

HEMO Study Form 15. Outcome Committee Hospitalization Review Form

This form will be completed by one Outcome Committee reviewer after review of the Hospitalization Review Packet. The reviewer will be blinded to the patient's treatment assignment. If the reviewer disagrees with the Principal Investigator regarding primary and secondary discharge diagnoses or the classification of the hospitalization, it will be reviewed by the chair or his designee.

1. Patient Identification Number....._ _ _ _ _
2. Patient Name Code_ _ _ _ _
3. Date of Hospital Admission..... _ _ / _ _ / _ _ _ _ _
4. Discharge Status (0=dead, 1=alive)....._ _
For the next item, fill in the date of death or discharge, whichever occurred.
5. Date of Death or Discharge _ _ / _ _ / _ _ _ _ _
6. Date Reviewed..... _ _ / _ _ / _ _ _ _ _
7. First initial and first seven letters of reviewer's last name....._ _ _ _ _
8. Were these conclusions reached by the initial Outcome Committee reviewer, or as a second review, by the Outcome Committee Chair (or his designee)?
(1=initial Outcome Committee review, 2=second review by Chair/designee)....._ _
9. Primary discharge diagnosis? (from Form 14 Hospital Code List)....._ _ _ _ _
10. Secondary discharge diagnosis? (from Form 14 Hospital Code List)....._ _ _ _ _
11. Third discharge diagnosis? (from Form 14 Hospital Code List)....._ _ _ _ _
12. Fourth discharge diagnosis? (from Form 14 Hospital Code List)....._ _ _ _ _

How should it be classified? Code 0=no, 1=yes.

13. Was this a "HEMO non-access hospitalization" event?_ _
 - a. Access Hospitalization Status_ _
 1 = This was a "HEMO Non-Access hospitalization,"
 admitted for a problem unrelated to access

- 2 = Admitted for an access problem, "HEMO Access hospitalization," without non-access complications
- 3 = Admitted for an access problem, "HEMO Access hospitalization," with non-access complications that were not due to access problems.
- 4 = This was a "HEMO Access hospitalization with non-access complications that were due to access problems.

For questions 14.a-e and 15.a-b, if there is disagreement between the Clinical Center PI and Outcome Committee reviewer, please discuss the items with the PI before completing the form.

14. Was this an "HEMO hospitalization for heart disease" event?.....__
- a. Was there new onset of or worsening angina pectoris?__
 - b. Was there new onset of or worsening congestive heart failure (left ventricular dysfunction)?.....__
 - c. Was there a myocardial infarction?__
 - d. Was there new onset of or worsening arrhythmias?__
 - e. Was there new onset of or worsening other heart disease (exclude pericarditis).....__
15. Was this an "HEMO hospitalization for infection" event?.....__
- a. Was there bacteremia or sepsis?__
 - b. Organ or deep tissue infection?.....__
16. What is the current thought of the reviewer regarding whether this hospitalization was related to a complication of the dialysis session?.....__
- 1 = Existing Relationship. This sort of event is commonly associated with the dialysis session or a temporal relationship with a dialysis session exists and no other etiology is apparent.
 - 2 = No Existing Relationship. This sort of event is not commonly associated with adialysis session, no temporal relationship with the dialysis session exists, and other etiology is possible.
 - 3 = Unknown Relationship. There are insufficient data to assess the

relationship of the event to the dialysis session.

- 17. a. What Kt/V goal does the reviewer think the patient was on?
(1=low, 2=high, 9=can't tell).....__

- b. What flux does the reviewer think the patient was on?
(1=low, 2=high, 9=can't tell).....__

c. What is the current thought of the reviewer regarding whether this hospitalization was related to the patient's randomized study Kt/V intervention?.....

d. What is the current thought of the reviewer regarding whether this hospitalization was related to the patient's randomized flux intervention?.....

- 0 = No relationship possible; the patient is still in Baseline.
1 = Existing Relationship. This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
2 = No Existing Relationship. This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology is possible.
3 = Unknown Relationship. There are insufficient data to assess the relationship of the event to the study intervention.
9 = Couldn't tell which intervention the patient was on.

18. Has complete agreement been reached between the Outcome Committee and the Clinical Center with respect to Items 14 and 15(Items 5 and 6 on Form 14)?

For initial reviews, choose 1, 2 or 3:

- 1=Yes, the initial reviewer agreed with the Clinical Center Staff on the basis of information provided in the initial packet without direct communication with the Clinical Center.
2=Yes, the initial reviewer agreed with the Clinical Center Staff after direct communication with the Clinical Center.
3=No. The initial reviewer could not reach agreement with the Clinical Center Staff despite direct communication with the Clinical Center. A second review is necessary.

For second reviews, choose 4 or 5:

- 4=Yes, the second reviewer agreed with the Clinical Center Staff.
5=No. The second reviewer and Clinical Center Staff "agree to disagree".

201. Date this form completed.....

202. Certification number of person completing this form (use Study Coordinator's certification number).....

For DCC Use Only:

101. Did the reviewer agree with the PI regarding primary and secondary discharge diagnoses? _

102. If no, second reviewer assigned _ _ _ _ _

103. Date sent to that reviewer _ _ / _ _ / _ _ _ _ _