



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)

FULMINANT STUDY
NIDDK Liver Transplantation Database

1. SYMPTOMS FOR CURRENT EPISODE OF ILLNESS (check all that apply)

___ 1.1 Confusion/encephalopathy Date of FIRST ONSET ___/___/___

___ 1.2 Jaundice/dark urine Date of FIRST ONSET ___/___/___
MM DD YY

2. Alcohol use (ever) Yes ___ No ___ Unk ___

IF YES

2.1 Number of years of use	_____
2.2 Number of drinks per week	_____
2.3 Date of most recent use	_____/_____/_____ MM DD YY

3. IV drug use (ever) Yes ___ No ___ Unk ___

IF YES

3.1 Number of years of use	_____
3.2 Date of most recent use	_____/_____/_____ MM DD YY

4. Drug/toxin exposure (within the past month) Yes ___ No ___ Unk ___

IF YES, check all that apply

4.1 Drugs	___ 4.1.1 Acetaminophen (greater than recommended dose)
-----------	---

FULMINANT STUDY
NIDDK Liver Transplantation Database

- ___ 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

FULMINANT STUDY
NIDDK Liver Transplantation Database

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

FULMINANT STUDY
NIDDK Liver Transplantation Database

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	_____
-------------------	-------------	-------

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	_____	_____	_____/_____/_____ MM DD YY	_____		
IF POS	<table border="1"> <tr> <td>Titer</td> <td>_____</td> </tr> </table>		Titer	_____		
Titer	_____					

FULMINANT STUDY
NIDDK Liver Transplantation Database

8.2 Anti-CMV IgM ___ ___ ___/___/___ ___
8.3 Anti-EBV (VCA) IgG ___ ___ ___/___/___ ___
8.4 Anti-EBV (VCA) IgM ___ ___ ___/___/___ ___
8.5 Anti-HSV ___ ___ ___/___/___ ___
8.6 Anti-HAV ___ ___ ___/___/___ ___
8.7 Anti-HAV IgM ___ ___ ___/___/___ ___
8.8 HBsAg ___ ___ ___/___/___ ___
8.9 Anti-HBc ___ ___ ___/___/___ ___
8.10 Anti-HBc IgM ___ ___ ___/___/___ ___

IF HBsAg POSITIVE

8.11 HBeAg	___	___	___/___/___	___
8.12 Anti-HBe	___	___	___/___/___	___
8.13 Anti-HDV	___	___	___/___/___	___

8.14 Anti-HBs ___ ___ ___/___/___ ___
8.15 Anti-HCV ___ ___ ___/___/___ ___
8.16 Anti-HIV ___ ___ ___/___/___ ___

IF HIV POSITIVE

8.17 Western Blot	___	___	___/___/___	___
-------------------	-----	-----	-------------	-----

8.18 Anti-HTLVI ___ ___ ___/___/___ ___

9. Histocompatibility testing Date of sample ___/___/___
 MM DD YY

9.1 HLA-A ___/___
9.2 HLA-B ___/___
9.3 HLA-DR ___/___

Optional:

9.4 HLA-BW4/6 ___/___ 9.7 HLA-DQ ___/___
9.5 HLA-C ___/___ 9.8 HLA-DP ___/___
9.6 HLA-DRW52/53 ___/___

FULMINANT STUDY
NIDDK Liver Transplantation Database

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)		_____	_____	_____	_____	_____	_____	_____

FULMINANT STUDY
NIDDK Liver Transplantation Database

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 _____

FULMINANT STUDY
NIDDK Liver Transplantation Database

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	_____	_____	_____	_____	_____	_____	_____

FULMINANT STUDY
NIDDK Liver Transplantation Database

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)	_____	_____	_____	_____	_____	_____	_____

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

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	_____	_____	_____	_____	_____	_____	_____

FULMINANT STUDY
NIDDK Liver Transplantation Database

	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		_____	_____	_____	_____	_____	_____	_____
-----------------------	--	-------	-------	-------	-------	-------	-------	-------

IF YES, record amount for

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

15. Exchange transfusion		_____	_____	_____	_____	_____	_____	_____
--------------------------	--	-------	-------	-------	-------	-------	-------	-------

16. Plasmapheresis		_____	_____	_____	_____	_____	_____	_____
--------------------	--	-------	-------	-------	-------	-------	-------	-------

17. Hemoperfusion		_____	_____	_____	_____	_____	_____	_____
-------------------	--	-------	-------	-------	-------	-------	-------	-------

18. Corticosteroids used		_____	_____	_____	_____	_____	_____	_____
--------------------------	--	-------	-------	-------	-------	-------	-------	-------

VII. FINAL ASSESSMENT

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

FULMINANT STUDY
NIDDK Liver Transplantation Database

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 _____ / _____ / _____ MM DD YY
2.2.3 DATE deactivated _____ / _____ / _____ 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

___ 4.1 < Stage III encephalopathy
___ 4.2 Patient died before monitor could be placed
___ 4.3 Refractory coagulopathy
___ 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

FULMINANT STUDY
NIDDK Liver Transplantation Database

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.)