



NIDDK
Liver Transplantation Database
FULMINANT STUDY FORM

11/25/1991

COMPLETION LOG

Data Collector ID _____ - _____
Center Initials

DATE

Data Collection _____ / _____ / _____

Data Entry _____ / _____ / _____

Sysid _____

Verification _____ / _____ / _____

Cleaned _____ / _____ / _____

Transfer _____ / _____ / _____
MM DD YY

FORM KEYS

Patient ID _____

FULMINANT STUDY
NIDDK Liver Transplantation Database

PATIENT ID _____ - _____

SSN CODE (last 4 digits) _____

THIS FORM IS TO BE COMPLETED FOR LTD PATIENTS WHO ARE GIVEN A DIAGNOSIS OF FULMINANT LIVER DISEASE

I. DEMOGRAPHIC DATA

1. Birthdate ____/____/____
MM DD YY

1.1 Is patient a pediatric case (age < 16 years)? Yes ____ No ____

2. Sex 1. Male ____ 2. Female ____

3. Race/ethnic background (check one)

1. Caucasian ____ 2. Black ____ 3. Am. Indian/Eskimo ____ 4. Hispanic ____

5. Oriental/Pacific ____ 6. Mideast/Arab ____ 7. Indian Subcont. ____

8. Other _____
specify (30 char)

4. Marital status (check one)

1. Never married ____ 2. Married/Cohabiting ____ 3. Separated ____

4. Divorced ____ 5. Widowed ____

5. Exposure to children at home? Yes ____ No ____

IF YES, specify number for each category

____ 5.1 Under 10 years
____ 5.2 10 - 16 years

6. Exposure to pets at home? Yes ____ No ____

IF YES, check all that apply

____ 6.1 Dog
____ 6.2 Cat
____ 6.3 Bird
____ 6.4 Other _____ specify (30 char)

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- ___ 4.1.2 Androgens
- ___ 4.1.3 Antabuse (disulfiram)
- ___ 4.1.4 Dilantin
- ___ 4.1.5 Estrogens
- ___ 4.1.6 Isoniazide (INH)
- ___ 4.1.7 Methotrexate
- ___ 4.1.8 Methyldopa
- ___ 4.1.9 Nitrofurantoin
- ___ 4.1.10 Oral Contraceptives
- ___ 4.1.11 Phenothiazines (Thorazine)
- ___ 4.1.12 Phenylbutazone
- ___ 4.1.13 Sulfas
- ___ 4.1.14 Tegretol
- ___ 4.1.15 Valproic Acid
- ___ 4.1.16 Other _____
specify (30 char)

4.2 Toxins

- ___ 4.2.1 Pesticides
- ___ 4.2.2 Industrial solvents
- ___ 4.2.3 Mushroom toxins
- ___ 4.2.4 Other _____
specify (30 char)

5. Prior blood transfusions (within the past 6 months) Yes ___ No ___ Unk ___

IF YES

5.1 Date of most recent _____/_____/_____ MM DD YY

6. Previous exposure within the past 6 months to person(s) with hepatitis/jaundice Yes ___ No ___ Unk ___

IF YES

6.1 Date(s) of exposure _____/_____/_____ _____/_____/_____ _____/_____/_____ MM DD YY

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7. HISTORY OF male homosexual contact (WITHIN THE PAST 6 MONTHS)? Yes ___ No ___ Unk ___

IF YES

7.1 Date of most recent _____ MM DD YY

8. Coexisting conditions (check all that apply)

___ 8.1 Neurologic _____
specify (30 char)

___ 8.2 Cardiovascular _____
specify (30 char)

___ 8.3 Renal _____
specify (30 char)

___ 8.4 Other _____
specify (30 char)

___ 8.5 Other _____
specify (30 char)

9. History of prior surgery (within the past 6 months) Yes ___ No ___

IF YES

9.1 Specify all type(s) _____ (30 char)
9.2 Date of most recent _____ MM DD YY

10. Were corticosteroids used (within the past 6 months)? Yes ___ No ___

IV. PHYSICAL EXAM AT TIME OF ADMISSION TO LTD CENTER

Date _____
MM DD YY

1. Height _____ cm

_____ ins x 2.54

2. Weight _____ kg

_____ lbs) 2.2

3. Temperature _____ °C

4. Blood pressure _____ / _____ mmHg

5. Pulse _____ beats/min

6. Liver span _____ cm

7. Palpable spleen Yes ___ No ___

8. Ascites Yes ___ No ___

9. Jaundice Yes ___ No ___

10. Spider angiomata Yes ___ No ___

11. Asterixis Yes ___ No ___

12. Coma (stage 4 encephalopathy) Yes ___ No ___

V. LABORATORY VALUES

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1. Red cell typing

1.1 Blood type (check one) 1. A ___ 2. B ___ 3. AB ___ 4. O ___

1.2 Rh factor (check one) Pos ___ Neg ___

Not done
(-2)

2. Serum iron _____ ug/dl _____
OR

3. Serum Ferritin	_____ ng/ml	_____
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4. Fibrinogen (Factor I) _____ mg/dl _____

5. Ceruloplasmin _____ mg/dl _____

6. Acetaminophen level _____ mg/L _____

7. Gases - in room air (if possible)

1. Arterial _____

2. Venous _____

7.1 FiO ₂	_____	_____
7.2 Hemoglobin O ₂ saturation	_____ %	_____
7.3 pO ₂	_____ mmHg	_____
7.4 pCO ₂	_____ mmHg	_____
7.5 pH	_____	_____
7.6 Base excess/deficit	_____ mEq/L	_____
7.7 Active bicarbonate	_____ mEq/L	_____

8. Viral serologies	Results		Date of Blood Sample	Not done (-2)		
	Pos	Neg				
8.1 Anti-CMV IgG	_____	_____	____/____/____	_____		
IF POS	<table border="1"> <tr> <td>Titer</td> <td>_____</td> </tr> </table>		Titer	_____	MM DD YY	
Titer	_____					

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VI. DAILY ASSESSMENT

To be recorded daily for up to seven days. If not assessed or not applicable, record NA in the space provided.

DAY	1	2	3	4	5	6	7
1. Date	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
	MM DD YY	MM DD YY	MM DD YY	MM DD YY	MM DD YY	MM DD YY	MM DD YY

2. Laboratory values	DAY	1	2	3	4	5	6	7
2.1 Hemoglobin (g/dl)		_____	_____	_____	_____	_____	_____	_____
2.2 Hematocrit (%)		_____	_____	_____	_____	_____	_____	_____
2.3 Platelet count x10 ³ (cells/mm ³)		_____	_____	_____	_____	_____	_____	_____
2.4 White blood cells x10 ³ (cells/mm ³)		_____	_____	_____	_____	_____	_____	_____
2.5 Alkaline phosphatase (U/L)		_____	_____	_____	_____	_____	_____	_____
2.6 Total bilirubin (mg/dl)		_____	_____	_____	_____	_____	_____	_____
2.7 SGOT (AST) (U/L)		_____	_____	_____	_____	_____	_____	_____
2.8 SGPT (ALT) (U/L)		_____	_____	_____	_____	_____	_____	_____
2.9 PT (pt/ctl) (secs)		___/___	___/___	___/___	___/___	___/___	___/___	___/___
2.10 Albumin (g/dl)		_____	_____	_____	_____	_____	_____	_____
2.11 BUN (mg/dl)		_____	_____	_____	_____	_____	_____	_____
2.12 Creatinine (mg/dl)		_____	_____	_____	_____	_____	_____	_____
2.13 Glucose-lowest value (mg/dl)		_____	_____	_____	_____	_____	_____	_____
2.14 Ammonia-highest value (umol/L)		_____	_____	_____	_____	_____	_____	_____

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DAY 1 2 3 4 5 6 7

3. Encephalopathy _____
(Code as specified on opposite page)

IF STAGE 4, check as appropriate for each item

3.1 Cranial nerves preserved?	_____	_____	_____	_____	_____	_____	_____
3.2 Tone							
Increase	_____	_____	_____	_____	_____	_____	_____
Decrease	_____	_____	_____	_____	_____	_____	_____
3.3 Posturing	_____	_____	_____	_____	_____	_____	_____
IF YES, check all that apply							
3.3.1 Decorticate	_____	_____	_____	_____	_____	_____	_____
3.3.2 Decerebrate	_____	_____	_____	_____	_____	_____	_____
3.4 Focality	_____	_____	_____	_____	_____	_____	_____
IF YES	specify under COMMENTS, section IX						
3.5 Seizure	_____	_____	_____	_____	_____	_____	_____

4. Abdominal ultrasound _____

5. Head CT _____

IF DONE, check all that apply

5.1 Edema	_____	_____	_____	_____	_____	_____	_____
5.2 Bleed	_____	_____	_____	_____	_____	_____	_____
5.3 Herniation	_____	_____	_____	_____	_____	_____	_____
5.4 Focality	_____	_____	_____	_____	_____	_____	_____
IF YES	specify under COMMENTS, section IX						

DAY 1 2 3 4 5 6 7

6. Intubation _____

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7. Highest FiO₂ _____

7.1 Lowest PO₂ at this highest FiO₂ _____

8. ICP Monitoring _____

IF YES

8.1 Type (code as specified on opposite page)	_____	_____	_____	_____	_____	_____	_____
8.2 Maximum reading	_____	_____	_____	_____	_____	_____	_____
8.3 Minimum reading	_____	_____	_____	_____	_____	_____	_____
8.4 Minimum cerebral perfusion pressure (MAP-ICP)	_____	_____	_____	_____	_____	_____	_____
8.5 Number of treatments given	_____	_____	_____	_____	_____	_____	_____
IF ONE OR MORE, complete for each treatment (code as specified on opposite page)							
8.5.1.1 Treatment	_____	_____	_____	_____	_____	_____	_____
8.5.1.2 Reading at start	_____	_____	_____	_____	_____	_____	_____
8.5.1.3 Reading at 1 hr	_____	_____	_____	_____	_____	_____	_____
8.5.2.1 Treatment	_____	_____	_____	_____	_____	_____	_____
8.5.2.2 Reading at start	_____	_____	_____	_____	_____	_____	_____
8.5.2.3 Reading at 1 hr	_____	_____	_____	_____	_____	_____	_____
8.5.3.1 Treatment	_____	_____	_____	_____	_____	_____	_____
8.5.3.2 Reading at start	_____	_____	_____	_____	_____	_____	_____
8.5.3.3 Reading at 1 hr	_____	_____	_____	_____	_____	_____	_____
8.5.4.1 Treatment	_____	_____	_____	_____	_____	_____	_____
8.5.4.2 Reading at start	_____	_____	_____	_____	_____	_____	_____
8.5.4.3 Reading at 1 hr	_____	_____	_____	_____	_____	_____	_____

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DAY 1 2 3 4 5 6 7

8.6 Monitor dysfunction	_____	_____	_____	_____	_____	_____	_____
IF YES, check all that apply							
8.6.1 Poor wave form	_____	_____	_____	_____	_____	_____	_____
8.6.2 Value < clinical manifestation	_____	_____	_____	_____	_____	_____	_____
8.6.3 Value > clinical manifestation	_____	_____	_____	_____	_____	_____	_____
8.6.4 Other	_____	_____	_____	_____	_____	_____	_____
IF YES,	specify under COMMENTS Section IX						
8.7 Monitor removed	_____	_____	_____	_____	_____	_____	_____

9. Intracranial bleed	_____	_____	_____	_____	_____	_____	_____
IF YES							

9.1 Site (code as specified on opposite page)	_____	_____	_____	_____	_____	_____	_____
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10. CNS infection	_____	_____	_____	_____	_____	_____	_____
11. Bacterial/fungal infection (other locations)	_____	_____	_____	_____	_____	_____	_____
IF YES							

11.1 Site (code as specified on opposite page)	_____	_____	_____	_____	_____	_____	_____
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12. Renal failure (Creatinine > 2.0 mg/dl)	_____	_____	_____	_____	_____	_____	_____
IF YES							

12.1 Spontaneous recovery	_____	_____	_____	_____	_____	_____	_____
12.2 Dialysis given	_____	_____	_____	_____	_____	_____	_____
IF YES, check reason(s)							
12.2.1 Metabolic	_____	_____	_____	_____	_____	_____	_____
12.2.2 Volume	_____	_____	_____	_____	_____	_____	_____
12.2.3 Encephalopathy	_____	_____	_____	_____	_____	_____	_____

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	DAY	1	2	3	4	5	6	7
13. GI bleed		_____	_____	_____	_____	_____	_____	_____

IF YES

13.1 Endoscopy	_____	_____	_____	_____	_____	_____	_____	_____
IF YES								
13.1.1 Diagnosis (code as specified on opposite page)	_____	_____	_____	_____	_____	_____	_____	_____

14. Transfusion given		_____	_____	_____	_____	_____	_____	_____
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IF YES, record amount for

14.1 RBC (cc)	_____	_____	_____	_____	_____	_____	_____	_____
14.2 Platelets (cc)	_____	_____	_____	_____	_____	_____	_____	_____
14.3 FFP (cc)	_____	_____	_____	_____	_____	_____	_____	_____

15. Exchange transfusion		_____	_____	_____	_____	_____	_____	_____
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16. Plasmapheresis		_____	_____	_____	_____	_____	_____	_____
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17. Hemoperfusion		_____	_____	_____	_____	_____	_____	_____
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18. Corticosteroids used		_____	_____	_____	_____	_____	_____	_____
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VII. FINAL ASSESSMENT

1. Was a liver biopsy done? Yes ____ No ____

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IF YES 1.1 Date of biopsy / / (Complete PP Form)
MM DD YY

2. Patient activation status (check one)

2.1 Activated to OLTX list DATE / /
MM DD YY

2.2 Activated, then deactivated

2.2.1 Specify reason _____ (30 char)
2.2.2 DATE activated <u> </u> / <u> </u> / <u> </u> MM DD YY
2.2.3 DATE deactivated <u> </u> / <u> </u> / <u> </u> MM DD YY

2.3 Not activated

2.3.1 Specify reason _____ (30 char)

3. Patient outcome (check one)

3.1 Alive, not transplanted

3.2 Transplanted DATE / /
MM DD YY

3.3 Died, not transplanted DATE / /
MM DD YY

4. Was ICP monitor ever placed? Yes No

IF NO, check reason

<input type="checkbox"/> 4.1 < Stage III encephalopathy
<input type="checkbox"/> 4.2 Patient died before monitor could be placed
<input type="checkbox"/> 4.3 Refractory coagulopathy
<input type="checkbox"/> 4.4 Other _____ specify (30 char)

VIII. LIVER DISEASE DIAGNOSIS

Use code(s) provided in Liver Disease Diagnoses list on opposite page. List in order - primary, secondary, etc., and specify when appropriate

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1. Referral diagnosis (at time of admission)

Code	Specification (for #5, 9, 12, 17, 19, 20, 27, 28, 32, 35)
1.1 _____	_____
1.2 _____	_____
1.3 _____	_____

specify (30 char)

2. Final diagnosis (at completion of the assessment period)

Code	Specification (for #5, 9, 12, 17, 19, 20, 27, 28, 32, 35)
2.1 _____	_____
2.2 _____	_____
2.3 _____	_____

specify (30 char)

ENCEPHALOPATHY CODE

- 0. No encephalopathy
- 1. Lethargy and/or asterixis
- 2. Confusion and disorientation
- 3. Stupor or coma, but arousable
- 4. Deep coma
- 5. Drug induced coma

ICP MONITOR TYPE

1. Epidural
2. Subarachnoid
3. Intraventricular

ICP MONITOR TREATMENT CODE

1. None
2. Mannitol
3. Pentobarbital
4. Hyperventilation
5. Prostaglandins
6. Other

INFECTION SITES

<u>Code</u>	<u>Site</u>	<u>Code</u>	<u>Site</u>
1.	Bile ducts	8.	Oral
2.	Blood	9.	Peritoneum
3.	Genital	10.	Skin
4.	Intestinal	11.	Upper respiratory tract
5.	Liver	12.	Urinary tract
6.	Lung	13.	Wound
7.	Meningi/Brain/CSF	14.	Other (specify under COMMENTS, section IX)
		15.	Unknown

INTRACRANIAL BLEED SITES

<u>Code</u>	<u>Site</u>
1.	Intraventricular
2.	Intracerebral
3.	Subdural/epidural

ENDOSCOPY DIAGNOSIS

<u>Code</u>	<u>Site</u>
1.	Gastritis
2.	Ulcer
3.	Variceal
4.	Undetermined
5.	Other (specify under COMMENTS, section IX)

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, non-syndromatic paucity of bile ducts, 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, polycystic liver disease, choledochal cyst, 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. Secondary 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.)