

DAC Study Form 361 – Clinical Center Hospitalization 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.

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. Was the patient discharged (code=1) or did the patient die in the hospital (code=2)...__
d. Date of Death or Discharge __ __/__ __/__ __
4. Primary reason for this hospitalization_____
(from code list on pages 361.3 to 361.12)
5. Secondary reason for this hospitalization
(from code list on pages 361.3 to 361.12)_____
6. a. Was there a surgery? (0=no, 1=yes, 9=unknown)__
b. If yes, was it planned? (0=no, 1=yes 9=unknown).....__
7. Was drug discontinued?.....__
(0=no, 1=yes, 8=N/A, patient is not randomized, 9=N/A, already off drug)
Note: If Yes, be sure to file Form 335 for temporary discontinuation, or Form 336 for permanent discontinuation of therapy.
8. Was an access diagnostic procedure done? (0=no, 1=yes).....__
Note: If Yes, be sure to file Form 354.
9. For a graft patient, was access repair or replacement done or for a fistula patient, was there an access repair/event? (0=no, 1=yes).....__
Note: If Yes, be sure to file Form 355 (or Form 352 for a fistula patient).
10. Was there a bleeding episode (0=no, 1=yes).....__
Note: If yes, be sure to file Form 363.
11. Did the event lead to permanent disability? (0 = no, 1 = yes).....__

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12. a. Which treatment does the study team think the patient was randomized to?.....__
- 1 = The team has been unblinded and knows it is placebo
 - 2 = The team believes it is placebo
 - 3 = The team does not know
 - 4 = The team believes it is active drug
 - 5 = The team has been unblinded and knows it is active drug
 - 8 = N/A, patient is not randomized
- b. If 1 or 5, date of unblinding __ __ / __ __ / __ __ __ __
13. What is the current thought of the Principal Investigator regarding whether this hospitalization was related to the patient’s randomized study intervention?
- 0 = **Not related to the study drug.**
 - 1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
 - 2 = **Possibly related to the study drug.**
 - 3 = **Probably related to the study drug.** 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.
 - 4 = **Definitely related to the study drug**
 - 8 = N/A, patient is not randomized
14. If the event was definitely, probably or possibly related to the study medication (i.e. Q13 = 2, 3 or 4), then what was the expectedness of it?
- 1 = Unexpected - not mentioned in the informed consent
 - 2 = Expected, but of greater severity than mentioned in the informed consent.
 - 3 = Expected and accurately described in the informed consent.
15. What was the severity of the event?
- 1 = Mild - awareness of the sign or symptom, but easily tolerated
 - 2 = Moderate - enough discomfort to interfere with usual activity
 - 3 = Severe - incapacitating, with inability to do usual work or activity
16. Did another event occur during this hospitalization, which caused prolongation of the hospitalization? (0=no, 1=yes).....__
- Note: Generally this means an event occurred that would have led to a hospitalization of NON-hospitalized patient.*
17. If yes, what was the reason for the prolongation? (from code list on pages 361.3 to 361.12)

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18. What is the current thought of the Principal Investigator regarding whether this prolongation of hospitalization was related to the patient’s randomized study intervention?

0 = **Not related to the study drug.**

1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.

2 = **Possibly related to the study drug.**

3 = **Probably related to the study drug.** 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.

4 = **Definitely related to the study drug**

8 = N/A, patient is not randomized

19. If the event was definitely, probably or possibly related to the study medication (i.e. Q18 = 2, 3 or 4), then what was the expectedness of it?

1 = Unexpected - not mentioned in the informed consent

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

3 = Expected and accurately described in the informed consent.

20. What was the severity of the event?

1 = Mild - awareness of the sign or symptom, but easily tolerated

2 = Moderate - enough discomfort to interfere with usual activity

3 = Severe - incapacitating, with inability to do usual work or activity

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

202. User ID of person completing this form __ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/ __ __/ __ __ __ __

Person Entering this Form _____

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DAC Studies: Hospitalization Admission and Discharge Code List of Diagnoses and Procedures (For Form 361)

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)

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03AK0 Pacemaker placement
03AL0 Pacemaker malfunction/repair

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04AA() Pericarditis
04AB() Endocarditis
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)

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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)*

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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

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10CD0 other treatment

11. **HEPATOBIILIARY 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

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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

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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)
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
15AE(_)	Orchitis
15AF(_)	Cystic kidney disease (PKD or acquired)
15AG(_)	Cyst-related hemorrhage
15AH(_)	Cyst-related infection
15AI(_)	Urinary tract hemorrhage
15AJ0	Nephrectomy unilateral
15AK0	Nephrectomy bilateral
15AL0	Prostatectomy (radical)
15AM0	Transurethral prostatectomy (TURP)
15AN0	Other transurethral procedures (cystoscopy included)
15AO0	Other urologic procedure
15AP(_)	Hematuria

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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

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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
21AJ	Start of hemodialysis

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

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- 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

25. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS RELATED TO THE ACCESS PUT IN FOR DAC

- 25AA0 Elective surgical access repair
- 25AB() Soft tissue infection, cellulitis, abscess (access related)*
- 25AC Bacteremia or sepsis, access related*
- 25AD() Clotted access
- 25AE() Venous thrombosis, access related
- 25AF() Arterial thrombosis or embolism, access related
- 25AG() Steal syndrome, limb ischemia, access related
- 25AH Hemorrhage from vascular access
- 25AI() Nerve entrapment, access related
- 25AJ0 Fistulogram, arteriogram, or other invasive imaging procedure
- 25AK0 Access declotting procedure
- 25AL0 Angioplasty or stent placement for vascular access
- 25AM0 Non-elective surgical access repair
- 25AN0 Temporary access placement
- 25AO() Pneumothorax, hemothorax as result of temporary access placement
- 25AP() Subclavian vein stenosis as result of temporary access
- 25AS() Other access-related condition
- 25AT0 Other access-related procedure
- 25 AU Access placement (only when hospitalization is prolonged by a complication)