

**“NATIONAL ORGAN AND TISSUE DONOR REGISTER: AN  
INITIATIVE OF NATIONAL ORGAN AND TISSUE  
TRANSPLANTATION ORGANIZATION (NOTTO)”**

**BY**

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**ABSTRACT**

This paper describes the importance of National Organ and Tissue Donor Register for increasing organ and tissue donation in the country akin to developed countries like USA and UK .It is yet to be initiated at national level in India. It highlights the increased potential of organ and tissue donation in India owing to the increased number of fatal road traffic accidents half of whom end up with brain stem death. Many of these brain stem dead patients could be potential donors for organs as well as tissues to patients in need, provided their wishes are registered in organ and tissue donor register. This paper explains the legal framework pertaining to the expressed will of the donor in India, the various opt-in mechanisms like pledging to donate organs and tissues as well as introduction of mandatory choice in driving licenses. Moreover, this paper mentions the various challenges India faces like integration of data from different networks or organizations of the country in one common electronic register; initiating waiting list registry and follow up registry of recipients; strong IEC campaigning; building and sustaining trust of people; besides taking policy level decisions whether to encourage reciprocity or allow free ridership. This paper also suggests creating opt-out mechanisms in the national organ and tissue donor register.

**KEY WORDS:** National Organ and Tissue Donor Register, legal framework, opt- in mechanism; expressed wish; pledge form; IEC

**INTRODUCTION TO NATIONAL ORGAN AND TISSUE DONOR REGISTER**

Demand for organs and tissues far exceeds the supply globally and India is no exception to that. India needs more than 2,60,000 organs every year. About 1,80,000 kidneys ; 30,000 livers and 50,000 hearts are required annually whereas approximately 6000 kidneys ,1200 livers and 15 hearts are transplanted every year (DGHS; NOTP ,2011). This supply of organs primarily comes either from the living related or living unrelated individuals and a very few from brain stem dead donors. To bridge the gap between the demand and supply of organs and tissues, India launched a new national programme in 2008-09 called National Organ Transplant Programme (NOTP). However to reduce the gap between the demand and supply of organs from brain stem dead

donors, the first and foremost initiative that India needs to take is the initiation of National Organ and Tissue Donor Register .

National Organ and Tissue Donor Register is an electronic register that registers choices of its countrymen regarding their will to donate organs and/or tissues if they're brain stem dead or dead respectively. Created with an intention to reduce refusal rates, the register allows access to the registered will of the person regarding donation of his organs and tissues to all the registered organ and tissue retrieval hospitals in the country. It thereby facilitates organ and tissue donation and transplantation as per the registered will but within the legal framework of the latest organ and tissue donation act and rules of the country.

People all over the globe pledge to donate organs / tissues in organ donor registers. The number of people registered on the Organ Donor Register is 20 million in UK(NHSBT 2014)<sup>i</sup>.as per the statistics of 2012-13 and 100 million in USA (UNOS 2011)<sup>ii</sup>.Many a times in my day to day interaction some questions are being asked by people as well as professionals such as: Why organ donor registry? Does it have a legal binding? If not, then what is its use? Every such question asked is justified in context of organ donation and transplantation. We need to understand that demand for organs comes from people suffering from end stage organ diseases of kidney, liver, lungs, heart, pancreas etc. Their lives in certain cases could be prolonged provided they get the required organ for transplantation either from living donors (kidney or a part of liver only) or from brain stem dead donors (heart, lungs, liver, pancreas, kidneys, intestines).There is a great demand for tissues too like corneas of eyes , bones, heart valves and skin etc. The supply of organs could come from people who are simultaneously dying from road traffic accidents, strokes etc. in ICU'S and are declared brain stem dead. The altruistic acts of donation in most of these cases could take place if they would have registered their willingness to donate organs and tissues in the National Organ and Tissue Donor Register. Any dead person can donate tissues within a specified time after death but brain stem dead donor can donate both tissues as well lifesaving organs. In India alone the number of road traffic accidents according to World Health Organization is the second major cause of death in the world. There were 1,30,000 road accidents (Krishnan Murali 2010)<sup>iii</sup> and half of such victims end up with brain stem deaths who could help people in prolonging lives provided their wishes to donate organs and tissues were registered and accessible to the retrieval hospital as is possible if a National Organ and Tissue Donor Register is in place.

## **LEGAL FRAMEWORK PERTAINING TO EXPRESSED WILL OF ORGAN AND TISSUE DONORS IN INDIA**

The organ donation has been made legal in 1994, through the Transplantation of Human Organs Act (THOA-1994)<sup>iv</sup> for regulation of removal, storage and transplantation of human organs for therapeutic purposes and prevention of commercial dealings in human organs. Even after two decades since THOA 1994 was passed, we have not achieved much and we are still nascent in this field in the absence of National Organ and Tissue Donor Register which is considered abig hurdle to organ donation and transplantation.(TOI 2013)<sup>v</sup> Tissue donation and transplantation was legalized while amending the act in 2011(THOA- 2011)<sup>vi</sup>.

Unfortunately we still lack database to connect donors and recipients all over the country. However National Organ and Tissue Transplant Organization (NOTTO) at Safdar Jang Hospital in New Delhi has been entrusted with the formation of an online national organ and tissue donor register. The theme of 4th Indian Organ Donation Day in 2013-14 was NOTTO initiative; donor register is one of the important NOTTO initiatives that the country is looking forward to.

Akin to many countries, the Indian system of organ donation is based on an opt-in mechanism. People opt-in during their lifetime to be an organ donor. In India there are two ways to make a will of organ and tissue donation during life through the opt-in mechanism -

### **1. OPT - IN THROUGH PLEDGING ORGANS AND TISSUES INSTATE, REGIONAL OR NATIONAL NETWORKS**

There is a form 7 in THOA Rules 2014 (**THOA 2014**)<sup>vii</sup> for pledging organs as well as tissues which can be done either online or off line. Pledging organs or tissues gives a direction to the family when encountered with a situation where they are supposed to decide on organ and tissue donation of their loved ones at the time of brain stem death/death. In studies involving donor and non donor families who granted permission or refused permission respectively, the will of the donor played an important role. Wherever people had made a will or registered their will in the National Organ and Tissue Donor Register in their respective countries, their families felt it their moral responsibility to respect the will of the people in majority of the cases. Most of the families who refused such donation did not know the wish of the person in various studies (**Martinez Lopez et al 2008**<sup>viii</sup> **Tymstra et al 1992**<sup>ix</sup>; **Pearson et al 1995**<sup>xxi</sup>).

As per THOA 2014 rules, only authorized medical staff of organ or tissue retrieval and transplant centers having been authorized by the State or the Central Government will have access to information recorded on the National Organ and Tissue Donor Register. The National Organ and Tissue Donor Register will have authorized medical staff who will have permission from the Government to check the donation decision of the person anywhere in India for 24 hours a day and for 7 days a week. The information of the registered will of the person shall help the organ transplant coordinators in each of the registered retrieval centers to further counsel the family. It is the family who ultimately has to decide either in favor or against such donation if the potential donor has consented to donate.

### **2.OPT-IN THROUGHDRIVING LICENCE**

People are supposed to make a choice in their driving licenses in a few cities like Bangalore, Mumbai and Pune whether they want to donate their organs/tissues; a practice that is followed widely in developed countries to opt-in for organ and tissue donation. Such initiative having given fruitful results in these cities has encouraged the Central Government to propose mandatory choice for drivers for organ and tissue donation while applying for driving licenses. The Road Transport and Highway Ministry is formulating a norm making it mandatory to incorporate option to pledge body organs and/or tissues in the application form for obtaining a

driving license. In Bangalore only 200 pledges were registered in the city in five years prior to the programme but till June 2013 there have been 17000 pledges (**Dash Deepak Kumar 2013**)<sup>xii</sup>.

As per THOA Rules 2014 dual donor centric opt-in system is in place which means that for organ and tissue donation to take place, the expressed will of the potential donor as well as the decision in favor of donation by the family is a must for organ donation to take place. Various options that have been created as a result of such legal bindings have equal chances of resulting in favor or against such donation as shown in table 1 below:

**TABLE 1: SHOWING THE OUTCOME OF VARIOUS REGISTERED OPTIONS AT THE TIME OF DEATH**

<b>S.NO</b>	<b>EXPRESSED WILL OF THE POTENTIAL DONOR</b>	<b>WISH OF THE FAMILY AT THE TIME OF DEATH</b>	<b>CAN ORGAN AND TISSUE DONATION PROCEED?</b>
1.	Has opted-in through Pledge Form or in Driving License	Willing to donate	Yes, organ and tissue donation can proceed as per the expressed will of donor.
2.	Has neither opted-in through Pledge Form nor in Driving License and has not given in writing anywhere during his life; his will against donation.	Willing to donate	Yes organ and tissue donation can proceed as per the will of family.
3.	Has opted-in through Pledge Form or Driving License	Not willing to donate	No, organ and tissue donation cannot proceed.
4.	Has opted-out in Driving License.	Willing to donate	No, organ and tissue donation cannot proceed.

### **OBJECTIVES OF NATIONAL ORGAN AND TISSUE DONOR REGISTER**

The main objective being reducing the refusal rate of organ donation from deceased donors the National Organ and Tissue Donor Register will allow:

- people to pledge their organs and/or tissues during their lifetime;
- all willing donors of a country to register in one common electronic register;
- access to all authorized organ and tissue retrieval hospitals of the country to organ and tissue donation will of the person at the time of brain stem death/death,
- organ transplant coordinators to counsel the families to donate organs or tissues as per the expressed will of the dead person,

- family to facilitate carrying out the will of the dead relative. In UK in 2010-11 the potential donor audit (NHSBT 2011)<sup>xiii</sup> revealed that where an individual's wish was known to his/her relatives, the refusal rate dropped to 6 percent whereas the refusal rate was 61 percent where the individual's wish was not known under their opt-in system as exists in India,
- retrieval hospitals to retrieve organs and tissues as per the will of donor;
- transplant hospitals to transplant organs and tissues and
- Nation to boast of its achievements in terms of total number of registered donors.

### **CHALLENGES TO NATIONAL ORGAN AND TISSUE TRANSPLANT ORGANIZATION IN CONTEXT OF NATIONAL ORGAN AND TISSUE DONOR REGISTER**

There are a number of challenges to National Organ and Tissue Transplant Organization for initiating National Organ and Tissue Donor Register as discussed below-

### **INTEGRATION OF DATA FROM DIFFERENT ORGANIZATIONS AND NETWORKS WITH NATIONAL ORGAN AND TISSUE DONOR REGISTRY**

Almost all nations are maintaining a database for example, USA has a national database maintained by United Network of Organ Sharing (UNOS)<sup>xiv</sup> and UK maintains a database through National Health Services Blood and Transplant (NHSBT)<sup>xv</sup>. In India in absence of National Organ and Tissue Donor Register, many private organizations and NGO'S are getting people registered in their own set up. At present we have people who have pledged their organs with different organizations for example, more than 60,000 people registered with Times of India during their one week campaign that ended on 6th August 2013 (TOI 2013), 50,000 people are registered with MOHAN foundation as was reported by Sunil Shroff on the 4th Indian Organ Donation Day at Safdar Jang hospital on 28th March, 2014 during a scientific session on organ donation and transplantation.

If a person dies in Tamil Nadu in the absence of a donor card, the person will not be identified as a potential donor if he has pledged his organs with an organization outside Tamil Nadu like Ganga Ram Hospital, Armed Forces Organ Retrieval and Transplant Authority (AORTA), Deceased Organ Retrieval and Sharing Organization (DORSO) etc. Such a situation can be avoided if National Organ and Tissue Donor Register is in place and registered retrieval centers of all the state and union territories have access to the registered will of the person.

Integration of data of all states and union territories in India is a great challenge given to understand that health is a state subject and multiple actors have evolved their own formats of registering the donation will of the people.

### **WAITING LIST REGISTRY AND RECIPIENT OUTCOME REGISTRY ARE EQUALLY IMPORTANT**

NOTTO does not require donor register only, the most important register at this time is the waiting list registry of recipients. Organ transplant coordinators of Delhi and NCR expressed the dire need of this

register during a workshop organized by Central Health Education Bureau in 2014. According to them in absence of a common waiting list of recipients it becomes very difficult to get the timely transplants done as they simply make phone calls from one hospital to another to find the recipients after obtaining family consent for organ donation from brain stem dead donor. Lot of their time is spent in these activities and at times organs too are lost in this process. It discourages their hectic efforts of persuading and motivating donor family when in the end they realize that recipient is not available. Besides this a recipient outcome registry too is required to track short and long-term results of transplant surgery for each organ to give feedback to the programme.

### **STRONG IEC CAMPAIGNING ON ORGAN AND TISSUE DONOR REGISTER**

Since family consent is a prerequisite to organ/tissue donation and transplantation, every individual should discuss death, brain stem death and organ donation with his/her family. It is very important for all the members of a family to discuss this topic and let the wish of all the individuals be known to family members. It is interesting to know that a Health Tambola on organ donation and transplantation was introduced by the CHEB and prepared by the author to create awareness in India International Trade Fair- 2013 and was used by NOTTO in 2014. Prepared with appealing captions, stories, concepts and slogans on organ donation and transplantation, it was based on the literature review of the PhD synopsis of the author, approved by the Committee of Advanced Study and Research in their 369<sup>th</sup> meeting at Jawaharlal Nehru University, Centre of Social Medicine and Community Health vide, order no SSS/2007-O8 dated 25<sup>th</sup> Jan 2012. This health awareness programme revealed certain facts about discussing organ donation with family members. Families do not want to discuss death and are superstitious when it comes to discussing death as was revealed by most of the people. According to them talking about death and donation is considered to be a bad omen. Some people especially the youth found that the word 'death' was bothersome to their family members no matter whether they talk about it in the morning, evening or at night. According to them if they discuss death in the morning, the family tends to be apprehensive of misfortune during the day and if they talk about death in the evening or at night, the family feels that something may happen to the individual during their sleep.

There is a need to address this issue with intensive IEC activities focusing on this area through print as well as electronic media. In UK or USA a lot of efforts have gone into promoting the Organ Donor Register with high profile campaigns involving celebrities and emphasizing the difference organ donation makes in the lives of recipients. About 18.5 million people had registered in the Organ Donor Register in UK by January 2012 (NHSBT 2012)<sup>xvi</sup> compared to 8.3 million in 2000 because of many awareness programmes. The aim of such campaigns is not only to sign the Organ Donor Register but encourage people to think and talk about their wishes regarding organ donation.

### **DECIDING WHETHER TO ENCOURAGE RECIPROCITY OR ALLOW FREE RIDERS**

Most people do not want to donate their organs after brain stem death/brain death but when it comes to receiving organs, they do not hesitate to get the same. Surveys by NHSBT in 2009 revealed that 96% people would like to accept an organ if they needed one but only 27% had

signed the donor cards. To discourage free riders in Israel, consent given by a person during his life to donate an organ following his death, accords both the person and his first degree relatives' priority in organ allocation. Further an organ donated by a person following his death accords his first degree relatives priority in organ allocation in Israel(Jacob Lavee et al 2009)<sup>xvii</sup> as well as in Japan(K Aita 2011)<sup>xviii</sup> a condition which was desired to be added by people in many awareness programmes organized by Central Health Education Bureau. Deciding to allow free riders or encourage reciprocity is a challenge to National Organ Transplant Programme.

## **BUIDING AND SUSTAINING TRUST OF PEOPLE**

In view of new definition of death in the form of brain stem death, it is ethically important to inform people in simple language what is meant by brain stem death as well as organ and tissue donation. If the option to be an organ donor is going to be given in driving licenses, someone should be there to honestly inform people as to what is meant by brain stem death. And if one decides to donate their organs, they need to inform their loved ones immediately and educate them on what will happen(Manning Alison 2013)<sup>xix</sup>.It is also very important to give three choices for organ donation in driving licenses i.e., 'Yes', 'No' and 'Let My Family Decide' to eliminate forced decision which could prove against organ donation as people in many awareness programmes organized by CHEB were indecisive while pledging to donate organs by saying that they would like to discuss it with their families.

## **CREATING AN OPT- OUT MECHANISM IN DONOR REGISTER**

As per THOA Rules -2014 the people who will have the opportunity to express their will in driving licenses can decide against such donation whereas non drivers will have no such choices to make even if they are against donation. It is unlikely that such communication will be given in writing to the family members as is required in THOA rules 2014 in case a person does not want to donate organs and tissues after death. Creating an opt-out option in National Organ and Tissue Transplant Register will serve the purpose of opting out of donations and shall be helpful in case India goes for opt-out system of organ and tissue donation in future as is repeatedly being discussed in Indian organ donation day awareness programme.

## **CONCLUSION**

Having legalized organ donation in 1994, India has a long way to go in overcoming challenges to organ donation and transplantation. Although National Organ Transplant Programme has been started in 2008, a lot of things need to be done to convery the efforts of all the government and non-government organizations for organ donation and transplantation. One big challenge is to connect all the organizations through National Organ and Tissue Transplant Register. Other challenges include the initiation of strong IEC campaigns, building and sustaining trust of people, initiating waiting list registry and follow up registry of recipients, taking policy level

decisions whether to encourage reciprocity or allow free ridership and create an opt-out mechanism for people who don't want to donate tissues and organs.

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