd.” and date of review, diagnosis, ECG reading e.g., *Hosp. 7-25-09, revd. 9-29-10, noncardiac chest pain, ECG shows no MI, no AF*
 - The documentation for stroke review should include Hosp./M.D. visit, date of hospitalization or visit, “revd.” and date of review, diagnosis including type of stroke, and date of diagnosis if stroke or TIA.
e.g., *Hosp. 7-30-09, revd. 10-1-10, def. CVA (ABI) on 7-30-09.*
 - In addition to the above, documentation for death reviews should include date of death, place of death if not a hospital, cause of death and autopsy information. See instructions for death summaries.
 - Keep entries lined up neatly and organized.


 - If multiple admissions are reviewed on the same day, note the review date once. If entries carry over to the next section of the Summary of Findings, note the review date again.
2. After each medical encounter reviewed is documented in the Summary of Findings, remove the evaluation form, SOE forms, flags and post it notes. Mark the medical encounter “R” in the upper left hand corner, staple and place inside chart.
3. Forms:
 - Copy first page of SOE form if definite SOE event (CHF, MI, CI, first AP, first IC) and place copy behind evaluation forms (arranged in reverse chronological order) and staple;
 - Clip original SOE forms behind stapled forms;
 - **Enter definite SOE events as listed above and deaths in appropriate SOE log;**
 - Place Evaluation and SOE forms in paper tray labeled *Review Forms to be Checked*. These forms will be checked for accuracy and compared to SOE log entries;
 - Place death certificate copy in yellow death certificate folder;
 - Stroke Review: File Neuro Tracking (ICD) forms;
Put 201/210, Stroke Classification, TPA and Stroke/TIA Imaging forms into *Stroke Review Forms To be keyed* folder.

4. Update Review Tracking (PTS):
Rev_Type: 1=regular, 2=stroke, 3=death;
Rev_Status: 2=closed;
Rev_Date: date of review;
Rev_Event: SOE death code.
Rev_Comment: enter CODI, if CODI was completed for death review.

5. Update Neuro Tracking for neuro cases:
RevStat: 2=reviewed;
StatusCase: 2=closed;
DiagDate: date of event;
DiagReview: type of event;
Data from Neurological (ICD) form if completed.

6. Using the scanner and computer in Room 248, scan the stroke cards.

7. File stroke cards in stroke card file draws in Room 214.

NOTES: If a medical encounter does not need review, shred the Evaluation form and SOE forms and note "No R" in the upper left hand corner of record.

Documentation of Deaths in Summary of Findings

Use the following examples of different scenarios when writing up deaths in Summary of Findings. If you come across a situation other than those listed below, see the Review Administrator.

Unable to obtain hospital records, no CODI:

*Died in hospital 1-24-08, unable to obtain records, death certificate revd. 9-2-08, other cause (COPD),
Autopsy shows no MI.*

Unable to obtain nursing home records, no CODI:

*Died in nursing home 1-23-08, unable to obtain records, revd. 9-2-08, cancer (lung),
No autopsy.*

Unable to obtain records, CODI revd:

*Died 1-24-08, unable to obtain hosp. (nursing home) records, CODI revd. 9-2-08,
Cancer (lung), no autopsy.*

Died at home, CODI revd:

Died at home 1-2-08, CODI revd. 3-5-08, cancer (lung), no autopsy.

Died at home, no CODI, cause unknown:

Died at home 1-2-08, revd. 6-1-08, cause unknown, no autopsy.

Died at home, no CODI, cause ascertained:

Died at home 1-2-08,(note source revd.), cancer (pancreatic), no autopsy.

Died at home with hospice services:

Died at home 1-2-08, hospice notes revd. 3-5-08, cancer (lung), no autopsy.*

Died in nursing home, records obtained:

Died in nursing home 2-3-07, revd. 9-8-08, cancer (lung), no autopsy.*

Died in hospital, records obtained:

Hosp. 1-2-08, revd. 9-2-08, def. CHF, ECG shows no MI, died 1-4-08, other CVD (CHF), no autopsy.*

Hosp. 2-5-08, revd. 9-2-08, def. CVA (ABI) on 2-5-08, died 1-6-08, CVA, no autopsy.*

Autopsy obtained:

Hosp. 1-2-08, revd. 9-2-08, def. CHF, ECG shows no MI, died 1-3-08, other CVD (CHF), autopsy shows no MI.*

* review date not necessary if already noted for previous hospitalization