

Legal & Ethical Issues

1. What is National Human Organs and Tissues Removal & Storage Network?

The Central Government has established a National Human Organs and Tissues Removal & Storage Network named NOTTO, which stands for National Organ and Tissue Transplant Organisation. NOTTO will have five Regional Networks ROTTO (Regional Organ & Tissue Transplant Organization) and each Region of the country will develop SOTTO (State Organ and Tissue Transplant Organisation) in every State/ UT.

Each hospital of the country related to transplant activity, whether as retrieval or transplant, has to link with NOTTO, through ROTTO/SOTTO as a part of National Networking.

2. What is National Registry?

The national registry for organ donation & transplant is as follows:-

I - Organ Transplant Registry:

The Organ Transplant Registry shall include demographic data about the patient waiting for transplant (Organ / hospital wise waiting list), donor (Living Donor including Related Donor, Other than Near Related Donor, Swap Donors and Deceased Donor), hospitals, follow up details of recipient and donor etc., and the data shall be collected from all retrieval and transplant centers.

Data collection may preferably be through a web-based interface or paper submission and the information shall be maintained both specific organ wise and also in a consolidated formats.

The hospital or Institution shall update its website regularly in respect of the total number of the transplantations done in that hospital or institution along with reasonable detail of each transplant and the same data should be accessible for compilation, analysis and further use by authorised persons of respective State Governments and Central Government.

II - Organ Donation Registry:

The Organ Donation Registry shall include demographic information of donor (both living and deceased), hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driving license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.

III - Tissue Registry:

The Tissue Registry shall include demographic information on the tissue donor, site of tissue retrieval or donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain stem dead donor, associated medical illnesses, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient, hospital conducting transplantation, transplant waiting list and priority list for critical patients, if these exist, indication(s) for transplant, outcome of transplanted tissue, etc.

IV - Organ Donor Pledge Registry:

The National Organ Donor Register is a computerized database which records the wishes of people who have pledged for organ and tissue donation. Person during their life can pledge to donate their organ(s) or tissue(s) after their death through Form 7 and submit it in paper or online to the respective networking organization and pledger has the option to withdraw the pledge through intimation.

There are many hospitals and organizations those are also maintaining the list of persons who have pledged organ donation with them, will be passed to National Organ & Tissue Transplant Organisation for National Register.

3. What is legal position on Organ Donation?

Organ Transplantation and Donation is permitted by law, and covered under the "Transplantation of Human Organs Act 1994", which has allowed organ donation by live & Brain-stem Dead donors. In 2011, amendment of the Act also brought in donation of human tissues, there by calling the Amended Act "Transplantation of Human Organs & Tissues Act 2011".

4. What is organ trafficking?

In the present scenario the demand for solid organs is far from reaching the requirements, so the people in desperate need opt for different ways to save their loved one's life.

In many instances, live donations have become commercialized, especially in the Living Unrelated group. This is a controversial issue. Poor and needy people get exploited; they give their organ in exchange for money, not understanding the seriousness of the surgery and post-operative care that has to taken. It is seen that patients from the developed countries usually come to developing countries for a transplant.

5. Can people buy / sell organs?

No. As per Transplant of Human Organ Act (THOA), buying/ selling of organ in any way is punishable and has significant financial as well judicial punishment. Not only in India, but in any part of world, selling of an organ is not permissible.

6. Whom do I report, in case, I find that there is a sale of organs?

In case, anybody submitting false records or any other delinquency should be reported to the Appropriate Authority of the State Government, Department of Health & Family Welfare. Any hospital, Authorization Committee, or a person can approach the State Appropriate Authority. The Appropriate Authority can file a case against the party.

As per the Amended 2011 THO Act offenses/punishments are as follow:

Offence (THO Act 2011 Amendment)	Imprisonment	Fine
Removal of organs without authority	10 years	Rs. 20 Lakh
Removal of organs without authority - Penalty for RMP	1st offence: de- registration for 3 years	2nd offence: permanent de- registration
Commercial dealing in organs, falsification of documents	5 to 10 years	Rs. 20 Lakh to 1 crore
Any violation of THOA	5 years	Rs. 20 Lakh

7. What are the ethical concerns with living unrelated donations?

Doctors are concerned with the possible emotional/ financial exploitation of donors, by recipient families, and from transplant hospitals. They are worried that, with the increasing demand of organs, the rights of the poor donor to live with dignity may be abused.

Transplant hospitals have become more careful with a good system of screening in place, and an Authorization Committee of Hospital/ District/State scrutinizes all the applications. Today, Living Unrelated donations have become more transparent and streamlined.

8. What is "Required Request"?

Required request is a way of getting consent of the person for the cadaver donor transplantation. Any person, who wishes to donate his/her organ and tissue after his death, has to affirmatively make a pledge that his/her organs after death can be used for transplantation and saving life of other person.

At the time of death, Hospital staff approaches family of the deceased person for donating their loved ones organs and tissues to save life of others. This approach is also called as opting in approach.

9. What is "Presumed Consent"?

In the presumed consent approach, every person is supposed to be agreeing for organ donation at the time of death, unless the person has decided during his/her life time that he/she is not willing for organ and tissue donation after death. This system is also called "opting out system. There are countries in the world who have presumed consent approach for organ donation and they believe that presumed consent approach usually increase organ donation rate. However, all do not agree for the same. India does not follow this approach.

10. What is "Informed Consent"?

Informed consent is a process, which is not specific to organ and tissue donation. This is a process of reaching an agreement based on a full understanding of what will take place, in the form of medical treatment. Informed consent involves information sharing as well as the ability to understand and freely make a choice in relation to medical treatment.

11. What is NOTTO Organ Donor Register?

The NOTTO Organ Donor Register is a computerized database which records the wishes of people who have pledged for organ and tissue donation and decided that, after their death, they want to leave a legacy of life for others. There are many hospitals and organizations those are also maintaining the list of persons who have pledged organ donation with them, will be passed to NOTTO website for National Register.

12. Who can join the NOTTO Organ Donor Register?

Everyone irrespective of age or health can join the NOTTO Organ Donor Register. Joining the Register expresses a wish to help others by donating organs or tissues after death but importantly, joining the Register also is a way to give legal consent or authorization for donation to take place.

13. What is the importance of a donor registry?

A registry is an essential part of understanding who and where potential donors are. A registry gives a planner enough information to devise strategies to get more public cooperation and commitment towards organ donation. Having a registry in place allows doctors and transplant coordinators to check if a brain dead person wished to donate and then approaching the family for consent becomes easier. It helps in saving crucial time in the process of organ donation.

14. What are medico-legal cases?

When an accident victim is brought to a hospital for emergency treatment, an FIR has to be filed by the family in the nearest police station. Such cases are usually called medico-legal cases. Also, any medical treatment (for suicide, assault, poisoning or fall) which needs that the police should be notified becomes a medico-legal case.

The police will conduct an inquest about the incident and take charge of the case. A forensic doctor will examine the patient and will allow or deny organ retrieval.

15. Is the police department involved in any way for the declaration of brain-stem death?

The police department has to be informed that a patient is brain dead if it is a medico-legal case, but the declaration of brain-stem death is only done by a panel of doctors.

16. Does Government of India financially support organ transplant?

Yes. Government of India has started National Organ and Transplant Program (NOTP), under which patients below poverty line are supported for the cost of transplant as well as cost of immunosuppressant after transplant for one year. Other than this, renal transplant in all public hospitals is subsidized as per Government of India policy.

17. Is it possible to jump the waiting list if you are rich, well connected and influential?

No. In India, the allocation of organs to recipients on the waiting list is based on predetermined criteria which include date of registration and medical criteria.

The wealth, race, or gender of a person on the waiting list has no effect on when and whether a person will receive a donated organ. The Transplantation of Human Organs Act of 1994 makes it illegal to buy or sell human organs in India.

18. If someone desperately needs an organ, is there any point in making a special appeal?

Any special appeal usually results in more people agreeing to become donors and can increase the number of organs pledging.

However, family appeals through the newspapers and television will not result in an organ immediately becoming available for the person on whose behalf the appeal was made. The patient will still be on the waiting list, just like everyone else, and the rules that govern the matching and allocation of donor organs to recipients still apply.

19. Whether adopted children can be considered as near relative?

Children who have been adopted through laid down legal procedures under the prevailing Adoption Act and Rules thereunder are to be treated as near relatives under the THOTA 1994.

20. If neuro experts are not available then who can certify BSD (Brain Stem Death) in ICU (Intensive Care Unit) in his/her place?

As per THOTA 1994, "Where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist who is not part of the transplant team nominated by the head of the hospital duly empaneled by Appropriate Authority may certify the brain stem death as a member of the said Board"

The intensivist may include the Medical Doctors who have a postgraduate qualification such as in Internal Medicine/Anesthesia/Pulmonary Medicine/Surgery or DM in Critical Care/Pulmonary Critical Care medicine etc.

21. Is it right to remove a healthy organ from a living person and give it to another?

Organ transplantation is undertaken only as a lifesaving treatment. It is best for the transplant team to decide whether to go ahead with a live organ donation, keeping in mind the two issues of doing no harm to the donor, and doing good for the recipient. Only the transplant team can decide whether the benefit to the patient is worth the risk faced by the donor. The transplant team takes into account the mortality and morbidity of the donor, though this can be accurately predicted.