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Developmental Perspective of Organ Transplantation

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Abstract:

Successful human transplantations of cells, tissues and organs have relatively quite a long history. The key problem, however, always remains rejection and the side effects of preventing rejection. There exist reports of a Chinese physician named Pien Chi'ao exchanging the heart of a man with a strong spirit and weak will with another heart of a man with a weak spirit and a strong will. This was reportedly done to achieve a balance in each man. Similarly, there are reports of Roman Catholic accounts during the third-century whereby saints Damian and Cosmas replaced cancerous leg of the Roman deacon Justinian with the leg of a recently deceased Ethiopian.

It has been widely quoted that the ancient Indian Sage Charaka deals with internal medicine while Sage Sushruta includes features of organ and limb transplants. However, skin transplantations are the ones which are likely to have happened in the earliest of times. There are accounts of Indian surgeon Sushruta in the second century BC, who used autografted skin transplantation in nose reconstruction. The outcome of such attempted procedures is not documented well. Hence, in light of above quotes, it can conclusively be stated that the Hindu teachings have given more importance to the concept of soul, rather than body. There exists no reference in any of ancient Indian (hence Hindu) scriptures which discourages the donation of human organs to others who need them.

Introduction:

"After I die if I am buried I will rot. If I am burnt I will become ash but if my body is donated I will live to give life and happiness to many."

- Amit Abraham

Organ transplantation refers to a medical process whereby one person's organ is removed and transplanted to another person. This requires the consent of the donor in case he is alive and requires the assent of the next of kin in case the donor is dead. In most cases, the end state organ failure's only treatment is organ transplantation. Although its types include heart, lung, liver, pancreas, cornea, skin, and other transplants, the most carried out transplant is kidney transplantation globally.

Indian Perspective:

In Indian culture, organ donation has been a significant part for those following the Hindu way of living, which has been guided in the Vedas. The idea of saving others' lives has always been looked up to in Hinduism and hence organ donation is in keeping with these

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beliefs. Although there exist no direct mentions of organ donations in Indian scriptures, certain references in some books and scriptures may be taken as an implied encouragement of organ donations. Manu-smriti quotes:

"of all the things what it is possible to donate, to donate your own body is enormously more worthwhile."

Moreover, the concept of yajna which literally means 'sacrifice' or 'offering' has been given utmost importance in the Vedas. Similarly, in the list of ten niyamas or virtuous acts according to Indian scriptures, the third is daan or selfless giving. The Indian holy book Bhagwat Gita through Chapter 2:25 states:

"The soul is spoken of as imperceptible, inconceivable, and unchangeable. Knowing this, you should not grieve for the body. "

It has been widely quoted that the ancient Indian Sage Charaka deals with internal medicine while Sage Sushruta includes features of organ and limb transplants. However, skin transplantations are the ones which are likely to have happened in the earliest of times. There are accounts of Indian physicians Sushruta in the second century BC, who used auto-grafted skin replacement in nose reconstruction. The outcome of such attempted procedures is not documented well. Hence, in light of above quotes, it can conclusively be stated that the Hindu teachings have given more importance to the concept of soul, rather than body. There exists no reference in any of ancient Indian (hence Hindu) scriptures which discourages the donation of human organs to others who need them.

Research Methodology:

Objectives of the research:

1. Analyze the historical perspective of organ transplantation
2. Apply the analysis to find out the lapses in current legislative system
3. Identify if The Transplantation of Human Organ Act has been successful to achieve Right to Life?

Research Questions

- Considering the historical perspective, has the new age legislation evolved in helping people achieving Right to Life?
- Comparatively does the new amendment, Transplantation of Human Organs (Amendment) Act, 2011 serves its legislative intention in India?

This research compares two legislations related to organ transplantation and relates it to the history to evaluate whether the legislation has been successful in achieving its goal and understanding the Right to Life component in it thereby.

Prehistoric

Many different lands and cultures have mentioned organ transplantation through various religious texts, tales, customs and folklores. Many of the mythological texts have a part

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which has dealth with transplantation in one way or the other. One cannot fail to mention the story of the great Hindu Lord Ganesha here. Lord Shiva in anger and fury decapitated the head of his own son, Ganesha. Lord Shiva then on the request of his wife Parvati to restore their son, sent his servants to obtain the head of the first living being they saw. The servants got the head of an elephant and thus Lord Ganesha gained a new head.[i] Sati the daughter of Daksha had married Lord Shiva in spite of forbiddance from her father. Sati, then went to attend a sacred ceremony to which she was not invited for by her father. On being humiliated by her father she jumped into the sacred fire to commit suicide. On the knowledge of this, enraged Lord Shiva beheaded Daksha. The followers of Lord Shiva requested and convinced him to resurrect Daksha. The goat present nearby which was to be used as a sacrifice in *yajna*, Lord Shiva transplanted the head of the goat on the beheaded Daksha.

Vedic Period

Sushruta an ancient Indian physician also known as the father of plastic surgery belonged to Banaras now known as Varanasi. He complied his work known as "*Susruta Samhita*" which translates to the compendium of susruta. His complied work is notable for the amount of detail mentioned about surgery in his work. His texted is considered as the oldest text in the world on the topic of plastic surgery. Though the practise of the plastic surgery was prevalent in India, it was not much developed and during the time of Sushruta different techniques were used. The credit to invention of cosmetic surgery belongs to Sushruta. Reconstruction of nose and ears was an area which he focused upon.[ii] These techniques and practises continued to be followed for many centuries. The same techniques and practises were claimed to be used in the Middle East. Later in the fourteenth century, ancient texts containing the knowledge were acquired and studied in Europe. New improvements to the methods and techniques used in old India were made by the brancas and Tagliacozzi. But ranging from Sushruta to Tagliacozzi there was no reference or mention to the aspect of using another person as a donor. The East India Company established itself in India, and entered into various trade agreements with the Local rulers. Later large parts of India were under British influence. Many people who visited India Observed that nose reconstruction was successful and still done with the use of old techniques, and hence led to passing of the knowledge to the European Continent.

Modern Era

British scientist Robert Hooke, was given the liberty to conduct transplantation experiments in society. He was the one who recognised for the first time the concept of cellular structure, which was described in the Micrographia (Royal Society, September 1665).[iii] At the same time, one cannot fail to mention about the contributions of Abraham Trembley and John Hunter. Abraham Trembley successfully grafted the polyps there by giving a hope to the people that detached parts of human body can be re-joined.[iv] Hunter has successfully performed a gland grating on hens and cocks by interchanging their reproductive glands. British Doctors who observed the nose reconstruction surgery reported it, and then it was further published in the 'The Gentleman's Magazine and Historical Chronicle' in the October 1794 edition. The method was then quickly adopted in the Europe as it was way ahead and

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better than any other method prevailing in the Europe at that point of time. This method also came to be known as the 'Hindu Method'.[v] Even after this, till the beginning of 20th century, progress in regard to vascular and gland grafting was notable, not much progress in relation to organ transplantation was seen.

20th Century

In the beginning of the 20th century, Ernst Unger a German surgeon set up his own clinic in Berlin and carried out around 100 experimental kidney transplants on animals, but when performed practically on humans, the patients died over the course of next few days. War has often given birth to advances in technology, inventions, medical and many more. World War I provided with medical advancements which revolutionized medicine. The solution which is still in use to treat wounds today, the Dakin's Solution (Sodium Hypochlorite) was invented during this duration. Antiseptics and Anaesthesia which are very common nowadays, have their roots deep down into the World War period. But the World War I was a hard blow on to the medical advances in regard to the research and development of organ and tissue transplantation.[vi] But World War II by chance provided an opportunity to an zoologist Peter Medawar, who later became a central figure in the field of transplantation.[vii] Research continued and made progress throughout the world and finally a breakthrough was on December 23, 1954, when for the first time in the history a human kidney transplant was successful. The donor in here was the identical twin of the patient. In the year 1958, another transplantation was carried out which was a very important achievement as it surpassed the genetic barrier established in the previous transplant carried out in 1954. Here the donor was not identical twin of the patient, and the patient went on to survive for the next 20 years.[viii]The next few decades did not mark any new landmark progress as such but a continuous growth was always seen in regard to the practical aspects of kidney transplants. These practical aspects led to the increase in the survival rate.

Kidney transplants were further made possible in a much numbers as brain death of a person was also considered one form of death. The Statement of the Committee of the Harvard Medical School to inspect the definition of Brain Death defined the permanent coma as brain death. Before 1968, death was defined as and when the heart stops beating and the respiration ends. Death was considered to occur at a precise time and was not believed to be continuous in nature. This was due to the fact that till then heart was considered to be the central organ of the body.[ix] The acceptance of brain death led to a lot of organ transplants. One more thing that is to be observed is that the donor was generally the relative of the patient so that there is a match and few chances of rejection. Brain death was adopted by the World Medical Assembly (WMA) on August 1968. The declaration came to be known as WMA Declaration of Sydney on the Determination of Death and the Recovery of Organs. Deceased donation presents neither risks nor benefits to the donor because the donation occurs after death. Furthermore, individuals offerconsent for donation in advance of death (often years or decades), making it incomprehensible what organs or tissue will be suitable to truly donate at the time of demise.

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The next landmark step in the history of transplant was achieved by preservation of organs, transporting and sharing them. Various methods were tried and tested in the early 20th century but failed to produced desired results. But by mid-20th century methods were devised which could preserve the organ for a couple of hours. The later developments were much helpful as they helped preserve the organ for around 2-3 days.[x] Further the University of Wisconsin cold storage solution (UW solution) made it possible to store the organs as long as possible and hence allowing them to transport to long distances.[xi]

The 1960s – Period of trial and test

Transplantation of other organs such as liver, heart, lungs and pancreas was also progressing at the same time. A lot of lung transplants were performed on animals and after a thorough research a lung transplantation was performed on a human body in the year 1963 by two surgeons Hardy and Webb at the University of Mississippi. The patient survived for 18 days after dying of renal infections. In the upcoming 10 – 15 years a number of lung transplants were performed[xii], but the patients could not survive for a period of more than 2-3 weeks. After this a few observations were made and problem was identified to be bronchial disruption. Various tests on animals were conducted in the labs to solve the issue of bronchial disruptions. The cause was identified to be the use of Immunosuppressant (prednisone and azathioprine) which would not allow the required bronchial healing to occur.[xiii]

1963 also marked for the year in which a first liver transplant was carried out. But sadly the patient who was a three-year-old boy died during the surgery. Later transplants were also not successful as the immunosuppressant's used to give to the patients of Liver transplant were the same as those given to the Kidney transplant.[xiv]This posed a large threat as the patients were vulnerable to infections.

In the year 1967-86 two heart transplant surgeries were performed. First in the year 1976, by Surgeon C. Barnard and the second in 1968 by Clane in UK. [xv] Over the course of next few years, more than hundred heart transplants were performed, by the results were very unsatisfactory as no one of them could survive.

Introduction of Cyclosporine

After a transplant, the body tends to reject the newly attached organ and treats it as a foreign. The body in-turn activates its immune system against the new organ to damage or destroy it. In order to prevent the rejection of the newly transplanted organs, immunosuppressant's are used. These drugs work by reducing the immunity or suppressing the immunity. Cyclosporine was discovered in the year 1976 and was used in the chemical process from1984 onwards. This drug brought a tremendous change in the field of organ transplantation.

It changed the scenario of organ transplant as it made the success rate of transplant of kidney, lung and heart much higher ever than before. Before the introduction of immunosuppressant's, the outcomes of transplants were extremely poor. Cyclosporine was a drug which did not cause any infections and also did not harm much vital processes in the

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body. A lot of kidney, liver, heart and lung transplants took place after the introduction and use of cyclosporine started. Mortality due to graft rejection started to become uncommon now.

Post 1990s organ transplantation was conducted on a very frequent basis. New surgery method known as Split Liver Transplant (SLT) made it possible to share one same liver with, adult, and a pediatrics. In some rare cases it could be shared between two recipients as well, but was since it was risk, it was not used frequently. Moreover, at the beginning of the 1990 two new immunosuppressant, Mycophenolate Mophetil (MMF), the 2-morpholino- ethyl ester of mycophenolic acid (MPA) were introduced and used. This in run became the most effective immunosuppressant and is the single most used immunosuppressant in solid organ transplantation.[xvi] New problems such as long-term effects of immunosuppressant, organ shortage, donor morbidity and allocation began to arise. In the year 1995, David White was able to transplant heart of a pig into a money. But these transplants pose a threat as, the species among which the transplant takes place are different and transfer of viruses. One more option was explored with the passage of time and that was of xenotransplantation.

Xenotransplantation

The Food and Drug Administration of USA defined Xenotransplantation as, "Xenotransplantation is any procedure that involves the transplantation, implantation or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, organs or tissues which have had *ex vivo*interaction with live non-human animal cells, tissues or organs."[xvii]Researches have always been performed on animals first and after that on man. Efforts have been made in the early 20th century after animal organs such as kidneys were transplanted to humans, but could not succeed. All the animal organs transplanted into humans have failed to perform the necessary function. In the year 1995, David White was able to transplant heart of a pig into a monkey. However, these transplants pose a threat as, the species among which the transplant takes place are different and transfer of viruses.

21st Century

Though cyclosporine changed the scenario of transplantation and allowed more transplantations to be carried out, there were some major adverse effects related to it. The new approach was to suppress the immune system, but only in relation to the newly transplanted organ. This approach was more focused upon as it reduced the risk of serious infections which could pose a threat to life. Ideal scenario was when the immune system of patient's body could tolerate the transplanted foreign organ without the use of immunosuppression. Tolerance now is one of the most sought-after goal by the doctors.[xviii]

The research and development in the field of organ transplantation still continues as there is always something new to innovate and improve the life of the patients. Wide range of organs can now be transplanted due to developments in clinical and surgical aspects. The advances in the field though always pose a challenge in some way or the other, they have always found

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a way to increase the life term of a patient with life threating illness. Organ donation remains the biggest problem in the field of organ transplantation.

India – History of Legislations

Health as a subject is mentioned in the state list In the Constitution of India. The list-II, i.e. the state list, entry 6 reads as Public Health and Sanitation; Hospitals and Dispensaries. Moreover, the Indian judiciary through its judgements has recognized the right to life and right to health in various cases. With the passage of time, there were developments in the medical field and accordingly the Indian Parliament has passed various legislations for the benefit of the fellow citizens. Gradually organ transplantation was introduced in India and was accepted by the public too. Many states had formulated and enacted their own legislations on organ transplantation to regulate the organ transplantation. The first legislation in regard to the organ transplantation in India was the BOMBAY CORNEAL GRAFTING ACT, 1957. The aim of the act was to regulate the donation of the eyes of a deceased person.[xix] The legislation enacted prior to the Transplantation of Human Organ Act, 1994 were very specific in nature, i.e. focused on a single organ in the specific act. This can be well justified with the following examples, Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 [DELHI]and the Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 [DELHI], The Maharashtra Kidney Transplantation Act, 1982. Tamil Nadu and Karnataka were the two other states who had legislations enacted prior to the enactment of the Transplantation of Human Organ Act, 1994.

The L. M. Singhvi Committee report played a very important role in the formulation of the THO legislation and defining brain death in the Indian Scenario. The committee defined death as brain stem cell death, they formulated guidelines for removal and transplant of the human organs, identified formalities to be completed before and after the transplant. It also recommended that the trade of human organs must be prohibited and made a punishable offence. It provided for a manner in which the brain death should be utilized to facilitate the organ transplantation.[xx]Based on the committee report, a bill was drafted and presented. It was passed in the year 1994, with effect from the 4th of February 1995.

The main aim why this act was enacted was related to the fact that there were a lot of unrelated transplants being done in exchange of the money. The weaker sections were the one who were the most involved in this kind of activity. There was a big criticism to this from all over the world. The THO Act made the unrelated transplants illegal and allowed for the provision of organ donation from the deceased who is brain dead. This move was supposed to over the shortage of organ supply as it would allow the organs to be extracted from the brain dead deceased. However, the act failed to achieve it ultimate aim, and there were many illegal renal transplants being conducted across the country without any due process followed. The illegal unrelated transplants were conducted under the seal form the authorization committee. This was then further challenged in the case of Balbir Singh v. The Authorization Committee. Thereafter a committee titles as the THOA review committee was constituted as per the reference to the judgement Balbir Singh v. The authorisation committee, delivered by Justice Man Mohan Sarin of High Court of Delhi in WP(C) 813/2004. The aim of the committee was

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to review the efficacy relevance and impact of the legal provisions contained in both the Transplantation of Human Organs Act, 1994 as well as the Transplantation of Human Organs Rules, 1994 (TOHO Rules). Various question in the form of terms of reference were address in the report of the THOA review committee. The committee conducted various meeting and with an interdisciplinary approach came to the conclusion on various issues and question raised before. The ground realities were considered in order to address the merit and demerits of the existing law at that point of time. In order for the act and rules to be properly implemented some necessary changes in the Act and the Rules were suggested.

The review committee suggested that the authorization committee should also be responsible for certifying the "near relative". This was suggested by keeping into account the valuable time, functional efficiency and to avoid duality of opinion. Other important suggestions are as follows,

- A national organ transplant program must be set up with a special emphasis on promoting cadaver donations;
- It should be made mandatory for all the ICU/Treating Medical Staff in all hospitals to request relatives of brain-dead patients to consider organ donation;
- Hospitals with adequate ICU facilities and availability of specialists to diagnose brain death should be designated as 'cadaver donor organ harvesting centers';
- Transplant coordinators should be assigned in hospitals with transplant activity, separate from the Transplant team, to liaise between the treating physician, the relatives of the potential brain-dead donor and the Organ Retrieval and Banking Organization (at the All India Institute of Medical Sciences);
- The next of kin of the deceased organ donor must be given preferred status in the organ transplantation waiting list if they require organ transplantation in the future;
- Promoting 'swap operations' where two different but willing 'near relative' donors are permitted to donate their organs in exchange without monetary consideration;
- Providing benefits to Live Donors through a comprehensive healthcare scheme to provide lifelong free renal/liver check-ups, and medical care; and to provide a customized Life Insurance Policy worth Rs. 2 Lakhs for 3 years (with one premium to be paid by the recipient) to secure the donor against mortality risk due to organ donation;
- Any expenditures or loss of income suffered due to organ donation/ transplantation must be compensated;
- Establishing a fund to promote Cadaver Organ Donations[xxi]

After the due consideration of the above-mentioned report, and the Draft Guiding Principles of Organ Transplantation of the World Health Organisation, the Transplantation of Human Organs (Amendment) Bill, 2009 was introduced.[xxii]The bill was passed and enacted into an Act called as, The Transplantation of Human Organs (Amendment) Act, 2011, with its key features as follows,

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a. it expanded the definition of 'near relative' to include grandparents and grandchildren;
b. it expanded the ambit of the Act to include tissues;
c. it provided for the appointment of transplant coordinators in hospitals to facilitate deceased donor donations;
d. it placed a responsibility on medical practitioners to ascertain whether the deceased person had expressed a wish to donate their organs at any time prior to their death;
e. it regulated the donation of organs to foreign nationals, allowing donation only to near relatives;
f. it provided for swap donations;
g. it provided for the appointment of Appropriate Authorities and a National Human Organs and Tissues Removal and Storage Network with regional equivalents and
h. it introduced new categories of offences and made the punishment for violation of the provisions of the Act more stringent.
i. A living donor is classified as either a near relative or a non-related donor. A near-relative needs permission of the surgeon of the transplant center to donate his/ her organ. A non-related donor needs permission of an Authorisation Committee established by the state to donate his organs.
j. The Act defines a "deceased person" as anyone who has no sign of life due to brain-stem death or in a cardiopulmonary sense. It also defines "brain-stem death". The Act stipulates that organs can be removed from cadavers only if the person or his near relative has authorised such removal.

A comparison table between the 1994 Act and the 2011 Act

	Transplantation of Human Organs Act, 1994	**Transplantation of Human Organs (Amendment) Act, 2011**
Scope	Regulates removal, storage and transplantation of human organs.	Includes tissues along with organs
Definition	"Near relative" means spouse, son, daughter, father, mother, brother, sister. "Tissue" and "Transplant Coordinator" not defined.	Grandparents and Grandchildren now included in near relatives. "Tissue" means a group of cells except blood performing a particular function in the human body.[xxiii] "Transplant coordinator" means a person of the hospital appointed for coordinating matters related to transplantation[xxiv]

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Removal of organs from deceased person	A donor may authorise removal of organs before his death for therapeutic purposes. If no such authorisation was given but no objection was expressed, the person who has legal possession of the body may authorise such removal unless he believes the near relatives of the deceased may object.	Adding a provision that a doctor/ surgeonwill ask the patient or family member of every person admitted to the ICU whether any previousauthorization had been made. If not, then the patient should be made aware of the option to authorize such donation.
Live donation	A near relative is permitted to donate his organ without approval of the Authorisation Committee. Any live donation to a non near-relative for reason of affection needs the approval of the Authorisation Committee.	Adds that if the donor or recipient is a foreign national, prior approval of the Authorisation Committee is required (transplantation will not be allowed unless they are near relatives). Prohibits removal of organs or tissues from a minor before his death except in a manner to be prescribed.
Organ swapping	No Provision	A pair of donor and recipient who are near relatives but whose organs do not medically match for transplantation are permitted to swap with another pair of such persons. This has to be approved by the Authorization Committee
Advisory Committee	No provision	The central and state governments shall provide for constitution of Advisory Committee for a period of two years to aid and advise the appropriate authority
Other provisions	No provision	The central govt. may establish a National Human Organs and Tissues Removal and Storage Network at any place. Rs 5 Crore has been assigned in the Financial Memo. The Central Government will have to keep a registry of the donors and recipients of human cells, organs and tissues.

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		It has been obligatory for the hospital staff to appeal relatives of brain-dead patients for organ donation.
Penalties	Penalty for removal of organ without any proper authority is punished with imprisonment for a maximum of five years and it's fined up to Rs. 10,000. Penalty for making or receiving payment for supplying human organs is imprisonment for 2-7 years and a fine between Rs.10,000 and 20,000. Penalty for contravening any other provisions is imprisonment for a maximum term of 3 years or with fine of up to Rs. 5,000	Increases penalty to imprisonment for a maximum of ten years and a fine of up to Rs. 5 lakh. Increases penalty to imprisonment for 5-10 years and a fine between Rs. 5 and 20 lakh. Adding offence of instigating in submission of false documents to prove the doner to be a near relative. Increases penalty to imprisonment for a maximum of 5 years or with fine of up to Rs. 5 lakh.
Brain death **Declaration**	Neurologist & Neurosurgeon	Neurologist & Neurosurgeon along with anesthetist and physician

Suggestions and Conclusion

Though organ transplant is a modern marvel which has saved lives of millions of patients, shortage of organs is a problem which all the countries face today. Improvement in the medical science and research has made it possible to perform transplants which man could not image a few decades ago. But the development has not been able to catch-up with the number of organs required for organs transplantation. There are a lot of people who await an organ transplant, but do not get one due to the organ shortage.

A lot of factors come into play while determining what might be the cause of shortage of organs. Somewhere it might be absence of medical infrastructure, while in other places it might be the determination of brain death, or in case like china, religious aspect would also come into play. (A standardisation of the procedure to determine brain death would help solve to problem to a great extent.)

Families often don not subscribe to the idea of brain death. When they are informed that the patient is brain dead, they have a misconception that the person is in come since the heart is beating, unknown to the fact that brain death in its very basic nature is irreversible. Moreover, the general public has no idea about organ donation, the organ donor card and the process of

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organ donation. If possible, every ICU ward inside hospital should display information about organ donation and its legal and ethical aspects.

Organs can be preserved only for a limited time. During this time, the organ has to be transported. In order to facilitate the transport, necessary infrastructure should be established. Green corridor which allows transportation of organs faster should be formulated and executed by the local city police when the need be.

As per the information provided by the International Registry in Organ Donation & Transplantation (IRODaT), the current organ donation rate in India is 0.65 per million population. 500,000 people die due to non-availability of organs, 200,000 people die due to vital organ diseases such as liver and 50,000 people die owing to heart disease. Besides, 150,000 people await a kidney transplant yet only 5,000 get among them.[xxv]

The most helpful would be the opt-out system which makes every person a donor after death.

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