

REVISED REGISTRATION FORMS THE NORDIC LIVER TRANSPLANT REGISTRY – 18-DEC-07

Nordic Liver Transplant Registry

Revised version 18. December 2007

Data from almost 4000 patients have now been entered to the NLTR. This represents a unique dataset spanning the years 1984 up until today. This amount of data is only achievable through the Nordic collaboration, and it is therefore important to continue the maintenance of the registry for future studies to be possible, even if local registries now exist at several hospitals. The updated NLTR aims to ensure the future of this database at Scandiatransplant.

Practical points:

- 1) Forms have been revised, but the general functionality of the NLTR is the same.
- 2) If there are questions regarding data entry/database functionality, please contact Frank Pedersen at Scandiatransplant at +4589495308.
- 3) *It is extremely important that each center makes sure that Form C is used at the follow-up of the patients. ONE person should have the responsibility to check this, but how it is practically done may vary from center to center.*
- 4) For "Liver tumor" in Form B, the post-pathology results may not be available immediately. It is important that the form is not considered complete until this data has been registered. The person who enters the rest of the data must make sure of this.

General notes to navigating/data entry in the NLTR:

To find a patient, enter the Scandianumber or person identification number and press "F12".

To navigate between fields use the «enter» key and "tab" key

To navigate between pages use the the "page down" and "page up" keys.

Pop-up: To enter a pop-up, press "F7". To submit a code, press "F10". To leave the pop-up window, press "F4" or ctrl+b.

List: To show list of possible parameters press "F5"

Commit: To enter the selected variable/entered variable into NLTR; press "F10".

Help: For list of commands, press ctrl-k

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Form A notes:

Blood group: It is now possible to state subtypes of A ("A1" or "A2") or only "A" (must also be entered/alterd) in the Scandiatransplant system.

Diagnosis: Diagnoses are now the same as in ELTR. Codes (e.g. A19) are entered after pressing "F7" to open up the "pop-up" window. The "old" codes are shown for patients where data have already been entered – NO new input should be entered into "old" – it is merely for showing old data. A separate list of diagnoses is included with the new forms and can be consulted, or one could press "F5" to list the diagnoses and select the appropriate one.

Re-transplantation diagnosis: These codes are now in line with ELTR. Please see list below , or press "F5" to view the different alternatives directly in the NLTR.

Previous malignancy: After opening the "pop-up" window by pressing "F7", one should enter "NONE" if no previous malignancy has been detected, "LPD" if a previous lymphoproliferative disease had been diagnosed (e.g. lymphoma) and "OT" for other malignancy (e.g. colon cancer). If you have no information at all please enter ND for Not done/unknown.

Encephalopathy: This has a new system, meaning N is NO encephalopathy, and 1-4 is the grade of encephalopathy. This replaces the old system of 1-4, and the field "old" is merely for showing old data.

Blood samples: Please make sure to enter the number according to the right scale (e.g. g/100ml vs. mmol/l).

Serology: In this "pop-up" (again enter by pressing "F7") there are several adjustments. Please note that the HCV PCR is only positive or negative - positive is stated when virus is found, regardless of the level. For HCV genotype, genotype (e.g. 1a) could be entered manually, or one can press "F5" to view the list of available genotypes.

Alfa-fetoprotein: Here some laboratories give a "lower than" value for the lowest values (e.g. <5). In this case, enter 0. For other values, the exact values should now be entered (compared with the previous "high/low" distinction).

Form B notes:

Simultaneous transplantations: Press "F7" to enter the "pop-up" window.

Encephalopathy: See form A.

Artificial liver support: Enter either N (none), M (MARS) or P (Prometheus).

Pre-pathology versus post-pathology: To enter the pre- and post-pathology variable "pop-up" screens, press "F7" and enter the variables. Pre-pathology is "yes" if one or more tumors were diagnosed prior to the pathological investigation (i.e. prior to the liver transplantation). Post-pathology is only possible to enter when pathological investigations have been performed, meaning that it may take some time for this data to be available. It is important not to consider data entry as finished until the post-pathology reports are entered. The abbreviations are HCC: HepatoCellular Carcinoma, CC: CholangioCarcinoma .

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Perfusion: Press "F5" to show list of perfusion possibilities.

Donor serology: Press "F7" to enter the "pop-up" window.

Liver segments: This is also a "pop-up", press "F7" and state the segments used.

Immunosuppression: Press "F7" to enter the "pop-up" window, then enter one or more medications. A medication list can be shown directly in NLTR by pressing "F5" at the first line.

Form C notes:

This form has been changed the most and is very important for the follow-up data to be collected on the patients. It is important to have a practical routine to ensure that data are updated for the patients at 1, 3, 5, 10, 15 etc. years, but it is also possible to enter data at other times (for instance if any center wishes to enter data at every control).

Events, portal vein thrombosis: If ultrasound/doppler has not been performed, it is important to enter DND (doppler not done) and not leave the space open.

Liver tumor and extrahepatic malignancy: Please enter type of tumor/malignancy under "comment".

New onset renal failure: Here it needs to be stated how the renal failure has been treated (medical treatment, dialysis or kidney transplantation).

Transplant other organ: Please enter type of organ under "comment".

Form D notes:

The list of causes of death has also been updated. To enter the diagnosis, simply enter the "pop-up" window by pressing "F7". Please see separate list of diagnoses, or press "F5" to see the list in NLTR. The "old" field should not (and cannot) be used, it is only for showing data with the old codes.

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FORM A ACCEPTANCE

Social security number _____
Surname _____ First name _____
A1A2B0 blood group _____
Weight _____ kg
Height _____ cm

Date of acceptance ____ ____ ____ (d m y)

Diagnosis first liver transplantation (see list):

Primary diagnosis _____

Secondary diagnoses _____

Diagnosis re-transplantation (see list):

Retransplantation diagnosis _____

Previous malignancy

- Type: _____ (NONE, lymphoproliferative [LPD] or Other)
- Year: _____
- Comment: _____

<p><i>Events (at <u>any time</u> up to acceptance):</i></p> <p>Encephalopathy _____ (N/1-4)</p> <p>Variceal bleeding _____ (N/Y)</p> <p>Ascites _____ (N/Y)</p>	<p><i>Events at acceptance on waiting list (within +/- 2 weeks):</i></p> <p>In hospital _____ (N/Y)</p> <p style="text-align: center;">(except control)</p> <p>Ventilator _____ (N/Y)</p>
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FORM A cont.

At acceptance on waiting list (within +/- 2 weeks for non-acute patients, within a few days for acute patients)

Biochemistry:		<u>Alternate unit</u>
Hemoglobin	_____ g/100ml	_____ mmol/l
Thrombocytes	_____ 10 ⁹ /l	
INR	_____	
ALAT	_____ U/l	_____ microkat/l
ASAT	_____ U/l	_____ microkat/l
Albumin	_____ g/l	_____ micromol/l
Bilirubin	_____ µmol/l	
Creatinine	_____ µmol/l	
Urea	_____ mmol/l	
Hemodialysis	_____ (N/Y)	(for MELD/PELD)

Serology:	
Anti CMV IgG	_____ (+/-/ND)
Hepatitis Bs antibody	_____ (+/-/ND)
Hepatitis Bc antibody	_____ (+/-/ND)
Hepatitis Bs antigen	_____ (+/-/ND)
Hepatitis Be antigen	_____ (+/-/ND)
Hepatitis B DNA PCR	_____ (+/-/ND)
Hepatitis C antibody	_____ (+/-/ND)
Hepatitis C RNA PCR	_____ (+/-/ND)
Anti HIV antibodies	_____ (+/-/ND)
EBV IgG	_____ (+/-/ND)
 Hepatitis C genotype	 _____

Alfa-1-foetoprotein	_____ µ/L	(if below 5, state 0)
CA19-9	_____ U/mL	
CEA	_____ ng/ml	

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FORM B TRANSPLANTATION

Scandiatransplant no. _____ Social security number _____
Surname _____ First name _____
Weight _____ kg Height _____ cm (only if age < 18 years)

Transplantation date _____ (d m y)

Simultaneous transplantations (state "Y" only if performed):

Heart	_____	(Y)
Kidney	_____	(Y)
Pancreas	_____	(Y)
Small Bowel	_____	(Y)
Lung	_____	(Y)
Pancreatic islets	_____	(Y)
Bone marrow	_____	(Y)

At Transplantation:

Encephalopathy _____ (N/1-4)
In hospital _____ (N/Y) (except for control)
Ventilator _____ (N/Y)
Artificial liver supp. _____ (N/MARS/Prometheus), no. treatments: ____

Biochemistry:

Alternate unit

Hemoglobin	_____ g/100ml	_____ mmol/l
Thrombocytes	_____ 10 ⁹ /l	
INR	_____	
ALAT	_____ U/l	_____ microkat/l
ASAT	_____ U/l	_____ microkat/l
Albumin	_____ g/l	_____ micromol/l
Bilirubin	_____ µmol/l	
Creatinine	_____ µmol/l	
Urea	_____ mmol/l	
Hemodialysis	_____ (N/Y)	(for MELD/PELD)

Pre-pathology: Liver tumor diagnosed _____ (N/Y)

Post-pathology: Liver tumor diagnosed _____ (N/Y)

Type _____ HCC/CC/OTher; comment: _____

Number _____

Diameter _____ (mm, largest lesion)

Extrahepatic growth _____ (N/Y)

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FORM B cont.

Donor:

Deceased/living Donor _____ (CDT/LDT/domino)
 Harvesting center _____
 Sex _____ (M/F)
 Age _____ years
 A1A2BO Blood group _____ (if no A subgroup available, state A)
 Weight _____ kg Height _____ cm
 Perfusion _____ (UW / Custodiol / Celsior)

Donor serology:

Anti CMV IgG _____ (+/-)
 Hepatitis Bs antibody _____ (+/-/ND)
 Hepatitis Bc antibody _____ (+/-/ND)
 Hepatitis Bs antigen _____ (+/-/ND)
 Hepatitis Be antigen _____ (+/-/ND)
 Hepatitis C antibody _____ (+/-)
 EBV IgG _____ (+/-)

Operation:

Whole/Partial/Split liver _____ (W/P/S)
 Liver segments _____ (I,II,III,IV...)
 Cold ischemia time _____ hours (whole numbers)
 Biliary anastomosis _____ (Chol-Cholstomy, Chol-Jejunostomy)
 Piggy-back _____ (N/Y)

Immunosuppression (during first month) – check box:

- | | |
|--|--|
| <input type="checkbox"/> glucocorticoids (GLU) | <input type="checkbox"/> mycophenolatmofetile (MMF) |
| <input type="checkbox"/> tacrolimus (FK) | <input type="checkbox"/> anti-thymocyte globulin (ATG) |
| <input type="checkbox"/> everolimus (EVE) | <input type="checkbox"/> anti-CD3 antibodies (OKT) |
| <input type="checkbox"/> sirolimus (SIR) | <input type="checkbox"/> basiliximab (BAS) |
| <input type="checkbox"/> cyclosporine A (CSA) | <input type="checkbox"/> daclizumab (DAC) |
| <input type="checkbox"/> azathioprine (AZA) | <input type="checkbox"/> other (OTH) |

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FORM C FOLLOW-UP ADMISSION
(Minimum use: 1, 3, 5, 10, 15, 20, 25, 30 years controls)

Scandiatransplant no. _____ Social security number _____
Surname _____ First name _____
Weight _____ kg Height _____ cm (only if age < 18 years)

Date at follow-up: ____ ____ ____ (d m y)

Biochemistry:

Alternate unit

INR	_____		
Bilirubin	_____	μmol/l	
Albumin	_____	g/l	_____ micromol/l
Creatinine	_____	μmol/l	
Hemodialysis	_____	(N/Y)	(for MELD/PELD)

Immunosuppression (at follow-up) – check box:

- | | |
|--|--|
| <input type="checkbox"/> glucocorticoids (GLU) | <input type="checkbox"/> mycophenolatmofetile (MMF) |
| <input type="checkbox"/> tacrolimus (FK) | <input type="checkbox"/> anti-thymocyte globulin (ATG) |
| <input type="checkbox"/> everolimus (EVE) | <input type="checkbox"/> anti-CD3 antibodies (OKT) |
| <input type="checkbox"/> sirolimus (SIR) | <input type="checkbox"/> basiliximab (BAS) |
| <input type="checkbox"/> cyclosporine A (CSA) | <input type="checkbox"/> daclizumab (DAC) |
| <input type="checkbox"/> azathioprine (AZA) | <input type="checkbox"/> other (OTH) |

Events (since last control):

Acute rejections (treated) _____ (N/Y), how many: _____
Recurrent disease _____ (N/Y)
Portal vein thrombosis (total) _____ (N/Y or doppler not done - DND)
A. hepatica thrombosis (total) _____ (N/Y or doppler not done - DND)
Biliary strictures (treated) _____ (N/Y)
Liver tumor _____ (N/Y), comment: _____
Extrahepatic malignancy _____ (N/Y), comment: _____
New onset diabetes (insulin) _____ (N/Y)
New onset renal failure _____ (N/Y),
- If yes: medical treatment only (MTO)/DIAlysis/TX: _____
Transplant other organ _____ (N/Y), comment: _____
Children (numbers) _____ (state for both females and males)

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FORM D DEAD (all patients)

Scandiatransplant no. _____

Social security number _____

Surname _____

First name _____

Date of survival status ____ ____ ____ (d m y)

For dead patients:

Date of death ____ ____ ____ (d m y)

Cause of death (see list):

Primary cause _____

Secondary causes _____

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List of diagnosis codes for first transplantation (Form A):

A1	Acute hepatic failure	Fulminant or subfulminant hepatitis	Virus A
A2	Acute hepatic failure	Fulminant or subfulminant hepatitis	Virus B
A3	Acute hepatic failure	Fulminant or subfulminant hepatitis	Virus C
A4	Acute hepatic failure	Fulminant or subfulminant hepatitis	Virus D
A5	Acute hepatic failure	Fulminant or subfulminant hepatitis	Other known
A6	Acute hepatic failure	Fulminant or subfulminant hepatitis	Other unknown
A7	Acute hepatic failure	Fulminant or subfulminant hepatitis	Paracetamol
A8	Acute hepatic failure	Fulminant or subfulminant	Other drug related
A9	Acute hepatic failure	Fulminant or subfulminant	Toxic (non-drug)
A91	Acute hepatic failure	Fulminant or subfulminant	Heat shock
A10	Acute hepatic failure	Post-operative	
A11	Acute hepatic failure	Post traumatic	
A12	Acute hepatic failure	Other	
A13	Subacute hepatitis	Virus A	
A14	Subacute hepatitis	Virus B	
A15	Subacute hepatitis	Virus C	
A16	Subacute hepatitis	Virus D	
A17	Subacute hepatitis	Other known	
A18	Subacute hepatitis	Other unknown	
A19	Subacute hepatitis	Paracetamol	
A20	Subacute hepatitis	Other drug related	
A21	Subacute hepatitis	Toxic (non-drug)	
B1	Cholestatic disease	Secondary biliary cirrhosis	
B2	Cholestatic disease	Primary biliary cirrhosis	
B3	Cholestatic disease	Primary sclerosing cholangitis	
B4	Cholestatic disease	Others	
C1	Congenital biliary disease	Caroli disease	
C2	Congenital biliary disease	Extrahepatic biliary atresia	
C4	Congenital biliary disease	Congenital biliary fibrosis	
C5	Congenital biliary disease	Choledochal cyst	
C6	Congenital biliary disease	Alagille syndrome	
C7	Congenital biliary disease	Others	
D1	Cirrhosis	Alcoholic	
D2	Cirrhosis	Autoimmune	
D3	Cirrhosis	Virus B	
D4	Cirrhosis	Virus C	
D5	Cirrhosis	Virus BD	
D6	Cirrhosis	Virus BC	
D7	Cirrhosis	Virus BCD	
D71	Cirrhosis	Combined virus C and alcoholic cirrhosis	
D72	Cirrhosis	Combined virus B and alcoholic cirrhosis	
D73	Cirrhosis	Virus E related cirrhosis	
D8	Cirrhosis	Virus Other	
D9	Cirrhosis	Drug related	
D10	Cirrhosis	Other	
D11	Cirrhosis	Unknown cause	

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List of diagnosis codes for first transplantation (Form A) – continued:

E1	Cancers	Hepatocellular carcinoma and cirrhosis	
E2	Cancers	Hepatocellular carcinoma and non-cirrhotic liver	
E3	Cancers	Hepatocellular carcinoma - Fibrolamellar	
E4	Cancers	Biliary tract carcinoma (Klatskin)	
E5	Cancers	Hepatic cholangiocellular carcinoma	
E6	Cancers	Hepatoblastoma	
E7	Cancers	Epithelioid hemangioendotelioma	
E8	Cancers	Angiosarcoma	
E9	Cancers	Secondary liver tumors - Carcinoid	
E10	Cancers	Secondary liver tumors - Other neuroendocrine	
E11	Cancers	Secondary liver tumors - Colorectal	
E12	Cancers	Secondary liver tumors - GI non colorectal	
E13	Cancers	Secondary liver tumors - Non gastrointestinal	
E14	Cancers	Other liver malignancies	
F1	Metabolic diseases	Wilson	
F2	Metabolic diseases	Haemochromatosis	
F3	Metabolic diseases	Antitrypsin deficiency	
F4	Metabolic diseases	Glycogen storage disease	
F5	Metabolic diseases	Hypercholesterolemia	
F6	Metabolic diseases	Tyrosinemia	
F7	Metabolic diseases	Familial amyloidotic polyneuropathy	
F8	Metabolic diseases	Primary oxaluria	
F9	Metabolic diseases	Protoporphyrria	
F91	Metabolic diseases	NASH	
F10	Metabolic diseases	Other Porphyria	
F11	Metabolic diseases	Crigler-Najjar	
F12	Metabolic diseases	Cystic fibrosis	
F13	Metabolic diseases	Byler disease	
F14	Metabolic diseases	Others	
G	Budd-chiari		
H1	Benign liver tumors or polycystic disease	Hepatic adenoma	
H2	Benign liver tumors or polycystic disease	Adenomatosis	
H3	Benign liver tumors or polycystic disease	Hemangioma	
H4	Benign liver tumors or polycystic disease	Focal Nodular Hyperplasia	
H5	Benign liver tumors or polycystic disease	Polycystic disease	
H6	Benign liver tumors or polycystic disease	Nodular regenerative hyperplasia	
H7	Benign liver tumors or polycystic disease	Other benign tumor	
I1	Parasitic disease	Schistosomia	
I2	Parasitic disease	Alveolar echinococcosis	
I3	Parasitic disease	Cystic hydatidosis	
I4	Parasitic disease	Other	
J	Other liver disease		
K	Not available		
L	TPN-induced cholestasis		
M	Hepatopulmonary syndrome		
N	Microangiopathy		
O	Small for size syndrome		

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List of codes for death (Form D) or re-transplantation diagnosis (Form A):

A1	Intraoperative (death on table)		
B1	Infection	Bacterial infection	
B2	Infection	Viral infection	
B3	Infection	HIV	
B4	Infection	Fungal infection	
B5	Infection	Parasitic infection	
B6	Infection	Other	
C1	Liver complications	Acute rejection	
C2	Liver complications	Chronic rejection	
C3	Liver complications	Arterial thrombosis	
C4	Liver complications	Hepatic vein thrombosis	
C41	Liver complications	Early portal vein thrombosis	
C42	Liver complications	Outflow impairment	
C5	Liver complications	Primary non-function (≤7 days)	
C6	Liver complications	Primary dys-function (>7 days)	
C61	Liver complications	Small for size syndrome	
C7	Liver complications	Anastomotic biliary complication	
C8	Liver complications	Non-anastomotic biliary complication	
C9	Liver complications	Recurrence of original disease	Virus B
C10	Liver complications	Recurrence of original disease	Virus C
C11	Liver complications	Recurrence of original disease	Virus D
C12	Liver complications	Recurrence of original disease	Alcoholic
C13	Liver complications	Recurrence of original disease	PBC
C14	Liver complications	Recurrence of original disease	PSC
C15	Liver complications	Recurrence of original disease	Autoimmune
C16	Liver complications	Recurrence of original disease	Budd-Chiari
C17	Liver complications	Recurrence of original disease	Other
C18	Liver complications	De novo Virus B	
C19	Liver complications	De novo Virus C	
C20	Liver complications	De novo Virus D	
C21	Liver complications	Massive hemorrhagic necrosis	
C22	Liver complications	Other viral hepatitis	
C23	Liver complications	Infection	
C24	Liver complications	Other	
D1	Gastrointestinal complications	GI hemorrhage	
D2	Gastrointestinal complications	Pancreatitis	
D3	Gastrointestinal complications	Visceral perforation	
D4	Gastrointestinal complications	Other	
E1	Cardiovascular complications	Myocardial Infarction	
E2	Cardiovascular complications	Other	
F1	Cerebrovascular complications	Intracranial hemorrhage	
F2	Cerebrovascular complications	Ischaemic stroke	
F3	Cerebrovascular complications	Cerebral oedema	
F4	Cerebrovascular complications	Cerebral infarction	
G1	Tumor	Recurrence of original tumor	
G2	Tumor	Recurrence of previously unrelated tumor	
G3	Tumor	De novo solid organ tumor	
G4	Tumor	Donor transmitted tumor	
G5	Tumor	Lymphoproliferative disease	
H1	Renal failure		
H2	Urinary tract infection		
I1	Pulmonary complications	Embolism	
I2	Pulmonary complications	Infection	
J1	Social complications	Non compliance immunosuppression	
J2	Social complications	Suicide	
J3	Social complications	Trauma	
K1	Bone marrow depression		
L1	Other		
M1	Not available		
N1	Neurological complication		
O1	NLTR pre-transplant specific causes of death	Hepatic	hepatorenal syndrome
O2		Hepatic	ascending cholangitis
O3		Hepatic	hepatocellular carcinoma
O4		Hepatic	cholangiocarcinoma
O5		Hepatic	metastasis to liver
O6		Other	extrahepatic malignancy