

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

FORM: MD (DEATH REPORT FORM)

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Purpose: To document the patient's cause of death and related information.

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Medical charts, physician(s) caring for the patient, death certificate, and laboratory test reports.

General Instructions: This form is to be completed as soon as the clinical center is notified of the patient's death.

- Completion Log:
- 1) Data Collector ID - Record the data collector ID in the space provided on the form cover sheet. Record the two-digit clinical center identification code and the data collector's three initials (first letter of first, middle, and last names).
 - 2) Data Collection Date – Record the date (month/day/year) on which the form is considered to be accurate and complete.
 - 3) The remaining completion log entries are for data entry use only.

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PATIENT ID

This is the identification number assigned to the patient upon entry into the LTD.

Completing Form: Record the clinical center identification code number before the hyphen, and record the assigned 7 digit patient identification number after the hyphen. The patient ID should be recorded in the space provided at the top of each page of the form.

I.1 DATE OF DEATH

The date of death should be the date listed on the death certificate, if available. If death certificate is not available, enter date as recorded in the medical chart.

Completing Form: Record the date of death (month/day/year) from the death certificate, if available. If death certificate is not available, enter date of death as recorded in the medical chart. If any part of the date is unknown, record UNK in that position (e.g., 01/unk/99).

I.2 TIME OF DEATH

The time of death should be the time listed on the death certificate, if available.

Completing Form: Record the time of death as hours and minutes in military time (add 12 to PM hours). If unable to obtain the time of death, record UNK for the time.

II. AUTOPSY

If death occurred at the patient's "home" hospital, this information can be obtained via telephone from the attending physician.

Completing Form: Check "Yes" if an autopsy was performed and document the additional information as specified. Check "No" if no autopsy was performed. Check "Unk" if it is unknown whether an autopsy was performed.

II.1 HOSPITAL

Document the name of the hospital where the autopsy was performed.

Completing Form: If an autopsy was performed, specify the name of the hospital where the autopsy was done. Note: hospital name specification is limited to 30 characters.

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II.2 TYPE OF AUTOPSY

Document the type of autopsy (whole body or limited) that was performed.

Completing Form: If an autopsy was performed, document the type that was done. Check “Whole body” if a complete whole body autopsy was performed. Check “Limited” if only specific organs or body areas were autopsied, and specify which areas/organs were autopsied. Note: specification is limited to 30 characters.

III. TRANSPLANT STATUS

Document the patient’s death status in relation to any liver transplant surgery.

III.1 POST-TRANSPLANT

Death occurred any time after the patient left the operating room following initial liver transplantation or retransplantation.

Completing Form: Check “Post-transplant” if the patient died after leaving the operating room following liver transplantation and not during the time of repeat transplantation.

III.2 INTRAOPERATIVE, DURING REPEAT TRANSPLANT

Patient was to receive liver retransplantation, was in the operating room, did or did not undergo the repeat transplantation, and died before leaving the operating room.

Completing Form: Check “Intraoperative, during repeat transplant” if death occurred during the surgery of a repeat liver transplant that took place after the operational phase of the LTD. Document the additional information as defined.

III.2.1 PATIENT RECEIVED A TRANSPLANT?

If the patient’s death was intraoperative, document whether the patient received the liver retransplantation. Liver retransplantation is considered to be complete if reperfusion of the liver began.

Completing Form: Check “Yes” if the patient received a retransplant. Check “No” if the patient did not receive a retransplant and specify the reason why the retransplantation was not done in section III.2.1.1. Note: specification is limited to 30 characters.

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III.2.1.2 STATUS OF NEW GRAFT

If the patient received a retransplant, check the appropriate condition (i.e., Non-functioning, Poor function, or Satisfactory) to document graft functioning status at the time of death.

III.2.1.3 DID GRAFT FUNCTIONING CONTRIBUTE TO DEATH?

If the patient received a retransplant, check "Yes" if graft functioning contributed to the patient's death. Check "No" if graft functioning did not contribute to the patient's death.

III.2.1.4 DID GRAFT TECHNICAL COMPLICATIONS CONTRIBUTE TO DEATH?

If the patient received a retransplant, check "Yes" if graft technical complications contributed to the patient's death. Check "No" if graft technical complications did not contribute to the patient's death.

III.2.1.5 LENGTH OF TIME OUT OF HOSPITAL SINCE MOST RECENT TRANSPLANT

Check the appropriate time period to document the length of time that the patient has been out of the hospital since the most recent liver transplant.

- | | |
|---------------------|-------------------|
| 1. Never discharged | 4. 7 – 9 months |
| 2. < 3 months | 5. 10 – 12 months |
| 3. 3 – 6 months | 6. > 12 months |

IV. CAUSE OF DEATH

This may be obtained from the autopsy report or death certificate. Record the underlying cause(s) of death as determined by the LTD PI at your center.

IV.1 MAJOR CAUSE

Document the major cause of death.

Completing Form: Refer to the list of conditions that follows in section IV.2. Locate the major underlying cause of death and record the corresponding code number (1-38) and specify the condition if required. If major cause of death was malignancy (codes 22 or 23), specify the type in the space provided. If the cause of death is not listed in section IV.2, record code "37. Other" and specify the cause of death in the space provided. Note: specification is limited to 30 characters.

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If major cause of death was recurrent disease, refer to the "Liver Disease Diagnoses" code list on the page opposite the question and record the code number that corresponds to the liver disease. If the recurrent disease requires specification as noted in the list (codes 5, 9, 12, 17, 19, 20, 27, 28, or 32), record the required information in the space provided. If the recurrent liver disease is not listed, record code number "35. Other" and specify the disease diagnosis in the space provided. Note: specification is limited to 30 characters.

LIVER DISEASE DIAGNOSES

1. Acute hepatitis A
2. Acute hepatitis B
3. Acute hepatitis B and D
4. Acute hepatitis C
5. Acute hepatitis other (specify: e.g., drug or toxin, presumed viral, CMV, EBV, etc.)
6. Acute hepatitis of unknown cause
7. Alcoholic liver disease (Laennec's cirrhosis)
8. Alpha-1-antitrypsin deficiency
9. Benign tumor (specify: e.g., adenoma)
10. Biliary atresia
11. Budd-Chiari syndrome
12. Chronic cholestatic syndrome of childhood (specify: e.g., Bylers, Alagilles, nonsyndromatic paucity, etc.)
13. Chronic autoimmune (lupoid) hepatitis/cirrhosis
14. Chronic hepatitis B/cirrhosis
15. Chronic hepatitis B and D/cirrhosis
16. Chronic hepatitis C/cirrhosis
17. Chronic hepatitis/cirrhosis other (specify: e.g., drug or toxin, presumed viral, etc.)
18. Chronic hepatitis/cirrhosis of unknown cause
19. Congenital biliary and fibrocystic disease (specify: e.g., congenital hepatic fibrosis, Caroli's disease, etc.)
20. Glycogen storage disease (specify type)
21. Hemochromatosis
22. Homozygous hypercholesterolemia
23. Hyperalimentation-induced liver disease
24. Malignancy, cholangiocarcinoma
25. Malignancy, fibrolamellar hepatocellular carcinoma
26. Malignancy, hepatocellular carcinoma
27. Malignancy, other (specify: e.g., angiosarcoma, hemangioendothelioma, hepatoblastoma, etc.)
28. Metastatic malignancy (specify: e.g., carcinoma of breast, colon, lung, etc.)
29. Neonatal or pediatric post-hepatic cirrhosis
30. Primary biliary cirrhosis
31. Primary sclerosing cholangitis
32. biliary cirrhosis (specify cause: e.g., gall stones, stricture, etc.)
33. Tyrosinemia
34. Wilson's disease
35. Other (specify: e.g., trauma, cystic fibrosis, etc.)

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IV.2 ASSOCIATED/CONTRIBUTING CONDITIONS

In addition to the major cause of death, these are other conditions that were associated with or contributed to patient death.

Completing Form: Check all the conditions that were associated with or contributed to the underlying cause of patient death as determined by the LTD PI. If an associated/contributing condition was malignancy, specify the type in the space provided. If an associated/contributing condition is not listed in section IV.2, record code "37. Other" and specify the condition in the space provided. Note: specification is limited to 30 characters.

If an associated/contributing condition was a recurrent disease, refer to the "Liver Disease Diagnoses" code list on the page opposite the question and record the code number that corresponds to the liver disease. If the recurrent disease requires specification as noted in the list (codes 5, 9, 12, 17, 19, 20, 27, 28, or 32), record the required information in the space provided. If the recurrent liver disease is not listed, record code number "35. Other" and specify the disease diagnosis in the space provided. Do not check the major cause of death. Note: specification is limited to 30 characters

V. COMMENTS

Use the comments section to document any additional pertinent information that is related to the patient's death.

Completing Form: Check "Yes" if there is additional information to be documented. If "Yes," document the additional information pertaining to patient death in the space provided. Comments related to specific questions on the form should be preceded by the question number and heading (e.g., "IV.2.23, Primary Malignancy..."). Check "No" if there is no additional information to be documented.