NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION

Purpose: To document the donor's postoperative follow-up information that occurred since previous evaluation.

Person(s) Responsible: LTD Clinical Coordinators.

Source(s) of Information: Medical records of the donor, information obtained from a phone call to the donor, physician(s), laboratory and other test results.

General Instructions: Complete the form using information obtained directly from the donor or from information documented in the medical record. Information for timepoints Day 1 through Month 6 should be recorded on pages 2-5 of the form, and information for timepoints Year 1 through Year 5, or for death, or lost to follow-up, should be recorded on pages 6-9.

PATIENT ID, TRANSPLANT NO.

The Patient ID and Transplant Number are those of the transplant recipient. The transplant number should be the 1st, 2nd or 3rd, etc., transplant for this recipient.

Completing Form: Record the Patient ID and Transplant Number.

EVALUATION TIMEPOINT

Note the number of allowable days listed below each protocol timepoint. Information must be obtained within the allotted period. For example, week 1 may be the date of day 7 +/- 2 days. If the date of "death" or "lost to follow-up" coincides with a routine evaluation timepoint, check "death" or "lost to follow-up", rather than the routine follow-up time. Continue these follow-up evaluations up to five years post transplant, or until death, or until the patient is lost to follow-up.

Completing Form: In the case of death or lost to follow-up, check the appropriate category.

I. EVALUATION DATE

This is the date that the patient was seen by a physician or contacted by an LTD coordinator for postoperative follow-up.

Completing Form: Enter the date of evaluation as month, day and year. If evaluation timepoint is "death" or "lost to follow-up", also enter the date of death or date patient was lost to follow-up as month/day/year. Then, specify the cause of death or reason lost to follow-up in the space provided.

I.1 PATIENT LOCATION

This is the location of the patient on the day of evaluation. If the patient was admitted for protocol testing but would otherwise be out of the hospital, check "home".

Completing Form: Enter the appropriate location using the codes provided.

I.2 FUNCTIONAL STATUS

This is the status of the patient on the day of evaluation. If the patient was admitted for protocol testing but would otherwise be out of the hospital, check "returned to normal activities".

Completing Form: Enter the appropriate functional status using the codes provided.

I.3 DISCHARGED FROM ICU FIRST TIME

Record whether patient was discharged from the ICU for the first time since partial hepatectomy.

Completing Form: Circle "yes" or "no". If "yes", enter the date of discharge as month/day/year.

Sections I.4, I.5, I.7, I.8. The information recorded should reflect the period of time from the date of the previous evaluation (or day of partial hepatectomy for Day 1) to the date of this evaluation. It should not reflect the patient's hospital or ICU stay from the time of partial hepatectomy except in the case of Day 1 evaluation. 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.

I.4 NUMBER OF DAYS IN ICU

Completing Form: Record the total number of days in the ICU for this evaluation period. If there were none, enter 0.

I.5 NUMBER OF ICU READMISSIONS

The number of ICU readmissions should include all ICU stays since the previous evaluation regardless of duration.

Completing Form: Record the number of ICU readmissions during this evaluation period. If there were none, enter 0.

I.6 DISCHARGED FROM HOSPITAL FIRST TIME

Completing Form: Circle whether patient was discharged from the hospital for the first time since partial hepatectomy. If "yes", enter the date of discharge as month/day/year.

I.7 NUMBER OF DAYS IN HOSPITAL

Completing Form: Record the total number of days in the hospital for this evaluation period. If there were none, enter 0.

I.8 NUMBER OF HOSPITAL READMISSIONS

Completing Form: Record the total number of hospital readmissions during this evaluation period. The number of hospital readmissions should include only those that lasted three or more days.

I.9 CT SCAN DONE

Completing Form: Record whether a CT scan was done in this evaluation period. If "yes", record the date the scan was performed as month/day/year. Then, record whether normal results were obtained. If normal results were not obtained, specify the findings in the space provided.

II. LABORATORY RESULTS

The laboratory data recorded here should reflect tests done within the allowable timepoints. Use the samples closest to the date of evaluation timepoint. If units differ from those stated on the form, conversion to the correct units must be made.

DATE OF SAMPLE

Completing Form: Enter date of sample as month/day/year.

II.1 WHITE BLOOD CELLS (WBC)

1. Normal range: 3.4 x 10^3 to 38.0 x 10^3 cells/mm^3.
2. Edit range: 1.0 x 10^3 to 71.0 x 10^3 cells/mm^3.

Completing Form:

1. Record as _ _._ x 10^3 cells/mm^3.
2. If not done, check the "Not Done" column.

II.2 HEMATOCRIT (HCT)

1. Normal range: 28.0% to 67.0%.
2. Edit range: 15.0% to 67.0%.

Completing Form:

1. Record results as _ _._ %.
2. If not done, check the "Not Done" column.

II.3 PLATELET COUNT

1. Normal range: 140 x 10^3 to 451 x 10^3 cells/mm^3.
2. Edit range: 10 x 10^3 to 600 x 10^3 cells/mm^3.

Completing Form:

1. Record as _,_ _ _ x 10^3 cells/mm^3.
2. If not done, check the "Not Done" column.

II.4 PROTHROMBIN TIME (PT) PATIENT AND PT CONTROL

1. Record actual laboratory result under PT.
2. For "Control" time, use actual value if available; otherwise record the highest value given for the "Normal" range at your center (e.g. if the normal range is 10.9 to 12.8, record 12.8 as control value).
3. Normal range: 9.5 to 15.9 seconds.
4. Edit range: 9.0 to 50.0 seconds for patient; 10.0 to 15.0 seconds for control value.

Completing Form:

1. Record as _ _._ seconds for actual PT.
2. Record as _ _._ seconds for control. If not recorded: 1) if test was done at center, should be obtainable; 2) if test was not done at center, enter as "UNK".
3. If not done, check the "Not Done" column.

II.5 PARTIAL THROMBOPLASTIN TIME (PTT) PATIENT AND PTT CONTROL

1. Record actual laboratory result under PTT.
2. For "Control" time, use actual value if available; otherwise record the highest value given for the "Normal" range (e.g. if the normal range is 25.0 to 41.0, record 41.0 under control).
3. Normal range: 23.0 to 60.0 seconds.
4. Edit range: 15.0 to 150.0 seconds for patient; 15.0 to 50.0 for control value.

Completing Form:

1. Record as _ _ _._ seconds for actual PTT.
2. Record as _ _._ seconds for control. If not recorded: 1) if test was done at center, should be obtainable; 2) if test was not done at center, enter as "UNK".
3. If not done, check the "Not Done" column.

II.6 SGOT (AST)

1. Normal range for SGOT is method dependent and will vary with each center (usual range: 0 to 40 U/L).
2. Edit range: 0 to 10,000 U/L.

Completing Form:

1. Record as _ _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

II.7 ALKALINE PHOSPHATASE

1. Normal range for alkaline phosphatase is method dependent and will vary with each center (usual range: 30 to 530 U/L).
2. Edit range: 30 to 5000 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

II.8 TOTAL BILIRUBIN

1. Normal range: 0.0 to 1.2 mg/dl.
2. Edit range: 0.0 to 76.0 mg/dl.

Completing Form

1. Record as _ _._ mg/dl.
2. If not done, check the "Not Done" column.

II.9 ALBUMIN

1. Normal range: 3.4 to 5.0 g/dl.
2. Edit range: 1.0 to 6.0 g/dl.

Completing Form:

1. Record as _._ g/dl.
2. If not done, check the "Not Done" column.

II.10 BLOOD UREA NITROGEN

1. If BUN is not available, and urea is available, convert urea to BUN: ie. urea ÷ 2.14 = BUN.
2. Normal range: 5.0 to 24.0 mg/dl.
3. Edit range: 1.0 to 180.0 mg/dl.

Completing Form:

1. Record as _ _ _._ mg/dl.
2. If not done, check the "Not Done" column.

II.11 CREATININE

1. Normal range: 0.2 to 1.4 mg/dl.
2. Edit range: 0.1 to 15.0 mg/dl.

Completing Form:

1. Record as _ _._ mg/dl.
2. If not done, check the "Not Done" column.

III. LIVER INSUFFICIENCY

Record whether patient had liver insufficiency at any time since previous evaluation. Liver insufficiency is defined as SGOT >200 U/L, or PT >15 sec, or total bilirubin >2.5 mg/dl.

Completing Form: Circle "y" or "n" whether patient had liver insufficiency since previous evaluation. If "yes", record the date of sample and results for SGOT, PT for patient and control, and total bilirubin at time of diagnosis.

IV. OTHER COMPLICATIONS

Completing Form: Record whether patient had other complications to report. If "yes", complete an LC Form for the corresponding timepoint.

V. COMMENTS

Use this space for any other information that is pertinent to this evaluation period.

Completing Form: Check whether there are any comments to be made. If "yes", write in any pertinent comments. If comment pertains to a specific item on the form, precede comment with section and item number (e.g. "I.9 CT Scan: . . .").