25. Outcomes Committee Review Work

Archive Note: Initially, a subset of hospitalizations was to be reviewed. However, early on in the Outcomes Committee (OC) review process, the OC decided to review all hospitalizations. Once the FHN Extension Study was completed and additional death data was obtained, the OC convened via conference call on 03/27/2013 to assign a final primary cause of death based on available information. The final classification documentation is included at the end of this chapter.

25.1 Introduction

This chapter describes Outcomes Committee and its formal review of hospitalizations and deaths.

25.2 Outcomes Committee Members

An Outcomes Classification Committee will be established. The Outcomes committee will be composed of Clinical Center Principal Investigators, Co-Investigators, and DCC members.

The Outcomes Committee will review all deaths and hospitalizations (for each study) to verify cause of death or hospitalization (see below). The members of the Outcomes Committee will be trained by the Data Coordinating Center in order to provide a standard classification system for patient deaths and hospitalizations. The Data Coordinating Center will remove any information that can identify the randomization status of the patient being reviewed so that members of the Outcomes Committee will be blinded to the patient's treatment allocation.

No member of the Outcomes committee may review a patient from within his or her own Clinical Center. The DCC will assign the reviews accordingly.

25.3 Getting permission to have hospitalization data released

After each hospitalization that does not lead to a death, a subject will sign a release to allow the hospital to provide the details of the hospitalization to the FHN Clinical Center team. (In addition, each subject will sign a blanket release form annually, to make it easier for the Clinical Centers to obtain details on hospitalizations that lead to death and to obtain details on deaths.)

The Study Coordinator or physician will present the release to the hospital where the patient was hospitalized to get hospital records.

25.4 Discharge Summary Submission Procedure

Enter Forms 302, 303 and 308 for a hospitalization

Enter Forms 305, 306 and 308 for a death

Hospitalization Discharge/Death summaries

- No more than 10 pages
- Include labs, x-rays, scans, blood cultures, labs as needed
- Black out all identifying and treatment information before faxing
- Write alpha code only at the top of each page
- Make sure pages are dark enough and legible before faxing

Fax these materials to the DCC, attn: Barb Weiss (DCC fax is 216-445-2781). The fax cover sheet should include patient ID, alpha code, hospital admission date or date of death, and the number of pages. The DCC will e-mail the center if there are any further questions or requests.

25.5 What data are on the Hospitalization Form 303 and SAE form 308

The hospitalization form 303 will be completed by the Site PI, Co-Investigator or Collaborator from the patient's Clinical Center and reviewed by the Core Consortium staff (i.e., the PIs (Chertow & Levin) and the lead study coordinators. The Clinical Center will contact the hospital involved. Data to be obtained and recorded on the hospitalization form include date of admission, date of discharge, whether a vascular access procedure was performed during the hospital stay, and the primary and secondary reason for hospitalization as coded by the categories on the form

All hospitalizations will be categorized by the Clinical Center (Site) PIs by

- access versus non-access hospitalization
- cardiovascular versus not cardiovascular
- primary and secondary reason for hospitalization

The answers to these questions will be based on either the discharge summary associated with that hospitalization or a narrative description of the hospitalization provided by a physician who was responsible for the care of the patient (a narrative description will be used when 6 months have elapsed and the discharge summary cannot be obtained). The FHN hospitalization form will also capture whether the Clinical Center PI's categorization was based on an actual discharge summary or some other form of documentation. The hospitalization form should be submitted to the Data Coordinating Center within 30 days of the patient's hospital discharge.

The standard adverse event questions about the expectedness and relatedness of the hospitalization are on the SAE form 308.

25.6 Hospitalization Report Folder for the Outcomes committee

For each patient, the DCC will prepare a Hospitalization Report Packet. The packet will include reports based on the detailed hospitalization form, serious adverse event forms dated before the hospitalization up to and including the date of the hospitalization, demographics, baseline co-morbidity, baseline MRI results and a blinded discharge summary for the particular hospitalization. An e-mail will be sent to the committee in advance of the call and will include the following attachments: a memo detailing the call including the cases to be discussed as well as a primary, secondary and third reviewer assigned to the case; pdf files of each hospitalization report packet blinded to patient identification and randomized assignment; and the Outcomes Committee Hospitalization Review Form 501.

25.7 Review of all Hospitalizations (for each study)

All hospitalizations will be adjudicated by the Outcomes Committee during the monthly conference call until resolution can be reached. The final categorization with respect to transplant status, access, cardiovascular, infection, trial relatedness, treatment arm and hospitalization codes will be recorded in the Form 501. The primary and secondary reviewers will be entered into the Outcomes Committee Hospitalization Review Documentation Form.

The DCC study coordinator on the conference call will complete Form 501 as adjudicated by the Outcomes Committee.

The clinical centers should check the weekly status reports and/or daily e-mail of critical F12/F14forms to view hospitalizations occurring more than 60 days ago where documentation has not yet been sent to the Outcomes Committee.

The order of hospitalization review will be determined by relatedness and date of hospitalization. Transplant hospitalizations will be reviewed last.

25.8 Deaths

The death Form 306 along with the SAE Form 308 will be completed by the Co-investigator from the involved Clinical Center, who will classify the death using a modification of the HEMO Study coding system. This system will allow for the classification of deaths by organ system, such as cardiac and infection-related.

A death discharge summary or other information will be sent by the Clinical Center to the Data Coordinating Center, who in turn will forward this data (as previously detailed in Section 25.6 of the MOP) to members of the Outcomes Committee. For hospitalizations resulting in death, the same information as described above for hospitalizations will be obtained. If the death did not occur in the hospital, then the principal investigator will

provide a narrative describing the circumstances of the patient's death and the presumed cause of death based on the patient's history and events leading up to the patient death. Assignments to reviewers will be done as detailed above for hospitalizations. The primary death code as confirmed or agreed upon by the Outcomes Committee will be entered into the Detailed Death Form 306 by the DCC. The DCC study coordinator on the conference call will complete Form 503 as adjudicated by the Outcomes Committee. The primary and secondary reviewers will be entered into the DCC Death Review Documentation Form. The death code chosen by the committee will be used for subsequent analysis.

FINAL FHN Cause of Death Classifications per Outcomes Committee*
Used for F305 and F305B Datasets – Field = OC_CAT

Post Study OC categories defined	Database code (FHN_Death_Notification, OC_CAT)	Confirmed by M. Rocco	Original F306 categories	F306 Category Description
CVD1	54DA	Atherosclerosis/ ischemic	01	01=Ischemic Heart Disease (includes atherosclerosis)
CVD2	54DB	CHF/Cardiomyopathy	02 and 04DK	02=Congestive Heart Disease (CHF) 04DK=Cardiomyopathy (without IHD or CHF)
CVD3	54DC	Arrhythmias	03	03=Arrhythmias and conduction problems (includes sudden death (due to arrhythmia, not due to IHD))
CVD4	54DD	Cardiac, sudden death; specific heart-related cause unknown; other heart conditions	04	04=Other Heart Diseases and Conditions (includes sudden death due to heart conditions other than IHD/arrhythmia)
Access-related infection	54DE		20DE	Other access infection
Non-access infection deaths	54DF		18DB	Other infection (not recorded in previous category)*
Other dialysis related deaths	54DG		21	Other hemodialysis complications
Other access deaths	54DH		20	Hemodialysis vascular access complications
GI Bleed	54DI		13DC	GI bleeding, site unknown
Cancer	54DJ		10	Malignancy
Accidental	54DK		23DF	Accident unrelated to treatment

deaths				
Other death	54DL	Other death (not recorded in previous categories)	--	--
Sudden death, unknown	54DM	Sudden death, unknown cause	24DA	Sudden death, unknown cause
Unknown death, unknown cause	54DN	Other death, unknown cause	24DB	Other death, unknown cause