

HEMO Study Form 14. Clinical Center Hospitalization Review Form

- This form is completed with the Principal Investigator or attending physician within two weeks after a patient is discharged or dies in the hospital. This review should be based on the hospital discharge summary or a phone call to the attending physician.
- If you receive a discharge summary, keep it on file with this form. The discharge summary will need to be copied and sent to the DCC if this hospitalization is selected for complete review. All "first post-randomization hospitalizations for heart disease" and "first post-randomization hospitalizations for infection" Form 14's will be selected for complete review.
- If the event leading to hospitalization began during a dialysis treatment, file a photocopy of that dialysis treatment's run sheet with this form and the discharge summary.

1. Patient Identification Number..... _ _ _ _ _

2. Patient Name Code _ _ _ _ _

3. a. Date of Hospital Admission _ _ / _ _ / _ _ _ _ _

b. Name of Hospital _____

c. Date of Death or Discharge..... _ _ / _ _ / _ _ _ _ _

4. Access Related Issues

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.

Code 0 = no, 1 = yes for parts b and c, as well as items 5 and 6 on page 2.

b. Was access repair required? _____

c. Was access replacement required? _

5. Cardiovascular disease

- 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)

6. Hospitalization for infection

- a. Was there bacteremia or sepsis?
- b. Organ or deep tissue infection (serious)?

7. What are the HEMO **admission** diagnoses by Principal Investigator? (See the attached HEMO Code List for Forms 14 and 15.)

- a. Primary admission diagnosis
- b. Secondary admission diagnosis

8. Was the patient ever in the Intensive Care Unit during this hospitalization?

9. What are the HEMO **discharge** diagnoses by Principal Investigator? (see the attached HEMO Code List for Forms 14 and 15.)

- a. Primary discharge diagnosis
- b. Secondary discharge diagnosis
- c. Third discharge diagnosis
- d. Fourth discharge diagnosis

10. Other active comorbid conditions during this hospitalization. (Code 0=no, 1=yes.)

- a. Cerebrovascular disease

- b. Peripheral vascular disease
- c. Malignancy
- d. Respiratory disease
- e. Gastrointestinal disease.....

11. What is the current thought of the Principal Investigator regarding whether the hospitalization was related to a complication of the most recent 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 a dialysis 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.

12. a. What is the current thought of the Principal Investigator regarding whether the hospitalization was related to the patient's randomized study Kt/V intervention?.....

b. What is the current thought of the Principal Investigator regarding whether the hospitalization was related to the patient's randomized flux intervention?

- Codes for a and b:
- 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 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.

201. Date this form completed..... / /

202. Certification number of person completing this form

<p>Clinical Center Use Only</p> <p>Data Form Entered ___/___/_____ Verified? _____</p> <p>Person Entering this Form _____</p>

<p>For DCC Use Only:</p> <p>101. Selected for Outcome Committee Review? (0=no, 1=yes) _</p> <p>102. If yes, why?</p> <p> a. First post-randomization hospitalization for infection (0=no, 1=yes) _</p> <p> b. First post-randomization hospitalization for cardiovascular disease (0=no, 1=yes) _</p> <p> c. Randomly selected (0=no, 1=yes) _</p> <p>103. Date copy of Form 8 and photocopy of discharge summary received from clinic ___/___/_____</p> <p>104. Initial reviewer assigned _____</p> <p>105. Date sent to initial reviewer ___/___/_____</p>

**HEMO Study: Hospitalization Admission and Discharge
Code List of Diagnoses and Procedures
(For Forms 14 and 15)**

Instructions to Coding: When parentheses () are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
Note: A terminal code of 0 indicates a procedure.

An asterik (*) indicates that the disease or condition is also classified as an "infection outcome".

1. ISCHEMIC HEART DISEASE (IHD)

Also see category: coronary heart disease (CHD) or coronary artery disease (CAD)

01AA()	Chest pain of non-cardiac or unclear etiology (R/O MI admission)
01AB()	CAD
01AC()	Angina
01AD0	Bypass surgery (CABG)
01AE0	Coronary angiography
01AF0	Coronary angioplasty (PTCA) or atherectomy
01AG	Myocardial infarction (acute)(MI)
01AH	Cardiac arrest

2. CONGESTIVE HEART FAILURE (CHF)

02AA()	CHF
02AB()	CHF due to volume overload
02AC()	Pulmonary edema (cardiogenic)
02AD()	Pleural effusions
02AE0	Thoracentesis (diagnostic or therapeutic)
02AF	Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03AA()	Syncope (also presyncope and syncopal episode)
03AB()	Atrial fibrillation
03AC()	Ventricular tachycardia
03AD()	Supraventricular tachycardia
03AE()	Sick sinus (tachy-brady) syndrome
03AF()	Atrioventricular conduction block
03AG()	Hyperkalemia
03AH()	Other new or other arrhythmia and conduction problem
03AI0	Cardioversion

- 03AJ0 Electrophysiologic studies (EPS)
- 03AK0 Pacemaker placement
- 03AL0 Pacemaker malfunction/repair

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

- 04AA() Pericarditis
- 04AB() Endocarditis* (* added July 2002, per Julia Lewis)
- 04AC() Myocarditis
- 04AD() Cardiomyopathy (without IHD or CHF)
- 04AE() Pericardial effusion
- 04AF() Aortic valve stenosis or insufficiency
- 04AG() Mitral valve stenosis, regurgitation, or prolapse
- 04AH() Other valve defect
- 04AI() Other condition
- 04AJ0 Cardiac tamponade
- 04AK0 Pericardiocentesis
- 04AL0 Aortic valve replacement
- 04AM0 Mitral valve replacement
- 04AN0 Balloon valvuloplasty

5. HYPERTENSION (HTN)

- 05AA() Hypertensive crisis or accelerated HTN

6. CEREBRAL VASCULAR DISEASE (CVD)

- 06AA() Transient ischemic attack (TIA)
- 06AB() Cerebral vascular accident (CVA)
- 06AC() Carotid artery stenosis
- 06AD() Cerebral artery aneurysm
- 06AE() Subarachnoid or cerebral hemorrhage
- 06AF() Other CVD condition
- 06AG0 Carotid endarterectomy (CEA)
- 06AH0 Carotid angiogram

7. PERIPHERAL VASCULAR DISEASE (PVD)

- 07AA() Deep vein thrombosis (DVT)
- 07AB() Pulmonary embolism
- 07AC() Peripheral vascular disease
- 07AD() Ischemic foot ulcers
- 07AE() Gangrene of toes or foot*
- 07AF() Abdominal aortic aneurysm (AAA)

07AG(_)	Thoracic aortic aneurysm (TAA)
07AH(_)	Hemorrhage from ruptured vascular aneurysm
07AI(_)	Aortic aneurysm (not specified)
07AJ(_)	Other aneurysm
07AK(_)	Mesenteric ischemia or infarction (ischemic bowel)
07AL(_)	Cellulitis (non-access related)*
07AM(_)	Gangrene with septicemia-shock due to PVD
07AN(_)	Other condition due to PVD or other disorder of arteries
07AO(_)	Polyarteritis nodosa and other arteritides
07AP	Arterial embolism
07AQ0	AAA repair
07AR0	TAA repair
07AS0	Angioplasty for PVD
07AT0	Bypass graft for PVD
07AW0	Amputation site: toe(s)
07AX0	transmetatarsal
07BA0	Left below the knee amputation
07BB0	Right below the knee amputation
07BC0	Left above the knee amputation
07BD0	Right above the knee amputation

8. **DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS**

08AA(_)	Diabetic foot infection*
08AB(_)	Gangrene of foot or toes (absence of PVD)*
08AC(_)	Hypothyroidism
08AD(_)	Other disorders of the thyroid gland
08AE	Diabetes with ketoacidosis
08AF	Diabetes with hyperosmolar state or coma
08AG	Hypoglycemic coma
08AH0	Pancreatic transplant
08AI(_)	Other endocrine disorder

9. **RESPIRATORY DISEASE**

09AA(_)	Asthma
09AB(_)	COPD
09AC(_)	Bronchitis
09AD(_)	Pneumothorax
09AE(_)	Empyema*
09AF(_)	Lung abscess*
09AG(_)	Pulmonary TB*
09AH(_)	Respiratory failure not requiring intubation and mechanical ventilation
09AI(_)	Respiratory failure requiring intubation and mechanical ventilation

09AJ()	Adult respiratory distress syndrome (ARDS)
09AK	Respiratory failure of unknown cause
09AL()	Other respiratory disease
09AM()	Pulmonary hemorrhage
09AN()	Pneumonia (nosocomial)*
09AO()	Pneumonia (community acquired)*
09AP()	Pneumonia-sepsis*
09AQ()	Pneumonia (bacterial)*
09AR()	Pneumonia (fungal)*
09AS()	Pneumonia (viral)*
09AT()	Pneumocystis pneumonia*
09AU()	Aspiration pneumonia*
09AV()	Pneumonia (unspecified pathogen)*
09AW0	Open lung biopsy
09AX0	Lung lobectomy
09AY()	Upper respiratory tract disorders
09AZ0	ENT procedures

10. MALIGNANCY

10AA()	Hematologic malignancy (AML, ALL, CLL)
10AB()	Lymphoma (unspecified)
10AC()	Hodgkin's lymphoma
10AD()	Non-Hodgkin's lymphoma
10AE()	Multiple myeloma
10AF()	Colon cancer
10AG()	Breast cancer
10AH()	Prostatic cancer
10AI()	Ovarian cancer
10AJ()	Lung cancer
10AK()	Gastric cancer
10AL()	Pancreatic cancer
10AM()	Thyroid cancer
10AN()	Cervical cancer
10AO()	Endometrial cancer
10AP()	Primary cancer of liver
10AQ()	Head and neck squamous cell carcinoma
10AR()	Testicular cancer
10AS()	Renal cancer
10AT()	Bladder cancer
10AU()	Melanoma
10AV()	Other skin cancer
10AW()	Other malignancy or neoplasia
10AX()	Metastatic carcinoma unknown primary

10AY(_)	Complication(s) of pre-admission diagnosed cancer
10BA0	Diagnosis:surgical biopsy
10BB0	other procedure for biopsy
10BC0	other diagnostic procedure
10CA0	Treatment:radiation therapy
10CB0	chemotherapy
10CC0	surgical excision
10CD0	other treatment

11. HEPATOBILIARY DISEASE

11AA(_)	Hepatitis B
11AB(_)	Hepatitis C
11AC(_)	Toxic/drug-induced hepatitis
11AD(_)	Hepatitis (other; unknown cause)
11AE(_)	Cirrhosis
11AF(_)	Ascites
11AG(_)	Portal hypertension or esophageal varices
11AH(_)	Variceal bleed
11AI(_)	Hepatic failure/severe dysfunction
11AJ(_)	Cholecystitis/cholangitis*
11AK(_)	Other hepatobiliary disease
11AL	Biliary sepsis*
11AM0	Cholecystectomy
11AN0	Liver transplant
11AO0	Shunt procedure
11AP0	Paracentesis (diagnostic or therapeutic)

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12AA(_)	Gout
12AB(_)	Wegener's granulomatosis
12AC(_)	Systemic vasculitis
12AD(_)	SLE
12AE(_)	Avascular necrosis
12AF(_)	Osteomyelitis*
12AG(_)	Septic arthritis*
12AH(_)	Back problems
12AI(_)	Other musculoskeletal or connective tissue disease
12AJ0	Bone fracture
12AK0	Parathyroidectomy
12AL0	Carpal tunnel surgery
12AM0	Arthroscopy
12AN0	Hip replacement

12AO0	Knee replacement
12AP0	Knee procedures (other than replacement)
12AQ0	Internal fixation or surgical reduction of bone fracture
12AR0	Other orthopedic surgery
12AS0	Back and/or neck procedure
12AT()	Hyperparathyroidism
12AU()	Hypoparathyroidism
12AV0	Other calcium-phosphorus disorder

13. GASTROINTESTINAL CONDITIONS (GI)

13AA()	Upper GI bleed
13AB()	Lower GI bleed
13AC()	GI bleeding, site unknown
13AD()	Peptic ulcer disease
13AE()	Gastritis
13AF()	Reflux esophagitis (with or without hiatal hernia)
13AG()	Diverticulitis*
13AH()	Colonic polyps
13AI()	Ulcerative colitis (UC)
13AJ()	Enteritis (Crohn's disease)
13AK()	Septicemia due to peritonitis*
13AL()	Pancreatitis
13AM()	Necrotising enterocolitis*
13AN()	<i>C. difficile</i> associated enterocolitis*
13AO()	Peritonitis*
13AP()	Fungal peritonitis*
13AQ()	Appendicitis*
13AR()	Ischemic bowel
13AS()	Intra-abdominal abscess*
13AT()	Abdominal pain, cause unknown
13AU()	Malabsorption
13AV()	Perforated viscus (peptic ulcer or bowel)*
13AX()	Gastroparesis
13BA0	Colectomy (partial or total)
13BB0	Gastrectomy
13BC0	Colostomy or ileostomy
13BD0	Gastrostomy/enterostomy
13BE0	Appendectomy
13BF0	Laparotomy
13BG0	Other GI condition or procedure

14. NONVASCULAR NERVOUS SYSTEM DISEASES

- 14AA() Mental status change (acute)
- 14AB() Seizure disorder
- 14AC() Disequilibrium - syndrome
- 14AD() Coma-stupor (traumatic cause)
- 14AE() Coma-stupor (toxic-drug induced)
- 14AF() Coma-stupor (metabolic cause, non-diabetic)
- 14AG() Coma-stupor (anoxic encephalopathy)
- 14AH() Coma-stupor (other unknown cause)
- 14AI() Alcohol non-accidental
- 14AJ() Drug overdose
- 14AK() Head trauma
- 14AL() Parkinson's disease
- 14AM() Multiple sclerosis
- 14AN() Subdural or epidural hematoma
- 14AO() Depression
- 14AP() Nervous system neoplasm
- 14AQ() Alcohol/drug abuse related (detoxification included)
- 14AR() Other psychiatric or mental disorder
- 14AS() Viral meningitis*
- 14AT() Meningitis (non-viral)* (* added July 2002, per Julia Lewis)
- 14AU() Other CNS infection*
- 14AV() Ataxia
- 14AW() Cranial or peripheral nerve disorder
- 14AX() Other nonvascular nervous system condition
- 14AY() Suicide attempt

15. URINARY TRACT CONDITIONS

- 15AA() Urinary tract infection requiring antibiotics*
- 15AB() Nephrolithiasis
- 15AC() Benign prostatic hypertrophy
- 15AD() Prostatitis* (* added July 2002, per Julia Lewis)
- 15AE() Orchitis* (* added July 2002, per Julia Lewis)
- 15AF() Cystic kidney disease (PKD or acquired)
- 15AG() Cyst-related hemorrhage
- 15AH() Cyst-related infection* (* added July 2002, per Julia Lewis)
- 15AI() Urinary tract hemorrhage
- 15AJ0 Nephrectomy unilateral
- 15AK0 Nephrectomy bilateral
- 15AL0 Prostatectomy (radical)
- 15AM0 Transurethral prostatectomy (TURP)
- 15AN0 Other transurethral procedures (cystoscopy included)

- 15A00 Other urologic procedure
15AP() Hematuria
15AQ Acute Transplant Rejection

16. **HIV/AIDS**

- 16AA() AIDS-related infection*
16AB() Other AIDS-related condition (non-infection)
16AC() HIV positive

17. **OPHTHALMOLOGIC CONDITIONS**

- 17AA() Retinal or vitreous hemorrhage
17AB() Endophthalmitis*
17AC() Other disorder of the eye
17AD0 Iris or lens procedure (cataract surgery included)
17AG0 Orbital procedure (vitrectomy included)
17AH0 Retina procedure (laser surgery included)
17AI0 Other ophthalmologic procedure

18. **INFECTIONS**

- 18AA() Abscess (lung, empyema, intra-abdominal, brain, soft tissue
--not access-related)*
18AB() Miliary TB*
18AC() Extrapulmonary TB*
18AD() Disseminated candidiasis*
18AE() Other fungal infection**
18AF() Viral infection (including CMV)*
18AG() Other viral infection (not hepatitis)*
18AH() Protozoan or parasitic infection (not PCP)*
18AI() Other infection (not recorded in previous category)*
18AJ Septic shock*
18AK Bacteremia (known source not access-related)*
18AM Bacteremia (unknown source, not access-related)*

19. **NON-MALIGNANT HEMATOLOGIC CONDITIONS**

- 19AA() Coagulation disorders
19AB() Thrombocytopenia (secondary)
19AC() Thrombocytopenia (idiopathic)
19AD() Disseminated intravascular coagulation
19AE() Other consumption coagulopathy

- 19AF() Thrombotic thrombocytopenic purpura (TTP)
and hemolytic uremic syndrome (HUS)
19AG0 Other

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

- 20AA0 Elective surgical access repair
20AB() Soft tissue infection, cellulitis, abscess (access related)*
20AC Bacteremia or sepsis, access related*
20AD() Clotted access
20AE() Venous thrombosis, access related
20AF() Arterial thrombosis or embolism, access related
20AG() Steal syndrome, limb ischemia, access related
20AH Hemorrhage from vascular access
20AI() Nerve entrapment, access related
20AJ0 Fistulogram, arteriogram, or other invasive imaging procedure
20AK0 Access declotting procedure
20AL0 Angioplasty or stent placement for vascular access
20AM0 Non-elective surgical access repair
20AN0 Temporary access placement
20AO() Pneumothorax, hemothorax as result of temporary access placement
20AP() Subclavian vein stenosis as result of temporary access
20AQ0 New access creation (AV-fistula)
20AR0 New access placement (AV-graft)
20AS() Other access-related condition
20AT0 Other access-related procedure

21. OTHER HEMODIALYSIS COMPLICATIONS

- 21AA Uremia
21AB Hemorrhage from dialysis circuit
21AC Air embolism
21AD Anaphylaxis, treatment related
21AE Hemolysis, treatment related
21AF Electrolyte and acid-base disorder (other than hyperkalemia),
treatment related
21AG Dialysis-induced hypotension
21AH Other accident related to treatment
21AI Febrile reaction, not infection

22. OTHER SURGICAL PROCEDURES

- 22AA() Trauma
- 22AB() Major hemorrhage (not C1 or pulmonary)
- 22AC() Hemorrhagic shock
- 22AD0 Skin graft/skin ulcer debridement
- 22AE0 Hernia procedure
- 22AF0 Other elective surgery procedure
- 22AG0 Kidney transplant

23. OTHER

- 23AA Withdrawal from dialysis
- 23AB Other hemorrhage
- 23AC Other trauma
- 23AD Drug overdose (accidental)
- 23AE Accident unrelated to treatment
- 23AF Drug reaction (anaphylaxis)
- 23AG Drug reaction (not anaphylaxis, not overdose)
- 23AH Other electrolyte/acid-base disorder, not treatment related
- 23AI Cachexia
- 23AJ Hospitalization for transplant evaluation

24. UNKNOWN