

Frequent Hemodialysis Network OUTCOMES COMMITTEE HOSPITALIZATION REVIEW - FORM #501

This form is to be completed by the assigned Outcomes Committee (OC) member.

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1. Participant ID #

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2. Alpha
Code

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3a. Date of hospital admission: dd/mon/yyyy

OC Member reviews the hospitalization and re-checks whether it was a CV or access-related hospitalization.

Transplant Status

- 3b. Transplant hospitalization status.....
- 1=There was no transplant during this hospitalization.
- 2=There was a transplant and new kidney is functioning. Patient no longer requires dialysis.
- 3=There was a transplant but it failed. Patient still requires dialysis.
- 4=There was a transplant, but the new kidney had delayed graft function. Patient required dialysis at time of hospital discharge.

Access Related Issues

4. Access Hospitalization Status.....
- 1=This was a "Non-Access hospitalization," admitted for a problem unrelated to access.
- 2=Admitted for an access problem, "Access hospitalization," without non-access complications.
- 3=Admitted for an access problem, "Access hospitalization," with non-access complications that were not due to access problems.
- 4=This was an "Access hospitalization" with non-access complications that were due to access problems.
5. **Cardiovascular disease** (For 5a-e: 0=No, 1=Yes)
- a. Was there new onset of or worsening angina pectoris or ischemic heart disease?.....
- 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)
- (Note - if any of the above are "Yes", this was a cardiovascular hospitalization)*

Hospitalization for Infection (Code 0=No, 1=Yes)

6. a. Was there bacteremia or sepsis?
- b. Was there organ or deep tissue infection (serious)?
- (Note - if either of the above are true, this was an infection hospitalization)*

Trial Relatedness

7. a. In the Reviewer's judgment, was this event caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol?
- 0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

Question 7 continued on next page

*Not Applicable - Extended Follow-Up Study Only.

Q7, continued

If the answer to question 7a was possibly, probably, or definitely, was the AE/SAE caused by: (Code 0=No, 1=Yes)

- 7.a.1. Hemodialysis machine
- 7.a.2. Blood tubing sets:
- 7.a.3. Dialyzer:.....
- 7.a.4. Dialysate:
- 7.a.5. Central venous catheter:.....
- 7.a.6. Enuresis alarms for detecting blood leaks.....
- 7.a.7. Dialysis needles:

b. In the Reviewer's judgment, was this event caused by the patient's randomly assigned dialysis regimen?

0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

c. If the event was possibly, probably, or definitely caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol by the patient's or by the patient's randomly assigned dialysis regimen, was it expected and accurately described in the study consent?

1=Unexpected – not mentioned in the consent

2=Expected, but of greater severity than mentioned in the consent

3=Expected and accurately described in the consent

8=Not Applicable*

Treatment Arm

8. Which treatment arm did the Outcomes Committee Reviewer think the patient was randomized to?

1=Definitely standard (3x) arm

2=Probably standard (3x) arm

3=Could not determine

4=Probably frequent (6x) arm

5=Definitely frequent (6x) arm

200. Date this form completed (dd/mon/yyyy)..... ____/____/____

201. Username of Outcomes Committee Reviewer completing of this form

For DCC Use Only:

202. Username of person entering this form:

203. Date entered: (dd/mon/yyyy) ____/____/____

Based on OC Review:

204. Hospitalization Code - Primary Reason:

205. Hospitalization Code - Secondary Reason:

206. Hospitalization Code - Other Reason: