



NIDDK

Liver Transplantation Database

POST-TRANSPLANT FOLLOW-UP FORM

LONG-TERM CLINICAL & LABORATORY DATA

02/12/1991

COMPLETION LOG

Data Collector ID _____
Center Initials

DATE

Data Collection _____/_____/_____

Data Entry _____/_____/_____

Sysid _____

Verification _____/_____/_____

Cleaned _____/_____/_____

Transfer _____/_____/_____
MM DD YY

<u>FORM KEYS</u>
Patient ID _____
Transplant No. _____
Evaluation Timepoint _____

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT ID _____

TRANSPLANT NUMBER _____

To be completed by the clinical coordinator at follow-up collection times (4 and 12 months and yearly thereafter) post-transplant. If the patient has returned home, the data are to be obtained from the local caretaking physician mail-in form and/or via telephone contact with the local physician or with the patient. If the patient has returned to the clinical center for this evaluation, the data are to be obtained from the examining physician or from the records at the clinical center.

I. 1. DATE OF EVALUATION/PATIENT CONTACT _____ / _____ / _____
MM DD YY

2. EVALUATION TIMEPOINT (check one)

- 9. Four months
- 10. Year 1
- 11. Year 2
- 12. Year 3
- 13. Year 4
- 14. Year 5

3. Was PATIENT AT CLINICAL CENTER for evaluation? Yes__ No__

IF NO, specify source of information (check one)

- 1. Physician Mail-In Form
- 2. Physician contacted by LTD coordinator
- 3. Patient contacted by LTD coordinator

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT

ID

II. CURRENT MEDICAL STATUS (Physician's Assessment)

1. Was PHYSICAL EXAMINATION performed? Yes__ No__

IF YES

1.1 Height _____ cm

1.2 Weight _____ kg

1.3 Nutritional status (check one)

1. Excellent (well nourished)

2. Fair (mild/moderate depletion or partially repleted)

3. Poor (severe depletion)

1.4 Muscle wasting Yes__ No__

1.5 Is patient a pediatric case (age < 16 years)? Yes__ No__

IF YES, COMPLETE for PEDIATRIC PATIENTS ONLY

1.5.1 Percentile height for age (NCHS chart) _____

1.5.2 Percentile weight for age (NCHS chart) _____

1.5.3 Head circumference (for patients ≤ 3 years of age) _____cm

1.5.3.1 Percentile for age (NCHS chart) _____

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT

ID

2. KARNOFSKY SCALE (check one)

- 1. Normal, no complaints, no evidence of disease. (Does not look or act like he/she has liver disease and, in the case of adults, admittedly feels fine).
- 2. Able to carry on normal activity, minor signs or symptoms of disease. (Works/attends school/ plays normally in spite of slight or intermittent evidence of disease, e.g. fatigue).
- 3. Normal activity with effort, some signs or symptoms of disease. (Works/attends school/plays normally but chronically does not feel well, e.g. chronic fatigue, chronic pruritus).
- 4. Cares for self (consistent with age) but unable to carry on normal activity or to do active work/ school/play. (Has had to quit usual work duties (in or outside of the home)/can no longer attend school/play is more passive than active at this point).
- 5. Requires occasional assistance (beyond general age appropriate level) but is able to care for most of own needs. (Experiences periods of time when activities of daily living are not possible for him/her to accomplish (appropriate for age). This is the younger child who usually can walk or sit by self but periodically cannot do this independently).
- 6. Requires considerable assistance and frequent medical care. (Can, at best, only assist with activities of daily living appropriate for age. This is the infant who now needs considerable help with feedings that formerly had been easy. Also has need of frequent clinic and/or hospital visits for management of signs/symptoms of end-stage disease (ie., recurrent cholangitis, encephalopathy, chronic unrelieved pruritus, ascites that is difficult to manage)).
- 7. Disabled, requires special care and assistance. (Requires total care of most of his/her needs including specialized needs that might include: hemodialysis, tube feeding, home hyperalimentation, etc.).
- 8. Severely disabled, hospitalization is indicated although death not imminent. (Is not well enough to be managed safely or completely at home any longer).
- 9. Hospitalization necessary, very sick, active support treatment necessary. (Constant medical and/or surgical intervention to keep patient alive such as: FFP infusions/exchange transfusions to control coagulopathy, frequent infections requiring one or more antibiotics, treatment of variceal bleeds, may or may not need ventilator assistance but probably requires O₂).
- 10. Moribund, fatal processes progressing rapidly. (May include the following: multiple infections, hepatic coma, active bleeding, and labile BP requiring vasopressors).

3. Was PROTOCOL BIOPSY performed? Yes___ No___

(Note: Biopsy date may be ± 2 months of one-year follow-up timepoint.)

IF YES

3.1 DATE	____/____/____
	MM DD YY

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT

ID

4. DRINKING HISTORY

4.1 Ever drink alcohol since most recent transplant or since last followup evaluation?

Yes__ No__ Unk__

IF YES

4.1.1 Currently drink?	Yes__ No__ Unk__
IF YES	4.1.1.1 Number of drinks during a typical week _____
IF NO	4.1.1.2 When did patient stop drinking? ____/____ MM YY
	4.1.1.3 Previous number of drinks during a typical week _____
4.1.2 Has patient ever thought or been told that he/she may have a drinking problem?	
Yes__ No__ Unk__	

III. MEDICATIONS on day of follow-up evaluation

(check all that apply)

1. Immunosuppressives

	Total Daily Dose (mg)
<input type="checkbox"/> 1.1 Cyclosporine	_____
<input type="checkbox"/> 1.2 FK506	_____
<input type="checkbox"/> 1.3 Imuran	_____
<input type="checkbox"/> 1.4 ALG	_____
<input type="checkbox"/> 1.5 Prednisone	_____
<input type="checkbox"/> 1.6 Prednisolone	_____
<input type="checkbox"/> 1.7 Solumedrol	_____
<input type="checkbox"/> 1.8 OKT3	_____
<input type="checkbox"/> 1.9 Other _____	_____
<input type="checkbox"/> 1.10 Other _____	_____
<input type="checkbox"/> 1.11 Other _____ specify (30 char)	_____

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT

ID

2. OTHER MEDICATIONS Yes__ No__

IF YES, code as specified in Appendix I

CODE	NAME (30 characters)	Check here if <u>Other</u> med.
1. _____	_____	_____
2. _____	_____	_____
3. _____	_____	_____
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____
7. _____	_____	_____
8. _____	_____	_____
9. _____	_____	_____
10. _____	_____	_____
11. _____	_____	_____
12. _____	_____	_____
13. _____	_____	_____
14. _____	_____	_____
15. _____	_____	_____
16. _____	_____	_____
17. _____	_____	_____
18. _____	_____	_____

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT

ID

IV. LABORATORY DATA

1. HEMATOLOGY Date of sample ____/____/____ Not Done (-2)
MM DD YY
- 1.1 Hemoglobin (HGB) _____. ____g/dl _____
- 1.2 Hematocrit (HCT) _____. ____% _____
- 1.3 Platelet count x 10³ _____, _____ cells/mm³ _____
- 1.4 White blood cells (WBC) x 10³ _____. ____ cells/mm³ _____
- 1.5 Prothrombin time (PT) _____. ____/____. ____secs. _____
Patient Control
- 1.6 Partial thromboplastin time (PTT) _____. ____/____. ____secs. _____
Patient Control

2. IMMUNOSUPPRESSIVE MEDS. LEVELS

- 2.1 CYCLOSPORINE LEVEL Date of sample ____/____/____ _____
MM DD YY

IF DONE

2.1.1 Specimen type:	1. Whole blood ____	2. Serum ____	
2.1.2 Trough level obtained at:	1. 6 hr ____	2. 8 hr ____	3. 12 hr ____
	4. 24 hr ____	5. Cont. Infusion ____	6. Other _____ specify (30 char)
			Not Done (-2)
2.1.3 HPLC level	_____ ng/ml		_____
2.1.4 RIA level	_____ ng/ml		_____
2.1.5 TDX level	_____ ng/ml		_____
2.1.6 Monoclonal RIA	_____ ng/ml		_____

- 2.2 FK506 LEVEL Date of sample ____/____/____ _____
MM DD YY

IF DONE

2.2.1 Method _____ specify (30 char)
2.2.2 Level _____ ng/ml

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

PATIENT _____

ID _____

3. CLINICAL CHEMISTRY

Date of sample ____/____/____
MM DD YY

Not Done
(-2)

- 3.1 Alkaline phosphatase _____ U/L _____
- 3.2 Total bilirubin _____ mg/dl _____
- 3.3 Direct bilirubin _____ mg/dl _____
- 3.4 SGOT (AST) _____ U/L _____
- 3.5 SGPT (ALT) _____ U/L _____
- 3.6 Gamma GTP _____ U/L _____
- 3.7 Albumin _____ g/dl _____
- 3.8 Alpha fetoprotein _____ ng/ml _____
- 3.9 Bicarbonate _____ mEq/L _____
- 3.10 Blood urea nitrogen _____ mg/dl _____
- 3.11 Calcium _____ mg/dl _____
- 3.12 Chloride _____ mEq/L _____
- 3.13 Cholesterol _____ mg/dl _____
- 3.14 Creatinine _____ mg/dl _____
- 3.15 Glucose _____ mg/dl _____
- 3.16 Potassium _____ mEq/L _____
- 3.17 Sodium _____ mEq/L _____
- 3.18 Total protein _____ g/dl _____

4. URINE STUDIES (at 4 mos and at yearly intervals)

Date of sample ____/____/____
MM DD YY

Not Done
(-2)

- 4.1 Creatinine clearance _____ ml/min _____
Number of hours _____

OR

4.2 GFR (glomerular filtration rate) _____ ml/min _____

5. CULTURES

RESULTS
Pos Neg

Date of Sample

- 5.1 CMV - blood _____ _____ ____/____/____ _____
- 5.2 CMV - urine _____ _____ ____/____/____ _____
MM DD YY

POST-TRANSPLANT FOLLOW-UP LONG-TERM - CLINICAL
NIDDK Liver Transplantation Database

		PATIENT		ID		
6. INFECTION SCREEN	RESULTS		Date of Sample		Not Done (-2)	
	Pos	Neg				
<u>Viral serologies</u>						
6.1 Anti-CMV IgG	___	___	___/___/___	MM DD YY	___	
Titer	_____					
6.2 Anti-CMV IgM	___	___	___/___/___		___	
6.3 Anti-EBV (VCA) IgG	___	___	___/___/___		___	
6.4 Anti-EBV (VCA) IgM	___	___	___/___/___		___	
6.5 Anti-HSV	___	___	___/___/___		___	
6.6 Anti-HAV	___	___	___/___/___		___	
6.7 Anti-HAV IgM	___	___	___/___/___		___	
6.8 HBsAg	___	___	___/___/___		___	
6.9 Anti-HBc	___	___	___/___/___		___	
IF HBsAg POSITIVE						
6.10 Anti-HBc IgM	___	___	___/___/___		___	
6.11 HBeAg	___	___	___/___/___		___	
6.12 Anti-HBe	___	___	___/___/___		___	
6.13 Anti-HDV	___	___	___/___/___		___	
6.14 Anti-HBs	___	___	___/___/___		___	
6.15 Anti-HCV	___	___	___/___/___		___	
** 6.16 Anti-HIV	___	___	___/___/___		___	
IF HIV POSITIVE						
** 6.17 Western Blot	___	___	___/___/___		___	
** 6.18 Anti-HTLV1	___	___	___/___/___		___	

