L T D

NIDDK

Liver Transplantation Database

COMPLICATIONS FORMS

12/09/1991

COMPLETION LOG

Data Collector ID   _____-_____
                       Center   Initials

                              DATE

Data Collection   _____/_____/_____

Data Entry   _____/_____/_____

        Sysid _____

Verification   _____/_____/_____

Cleaned   _____/_____/_____

Transfer   _____/_____/_____
             MM   DD   YY

FORM KEYS

Patient ID _____

Transplant No. _____

Evaluation Timepoint _____

COMPLICATIONS FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

TRANSPLANT NO. _____

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

2.   Evaluation period (check one)

__ 1. Week 1   __ 9. Retransplant: Date_____/_____/_____
                                                     MM   DD   YY
__ 2. Week 6

__ 3. Month 4   __10. Death: Date   _____/_____/_____
                                                     MM   DD   YY
__ 4. Year 1
                          __11. Lost to follow-up:
__ 5. Year 2
                                Date of last contact   _____/_____/_____
__ 6. Year 3   MM   DD   YY

__ 7. Year 4   __12. Patient dropout: _____/_____/_____
                                                        MM   DD   YY
__ 8. Year 5

3.   STATUS/LOCATION OF PATIENT on day of evaluation (check one)

__ 1. In hospital: ICU/Step down unit   __ 5. Retransplant

__ 2. In hospital: floor   __ 6. Died

__ 3. Outpatient: local   __ 7. Lost to follow-up

__ 4. Home   __ 8. Rehabilitation institute

COMPLICATIONS FORM
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PATIENT ID _____-_____

4. During this evaluation period

4.1 Was patient discharged from the ICU for the first time since transplantation?   Yes__   No__

IF YES

> 4.1.1 Date of discharge _____/_____/_____
> MM   DD   YY

4.2 Number of ICU re-admissions   _____

4.3 Total number of days in ICU   _____

5. During this evaluation period

5.1 Was patient discharged from the hospital for the first time since transplantation?

Yes__   No__

IF YES

> 5.1.1 Date of discharge _____/_____/_____
> MM   DD   YY

5.2 Number of hospital re-admissions (> 3 day duration)   _____

5.3 Total number of days in hospital   _____

COMPLICATIONS FORM
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PATIENT ID _____-_____

II.   COMPLICATIONS since last evaluation?   Yes__   No__

IF YES, check all that apply

	CONTINUATION STATUS		SINCE LAST EVALUATION				STATUS CODE* at time of this eval.
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	

GRAFT FUNCTION

__ 1. Rejection (complete Rejection Form)	_____	_____	__/__/__ MM DD YY	_____	_____	_____	_____
__ 2. Primary dysfunction/non-function	_____	_____	__/__/__	_____	_____	_____	_____

ABDOMINAL

__ 3. Intra-abdominal bleed	_____	_____	__/__/__	_____	_____	_____	_____

_____
specify source (30 char)

__ 4. Upper GI bleed	_____	_____	__/__/__	_____	_____	_____	_____
__ 5. Lower GI bleed	_____	_____	__/__/__	_____	_____	_____	_____
__ 6. Obstruction of hepatic artery	_____	_____	__/__/__	_____	_____	_____	_____
__ 7. Obstruction of portal vein	_____	_____	__/__/__	_____	_____	_____	_____

_____
* see opposite page for codes

COMPLICATIONS FORM
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PATIENT ID _____-_____

	CONTINUATION STATUS		SINCE LAST EVALUATION				STATUS CODE*
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	at time of this eval.
__ 8. Obstruction of vena cava	_____	_____	___/___/___	_____	_____	_____	_____
__ 9. Pancreatitis	_____	_____	___/___/___	_____	_____	_____	_____
__10. Abscess	_____	_____	___/___/___	_____	_____	_____	_____
__11. Liver biopsy complications	_____	_____	___/___/___	_____	_____	_____	_____

_____
specify (30 char)

RENAL

__12. Renal failure (creatinine > 2.0 and/or
    urine output < 10 ml/kg/24 hrs)   _____   _____   ___/___/___ _____   _____   _____   _____

     IF YES | 12.1 Dialysis given?   Yes__   No__ |

BILIARY

__13. Bile peritonitis	_____	_____	___/___/___	_____	_____	_____	_____
__14. CC leak	_____	_____	___/___/___	_____	_____	_____	_____
__15. CJ leak	_____	_____	___/___/___	_____	_____	_____	_____

COMPLICATIONS FORM
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PATIENT ID _____-_____

	CONTINUATION STATUS		SINCE LAST EVALUATION				STATUS CODE*
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	at time of this eval.
__16. JJ leak	_____	_____	___/___/___	_____	_____	_____	_____
__17. T-tube tract leak	_____	_____	___/___/___	_____	_____	_____	_____
__18. Anastomotic strictures	_____	_____	___/___/___	_____	_____	_____	_____
__19. Intrahepatic strictures	_____	_____	___/___/___	_____	_____	_____	_____
__20. Stones/debris	_____	_____	___/___/___	_____	_____	_____	_____
__21. Other obstruction	_____	_____	___/___/___	_____	_____	_____	_____
__22. Cholangitis	_____	_____	___/___/___	_____	_____	_____	_____

CARDIOPULMONARY

__23. Hypotension	_____	_____	___/___/___	_____	_____	_____	_____
__24. Hypertension (treated BP > 150/95)	_____	_____	___/___/___	_____	_____	_____	_____
__25. Myocardial infarction	_____	_____	___/___/___	_____	_____	_____	_____
__26. Congestive heart failure	_____	_____	___/___/___	_____	_____	_____	_____
__27. Pneumothorax (requiring chest tube)	_____	_____	___/___/___	_____	_____	_____	_____
__28. Pleural effusion (requiring thoracentesis)	_____	_____	___/___/___	_____	_____	_____	_____
__29. Cardiopulmonary arrest	_____	_____	___/___/___	_____	_____	_____	_____
__30. ARDS	_____	_____	___/___/___	_____	_____	_____	_____
__31. Atrial arrhythmia	_____	_____	___/___/___	_____	_____	_____	_____
__32. Ventricular arrhythmia	_____	_____	___/___/___	_____	_____	_____	_____

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PATIENT ID _____-_____

	CONTINUATION STATUS		SINCE LAST EVALUATION				STATUS CODE*
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	at time of this eval.
__33. Reintubation	_____	_____	__/__/__	_____	_____	_____	_____
__34. Pulmonary edema	_____	_____	__/__/__		_____	_____	_____

NEUROLOGIC

__35. CNS CsA toxicity	_____	_____	__/__/__	_____	_____	_____	_____
__36. Seizures	_____	_____	__/__/__	_____	_____	_____	_____
__37. Hepatic encephalopathy	_____	_____	__/__/__	_____	_____	_____	_____

IF YES

> 37.1 Specify code for worst stage   _____
>
> 1. Lethargy and/or asterixis   3. Stupor or coma, but arousable
> 2. Confusion and disorientation   4. Deep coma

__38. Other encephalopathy	_____	_____	__/__/__	_____	_____	_____	_____

IF YES

> 38.1 Type _____
>   (30 char)
>
> 38.2 Specify code for worst stage   _____

__39. Other CNS	_____	_____	__/__/__	_____	_____	_____	_____

_____
specify (30 char)

COMPLICATIONS FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

| | CONTINUATION STATUS | | SINCE LAST EVALUATION | | | | STATUS CODE* |
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	at time of this eval.

RECURRENCE OF DISEASE

__40. Primary biliary cirrhosis _____ _____ __/__/__ _____ _____ _____ _____

__41. Primary sclerosing cholangitis _____ _____ __/__/__ _____ _____ _____ _____

__42. Neoplasm _____ _____ __/__/__ _____ _____ _____ _____

   IF YES

   | 42.1 Type _____ |
   | (30 char) |
   | |
   | 42.2 Site   1. Intrahepatic ___   2. Extrahepatic ___ |

__43. Hepatitis _____ _____ __/__/__ _____ _____ _____ _____

   IF YES, check type(s)

   | __ 43.1 A   __ 43.4 C |
   | |
   | __ 43.2 B   __ 43.5 Other _____ |
   | specify (30 char) |
   | |
   | __ 43.3 B & Delta |

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PATIENT ID _____-_____

	CONTINUATION STATUS		SINCE LAST EVALUATION				STATUS CODE*
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	at time of this eval.

OTHER

__44. Diabetes Mellitus (requiring treatment)	_____	_____	__/__/__	_____	_____	_____	_____
__45. Fractures/osteoporosis	_____	_____	__/__/__	_____	_____	_____	_____
__46. Nutritional insufficiency	_____	_____	__/__/__	_____	_____	_____	_____
__47. Cerebrovascular accident	_____	_____	__/__/__	_____	_____	_____	_____
__48. Neoplasm: metastatic	_____	_____	__/__/__	_____	_____	_____	_____

_____
specify (30 char)

__49. Neoplasm: new	_____	_____	__/__/__	_____	_____	_____	_____

_____
specify (30 char)

__50. Groin/axillary lymphocele (requiring drainage)	_____	_____	__/__/__	_____	_____	_____	_____
__51. Wound dehiscence	_____	_____	__/__/__	_____	_____	_____	_____

COMPLICATIONS FORM
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PATIENT ID _____-_____

	CONTINUATION STATUS		SINCE LAST EVALUATION				STATUS CODE*
	Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation	Date of first new episode	Number of episodes	Number of hospital readmissions	Check if REQUIRED SURGERY	at time of this eval.
__52. Drug-related (exclude CNS CsA toxicity)	_____	_____	___/___/___	_____	_____	_____	_____
_____ specify (30 char)							
__53. Other complications	_____	_____	___/___/___	_____	_____	_____	_____
_____ specify (30 char)							
__54. Other complications	_____	_____	___/___/___	_____	_____	_____	_____
_____ specify (30 char)							
__55. Other complications	_____	_____	___/___/___	_____	_____	_____	_____
_____ specify (30 char)							
__56. Other complications	_____	_____	___/___/___	_____	_____	_____	_____
_____ specify (30 char)							

COMPLICATIONS FORM
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PATIENT ID _____-_____

III. TREATED INFECTIONS: code as specified on opposite page

	Site	Organism	Episode Number	CONTINUATION STATUS		Date of sample first positive culture MM DD YY	Treatment Code	Severity	Since last evaluation Number of hospital readmissions	Status Code at time of Eval.
				Existing Pre-tx continuing Post-tx	Continuing from last Post-tx evaluation					
1.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
2.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
3.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
4.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
5.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
6.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
7.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
8.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
9.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
10.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
11.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
12.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
13.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
14.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____
15.	____	_____	_____	_____	_____	___/___/___	_____	_____	_____	_____

COMPLICATIONS FORM
NIDDK Liver Transplantation Database

PATIENT ID _____-_____

IV. COMMENTS: Yes__   No__

IF YES

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

(60 char/line)

<u>STATUS CODE</u>

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

STATUS CODE

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

BILIARY TREATMENT CODES

0. No Intervention
1. Surgical
2. Radiological
3. Endoscopic
4. Surgical/Endoscopic
5. Surgical/Radiological
6. Radiological/Endoscopic

STATUS CODE

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

BILIARY TREATMENT CODES

0. No Intervention
1. Surgical
2. Radiological
3. Endoscopic
4. Surgical/Endoscopic
5. Surgical/Radiological
6. Radiological/Endoscopic

<u>STATUS CODE</u>

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

STATUS CODE

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

STATUS CODE

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

<u>STATUS CODE</u>

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died

INFECTION SITES

Code	Site		Code	Site
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
			15.	Unknown

MICROORGANISMS

Code	Type		Code	Type
Bacterial			**Fungal**	
1.	Achromobacter		25.	Aspergillis
2.	Acinetobacter		26.	Candida
3.	Alcaligenes		27.	Cryptococcus
4.	Anaerobes		28.	Histoplasma
5.	Bacteroides		29.	Mucormycosis
6.	Citrobacter		30.	Torulopsis glabrata
7.	Clostridium		31.	Other
8.	Corynebacterium		**Protozoal**	
9.	E. Coli		32.	Pneumocystis carinii
10.	Enterococcus (Strep D)	33.		Toxoplasma
11.	Enterobacter		34.	Other
12.	Klebsiella		**Viral**	
13.	Legionella		35.	Adenovirus
14.	Listeria		36.	CMV
15.	M. tuberculosis		37.	CMV serology conversions
16.	Neisseria		38.	EBV
17.	Pneumococcus		39.	HIV
18.	Pseudomonas		40.	HSV
19.	Serratia marcescens		41.	HZV
20.	Shigella	42.		RSV
21.	Staphylococcus aureus		43.	Viral hepatitis A
22.	Staphylococcus coagulase negative		44.	Viral hepatitis B
23.	Streptococcus (non-enterococcal)		45.	Viral hepatitis B plus hepatitis Delta
24.	Other		46.	Viral hepatitis C
			47.	Other
			48.	Unknown

SEVERITY CODES
1. Mild to Moderate
2. Life Threatening Shock (SEP < 80)

TREATMENT CODES

1. Medical
2. Radiological
3. Surgical
4. Combination
5. None

STATUS CODES

1. Resolved (controlled)
2. Unresolved/continuing/worsening
3. Retransplant
4. Died