

**NIDDK Liver Transplantation Database  
MANUAL OF OPERATIONS (MOOP) DEFINITION**

**FORM: MF (COMPLICATIONS FORM)**

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Purpose: To document all major complications, including treated infections, that the patient may have experienced during specified time periods post-transplantation.

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Medical chart; laboratory/test reports; physician(s) caring for the patient.

General Instructions: This form should be filled out at each of the specified post-transplant timepoints (weeks 1 and 6, month 4, and yearly) to provide the requested information regarding any major complications the patient may have experienced during each evaluation period. Infections should be included only if they were treated, and not if they were simply identified by positive cultures but were not treated. The exception is CMV infection which should be recorded regardless of treatment. If a patient died, was retransplanted or became lost to follow-up, this form should be completed and all complications that occurred up to that time should be recorded.

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**TRANSPLANT NO.**

This is the number of liver transplants the patient has received to date. Do not include any other organ transplant.

Completing Form: Enter the number of liver transplants the patient has received as of the "Date of evaluation" listed below.

**I.1 DATE OF EVALUATION**

This is the date that the patient was seen by a physician or contacted by the LTD coordinator for postoperative follow-up. This date should coincide with the evaluation period checked below, and with the date of evaluation recorded on the CO Form (Post-transplant Long-term Follow-up).

Completing Form: Enter the month, day and year of the evaluation.

**I.2 EVALUATION PERIOD**

The timepoint for this evaluation should correspond with the protocol data collection timepoints for the CI and CO forms; i.e., information collected for the week 1 evaluation may be dated +/- two days of post-operative day 7, week 6 may be +/- seven days of post-operative day 42, month 4 may be +/- one month and yearly evaluations may be +/- 2 months of the actual date. This form should also be completed at any time that the patient was retransplanted, died or was lost to follow-up. If the date of "retransplant", "death" or "lost to follow-up" coincides with a routine evaluation timepoint, check "retransplant", "death" or "lost to follow-up", rather than the routine follow-up time. This form must be completed for each patient whether or not there was a complication. Continue these follow-up evaluations up to five years post transplant, or until retransplantation, death or until the patient is lost to follow-up, if any of these occur during the 5 year follow-up. In the case of a retransplantation, start again at week one and follow the same sequence of follow-ups for the most recent graft.

Completing Form: Check only one timepoint. For a retransplant, death or patient dropout enter the date (month/day/year). For lost to follow-up, enter the date of last contact.

**I.3 STATUS/LOCATION OF PATIENT ON THE DAY OF EVALUATION**

This indicates the patient's location or why an evaluation is being filled out at this time. If the patient was admitted for protocol testing but would otherwise be out of the hospital, check either "outpatient: local" or "home".

Completing Form: Check only one status/location.

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**I.4-5 DURING THIS EVALUATION PERIOD**

Sections I.4 and I.5 are self explanatory. The information recorded should reflect the period of time from the date of the previous evaluation to the date of this evaluation. It should not reflect the patient's hospital stay from the time of transplantation. The number of ICU readmissions should include all ICU stays regardless of duration. The number of hospital readmissions should include only those that lasted three or more days. In the case that a patient is admitted directly to the ICU from the community, and his total hospital stay is greater than three days, this event would count as both an ICU and hospital readmission. All readmissions are to be recorded whether or not the admitting hospital is an LTD center.

Completing Form:

- I.4.1 Check whether patient was discharged from the ICU for the first time since transplantation. If "yes", enter month, day, year of discharge from ICU.
- I.4.2 Record the number of ICU readmissions during this evaluation period. If there were none, enter 0.
- I.4.3 Record the total number of days in the ICU. If there were none, enter 0.
- I.5.1 Check whether patient was discharged from the hospital for the first time since transplantation. If "yes", enter month, day, year of discharge from the hospital.
- I.5.2 Record the number of hospital re-admissions that lasted 3 or more days during this evaluation period. If none, enter 0.
- I.5.3 Record the total number of days in the hospital. If there were none, enter 0.

**II. COMPLICATIONS SINCE LAST EVALUATION**

Any complications, excluding treated infections, that the patient may have experienced since the last evaluation should be documented here, and the subsequent information must be provided as defined.

- 1) Existing pre-transplant continuing post-transplant: This is a complication that existed prior to this transplant for the patient, and continues post-transplant.
- 2) Continuing from last post-transplant evaluation: This is to record a post-transplant complication that was present during the previous evaluation period and continuing into this evaluation period. The complication cited must be documented on a previous Complications Form.
- 3) Date of first new episode since last evaluation: This is the date the particular complication was first diagnosed within the period of time covered under this evaluation only. For example, the patient may have experienced several upper GI bleeds since his surgery. The date recorded here should reflect the first bleed since the "date of evaluation" of the previous evaluation period.
- 4) Number of episodes since last evaluation: This is the number of separate episodes the patient experienced during this evaluation period only. In some cases a patient may be treated several times for an ongoing complication (for example, rejection, pancreatitis or renal failure). However, in these cases the patient has experienced only one "episode". If it is difficult to distinguish between separate episodes and one ongoing complication,

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consult a physician involved in the patient's care.

- 5) Number of hospital readmissions since last evaluation: For each complication, this is the number of hospital readmissions the patient had, not necessarily for this specific complication, during this evaluation period only. If the patient was never discharged, enter 0.
- 6) Required surgery: a surgical intervention was required to treat this complication. Examples include tracheostomy, embolization, and bowel resection. Biliary complications have more specific types of intervention.
- 7) Status code at the time of this evaluation: This is the outcome of the complication at the time of this evaluation. 1: the complication is completely resolved at the time of this evaluation (such as a pneumothorax), or is controlled (such as hypertension, atrial arrhythmia, etc). 2: the complication is unresolved, continuing and/or worsening. In this case the complication will be noted as a "continuing episode from last evaluation" at the next evaluation timepoint. If the patient received a retransplantation or died while experiencing the noted complication, enter 3 or 4 if the complication contributed to the patient's need for retransplantation or cause of death, otherwise enter 1 or 2 for resolved or continuing at the time of retransplantation or death.

GENERAL INSTRUCTIONS: Check whether there were complications (excluding treated infections) since the last evaluation. If "yes" check those present from the list provided, and complete the information defined in 1) - 7) above.

- 1) Place a check in this column if the complication existed pre-transplant and is continuing post-transplant.
- 2) Place a check in this column if the complication is continuing from the previous evaluation period. Otherwise leave this space blank.
- 3) Enter the month, day and year of the first new episode since the date of the last evaluation.
- 4) Enter the number of episodes that occurred since the date of the last evaluation.
- 5) Enter the number of hospital readmissions that occurred since the date of the last evaluation. If none or never discharged, enter "0".
- 6) Place a check in this column if the complication required surgery.
- 7) Enter the status code as defined on the opposite page of the form to indicate the outcome of the complication at the time of this evaluation.

**II.1 REJECTION (COMPLETE REJECTION FORM)**

Any rejection of the transplanted liver confirmed by biopsy. It may be difficult to differentiate between several episodes of acute rejection and ongoing rejection. In this case consult a physician involved in the patient's care to assess how many separate episodes have occurred.

Completing Form: Check if rejection occurred, and complete remaining columns as instructed under General Instructions for Section II.

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**II.2 PRIMARY DYSFUNCTION/NON-FUNCTION**

Lack of liver function immediately post-transplantation. It is manifested by increasing enzymes, coagulopathy and no bile production. Primary dysfunction/non-function usually results in retransplantation.

Completing Form: Check if primary dysfunction/non-function occurred, and complete remaining columns as instructed under General Instruction for Section II.

**II.3 INTRA-ABDOMINAL BLEED**

Any bleeding within the abdomen. If a patient experiences a series of bleeds over several days but never fully recovers between them, this constitutes only one "episode". It may be difficult to differentiate between several episodes and one ongoing bleed. In this case consult a physician involved in the patient's care to assess how many separate episodes have occurred.

Completing Form: Check if intra-abdominal bleeding occurred and specify the source(s) of bleeding in the space provided. Complete remaining columns as instructed under General Instructions for Section II.

**II.4 UPPER GI BLEED**

Bleeding communicating with the esophagus, stomach or duodenum. If a patient experiences a series of bleeds over several days but never fully recovers between them, this constitutes only one "episode". It may be difficult to differentiate between several episodes and one ongoing bleed. In this case consult a physician involved in the patient's care to assess how many separate episodes have occurred.

Completing Form: Check if upper GI bleeding occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.5 LOWER GI BLEED**

Bleeding communicating with the small intestine, distal to the duodenum, colon or rectum. If a patient experiences a series of bleeds over several days but never fully recovers between them, this constitutes only one "episode". It may be difficult to differentiate between several episodes and one ongoing bleed. In this case consult a physician involved in the patient's care to assess how many separate episodes have occurred. Do not include minor bleeding from hemorrhoids for example; include only bleeding requiring medical treatment.

Completing Form: Check if lower GI bleeding occurred, and complete remaining columns as instructed under General Instructions for Section II.

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**II.6 OBSTRUCTION OF HEPATIC ARTERY**

Any obstruction of the hepatic artery confirmed by diagnostic testing such as angiogram, duplex ultrasound or surgical exploration. If a patient experiences an obstruction of the hepatic artery and the condition is not treated, note it here with a status code of 1. This complication should not be documented on subsequent follow-up unless the patient's condition worsens. If needed, record information under "COMMENTS" (section IV of the form), starting with the section no. and item name (e.g. II.6 "Obstruction of hepatic artery . . .").

Completing Form: Check if obstruction of hepatic artery occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.7 OBSTRUCTION OF THE PORTAL VEIN**

Any obstruction of the portal vein confirmed by diagnostic testing or surgical exploration. If a patient experiences an obstruction of the portal vein and the condition is not treated, note it here with a status code of 1. This complication should not be documented on subsequent follow-up unless the patient's condition worsens. If needed, record additional information under "COMMENTS" (section IV of form) as instructed.

Completing Form: Check if obstruction of the portal vein occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.8 OBSTRUCTION OF VENA CAVA**

Any obstruction of the vena cava confirmed by diagnostic testing or surgical exploration. If a patient experiences an obstruction of the vena cava and the condition is not treated, note it here with a status code of 1. This complication should not be documented on subsequent follow-up unless the patient's condition worsens. If needed, record additional information under "COMMENTS" (section IV of form) as instructed.

Completing Form: Check if obstruction of the vena cava occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.9 PANCREATITIS**

Acute or chronic inflammation of the pancreas generally associated with hyperamylasemia. Pancreatitis may be confirmed by CT, ultrasound, MRI, or surgical exploration.

Completing Form: Check if pancreatitis occurred, and complete remaining columns as instructed under General Instructions for Section II.

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**II.10      ABSCESS**

A localized collection of pus, bacteria, fungus, etc. Record only abdominal abscesses here. If there is a positive culture of the abscess available, record it in the "Treated Infections" section of this form also. However, it is possible to have an abdominal abscess without a positive culture if it is confirmed by surgical exploration, CT, ultrasound or MRI.

Completing Form: Check if abscess was present, and complete remaining columns as instructed under General Instructions for Section II.

**II.11      LIVER BIOPSY COMPLICATIONS**

Any adverse condition arising as the direct result of a liver biopsy. Examples may include intra-abdominal bleeding, infection, hematobilia and hemothorax.

Completing Form: Check if liver biopsy complications occurred, and specify in the space provided. Complete remaining columns as instructed under General Instructions for Section II.

**II.12      RENAL FAILURE**

A sustained creatinine greater than 2.0 mg/dl with or without a urine output less than 10 ml/kg for 24 hours.

Completing Form: Check if renal failure occurred and indicate whether or not the patient was treated with dialysis. Complete remaining columns as instructed under General Instructions for Section II.

**II.13      BILE PERITONITIS**

Inflammation of the peritoneum secondary to bile irritation. Bile peritonitis is usually the result of an anastomotic leak or liver injury that may be secondary to a biopsy.

Completing Form: Check if bile peritonitis occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.14      CC LEAK (CHOLEDOCHOLEDOCHOSTOMY)**

Any biliary leak from a choledochocholedochostomy. Diagnosis is made by contrast radiography or surgical exploration. This type of leak may result in bile peritonitis.

Completing Form: Check if a choledochocholedochostomy leak occurred, and complete remaining columns as instructed under General Instructions for Section II.

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**II.15 CJ LEAK (CHOLEDOCHOJEJUNOSTOMY)**

Any biliary leak from a choledochojejunostomy. Diagnosis is made by contrast radiography or surgical exploration. This type of leak may result in bile peritonitis.

Completing Form: Check if a choledochojejunostomy leak occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.16 JJ LEAK (JEJUNOJEJUNOSTOMY)**

Any biliary leak from a jejunojejunostomy. Diagnosis is made by contrast radiography or surgical exploration. This type of leak may result in bile peritonitis.

Completing Form: Check if a jejunojejunostomy leak occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.17 T-TUBE TRACT LEAK**

Any bile leak along the t-tube usually confirmed by cholangiogram. This complication may be seen after t-tube removal.

Completing Form: Check if a t-tube tract leak occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.18 ANASTOMOTIC STRICTURES**

These are CC or CJ strictures. Diagnosis is made by ERCP or transhepatic cholangiography.

Completing Form: Check if any anastomotic stricture(s) occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.19 INTRAHEPATIC STRICTURES**

These may be diagnosed by ERCP or transhepatic cholangiography.

Completing Form: Check if any intrahepatic stricture(s) occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.20 STONES/DEBRIS**

Any stones or debris demonstrated in the biliary system by diagnostic testing such as a cholangiogram. The patient may or may not be symptomatic. If this condition is not treated note it here with a status code of 1. This complication should not be documented on subsequent follow-up unless the patient's condition worsens. If needed, record additional information under "COMMENTS" (section IV of form) as instructed.

Completing Form: Check if stones/debris were present, and complete remaining columns as



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instructed under General Instructions for Section II.

**II.21 OTHER OBSTRUCTION**

Any other obstruction of the biliary tract for any reason. If caused by stones or debris check here as well as under "stones/debris" (II.20).

Completing Form: Check if other obstruction of the biliary tract occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.22 CHOLANGITIS**

Inflammation/infection of the biliary tract usually due to biliary obstruction (strictures/stones/debris). Diagnosis is made by liver biopsy, ERCP or transhepatic cholangiography.

Completing Form: Check if cholangitis occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.23 HYPOTENSION**

A sustained low blood pressure which has required medical therapy such as vasopressors or IV fluids to maintain adequate tissue perfusion.

Completing Form: Check if hypotension occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.24 HYPERTENSION**

A sustained blood pressure greater than 150/95 which has required medical treatment such as drug and/or diet therapy.

Completing Form: Check if hypertension occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.25 MYOCARDIAL INFARCTION (MI)**

An interruption of blood supply to an area of the myocardium causing necrosis. Diagnosis is made by EKG with positive CPK and MB bands. In the case that an EKG reveals a probable silent MI in the past, check here and record "unk" under "date of first new episode". Record findings under "COMMENTS" (section IV of form) as instructed.

Completing Form: Check if myocardial infarction occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.26 CONGESTIVE HEART FAILURE (CHF)**

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The inability of the heart to maintain adequate blood flow. This results in congestion of blood in certain veins and organs with an inadequate supply of blood to body tissues.

Completing Form: Check if congestive heart failure occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.27 PNEUMOTHORAX (REQUIRING CHEST TUBE)**

Air or gas in the pleural space. Document only those cases resulting in pressure large enough to require chest tube placement to allow for adequate lung expansion. Pneumothorax is confirmed by chest x-ray.

Completing Form: Check if pneumothorax occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.28 PLEURAL EFFUSION (REQUIRING THORACENTESIS)**

The presence of fluid in the pleural space. All transplant patients suffer from pleural effusions. Record only those cases when the effusion was so large and persistent that it required drainage via thoracentesis (also known as thoracocentesis, and pleuracentesis).

Completing Form: Check if pleural effusion occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.29 CARDIOPULMONARY ARREST**

A sudden cessation of the heart associated with a lack of respiration. Document only complete cardiopulmonary arrests requiring CPR. Do not check here if the patient suffered only a respiratory arrest that was not accompanied by ventricular fibrillation or ventricular standstill.

Completing Form: Check if cardiopulmonary arrest occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.30 ARDS**

Adult respiratory distress syndrome (ARDS) is decreasing pO<sub>2</sub> and lung compliance combined with a worsening physiologic shunt due to an increase in microvascular and epithelial permeability in the lung.

Completing Form: Check if ARDS occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.31 ATRIAL ARRHYTHMIA**

Any deviation from normal sinus rhythm which originates in the atrium. Examples include frequent PAC's, prolonged sinus tachycardia and bradycardia. The arrhythmia should be

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prolonged and/or treated to be noted as a complication. Do not record occasional arrhythmias observed on EKG.

Completing Form: Check if atrial arrhythmia occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.32 VENTRICULAR ARRHYTHMIA**

Any deviation from normal sinus rhythm that originates in the ventricles. The arrhythmia should be prolonged and/or treated to be classified as a complication. Examples of ventricular arrhythmias include frequent PVC's and ventricular tachycardia not associated with cardiopulmonary arrest.

Completing Form: Check if ventricular arrhythmia occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.33 REINTUBATION**

Insertion of an endotracheal tube, nasotracheal tube or tracheostomy to maintain a patent airway for adequate ventilation. Record only episodes of reintubation for respiratory failure. Do not include routine intubation experienced immediately post op or when a patient's tracheal tube or site is changed.

Completing Form: Check if reintubation occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.34 PULMONARY EDEMA**

Extravascular accumulation of fluid in the lung tissue or air spaces secondary to hydrostatic changes in the capillary permeability. Diagnosis is confirmed by chest x-ray. Document all cases of pulmonary edema, treated or untreated. It may be difficult to differentiate between several episodes of pulmonary edema and one ongoing incident. In this instance contact a physician involved with the patient's care.

Completing Form: Check if pulmonary edema occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.35 CNS CSA TOXICITY**

Central nervous system disorders believed to be the direct result of toxic levels of cyclosporine. Symptoms often include, but are not limited to: seizures, ataxia, aphasia, cortical blindness, psychotic behavior and/or neuropathy. Other factors such as metabolic imbalances may result in CNS disturbances. These other possible causes should be ruled out before a diagnosis of CNS CsA toxicity is made. Because patients experience CNS CsA toxicity at different blood levels of cyclosporine, a cut-off blood level cannot be given.

Completing Form: Check if CNS CsA toxicity occurred, and complete remaining columns as

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instructed under General Instructions for Section II.

**II.36 SEIZURES**

Any seizure believed to be unrelated to cyclosporine toxicity. Record all treated and untreated seizures. Examples include grand mal, focal, psychomotor, status epilepticus, etc.

Completing Form: Check if seizures occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.37 HEPATIC ENCEPHALOPATHY**

Resulting from liver disorder and characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels. It is graded by levels of severity into four stages ranging from lesser (stage 1) to most severe (stage 4). Asterixis is arrhythmic hand flapping evoked with the arms outstretched and dorsiflexed.

Completing Form: Check if hepatic encephalopathy occurred and enter the code as provided, for the worst stage the patient experienced. Complete remaining columns as instructed under General Instructions for Section II.

**II.38 OTHER ENCEPHALOPATHY**

Not resulting from liver disorder and characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels. It is graded by levels of severity into four stages ranging from lesser (stage 1) to most severe (stage 4). Asterixis is arrhythmic hand flapping evoked with the arms outstretched and dorsiflexed.

This variable was added to this form on February 12, 1991. Records prior to this date may have missing data for this question.

Completing Form: Check if other encephalopathy occurred and enter the code as provided, for the worst stage the patient experienced. Complete remaining columns as instructed under General Instructions for Section II.

**II.39 OTHER CNS**

Central nervous system disorders resulting from causes other than toxic levels of cyclosporine. Symptoms often

This variable was added to this form on February 12, 1991. Records prior to this date may have missing data for this question.

Completing Form: Check if other central nervous system disorder occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.40 PRIMARY BILIARY CIRRHOSIS (PBC)**

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Check here if the patient was diagnosed with primary biliary cirrhosis pre-transplant and the disease has recurred since transplantation. This diagnosis must be confirmed by biopsy.

Completing Form: Check if PBC recurred, and complete the remaining columns that are pertinent, as instructed under General Instructions for Section II.

**II.41 PRIMARY SCLEROSING CHOLANGITIS (PSC)**

Check here if the patient was diagnosed as having primary sclerosing cholangitis pre-transplant and the disease has recurred since transplantation. This diagnosis must be confirmed by biopsy.

Completing Form: Check if PSC recurred, and complete the remaining columns that are pertinent, as instructed under General Instructions for Section II.

**II.42 NEOPLASM**

A recurrence of a tumor which was diagnosed and removed prior to the time of liver transplantation. The tumor may or may not be malignant.

Completing Form: Check if a tumor recurred, and specify the type in the space provided, and indicate whether the tumor recurrence is intra or extra hepatic. Complete the remaining columns that are pertinent, as instructed under General Instructions for Section II.

**II.43 HEPATITIS**

Refer to section V. 9-12 of the CE (initial evaluation) form for definitions of A, B, C and Delta hepatitis. If a fifth type of hepatitis is suspected check other and write in the diagnosis given. Record here only the recurrence of a specific type of hepatitis that was diagnosed pre-transplant. Do not record here any new diagnosis of hepatitis A, B, C, Delta or "other".

Completing Form: Check if hepatitis recurred and the type(s) that recurred. If "other" type, specify in the space provided. Complete the remaining columns that are pertinent, as instructed under General Instructions for Section II.

**II.44 DIABETES MELLITUS (REQUIRING TREATMENT)**

Any new onset of diabetes mellitus types I or II requiring prolonged treatment such as hypoglycemic drugs and/or diet therapy to maintain a serum glucose level within acceptable limits. Do not include occasional insulin coverage that may be needed during the immediate post operative period or during a steroid bolus.

Completing Form: Check if diabetes mellitus occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.45 FRACTURES/OSTEOPOROSIS**

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Any new fracture or new diagnosis of osteoporosis confirmed on x-ray. Osteoporosis is demineralization of bone often seen on lumbar/sacral spine films.

Completing Form: Check if fractures/osteoporosis occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.46 NUTRITIONAL INSUFFICIENCY**

Document only new episodes of nutritional insufficiency that have occurred or worsened after surgery.

Completing Form: Check if nutritional insufficiency occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.47 CEREBROVASCULAR ACCIDENT (CVA)**

Any permanent damage to the blood vessels of the brain. Examples include stroke and hemorrhage but not TIAs.

Completing Form: Check if CVA occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.48 NEOPLASM: METASTATIC**

Any new tumor growth originally diagnosed in one organ or part of the body that is now found growing at a distant location not directly connected to the primary site. Do not record the recurrence of a tumor removed for transplant here (see II.40) unless it has now metastasized. Any newly diagnosed neoplasm that has not metastasized should be recorded under section II.49 "neoplasm: new."

Completing Form: Check if metastatic neoplasm occurred, and specify the type and site(s) of metastasis in the space provided. Complete remaining columns as instructed under General Instructions for Section II.

**II.49 NEOPLASM: NEW**

Any tumor that has been newly diagnosed since the patient's most recent liver transplant. Do not record metastatic neoplasms or recurrent hepatic tumors here (see Sections II.48 and II.42 respectively).

Completing Form: Check if a new tumor is present and specify the type and site in the space provided. Complete remaining columns as instructed under General Instructions for Section II.

**II.50 GROIN/AXILLARY LYMPHOCELE (REQUIRING DRAINAGE)**

Fluid collection found in the groin or axilla large enough to require drainage.

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Completing Form: Check if groin/axillary lymphocele occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.51 WOUND DEHISCENCE**

Any partial or complete separation of a surgical wound. Include any wound dehiscence; for example, at the bypass sites, not just a dehiscence of the transplant incision.

Completing Form: Check if wound dehiscence occurred, and complete remaining columns as instructed under General Instructions for Section II.

**II.52 DRUG-RELATED (EXCLUDE CNS CSA TOXICITY)**

Any serious incident directly caused by a medication administered to the patient. For example, renal failure, bleeding, anaphylactic shock, etc. Do not include minor complaints such as headaches, GI upset, drowsiness, etc. Those CNS symptoms caused by cyclosporine toxicity should be noted by checking section II.35, not here. Any infections believed to be caused by immunosuppression should be noted in Section III "Treated infections".

Completing Form: Check if any drug-related (excluding CNS CsA toxicity) complication occurred and specify the complication in the space provided. Complete remaining columns as instructed under General Instructions for Section II.

**II.53-56 OTHER COMPLICATIONS**

Any other complications that are not listed.

Completing Form: Check if any other complications occurred that are not listed and specify in the space provided. If more than four other complications occurred, record the remainder under "COMMENTS" (section IV of form) as instructed. Complete the remaining columns as instructed under General Instructions for Section II.

**III. TREATED INFECTIONS**

Infections that warranted treatment and not simply identified as positive cultures, or CMV infections regardless of treatment. Document infections by site and organism, and provide the subsequent information:

- 1) Episode number - this number will be used to track a continuing infection, such as e. coli, an infection of the urinary tract that continues through evaluation periods; or to track multiple sites for the same organism such as e. coli of the urinary tract and of a wound. Episode numbers should be documented as follows:
  - a) At a given time, multiple organisms at the same site constitute an infection episode.
  - b) At a given time, single organisms at multiple sites constitute an infection episode.
  - c) However #1 and #2 together may constitute one episode if there are any shared

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- organisms and sites.
- d) Specific organism(s) at a specific site occurring at the same time as some other organism(s) at another site are considered 2 separate episodes, and hence should be numbered consecutively.
  - e) Infections are followed by patient and not by graft, i.e., for transplant #2, the first infection episode will be the next consecutive episode # for the patient and not restart with episode #1.
  - f) In the case of an unresolved infection that continues into the next evaluation period, it will not have a new episode number but will keep its number from the previous evaluation period.
- 2) Existing pre-transplant continuing post-transplant - this is an infection that existed prior to this transplant and continues post transplant.
- 3) Continuing from last post-transplant evaluation - This is to record a post-transplant infection that was present during the previous evaluation period and continuing into this evaluation period. The infection cited must be documented on a previous Complication Form.
- 4) Date of sample of first positive culture: Use the date the sample was obtained, not the date the lab reported the results. If this is a continuing infection, note here the date of sample for the first positive culture.
- 5) Treatment code: given as
- a) Medical - e.g. antibiotic therapy.
  - b) Radiological - e.g. a sonogram guided placement of drainage tube.
  - c) Surgical - e.g. an incision and drainage.
  - d) Combination - e.g. surgical incision and drainage along with antibiotic therapy.
  - e) None - if no treatment was given.
- 6) Severity: given as
- a) Mild to moderate.
  - b) Life threatening/shock (SBP < 80).
- 7) Number of hospital readmissions since last evaluation: This is the number of hospital readmissions that the patient had for this episode of infection since the last evaluation date.
- 8) Status code at time of evaluation: given as
- a) Resolved/controlled
  - b) Unresolved/continuing/worsening
  - c) Retransplant
  - d) Died

Completing Form: For each site, code the site and the organism(s) one per line, using the codes provided on the opposite page of the form for site and organism. If site is not listed, code "other"; if organism not listed, code "other" from the correct category of microorganism, e.g. bacterial, viral, fungal, protozoal. Then for each site and each organism, complete the following.



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- 1) Episode number - enter an episode number for each infection that is new for this evaluation period. If the infection is continuing from a previous evaluation period use the episode number from that period, and check the "continued from last evaluation" column.
- 2) Place a check in this column if the infection existed pre-transplant and continues post-transplant.
- 3) Place a check in this column if the infection is continuing from the previous evaluation timepoint.
- 4) Enter the date of sample of first positive culture as month/day/year.
- 5) Enter the treatment code as specified on the opposite page of the form.
- 6) Enter the severity code as specified on the opposite page of the form.
- 7) Record the number of hospital readmissions the patient had for this episode of infection since the last evaluation date. If patient was never discharged from the hospital, enter "0".
- 8) Enter the status code as specified on the opposite page of the form to indicate the status of the patient at this time point.

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**IV. COMMENTS**

Use this space for any comments that are pertinent and have not been documented elsewhere on the form.

Completing Form: Check whether there are any comments to be made. If "yes" write in the pertinent comments.