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सत्यमेव जयते

புதுச்சேரி மாநில அரசிதழ்

La Gazette de L' État de Poudouchéry

The Gazette of Puducherry

PART - II

சிறப்பு வெளியீடு **EXTRAORDINAIRE** **EXTRAORDINARY**

அதிகாரம் பெற்ற வெளியீடு | Publiée par Autorité | Published by Authority

எண்		புதுச்சேரி	திங்கட்கிழமை	2025 ஆம்	மே மீ	19 உ
No.	41	Poudouchéry	Lundi	19	Mai	2025
No.		Puducherry	Monday	19th	May	2025

(29 Vaisakha 1947)

GOVERNMENT OF PUDUCHERRY

CHIEF SECRETARIAT (HEALTH)

(G.O. Ms. No. 16, Puducherry, dated 13th May 2025)

NOTIFICATION

Considering the large number of patients who are suffering on account of serious organ ailments ranging from heart, liver, kidney *etc.,* and could otherwise lead healthy life if, they had the opportunity to have transplant surgery and its awareness among general public, there is a need for streamlining the procedures for deceased donor transplants in Government and Private hospitals,

2. As per sub-rule (4) (c) of rule 31 of Transplantation of Human Organs and Tissue Rules, 2014, the allocation of the organ to be shared is to be decided by the State Networking Organization.

3. Further, as per sub-rule (4)(f) of rule 31 of Transplantation of Human Organs and Tissue Rules, 2014, the allocation criteria may be State specific which shall be finalized and determined by the State Government in consultation with the State Level networking organization wherever such organization exists.

4. As per sub-rule 5 of Rule 31 of Transplantation of Human Organs and Tissue Rules, 2014," the networking organizations shall coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and tissues and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible".

5. Accordingly, the Government has requested Transplant Expert Committee reconstituted by Chief Secretariat (Health), Puducherry *vide* G.O. Ms. No. 63, dated 31-12-2024 to suggest the way forward to formulate such guidelines/policy. In response, the said Committee has submitted the proposal *vide* E-office No. 1649 of Directorate of Health and Family Welfare Services, Puducherry. The same has been analysed and the Hon'ble Lieutenant-Governor, is pleased to frame the Guidelines for allocation criteria for cadaver organ transplant as in the Annexure-I, II and III.

(By order of the Lieutenant-Governor)

S. MURUGESAN,
Under Secretary to Government (Health-I).

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ANNEXURE-I

ALLOCATION CRITERIA FOR DECEASED DONOR KIDNEY TRANSPLANT (GUIDELINES)

Preamble

Organ transplant has two sources : living donor and deceased donor. In case of living donor source, donor is already decided for a specific recipient. For deceased donor source, recipient needs to be selected out of a large recipients' pool. The allocation of organ is a complex process, influenced by a number of factors including medical urgency and donor, and recipient matching. Following facts need to be kept in mind for organ allocation for kidney transplantation.

Certain Facts for End Stage Renal Disease (ESRD)

1. There is disparity between number of recipients requiring kidney transplant and the deceased organs available for kidney transplantation.
2. Some patients need kidney transplant on priority basis because of their medical condition, as delay in transplant may lead to mortality.
3. For End Stage Renal Disease (ESRD), maintenance dialysis is an acceptable and reasonably good alternate therapy so for majority of ESRD patients, renal transplant is not an emergency procedure.

Recipient Registration, Listing and Scoring System in the Waiting List

(Before deceased donor availability).

1. Patient is to be registered by the concerned hospital through online registration form on website ***www.notto.mohfw.gov.in***

2. Kidney Advisory Committee/Nephrologist of the Institution will approve registration.

The Kidney Advisory Committee/Nephrologist of the Institution will confirm the need for renal transplant of every newly registered patient. Once approved, ONLY then the patient will be put on active list in the system and ALLOCATION SCORING for that patient will be done based on the guidelines formed.

3. Patient should be a case of End Stage Renal Disease on Maintenance dialysis for more than three months on regular basis.

4. Patient should not have an absolute contraindication for renal transplant, as given under:

- Advanced untreatable cardiovascular disease
- Irreversible cerebrovascular accident
- Inoperable malignancy
- Untreatable major psychiatric illness (to be certified by a psychiatrist).

5. Patient should be registered ONLY in ONE hospital registered under the Transplantation of Human Organs and Tissues Act (THOTA) with SOTTO, Puducherry. However, he/she can change the hospital at any stage and his allocation scoring and seniority in central waiting list will not change. However, his/her seniority in the waiting list of locally available kidney, with the new Hospital will be applicable one month after date of change.

6. Patient can be registered for deceased donor even though the patient is waiting for living donor transplant.

7. Status of patient must be updated regularly by the hospital in one of the following status:

- Active
- Suspended
- Lost to follow-up
- Transplant done
- Death

Organs Allocated to the Hospitals may be Utilized as Per Seniority/Scoring System for Making Priority:

Sl. No.	Criteria for scoring	Points allotted
(1)	(2)	(3)
1	Time on dialysis	(0.1) for each month on Dialysis.
2	Previous immunological graft failure within 3 months of transplantation.	(+3) for each graft failure
3	Age of recipient	(+3) for less than 6 years (+2) for 6 to less than 12 years. (+1) for 12 to less than 18 years.

(1)	(2)	(3)	
4	Patient on temporary Vascular access		Only after certification of the Nephrologist of the Institution, the scoring will be done.
4(a)	With Failed all A V Fistula sites	(+2)	
4(b)	With failed AV Graft after all failed AVF sites.	(+4)	
5	PRA (Panel Reactive Antibody)	(+0.5) for every 10% above 20 % Scoring subject to submission of Certificate from luminous based NABL accredited lab.	
6	Previous Living donor now requiring Kidney Transplant.	(+5)	
7	Near relative (as per definition of THOTA) of previous deceased donor requiring kidney transplant.	(+5)	

Note : Patients with the same score, priority will be decided based on the seniority in the waiting list.

Allocation Principles:

1. Allocation will be done first based on Union territory of Puducherry waiting list. If, no eligible recipient in the waiting list then organ will be shared by SOTTO, Puducherry to South ROTTO.

2. In order to minimize cold ischemia time, most donated organs should be allocated within the Union territory of Puducherry where retrieval has been done.

3. Kidney from Paediatric donor (less than 18 years) first will go to paediatric patient. If, no paediatric patient eligible, then to adult patient.

4. Kidney from elderly (age more than 65 years) donor may preferably allotted to an Elderly Recipient (older above 50 years).

5. Blood group "O" kidney will be allocated to recipient with group "O", then to next available on waiting list of other compatible blood groups *i.e.,* first group "A", then group "B" and lastly group "AB" in that sequence.

6. In case of blood group "A" or "B", the organ will be allocated to same blood group failing which to blood group "AB". "AB" will be allocated to "AB" only.

Allocation Algorithm

Once there is a call for possible deceased donor

Step-1 : Check Blood Group of available deceased donor to follow principle of allocation based on blood group as above.

Step-2: Recipient requiring multi-organ transplant will get priority. If, there are more than two recipients in the multi-organ recipient list, then allocation will be done to patient having more points in the scoring system.

Step-3: If, NO multi-organ recipient, then allocation will be done to patient registered for 'Kidney alone' transplantation based on the status of hospital doing retrieval of kidneys means whether it is transplant hospital or retrieval only hospital.

If, Transplant Hospital

o One kidney be used by that Hospital and other will be allocated.

If, Retrieval Hospital

o Both will be allocated

Step-4: Kidneys retrieval hospital, whether it is Government Hospital or Private Hospital:

1. Other Kidney retrieved from a Government Hospital will be allocated as follows:

(a) First to patients listed in the Combined Government Hospitals list of the State, then,

(b) Patients listed in the combined private hospital list in the State, then,

(c) Patient listed in South ROTTO.

2. Other Kidney retrieved from a private hospital will be allocated as follows:

(a) First to patients listed in the Government hospitals list of UT by Rota, then,

(b) Patients listed in the private hospital list by Rota, then patient listed in South ROTTO.

Inter-State Issues

The Transplant Expert Committee of State Government in consultation with SOTTO, Puducherry, will approve the inter-state transport of organs for transplantation.

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ANNEXURE-II

ALLOCATION CRITERIA FOR DECEASED DONOR LIVER TRANSPLANTATION RECIPIENT REGISTRATION AND LISTING

1. Patient is to be registered by the concerned hospital through online registration form on ***www.notto.mohfw.gov.in.***

2. Liver Transplant advisory Committee/Surgical Gastroenterology of the institution will approve the registration. The Committee Members will periodically review/update the guidelines.

3. Patient should be less than 65 years of age at the time of listing.

4. Patients with decompensated cirrhosis of liver should meet standard criteria for need for liver transplant with Model for End-stage Liver Disease (MELD) score greater than 15 in patients aged 12 years or more. Those with cirrhosis of liver with hepato-cellular carcinoma should be with-in UCSF criteria;

5. Super-Urgent listing can be done in the following situations:-

(a) Primary Non-Function (PNF) of liver allograft.

(b) Living liver donor who develops life threatening liver failure.

(c) Early Hepatic Artery Thrombosis (HAT) needing re-transplant.

(d) Fulminant Hepatic Failure (FHF).

6. Patients with metabolic disorders and for those with quality of life issues who do not have the minimum required MELD score *e.g.,* chronic hepatic encephalopathy, intractable pruritus and polycystic liver disease will not be considered for listing for Deceased Donor Liver Transplant (DDLT) for now.

7. Contraindications to listing for liver transplantation:-

(a) MELD Score <15

(b) Severe cardiac or pulmonary disease, who is unfit for general Anaesthesia.

(c) AIDS

(d) Hepatocellular carcinoma beyond UCSF criteria

(e) Uncontrolled sepsis

(f) Intrahepatic Cholangiocarcinoma

(g) Extra-hepatic malignancy

8. Patient should be registered only in one hospital registered under Transplantation of Human Organs and Tissues Act (THOTA).

9. Patient can be registered for deceased donor even while the patient is waiting for living donor transplant.

10. Status of the listed patient must be updated by the hospital monthly.

Allocation Principles

1. Allocation will be done first based on State waiting list. If, no recipient is eligible in the State waiting list then allocation will be done to Regional Organ and Tissue Transplant Organization (ROTTO SOUTH) and then to other ROTTO nationally.

2. Liver from Pediatric donor (less than 16 years) first will go to Pediatric patient. If, no Pediatric patient eligible, then to adult patient.

3. Blood group “O” Liver will be allocated to recipient with group “O”, then to any other group.

4. Other than “O” blood group; that is “A”, “B” and “AB” will be preferably allocated to same blood group, failing which to “AB” group.

Allocation Algorithm

Once there is consent for deceased donation

Step-1: Check Blood Group and age of the available deceased donor and then follow principle of allocation based on blood group as above.

Step-2: First, the liver will go to the recipient requiring simultaneous multi-organ transplant *i.e.,* simultaneous liver-kidney transplant. If, there are more than two recipients in the simultaneous multi-organ list, then allocation will be done to the patient who has been waiting longer while on the list.

Step-3: If, there is no multi-organ recipient, then allocation will be done based on the status of hospital doing the liver retrieval. Status means whether it is transplant hospital or Non-Transplant Organ Retrieval Centre (NTORC).

If, Transplant Hospital:

- The Liver will be allocated to the local transplant hospital and the hospital will not lose its turn.

If Non-Transplant Organ Retrieval Centre:

- The liver will go to the common pool from where it will be allocated to the Transplant hospital as per the Rota.

Note:

Each hospital to maintain their own waiting list that should be uploaded on website of SOTTO.

Once allocated to a hospital, the organ will be used only in a recipient previously registered with SOTTO at least 48 hours before organ allocation and as per the seniority on the waiting list.

Step-4: Liver retrieval hospital could be a Government or a Private hospital:

1. Liver retrieved from a Government hospital will be allocated as follows:

   - Government hospitals by rotation.
   - If, there are no takers in the Government Hospitals, to be offered to private hospitals as per rota.

2. Liver retrieved from a private hospital will be allocated as follows:

- Rota of private hospitals
- If, no takers in private hospitals, to be offered to Government Hospitals

Note :

(a) If, there is a marginal donor, that has been refused by other center(s) then the center which agrees to use the organ will not lose its priority in the next round of allocation.

(b) If, a center splits an organ then it is allowed to use for the 2nd recipient at their center and will be counted as one. Further, they can share one of the split parts with another center, provided the organ is utilized for a patient registered with SOTTO.

(c) Foreigners will be the last priority *i.e.,* only after the organ is not used for any Indian patient in the country. This clause will override any center specific waiting list.

Inter-State Issues

ROTTO in consultation with SOTTO will approve the inter-state transport of organs for transplantation.

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ANNEXURE-III

ALLOCATION CRITERIA FOR HEART, LUNG AND HEART-LUNG CONTENTS

The allocation policy of donated heart and lungs under the following heads -

(A) Registration of potential recipients

(B) Criteria for suitable donors for Heart and Lung

(C) Criteria for allocation of Heart, Lung and Heart-Lung

(D) Details to be recorded on the website

(E) Post-operative update

(F) Donor harvesting charges and charges to recipients

(G) Recognition of hospitals for organ transplantation

Registration of potential recipients for heart, lung and heart-lung transplantation:

1. All hospitals should do all necessary investigations needed for their potential patients waiting for heart, lung and heart-lung transplantations and then register them with NOTTO portal. Patient is to be registered by the concerned hospital through online registration form on website ***www.notto.mohfw.gov.in***

2. Only those patients for whom all the necessary data is provided and registration charges are paid will be considered in the active waiting list.

3. The registrations for transplantation will have to be updated and re-registered every month. Status of patient must be updated regularly by the hospital to one of the following status:

- Active
- Unfit
- Recipient frequently refused
- Lost to follow-up
- Transplant done
- Death

4. At any time one patient can register only with one transplantation center. In case he/she wants to shift to some other center, they need to de-register with first center and then only register with second center. There should be at least 72 hours of gap before the next deceased donor's organ retrieval.

5. Registration of Heart and Heart-Lung recipients:

Three categories are proposed:

Priority 1 (emergency) : These are patients on ventricular assist devices, but still critical, Intra-aortic balloon pump (IABP) waiting for heart/heart-lung transplantation. These recipients will get priority based on blood group and size matching. Their status need to be confirmed on weekly basis.

Priority 2 (semi emergency) : These are patients in intensive care unit depending on ionotropic supports for at least a week and not maintaining hemodynamics if, inotropes are being weaned off. Their category needs to be updated every 48 hours. Based on their progress they may stay in priority 2 or change to other priorities. If, a deceased donor organ is available, their status need to be confirmed by 3 members of the Heart Sub Committee as appointed by the Chairman of the Sub Committee.

Priority 3 (elective) : These are patients electively waiting for transplantation. Their status need to be confirmed or changed as per their progress on monthly basis. The concerned hospital needs to be given a user name and password to enable them to register the recipients and enter data. They can see only their waiting patients. The Sub Committee Members to be given a separate user name and password and they should be able to see all the waiting list members for heart, lung and heart- lung transplantation and their details.

Criteria for suitable donors for heart and lungs:

Apart from the general criteria for donors, the following criteria are needed :

1. ***Heart***

(a) Age less than 60 years. If, donor is more than 40 years, coronary angiogram is desirable to exclude asymptomatic coronary artery disease.

(b) No history of heart disease and echo-cardiogram showing good cardiac function and no anatomical abnormalities.

(c) Maintaining good haemodynamics and not on high doses of inotropes (dopamine less than 10 micrograms/kg./min; epinephrine, nor epinephrine less than 0.1 micrograms/kg./mn, dobutamine less than 10 micrograms/kg./mn)

(d) Cardiac arrest - Donors revived after a brief cardiac arrest must be assessed extra carefully but, can be considered if, the cardiac function is absolutely normal.

2. ***Lung***

(a) Age less than 55 years

(b) No active sepsis/malignancy in the lungs and outside

(c) No history of significant chronic obstructive pulmonary disease

(d) Chest X ray shows clear lung fields without any evidence of trauma to lungs.

(e) Arterial Blood gases: On 100% oxygen and PEEP of 5 mm of Hg. After 5 mn, PaO2 should be more than 300 mm of HG

(f) If smoker, a smoking history of < 20 pack -years

Criteria for allocation of heart, lung and heart-lung:

Matching of Heart and Lungs are done based on

- Blood group matching and
- Size matching
- Geographical distance

Blood Group Matching.— O group donor organ is matched with O first. If, no O group recipient is available, then it can be given to other group recipients as per the following criteria. Once a deceased donor heart and lungs are available, the hospital/s with first two recipients in the order of allocation will be informed. If, the first recipient is not confirmed in 2 hours after that, the organ will go to the next recipient in the list and so on.

Size and weight mismatch.— There should not be more than 20 percent size mismatch between the donor and the recipient heart/lung. Larger hearts can go to smaller patients and more mismatch is acceptable but, problems can occur with small hearts in large recipients. In children more mismatch is acceptable.

Distance.—The donated Heart should be allocated to a hospital which is well within the geographical limit of cold-ischemia time for heart/ lung.

For a heart/lung donated at a Government hospital, the first priority for allocation should be for a recipient registered with a Government hospital.

If, any controversies arise in allocation, the decision of the Advisory sub-committee is final.

1. ***Heart and Heart-Lung***

(a) If deceased donor organs are harvested in an Organ Transplantation center, heart will go to that center. One lung will go to that center (both lungs may be used in one patient at the discretion of Transplant team) and the other lung will go to the general pool. If, the hospital does not have recipients, then the heart and both lungs will go to the general pool.

(b) If deceased donor organs are harvested in a center recognized only for organ harvesting, heart and both lungs will go to the general pool. General pool organs will be distributed first to patients in the priority 1, then to priority 2 and then to priority 3. If, multiple patients are there in each category, then heart will be distributed in the chronological order of patient's registration with NOTTO portal. If, donor is CMV positive, and there is a recipient who is CMV positive, they will be matched provided there is no waiting patient in priority 1 and 2.

2. ***Lung***

1. If deceased donor organs are harvested in an Organ Transplantation center, one lung will go to that center (both lungs may be used in one patient at the discretion of Transplant team) and the other lung will go to the general pool. If, the hospital does not have recipients, then the heart and both lungs will go to the general pool.

2. If deceased donor organs are harvested in a center recognized only for organ harvesting, both lungs will go to the general pool.

Details to be recorded on the website:

The following details should be available on the website regarding the patients waiting for heart, lung and heart-lung transplantation:

First name :		Last name :
Age:	Sex:	Height:
Weight:	Diagnosis:	
Hospital where registered		Date of Registration:
Diabetic: Y/N		
Blood Group:		Rh Typing:
CMV IgG		
Positive/Negative		
PRA I: Percentage:		Positive/Negative:
PRA II: Percentage:		Positive/Negative:
Hbs Ag:		
Positive/Negative:		Hep C: Positive/Negative:
HIV: Positive/Negative:		
For Heart patients:		Transpulmonary grtadient:
PVR		
For Lung recipients:		
Room Air ABG report		
6 min walk test results:		

Plan : Heart/single lung/bilateral lung/heart-lung transplantation. Priority: 1/2/3.

Post-operative update

It is the responsibility of the hospital to update about the recipient condition on a monthly basis in the first 6 months, then once in 2 months for the next 2 months and then every 6 months and whenever patient is readmitted.

Recognition of Hospitals for Organ Transplantation:

It is noted that some hospitals have applied for transplantation permission at multiple branches. It is recommended that only those hospitals/branches which have in-house full time transplantation team are to be permitted to enable round the clock care.

Appropriate recognition of a centre should be in-place as either a “harvest” centre or as a “harvest plus transplant” centre.

The above Guidelines are subject to change in the future consequent to changing patterns of patient management and are to be changed after adequate consultation with the stakeholder.

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online publication at **“https://styandptg.py.gov.in”**
Published by the Director, Government Press, Puducherry.