Jeevandan

Scheme for cadaver organ transplantation

(Established under G.O.Rt.No.1462, HM&FW(M1) Department, dated: 11.11.2009)

AACT Sub-Committee (Liver and Pancreas)

Donor Organ Sharing Scheme

Operating Principles for Liver Transplant Units in Telangana

Prepared by
AACT Sub-Committee (Liver and Pancreas)

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A. Back ground

1. The Government of Andhra Pradesh initiated a scheme for cadaver organ transplantation called "Jeevandan" with the objective of promoting and regulating the transplantation of human organs.[1]

2. The legal authority for governing the various aspects relating to the organ transplantation was vested with "Appropriate Authority for Cadaver Transplantation" (AACT) the structure and functions of which were well-defined.

3. A virtual internet-based co-ordinating mechanism named APNOS was also established within AACT for co-ordinating the activities of various centres and NGOs.

4. The AACT formed a sub-committee for liver and pancreas with a mandate to prepare guidelines for organ harvesting, transportation, organ allocation and other issues related to cadaver transplantation. The following members were appointed for the Liver and Pancreas Sub-Committee.[2]

Name	Hospital
Dr.R.A.Sastry	KIMS
Dr.Sharath Putta	KIMS
Dr.N.Bheerappa	NIMS
Dr.Sukanya	NIMS
Dr.R.Pratap Reddy	OMC
Dr.Ch.Madhusudan	OMC
Dr.Panduranga Rao	OMC
Dr.K.Ravindranarh	Global Hosp.
Dr.Balbir Singh	Global Hosp.
Dr.Dharmesh Kapoor	Global Hosp.
Dr.P.N.Rao	AIG
Dr.Pradeep Rebela	AIG

5. The Committee in its formal and informal meets deliberated and suggested the following guidelines as operating principles for implementation of Liver Transplantation programme in the state.

[1] G.O.Ms.No.184 dt. 16-08-2010

[2] Rc.No.38346/MAK(JVN)/2013 dt.31-01-2013

B. General Principles

The Donor Organ Sharing Scheme principles set out below are those specified by Liver and Pancreas Sub-Group of AACT.

a) Registration of new recipients

- All patients awaiting a transplant must be registered on APNOS. The recipients that are registered on the portal through an OTC will only be considered for allotment in the allotment sequence irrespective domicile or any other factor. Registration will be done in two categories.
    - Super urgent transplantation (see below)
    - Elective transplantation
- Registration will be Institution-based in either category after on-line application in the appropriate format and after the required payment is made. Patients will be placed on the Transplant Database waiting list on the day on which complete details are received at APNOS. Discrepancies or missing information will be followed up with the OTC and might cause a delay.
- The applications for super urgent transplantation will be circulated to other OTCs for peer review as soon as they are registered. If there is no objection within 24 hrs. the applications will be accepted for registration.
- The registration for super urgent transplantation will have to be updated and reregistered every 24 hrs.
- The registrations for elective transplantation will have to be updated and reregistered every one month. The priority sequence of recipients from that each OTC will accordingly be updated.
- Transfer from super urgent list to elective list and vice versa should be done as soon as the condition of the recipient changes.
- Delisting from an OTC's waiting list and relisting on another OTC's list is permissible. But the change of centre will not be taken cognizance for allotment unless done at least 72 hrs. before a deceased donor's organ retrieval.
- The priority sequence in waiting lists of recipients and the criteria adopted will have to be declared by the OTCs. If for any reason, the criteria are not followed in any given case, a valid explanation will have to be provided. All the waiting lists, the allotment criteria and exceptions if any, will be published on the portal.

b) Donor Information and Registration

- All potential liver donors in Andhra Pradesh must be reported by telephone or internet to the AACT/APNOS as soon as either:
    - the brain stem death tests have been confirmed; or
    - relatives' consent has been obtained;
- They must be registered on APNOS as soon as possible through an on-line application in the appropriate format.

c) Contraindications for donor acceptance:

- Potential donors found to be positive for HIV antibody are an absolute contraindication to organ donation.
- Neither donor units nor AACT will offer livers from donors who have not been tested for Hepatitis B surface antigen, Hepatitis C antibody or HIV antibody.

- Livers from donors found to be positive for Hepatitis B surface antigen, Hepatitis B core AB, or for Hepatitis C antibody will be offered to OTCs for use in life-saving situations. The final decision whether or not to accept the organ lies with the transplant surgeon.

C. Priorities of Allotment

a. Elective List

- First priority shall be given to the OTC where the deceased donor is located. If for any reason, the OTC is not able to accept the organ, the organ will be passed on to the general pool (see below). If none of the registered OTCs in the state is in a position to accept the offer, the organ will be offered to the OTCs outside the state provided such a request has been registered with the Jeevandan portal. If the organ still remains unutilized after exhausting all the above criteria, it will be offered to any foreign national registered in an OTC.

General Pool:

- Livers retrieved in the following situations are defined as general pool.
    - Livers retrieved at NTOHCs (non transplant centres)
    - Liver retrieved from an OTC where the deceased donor was located but the liver could not be utilized at that centre for any reason.
    - Liver retrieved from an OTC where the deceased donor was located but the donor was shifted from an NTOHC less than 72 hrs. of brain stem death declaration. However, If a donor is transferred from an NTOHC to an OTC more than 72 hrs. before declaration of brain stem death, then the OTC will be deemed to be the source of the organ.

Allotment Principles:

- In order to encourage the budding transplant programmes in the state and for an equitable distribution of the scarce organs, the following principles will be followed.

- The allotment of liver from a deceased donor will be OTC-based and in the following sequence.

- Currently four OTCs are actively involved in the deceased donor liver transplant programme. They are:

    1. Asian Institute of Gastroenterology
    2. Krishna Institute of Medical Sciences
    3. Global Hospital and
    4. Apollo Hospital

- As more centres become active and register their potential recipients on APNOS they will be added in their chronological sequence to the above.

- Donor liver offers for non-Super Urgent recipients will be in accordance with the "liver allocation sequence". The sequence will comprise all the OTCs registered with APNOS in the order mentioned above, always headed by the organ retrieval centre.
- Offers will be made to the registered OTCs in the liver allocation sequence, on the basis of a firm offer to the first centre and a provisional offer to the second in line.
- For all cases, centres with a firm offer must advise AACT within 60 minutes whether they wish to accept or decline the offer. If the organ is declined, it will be offered to the second in line as a firm offer and to the third in line as a provisional offer, and so on through the liver allocation sequence.
- For first offers made to a centre previously advised provisionally, AACT must be advised within 45 minutes whether they wish to accept or decline.
- A centre declining an offer will not retain its place on the liver allocation sequence.
- However, when an OTC decides to decline a liver offer because of alleged marginal quality it will be offered to the next OTCs in sequence and if all the other OTCs also decline the offer, then the first OTC will retain its place in the allotment sequence.
- An OTC that has accepted the offer of a liver is expected to follow the priority sequence declared by them in selecting the recipient. **If for any reason, the criteria are not followed in any given case, a valid explanation will have to be provided.**

b. Super urgent liver scheme

i. Super urgent diagnosis

To be registered on the Super Urgent Liver Scheme, the patient should belong to at least one of the categories listed in Annexure V.

ii. Super urgent liver scheme registration

- The applications for super urgent transplantation will be circulated to other OTCs for peer review as soon as they are registered. If there is no objection within 24 hrs. the applicants will be accepted for registration.

- The registration for super urgent transplantation will have to be updated and reregistered every 24 hrs.
- Transfer from super urgent list to elective list and vice versa is desirable as soon as the condition of the recipient changes.
- A summary of recipients on the Super Urgent Liver Scheme will be shown on the APNOS. The summary will show the date and time of registration on the Super Urgent Liver Scheme.
- The sequence of offers for recipients registered as Super Urgent will be strictly in relation to blood group and the time of registration; the blood group compatible patient having been registered the longest at any one time taking priority, and thereafter in reverse-chronological order by time of registration. For this purpose, APNOS will maintain a list of Super Urgent registrants.

iii. Exceptions

- Units which have a Super Urgent recipient registered, and subsequently identify a suitably matched blood group local donor, may retain the local donor for their Super Urgent recipient irrespective of other Super Urgents registered at the time. However, the Super Urgent recipient must already be registered with APNOS.
- If a unit has accepted an offered liver for a Super urgent recipient and subsequently identify a suitably matched blood group donor, they should either:
    - give up the right to the offered liver if the offered liver is not en route to them; or
    - retain the offered liver and the local liver if the offered liver has been received or is en route to them.
- Above disputes should be decided by mutual consent surgeon to surgeon. Until the APNOS receives further clarification, the patient will remain on the super-urgent list.
- When a Super Urgent patient is registered at APNOS after a liver has been offered to and accepted by a unit for a non Super Urgent patient but is not yet implanted, the non Super Urgent recipient shall retain priority for using the liver. However, the AACT will advise the transplanting unit of the newly-registered Super Urgent recipient and it is for the transplanting unit to decide whether to retain the offer or to give it up. In such cases it will not be possible for AACT to organise peer review prior to advising the transplanting centre of the newly-registered Super Urgent case. If the patient does not receive the previously accepted liver, peer review will be carried out in the normal way.
- When a liver has been accepted for a Super Urgent patient and the transplant does not proceed, for recipient reasons, the organ should first be offered back to the OTC where the deceased donor was located. If not accepted by the zonal team, the liver will go to the general pool and get allotted.

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Annexure 1

CADAVER PROFORMA

Name of the Potential Donor: ……Age/Sex…… Blood Group: …….

Height:…….. Weight:…….

Donor Hospital: …….. Date:……

Reason for hospitalization:…….. Date:……

Date of Ventilation:…… ICU stay (No. of days) ……

Cause of Brain Death:……Date:……

Time of Brain Death Declaration: First:……...

Second:…….

Inotropic support: Dopamine/ Dobutamine/…….

Episodes of Hypotension:…… SaO2: ……..

Antibiotics……

Urine output:…….. Blood Pressure:…….. Heart Rate:……..

History of

Family status

Medical History

DM / HTN / Thyroid status / Long term medication

Previous surgeries **Abdominal trauma: …….**

Blood Transfusions

ALCOHOL **SMOKING**

SAMPLES REQUIRED:

PARAMETERS	NORMAL RANGE	UNITS	RESULT
LFT			
TOTAL BILIRUBIN	Upto : 1.0	mg/dl	
DIRECT BILIRUBIN	Upto : 0.3	mg/dl	
INDIRECT BILIRUBIN	Upto : 0.5	mg/dl	
SGPT	Upto : 40	U/L	
SGOT	Upto : 42	U/L	
TOTAL PROTEINS	6.5 - 8.5	gm/dl	
ALBUMIN	3.5 - 5.0	gm/dl	
GLOBULIN	2.5 - 3.5	gm/dl	
A/G RATIO			
ALK. PHOSPHATASE	32 - 92	iu/l	
LACTATE			
PANCREAS TESTS			
RANDOM BLOOD SUGAR	70 - 180	mg/dl	
AMYLASE	25 - 125	U/L	
LIPASE	Upto : 190	U/L	
KIDNEY FUNCTION TESTS			
UREA	15 - 40	mg/dl	
CREATININE	0.5 - 1.5	mg/dl	
ELECTROLYTES			
SODIUM	135 - 145	mmol/l	
POTASSIUM	3.5 - 5.1	mmol/l	
CHLORIDE	96 - 108	mmol/l	
CALCIUM	8.5 - 10.5	mg/dl	
CBP			
HAEMOGLOBIN	Male: 14 - 18	gm%	
	Female: 12 - 16		
HAEMATOCRIT (PCV)	Male: 42 - 52	vol%	
	Female: 37 - 47		
TOTAL WBC COUNT3	4500 - 10500	Cells/cumml	
PLATELET COUNT	1.5 - 4.0	Lakhs/cumm	
SEROLOGY			
HIV			
HBsAg			
HCV			
CMV IgG			
CMV IgM			
Anti HBc (Total)			
Anti HBs Antibodies			
CULTURES			
Blood			
Urine			

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Annexure II

Adult Liver transplant candidate Registration Form

Note: This form is provided as a guide to what data will be required in the online APNOS website.

Provider Information:

Organ Transplant Centre (OTC): KIMS/Apollo/AIG/Global/any other registered OTC

Date:

Candidate Information:

Organ Registered:	Liver/Liver+other organs
First (Given) Name:	
Last Name (Family) Name:	
Gender:	Male/Female
DOB:	
State of permanent Residence:	
Identification by :	Driving License/Passport/Aadhar card/Ration Card/PAN card
ID Card No.:	
E-mail :	
Ethnicity (Race):	Indian/Non-Indian
If Non-Indian specify:	
Citizenship:	Indian citizen/Non-Indian Citizen
if Non-Indian citizen specify:	
Highest Education Level:	Primary school/Secondary school/Junior College/Graduate/PG
Working for income:	Yes/No/Unknown
If Yes:	Working full time/Working part time
Source of Payment:	Primary/Secondary
Medical condition at listing:	in ICU/Hospitalized; not in ICU/not hospitalized

Patient on life support:	yes/no	
If yes:	on ventilator/artificial liver/other (specify)	
Previous Transplants:	Organ:	date:

Clinical Information: AT LISTING

Height:	cm
Weight:	kg
BMI:	kg/m^2
ABO Blood Group:	A/B/AB/O
Primary Diagnosis:	
Secondary Diagnosis:	
Any other diagnosis	
General Medical Factors:	
Diabetes:	No/TypeI/TypeII
Dialysis:	No dialysis/Hemodialysis/Peritoneal dialysis/CAVH
Peptic ulcer:	No/Yes, active within last one year/not active within last one year
Angina:	No/Yes, documented CAD/Yes, no documented CAD
Drug treated Hypertension:	Yes/No/Unknown
Symptomatic Cerebrovascular Disease:	Yes/No/Unknown
Symptomatic Peripheral vascular Disease:	Yes/No/Unknown
Drug treated COPD:	Yes/No/Unknown
Pulmonary embolism:	Yes/No/Unknown
Any previous malignancy:	Yes/No/Unknown
If yes, specify:	
Functional Status:	0/1/2/3/4/5

ECOG PERFORMANCE STATUS

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

Liver Medical Factors:

Serum Creatinine: mg/dl

INR:

Serum Sodium:

Serum Bilirubin:

MELD Score:

Variceal bleeding within last two weeks:

Previous abdominal surgery:

Spontaneous bacterial peritonitis:

History of Portal vein Thrombosis:

History of TIPSS:

Indication for transplantation:

1. Acute liver failure (fulminant hepatic failure).
2. Chronic liver failure.
3. Metabolic liver disease.
4. Liver cancer.
5. Other metabolic diseases caused by liver based inborn errors of metabolism.

Annexure III

How Status on the Waiting List is Determined and a particular donor liver is allocated to an individual patient

After careful research, many Networks the world over for organ sharing, implemented a system for prioritizing patients for liver transplantation. This system, the Model for End Stage Liver Disease (MELD), is based on a statistical formula that is very accurate for predicting which individuals are most likely to die the soonest from liver disease.
MELD uses a mathematical formula based on three routine blood tests to generate a score for each patient. The score can range from 6 to 40. A patient's need for transplant is greater when the score is higher. The blood tests that are used to determine each individual's score are:

1. Bilirubin, which measures how effectively the liver excretes bile. When the bilirubin is high in the blood, a patient may appear yellow, or jaundiced.
2. INR (prothrombin time), which measures the liver's ability to make clotting factors
3. Creatinine, which measures kidney function. Impaired kidney function is often associated with severe liver disease.

Research has shown that the MELD formula can accurately predict the short-term (three months or less) risk of death for most patients with liver disease, without receiving a transplant. The accuracy of the formula did not improve when other factors such as the cause of liver disease or symptoms (e.g., ascites, encephalopathy, variceal bleeding) were added.
Each patient's MELD score must be updated according to a schedule determined by an OTC. A patient's score may go up or down over time, depending on the status of his or her liver disease. Due to the patient's changing condition, his or her MELD score may need to be reassessed weekly, monthly, every three months or annually. The higher the score, the more frequently it will need to be reassessed. MELD scores automatically revert back to the previous lower score if the score is not updated in APNOS within the specified time period.
Time on the waiting list is not a factor in getting a liver transplant. The only factor that should decide who receives an organ is the severity of a patient's illness, as reflected in the MELD score.

Within each liver transplant Unit (OTC) the decision to allocate a particular donor liver to an individual patient is based on the following variables:

- donor and recipient blood group
- size donor/size of recipient of liver
- severity of liver disease. This is based on objective criteria such as MELD score
- matching of functional status of donor with severity of liver disease and predicted outcome post transplant. e.g. a “marginal” donor may not be as suitable for a very sick and unstable patient. The status of the donor liver will depend on liver function and anticipated ischemic time
- Hepatitis B and C status of donor and recipient

Annexure IV

Listing a patient for elective liver transplant

Each liver transplant Unit has a list of patients who are waiting for liver transplant. The criteria for being placed on the list include terminal liver disease, hepatocellular cancer fulfilling "San Francisco" criteria and severe symptomatic liver disorders such as polycystic liver disease. Examples of general guidelines for selection for specific disease are:

1. Hepatocellular Cancer
    - San Francisco criteria:
    - Single tumour ≤ 6.5cm in maximum diameter
    - Multiple tumours ≤ 3cm in number) with the largest diameter being ≤ 4.5cm and a total tumour diameter of ≤ 8.0cm
    - No extra-hepatic spread
2. Cirrhosis (all forms)
    - Decompensated liver disease
    - Correctable extrahepatic manifestations of cirrhosis e.g. hepatopulmonary syndrome, failure of growth and/or neurodevelopment
3. Metabolic disorders
    - Life threatening conditions curable by liver transplantation
    - Severe uncontrolled symptomatic disease
4. Alcoholic Liver Disease
    - Liver failure following -
        - 6 months abstinence
        - Considered at low risk for continued alcohol abuse
5. HIV positive patients
    - are acceptable candidates for transplant providing the individual prognosis from HIV infection is acceptable. In patient receiving HAART at the time of listing, HIV should be fully suppressed (HIV RNA undetectable and CD4 >100). In patients unable to tolerate HAART because of liver failure, there should be evidence of fully suppressible HIV (absence of multiresistance) prior to HAART withdrawal.
6. Retransplant
    - Is considered only in patients with an acceptable predicted survival (>50-% at 5 years).
7. Exclusions Include
    - Metastic liver disease (non – neuroendocrine)
    - Significant co-morbidities impacting on life expectancy
    - Persisting alcohol and/or substance abuse

Annexure V

Listing for super urgent liver scheme

To be registered on the Super Urgent Liver Scheme, the patient should belong to at least one of the categories listed below.

Category 1: Aetiology: Paracetamol poisoning:

- pH <7.25 more than 24 hours after overdose and after fluid resuscitation.
- Co-existing prothombin time >100 seconds or INR >6.5, and serum creatinine >300 µmol/l or anuria, and grade 3-4 encephalopathy.
- Serum lactate more than 24 hours after overdose >3.5 mmol/l on admission or >3.0 mmol/l after fluid resuscitation.
- Two of the three criteria from category 2 with clinical evidence of deterioration (e.g. increased ICP, FiO2 >50%, increasing inotrope requirements) in the absence of clinical sepsis.

Category 2: Aetiology: Seronegative hepatitis, hepatitis A or hepatitis B, or an idiosyncratic drug reaction.

- Prothrombin time >100 seconds or INR >6.5, and any grade of encephalopathy.
- Any grade of encephalopathy, and any three from the following: unfavourable aetiology (idiosyncratic drug reaction, seronegative hepatitis), age >40 years, jaundice to encephalopathy time >7 days, serum bilirubin >300µmol/l, prothrombin time >50 seconds or INR >3.5.

Category 3: Aetiology: Acute presentation of Wilson's disease, or Budd-Chiari syndrome.

- A combination of coagulopathy, and any grade of encephalopathy.

Category 4: Hepatic artery thrombosis on days 0-14 days after liver transplantation

Category 5: Early graft dysfunction on days 0 to 7 after liver transplantation with at least two of the following:

- AST >10,000,
- INR >3.0,
- serum lactate >3 mmol,
- absence of bile production.

Category 6: total absence of liver function (e.g. after hepatectomy).