

Legal Framework, Issues and Challenges of Living Organ Donation in India

Reeta Dar (Khashu) * DR. Sunil Kumar Dar**

*Central Health Education Bureau; Directorate General of Health Services, MoHFW, Government of India

**State RMNCH+A Technical Officer, IPE Global Private Limited

Abstract: This paper gives insights into living organ donation practices in India in context of the Transplantation of Human Organs Act (THOA) 1994 and its amended version –Transplantation of Human Organs (THO) amendment Act -2011. The paper classifies “Known Living Donors” into “near relatives” and “other than near relatives” and “Unknown Living Donors” as “altruistic”, “quasi-altruistic” and “non-altruistic” organ donors and discusses their nuances and subtleties. The paper delves into multiple roles of “Competent Authority” and “Authorization Committees” in ensuring that no commercial consideration, pressures and coercion is involved in living organ donation and transplantation. The role of “Appropriate Authority” in issuing licenses to retrieval and transplant hospital is briefly described. This paper deliberates upon some issues like infrastructural and manpower limitations for live organ donations in Government sector; non-availability of comprehensive data on risk assessment for living donors, gender bias, role of the “Authorization Committees”, misuse of modern technology by unscrupulous elements which leads to over-cautious approach by the health system, lack of concern for futuristic health problems of the donors, exorbitant costs of transplant as well as post-transplant and lack of focus on living organ donation. Motivating all Indian States to adopt Transplantation of Human Organs (THO) amendment Act-2011 and Transplantation of Human Organs and Tissue (THOT) Rules 2014 that has extended the list of near relatives and permitted swap transplants, registering more people for running swap and domino chains, preventing private hospitals from ensnaring patients and relatives, and focusing on living donation as well are some of the challenges that are briefly explained in this paper. This paper shows the way ahead in addressing these issues and meeting the challenges. It also describes the important role played by National Organ Transplant Programme (NOTP) and National Organ and Tissue Transplant Organization (NOTTO) in India.

Key Words: Living Organ Donation in India; “Competent Authority”, “Authorization Committee”, “Appropriate Authority”, National Organ Transplant Programme (NOTP), National Organ and Tissue Transplant Organization (NOTTO)

Living organ donors are those donors who donate organs like one kidney, a part of liver, a part of pancreas or a part of lung to an ailing person for his /her therapeutic benefit during life. In India donation of organs from living as well as brain stem dead donors for transplantation into patients for therapeutic purpose was made legal under the Transplantation of Human Organs Act (THOA) in 1994(1). The Act was amended in 2011 that legalized swap transplants among incompatible living donor and recipient pairs under Transplantation of Human Organs (amendment) Act 2011 (2) which was followed by Gazette notification of Transplantation of Human Organs and Tissue (THOT) Rules 2014(3). However, organ donation from live donors is restricted mostly to two organs –one kidney or a part of live only. It is interesting to note that a human being is born with two kidneys and can live with one after donating the other to a needy person. A living donor can donate a part of liver which usually regenerates in donors within 3 months.

The prerequisite for a living donor is that the person should not be suffering from HIV, hepatitis, acute infection, uncontrolled high B.P; diabetes, cancer, psychiatric condition and be above 18 years of age. In India, it is mandatory for living donors to donate organs out of pure love, affiliation and affection. As per the figures available with DGHS for the year 2011, India has seen 5,719 transplants which includes 4795 kidney, 870 liver, 15 heart, 39 lung and pancreas transplants (DGHS;NOTP 2011). These involve donation of organs from both live and brain stem dead donors.

Two types of living donors who can donate organs are:

1. **Known Organ Donors**
 - 1.1. **Near Related Organ Donors**
 - 1.2. **Other Than Near Relatives**

2. Unknown Organ Donors

2.1. Purely Altruistic donors

2.2. Quasi - altruistic donors

2.3. Non-altruistic donors

1. Known Organ Donors – This category of organ donors are always known to the recipient - either through biological or long-existing social relationship. Such donors share a bond of love and affection with the recipient. They share organs to save the life of their loved one. However a lot of documents are required by the “Competent authority”/ “Authorization Committee” to authenticate such relationships as shown below in Table No1. Known organ donors are again of two types:

1.1 Near Related Organ Donor

As per THOT-Rules, 2014, the transplant of organs is permitted between near relatives like spouse, mother, father, brother, sister, son, daughter, grandfather, grandmother and grandchildren after approval by the “Competent Authority”. The “Competent Authority” is the Director or Medical Superintendent or in-charge of a hospital. It ensures that the donor-recipient relationship is genuine and there is no coercion or pressure on the donor.

1.2. Other than Near Relatives:

In India, organ donation by other than near relatives like friends, uncles, aunts, cousins etc. is also permitted but only after approval by the “Authorization Committee” of a hospital, a district or a State. If a hospital performs more than 25 transplant surgeries per year it can have a “Hospital Authorization Committee.” In the year 2011, out of 5719 transplants, 1495 organ donors were other than near relatives (DGHS; NOTP 2011).

Table 1 Showing requirements of various documents and their purpose for facilitating living organ donation and transplantation as per THOT Rules 2014

S.NO	DOCUMENTS REQUIRED	PURPOSE OF THE DOCUMENT
1.	Ration card or Pan card or Aadhaar card or Voter Identity card or Passport	For identity and proof of residence
2.	Birth certificates ,Marriage certificates, Other relationship certificate from Tehsildar or, Sub divisional Magistrate Or Metropolitan Magistrate or Sarpanch	For ensuring existence of relationship among Indians
3.	Relationship certificate to be certified by a senior embassy official as per Form 21(Refer Table. 2)	For ensuring existence of relationship of foreign nationals having embassy in India
4.	Relationship certificate to be certified by Govt. of that country to which the foreigner belongs as per Form 21(Refer Table. 2)	For ensuring existence of relationship of foreign nationals not having embassy in India

The “Authorization Committees” are supposed to meet regularly to scrutinize applications for organ donations. Its work involves ensuring that living donor is doing the deed purely out of love and affection for the recipient. This is done through personal interviews of the donor, recipient and members of their families. Such interviews are recorded on video. The Indian system is very cautious in giving a stamp of approval to the donor-recipient tie-ups due to gross social and economic inequalities, absence of a national health insurance policy and reported organ trade cases.

As per the rules, the “Authorization committees” require various Forms (duly filled in) before evaluating various types of live donations. These are listed below in Table No 2.

Table No 2. Depicting Form Numbers and purpose of these forms for facilitating living organ donation and transplantation as per THOT Rules 2014

S NO	NUMBER	PURPOSE OF THE FORM	TO BE FILLED BY
1.	Form 1	For organ donation from living near related donor	Living related donor
2.	Form 2	For organ donation from living spousal donor	Living spousal donor
3.	Form 3	For organ donation from “other than near relative “ donor	Living known “other than near relative “donor
4.	Form4	For certificate of medical fitness of living donor	Registered medical practitioner
5.	Form5	For certificate of genetic relationship of living donor with recipient	Head of pathology certifying relationship
6.	Form6	For spousal living donation	“Competent authority” in case of Indian nationals and by “Authorization Committee “in case of foreigners after verifying the marriage through documentary evidence.
7.	Form 11	Application for approval of transplantation from living donor	Jointly by proposed recipient and proposed donor
8.	Form 18	Certificate by the “Authorization Committee” of hospital or district or state authorization committee	The “Authorization Committee” where transplantation has to take place (to be issued on letter head)
9.	Form 19	Certificate by “Competent Authority” in case of near relatives other than spousal donation	“Competent Authority”
10.	Form 20	Verification certificate in respect of domicile status of recipient or donor	Tehsildar or other authorized officer required only for donor other than near relative /recipient if they do not belong to the state where transplant hospital identified for operation is located.
11.	Form 21	Certificate of relationship between donor and recipient in case of foreigners	Embassy concerned

2. Unknown Organ Donors – These are the donors who are unknown to the recipient. The two do not share any bond of love. Such donors are again of three types as mentioned below :

2.1. Purely Altruistic Organ Donors

Many people donate organs to strangers in response to their appeals in print or electronic media; others donate to anyone on the waiting list or initiate a domino chain of organ donation (4). The Indian law does not allow such living donors - called altruistic or anonymous organ donors though in advanced nations like USA and UK, such donations are permitted.

2.2 . Quasi - Altruistic Organ Donors

A quasi altruistic donor donates an organ after receiving the same organ either from a living donor or a deceased donor. Such kind of quasi-altruistic organ donors are usually heart or liver domino donors. The quasi altruistic domino heart donor donates his healthy heart to a person in need after getting two lungs along with healthy heart from a deceased donor. The quasi-altruistic domino liver donor donates his liver to another recipient after getting a part of liver either from a living donor or from a deceased donor. In these cases the donor gets a chance to become a recipient and donor simultaneously (5).Domino donor does not have to be 18-yearold. As per my understanding of THOA-1994, this is the only permitted form of live donation as it serves the therapeutic benefit of both the donor as well as the recipient.

Non-altruistic organ donors

In this category the donor is unknown to the recipient. Donors donate organs to strangers in exchange for getting the best matched organ for their own relatives or friends to whom they intend to donate organs (5). This type of transplant is called swap transplant. When organs are swapped between more than two donor-recipient incompatible pairs it is called domino transplant.

It is important to note that no hospital or institution can perform organ retrieval and transplant surgeries without getting a license from ‘‘Appropriate Authority’’ that is constituted by the State Government. The license for removal, storage and transplantation of human organs can only be given to hospitals after verifying their capacity and infrastructure. Besides trained manpower, such hospitals should have facilities like operation theatres, laboratory services, intensive care units and communication system working round the clock.

A few responsibilities of the ‘‘Appropriate Authority’’ are:-

- to inspect and grant registration to the hospitals either for retrieval or for transplant surgery or for both retrieval and transplantation for a period of 5 years only;
- to conduct regular inspection for enforcing the required standards for hospitals;
- to carry out investigation in case of any complaint pertaining to the quality of transplantation and follow-up of medical care of donors and recipients;
- to suspend or cancel the registrations of erring hospitals and
- to renew the license after every five years.

While Transplantation of Human Organs (THO) Rules 1995 comprises of 13 forms (6), Transplantation of Human Organs and Tissue (THOT) Rules 2014 comprises of 21 forms (3). Out of 21 forms 2 forms can be used for applying for licenses by organ retrieval and/or transplant hospitals and 2 forms are used by the ‘‘Appropriate Authority’’ for issuing and renewing certificates/licenses as shown below in Table No.3.

TABLE NO.3:- Showing number and purpose of various forms for obtaining license by organ transplantation /retrieval hospitals from the ‘‘Appropriate Authority’’ in accordance with Transplantation of Human Organs and Tissue (THOT) Rules 2014

S.NO	FORM NUMBER	PURPOSE OF THE FORM
1.	Form 12	Application for registration of hospital to carry out organ or tissue transplantation other than cornea
2.	Form 13	Application for registration of hospital to carry out organ or tissue retrieval other than cornea retrieval
3.	Form 16	Certificate of registration for performing organ /tissue transplantation and/or tissue banking
4.	Form 17	Certificate of renewal of registration

ISSUES AND CHALLENGES TO LIVING ORGAN DONATION

Some of the important issues and challenges of living organ donation in India are:

1. INFRASTRUCTURAL AND MANPOWER ISSUES IN GOVT. SECTOR

There is a lack of infrastructure as well as manpower for transplant surgeries in Govt. hospitals. India has approximately 250 transplant centers and most of these are in private institutions. Accordingly, about 90% of transplant surgeries are carried out in private hospitals. There is scarcity of transplant surgeons too. This leads to a long waiting list of transplant surgeries especially in Govt. hospitals. A man who had received funds from Prime Minister’s Office for kidney transplant surgery died waiting for his turn for surgery (7).

2. NON AVAILABILITY OF COMPREHENSIVE DATA TO ASSESS RISKS

It has been found that social norms are ingrained in most of these living donations. As a result living donor mostly decides to donate instantaneously due to moral obligation towards family, friends or society. He does not weigh the pros and cons of such decisions on his life and health. There are instances of people donating organs to make penance for their past guilt. Presently, there is no mechanism in place to follow up the donors. There is no comprehensive data on post donation outcomes of such donors which makes it impossible for donors to accurately assess the risks (8).

3. GENDER ISSUES

It is a fact that the organ donation regime has put the burden of donating organs on female living donors across the world. Even in advanced countries like USA and UK, this trend is prevalent. According to

data on organ donation and transplantation presented by United Network of Organ Sharing (UNOS) in USA (9) and National Health Service Blood and Transplant (NHSBT) in UK (10) female living donors have outnumbered male living donors every year. Women live organ donors constitute about 95% in Pakistan and 80% in India (11). A veteran psychiatrist involved in evaluating mental status of donors in a reputed Indian hospital revealed that the mother and sister donors usually donate because of unconditional love for the recipient. There is a direct or subtle domestic pressure on these women to save the recipient and they, sometime, also fear disapproval by either the parental or in-laws family or society in case they do not agree to be the donor. Organ donation demands may have created new domestic battlefields which need to be exposed.

4. ISSUES WITH “AUTHORIZATION COMMITTEES”

There are number of issues with “Authorization Committees” that has resulted in delayed permissions. A few of these are:

- **DELAYS IN SCRUTINIZING APPLICATIONS**

The “Authorization committees” are not meeting regularly to assess the donor-recipient motives which lead to delays in approvals and transplantation surgeries. This causes anguish for the desperate recipient and his family. At times people have preferred to go abroad to overcome such hassles. A domino chain of organ donation could not take place as a result of delayed scrutiny by one such authorization committee (12). The inherent problem with such committees is their basic constitution. Such committees comprise of very senior people like Director of Health Services or Secretary, Health Services. As these officers have a lot of routine works and responsibilities they may not be able to find time for holding meetings to evaluate donor-recipient applications. In some cases delays happen because authorization committees comprise of members who cannot understand the medical urgencies like swap transplant for tissue unmatched pairs. According to a senior transplant coordinator with a reputed Indian hospital, many a time such members tend to seek a lot of explanations, which causes delay and wasting the precious time for saving a life.

- **ABUSE OF ORGAN DONATION LAWS AND AN OVERCAUTIOUS HEALTH SYSTEM**

The organ trade rackets are unearthed each year. This has made the health system very cautious even in genuine cases (13). Some people also misuse technology to photo shop photographs, produce fake documents and marriage certificates to hoodwink the authorities. Sometime, a fake identity of paid living donors is created. Such a ‘proxy’ is well trained and can pass off as kin or close relative of the organ recipient.

The two cases of live donation by two donor recipient pairs of one particular country was received for reconsideration in “Appellate Authority” after getting rejected by “Authorization committees”. It was surprising to know that they had come prepared with identical stories like the living donors are the brothers-in-law to the recipients and have married the recipients’ sisters and sisters of both the recipients cannot donate as they are pregnant.

At times it becomes difficult for “Authorization Committees” to understand the true motives of highly motivated living donors. To get a respectable place in her matrimonial house, apprehension of rejection by family or society, promises of foreign trip and job abroad, job in family business are some of the underlying motives of such donors, as reported by a key person in DGHS.

The “Authorization Committees” sometime face ethical dilemma as they have to choose between following a strict legal course and tweaking rules a wee bit to save a life. In case they adhere to stringent legal formalities, they face the risk of being called irresponsible having caused death to people who needed organ transplant (12). If they focus on saving lives and relaxing norms a bit they are blamed for not following the rules.

The overcautious health system, at times, leads to unnecessary delays in transplants by seeking approval from “Authorization Committees” even in case of near relatives – something that is not required. Instead of seeking approval from “Competent Authority” which is less time consuming and much easier, near related donors and recipients are referred to “Authorization Committees” which are already overtaxed. In response to such grievances the Ministry of Health and Family Welfare had issued a circular asking the States not to follow such unnecessary procedures (14).

5. LACK OF CONCERNS ABOUT UNFORESEEN MEDICAL PROBLEMS OF THE DONOR

Unforeseen medical problems of the living donor after donation are nobody’s concern. We safeguard money of the rich people and the donor’s health is nobody’s concern. Is money important than an organ? The decision in being a living donor involves risk of a major surgical procedure, complete recovery and disability. It could also have long term financial implications for his life and family. The risks can be compounded in absence of life insurance and medical insurance coverage. What if a donor does not recover completely; is not able to be productive after surgery? Who will take care of these risks associated with such surgical procedure? Data from

individual transplant centers in USA reveals that out of 10 living donors' one is expected to develop complication over a period of two years. There are cases of living donors losing life after the surgery. At least 177 kidney donors (since 1993) have found themselves in need of a kidney donor (15).

6. UNREGULATED COSTS OF TRANSPLANT SURGERIES

The cost of transplant surgeries is definitely not within the reach of poor people. This is not even regulated except for the CGHS beneficiaries. The cost of liver transplant surgery for a CGHS beneficiary in private empanelled hospitals is 14 lacks in case of donation from a live donor and 11 lacks in case of a deceased donor (16). Interestingly, the cost of the same transplant surgery for a non-CGHS recipient in the same hospital is 24-30 lakhs (17).

7. POST- TRANSPLANT AFFORDABILITY

Not only the transplant surgeries but also the post- operative care of the transplanted organ can only be afforded by the rich. According to a senior transplant surgeon, the lifelong need for immunosuppressant's at the rate of Rupees 19,000 to 20,000 per month to prevent rejection of transplanted organ, is not within the reach of common man in India.

8. ENTIRE FOCUS ON DECEASED DONATION

The main focus of National Organ Transplant Programme (NOTP) today is the deceased donation. In India, however organs from deceased (Brain Stem Dead) donors are not that common owing to plethora of debates and dilemmas from medical perspectives (18) as well as people's perspectives (19).

The challenges to donation of organs from brain stem dead donors are different (20) in comparison to challenges from live donors. A number of challenges with living organ donation in India are:

1. CHALLENGE TO MEET THE REQUIREMENT FOR ORGAN TRANSPLANTATION

There is a huge demand of organs in India. The demand for organ donation cannot be solved by focusing only on deceased donation in India but on living donation too. India has 41 million people with diabetes (21). Also one-third of urban adult and close to one fourth of rural adult Indians are hypertensive (22). With these two diseases the organ failures are going to increase in India. The focus on living organ donation along with deceased organ donation is therefore the need of the hour. In countries where deceased donation rates are high the living organ donation and transplantation are also going on simultaneously. Spain, a country with highest deceased organ donors had 35.1 pmp (per million population) deceased donors and 8.6 living organ donors pmp in 2013. Similarly USA that had 25.9 deceased donors pmp, the living organ donors were 18.8 pmp during the same year (23).

2. CHALLENGE TO PERSUADE ALL STATES TO ADOPT THOA- 2011 AND THOT -RULES 2014

Health is a state subject and as such none of the States except Manipur, Rajasthan and Maharashtra have adopted THOA-2011 that has legalized swap transplants. THOA- 1994 has been adopted by all states except J and K and Andhra Pradesh. The states adopted this legislation over a period of many years (13). The THOA amendment 2011 also faces such challenges and benefit of extended list of donors and swap transplant may not reach all the people across the country till all the states adopt this legislation. Persuading states to adopt amended act and rules remains a major challenge.

3. CHALLENGE TO REGISTER MORE PEOPLE FOR RUNNING SWAP AND DOMINO CHAINS

Swapping donor organs for getting most compatible organ for the intended recipient is a very optimistic procedure for a number of donor recipient incompatible pairs (blood group mismatch or tissue type mismatch or both blood group and tissue type mismatch). It is a well-known fact that more the incompatible donor and recipient pairs register more the people match. At present we have Bombay based Apex Swap Transplant Registry (ASTR) which was initiated with the sole purpose of overcoming the problem of donor recipient incompatibility among a number of donors and recipients. It has been playing a key role in swap and domino transplantation (5). National Organ Transplant Programme has a long way to go first by establishing Regional Organ and Tissue Transplant Organizations (ROTTO) and State Organ and Tissue Transplant Organization (SOTTO). Creating several paired donation transplant registries all over the country at ROTTO and SOTTO and integrating the efforts of all these registries at National Organ and Tissue Transplant Organization (NOTTO) is a great challenging task as consensus and very active participation of all the states is required.

4. CHALLENGE TO PREVENT ENSNARING, EXPLOITATION OF PATIENTS AND RELATIVES

The living donors and relatives who have to bear the cost of such surgeries are given selective information regarding the costs and risks involved in such surgeries. They are trapped and are made to pay through their nose. An amount of 45 lacks from a living liver donor and recipient both of whom lost their lives before leaving the hospital speaks volumes about unethical practices of many such hospitals (24). Our health system is obsessed with financial transactions and ensures that there is no benefit to the donor involved. We safeguard money of rich people and do not focus on instruction given to the donors. The living donors are not given all pertinent information regarding the operation as was reported by some key health professionals.

The Road Ahead

- In the present circumstances, improving government infrastructure for such surgeries is not that feasible, since the system is already bogged down in other areas for public health. NOTTO has been entrusted with the responsibility of cobbling data from all over the country through ROTTO and SOTTO to create a comprehensive data base on living donors available in due course of time. This also involves total cooperation from the States.
- A Donor follow up register should be maintained at NOTTO, ROTTO and SOTTO for the benefit of living donors. This will give a comprehensive data, which, in turn, should be made available to the prospective donors for weighing the risks involved and taking an informed decision.
- Delay in approvals by “Authorization Committees” can be prevented by making it mandatory for them to scrutinize *such* applications within 2 weeks’ time.
- To show concern for living donors let us adopt the practices followed in Israel and Singapore where living donor’s health is insured. We need to be concerned about the unforeseen medical problems of the donor post-donation. We need to think about making it mandatory for the recipient family to pay money towards risk coverage to the donor on the lines of risk coverage allowance for health professionals.
- Unregulated costs of transplant surgeries need to be regularized the way it is done for CGHS beneficiaries by the Govt.
- Gender issues have to be dealt with utmost sensitively on account of patriarchal society at large. Govt. needs to be sensitive to women who usually end up being donors and do not get donors in case they require organs. Women need to be given priority in waiting list for deceased donation.
- Health as a state subject is posing challenges as THO amendment Act-2011 and THOT Rules 2014 have not been adopted by all states. The impact of THO amendment Act -2011 can only be witnessed once all the states adopt this amendment. Persistent and tireless efforts of officials at National Organ Transplant Programme (NOTP) along with National Organ and Tissue Transplant Organization (NOTTO) to persuade all the States through letters, hold national level conferences, workshops etc. are going on to meet such challenges. Once this is achieved more and more people could be registered for swap transplants by Regional Organ and Tissue Transplant Organization (ROTTO) and State Organ and Tissue Transplant Organization (SOTTO) that are in the process of getting established in the country.
- For checking the exploitation of hapless patients waiting for transplants and their relatives it should be mandatory for all the transplant hospitals to provide the list of patients having undergone these surgeries along with total payments made to the hospital by them. It should be made mandatory for all hospitals to disclose survival rates of these transplant surgeries on their websites. Let there be competition among hospitals and let families choose the best hospital for a transplant surgery.
- The govt. should think of providing lifelong coverage for post- transplant medical costs of patients to do justice to the less affluent people.

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