TRANSPLANTATION OF HUMAN ORGANS: THE INDIAN SCENARIO

Dr. Anju Vali Tikoo*

And Lord Shiva was enraged and beheaded Ganesha; And Parvati was pained beyond grief. “Ganesha! Oh My Son! Be it that it were me.” She wailed, and Lord Shiva was moved and transplanted an elephant’s head onto Ganesha and Ganesha became the Deity of Learning and Wisdom.

†Hindu Mythology‡

Abstract

Preservation of human life is of paramount importance. ‡Right to life§ under article 21 of the Indian Constitution has been construed as not mere physical existence but also the quality of life in its widest amplitude including the ‡right to health§ And ‡right to health§ of people suffering from end- stage organ failure is being substantially enhanced through organ transplant technology. The Transplantation of Human Organs and Tissues Act, 1994 has the potential to ameliorate the plight of such people by regulating organ transplants in India. It is argued that even after more than two decades of its implementation the law has not been able to achieve either of its two laudable objectives; (i) promotion of cadaver donation, and (ii) prevention of commercial dealings in human organs.

I Introduction

RECOGNITION OF ¤right to health§ is the benchmark of developed human societies. International concern for ¤right to health§ evolved and a framework of norms were developed requiring States to facilitate the right to health of the individual. The Constitution of the World Health Organisation defines health as, ¤É a state of complete physical, mental and

* Assistant Professor, Faculty of Law, University of Delhi.

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social well-being and not merely the absence of disease or infirmity. States are under an obligation to make provision of a clean living environment, protections against hazardous working conditions, education about disease-prevention and social security measures in respect of disability, unemployment, sickness and injury at the societal level in order to provide health to an individual. The individual-centric approach for providing curative treatment, medicines etc. to an individual has shifted towards the public health to a larger extent. In the words of K.G. Balakrishnan: “There is an obvious intersection between healthcare at the individual as well as societal level and the provision of nutrition, clothing and shelter.” The Supreme Court has held that the right to health is an integral part of the right to life under article 21 of the Constitution. And that preservation of human life is of paramount importance.

Organ transplant technology has emerged on the scientific horizon as a gift of life to people suffering from end stage organ failure disease. The development in transplant technology with immunosuppressant drugs has made the transplant of both (i) living related or/and unrelated and (ii) deceased organs, a viable option for people suffering from organ failure. Their chances of survival and ability to lead a healthy, prolonged life is completely dependent on availability and accessibility of transplantable human organs. The Transplantation of Human Organs and Tissues Act, 1994 regulates the practice and procedure of donation, retrieval and transplantation of human organs. This article deals with the impact assessment of this Act after more than two decades of its implementation to evaluate its efficacy in achieving its two objectives and suggest changes to ensure that the scientific evolution of transplant technology proves beneficial for advancing human health and a life of dignity.

II RIGHT TO HEALTH AND THE INDIAN CONSTITUTION

Under the Indian Constitution the right to health does not find a mention in the fundamental rights chapter III but finds its place in directive principles of state policies under chapter IV of the Constitution which are non-justiciable in the courts of law.

3 Parmanand Katara v.Union of India, AIR 1989 SC 2039.
Health—a ‘state’ subject in Indian Constitution

Subject of ‘health’ falls under entry 6, list-ii (state list) in the seventh schedule to the Constitution of India which reads ‘Public Health and Sanitation, Hospitals and Dispensaries’. The other two lists being the ‘The Union List—List I’ and ‘The Concurrent List—List III’ But under special provisions in the Constitution, the Parliament can also enact laws for the states. Article 252 read with article 249 of the Constitution are special provisions which confer power on the Parliament to legislate for two or more states by consent or by adoption of such legislation by any other state.

In the history of Indian judiciary the case of Maneka Gandhi v. Union of India has been a watershed in expanding the horizons of fundamental rights in general and article 21 in particular. The court moved from a pedantic to a purposive approach in construing the sweep of the right to life under the Constitution. Maneka Gandhi judgment became a springboard for the evolution of human rights jurisprudence and the basis for the subsequent expansion of the understanding of the ‘protection of life and liberty’ under article 21 through expansive interpretation of Fundamental Rights guaranteed in part III of the Indian Constitution. The Supreme Court of India further went on to adopt an approach of harmonization between fundamental rights and directive principles in Indian Constitution in several cases.5

Judicial activism and right to health

In India during the last four decades or so, the issue of health has gained momentum. Judgments delivered in Parmanand Katara v. Union of India, Indian Medical Association v. V.P. Shantha and Paschim Banga Khet Mazdoor Samiti v. State of West Bengal are few amongst many Supreme Court decisions which strengthened the recognition of the ‘right to health’. The apex court’s activism through various decisions observed that denial of immediate medical attention to a patient in need amounts to violation of ‘protection of life and liberty’ guaranteed under article 21. Likewise holding that a provision of a medical service (whether diagnosis or treatment) in return for monetary consideration amounts to a

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4 AIR 1978 SC 597. The judges in Maneka Gandhi repented the decision of A.D.M. Jabalpur v. S.S. Shukla, AIR 1976 SC 1207 as it had endorsed the violation of the fundamental rights of a large number of people during the dark period of emergency and even in the years to follow.
5 Minerva Mills Ltd. v. Union of India, AIR 1980 SC 1789
6 Supra note 3.
7 AIR 1996 SC 550.
8 AIR 1996 SC 2426.
"Service" for the purposes of Consumer Protection Act, 1986 went a long way in protecting the interests of the patients.9

**Laws promoting human health- Transplantation of Human Organs and Tissues Act, 1994**


One disease which captured the attention of the medical professionals all over the world in early 1900s and throughout the first half of the 20th century was solid organ failure.10 With the advent of advanced medical technology in transplant procedures an end stage organ failure patient11 got a ray of hope to lead a healthy and prolonged life by undergoing organ transplant12. Human body has certain essential organs like kidneys, lungs, cornea that are in pairs, making it possible to part away with one of the two during the lifetime and still be able to lead a healthy life. Whereas other significant organs like heart, pancreas etc. can be used only after the death of a human being but before the organs become obsolete on account of discontinuation of blood supply. There are regenerative and non-regenerative transplantable tissues/organs like liver, blood, bone marrow, stem cells etc.

Law and medicine join a common pilgrimage towards all pervasive welfare of human life.13 Over the years, with the revolutionary changes brought about in social, economic, political and scientific fields of human activity, human organ transplant as a curative medical

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9 *Supra* note 7.
10 Kidney, liver, lung, heart, and skin are among those solid organs that are commonly affected and frequently lead to organ dysfunction and eventually to end stage organ failure and death. K. Upadhyay, R. N. Fine, "Solid organ transplantation following end-organ failure in recipients of hematopoietic stem cell transplantation in children" *available at*: https://www.ncbi.nlm.nih.gov/pubmed/23949630, last visited on May 10, 2017.
11 Hereinafter referred as ESOF.
12 Organ Transplantation is the medical procedure whereby living tissue from a human body is removed and transferred to some other part of that body or to another person. An example of transferring tissue from one part of the body to another is a skin graft. Where the transfer is from one person to another, the one supplying the tissue is the donor and the one receiving it is the recipient.
13 Anju Vali, "Organ Transplantation-Some Issues" *DLR* 118 (1991)
technique gained public acceptance in India too. To facilitate transplants for saving the lives of organ failure patients and to safeguard the interests of the organ donors, the Transplantation of Human Organs and Tissues Act was passed in India in 1994. The enactment furthers the cause of human existence by regulating and facilitating transplants, gives thrust to policies recognising values which are integral to dignified human existence. It has come as a boon to trillions of humans suffering from ESOF. Various organs can be legally transplanted by virtue of THOTA, 1994 giving gift of life to people otherwise doomed to die on account of ESOF.

The THOTA, 1994 was enacted at the time when in India due to absence of any legislation, rampant sale of human organs was going on. The Act aims to provide for (i) the regulation of removal, storage and transplantation of human organs for therapeutic purpose and for (ii) the prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto. There are two types of organ donations envisaged under the Act viz., (i) Living Donation and (ii) Cadaver/Deceased Donations. Broadly, the Act for the first time recognised brain death as the moment of death for facilitating retrieval of organs. Thus owing to THOTA, 1994, persons in vegetative / brain dead state with beating heart have become a viable source of organ pool for the purposes of transplantation and the sale of organs is now a punishable offence. With the acceptance of brain death, it has become possible to undertake solid organ transplants.

III THOTA 1994- Impact assessment after two decades

The transplantation of organs from one individual to another has increased dramatically in recent years. The advent of new immuno-suppressive drugs and the donor specific blood transfusion have greatly improved the survival of grafted organs. While the medical technology and knowhow continue to expand the possibilities of organ transplantation and increased success rates of such transplant surgeries, the number of organ donors does not increase correspondingly. This gap in demand and supply of transplantable organs results in

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14 Hereinafter referred as THOTA,1994.
15 THOTA, 1994, s. 2(d) states, “brain-stem death” means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-s. (6) of s. 3.
16 Currently around 5,000 kidneys, 1000 livers and around 15 hearts are transplanted annually. There is a need of roughly 200,000 kidneys, 50,000 hearts and 50,000 livers for transplantation each year. For details see, A Study of the Deceased Organ Donation Environment in Delhi/NCR, available at:
illegal trade in organs. Despite the legislation, organ commerce generally and especially kidney scandals are regularly reported in the Indian media. In most of the reported instances, the implementation of the law has been flawed and more often than not its provisions have been abused. Though the living related and unrelated donation program has established itself but the deceased donation program is still in its nascent stage only.

Initially for many years there was a lack of initiative from the government to find solution to rampant sale of organs after the Act was passed. Whenever a kidney scandal was unearthed there was an instant reaction from different quarters, there was some media outcry and if the allegations were found to be serious a few small time brokers were rounded up and life carried on till another such episode came to light and the same act was repeated. Realising the need to move forward with changing needs of the society and to make the regulation of organ transplant procedure with all the incidental paraphernalia meaningfully effective, periodic amendments have been made to the THOTA, 1994 in more than two decades since its enforcement.

Even a cursory look into the statistics available on the official website of National Tissue and Transplant Organisation reveals the fact that despite amendments in the Act, the cadaver organ donation program has not picked up over the years. In the face of all organ donations numbering 14038 from living donation category from 1971-2017, the figures for deceased (cadaver) donation in the same period stand at a dismal 315 only. The high demand of organs has led to its commodification, more so in developing countries where there is a large population base below the poverty line with weak regulatory authorities like in India. But
there are examples of legislations in countries like Spain, Iran and Iraq which have been successful in bridging the gap between demand and supply of transplantable organs. Countries with laws legalising ‘presumed consent’ and actively involved transplant coordinators\(^{21}\) in ICUs have succeeded in meeting the dearth of donor organs.

The reason for miniscule organ donation in India can be attributed to lack of awareness about the concept of organ donation in masses. Another important factor is the ethical, religious, and emotional constraints which discourage individuals to go for organ donation.\(^{22}\) In India, the potential for deceased donation is huge due to the high number of fatal road traffic accidents but this pool is yet to be tapped.\(^{23}\) Frequent amendments made to the Act are testimony to the fact that in past Indian legislation has somewhere lagged behind in comparison to other countries which have incorporated new ways to find solution to the problem of organ shortage. The following section identifies the stumbling blocks in achieving the objectives of the legislation.

### IV Bottlenecks in the implementation of THOTA, 1994

Patients’ silent screams, their family’s unending efforts and doctors’ helplessness in saving the patient due to scarcity of compatible donor organs, all point in the direction that there still are issues which have been left unattended and need some solutions. The Transplantation of Human Organs and Tissues Act, 1994 banned organ trade more than two decades ago but it cannot be overlooked that an arrangement of buying and selling of organs is still continuing. Some issues which have marred the organ donation and transplantation programme in India have been discussed hereunder.

\(^{21}\) THOTA, 1994, s. 2(q) states, ‘transplant co-ordinator’ means a person appointed by the hospital for co-ordinating all matters relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance with the provisions of s. 3.

\(^{22}\) All major religions of the world like Buddhism, Hinduism, Islam, Judaism, Sikhism, Christianity believe in organ donation and in fact encourage the same. The faith leaders of respective religions have to take a conscientious stand on the basis of factual knowledge from their respective scriptures and not to propagate myths adversely affecting organ donation. For details see ‘Religion-Orga Donation’ available at: https://www.organdonation.nhs.uk/faq/religion/ visited on 04.05.2017. Also see, ‘Religious Views on Organ Donation’ available at http://donatelifecalifornia.org/education/faqs/religious-views-on-organ-donation/ visited on 04.05.2017.

‘Consent’ and organ donation

In cadaver donation the consent of the deceased before his death is a pre-requisite for removal of his/her organs upon death. There are three processes through which consent may be given. First is ‘opt-in’ consent, second is ‘opt-out’ and the third is ‘mandated choice’. In India we have the ‘opting-in’ form of consent for retrieval of organs from deceased. 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 or ‘presumed consent’. Authorisation to remove an organ of a deceased reflects the principle of ‘consent’ on which the THOTA, Trans1994 is based.

Section 3(1) of the Act permits any donor subject to prescribed conditions and the procedure to donate or authorise the removal of any of his organs or tissues of his body, before his death only for therapeutic purposes. The consent for the donation of organs can also be given by the kin of the deceased, under section 3(3) of the Act provided the deceased had not objected to the donation during his lifetime.

Such consent can be in writing, in presence of two or more witnesses, one of whom has to be a ‘near relative’. And if it is so, then besides the relatives in whose possession the dead body is, even the person, other than the relatives, can grant all reasonable facilities to a registered medical practitioner for the removal of the human organ of the deceased person for therapeutic purposes, provided that such removal can be made only and only by a registered medical practitioner. Here only embargo being that relative or person in whose possession the body is, should be sure that deceased had not subsequently revoked that authority or person

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24 The ‘Opt-in’ or ‘contracting in’ kind of consent requires that the prospective organ donor should give authority for the removal of his organs or tissues, or, if he indicates nothing in his lifetime, his near relatives can authorise the removal of organs. The second type of consent is the ‘Opt-out’ consent. This type of consent does not require a direct consent from the donor or the next of kin. An ‘opt-out’ or ‘contracting out’ system is one which presumes consent for retrieval of organ and permits organs to be removed after death for transplantation unless an appropriate objection is made. Whereas the third type of consent i.e., ‘Mandated choice’ is a legally mandated decision. Under mandated choice all adults would be mandated by law to indicate their wishes regarding use of their organs after death.

other than the relative has a reason to believe that any near relative has no objection to such a removal. This type of consent is known as opt-in concept, in which the deceased person has already opted for the removal of the organ before his death.

**Deceased organ donation - role of relative**

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. Despite the open declaration of his consent and wish to donate organs after his death, its the approval of family which is needed for such donation. Thus the provision of free will of the deceased is nothing but a misnomer because inspite of his opting for the organ donation, his wish becomes secondary to the wishes of his family. For the Act to be effective in its real sense the opt-in-consent provision should be made effective meaningfully to respect the wish of the deceased donor. And with large scale awareness programmes about organ donation and more and more people coming forward to pledge their organs, the dual objectives of the Act could easily be achieved.

**Obtaining consent from relatives – emotional, ethical and religious constraints**

As per section 3 (2) the person in lawful possession of the dead body of the donor who had during his life time, given consent as required by law for removal of his organs after death, such person has to give approval for removal of organ(s), unless he has reason to believe that deceased had revoked consent afterwards. In practice generally the power given under sec.3 (2) is not used. The relative(s)/person(s) in lawful possession of the dead body, who are authorised to give consent for organ removal, are not prepared for such authorisation and thus no removal of deceased organ is possible. The act of obtaining consent of the relative(s) acts as a stumbling block in successful running of the cadaver donation program. The relatives of the patient are not forthcoming, and the doctors not motivated enough to encourage donation. Additionally, patients may not have relatives or may not have them in attendance when the diagnosis of brain death is made. Generally the grieving relatives are reluctant to even think of donating organs of their loved ones.

In India, where the cultural ethos and religious beliefs are stronger than other counties,

generating awareness is the need of the hour for effective implementation of cadaver donation program. Cultural perception of charity and donation is different in different religions. In India, religious beliefs generally discourage practices such as stockpiling and collecting organs from cadavers. It is difficult for a grief stricken family to understand the concept of cadaver donation when his loved one has been declared dead and to take a decision of permitting doctors to retrieve organs for which the corpse would be mutilated. Myths and fears dominate their minds. The very thought of dismemberment of the body of their loved one makes them repulsive to the idea of organ donation. The pre-conceived religious beliefs/myths that in rebirth a person is born in the same state of body condition as he was at the time of death deters them to give consent for removal of any of the body parts. They find taking out organs/tissues very repulsive and perceive it as a kind of disrespect for the dead body of their relative. Though generally all religions permit donation, people are still unwilling to donate organs. Instead they use religious misconceptions as excuses for not donating organs. Thus permission for cadaver donation by family of the deceased has still not gained momentum.

**Distrust against the medical staff**

It is trickier and very difficult situation to approach a grieving family asking them for donation of organ(s) of their beloved one especially when his heart is beating which creates a wrong impression in their minds that there can be some mischievous intentions on the part of the medical/hospital staff. The emotional turmoil of losing a dear one deprives them of their logical thinking. They apprehend that if they agree for donation the hospital staff may not take proper care of their beloved one because somewhere underneath they are unaware about the brain-stem death concept. Hence they believe that their beloved could be saved even after brain death.

Likewise the written consent for donation of organs post demise, that can be given during the lifetime by a prospective donor, may not be given by the person concerned. This would be so

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27 Supra note 22.
29 Ibid.
on account of entertaining a belief that in order to generate organ resources the hospital administration might not provide him that standard of medical care as might be required by him to recuperate fully and to walk out of the hospital in a healthy state.

**Ascertaining consent - ‘near’ relative v. ‘nearest’ relative hierarchy**

section 3(3) of the Act deals with the cases of adult deceased who have not expressed any formal wishes. In such situations the nearest relative or person in lawful possession has the capacity to authorise the removal/donation of organs with a rider that neither the deceased during his lifetime nor his *near relative* has any objection to it.\(^{30}\)

It is suggested that the meaning of term *near relative* used in section 3(3) of THOTA should be different from the definition as given in the section 2(i) and read into section 9(1) and section 3(1A) (i)(ii).\(^{31}\) Reason being if a person is staying away from his family and/or doesn’t have close bonds with his *near relatives* before his death then in that case his close associates or friends who are with him for considerably long periods before his death, can be contacted to seek organ donation. The author is of the considered view that there is a need of amending the concept of *near relative* as used in section 3(3) to enlarge it to include close associates/aides/friends associated with the deceased prior to his demise, to ensure that a huge cadaver organ pool/resource does not go waste in the face of either the *near relative* as defined by the existing law not being there or where near relative may not be maintaining a good relation with the deceased to be able to give consent on behalf of the deceased. Hence in order to ensure optimal use of organs of a deceased and to rule out the possibility of wastage of organs because of absence of unequivocal consent of the person admitted in ICU or of the brain dead person under section 3(1A) (i)(ii) where near relatives are not present for some reason or the other, the Act should include the *nearest relative* hierarchy aiming to identify the person closest to the deceased in life. So that the close person may be able to express the deceased’s wishes about organ donation.

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\(^{30}\) THOTA, 1994, s. 3 : Where no such authority as is referred to in sub-section (2), was made by any person before his death but no objection was also expressed by such person to any of his [human organs or tissues or both] being used after his death for therapeutic purposes, the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person’s [human organs or tissues or both] being used for therapeutic purposes, authorise the removal of any [human organ or tissue or both] of the deceased person for its use for therapeutic purposes.

\(^{31}\) For reference see s.9 (1) and s.3 (1A) (i)(ii) of the Act.
Opt-in consent-a misplaced strategy

The underlying premise for organ donation under THOTA 1994 is the existence of opt-in consent. The incorporation of concept of ‘brain death’ intended for increasing the deceased donor pool along with ‘opt-in’ consent in Indian law has miserably failed to achieve the two pronged objectives of having (i) a functional Cadaver donation system in place and (ii) removing the organ trade from Indian horizon under THOTA, 1994.32

Respect for the autonomy of the deceased

“All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.”33 Thus we all have a duty to act at all times in the best interests of human kind. This includes respecting the autonomous choices made by persons regarding the treatment of their body after their death. Autonomy is a kind of deliberated self-rule which makes us to act according to our own wishes on the basis of informed choices, thought and decision, freely and independently.

THOTA 1994 provides that a person can make a wish to donate his organs/tissues or can also register his objection for such donation after his death. Indian legislation in this context is debatable. As per the Act even if the deceased had consented to donation of organs during his life-time, the wishes of his near ones are given priority over the deceased’s wishes and organ retrieval cannot be done without the consent of the near relatives.34 In such a situation autonomy of the deceased is not respected. The wishes of the near relatives of the deceased are given priority over the wishes of the deceased.

But at the same time, if the person had registered his objection to donate organs after his death or had revoked his earlier consent to donate, then in that case even the near relative’s authorization to donate is of no consequence.35 In Indian law autonomy of deceased is respected in objecting to donation but not when he agrees to organ donation. In this context provisions of the THOTA, 1994 seemingly tilt in obstructing rather than facilitating organ donation and are differentially applicable in respecting the autonomy of the deceased.

32 For appreciating the magnitude of the problem see supra note 15.
33 Universal Declaration of Human Rights, 1948, art. 1.
34 For reference see Rule5(4)(a) of the Act.
35 THOTA, 1994, s. 2and 3.
In England the Human Tissue (Scotland) Act, 2006 sets out that any adult or child aged 12 and over, who is able to make their own decisions, can give permission for donation of their organs or tissue. A person's own decision is most important and to be respected. A relative does not have the right to change this decision after the person has died. Children under the age of 12 cannot give permission themselves. For a child under the age of 12, only their parent(s) or guardian can give permission.36

Section 9 THOTA, 1994 vis-à-vis right to life of a specific class of ESOF patients

In the present dismal state of cadaver organ programme, the laws regulating transplants and activities associated with it have adversely affected a particular class of patients. Now the question arises what this particular class of patients is? In the process of fulfilling its objective of regulating and facilitating the transplants and also to curb the organ sale, norms under section 9 of the Act for procurement of organs for transplantation. The ways in which a donor organ can be procured as provided in the Act does not entitle all the ESOF patients to procure a donor organ.

By virtue of section 9 of the Act37 a class of ESOF patients is excluded from transplant treatment who are in desperate need of the transplantable organ to save their lives but neither have a biologically compatible near relative nor an altruistic donor. Nuclear families with one or two children who may not be biologically compatible and the related contextual social architecture of families reduces the possibility of finding a live donor from amongst near relatives. For example an orphan, a person losing his family in a train accident or in floods or in some other natural calamity will not have any near relative. This class of patients are solely dependent on the cadaver donation and in the absence of an efficient and functional cadaver organ donation programme the patients belonging to this class are bound to die waiting for the transplantable organ. Thus this class of ESOF patients is denied their right to health and cannot save their lives in present scenario. At the same time it should not be

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37 THOTA, 1994, s. 9 states, “Restrictions on removal and transplantation of [human organs or tissues or both]. (1) Save as otherwise provided in sub-section (3), no [human organ or tissue or both] removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.”
forgotten that article 21 besides ensuring 'right to Health' and 'healthcare' also ensures 'right to self-preservation' to everyone.\(^\text{38}\)

In its ambitious journey to regulate organ transplantation by promoting cadaver donation and prohibiting commercial dealings in organs, section 9 of THOTA 1994 restricts a critical patient's right to life, to avail the latest available medical procedures more so in the absence of any effective cadaver donation program. The real and direct effect of section 9 of the Act is impairing the right to life of the class of patients who do not have 'near relative' willing relative or no altruistic donor. Though under the Act provisions are laid down for procurement of organs but the special class of patients as noted cannot have access to any type of donor organ and thus the direct effect of the legislation is infringing patient's right to health.

**Public policy for welfare of the community**

In a welfare state, legislations should be in consonance with the needs of the society, for the collective good of the people. Such needs-interests defined in broad terms as social welfare, are labelled as public policy for the good of the collective body.

The proposition that enactment and implementation of THOTA, 1994 was in public interest for curbing human organ trafficking and regulation of transplants cannot be denied. At the same time it also has to be evaluated on the touchstone of Fundamental Rights, the nature of the right alleged to have been infringed, the underlying purpose of the restrictions imposed, the extent and urgency of the evil sought to be remedied, thereby, the disproportion of the imposition, if any, the prevailing conditions at the time should all be considered for reaching a judicious conclusion.

But the post THOTA,1994 legal regime is witness to the recurring reports of organ trade rackets pointing to the hasty passing of THOTA,1994, without developing a well thought out and functional cadaver organ program, leaving the ESOF patients to die by depriving them to exercise their 'right to life' and also their 'right to self-preservation'. No one appreciates the harrowing life experiences of patients in need of donor organs. Patients in need of solid organ transplant and having no one to donate alive or dead are bound to die and become the

\(^{38}\text{Surjit Singh v State, AIR 1996 SC 1388.}\)
victim of indirect prohibition through this legislation.

The Act should have put restrictions as envisaged under Sec.9 and prohibited sale of organs only after developing a very effective working cadaver programme. With the changing needs of the society, progressive laws are welcomed. But having progressive laws alone is not enough, it should also be ensured that they do not impliedly infringe the Fundamental Rights of the people.

Section 9, THOTA,1994 -Needs rethinking

Currently though organ donation from the brain dead to patients-in-need is facilitated by law but its in a dismal state. 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 State. If data pertaining to different countries and specially India is compared, it clearly depicts that even after implementing THOTA, the number of ESOF patients/recipients dying because of unavailability of donors has been on the rise. Though number of donations has increased but still is abysmally low in comparison to demand of donor organs. Consequently section 9 of the Act needs rethinking. It should be amended till the cadaver organ donation network is so well developed throughout the country that not a single ESOF patient is deprived of organ transplant in the absence of available organs. A multipronged approach should be adopted to improve the cadaver organ program, by incorporating strategies and processes established in other countries having successful systems regulating organ transplants.

Transplant coordinator(s) and organ donation/ retrieval

According to section14 (4) of THOTA,1994, hospitals engaged in transplants and related activities along with organ retrieval centers engaged in organ retrieval activities are required to register. And the registration of such facilities would be done only if they have appointed transplant coordinators who will work for increasing the cadaver donor organ pool. The amendments made it mandatory to appoint transplant coordinators in hospitals

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40 THOTA,1994, s.14 (4) of states, No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant coordinator having such qualifications and experience as may be prescribed.
41 Supra note 21.
having Intensive Care Unit facility, who in consultation with registered medical practitioners are duty bound to make relatives of the brain dead person in the ICU. Aware about the concept of organ donation and consequently their option to donate organs of their loved ones. Though THOTA, 1994 mandates appointment of transplant coordinators, factual analysis reveals that more numbers of transplant coordinators are required for efficacious cadaver donations.

In Delhi only one or two transplant coordinators are there in each leading hospital registered for transplants. With overburdened ICUs and tired nursing staff, technicians coupled with less number of transplant coordinators, it becomes difficult to convert potential donors into real donors. The website of Institute of Liver and Biliary Sciences, Delhi shows Vibhuti Sharma as the only transplant coordinator. Max Hospital Saket, Delhi has only two transplant Coordinators. A. S. Soin, a renowned surgeon of Medanta Hospital, Gurugram, Haryana has a large team of 130 specially trained staff for conducting transplants in the hospital that consists of 8 Consultant Liver Transplant Surgeons, 4 Consultant Liver Transplant Physicians, 3 Liver Transplant Surgical Fellows, 3 Hepatology Fellows, 7 Consultant Liver Transplant Anaesthetists, 5 Consultant Intensive Care Specialists and other specialists, but have only 5 Transplant Coordinators.

The amendments made in the Act mandating appointment of ‘transplant coordinators’ for facilitating organ retrieval from ‘brain-stem dead’ patients hasn’t so far changed the state of cadaveric donations in India. Private hospitals are reluctant to appoint team of transplant coordinators which is the need of the hour.

Union Health Minister J.P. Nadda disclosed government’s plan to appoint coordinators in each hospital having ICU at government expense. Every hospital that starts retrieval and

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42 THOTA, 1994, s. (1A) (ii), (iii).
44 Medanta Liver Transplant Team, http://www.livertransplantindia.com/liver-transplant-team.asp, visited on 05.06.2017
45 *Supra* note 15.
transplantation can employ two transplant coordinators at the government’s expense.\textsuperscript{46} Government felt the need of appointing coordinators at government expense as the private hospitals with overburdened ICUs may not be able to convert potential donors into real donors as they may not employ adequate number of well qualified coordinators in order to save money. Data collected from the websites of few private hospitals as mentioned above proves the fact of underemployment of transplant coordinators for economic reasons.

In Delhi there are 933 private nursing homes\textsuperscript{47} or hospitals which are registered under the Delhi Nursing Homes Act 1953.\textsuperscript{48} There are approximately 576 hospitals which are registered in Delhi.\textsuperscript{49} As per THOTA 1994 hospital\textsuperscript{50} includes nursing homes etc. As per section 14 (3)\textsuperscript{51} only those hospitals would be registered under THOTA, 1994 which have specialised services and facilities, possess skilled manpower and equipment and maintain prescribed standards, necessary for the removal, storage or transplantation of any human organ or tissue or both for therapeutic purposes and as per section 14 (4)\textsuperscript{52} appointment of transplant coordinator is a prerequisite for such registration. Thus only well-equipped hospital fulfilling the criteria laid down in section 14(3) will compulsorily appoint transplant

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\textsuperscript{47} List of registered private nursing homes or hospitals in Delhi, available at: http://www.delhi.gov.in/wps/wcm/connect/DoIT_Health/health/our+services/list+of+registered+private+nursing+homes+or+hospitals+in+delhi, last visited on June 6, 2017.

\textsuperscript{48} Delhi Nursing Home Registration Act 1953, Sec.2(iv)- Nursing Home means any premises used or intended to be used for the reception of persons suffering from any sickness injury or infirmity and the providing of treatment and nursing for them and includes a maternity home and maternity home means any premises used or intended to be used for the reception of pregnant women or of women in or immediately after child birth, Act (Pdf), available at www.delhi.gov.in/wps/wcm/connect/.../ACT.pdf?MOD=AJPERES&imod, visited on 6.06.2017.

\textsuperscript{49} Delhi list of registered hospitals at Delhi, available at: http://www.delhi.gov.in/wps/wcm/connect/b9900a804020417ea2e5fe8bdf93f2e/LIST+OF+REGISTERED+PVT.+HOSPITALS last visited on June 5, 2017.

\textsuperscript{50} As per Section 2(g) of the Act - hospital includes a nursing home, clinic, medical centre, medical or teaching institutions for therapeutic purposes and other like institutions.

\textsuperscript{51} For reference see s. 14 (3) of the Act - No hospital shall be registered under this Act unless the Appropriate Authority is satisfied that such hospital is in position to provide such specialized services and facilities, possess such skilled manpower and equipment and maintain such standards as may be prescribed.

\textsuperscript{52} For reference see s. 14 (4) of the Act- No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant coordinator having such qualification and experience as may be prescribed.
\end{flushleft}
coordinators under section 14(4). Accordingly hospitals other than the well-equipped hospitals are not bound by the Act to appoint transplant coordinators. So even if these provisions of THOTA, 1994 are implemented and are not left only on papers, still the number of cadaver donor organs would not increase substantially in the absence of the services of transplant coordinators. Those hospitals which are registered under the Delhi Nursing Home Registration Act, 1953, but are not equipped and registered for the purpose of transplant activities and organ retrieval activities under THOTA, 1994 can play a major role in generating awareness about the cadaver donations. Thus appointment of transplant coordinators should be made mandatory in small nursing homes and medical centres registered under the Nursing Home Registration Act which though do not fulfil the criteria laid down under Rule 26 and Rule 27 of the Act but can have potential donor/brain dead patients.

As per NOTTO website there are only 201 centres all over India which are deemed capable of organ transplant and retrieval centres. Thus it can be concluded that in Delhi 933 registered Nursing homes/ hospitals are there but only 36 fulfil the criteria under the Act and will have transplant coordinators. In Maharashtra, hospitals equipped with an ICU and operation theatre to retrieve organs for harvesting are mandated to officially identify brain dead patients. This would allow hospitals which don’t have organ transplant facilities to at least harvest organs from brain dead patients for use by the facilities which can at least increase the availability of organs. Thus to increase cadaver organ pool, appointment of transplant coordinators should be made compulsory in all registered hospitals.

It is estimated that around 1,75,000 kidneys and 100,000 livers are needed every year in India and only about 2-3% get it. By conservative estimates over one lakh Indians die in road accidents every year and 40% of those people are left brain dead. Many NGO have been working towards increasing the reach of the THOTA, 1994. Multi-Organ Harvesting Aid

Network is one of such an organisation. 57 Sunil Shroff, Professor and Head of Urology and Renal Transplant, and chairperson of the MOHAN foundation estimates that 50% of all organ donation needs could be met by simply using organs from road accident casualties.

In present scenario even if we presume that these efforts prove fruitful and considerable number of donor organs is generated, it would still be a long journey in the absence of appropriate infrastructure.

Post mortem and organ donation/retrieval

Initially in Delhi, Subzi Ī Mandi mortuary was the only one where post-mortems were conducted. Now due to decentralization post-mortem is done in many government hospitals. The post-mortems are done only on the request of the police. After completion of the formalities by the police the body is sent to the mortuary. In all medico-legal cases the body is sent to government hospitals. The office hours of the post-mortem doctors are from 9.00am to 4.00pm on all working days and from 9.00am to 1.00 pm on Saturdays, Sundays and holidays. The request for the post-mortem should reach the doctors till one hour before the closing hour.

In a PIL filed over the grievance pertaining to delay in conducting the post-mortem a Bench of Chief Justice G. Rohini and R. S. Endlaw J directed the City Government and Delhi Police to issue a notification within 60 days to enable the investigating officer to directly approach the hospital concerned and also for constitution of standing and roaster based board of doctors to handle medico-legal cases. The directions were also given for having a continuing panel of doctors for conducting the post-mortem and any one/two/three doctors from which

57 MOHAN Foundation is a not-for-profit, non-governmental organization started to promote organ donation in 1997 in Chennai by philanthropists and medical professionals led by Dr. Sunil Shroff. MOHAN Foundation was started by a group of like-minded and concerned medical and non-medical professionals committed to increasing the reach of the Transplantation of Human Organs Act.


panel may constitute the board.60

The Delhi government also made the declaration in an affidavit in high court that post-mortem examinations and medico-legal tests of prisoners who died in judicial custody will be conducted at thirteen demarcated government hospitals, on Sundays and holidays, too.61 Only if procedure of post-mortem is expedited, the relatives of the deceased can have a chance of donating the biologically viable organs.

One of the areas in which efforts could be made to increase the cadaver donor pool is to allow autopsy in private hospitals by private doctors. About 95% transplants are being done in private sector. Because facilities required for transplants and organ retrieval are available only in metropolitan cities and that also in private hospitals. So provision of autopsies in private hospitals by private doctors can boost the cadaver organ donation. The chances of private doctors becoming amenable to influence and issue bogus post-mortem certificates can be curtailed by video graphing the whole autopsy procedure and at the same time private doctors can also be made liable. A Division Bench of JJ. S. Rajeswaran and P N Prakash of High Court of Tamil Nadu said in a case before them that, "the IPC had enough provisions to prosecute a doctor. The legislature can also bring in an amendment to the definition of "public servant" found in section 21 of IPC and in section 2(c) of the Prevention of Corruption Act, 1988 by including 'doctors who perform autopsy at the request of a police officer, so that they could be prosecuted."62

60 ŠDelay in Post-Mortem: Delhi High Court Directs City Government to Ease ProceduresÓ Delhi , Press Trust of India , available at:

61 ŠAutopsy in Delhi Govt. hospitals on holidays, Agencies,ÓDec 1, 2013, 04.29 AM IST, available at:

62 ŠAllow private doctors, hospitals to do autopsies, suggests HC,ÓTNN, Nov 2, 2014, 02.17 AM IST available at:
**Infrastructural constraints**

Cadaver transplants require expensive, specialized and diverse infrastructure systems to be in place and functioning. Hospitals need the required facilities, such as equipment, operating rooms, laboratories to conduct cross-matching and trained personnel available at short notice and around the clock for such transplants.\(^{63}\) Time is of essence in such transplants, because organs have a limited life span, before expiry of which both removal and transplantation have to be effectively carried out.\(^{64}\) With 17 lives lost in road accidents every hour last year and 390 fatalities recorded daily, the Union Health Ministry said organ donated from such victims with proper consent of their family members can help the country’s abysmally low organ donation rate.\(^{65}\) For brain death patients to convert into real donors a responsive, rapid and efficient medical facility is crucial.

Transplantation operations involving cadavers in India are more complicated and rare due to the lack of facilities e.g., facility for the resuscitation of the victim at the accident spot, lack of well-equipped hospitals, shortage of trained personnel in the ICUs, lack of quick communication and proper transport facilities, as well as inadequate public awareness amongst other reasons. Thus for all practical purposes cadaveric donation technology is almost missing or negligible considering the number of brain-stem death patients in India. Presence and availability of such an infrastructure along with the availability of cadaver organs together can make transplants possible. And for such specialised, diverse and expensive infrastructure, availability of funds plays a very significant role.

In India, the budgetary allocation of funds for health sector is one of the lowest in comparison to other countries. In order to make the Act really effective funds should be provided in the budget.

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<th>Country</th>
<th>Expenditure in % of annual Budget</th>
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\(^{64}\) *Ibid*.


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There is no data available to tell how many ESOF patients have died due to unavailability of donor organs till today. ESOF patients come to the hospital in a hope to walk back healthy, but die enduring pain, suffering, waiting and leaving their families distraught and under huge debt which takes years for them to come back to life.\(^6\) Sanjay Aggarwal, head of nephrology department at AIIMS said: \(^6\)


Dialysis being very costly almost costing Rs.32,000 per month, it is only the rich who can afford to live on dialysis that too for few years. A poor or middle class patient does not have economic capacity to survive on dialysis in India. In case an ESOF patient cannot arrange a a
biologically compatible ‘near relative’ organ donor for himself or who has no willing family member to donate and none feeling enough love and affection to donate an organ to save him, is bound to die. And considering the poor and abysmally low organ donation rate what would be the fate of an orphan who is diagnosed as being at the critical state of ESOF having neither family nor friends is not unimaginable. For him going by law means waiting for DEATH.

In retrospect, neither has organ commerce been curtailed nor has cadaveric donation become the norm. Somewhere in all these years various factors have been responsible in failing the Act to achieve its objectives of facilitating transplants and banning organ trade.

**Section 9(3) ‘affection’ clause most flouted**

Indian transplant scenario since the passing of THOTA, 1994 reflects that the law has been more flouted than followed. The “affection” clause in section 9(3) THOTA, 1994 is the gateway for the maximum number of transplants in the country so far. In state after state, authorisation committees have rejected a microscopic percentage of applications under this clause, turning a blind eye to what are obviously financial transactions.

Three months data from May-July 2016 regarding number of transplants approved at Sir Ganga Ram Hospital, Delhi reveals that out of total of 29 application 26 applications for transplants were approved, only one was rejected on ground of suspicion as the statements of the donor and the relatives of the donor did not corroborate and one was rejected as the kidneys of donor were not healthy. The data cannot be said to be conclusive on the issue as the website of the hospital in public domain do not show the status of the donor i.e., whether donor and recipient are distant relative or unrelated. But as per the Indian transplant registry data the total live transplants done from 1971 to 2016 are 20612 while the total number of transplants done in the same period is 21395. It gives a strong indication that approving live transplants is the norm

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70 THOTA, 1994, s.9(3) states, “If any donor authorises the removal of any of his [human organs or tissues or both] before his death under sub-s. (1) of s. 3 for transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such [human organ or tissue or both] shall not be removed and transplanted without the prior approval of the Authorisation Committee.”

71 THOTA, 1994, s. 9(4) and(5) : deals with the composition and power of the authorisation committee which is the statutory body created for approving/rejecting living organ donation and transplantation thereof.


73 Indian Transplant Registry, Year wise Report, available at:
which mainly includes transplants out of affection and attachment.

The arrest of persons involved in transplants done in Indraprastha Apollo Hospital Delhi\textsuperscript{74} and Hiranandani Hospital, Mumbai\textsuperscript{75} on the basis of fake documents depicts the sad story of how unscrupulous people in medical field are having their way and have made it an industry. The committee noted that there were no medical records, evidence of consent or even evidence of basic medical infrastructure.

In Gurgaon kidney racket senior Delhi police officials confessed that Kumar was first arrested (as Santosh Raut) in 1994 along with a group of surgeons and anaesthetists for conducting kidney transplants at a nursing home in Mumbai which had no license for conducting surgery. Kumar was arrested at least four times between 1994 and 2008, and obtained bail each time, following which he would disappear and resurface, running the same business in another part of the country. A government-appointed committee concluded that as many as 450 kidney transplants on foreign patients had been done in the nursing home within a span of four years i.e. from 1991 to 1994.\textsuperscript{76}

In Jan 2016 police arrested Prajapati hailing from Ahmedabad in an organ trade racket having links in Sri Lanka.\textsuperscript{77} But despite the arrest the kingpin of the organ sale racket is again out. Large scale organ sale rackets have been often reported in the country in over two decades but only handful of them have been reported to be prosecuted for violating THOTA. India has a flourishing, and illegal, trade in human organs. And the legislation designed to prevent it has failed.
V Need of health legislation

The scope of health legislation some 50 or 60 years ago was quite different to what it is today. In a sense, the evolution of health legislation is partly the story of evolution of medical and public health. In the last few decades the WHO has repeatedly advocated the use of health legislation as a potent means to achieve the well declared objective of health for all that initiated a global effort to define health and evolve and adopt legal strategies to implement the avowed targets. This strategy became necessary as the health status of hundreds of millions of people around the globe is not only worrisome but unacceptably pathetic. More than half the population of the world does not have access to adequate health care.

The WHO Constitution and several resolutions of the World Health Assembly have affirmed that health is a basic human right and worldwide social goal. Providing basic human needs and improvement in the quality of life of the people should be the main social plank of governments and WHO in the coming years. All the governments of the world, particularly developing countries like India have to devote their energies, efforts and resources towards the attainment by all citizens of a level of health that will permit them to lead a socially and economically productive life and formulating a health legislation will definitely prove to be effective in safeguarding the right to health of the citizens.

The international community is according more attention to fundamental rights, there has been a greater awareness among health policy-makers, administrators, consumers, and health activists about the rights of individuals with regard to access to health care facilities and related matters. In some countries this awareness has resulted in health-related rights being articulated in national constitutions and health codes. Many Fundamental Rights like right to life, right to work, right to education and right to security and social welfare etc. are related to right to health. The law conferring a right to health to a citizen correspondingly...
confers a duty on the State to protect that right and in an event of infringement of that right, the courts can adjudicate on the issue of infringement of the right to health and provide redressal.

**National Health Policy 2017**

The primary aim of the National Health Policy, 2017, is to inform, clarify, strengthen and prioritize the role of the government in shaping health systems in all its dimensions.\(^8\) The policy envisages as its goal the attainment of the highest possible level of health and well-being for all at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence.\(^9\)

The National Health policy emphasizes the key principles of affordability, universality, accountability from sustainable developmental goals aiming at achieving progressive universal health coverage. Highlighting the need of collaboration between the public and private sectors it specifically states that, tissue and organ transplantations and voluntary donations are areas where private sector provides services but it needs public interventions and support for getting organ donations. Recognising the need for awareness, the private sector and public sector could play a vital role in awareness generation.\(^10\) It also envisions the creation of appropriate Standard Regulatory framework for laboratories and imaging centers, specialized emerging services such as assisted reproductive techniques, surrogacy, stem cell banking, organ and tissue transplantation and nano-medicine.\(^11\)

Addressing the fundamental policy question as to whether health rights bill should be made to create right to health as a Fundamental Right at par with right to education, the policy document states, Right to healthcare covers a wide canvas, encompassing issues of preventive, curative, rehabilitative and palliative healthcare across rural and urban areas, infrastructure availability, health human resource availability, as also issues extending beyond health sector into the domain of poverty, equity, literacy, sanitation, nutrition, drinking water availability, etc. Excellent health care system needs to be in place to ensure


\(^{9}\) Id., para 2.1

\(^{10}\) Id. at 21.

\(^{11}\) Id. at 22.
effective implementation of the health rights at the grassroots level.\textsuperscript{85} The policy while supporting the need for moving in the direction of a rights based approach to healthcare takes note of financial and infrastructural constraints as major challenges to be overcome in order to ensure that the poorest of the poor stand to gain the maximum and are not embroiled in legalities. The policy therefore advocates a progressively incremental assurance based approach, with assured funding to create an enabling environment for realising health care as a right in the future.\textsuperscript{86}

A number of international covenants to which India is a joint signatory give us such a mandate and this could be used to make a national law. Indian judiciary has also given rulings to the effect that health care should be seen as fundamental right and a constitutional obligation flowing out of the right to life.

It also aims to improve population health status through concerted policy action in all sectors and expand preventive, promotive, curative, palliative and rehabilitative services provided by the public health sector and to achieve a significant reduction in out of pocket expenditure due to health care costs and also to assure universal availability of free, comprehensive primary health care services, as an entitlement in all spheres of health. The implementation of the policy will transform ‘right to health’ as enshrined in ‘right to life’ under article 21 of citizens of India into a reality.

\textbf{VI Conclusion}

The huge gap between the demand and supply of donor organ in India is evident of the fact that legislation has failed to achieve its purpose. Every year thousands of patients die of ESOF disease. National Organ and Tissue Transplant Organization, a national level organization set up under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India established in November 2015 in Delhi has to adopt a comprehensive approach for ensuring that ESOF patients do not die for want of a transplantable organ.

Legal tools are a necessity in organ procurement to allow transplant surgeons to remove

\textsuperscript{85} Id. at 27.
\textsuperscript{86} Id. at 28.
organs from potential sources. Legislations regulating transplants must have provisions to increase donor pool. In India THOTA, 1994 was enacted with intent to pave the way for smooth procedure for organ transplants so that lives of patients suffering from organ failure could be saved. 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.\textsuperscript{87} But the law has not been able to fill the gap between demand and supply of organs. The progressive law to promote organ donation has been brought on the statute book but in reality and for practical reasons it has not yielded desired results. It is suggested that we need to switch over to either presumed consent or Opting-out system of consent and tap cadaver organ pool from traffic accidents, brain dead patients along with generating awareness amongst masses about organ donation.