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**ORGAN TRANSPLANTATION: TOWARDS ACHIEVING HUMAN HEALTH**

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**Abstract**

With the advent of medical technology of transplantation in 1950s and the increasing incidences of vital organ failure the demand for donor organs increased and the consequent huge gap between the supply and demand of the transplantable organ resulted in an uncontrollable market of sale of organs globally. The countries with poor population were specially affected as the poor were easily enticed to part away with one of their paired organs e.g. a kidney or a lobe of their liver to save a rich patient for monetary consideration. India was one of those countries where medical tourism for transplantations developed to such an extent that India came to be known as 'ware house' for organs.

Before 1994 in India there was no legislation regulating transplants. Some countries had already passed legislation for streamlining the process of transplantation. In India live donations were the only source of donor organs for transplants. The concept of brain death had not been recognised in India till then. And this was the reason for organ rackets flourishing and establishing its roots in the country. Unregulated transplants were being done in the country and the consequences were alarming and undesirable. Thus a dire need was felt to establish a system of cadaver organ transplant in India. In absence of any legislation on transplantation, establishing cadaver organ programme was a remote and unthinkable possibility in India. To secure the health of the people, seeking to streamline the ongoing process of unregulated organ transplantation and to curb instances of illegal dealings the law was enacted and rules were framed thereunder in 1994.

**History**

*The Transplant of Human Organs and Tissues Act 1994<sup>i</sup> (THOTA) was enacted in the midst of controversies pertaining to ethical issues regarding transplants. The Act was enforced initially in only three States in India i.e. Goa, Himachal Pradesh and Maharashtra. The Act had the philanthropic vision of helping thousands of patients dying each day due to organ failure and to give them a chance to live relatively longer and healthy life again, through surgical technique of transplant. The Act contained provisions for facilitating transplants and also to curb the commodification of human organs. For retrieval of organs for transplantation the brain death concept was incorporated in the Act. In the years to follow of its enactment several changes were made to promote and streamline the process of transplants.*

At the time of enacting the Act certain ethical principles were evolved to ensure that transplantation would be within the bounds of ethics. Cadaver donation was thought to be the feasible source of donor organs. This belief originated with the support emanating from the deliberations of WHO. The Committee on Morals and Ethics of the Transplantation Society in 1972 said, 'we strongly believe that it is morally desirable to use suitable cadaver organs and tissues that could save life and restore health. We encourage the passage of legislation facilitating cadaver programme for transplantation.'<sup>ii</sup> The World Health Assembly first expressed its concern regarding trafficking in organs and the need for global standards for transplantation in Resolution WHA40.13 adopted by the 40th World Health Assembly in May 1987<sup>iii</sup>. The assembly requested the Director-General "to study, in collaboration with other

organizations concerned, the possibility of developing appropriate guiding principles for human organ transplants". The response to this request was initiated in June 1989 following the adoption by the Forty-second World Health Assembly, in May 1989, of resolution WHA42.5 (Preventing the purchase and sale of human organs). The Principle 5 of the Draft Guiding Principles on Human Organ Transplantation prepared by the Director-General of WHO, provides that

"The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited." <sup>iv</sup>

In response to these resolutions, the World Health Assembly in 2010 adopted Resolution WHA44.25 endorsing a set of Guiding Principles on Human Organ Transplantation. These Guiding Principles whose emphasis include voluntary donation, non-commercialisation, genetic relation of recipients to donors and a preference for deceased over living donors as sources of donor organs have considerably influenced professional codes, legislation and policies globally.<sup>v</sup>

### **Organ Donation under the Act**

Certain criteria were made for live and cadaver donations. The live donation was permitted under the law only if it was for altruistic purposes and given without any coercion or any other form of external pressure, not to impair the health or functional integrity of the donor. To be assured that the benefits expected to be given to the recipient bear an acceptable proportion to the harm likely to the donor, it was mandated that donor should be fully informed beforehand about the nature of the transplant procedure and the possibility of rarely happening complications. Further it was assured under the law that there must be no element of commercialisation or exploitation in the donation and for this purpose giving or receiving money in the process of transplantation was made an offence.

### **Consent for cadaver donation**

In India the current system of consent for retrieval of organs from deceased is of 'opting in' concept. It is based on the principle of 'authorisation', an expression which is intended to convey that people have the right to express, during their lifetime, their wishes about what should happen to their bodies after death, in the expectation that those wishes will be respected. It is a positive concept, representing a positive attitude to the issue, and replaces the 'lack of objection'. Authorisation to remove an organ of a deceased equates to the principle of 'consent' on which the THOTA is based.

In case of cadaver donations the family was given the ultimate power to give consent for donation despite making a provision for voluntary consent of the person which he/she can make during his lifetime for removal of his/her organs after his/her death. The opt-in consent is in fact a misnomer under the Indian legislation as it is made conditional to the permission of the family of the deceased. Under the Act even if the individual has opted-in or has given his consent for organ donation after his death, his wish to donate his organs cannot come true if his family is not ready for the donation.<sup>vi</sup> It is trickier and very difficult situation to approach a grieving family to ask them to take out an organ of their dear one for donation especially when his heart is beating which creates a wrong notion in their minds that there can be some ill intentions on part of the official staff in the present scenario of distrustful medical care system. Their emotional turmoil of losing a dear one deprives them of their logical thinking. The distrust in the medical care system in India dissuades them from giving permission for removal of organs

from the deceased. They think that if they agree for donation the official staff may not take proper care of their beloved one because somewhere underneath they are unaware about the brain death concept. They believe that their beloved could be saved even after brain death. And the fact that a deceased has already given consent for removal of his organs after his death is of no consequence because it is only the family of the deceased which can give the final permission.

### **Dismal state of cadaver donation**

The incorporation of concept of 'brain death' and 'opt-in-consent' in Indian law for increasing the cadaver donor pool for facilitation of transplants has over the year since the enactment of the transplant legislation has proven to be a complete failure. At the occasion of launching of Transplant Registry in 2015 the Health minister Sh. J.P. Nadda said, "According to the government data, India needs around 2 lakh kidney donations every year, however, only 7,000-8,000 requirements are met... Over 2.5 lakh people in the country require organ transplantation in a year, but less than 10 per cent get timely help, the data added." <sup>vii</sup>

J. P. Nadda health Minister also said that "data pertaining to liver transplants are also in the same sordid state as kidney transplants. Likewise against a requirement of 30,000 liver transplantations, only about 1000 transplants are done."<sup>viii</sup> The Health Minister attributed inefficient cadaver programme as the reason for shortage of donor organs. The NOTTO reports reveal that in a span of almost twenty years i.e. from 1994 to 2014 only 315 cadaver transplants have been done and living donations done in the same period are 14038.<sup>ix</sup> The data depicts the dismal state of cadaver donation in India.

The fault lies in the laws to some extent and mainly in its implementations. "With around 1,60,000 people dying in road mishaps in the country every year, the pool of potential brain dead donors is large. In fact if all brain dead accident victims are declared donors, maintained and taken up for organ retrieval there would be no need for the living to donate organs to relatives."<sup>x</sup> The need is to locate the stumbling blocks in the laws and to overcome them and at the same time developing infrastructure needed for cadaver donations.

### **Global Scenario in relation to transplant Legislation**

One of the basic requirements in increasing the cadaver donation is the consent/permission for removal of the organ from the body of the deceased. The opt-in concept in Indian legislation has its limitations and has not been very successful in increasing the cadaver organ pool. To overcome the shortage of transplantable organs, countries all over the world have incorporated other types of consent as well. There are three processes through which consent may be given. First is 'opt-in' consent e.g. in India, the second is 'opt-out' and the third is 'mandated choice.'

An "opt-out" or "contracting out" system is one which permits organs to be removed after death for transplantation unless an appropriate objection is made. This is also termed as 'presumed consent'. "Under a system of "opting out" or "presumed consent", every person living in that country is deemed to have given their consent to organ donation unless they have specifically "opted out" by recording in writing their unwillingness to give organs. With presumed consent, the default position in the absence of express objection is donation."<sup>xi</sup> "A [systematic review published in BMJ](#) in 2009 found countries that introduced presumed consent systems lifted their organ donation rates within a few years. In Austria, the rate increased from 4.6 donors per million people per year to 10.1 per million.<sup>xii</sup> "Germany, which

uses an opt-in system, has an organ donation consent rate of 12% among its population, while Austria, a country with a very similar culture and economic development, but which uses an opt-out system, has a consent rate of 99.98%. In recent years, many countries have shifted towards the view that opt-out system of consent can be of great help in promoting the organ donation. Wales recently has switched of its transplant laws from opt-in consent to opt-out consent. And Chile has introduced harder form of presumed consent to increase the cadaver donation rate where once the person has opted-in, he can deregister himself as donor only through notarised document.<sup>xiii</sup>

Many other countries such as France, Greece, Portugal, Spain, Luxemburg, Denmark, Great Britain, Italy, Norway, Sweden, Turkey, Japan, Switzerland, Poland etc. have tried to increase organ donation rates by implementing a presumed consent or opt out approach to organ donation. The most celebrated success of these experiences is the case of Belgium, where organ recovery more than doubled following implementation of its policy of presumed consent. Kidney donation in Belgium increased from 18.9 to 41.3, while in Singapore it increased from 3.7 to 31.3.<sup>xiv</sup> But due to lack of awareness among people it had to be abandoned.

Spain has the world's largest donation rate. The number of organ donors in Spain has risen continuously from 14.3 per million population in 1989 to 25 per million in 1994. "Spain now has a donor rate approaching 35 per million, and performs 2,600 kidney transplants a year. Less than 1 per cent of donated organs in Spain come from live donors."<sup>xv</sup> With presumed consent one of the special features of Spanish transplant law is the role of 'transplant coordinators' in cadaver donation. A three tiered system of transplant coordinators in Spain has boost the organ donation rate. Indian legislation brought this feature by making it mandatory appointment of transplant coordinators in hospitals where transplants are done and also in organ retrieval centers.

Countries like Israel, Singapore and Chile have priority point system for allocation of organs which works as an incentive for people to pledge their organs. Priority point system in Israel is based on Mutual Aid Principle which means "don't give don't get". Priority points are also given to the persons pledging their organs. India has also introduced priority points system for allocation of organs in April 2016.<sup>xvi</sup> "If a person can be an organ recipient, they should also be able to give an organ, and vice versa. Given that pragmatism prevails in society, it is hoped that the priority rule will prompt people who opted out of donor programmes to reconsider their choice."<sup>xvii</sup>

Mandated Choice (MC) is a legally mandated decision. Under MC, all adults would be mandated by law to indicate their wishes regarding use of their organs after death. This could be done through the electoral roll, given that all adults are represented on the roll in contrast to driving licences, tax returns etc. and also be made mandatory by registering with a general practitioner or some other mechanism that a working group would need to explore. Under MC, family members will know that a genuine choice has been made by the deceased. This has the potential to relieve distress of the relatives. If relatives wish to refuse organ retrieval, then MC would relieve the uncomfortable action of refusal itself. Instead with MC, they are comforted in knowing that wishes of their deceased relatives have been honoured.<sup>xviii</sup>

Those who are in favour of a policy of MC argue that it is better to have it over the presumed lack of objection/presumed consent as it removes confusion in regard to the state of the consent and saves the precious time. Many believe that there are ethical advantages in MC that make a compelling case for its consideration. In some countries while applying for the driving license, the applicant has to fill the column where they can express their wish in regard to be an organ donor or to write their objection to

organ donation after death. This written form of the consent gives clarity to the autonomy of the deceased and his wishes of being a donor or not being a donor can be respected. In California it is mandatory for the persons to fill up the clause while issuance or at the time of renewal of the driving licence that whether they want to be an organ donor or not.

### **Ways towards increasing cadaver donor pool in India- Mandated and easier ways of registering consent**

In a survey it was found that almost 100% people were aware of the organ donation in the cities of Delhi, Mumbai and Bangalore, 99% in Kolkata and Pune and 98% in Hyderabad. Only 7% of people having awareness about the organ donation had signed up for organ donation. Mumbai has the highest number (29%) of those who have signed up as per this survey.<sup>xix</sup>

In absence of any law mandating to express the choice for donation and easier ways of registering consent people rarely come up to register their consent. In India the road accident victims can be potential source of organ donors. Thus acknowledging consent for donation of organs after death can be made compulsory while filing application for getting a driving license or while getting it renewed. Proposals are there in India of organ pledging on driving licence. The Director of NOTTO said, "the government is working on linking the driving licence application system with a pledge to donate organs and meetings with the Ministry of Road, Transport and Highways are being held in this regard to evaluate how this proposal can be implemented across the States in India."<sup>xx</sup> Linking driving licence applications with organ pledge will help in tapping this source of organs for saving lives of lakhs of patients.

Another option for pledging organs can be of health records of a person. The Health Record with the General Practitioner (GP) will offer people a convenient vehicle in future for recording their wishes as to what should happen to their body after death. Other documentary evidence can be identity and residence proof of the proposed donor e.g., Ration Card or Voters Identity Card, Passport, PAN Card, or Bank Account. Income tax returns can also have provision of making such a wish.

One feasible and promising way of documenting consent can be on Aadhar card. In India while issuing 'Aadhaar' card provision could be made to give a person's choice in relation to organ donation after death.<sup>xxi</sup> It is advisable to give option of giving consent on Aadhar card because in comparison to other ways opting consent or objection on driving license or tax returns, the Aadhar card would be a better option because every person in India will be having Aadhar card as lifetime digital identity, but he may not own a vehicle and may not have a driving licence. And in the same way in Indians are not under compulsion to file tax- returns.

Another way to make this option of pledging for organ donation more promising and viable is making enrolling for 'Aadhaar' card mandatory. There would be no influence on the decision itself, of course. Because mandated consent replaces the implied consent under 'presumed consent' with real consent.<sup>xxii</sup>

### **Incentives for Signing Up Donor Card**

Some favour monetary incentives other than cash for signing up a donor card which can encourage people to come forward for cadaver donation. Policies like rebates in income tax returns, concessions in premiums of insurance policies of the individual signing the donor card, yearly free medical check-ups

etc. are some of the ways which can work as incentives for signing the donor card and result in increasing the cadaver organ donation.

### **Significance of the consent of the family of the deceased in organ donation**

Next impediment under the Act is that cadaver donation is mainly dependent on the permission of next of kin of the deceased. Because under the Indian transplant legislation the written consent of the deceased for organ donation is of no significance and is secondary to the wishes of the family of the deceased. The awed purpose of saving lives of end stage organ failure patients through the Indian transplant legislation can only be made possible if basic premise i.e. of consent of the deceased for cadaver donation is made supreme to the wishes of the family of the deceased.

### **Autonomy of the deceased should be respected**

Thus most needed and significant changes which should be brought to the present legislation relates to the role of the donor's nearest relatives in giving consent. The refusal of families to grant permission is a major impediment to cadaver organ donation. Organ procurement happens at a time of tremendous stress and grief. Health professional's experiences to deal with the families for getting consent have been very difficult one. But policy of asking consent from families when signed donor cards are present is inconsistent with the basic purpose of facilitating organ transplants through cadaver donations. At present, organ donation only goes ahead if that is the wish of the relatives. Giving relatives right to give consent even if the wishes of the deceased are clear will result in vetoing of deceased's wishes. The whole purpose of the Act, recognition of brain death concept for increasing deceased donation, developing infrastructure for facilitating transplants would be defeated if the consent cannot be obtained for removal of organs even if documented wishes of the deceased are available. Where the wishes of the deceased adult are clear no authorization should be required from the near relatives. The deceased's wishes in these cases are all that are needed to allow the removal of body parts to proceed lawfully.

### **More Trained Counsellors – Need of the Hour**

Several factors have been shown to improve family consent rates. One of the aspects which contribute to family refusal is that consent is asked at a time when the family is overwhelmed with the shock of losing their loved one. It is highly difficult time for the family when the emotional burden is huge in the form of stress and grief. The request for organs should be made by trained coordinators along with the hospital staff as a team. Transplant coordinators are the persons well trained to have a dialogue with the relatives of the family of the brain dead persons to make them aware about the organ donation concept and also to convince them for organ donation. It is preferable that the physician or nurse caring for the patient do not discuss organ donation with the family prior to coordinator. The request should be made in a private and quiet setting. Higher consent rates have been shown to occur when these procedures are followed.<sup>xxiii</sup>

There is an urgent need to increase the number of transplant coordinators in hospitals where transplant facilities are available and also in hospitals which are registered as the organ retrieval centers. More the number of transplant coordinators in ICU of a hospital less would be the burden on the transplant coordinator working in the ICU and resultantly better results could be expected in form of increased organ donation rates.

And as the time is precious and important factor in procedure of retrieval of organs for transplant, no time can be lost to keep the organs viable for transplant purposes. Therefore it is the convincing techniques of skilled counsellors to convince the family of the deceased for organ donation which is important. This can be helpful in preventing organs going waste. Here the role of transplant coordinators becomes very important. Thus it is necessary that coordinators should be well trained to make the grieving family understand about the significance of brain death concept, ask them for organ donation and convince them for organ donation as time is the essence for the viability of cadaver organs for transplantation purposes. Thus more number of trained transplant coordinators is required at hospitals and at retrieval centres.

### **Incentives for families of the deceased for giving consent**

In India masses are uneducated about organ donation. By motivating families to come forward for donation some jurists, persons from medical field opines that government can give incentives to the donor's family like lifelong free medical check-up and care in the hospital where the organ donation takes place. A life insurance policy for three years with one-time premium to be paid by the recipient can also be given. The Allocation guidelines issued by NOTTO for kidneys have made provision for such incentive and five points are provided for that.<sup>xxiv</sup> Allocation Criteria for Deceased Donor Liver Transplantation in Delhi/NCR and Allocation Criteria for Heart, Lung & Heart-Lung have also been issued by NOTTO.<sup>xxv</sup>

### **Increasing cadaver donation: Public awareness a key to success**

In India where the cultural ethos and religious beliefs are stronger than other countries, the awareness is needed most in India for the effective working of cadaver donation program. For all practical purposes cadaveric donation technology is almost missing or negligible considering the number of brain-stem death patients in India. For cadaver donation of organs from accident victims, time is the essence and very prompt action is needed to procure organs. Presence and availability of an infrastructure for retrieval of organs along with the availability of cadaver organs can make transplants possible.

The success of organ donation programme revolves around the level of awareness among the masses about the concept of organ donation though literacy plays an important role in it. Republic of India has the largest illiterate population compared to other nations. As per Population Census of India 2011, the Literacy rate of India has shown improvement of almost 9.2 percent.<sup>xxvi</sup> Awareness programme to some extent can be successfully executed if the subjects are literate. In a survey conducted in city of Mangalore, India 863 participants were included in the study. The overall literacy rate of the participants was high. The result of the study showed that all of the participants had heard about organ donations. And almost 60% of them expressed their willingness to donate organs though had not register themselves for lack of easily available registering platforms for organ donation.<sup>xxvii</sup> Thus awareness about organ donations is the only key to increase organ donation rate in view of the present transplant laws in India. Thus government, NGOs and organisations should make policies to conduct more awareness programmes.

Including subject of organ donation in the curriculum of the school can educate children and parents about cadaver donation. Promoting Awareness by famous personalities /ambassadors has potential to attract masses thus organ donation can be promoted through public figures/ celebrities. Student/college initiatives, exhibitions and advertising campaigns across all medias e.g. TV, print, radio, in-cinema ads

can be really effective in increasing awareness about organ donation. Likewise theatres, street plays and events like marathons, concerts etc. along with award programmes events can be helpful in promoting cadaver donation in the country.

Awareness programmes for organ donations launched by different organisations are giving better results. The people are coming forward for organ donation by registering themselves. Number of people willing for organ donation after death has gone up from 190 in 2012 to 570 in 2015 as result of awareness campaigns.<sup>xxviii</sup> The objective of the THOTA can only become true if more and more people come forward for organ donation after death. The new ways should be adopted through which maximum people could be reached to make them aware about the concept of organ donation.

The transplant legislation in India was enacted with intent to pave the way for a smooth procedure for organ transplants so that lives of lakhs of patients due to organ failure could be saved. But the law has not been able to fill the gap between demand and supply of organs. The progressive law to promote organ donation have been brought on the Statute books but in reality and for practical reasons they are redundant as they are not able to meet the demand for transplantable cadaver organs. The main problem with current express consent system for cadaveric donation is that it has consistently failed to provide enough donor organs to keep pace with the ever-growing demand for transplantation. So it's time that we should look for other means to make the compulsive use of the cadaver organs which are being wasted under the present law. A well-run organ donation program at different levels in India is need of the time. "Even today the rate of organ donation in India is only 0.16 per 1 million population, compared to 40 in Spain and 35 in the United States."<sup>xxix</sup> The data on organ donation in India points in the direction that still there are areas in the Act which needs overhauling in order to improve from the present state.

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<sup>i</sup> The nomenclature of the Act as it was before 2011 amendments. The nomenclature was changed to Transplantation of Human Organs and Tissues Act 1994 vide (Amendment) Act, 2011, at 'Act and Rules under Transplant of Human Organs Act (THOA),' THOA amendment 2011, Retrieved from <http://www.notto.nic.in/act-end-rules-of-thoa.htm>

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- xxi Aadhaar is the instantly verifiable [national identification number](#) assigned to residents of India. It is not a proof of citizenship. It only guarantees identity; not rights, benefits or entitlements. Aadhaar program is operated by the [Unique Identification Authority of India](#) (UIDAI), an authority of the [Government of India](#). It was established in January-2009 under the [Planning Commission of India](#). Aadhaar is expected to play the most prominent role in India Reforms from 2014 onwards. The prime objective of Aadhaar is to provide lifetime [digital identity](#) which is verifiable instantly at the point of service with biometrics in paperless way.
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