MAHARASHTRA STATE APPROPRIATE AUTHORITY GUIDELINES FOR CADAVER TRANSPLANT PROGRAM

BY

THE STATE APPROPRIATE AUTHORITY

GOVERNMENT OF MAHARASHTRA

COLLABORATING OFFICES

- Directorate of Health Services
- Department of Medical Education & Research
- Deputy Director Health Services (THOA)
- State Organ and Tissue Transplant Organization (SOTTO, Maharashtra)

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FOREWORD

BACKGROUND

The state appropriate authority formulated the following guidelines to have uniformity of organ allocation and transplant processes across the state of Maharashtra. These were developed under the guidance of DHS and DMER, with the coordination of ROTTO-SOTTO, and inputs from all the four ZTCC of Maharashtra and the subject experts from all over the state. These guidelines will form the framework for the field of organ donation and transplant for the state of Maharashtra. These guidelines will evolve as the field advances and more experience is gained in this important field. A meeting was held on 11.12.2020 at the office of the state appropriate authority which approved the guidelines drafted by the subject experts. The meeting was attended by:

Sr. No	**Name**	**Designation**
1.	Dr. Sadhana Tayade	Director, Directorate of Health Services
2	Dr. Arun Yadav	Assistant Director, THOTA, DHS, Mumbai
3.	Dr. Sujata Patwardhan	Director In charge-ROTTO-SOTTO
4.	Dr. Akash Shukla	Joint Director In-charge, ROTTO-SOTTO
5	Dr. Tukaram Jamale	President, Kidney committee
6.	Dr. Bharat Shah	Secretary, Kidney Committee
7.	Dr. S.K. Mathur	President, Liver Committee
8.	Dr. K.N. Bhosle	President, Heart Committee
9.	Dr. Milind Nadkar	President, Critical Care Committee
10.	Dr. Ravi Mohanka	Donation after Circulatory Death (DCD) Committee
11.	Dr. Vinita Puri	President, Hand committee

CONTRIBUTORS

Heart / Lungs Guidelines	**Liver / Pancreas / Intestine Guidelines**	**Kidney Guidelines**

• Dr. K. N. Bhosale, President • Dr. Anvay Mulay, Secretary • Dr. Suresh Joshi • Dr. Nandakishor Kapadia • Dr. Ashish Khanijo • Dr. Chandra Shekhar Makhale • Dr. Anand Deodhar • Dr. Balaji Aironi • Dr. Preeti Meshram • Dr. Amita Athavale • Dr. Unmil Shah	• Dr. S K Mathur, President • Dr. Darius Mirza, Secretary • Dr. Parijat Gupte, Joint Secretary • Dr. Akash Shukla • Dr. Abha Nagral • Dr. Ravi Mohanka • Dr. Sheetal Mahajani • Dr. Bipin Vibhute • Dr. Rahul Saxena • Dr. Vrushali Patil	• Dr. Tukaram Jamale, President • Dr. Bharat Shah, Secretary • Dr. Shrirang Bichu • Dr. Atul Mulay • Dr. Abhay Huparikar • Dr. Sudhir Kulkarni
Pediatric brain death Guidelines	**DCD Guidelines**	**Hand Guidelines**
• Dr. Soonu Udani • Dr. Milind Nadkar, Chairperson • Dr. Rahul Pandit, Secretary • Dr. Indraani Chincholi • Dr. Kapil Zirpe • Dr. Urvi Shukla • Dr. Shrikant Sahasrabuddhe • Dr. Vishal Gupta	• Dr. Ravi Mohanka • Dr. Rahul Pandit • Dr. Prashant Borade • Dr. Abdul Samad Ansari	• Dr. Vinita Puri, Chairperson • Dr. Nikhil Panse • Dr. N. Venkateshwaran • Col (Dr.) Gopi Renganathan • Dr. Astrid Lobo Gajiwala

INTRODUCTION AND OBJECTIVES

INTRODUCTION

The Transplantation of Human Organs Act (THOA), 1994, for the regulation of removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs was adopted by the State of Maharashtra on 23rd February 1995. After implementation of the Act, the Government of Maharashtra appointed Director of Health Services as "Appropriate Authority" vide notification dated 23rd March 1995. The Authorization Committee was also appointed comprising of the following members vide Govt. resolution dated 29th March, 1997.

1. Director of Medical Education and Research (DMER), Mumbai — Chairman
2. Director of Health Services (DHS), Mumbai — Member
3. Dean, Grant Medical College, Mumbai — Member

The 2011 amendment to THOA was passed in 2014, including the rules. The Government of Maharashtra adopted the Transplantation of Human Organs and Tissues Rules, 2014, on 28th July, 2015.

According to THOA (No. 31):

1. There shall be an apex national networking organisation at the centre, as the Central Government may by notification specify.
2. There shall also be Regional and State level networking organisations where large number of transplantation of organ(s) or tissues(s) are performed as the Central Government may by notification specify.
3. The State units would be linked to hospitals, organ or tissue matching laboratories and tissue banks within their area and also to Regional and National networking organizations.

In accordance with THOA, the Regional cum State Organ and Tissue Transplant Organisation (ROTTO-SOTTO), the networking organization for the Western Region and State of Maharashtra, was established in February 2017 by the Ministry of Health and Family Welfare, Government of India, under THOA with headquarters at King Edward Memorial Hospital and Seth Gordhandas Sunderdas Medical College, Acharya Donde Road, Parel, Mumbai 400012.

According to the Transplantation of Human Organs and Tissues Rules, 2014, (No. 31 (5)) "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". Due to advancement in the field of transplants and increase in the number of transplants happening, there was a need to revise the state guidelines originally created in 1998. The revised guidelines have been formulated by the Appropriate Authority which is Director of Health Services, Mumbai, as per the recommendations of the Panel of Experts established by the Authority and coordinated by SOTTO-ROTTO to fulfill its mandate under Rule 31 (5) of the Transplantation of Human Organs and Tissues Rules, 2014. The Appropriate Authority had several meetings and discussions with the various experts and based on their recommendations, the draft norms / guidelines have been formulated. These guidelines are to be followed in addition to other guidelines by Appropriate Authority and State Government.

OBJECTIVES OF THE MAHARASHTRA STATE GUIDELINES

The objectives of the Maharashtra State Guidelines are as follows:

1. To ensure compliance with the THOA, 1994 including its amendments and the Transplantation of Human Organs and Tissues Rules, 2014
2. To ensure the implementation of uniform guidelines across the State of Maharashtra for the purpose of organ donation, allocation and transplantation
3. To enable monitoring and surveillance of organ donation, allocation and transplantation activities in the state of Maharashtra
4. To facilitate the development of common waiting lists for organs in the state of Maharashtra
5. To assist with the maintenance of transplant related databases in the state of Maharashtra.

GENERAL GUIDELINES

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- Each hospital and organ transplant centre should be registered with Appropriate Authority, NOTTO and ZTCC, who in turn will maintain the city waiting lists for each organ in accordance with established norms.
- Each hospital should establish local Brain Stem Death Committee in their hospital as per THOA and approved by Appropriate Authority.
- This committee will be responsible for certification of Brain death in accordance with THOA in the prescribed form. No member involved in the transplant of organs should participate in the diagnosis of brain stem death.
- All potential brain deaths (GCS < 5) and certified brain death cases should be reported to Appropriate Authority as per circular issued in November 1996.
- If the brain-dead patient is a female, it should be ensured that she is not pregnant and if so, organ donation is not considered at all except when there is foetal death.
- All potential organ donors should be specifically informed to the respective zonal transplant coordination committee (ZTCC) and Appropriate Authority and updated on Mahaayudaan software, including updates of these cases.
- The committee will also submit proposals for developing brain death programme in its region.

DONOR MAINTENANCE, INFORMATION, TRANSFER GUIDELINES

- Donor management / maintenance should be done under the guidance of senior / trained intensivists in each hospital. In case such expertise in not available at any hospital, guidance can be provided by ZTCC / SOTTO / ROTTO ICU subcommittee members.
- After brain stem death certification, no charges will be billed to / recovered from the donor family.
- All possible help should be extended to the donor family, including social obligations to ensure early and smooth and respectful handling and handover of the body.
- Records related to brain death and transplantation should be maintained / preserved as per the existing state government rules. Donor hospital will maintain records of brain stem death and retrieval for 15 years.

- Organs from deceased donors are precious and rare resources and they should be distributed equitably to most deserving patients, following the principles of utility, beneficence and justice. Allocation systems for these organs should optimize benefits to maximum patients.
- Consent for organ donation should be obtained from the next of the kin of brain death cases in accordance with the prescribed consent form.
- If brain stem dead case is unclaimed, the consent of administrative head of the institution should be obtained before harvesting is performed.
- Transplant hospitals should coordinate with ZTCC and SOTTO before performing any organ harvesting to enable beneficial distribution of organs in accordance with existing norms.
- The following data from each donor should be sent to ZTCC:
    - Admission notes
    - Clinical history and medical summary ○ ICU chart (images clicked / copies for all days) ○ Investigation chart / table ○ Imaging, histopathology, endoscopies and other reports relevant to the case ○ Angiography, bronchoscopy, etc.
    - Culture reports
    - Procalcitonin (if relevant)
- Organ harvesting should be performed in the same hospital where brain stem death is diagnosed, if it is registered with Appropriate Authority as a transplant centre or NTORC, and no case should be transferred to another hospital except when there is an absolute necessity. In case of brain death diagnosis at a hospital not registered with Appropriate Authority as a transplant centre or NTORC, transfer of such a patient for the purpose of brain-stem death declaration and potential organ donation should be done in coordination with the ZTCC. The hospital in which brain stem death is diagnosed will be responsible for issuing death certificate.
- The donor hospital will report the donor only to ZTCC. There will be no financial transactions in any form between the donor hospital and the recipient hospital directly. The donor hospital will be compensated for maintenance of brain-stem dead donor and retrieval surgery as per rules of ZTCC.
- Any consumables / disposable items utilized by the retrieval team during organ retrieval surgery in the donor hospital will have to be replaced or paid for by the recipient

- hospitals. ZTCC/ROTTO-SOTTO will have no role in any dispute arising out of above transactions.
- Recipient hospital will pay service charges to ZTCC as per the existing rules.
- Each transplant centre should provide reports and statistics of brain stem death identification, organ transplant donors and recipients (both from living and cadaveric donors), their outcomes (graft function/patient survival in the hospital) and IEC (Information, Education, Communication) activities every month to ZTCC, ROTTOSOTTO and Appropriate Authority in the prescribed format and also updated in Mahaayudan Software.
- For the purposes of these guidelines, donors or recipients ≤ 15 years of age will be considered as pediatric. If a child is > 40 kg, he / she may be considered for listing in the adult list.

GENERAL CAUTIONS FOR ORGAN DONATION

Organs from following donors may be considered unsuitable or used with caution as extended criteria donors (ECD)

Table 1: Tumors in donors should be classified as per WHO guidelines to estimate the risk of transmission to the recipient into the following

Category	**Tumors**	**Recommendation**
Absolute contraindication	• Primary cerebral lymphoma • All secondary intracranial tumors • Active cancer with spread outside the organ of origin • Active haematological malignancy	Contraindicated
High risk (>10% risk of transmission)	• Malignant melanoma • Breast carcinoma >stage 0 (active) • Colon carcinoma >stage 0 (active) • Choriocarcinoma • CNS tumor (any) with ventriculoperitoneal or ventriculoatrial shunt, surgery (other than uncomplicated biopsy), irradiation or extra-CNS metastasis • CNS Tumor WHO grade III or IV	Use of these donors is discouraged except in rare and extreme circumstances

Intermediate risk (1–10% risk of transmission)	• Breast carcinoma (stage 0 i.e., carcinoma in situ) • Colon carcinoma (stage 0 i.e., carcinoma in situ) • (Resected) solitary renal cell carcinoma T1b (4–7 cm) well differentiated (Fuhrman 1–2) stage I • History of treated non-CNS malignancy (≥5 years prior) with probability of cure between 90–99%	Use of organs from these donors is generally not recommended. It may be acceptable if recipient expected survival without a lifesaving transplantation is short (e.g., a few days or less).
Low risk (0.1–1% risk of transmission)	• (Resected) solitary renal cell carcinoma, >1.0 cm ≤2.5 cm, well differentiated (Fuhrman 1–2) • Low grade CNS tumor (WHO grade I or II) • Primary CNS mature teratoma • Solitary papillary thyroid carcinoma, 0.5–2.0 cm • Minimally invasive follicular carcinoma, thyroid, 1.0–2.0 cm • History of treated non-CNS malignancy (≥ 5 years prior) with > 99% probability of cure	Use in recipients at significant risk without transplant.
Minimal risk (<0.1% risk of transmission)	• Basal cell carcinoma, skin • Squamous cell carcinoma, skin without metastases • Carcinoma in situ, skin (nonmelanoma) • In situ cervical carcinoma • In situ vocal cord carcinoma • Superficial (noninvasive) papillary carcinoma of bladder (T0N0M0 by TNM stage) (nonrenal transplant only) • Solitary papillary thyroid carcinoma, ≤0.5 cm • Minimally invasive follicular carcinoma, thyroid, ≤ 1.0 cm • (Resected) solitary renal cell carcinoma, ≤1.0 cm, well differentiated (Fuhrman 1–2)	Based on clinical judgment with informed consent

- The risk of transmission of hormonal tumors to opposite gender is not clear in the literature (e.g., donor with breast cancer to a male recipient OR donor with prostate cancer to a female recipient). Such donations may be accepted in view of low risk of transmission if the transplant team, the patient and their family feels that the risk of transmission is acceptable.

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- The risk of transmission of tumors from donors to recipients should be discussed with the recipient and their families by the transplant team, documented and a copy of the consent including all details should be submitted to the ZTCC.
- **Infections** in donors may often be undiagnosed or culture reports may be pending. The transplant team should obtain a copy of all culture reports from the donor hospital. Pending reports should be sent / collected once available. Donor blood / urine and other samples should be carried in appropriate media by the transplant team for culture at their own hospital with the organ.
- In case of a known infection in the donor, the nature of bacteria, extent of infection and susceptibility to antimicrobials should guide organ selection. The transplant team should be very cautious in using organs from donors with Herpes simplex encephalitis, multi-drug resistant (MDR) infections causing septic shock or multi-organ failure. The risk of a suspected or known infection in the donor and the risk of transmission should be weighed against the patient's condition and the same discussed with the recipient and family, documented and a copy of the consent submitted to ZTCC. Tuberculosis is not a contraindication for donation, because of its indolent nature and availability of effective drugs, however, inadequately treated MDR TB may be a relative contraindication.
- In India infections such as Dengue, Leptospira, Malaria and others are common and are tested for when clinically suspected. However, donors are not routinely screened for rare infections such as Chagas disease, lymphocytic choriomeningitis virus (LCVM), Mycobacterium tuberculosis, Rabies, West Nile virus (WNV) and others, although the risk of transmission and of mortality is high with transmission of these infections. The transplant team should make the decision based on the risk – benefit to the recipient.
- Donor's medical history to be recorded to determine risk of infection transmission as follows:
    - Infections in the current /recent admissions ○ Use of live vaccines (especially in paediatrics) ○ Occupational exposures ○ Recent international or domestic travel history ○ Recent Transfusions with blood or blood products ○ Any contact with people with HIV, HBV, HCV or other transmissible diseases ○ Tattooing, ear piercing or body piercing ○ Use of illicit drugs ○ Unsafe sexual practices

- Routine infection screen suggested for all donors is:
    - HIV antibody ○ HBV serology, including HBsAg ○ HCV antibody ○ Blood and urine cultures
- Organs from donors with infections such as HIV, HBV and HCV may be used for recipients with the similar infections if found suitable by the transplant team with plan for continued treatment of the infection in the recipient. If, there is no suitable recipient, it can be offered to recipients negative for these infections. If organs from such donors are offered to patients without such infections, positive viral status of the donor and the risk of transmission / reactivation should be discussed with the recipient and their families, documented and a copy of the consent including all details submitted to ZTCC.
- **Risk classification for infections** is as below:
    - **Unacceptable risk:** Includes absolute contraindication ○ **Increased but acceptable risk:** Includes cases where transmissible organisms or diseases are identified during the evaluation process of the donor, but organ utilization is justified by the specific health situation of the recipient or the severity of their clinical condition.
    - **Calculated risk:** includes all cases where, even in the presence of transmissible diseases, transplantation is allowed for recipients with the same infection or with protective serological status. This risk category also applies to donors with documented bacteremia and / or bacterial meningitis provided that the donor was on targeted antimicrobial treatment for a minimum duration of 24–48 hours.
    - **Not assessable risk:** includes cases where the evaluation does not allow appropriate risk assessment for transmissible diseases.
    - **Standard risk:** includes cases where the evaluation process did not identify a transmissible disease.
- For COVID 19, specific DHS SOP released for the same should be followed.
- **Poisoning:** Organo-phosphorus, organo-chloride poisoning can cause brain death but may be suitable organ donors. Snake bite, which is common in India, can cause hemolysis, DIC and / or ATN, but may be suitable organ donors. Similarly, in other poisonings, the decision should be based on a case-to-case basis.

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- **Trauma:** donation from donors with trauma to abdominal or thoracic organs should be undertaken after evaluation and understanding of the extent of injury and its impact on transplantation on a case-to-case basis.
- The role of ZTCC / SOTTO / ROTTO is limited to impartial and transparent distribution of organs as per the provisions of law. ZTCC / SOTTO / ROTTO will not be legally responsibility of the outcome of any donation from normal / ECD organs with respect to surgical or anaesthesia related or any other complications, graft function of transplanted organ, episode of rejection, any infections/diseases/malignancies unknowingly transmitted from deceased donor and manifesting at any point of time post-transplant surgery.
- The distribution of organs from deceased donors is done based on scientific guidelines but to accept or deny an offer is the responsibility of the transplant team and patient. The distribution agency which covers all the ZTCCs, ROTTO, SOTTO, NOTTO are not responsible for quality of organs.

REGISTRATION, STATUS UPDATES, AND TRANSFER

REGISTRATION

- Patients can only be registered / listed for organ transplant through any one transplant centre within one SOTTO area.
- Patients should be evaluated and found medically suitable for undergoing the transplant by a multi-disciplinary team (MDT). All recognized transplant centers will do the necessary investigations needed for their recipients prior to registration / listing application. Failure to do so would result in automatic de-registration.
- Registration with NOTTO and NOTTO ID is mandatory in the application form.
- Registration charges and transfer of registration charges will be as per ZTCC norms. There will be no registration charges for public sector hospitals.
- At the time of registration, patients will need to opt-in for accepting organs in the one or more of the following categories: ○ Standard criteria organ ○ Extended criteria organ (ECD)
- The application will be verified by ZTCC at the time of registration. Only complete applications with necessary patient details, investigation reports and registration

charges will be considered for listing. Incomplete forms will not be considered for listing.

- All patients primarily registered with respective ZTCCs will automatically get registered with SOTTO.
- The decision of listing will be conveyed to the applying hospital by email.
- The date and time of receipt of application will be the listing date and time. Patients listed for transplantation will be eligible to receive an organ allocation offer after a minimum five days of listing, except for Super-Urgent registration. This rule may be relaxed only if there are no other patients on the same blood group waiting list willing to accept the liver, to avoid wastage of organs, before offering it to other ZTCCs.
- All forms should be accompanied with supporting documents, including, but not limited to:
    - Valid ID showing Date of Birth (Aadhar card or Passport]. The copy of same will be sent to NOTTO or the same document should have been submitted at the time of NOTTO registration.
    - Signed patient guidelines ○ Statement certifying that they are currently not already listed / registered within the state.
    - All reports to support the application with relevant calculated scores, performed within 1 month of the application from a lab which is either part of a licensed transplant hospital, government institute or is a NABL accredited lab.
    - Patients willing to accept an ECD organ should submit the ECD acceptance consent form
    - Request for exception points (for liver transplant) with justification and supporting reports. All requests for exception points require review and approval by the SOTTO / ROTTO LSC. All such applications would be closed within 21 days of application. The decision of LSC regarding suitability and number of exception points will be final and binding.
    - For patients requiring organ as a part of multiple organ transplant, primary application is made for the organ highest on the organ of priority (OP) list with other organs requested additionally, except patients registering for simultaneous pancreas-kidney transplant (SPK) whose names will be maintained on both pancreas and kidney waiting lists.

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- General recipient exclusions for listing / registration ○ Active / metastatic malignancy
    - Active MDR infection with sepsis or septic shock ○ Severe irreversible systemic disease (cardiac, pulmonary, neurological or others with very short longevity)
    - Active or recent major unresolved psychiatric illness ○ High risk of non-compliance with long-term immunosuppression ○ Lack of social or family support

TRANSFER OF REGISTRATION

- Patients who wish to change their registration from one hospital to another may submit a written request / application through the new hospital to ZTCC within working hours (11 to 5 pm) on working days (except Super-Urgent cases) for transfer of registration with a copy of the intimation letter to the previous hospital.
- The transfer will be effective only after 5 days, except for super-urgent listing, where the transfer will be effective immediately. During this period, the patient will remain active on the previous hospital's waiting list.
- Patients will continue to maintain their position on the city waiting list after the transfer, including those on the Super-Urgent waiting list.
- Transfer of registration is permitted only once in 3 months and not more than 2 transfers every calendar year.
- If there is an interruption of a transplant program (temporarily or permanently) for any reason, for any organ, patients on their waiting list may be permitted to transfer their registration to another hospital of their choice provided they apply to ZTCC for the transfer.
- The above rules shall apply for transfer among hospitals between different ZTCCs.

UPDATES / HOLD / DELIST

- For patients on the elective list, hospitals are required to send an update on recipient status on monthly basis to ZTCC. Patients under Priority-One or Super-Urgent category should be updated every 24Hrs. Additional updates may be sent in case of any

significant change in the patient's condition at any time. For Semi-Emergency category, status should be updated on a weekly basis.

- For Super-Urgent or Priority-One patients, if updates are not received for 2 consecutive days, the patient may be put on hold and a reminder sent to the hospital. Failure to receive updates for another 2 days will result in delisting. All patients on super-urgent list are subject to a formal review every 5 days when the respective expert organ specific committee could suggest their continuation on super-urgent list or downgrade.
- For routine patients, updates are required as per the required frequency in organ specific guidelines. After an update, patients will be eligible for organ allocation by upward revision of registration category only after 48 hours of submission to ZTCC.
- Updates about patients who have expired, undergone transplant or have significant change in their condition, or scores should be made immediately, certainly within 24 hours of the event, with the date and details.
- In case of failure of updation of clinical condition, reports and scores as per the required frequency, the hospital will be sent a reminder. If there is lack of a response the 2nd time, the patient will automatically be put on “hold” and informed. On 3rd failure, patient would be de-listed in the absence of a justifiable reason. The patient may be reactivated for hold status on receiving updates, although they will not receive waiting time points for the duration when updates were not received.
- Patient on the liver waiting list can remain on the Hold status for 3 months after which they have to decide to either become active again or de-list. Patients on hold status will be automatically de-listed after 3 months if no updates are received from the hospital. If the patient needs to continue on hold status for a medical reason, the same can be requested by the hospital.
- Re-registration will be considered as a fresh application with new priority. ZTCC / ROTTO / SOTTO may directly inform the patient about delisting.
- Patients can be put on "hold" status, by an application through their transplant centre, with the reason for the same. Patients on "hold" will not receive any offers. Request for "hold" status should be signed by the patient, treating physician and transplant surgeon. A patient can remain on "Hold" status for 3 months, after which they have to make a decision to become active again or de-list. Patients will retain their original position on

- the waiting list on reactivation but will not get vintage points for the duration of hold status.
- Each hospital is required to send comprehensive updates of all their patients by the 5th of each month failing which the hospital could be fined (1st failure) or allocation to their patients suspended (2nd failure), until updates are provided.
- Patients will be able to receive updates about their registration status and their position on the waiting list only through the hospital, and not by contacting ZTCC / SOTTO directly.
- ZTCC should inform about change in registration status such as hold/unhold/delisting to SOTTO within 24 hours. The status of the patient must be updated regularly by the hospital to one of the following: ○ Active
  ○ Unfit ○ Recipient frequently
  refused ○ Not contactable ○
  Lost to follow-up ○ Transplant
  done ○ Death

WAITING LISTS

Each ZTCC will maintain following blood group wise waiting lists:

- Super-Urgent waiting list (for heart, lungs and liver)
- Semi-Urgent waiting list (for heart)
- Routine waiting list (for all organs and tissues)

REVIEW OF SUPER-URGENT LISTING

- All applications for super-urgent registration / listing are subject to review by at least 3 independent members of the SOTTO / ZTCC Super-Urgent committee. All replies by members within 4 hours will be considered for decision. Any members with direct conflict of interest shall abstain from voting.
- In case more details are requested, or any queries or objections raised by any member, the same is conveyed to the applying hospital through concerned ZTCC / SOTTO. All such queries and objections should be clarified / resolved before listing.

- If the application is approved by majority and objections clarified, the patient can be listed on the super-urgent list.
- In case of persistent discordance among members, dispute or tie, the decision of LSC chairman in consultation with the SOTTO Joint Director / ROTTO director would be final and binding and will be communicated by the same.
- The final decision is conveyed to the applying hospital, other hospitals and ZTCC by email / messages and all other ZTCCS and SOTTO are also alerted
- For heart, patient may remain in Priority 1 waiting list for 30 days, following which he/she will be moved to Priority 2 waiting list.

PRINCIPLES OF ORGAN ALLOCATION

Following principles should be followed in organ allocation:

- Urgency of transplant.
    - Super-urgent ○ Routine
- Blood group compatibility: The outcomes of liver transplant in identical and compatible blood group (ABO) transplants are similar and superior to ABO incompatible transplants, therefore, allocation should preferably done in the following order: ○ Blood group identical (same as the donor's blood group) ○ Blood group compatible (non-identical) (compared to donor's blood group) ○ ABO incompatible (compared to donor's blood group) ○ Prioritization of blood group compatible (non-identical) for super-urgent category is allowed
    - Blood group O donor organ (for patients other than super-urgent category) should be offered in the following order:
        - ✦ Blood group O patients on the donor hospital list
        - ✦ Blood group O patients on the city list
        - ✦ Blood group O patient on the state list
        - ✦ Other Blood group patients on the donor hospital list
        - ✦ Other blood group patients on city list
        - ✦ Other blood group patient on the state list

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- All organs are first allocated in the following order (one kidney is shared to ZTCC list if both are transplantable) ○ In-house to the donor hospital's waiting list ○ ZTCC list ○ SOTTO list ○ ROTTO list ○ NOTTO list

  In case a donor is shifted from a non-registered centre / hospital to a transplant centre for the retrieval, the transplant hospital will be allowed to use any one organ of their choice as an in-house organ. All other organs will be allotted to the ZTCC list in the above order.

  A ZTCC / city list organ is one donated:

  - At a registered liver transplant centre but not used "in-house" by them for their patients. One kidney from donations even at transplant centre is given to ZTCC list
  - In case a donor is shifted from a non-registered centre / hospital to a transplant centre for the retrieval, except one organ of their choice, all other organs will be

    ZTCC list organs ○ At a registered transplant centre

    not doing transplants
  - At a NTORC ○ Imported from outside the ZTCC/SOTTO/ROTTO/NOTTO
- Recipient's Nationality: priority is given based on recipient's nationality, as mandated in THOA, as follows: ○ Indian nationals ○ Overseas Citizen of India (OCI) card holders ○ Foreign nationals

  Allocation to overseas citizens and foreign nationals will be done through NOTTO
- Multi-visceral transplants: Multi-visceral transplants with all organs from the same donor confers an immunological advantage to the patient. Therefore, organs are ordered based on their life saving potential and benefit of multi-visceral transplant in the following sequence, called as **organ of priority (OP)**:
  - Heart ○ Lungs
  - Intestine ○ Liver ○

    Pancreas ○ Kidney

- Composite tissue, including hand
- Uterus
- Any other as specified

Patients requiring a multi-visceral transplant are primarily listed for the organ with highest OP priority and other required organs are designated as additional organs. When the patient is allotted the OP, other organ/s required for the patient are also allotted from the same donor to the recipient.

ORGAN OFFERS

- Once an offer is made to a hospital, the decision about its acceptance should be made by the center within 1 hour.
- Kidney offers are provisional pending a negative cross-match report, whereas a firm allocation may be made for all other organs.
- Once an organ has been allotted to any recipient, it is final, and even if another patient is listed as super-urgent after that, they will not be eligible for that particular organ allocation.
- Once a refusal has been communicated by the hospital, either due to their patient not willing or patient not contactable, and the organ has been allocated to the next recipient, the allocation will not be reversed even if subsequently earlier recipient becomes available or shows his / her willingness to accept the organ.
- In case new donor information becomes available or significant change in donor's condition or previously provided information occurs, the transplant teams may change their decision for acceptance of the organ.
- ZTCC / SOTTO / ROTTO may also directly contact the primary and standby / backup recipients to confirm their willingness to accept the organ and other details.
- For in-house organs, two standby recipients have must be kept ready in the same hospital and two more standby patients in the city list. For ZTCC / city organs, two more patients should be kept as standby for the same organ.
- It is a prerogative / privilege of the transplant team to determine the suitability of a particular organ for a particular reason. Hospitals / patients may refuse a liver offered to them for one of the following reasons:

-
    - Logistic (non-availability of the transplant team, patient not contactable or available, patient presently not ready or willing for transplant and others) or
    - Recipient Medical Reasons (patient too well for transplant, patient temporarily unfit for transplant, donor's organ is unsuitable for the patient and others).
    - Donor reasons (donor malignancy, infection, donor unstable, etc.)

  A patient / hospital can refuse for logistic / personal reason 3 times after which they will be automatically be put on hold for 3 months and may be delisted unless a valid justification is provided by the hospital or with prior intimation to ZTCC.
- In case of acceptance of offer by a hospital and eventual non-usage, leading to wastage of the organ, the penalty may extend upto 6 months suspension of allocation to that centre
- Any offers for ECD organs or where the organs are rejected by all centers would not count towards the number of offers for a patient.

RETRIEVAL

- The sequence of retrieval will be in the following priority, unless there is a medical reason mutually acceptable to concerned retrieval teams ○ Hands ○ Lungs ○ Heart ○ Intestine ○ Liver ○ Pancreas ○ Kidneys ○ Uterus ○ Any other as specified
- Retrieval time is decided by the donor hospital which is communicated to all by ZTCC. If any retrieval team needs a change of retrieval time, they could contact the donor hospital directly and understand donor family's requests for handover and coordinate with other retrieval teams. The change may be allowed by ZTCC if mutually acceptable to all.
- The retrieval team should reach the donor hospital within 4 hours after accepting the organ or at the retrieval time communicated by ZTCC
- The transplant team may send their own retrieval team, a local retrieval surgeon or nominate a recognized trained surgeon from another center to retrieve the organ on their behalf.
- In outstation retrievals where a chartered flight is used, attempts should be made to share a single chartered aircraft to transport more than one organ to save costs after mutual discussion. In such situations, it is suggested that 3 members of the heart team and 2 from the liver / pancreas team should travel for retrieval. Transplant centers

should send experienced retrieval surgeons for remote retrievals and carry out maximal dissection during the warm phase, to keep cardiac cold ischemia time as short as possible. A time limit of 30 minutes from heart-on-ice to liver-on-ice is acceptable.

- Cross clamp should be done by the retrieval team only if they have decided to use the organ.
- If the retrieving team is likely to not accept an organ:
    - They should immediately alert ZTCC and the retrieval team of standby patients for them to assess the organs.
    - Retrieval team from standby recipient hospitals should be ready to go to the donor hospital for assessment or retrieval. The primary retrieval team should leave only after handing over retrieval to the second team in person or if mutually acceptable, complete the retrieval on their behalf.
    - Retrieval surgeon should take photos of gross liver and send to next standby hospital coordinator and ZTCC coordinator.
    - A frozen section liver biopsy is required for all livers before rejecting the liver by any team unless the liver is grossly cirrhotic or facility for frozen section is not available. ○ All vital decisions such as cross-clamp should only be made after discussion with ZTCC and standby hospital's surgeons' assessment and approval and confirmation from the chair or co-chair of the liver sub-committee.
    - The team that finally accepts / agrees to use the organs should bear the cost of the perfusion fluid, even if the organs are not used, irrespective the retrieval is done by them or by some other team on their behalf.
- Recipient team should collect and carry donor's blood samples and required tissues for more tests and cryopreservation of donor blood and tissue samples.
- Machine perfusion may be utilized by centres, especially for ECD organs.
- In case of multi-visceral retrieval, the preservative solutions could be shared as follows:
    - HTK: 6 Lit (liver) and 2 litres each for each kidney ○ UW: 4 litres for liver and 1 litre each for each kidney
- Organ quality and characteristics form should be sent to ZTCC after retrieval.

For simultaneous pancreas-kidney retrieval: The pancreas team will get the first choice for which side kidney to take for SPK during procurement and get preference for blood vessels.

-

- **For liver and pancreas retrieval:** If there is a replaced / accessory right hepatic artery arising from the SMA the liver and pancreas teams should mutually and optimally share parts of the artery to ensure that both organs can be transplanted, even if an additional vascular reconstruction is required.
- **For liver and intestine retrieval:**
    - The liver team will not dissect into the gastro duodenal artery or perform any dissection into the pancreas parenchyma with the intention of getting vessel length.
    - The liver team will avoid inferior mesenteric vein flush (dual flush) to avoid flooding the pancreas and avoid edema. If a dual perfusion technique is used when the liver is procured from the same donor as the pancreas, portal perfusion must be via a cannula in the portal vein with the vein vented on the side of the pancreas.
    - At least 1 cm of the portal vein should be preserved with the pancreas for implantation.
    - If a pancreas team chooses UW solution for in-situ perfusion of the pancreas, the liver team will have to accept the same. The liver team may choose HTK or their preferred solution on back table. The cost of UW solution will be shared equally between the liver and pancreas teams.
    - In case of replaced / accessory right hepatic artery arising from SMA, if liver and intestines have been allotted to different recipients, both liver and the intestinal teams should mutually and optimally share parts of the artery to ensure that both organs can be transplanted, even if an additional vascular reconstruction is required. If it is not feasible to salvage both the grafts, then the liver graft gets preference.
- **For pancreas and intestine retrieval:** offered to two different recipients, both the pancreas and the intestinal team should discuss strategies to utilize both pancreas and intestines. If it is not feasible to salvage both the grafts, then the intestinal graft gets preference.
- During retrieval of the hand, it is the responsibility of the transplant team to provide for suitable prostheses for the donor after retrieval of the donor upper limbs. Hence these need to be available at all times with the transplant team

- Special requirements such as harvesting of abdominal wall to increase cavity space should be conveyed to the coordinator in advance and permission for the same should be sought from the donor family.
- In the interest of maximal utilization of as many organs as possible, all retrieval teams, especially during multi-visceral retrievals, are expected to coordinate and accommodate each other regarding choice and technique of preservative flushing, cross-clamp, order of retrieval and surgical dissections to ensure to maintain optimum organ quality. In case of differences of opinion on preference of organs to be prioritized, sharing or reconstruction of blood vessels, especially with variant anatomy in multi-visceral retrievals, the issue should be escalated to the multi-visceral committee, who may offer help, and whose say will be final and binding. In exceptional circumstances, in best interest of patients or the donor family, ZTCC or SOTTO may allow deviation from above protocols.

FOLLOW-UP / AUDIT

A detailed scientific annual report about the results of transplantation performed in the centre must be forwarded to ZTCC, ROTTO-SOTTO, Appropriate Authority. It should include the following points.

1. Patient status
2. Graft status
3. Complications

The ROTTO-SOTTO organ specific transplant committee will meet annually to review all the reports from different transplant centres in the state including mortality rate, incidence of organ rejection, complications of transplantation.

All severe adverse events experienced by living donors should be notified to SOTTO and the Appropriate Authority within 7 days.

HEART GUIDELINES

HEART SPECIFIC DONOR CRITERIA

- Hemodyamically stable with optimal ionotropic support
- No significant coronary artery disease (Coronary Angiography indicated for age more than 40 years)
- No significant structural heart disease on ECHO
- Ejection fraction > 45% by ECHO
- Weight / Size matching

HEART SPECIFIC ECD CRITERIA

- Significant cardiac anomalies
- Significant CAD or History of MI (Myocardial Infarction)
- Significant valvular abnormalities. • Refractory ventricular arrhythmias
- Ejection fraction < 45% by Echo.
- Size/ Weight mismatch

HEART SPECIFIC MINIMAL LISTING CRITERIA

For Heart or Heart-Lung transplantation, patients may be registered in the following categories:

- **Priority 1 / Emergency / Super Urgent:** Recipients on mechanical circulatory assistance and critical clinically will be registered as Priority 1 and will get top priority in allocation based on blood group and size matching. Prior to registration their status will be confirmed and approved by at least 3 members of the Super-urgent Heart Subcommittee appointed by SOTTO. ○ Patient who requires mechanical circulatory support (less than 30 days) with one of the following devices:
    - ✦ IABP (Intra-aortic balloon pump)
    - ✦ ECMO (Extra Corporeal membrane oxygenation)
    - ✦ LVAD / RVAD/ Bi-VAD (Left Ventricular Assist Device or Right Ventricular Assist Device or Bi Ventricular Assist Device)
    - ○ Recipient on mechanical circulatory support for more than 7 days with device related complications.
    - ○ Patient on mechanical ventilation with high ionotropic support.

- **Priority 2 / Semi Emergency:** Recipients requiring ICU care and dependent on ionotropic support for at least a week, and not maintaining acceptable haemodynamics if ionotropes are attempted to be weaned off. Prior to registration their status should be confirmed and approved by at least 3 members of the Super-urgent Heart Subcommittee appointed by SOTTO. Patients with prolonged ventilation having good physical status.
    - Patient on mechanical circulatory support for more than 30 days, with optimized status without any device related complications.
    - Patients in ICU for more than 72 hours on ionotropic support with or without ventilator.
- **Priority 3 / Elective:** Recipients who are ambulatory and stable on medical management should be registered under this category. Their status should be updated at least on a monthly basis.
    - Patients who are stable but symptomatic in NYHA class III / IV on maximal medical treatment with oral medications.
    - Patient on ionotropes, who is optimally stable at home.
    - Patient with severe Heart failure (EF < 20%) despite maximal medical therapy ○ Ischemic cardiomyopathy ○ Non-ischemic cardiomyopathies: Dilated, Hypertrophic, Restrictive ○ Irreversible myocarditis ○ Intractable arrhythmias
    - Complex congenital heart disease not amenable to corrections ○ Complicated valvular heart disease ○ Significant functional limitation despite maximal drug therapy: NYHA III-IV ○ Congenital/ valvular heart diseases not amenable to interventional or surgical procedure
    - Life threatening arrhythmia despite maximal medical / device therapies ○ Meets CEPT Criteria: RER > 1.05, peak VO2 < 14 ml/kg/min & < 12 on Beta Blocker

HEART SPECIFIC EXCLUSION CRITERIA FOR LISTING

- Age more than 65 years
- Severe cardiac cachexia: Nephropathy, Neuropathy etc.
- Diabetes with end organ diseases
- Baseline GFR < 40 ml/min., Baseline serum creatinine > 2.5 mg/dl
- Severe cerebrovascular disease
- Severe obesity BMI > 30

- Severe primary pulmonary disease
- Pulmonary Hypertension PASP > 50 mmHg unresponsive to vasodilator challenge

HEART SPECIFIC ALLOCATION PROTOCOL

- In a situation of more than two patients in the same priority listing, organ allocation preference will be done according to the following considerations: ○ Urgency: Priority 1, Priority2, Priority 3 ○ Blood group matching: identical first, compatible next ○ Waiting time: Higher to lower chronology after registration ○ Pediatric donor to pediatric recipient

LUNGS GUIDELINES

LUNG SPECIFIC DONOR CRITERIA

Table 2: Lung Ideal donor criteria (ISHLT)

Characteristics	**Description**
Donor PAO2/FIO2 ratio	Ratio > 400 (FIO2 = 1.0, PEEP = 5–8 cm H2O)
Donor age	Less than 55 years
Smoking history	<20 pack-year
Chest radiograph	Normal chest radiograph without infiltrate
Bronchoscopy	Normal bronchoscopy without significant secretions
Sputum	Absence of organisms on sputum gram stain

- Every lung transplant program should also be aware of Extended Donor Criteria (ECD) – not fitting in above criteria.
- Reasons to decline lungs at the procurement center (ISHLT):
  ○ Inability to recruit ○ Unacceptable PaO2:FiO2 (P/F) ratio ○ Unanticipated confirmation of primary or non-primary malignancy ○ Severe trauma not appreciated on CT ○ New data on non-compatibility ○ Demise of original recipient during transit ○ Withdrawal of consent from the donor's decision maker

LUNGS SPECIFIC MINIMAL LISTING CRITERIA

- For registration of Lung transplantation, the following categories of waiting lists of recipients are proposed:
- Supra-Urgent Listing:
    - End Stage Lung Disease patients with ECMO support with/without mechanical ventilation
    - End Stage Lung Disease patients on NOVA lung
    - End Stage Lung Disease patients with respiratory failure dependent on Mechanical Ventilation (not weanable). Prior to registration their Status will be confirmed and approved by at least 3 members of the Super-urgent Heart Subcommittee appointed by SOTTO.
- Elective Listing: All other End Stage Lung Disease patients qualifying for candidacy of lung transplantation (As per ISHLT Criteria)

LUNGS SPECIFIC ALLOCATION PROTOCOL

The order of allocation will be based on the principles outlined herewith:

- **Super-urgent** category - With blood group matching, size matching, geographical and logistic feasibility. Priority 1/ Emergency/ Super urgent registered recipient under SOTTO, will get first preference.
- **Elective** category - with blood group matching, size matching, geographical and logistic feasibility.
- **The order of allocation within each category:** in-house, ZTCC, SOTTO, ROTTO, NOTTO, foreign nationals
- **Age and Size Matching:** It is preferable to have less than 20% size mismatch between the donor and recipient. Higher mismatch maybe acceptable in paediatric recipients. For Lung Transplantation, calculating pTLC (predicted Total Lung Capacity) for both recipients and donors is important for deciding size matching. Also, primary underlying pathology of recipient would dictate acceptable pTLC(D)/pTLC (R) ratio for size matching.

LIVER GUIDELINES

In addition to the general principles, liver allocation is based on the following principles

- Within the super-urgent category, the order of priority is as follows:
    - Post op liver failure after living donor hepatectomy ○ Primary Non-Function (PNF) ○ Anhepatic patient ○ Acute Liver Failure (ALF) ○ Hepatic Artery Thrombosis (HAT)
    - Acute presentation of Wilsons disease, Budd Chiari Syndrome, Auto-immune Hepatitis (AIH), HBV reactivation, etc.
- Pediatric Donors and Recipients: Since there are fewer pediatric donors and organs from such donors may be more suitable for pediatric patients, therefore, organs donated by pediatric (<15 years) donors and / or smaller lobe of a split liver may be preferably allotted to pediatric patients on the waiting list.

EXTENDED CRITERIA DONOR (ECD) FOR LIVER

Any donor / liver meeting the following criteria:

- Macrosteatosis > 30%
- Age > 70 years
- High Ionotropes (Single ionotrope at doses as below or 3 or more ionotropes at any doses) ○ Dopamine > 15 micrograms/kg/min ○ Noradrenaline > 0.3 micrograms/kg/min ○ Adrenaline > 0.3 micrograms/kg/min ○ Vasopressin > 2.4 units/hour
- Transaminitis (raised AST / ALT) ○ 10 times ULN ○ 5 times ULN and rising trend
- Cholestatic Liver: Bilirubin > 5 mg/dL
- Positive blood culture within last 5 days
- Anti-HCV, HBsAg, HBcAb, HIV positive

Expected Cold Ischemia Time (CIT) > 10 hours

- Partial / Split graft
- Last pre-retrieval serum Sodium >160 mEq/L

SPLITABLE LIVERS

Liver from a donor meeting the following criteria should be considered for splitting:

- Age ≤ 40 years
- BMI ≤30
- ICU stay ≤5 days
- SGOT (AST) / SGPT (ALT) ≤ 3x ULN (upper limit of normal)
- On a single or no vasopressor

MAHARASHTRA LIVER ALLOCATION SCORE (MLAS)

Patients with more severe liver disease with higher waiting list mortality risk are prioritized by the allocation system with highest priority to super-urgent patients followed by Maharashtra Liver Allocation Score (MLAS) for routine patients, with provision for exception points for conditions where MELD score may not accurately reflect disease severity. MLAS will comprise of the following components

MODEL FOR END STAGE LIVER DISEASE (MELD)

MELD score = 9.57 x Log_e(Creatinine mg/dL) + 3.78 x Log_e(Bilirubin mg/dL) + 11.20 x Log_e(INR) + 6.43

- Lab values < 1 are set to 1 for calculation
- Sodium values < 125 mmol/L are set to 125 mmol/L
- Sodium values > 137 mmol/L are set to 137 mmol/L
- Following patients' creatinine is set to 4 mg/dL:
    - Creatinine > 4 mg/dL
    - Patients who have undergone ≥ 2 sessions of dialysis or have undergone 24 hours of CVVHD in last 7 days
- The score is rounded off, Maximum MELD-Na is 40
- All reports used for MELD score calculation should have been performed within 7 days of updating, performed on the same day (or within 48 hours of each other) and must be

- from a single lab which is either part of a licensed transplant hospital, government institute or is a NABL accredited lab.

PEDIATRIC END STAGE LIVER DISEASE (PELD)

PELD Score = 10* (0.480 x Log_e(Bilirubinmg/dL) + 1.857 x Log_e(INR) - 0.687 * Log_e(Albuming/dL) + 0.436 (if patient < 1 year: scores for patients listed for liver transplantation before the patient's first birthday continue to include the value assigned for age (< 1 Year) until the patient reaches the age of 24 months) + 0.667 (if patient has growth failure (<2 Standard deviation))

COMPLICATION SCORE

Complication score will be calculated as follows:

Table 3: Liver complication score

Complication	**Points Allotted**
SBP (Absolute Neutrophil count>250)	2
Hepatic hydrothorax (Moderate to severe as seen on the HRCT thorax/CXR/USG thorax ,≥ 2 therapeutic taps), **OR Refractory ascites** needing at least 2 LVPs (At least 5 liters each time) every month/ diuretic resistance/ being treated by noradrenaline/midodrine/terlipressin	2
Past or current HE ≥ grade 3 requiring hospitalization (ICU) after exclusion of structural neurological diseases	2
Recurrent variceal bleed not amenable to endotherapy and / or TIPSS	2
• Complication points are capped at 6 points • Complication points will not be given for MELD > 30	

WAITING TIME SCORE

The waiting time score will be calculated as follows:

Table 4: Liver waiting time score

Waiting time (months)	**3 – 6**	**6 – 9**	**9 – 12**	**> 12**
Points	2	4	6	8

- MLAS score should be updated at following frequeny:
  - Every 15 days if MELD is more than 30
  - Every month if it is between 20 - 30
  - Every 3 months if is less than 20

The score can be updated anytime there is a change in the patients condition or score as and when needed.

- Failing to update the MLAS, the allocation will take place based on the listing MELD and additional points for waiting time will not be granted

MELD EXCEPTION POINTS

Patients may be given MELD exception for the following conditions

Table 5: Liver MELD exception points

MELD Exception criteria	Points
HPS (all of the following) – • PaO_2 < 60 mm Hg on room air • Alveolar arterial oxygen gradient ≥ 15 Hg, > 20 mmHg if >64 yrs age • Evidence of a shunt by Bubble ECHO or MAA scan • Clinical evidence of liver disease and portal hypertension • No significant underlying primary pulmonary disease	22
PAH (all of the following) • Post-treatment Mean pulmonary arterial pressure (MPAP) between 25 and 35 mmHg • Post-treatment pulmonary vascular resistance (PVR) between 120 and 400 dynes/sec/cm • Pulmonary Capillary Wedge Pressure (PCWP) < 15 mmHg	22
HCC (all of the following) • Currently within UCSF (as follows), without or after treatment, successfully downstaged patients meeting UCSF criteria would also be eligible for exception points ○ Single tumor ≤ 6.5 cm OR ○ ≤ 3 tumors with ✦ Largest tumor ≤ 4.5 cm and ✦ Total tumor diameter ≤ 8 cm ○ No active portal vein tumor thrombus (bland PVT is acceptable) ○ No extrahepatic disease • At least one lesion should be > 2 cms • AFP < 1000 • HCC patients would also be eligible for waiting time points only as long as they continue to fulfill above criteria • Repeat triphasic liver CT / MRI should be submitted every 3 months and repeat metastatic workup (Bone scan + chest CT scan or PET CT) submitted every 6 months, failing which any exception points or waiting time points granted in the past would be revoked	Largest tumor > 4 cm: 25 ≤ 4 cm: 22
Primary Sclerosing Cholangitis (PSC) : proven on MRCP • Recurrent cholangitis (>= 4 episodes in a year) • Refractory cholangitis • Severe Intractable itching after therapy	18

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Primary Biliary Cholangitis (PBC) AMA positive ± biopsy proven • Severe intractable pruritus after treatment • Severe metabolic bone disease (non-traumatic fractures or Z score < - 4 on DEXA scan)	18
Post-transplant patient requiring **re-transplant** (not eligible for super-urgent listing such as rejection, late HAT, ischemic type biliary lesions [ITBL])	18
Metabolic liver diseases in which the native liver is offered for used as a Domino • Familial amyloid polyneuropathy • Maple syrup urine disease	22
Other metabolic liver diseases needing liver transplant other than Wilsons • Familial hypercholesterolemia • Sickle cell hepatopathy • Primary hyperoxaluria • Polycystic liver disease	18
Non-HCC liver tumors • Hepatic epithelioid haemangioendothelioma • Bilobar NET (Neuro Endocrine Tumor) liver metastases at least 6 months after resolution of primary tumor with confirmed metastasis restricted to liver by whole body special scans	15
Liver (cirrhotic) + Kidney (CKD) Multi-visceral transplant	22

- Prioritization for Hilar cholangio carcinoma was discussed and not considered suitable for exception points will not be included at this point and may be considered later if additional evidence is available

MLAS calculation is done as follows (Whichever is higher of the two)

- MLAS = MELD / PELD score (A) + complication score (B) + waiting time score (C)
- MLAS = MELD exception points (D) + waiting time score (C)

CRITERIA FOR ABSENCE OF CLD (CHRONIC LIVER DISEASE)

- Normal appearance of liver
- Normal appearance and size of spleen
- No ascites
- Absence of cirrhosis on biopsy

CRITERIA FOR OBVIOUS CLD (CHRONIC LIVER DISEASE)

- Uniformly nodular liver

- Collaterals / varices +
  Moderate splenomegaly (> 12 cm in children, > 14 cm in adults)
- Gross ascites
- Cirrhosis documented on biopsy
- Previous hospitalization for decompensation of cirrhosis

ACUTE LIVER FAILURE (ALF) PHENOTYPE

- Acute hepatic liver injury AST / ALT > 5 – 10x ULN
- Baseline unknown liver disease
- Acute worsening of liver function leading to jaundice and hepatic encephalopathy within 4 weeks

MINIMAL LISTING CRITERIA FOR REGISTRATION ON SUPERURGENT LIST

Patients with the following conditions may be eligible for super-urgent listing, only after approval by the liver sub-committee

- **Liver failure in a living liver donor:** Any patient who has been a living liver donor who develops severe liver failure within 4 weeks of the donor operation
- **Primary Non-Function (PNF):** Graft dysfunction within 7 days after liver transplantation, provided other causes for the same have been ruled out e.g. vascular complications such as congestion, ischemia, sepsis, etc.
  - Essential criteria (only for whole DDLT graft): AST > 3000 AND
  - Any one of the following criteria:
    - INR ≥ 2.5
    - Arterial pH ≤ 7.30
    - Venous pH ≤ 7.25
    - Lactate ≥ 4 mmol/L
- **Anhepatic patient** after total hepatectomy e.g. for trauma, etc.
- **Paracetamol poisoning** (should meet one of the following criteria) ○ pH <7.25 more than 24 hours after overdose and after fluid resuscitation ○ Significant liver injury and coagulopathy following exclusion of other causes of hyperlactatemia (e.g. pancreatitis, intestinal ischemia) after adequate fluid resuscitation
    - Arterial lactate >5 mmol/l on admission

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    - ✦ Arterial lactate > 4 mmol/l after 24 hours of fluid resuscitation
    - ✦ Clinical hepatic encephalopathy ○ All 3 criteria fulfilled:
    - ✦ Prothrombin time > 100 seconds or INR > 6.5
    - ✦ Serum creatinine >300 μmol/l (3.39mg/dL) or anuria
    - ✦ Grade 3–4 encephalopathy ○ Two of above three criteria from category with clinical evidence of deterioration (e.g. increased ICP, FiO2 >50%, increasing inotrope requirements) in the absence of clinical sepsis
- **Favorable etiologies** (HAV, HEV, Ecstasy, Cocaine toxicity, etc.) ○ Clinical hepatic encephalopathy is mandatory ○ Prothrombin time >100 seconds or INR >6.5 or ○ Any three of the following
    - ✦ Age > 40 or < 10 years
    - ✦ Prothrombin time > 50 seconds or INR > 3.5
    - ✦ Any grade of hepatic encephalopathy with jaundice to encephalopathy time > 7 days
    - ✦ Serum bilirubin >300 mol/l (17.54 mg/dL)
- **Unfavorable etiologies** (seronegative hepatitis, idiosyncratic drug reactions, drug induced liver injury (DILI), others) ○ Prothrombin time > 100 seconds or INR > 6.5 or ○ In the absence of clinical hepatic encephalopathy
    - ✦ INR > 2 after vitamin K repletion is mandatory and ✦
    - Any two from the following
- Age > 40
- Age < 10 years
- Prothrombin time > 50 seconds or INR > 3.5
    - ○ If hepatic encephalopathy is present
        - ✦ Jaundice to encephalopathy time > 7 days
        - ✦ Serum bilirubin >17.54 mg/dL (>300 mmol/l)
- **Ratol poisoning:** Patients meeting 3 of the following 4 criteria:

1. Prothrombin time > 100 seconds or INR > 6.5 after Vitamin K repletion. In patients undergoing plasmapheresis, 12 hrs after second set of plasmapheresis if INR > 2.5
2. MELD > 37
3. HE ≥ grade II
4. Arterial lactate (24 hrs after admission) ≥ 6 mmol/L after fluid resuscitation ○ Active cardiac dysfunction (EF < 50%) at the time of allocation will be a contraindication for allocation

- **Hepatic artery thrombosis (HAT):** HAT within 21 days after liver transplantation after failure of revascularisation (Radiological or Surgical)
- **Acute presentation of Wilson's disease** (meeting all of the following criteria) ○ In case of no CLD or doubtful CLD
    - ✦ Leipzig score ≥ 3
    - ✦ Coombs negative hemolytic anemia (not mandatory, positive result strongly supports diagnosis)
    - ✦ ALF phenotype
    - ✦ Other etiologies have been ruled out ○ In case of obvious CLD, to be presented to LSC
- **Acute presentation of Budd-Chiari syndrome (BCS)** ○ Essential criteria: Cross-sectional (CT / MRI) imaging showing no chronic hepatic vein thrombus AND no atrophy hypertrophy complex
    - ○ In addition, meeting any of the following criteria
        - ✦ BCS patients meeting new NHS criteria for unfavorable etiologies
        - ✦ BCS patients with ALF (INR > 1.5 and grade ≥ 3 hepatic encephalopathy)
        - ✦ BCS with ALF where TIPSS is contraindicated or not feasible
- **Acute presentation of Auto-immune Hepatitis (AIH)** meeting both these criteria:
    - ○ No CLD or doubtful CLD
        - ✦ ALF phenotype
        - ✦ HE
    - ○ if no HE (all 3 criteria to be met)
        - ✦ Histology is mandatory showing

- Confluent or massive hepatic necrosis (AIH / DILI)
- Marked microvesicular steatosis (DILI)
- Cholestatic hepatitis with ductopenia (DILI)
    - ✦ MELD > 28
    - ✦ No improvement in Bilirubin / INR with steroids for 5 days
- **HBV reactivation** ○ No CLD or doubtful CLD ○ ALF phenotype ○ IgM core positive ○ Other causes ruled out
- **Pediatric patients:** Acute liver failure in children under two years of age with either ○ INR > 4 or ○ Grade 3-4 encephalopathy ○ Multisystem disorder in which severe acute impairment of liver function with or without encephalopathy occurs in association with hepatocellular necrosis in a child with no recognized underlying chronic liver disease. Children with leukaemia, lymphoma, haemophagocytosis and disseminated intra-vascular coagulopathy are excluded
- **Hepatoblastoma**
    - ○ Pretext III / Pretext IV disease with good response to 6 cycles of chemotherapy with no extra-hepatic disease (Total Hepatectomy is the only surgical measure to achieve R0)
    - ○ Complete response to chemotherapy / R0 resection of any extra-hepatic disease with above criteria
    - ○ Priority given only for splittable livers

MINIMUM LISTING CRITERIA FOR ROUTINE WAITING LISTING

- Routine waiting list: MELD ≥ 15 or CTP Score ≥ 8
- For patients with alcoholic liver disease, 3 months abstinence from alcohol is mandatory, to be certified by the patient, psychiatrist, transplant surgeon and hepatologist. Psychiatrist should evaluate and state patient's motivation and likelihood of abstinence from alcohol and risk of recidivism.
- For patients with hepatocellular carcinoma (HCC), tumors within UCSF criteria (considering only LIRADS 5 lesions) on triphasic CT/MRI within preceding 1 month is mandatory. For tumors with previous loco-regional interventions e.g. RFA / TACE / TARE / Resection etc., pre-intervention imaging should also be sent for comparison.
- For patients requiring simultaneous liver and kidney transplant, in addition to fulfilling the liver transplant criteria, the patient should have:

- Chronic Kidney Disease, defined as documented eGFR of < 30 by Cockcroft Gault formula for 3 months (minimum 2 calculations ≥ 3 month apart are required)
- Need for dialysis for ≥ 3 months ○ Primary hyperoxaluria

- For patients requiring combined heart / lung and liver transplant, one of the following minimum criteria for liver disease should be met: ○ Cirrhosis on USG / CT / MRI or biopsy ○ CTP score ≥ 8 or MELD score ≥ 12 ○ HVPG ≥ 10
- Patients with treated or current extrahepatic malignancy can be accepted for listing if in opinion of an independent oncologist (not involved with any transplant program), the patient's expected 5-year survival is > 50% from the tumor point of view. All such applications will need approval by the LSC, who may, in case of any objections seek an additional oncologist's opinion.
- Patients with hilar cholagiocarcinoma meeting the following criteria will be eligible for applying to LSC for registration:
  - Before neoadjuvant chemotherapy
    - ✦ Imaging s/o hilar cholangiocarcinoma
    - ✦ Size < 3 cm
    - ✦ Any 1 diagnostic criterion positive
- CA 19-9 > 100
- Brush cytology positive
- FISH positive
  - After completion of neoadjuvant chemotherapy
    - ✦ No extrahepatic (liver, lungs, regional LN, peritoneal) disease on PET scan, EUS or diagnostic laparoscopy

LIVER SPECIFIC UPDATES / HOLD / DELISTING

- When updates result in upward revision of MELD score, patients will be eligible for allocation based on the higher score only after 48 hours of update submission. However, downward revision will be effective immediately. No updates after a donor is announced will be used for allocation of that donor.

- Reports used for MELD calculation should have been performed on the same day (or within 48 hours of each other) and must be from a single lab which is either part of a licensed transplant hospital, government institute or is a NABL accredited lab.
- For patients with alcoholic liver disease, if there is history of resumption of alcohol intake or abuse while on the waiting list, the transplant team is responsible for informing the ZTCC / SOTTO / ROTTO as soon as it comes to their attention for delisting the patient. If the patient meets the abstinence criteria in the future again, a fresh application may be made. A monitoring mechanism for compliance may be implemented by each ZTCC.
- For patients with HCC, re-Imaging with contrast CT / MRI is required every 3 months. Transplant teams are responsible for updating SOTTO / ROTTO of all subsequent imaging, tumor makers and treatment details. If an update is not received at 3 monthly intervals, the patient would automatically be put on hold. Patients whose disease has progressed on the waiting list beyond the UCSF criteria should be informed to SOTTO / ROTTO. Patient subsequently successfully downstaged to within UCSF criteria, may be reactivated on the list, and their vintage points be restored for the entire duration of waiting time. HCC patients who respond well to interventions and currently do not have an active tumor may be allowed to be on hold status for upto 2 years at the discretion of LSC on application.

LIVER ALLOCATION

ALLOCATION OF LIVER FROM A PEDIATRIC DONOR (UPTO 15 YEARS AGE)

1. Blood group identical Indian Pediatric Super-Urgent patients “in-house” followed by “city-list”.
2. Blood group identical Indian Pediatric Urgent patients “in-house” followed by “citylist”
3. Blood group compatible Indian Pediatric Super-Urgent patients “in-house” followed by “city-list”
4. Blood group compatible Indian Pediatric Urgent patients “in-house” followed by “citylist”
5. Blood group identical Indian Adult Super-Urgent patients “in-house” followed by “city-list”

6. Blood group identical Indian Adult Urgent patients “in-house” followed by “city-list”
7. Blood group compatible Indian Adult Super-Urgent patients “in-house” followed by “city-list”
8. Blood group compatible Indian Adult Urgent patients “in-house” followed by “citylist”
9. As a part of blood group identical pediatric multi-visceral transplant, as per OP higher than liver
10. Blood group identical Indian Pediatric patients on routine waiting list “in-house” followed by “city-list”.
11. As a part of blood group compatible pediatric multi-visceral transplant, as per OP higher than liver
12. Blood group compatible Indian Pediatric routine patients “in-house” followed by “citylist”.
13. As a part of blood group identical adult multi-visceral transplant, as per OP higher than liver
14. Blood group identical Indian Adult patients on routine waiting list “in-house” followed by “city-list”.
15. As a part of blood group compatible adult multi-visceral transplant, as per OP higher than liver
16. Blood group compatible Indian Adult routine patients “in-house” followed by “citylist”.
17. To other zones through SOTTO
18. To other regions through ROTTO
19. Nationally through NOTTO
20. OCI card holders (in sequence from 1 - 19)
21. Foreigner patients (in sequence from 1 - 19)

ALLOCATION OF LIVER FROM AN ADULT DONOR

1. Blood group identical Indian Super-Urgent patients “in-house” followed by “city-list”.
2. Blood group identical Indian Urgent patients “in-house” followed by “city-list”
3. Blood group compatible Indian Super-Urgent patients “in-house” followed by “citylist”
4. Blood group compatible Indian Urgent patients “in-house” followed by “city-list”
5. As a part of blood group identical multi-visceral transplant, as per OP higher than liver
6. Blood group identical Indian patients on routine waiting list “in-house” followed by

"city-list".

7. Blood group identical Indian patients on routine waiting list "in-house" followed by "city-list".
8. Blood group compatible Indian patients on routine waiting list "in-house" followed by "city-list".
9. Blood group compatible Indian patients on routine waiting list "in-house" followed by "city-list".
10. As a part of blood group compatible multi-visceral transplant, as per OP higher than liver
11. To other zones through SOTTO
12. To other regions through ROTTO
13. Nationally through NOTTO
14. OCI card holders (in sequence from 1 - 13)
15. Foreigner patients (in sequence from 1 - 13)

ALLOCATION OF A SPLITTABLE LIVER

- If the donor liver is suitable for splitting, it must be split, unless the donor hospital has sound justification for not splitting the liver. Only if there are no suitable recipients for the two lobes, the liver from donors meeting the above criteria can be offered as a full graft.
- In case there are no super-urgent or urgent patients on the waiting list, both lobes can be utilized by the donor hospital "in-house".
- The right lobe / right extended lobe for the split is distributed as an adult donor liver and the left lobe / left lateral segment is distributed as a pediatric donor liver.
- When a liver is split, the transplant team of the patient higher on the waiting list will decide the suitability for splitting, first choice of the lobe, sharing of vessels and bile duct and technique of splitting.
- In case one lobe from a split liver is used "in-house" and the other lobe is offered to the "city-list", payback will not be applicable

Clarifications on above allocation rules

- Liver will be offered to patients on the blood-group specific waiting list according to the MLAS score.
- If a patient for super-urgent listing has doubtful CLD based on clinical, laboratory or imaging parameters i.e. the patient does not have absence of CLD or obvious CLD criteria above, a liver biopsy may be asked for by the LSC. If a biopsy is not medically suitable or possible, the super-urgent listing may be granted by LSC subject to the hospital agreeing to submit intra-operative photo of the liver and histopathology report of the explanted report to ROTTO / SOTTO LSC within 15 days of the transplant. If the explant shows cirrhosis, the centre would subject to payback rules for one liver. In case a liver is allocated under super-urgent category but there is a doubt about underlying chronic liver disease based on clinical, laboratory or abdominal imaging, a liver biopsy maybe performed by the centre. Histopathology reports of all explants allotted under Super-Urgent category has to be mandatorily submitted to the ZTCC within 15 days of transplant. If there is evidence of cirrhosis on explant, payback rule will be applicable to that centre.
- If more than one patient is on the super-urgent waiting list, the following order will be used:
    - Blood group (identical followed by compatible) ○ Order of priority as per etiology, given above ○ Waiting time (highest to lowest, for similar etiologies)
- For more than one patient with same MLAS score, prioritization will be done in the following order:
    - Blood group (Identical followed by compatible) ○ Waiting time (Highest to Lowest) - excluding time on hold
- For in House Donor: Any out-of-turn allocation / use of liver can only be done with information / permission from ZTCC / SOTTO. All such deviations must be reported to ZTCC / SOTTO with clinical justification and supporting laboratory and other parameters. All such cases would be scrutinized by the liver committee and discussed in the next liver committee meeting.

LIVER SPECIFIC PAYBACK SYSTEM

If a transplant centre gives up an in-house liver to another hospital for super-urgent or multivisceral transplant, the next liver allotted to an elective patient of that recipient hospital from the city pool or next "in-house" donor in that recipient hospital (whichever happens earlier), will be allotted to the patient of donor hospital which gave up the liver. However, if a liver offered through this payback system is not accepted by the hospital which is being compensated and some other hospital uses it, then hospital being compensated would lose the chance.

KIDNEY GUIDELINES

KIDNEY SPECIFIC ECD CRITERIA AND CONTRAINDICATIONS FOR DONATION

- Contraindication for donation: Donors with established CKD
- ECD criteria (any one of the following) ○ Donor older than 60 years without comorbidities ○ Donor older than 50 years with at least two of the following:
    - ✦ Hypertension
    - ✦ Terminal serum creatinine> 1.5 mg/dL or
    - ✦ Cerebrovascular cause of death

MINIMAL LISTING CRITERIA FOR KIDNEY TRANSPLANT

- Patient should have ESRD and should be placed on hemodialysis or CAPD as a prerequisite for enrolment on cadaver transplant list.
- All absolute contraindications for kidney transplant should be excluded, such as:
    - Active malignancy or active infection ○ Severe irreversible extrarenal disease (cardiac, pulmonary, neurological or any condition which can shorten the longevity)
    - Poorly controlled psychiatric illnesses
- The patient should be certified as fit for transplant by a multi-disciplinary team (MDT)

KIDNEY SPECIFIC UPDATE / HOLD / DELISTING CRITERIA

- If patients refuse deceased donor kidneys or are not contactable for more than three times then they will be kept on hold till they request to activate their names on the list with a written explanation. Patients who are on hold will not be considered while distributing organs.

KIDNEY SPECIFIC PROTOCOL FOR ALLOCATION

- Of the two kidneys retrieved one will be allotted to the patient first on the retrieving hospital waiting list and the second will go to the ZTCC city waiting list. If for any reason any patient who is first on the list is not contactable, not ready for transplant because of financial / other reasons or if he/she is medically unfit for transplant then the kidney will be allotted to the second patient on the list. The transplant coordinator should send a note to ZTCC by email charting the name of patients and reasons for refusal. This should be done within a week of the transplant.

Table 6: Maharashtra Kidney Allocation Score (MKAS)

Age group (years)	0 – 6 6 – 12 12 – 18	3 points 2 points 1 points
Donor age matching	Recipients are classified according to following age groups: • 0-18 years • >18-45 years • >45 years and above	2 points will be given to all the patients in the same age group as the donor
Female patients		1 point
Period on dialysis		0.1 points per month on dialysis
Period of registration		0.1 points per month on list
Identical blood group		3 points
Failure of dialysis access		0.5 points
Previous failed grafts		2 points for each failed graft
PRA	For positivity to Class 1 or 2 For positivity to both classes	5 points 10 points

Living donor needing a transplant		10 points

- The transplant team of the hospital which is offered a kidney has the right to refuse the kidney if in his / her opinion the kidney is not good for use in his / her patient.
- The decision to accept ECD kidneys should be taken by the transplant team of the recipient hospital on a case-to-case basis. The prospective recipient should however be informed about the ECD status of the kidney and informed consent obtained after explaining the pros and cons in details.
- For an ECD donor, the second kidney should be offered to the first fit patient on the city waiting list. If this kidney is refused by the transplant team of that hospital because of ECD, then the said kidney will be offered to the next fit patient on the city list.
- In cases of ECD, if the retrieving hospital's transplant team is of the opinion that the kidneys are only suitable for DKT and not suitable for single kidney transplantation then this decision must be endorsed by the Chairperson and Co-chair of the kidney committee of ZTCC. If the office bearers do not agree, then the second kidney should be offered to first fit patient on the city waiting list.
- To aid decision making, following criteria may be used but are in no way mandatory: DKT may be considered if any two of the following are present:
    - Donor age greater than 60 years.
    - eGFR by CKD–EPI equation is less than 65 mL/min based upon serum creatinine concentration upon admission.
    - Rising serum creatinine concentration (greater than 2.5 mg/dL) at time of retrieval.
    - History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus).
    - Adverse donor kidney histology by frozen section (defined as mild to moderate glomerulosclerosis [greater than 15 and less than 50 percent]).
    - Doing a donor kidney biopsy is no way mandatory, given the ground realities at present. However, an attempt should be made to do it whenever feasible.
- In case of refusal by that transplant team also because it is ECD then both the kidneys should be offered to the retrieval hospital patient for dual kidney transplant (DKT) where both kidneys will be offered to one recipient.

- The transplant team should convey the acceptance/ refusal of organ within an hour of contact.
- Donors with clinical acute kidney injury (prerenal azotemia or acute tubular injury) due to hemodynamic instability can be accepted on a case-to-case basis. The decision to accept such a donor should be taken by the transplant team of the recipient hospital with clear explanation about the status of the donor kidney and an informed consent obtained.

PANCREAS GUIDELINES

PANCREAS SPECIFIC DONOR CRITERIA

- Age ≤ 55 years
- BMI ≤ 28 kg/m2
- No history of Diabetes Mellitus
- No history of Alcohol abuse
- Donor Hyperglycemia (high blood sugars) due to current acute illness (Brain death, Dextrose infusions, steroids, CNS injury can lead to hyperglycemia in donor) may be acceptable
- HBA1C ≤ 7
- Blood sugars, Serum Amylase, Serum Lipase, and HBA1C is required for all donors (No donor pancreas will be allocated without these tests)

CONTRAINDICATIONS FOR PANCREAS DONATION

- History of Diabetes Mellitus
- History of Chronic Alcohol abuse (Allowed for cell Islet transplant retrieval)
- History of Pancreatitis, Pseudocyst, Pancreas surgery (Allowed for Islet cell transplant retrieval)

MINIMAL LISTING CRITERIA: PANCREAS TRANSPLANT ALONE (PTA) OR PANCREAS AFTER KIDNEY TRANSPLANT (PAK)

Each candidate registered on the pancreas waiting list must meet ANY ONE of the following requirements:

- Be diagnosed with diabetes ○ For type I DM

- ✦ Frequent episodes of Hypoglycemia unawareness
- ✦ Brittle Diabetes
- ✦ Secondary Complications of diabetes
- ✦ Poor quality of life with Insulin ○ For type II DM
- ✦ Insulin dependent
- ✦ Age < 55 years
- ✦ BMI < 28 kg/m2
- ✦ No or minimal coronary risk or with corrected coronary disease and therefore low cardiac risk.

- Have pancreatic exocrine insufficiency
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

MINIMAL LISTING CRITERIA FOR SPK TRANSPLANT

- Must meet ANY ONE of the following requirements:
  - ○ Must be diagnosed with diabetes (defined as above) with renal insufficiency (Creatinine Clearance < 30 mL/min using Cockcroft-Gault method) ○ Should pancreatic exocrine insufficiency with renal insufficiency (Creatinine Clearance < 30 mL/min using Cockcroft-Gault method)

PANCREAS SPECIFIC REGISTRATION

Pancreas may apply for pancreas transplant waiting list under one of the following 3 categories

- SPK – Simultaneous Pancreas Kidney Transplant
- Pancreas Transplant:
  - ○ PAK - Pancreas after Kidney ○ PTA- Pancreas Transplant Alone
- A patient listed for Simultaneous Pancreas Kidney transplant (SPK) will also be listed on the kidney transplant list. The patient will be listed according to the kidney listing policy and points given as per kidney listing criteria

PANCREAS ALLOCATION

- Provisional allocation will be done in the following order:

- For SPK:
    - Type 1 DM will get preference over Type 2 DM
    - Waiting time + Kidney Listing points - For PAK
    - Type 1 DM will get preference over Type 2 DM
    - Waiting time - PTA
    - Type 1 DM will get preference over Type 2 DM
    - Waiting time alone

- Final allocation will be done to patients with a negative cross match, unless there is no matching patient with a negative cross match and both the patient and the transplant team understand the higher risk of rejection with a positive cross match transplant
- If a patient on SPK list undergoes a living donor kidney transplant, he / she will keep his position on the pancreas alone transplant list
- If the patient on SPK list gets an offer for a kidney while on the kidney waiting list, the patient can choose to accept the kidney and place his / her name on the pancreas alone list and can use his / her pancreas waiting time to go on the pancreas alone list. This is to encourage SPK patients to use the offer of a good living donor or a good kidney from a deceased donor and will also encourage more pancreas alone to be utilized.

PANCREAS SPECIFIC PAYBACK SYSTEM

- Payback for giving up both kidneys (one for a simultaneous liver-kidney transplant and another for SPK): Donor hospital will receive a standard criteria donor kidney (any blood group) as a payback from the next common pool kidney donor pool of the ZTCC.

INTESTINE GUIDELINES

REGISTRATION

Registration may be done in one of the following categories:

- Isolated intestinal transplant
- Liver-intestinal transplantation (LIT)
- Multi- visceral transplantation (MVT)

MINIMAL LISTING CRITERIA FOR ISOLATED INTESTINAL TRANSPLANT

- Primary Intestinal failure ○ Massive bowel resection ○ Crohn's disease ○ Necrotizing enterocolitis ○ Malabsorption syndromes ○ Tumors such as massive mesenteric desmoids ○ Visceral myopathy ○ Pseudo obstruction
- Failure of Parenteral Nutrition ○ Impending or overt liver failure due to TPN-induced liver injury ○ Thrombosis of two or more central veins ○ Two or more episodes per year of catheter-related systemic sepsis that requires hospitalization
    - A single episode of line-related fungemia, septic shock, or distress syndrome
    - Frequent episodes of severe dehydration despite in supplementation in addition to TPN

MINIMAL LISTING CRITERIA FOR LIVER-INTESTINAL TRANSPLANT

- Additional liver dysfunction or failure due to long term total parenteral nutrition
- Extensive thrombosis of porto-mesenteric axis with or without liver failure

Following are the guidelines for a standard intestinal donor, however, the final decision for accepting any intestine depends on the transplant centre:

- Age < 65 yrs
- BMI < 30 Kg/m^2

INTESTINE SPECIFIC DONOR CONTRAINDICATIONS

- Extensive atherosclerotic disease of Aorta, SMA

INTESTINE ALLOCATION

- A common waiting list for Multi-visceral and Liver-Intestine transplant (MVT-LIT) will be maintained
- A separate waiting list for Isolated intestine transplant will be maintained
- If there is a patient on the super-urgent liver waiting list in the city of compatible blood group, The liver will go to the super-urgent liver patient, isolated intestine can be offered to a patient in-house or to the city intestinal waiting list, chronologically by the date of listing
- Otherwise
    - If donation is in a Intestinal transplant centre, the intestine is offered in-house first to patients on MVT-LIT list followed by isolated intestinal transplant patients listed with that centre
    - If donation is in a liver-transplant centre, the liver is offered in-house to that centre and isolated intestine is offered the city intestinal waiting list
    - If donation is in a non-liver transplant centre
        - ✦ First priority is given to patients listed for MVT-LIT, chronologically by the date of listing and if accepted the liver from the same donor will be allotted to the same recipient
        - ✦ Second priority is given to patients listed for isolated intestinal transplant patients, chronologically by the date of listing
    - For donors <35 kg body weight, first priority should be given to pediatric recipients <18 years of age listed under MVT-LIT or isolated intestine list.

HANDS GUIDELINES

Hands (upper limbs) are vascularised composite allografts that contain multiple tissue types (skin, muscle, bone, nerves, and blood vessels) and require to be surgically connected to ensure blood flow in the recipient. Like organs they are recovered and transplanted as an anatomical/structural unit to perform the same functions in the recipients as in the donor and are susceptible to ischemia and allograft rejection. They require immunosuppression. Since vascularized composite allotransplantation is more similar to organ than to tissue transplantation, in some countries vascularsied composite allografts like the limbs, are recognised as organs.

Given the present-day advances in the field of hand transplantation, the ROTTO-SOTTO Guidelines will help to enforce uniformity and better standards of specialized health care required in this super specialty field.

The transplant team must have printed Standard Operating Procedures (SOPs) for the surgery, pre-op procedures, and the post-op immunology and rehabilitation.

Monitoring of the flap may require multiple skin biopsies. Hence a skin biopsy protocol should be available with the team.

HANDS SPECIFIC DONOR CRITERIA AND CONTRAINDICATIONS FOR DONATION

- Weight/ Size Matching
- No trauma to the limb being procured
- No neurological disease or deformities in the limb being procured
- No implant inside the limb being procured

MINIMAL LISTING CRITERIA FOR HANDS

- Patient with amputated upper limb unilateral or bilateral at levels distal to mid- arm.
- Significant functional limitation despite using prosthesis.
- Loss of hand or part of upper limb not suitable to any other surgical procedure for near complete hand function for activities of daily living.

HANDS SPECIFIC CONTRAINDICATIONS FOR LISTING

- Congenital absence of limb (relative contraindication)
- Severe cachexia: Nephropathy, Neuropathy etc.
- Diabetes with end organ diseases
- Baseline GFR < 30 ml/min
- Severe cerebrovascular disease
- Malignancies with expected life span < 10 yrs
- Severe obesity BMI > 30
- Severe primary pulmonary disease
- Pulmonary hypertension PASP > 50 mmHg unresponsive to vasodilator challenge

HANDS ALLOCATION

- The hand will be allotted only to patients registered under ZTCC / SOTTO.
- In the case of pediatric donors [up to 15 years] the hands will be allotted to registered pediatric recipients [up to 15 years] on the list of the same blood group / next compatible group.
- Blood group identical in-house listed Indian patient [under supervision of ZTCC / SOTTO] will get first priority. If there is no suitable recipient in the donor hospital the following order for allocation will be followed:
- Blood group identical ZTCC /SOTTO listed patient
- Blood group compatible [non-identical] in-house listed Indian patient
- Blood group compatible [non-identical] ZTCC listed patient
- If there is no suitable recipient within the zone then the donated limb(s) will be allotted in the following order: SOTTO, ROTTO, NOTTO
- OCI Card holders
- Foreign nationals. All foreign nationals must register with NOTTO.
- **Age and size matching:** It is preferable to have age and size matching.
- It is essential and of importance, that the donor hand (upper limb) should reach the recipient hospital within the CIT time limit of 6 hrs.

FOLLOW-UP PROTOCOL

- It is the responsibility of the transplant hospital to update ZTCC and SOTTO about the recipient condition every month for the first 6 months, then every 3 months over two years, and every 6 months thereafter.
- ZTCC / SOTTO should be updated whenever the patient is re-admitted for any event related to the hand transplant.

DONATION AFTER CIRCULATORY DEATH (DCD)

When organs are donated after the donor's circulatory death, rather than brain-stem death, the type of donation is called Donation after Circulatory Death (DCD). DCD was previously also known as donation after cardiac death or non-heart-beating organ donation. Organ donation

after either brain-stem death or DCD are permitted under the Transplantation of Human Organs and Tissues Act (THOA), 1994.

DIFFERENCE BETWEEN DONATION AFTER BRAIN DEATH AND CIRCULATORY DEATH

In brain-stem death, the potential donor suffers from severe irreversible damage to the brain. Circulation is maintained spontaneously (or with the support of ionotropic drugs), and oxygenation supported by a ventilator, because of which the thoracic and abdominal organs are preserved and suitable for transplantation, if donated. The detailed process for certification of brain-stem death is specified in the THOA and must be documented in a specified format (Form 8). Consent for organ donation is also obtained in a prescribed format (Form 10). Generally, most brain-dead patients remain stable for a couple of days (with supportive care) before progressing to circulatory death, typically manifesting as cardiac arrest. This period is utilized for family counselling, organ allocation and organizing the logistics for organ retrieval. Brainstem death donors can donate all medically suitable organs for which the family gives written consent.

In DCD, since the donation happens after cardiac arrest / circulatory death, the heart cannot be donated for transplantation and there is potential for immediate damage to most other vital organs. In view of this, there is an urgency for retrieval of organs immediately after death using the rapid retrieval technique. DCD has therefore been successful in countries where families can opt for withdrawal of life-support in terminally ill patients to avoid the futility of medical care, and in countries with robust emergency medical services (EMS) services for patients suffering a cardiac arrest in the community. Efficient cardio-pulmonary resuscitation (CPR) within minutes of cardiac arrest by para-medical teams and quick transfer to the hospital by a coordinated network of ambulances maintains circulation and oxygenation of vital organs, increasing the chance of successful resuscitation, but in case it is unsuccessful, DCD can be done. However, several innovations over the last few years (such as hypothermic oxygenated perfusion [HOPE] and normothermic regional perfusion [nRP]) have allowed better preservation and assessment of such organs significantly improving the results of transplantation. Since most people are familiar with circulatory death after cardiac arrest it may be more acceptable as a natural form of death by society, and the family members of the deceased person may be more willing to consider organ donation, to fulfil the wishes of the

deceased person. The newer techniques also allow a few hours for retrieval, reducing the urgency of the procedure.

IMPACT OF DCD DONATION

The following charts highlight the impact of DCD on the number of organ donations and transplants (Figure 1, 2):

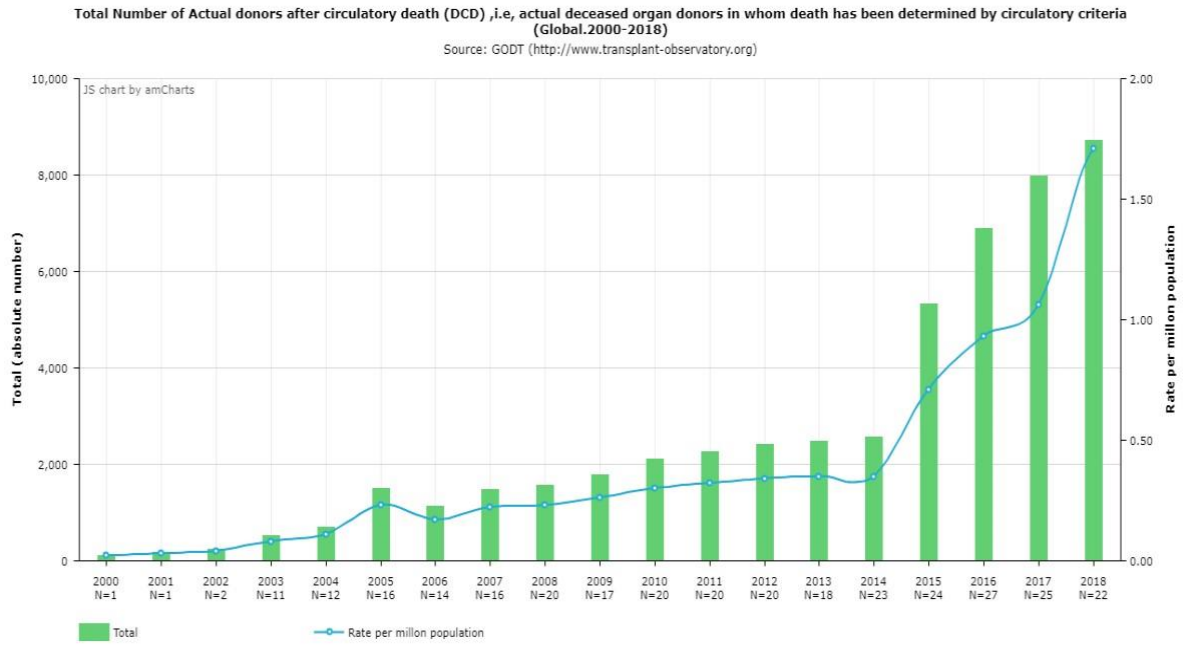


Figure 1: Increase in DCD globally

The impact has been higher in some countries compared to others. In several countries DCD contributes almost 50% of all organ donations. In India, there is a paucity of organ donations, compared to the number of patients with end-stage organ failure requiring a transplant, despite concerted efforts by the government and many NGOs. A successful DCD program may significantly increase the number of donations and bridge this gap, reducing a patient's waitlist mortality. It may be especially helpful in India, where the number of organ donations are low, the waiting list is huge, and the wait-list mortality is high. In India, introduction of DCD would involve training at all levels intensivists, surgeons, perfusionists, transplant coordinators and mass awareness programs for the public.

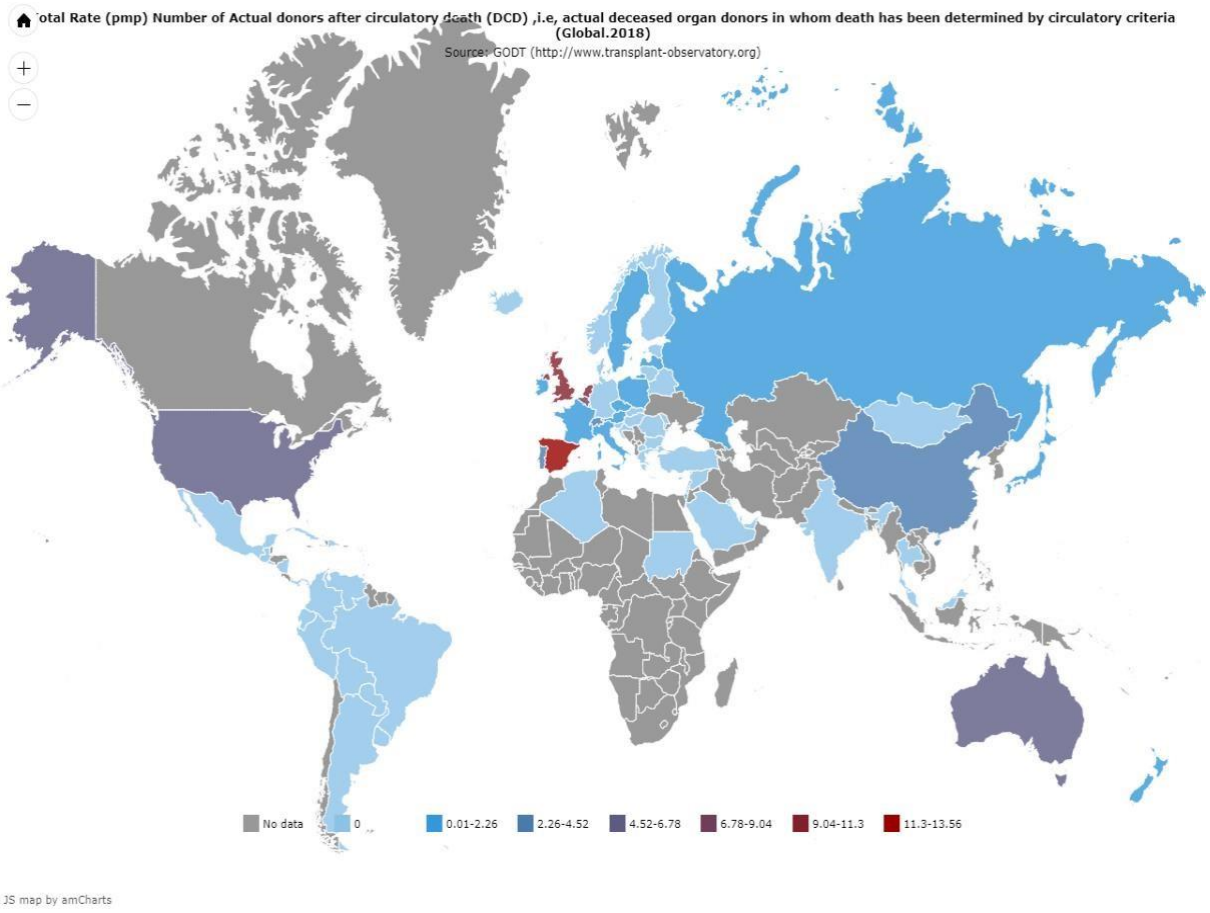


Figure 2: Frequency of DCD (PMP) Globally

DCD TRANSPLANT OUTCOMES

Outcomes of various transplants (kidney, liver and lungs) have been described below. The results have been described before and with the use of newer preservation and retrieval techniques in DCD.

KIDNEY TRANSPLANT

- Despite higher incidences of early graft loss and delayed graft function (DGF) in DCD grafts, 10-year graft and recipient survival were similar between DBD and DCD kidney grafts in Netherlands (Schaapherder 2018).
- Extended UK registry analysis shows that longer-term transplant outcomes in DCD donor kidneys are also similar to those for DBD donor kidneys (Summers 2015).
- During 1998-2008 DCD kidney transplants were associated with higher DGF, early graft loss, impaired 1-year renal function, and inferior graft survival, whereas between

2008-2018 despite more adverse recipient and donor risk profiles, equivalent outcomes between DBD and DCD kidney transplants were observed (de Kok 2020).

- DCD kidneys with are an additional source of valuable transplants. nRP decreases graft failure by restoring oxygenated blood (Antoine 2020)

LIVER TRANSPLANT

- DCD liver graft recipients without other ECD features have similar patient survival compared to DBD graft recipients (Pandya 2020).
- Graft loss was significantly less in HOPE-treated DCD livers, despite longer donor warm ischaemia times (Schlegel 2019).
- Using nRP, results of DCD liver transplant are similar to the standard brain-dead donation for early allograft dysfunction, ischemic cholangiopathy, patient and graft survival (Muñoz 2020).
- DCD livers recovered with nRP offer comparable results to livers recovered from DBD donors (Hessheimer 2020)
- In situ NRP helps reduce biliary complications and graft loss among DCD livers. Ex situ NMP allows for viability assessment of marginal livers prior to transplantation (Hessheimer 2019).

LUNG TRANSPLANT

- 5-year follow-up of ISHLT DCD registry demonstrated similar excellent long-term survival in DCD lung donor recipients from 23 experienced centers (Raemdonck 2019).

MODIFIED MAASTRICHT CLASSIFICATION AND CLINICAL SITUATIONS FOR DCD

There are various situations in which the family of a person who had circulatory death could be a potential organ. The situations are best understood using the modified Maastricht classification of DCD (Table 1) (Cho 2018). DCD donation and transplant is most successful when effective measures were used to resuscitate the donor before their death and organs were rapidly retrieved and preserved after death. There is huge variability in the availability of infrastructure, teams, and systems for resuscitation of a person suffering from cardiac arrest in the community (outside the hospital) between different countries. In India, we do not have robust systems for rapid and effective resuscitation and transfer of patients from the community to hospitals. A successful DCD program would incorporate existing local laws and practices.

Category	Clinical status
I (uncontrolled)	Found dead: sudden unexpected cardiac arrest without any attempt of resuscitation by a life-medical team IA: out of hospital IB: in hospital
II (uncontrolled)	Witnessed cardiac arrest: sudden unexpected irreversible cardiac arrest with unsuccessful resuscitation IIA: out of hospital IIB: in hospital
III (controlled)	Planned withdrawal of life-sustaining therapy
IV (UC or C)	Sudden cardiac arrest after diagnosis of brain death
V	Medically assisted cardiac arrest and subsequent organ donation in some country

In **category I** donation, due to the lack of resuscitation, DCD is rarely successful.

In **category II** donation, the cardiac arrest is sudden, but the patient receives prompt medical attention and resuscitation. Although the resuscitation efforts are unsuccessful, the adverse effects on organs may be acceptable.

- Patients who suffer cardiac arrest outside the hospital, had resuscitation efforts or were promptly (within 15 minutes) brought to the hospital Casualty / Accident & Emergency / Emergency Department / Emergency room and have an unsuccessful attempt at cardiopulmonary resuscitation (CPR) could be potential DCD donors (category IIA). If the family consents for organ donation, after a “watch time”/”no touch period” of 5 minutes (during which time death certificate [DC] is also made), circulation is restarted with mechanical support.
- Patients in the ICU who are clinically brain-dead but their certification is not possible because of any technical reason or whose families are keen on organ donation only after circulatory death would also fall in this category after they progress to circulatory death (Category IIB).
- Terminally ill ICU patients who are not brain dead and likely to have cardiac arrest in the hospital, and whose families refuse resuscitation / CPR efforts and wish to proceed organ donation after circulatory death could be potential DCD donors after circulatory death (category IIB).

For **category III** donation, withdrawal of life-support is required. In some countries families of terminally ill patients can opt for withdrawal of life-support to avoid futility of medical care. This practice is not explicitly supported by law in India and therefore we do not currently have the infrastructure, framework and protocols to consider DCD donations from such patients.

Category IV donation is possible from a certified brain-stem dead donor who suffers a cardiac arrest before donation. Generally, in such a situation organ allocation and retrieval that have been planned need to be expedited. Often a clinically brain-dead patient with a positive (confirmatory) 1st apnoea test who has cardiac arrest before the 2nd apnoea test is also classified in this category (Ashish Sharma Refs).

Category V is donation after active or passive euthanasia, which is currently not supported by law in India, except very selected cases.

For DCD donation, death is certified in the standard death certificate in use as per prevalent practice in the hospital.

HOSPITAL REQUIREMENTS FOR DCD DONATION

The hospital wishing to undertake DCD donation should have:

- Intensivists and emergency physicians who understand DCD donation in above categories and are comfortable in maintaining and monitoring patients on cardiopulmonary bypass (CPB) or ECMO after declaration of death.
- Transplant / retrieval surgeons who are trained / comfortable in maintaining and monitoring potential DCD donors on CPB or ECMO and in retrieval and assessing suitability of organs for transplant.
- Perfusionist trained / comfortable with CPB and / or ECMO as is available in the hospital.

The list of equipment / instruments and consumables required for effective DCD donation:

- CPB with relevant cannulae, membrane oxygenator and other accessories
- ECMO with all accessories

Hospitals that fulfil the above manpower and infrastructural requirements could indicate their willingness to perform DCD donation to the Appropriate Authority. Since portable ECMO or

CPB machines are available, the teams once allowed could perform the donation at any registered transplant hospitals and non-transplant organ retrieval centres (NTORCs).

STANDARD OPERATING PROCEDURES (SOP)

STEPS FOR CATEGORY IV OR IIB

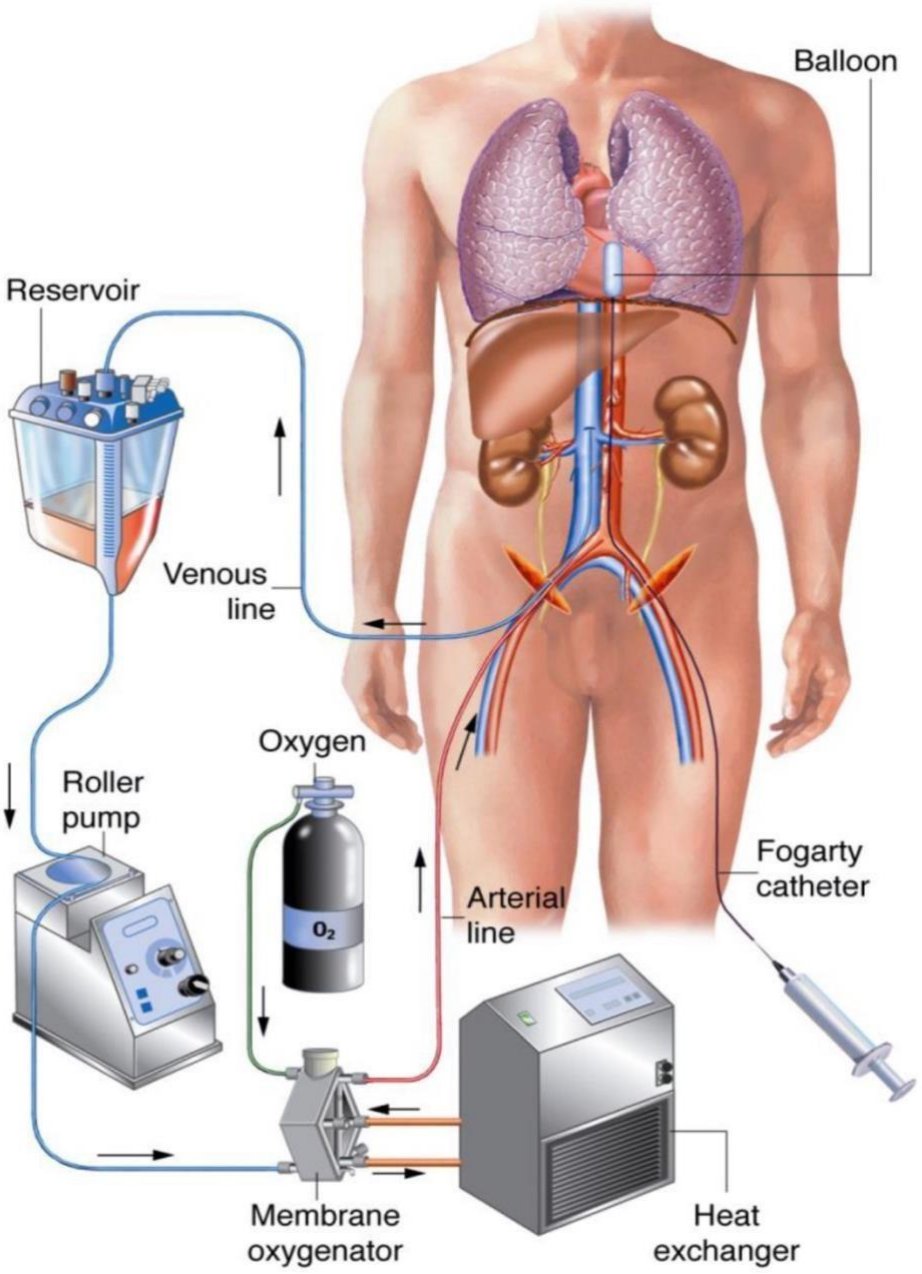
- Family verbally expresses wishes for organ donation / consents to donate organs, a verbal consent is obtained
- ZTCC informed about a potential DCD donor ○ Cross match sent for kidney recipients, provisional alert for Liver and Lung recipients
    - Provisional organ allocation done subject to patients accepting Extended Criteria Donor organs ○ Following arrangements done

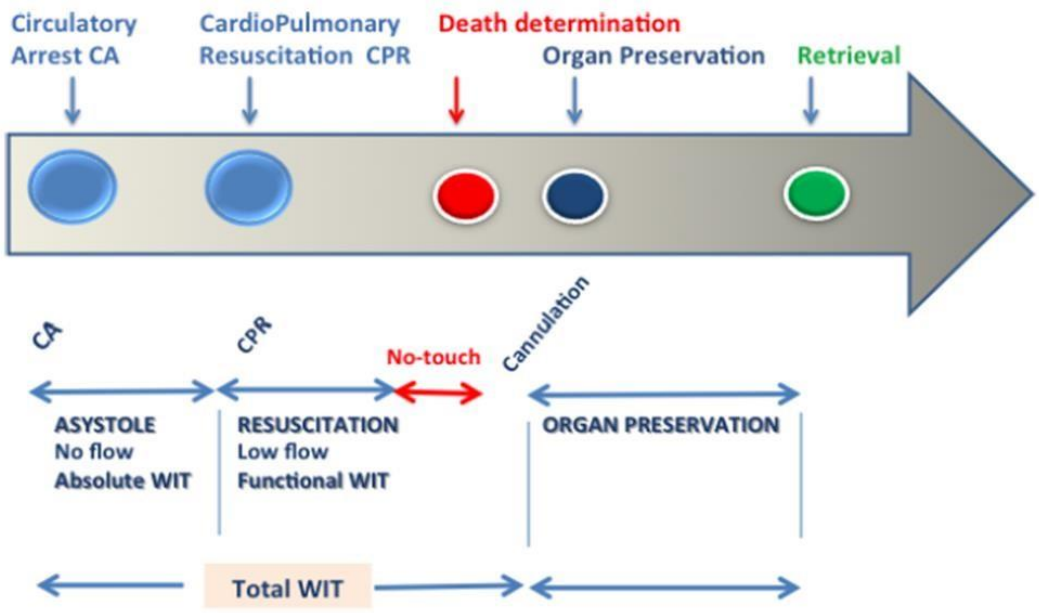
    in anticipation of arrest
        - ✦ Heparin loaded and kept by the bedside
        - ✦ ECMO or cardiopulmonary bypass machine pumps including cannulas kept by the bedside for Normothermic Regional Perfusion (nRP)
        - ✦ Alert retrieval team and perfusionist
        - ✦ Identified recipients
- At the time of cardiac / circulatory arrest ○ CPR as per standard protocol ○ 5 minutes "no-touch" period after unsuccessful CPR ○ Certification of Death
- Post certification of death, organ perfusion measures ○ Heparin to be given ○ Cardiac compression and ventilation till nRP commenced
    - Femoral cannulation done and ECMO, cardiopulmonary bypass pump started for nRP
    - Lactate, transaminitis and urine output monitored every 30 minutes for 1 to 4 hours
    - Shifted to OT for retrieval ○ Important Timings to be recorded

STEPS FOR CATEGORY IIA

- Patient arrives to the hospital Accident & Emergency / Emergency Department / Casualty with cardiac arrest followed by unsuccessful cardiopulmonary resuscitation
- Certification of Death

- Family expresses wishes for organ donation / consents to donate organs (within 10 mins of certification of Death), a written consent is obtained
- Post certification of death and family's written consent, organ perfusion measures ○ Heparin to be given ○ Cardiac compression and ventilation till nRP commenced ○ Femoral cannulation done and ECMO, cardiopulmonary bypass pump started for nRP
    - Lactate, transaminitis and urine output monitored every 30 minutes for 1 to 4 hours
    - Shifted to OT for retrieval ○ Important timings to be recorded
- ZTCC informed about a DCD donor simultaneously post certification of death and family's consent ○ Cross match sent for kidney recipients, alert for Liver and Lung recipients ○ Provisional organ allocation done subject to patients accepting Extended Criteria Donor organs.


Balloon
Reservoir
Venous line
Oxygen
Roller pump
Fogarty catheter
Arterial line
O_2
Membrane oxygenator
Heat exchanger



WIT: Warm Ischaemia Time

	Liver	Kidney
No flow period (Absolute WIT)	≤ 15 minutes	≤ 30 minutes
CPR duration	≥ 30 minutes	
No-touch period	5 minutes	
Total WIT	120 minutes	150 minutes

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GUIDELINES FOR PEDIATRIC DECEASED DONORS

BRAIN DEATH CURRENT CONSENSUS

- Absent cerebral function
- Absent brainstem function
- Apnea

1. Most of the issues that have been decided for the adult donor apply to the child donor
2. Pledging of organs is not valid for anyone under 18 years of age
3. A child can be a deceased donor if the parents or guardian give consent
4. Forms 8 & 10 need to be properly filled. Form 10 needs to be signed by all the members of the "board of medical experts "
5. At present, there is no clear moral framework for donation from children and it seems that there is a wide range of views regarding what constitutes best practice in this area. For an adult donor, decisions regarding organ donation are generally created on behalf of an individual, on the basis of that person's known needs and beliefs. Organ donation made on behalf of children differs owing to these important factors:
    a. Children have differing abilities to form decisions depending on their age or maturity and many are unable to make any decisions at all
    b. Very often there is little or no proof of a child's wishes or beliefs on which to base a call about donation.
    c. The nature of care in pediatric medicine is more family-centered than in adults. This im-plies that working within the limits of the child's interests, pediatricians encourage families to reach a decision about a child's care that is right for the family as a whole and which therefore takes under consideration the interests of a wider group of individuals than only the child who is the patient.

ANCILLARY STUDIES

Ancillary studies are not required to establish brain death and should not be viewed as a substitute for thorough neurological examination. These may be used to assist doctors and family in making the diagnosis of brain death but are not to be included in the brain death certification forms:

1. When apnea testing cannot be completed safely

2. If there is uncertainty regarding the results of the neurological examination
3. If a medications residual impact may be present
4. To reduce the inter-examination observation period
5. For social reasons, allowing members of the family to better comprehend the diagnosis of brain death.

NUMBER OF EXAMINATIONS AND EXAMINERS

Nakagawa TA, Ashwal S, Mathur M, et al. Guidelines for the determination of brain death in in-fants and children: An update of the 1987 task force recommendations. Crit Care Med. 2011;39(9):2139-55.

Endorsed by:

- Society of Critical Care Medicine
- Section on Critical Care, AAP
- Section on Neurology, AAP
- Child Neurology Society
- Many others.

Recommended observation periods between brain death examinations based on age and the results of neurodiagnostic testing:

- Two examinations separated by a minimum of 48 hours are to be performed for infants of 7 days to 2 months.
- Two examinations separated by a minimum of 24 hours are to be performed for children 2 months to 1 year.
- For children 1 year and above, an observation period of 12 hours is needed and ancillary testing is not required when an irreversible cause exists.

The general consensus is that younger the child, the longer the waiting period unless repeated clinical examinations have supported the clinical diagnosis of brain death, then observation period could be shortened. These examinations should be performed by at least two different members of the brain death certifying committee of the hospital who have no interest or connection with the proposed organ donation.

NEWBORNS

1. Brain death can be diagnosed in term newborns (37 weeks gestation) and older, provided the physician is conscious of the limitations of the clinical examination and ancillary studies in this age group.
2. It is vital to carefully and repeatedly examine term newborns with particular attention to examination of brainstem reflexes and apnea testing. Like with older children, assessment of neurological function in the term newborn may be unreliable immediately after an acute catastrophic neurological injury or cardiopulmonary arrest. A period of 24 hours is usually recommended before evaluating the term newborn for brain death.
3. Neonatal studies reviewing PaCO2 thresholds for apnea are limited. However, information from neonates who were ultimately determined to be brain dead revealed a mean PaCO2 of 64 mm Hg suggesting that the threshold of 60 mm Hg is also valid within the newborn.
4. Apnea testing in the term newborn is also complicated by the following:
    a. Treatment with 100% oxygen might inhibit the potential recovery of respiratory effort and profound bradycardia might precede hypercarbia and limit this test in neonates.
    b. A thorough neurological examination should be performed in conjunction with the apnea test to make the determination of death in any patient.
    c. If the apnea test cannot be completed as previously described, the examination and apnea test are often tried at a later time
    d. Ancillary studies in newborns are not sensitive and are not needed to certify brain stem death.

OBSERVATION PERIODS IN TERM NEWBORNS

Based on information extracted from available literature and clinical expertise, the committee recommends the observation period between examinations should be 24 hours for term newborns (37 weeks) to 30 days of age.

The diagnosis should be made clinically and based on repeated examinations.