



# Organ Transplantation; an Analysis on Legal Validity of Organs Transplantation in Sri Lanka and Some Other Countries

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## Keywords

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## ABSTRACT

Organ transplantation has vital importance in the medico-legal system throughout the world. The transplantation of organs is done according to the legal framework of each country and based on rules, regulations, circulars, protocols and guidelines of health and legal authorities. Because of this egregiousness procedure, very clear knowledge and experience regarding medico-legal issues and ethical aspects are mandatory for an effective transplantation system. Here in this article, attempts to critically evaluate the medico-legal and ethical aspects pertaining to the existing system of organ transplantation process in Sri Lanka and compare such local provisions with some other countries.

## Introduction

Transplantation is a medical procedure that restores the function of a person's inactive organ or tissue by replacing it with a healthy one. In some cases, despite great advances in medicine, transplantation is the only option. Transplants greatly improve the patient's quality of life and give them another chance to live. A transplant can only take place if there is an organ from the donor. Patients can also receive organs from living people as well as dead people. Living people can donate organs such as kidneys, liver, lungs, pancreas, intestines, and blood and also after donation still live a normal life. However many of the transplanted organs are from deceased donors and by law, the sovereignty of the decision for deceased donors ultimately rests with the next of kin of the deceased. Thus, organ donors may comprise living, brain dead, or die through circulatory death. Tissues can be retrieved from donors who die of circulatory death as well as brain death within 24 hours of cardiac arrest. From dead person organs that can be donated include the kidneys, lungs, liver, pancreas, and heart, as well as tissues that include the eyes, bone marrow, skin, bones, heart valves, nerves, brain, ear bones and eardrum.

## **The History of Organ Transplantation**

The first triumphant organ transplant took place in 1954 with a kidney transplant between Dr. Joseph Murray and his team of identical twin brothers in Boston. This is not the first time a kidney transplant has been reported. In 1936, Dr. Yu Yu Voronoi reported a kidney transplant using a deceased donor. That and several kidney transplants in Boston by Dr. David Hume in the early 1950s were unsuccessful. After the success of the transplant was demonstrated and the production of immunosuppressive drugs allowed the survival of the identical twins' organs, the transplant progressed rapidly.

In the 18th century, organ transplants experimented on animals and humans. There have been many failures over the years, but by the middle of the 20th century, scientists had successfully transplanted organs. Kidney, liver, intestinal, lung, pancreas, and heart transplants are now considered common medical treatments.

Significant medical advances, such as tissue typing and immunosuppression, have led to more organ transplants and longer survivors. The most notable development in this area was the discovery of an immunosuppressive drug by Jean Borel in the mid-1970s. Cyclosporine was approved for business use in November 1983. Unluckily, the need for organ transplants outweighs the supply of organs. But as medical technology advances and more donors become available, the number of people living longer and healthier lives continues to rise each year.

## **Types of Organ Transplantation**

Autotransplant; the first types of transplantation is automatic transplantation. That is, he will be the person in charge of providing what the patient needs. However, this can be done when a patient needs a piece of skin from another part of the body, and this automatic transplant is done when the bone marrow is self-donating if there is cancer. This transplant is very safe, but most of all, it has the advantage that our body does not refuse to donate because it is our flesh and bones.

Isotransplant; this transplant is completely different from the previous automatic transplant method. In this case, the donor and the recipient are different, genetically they are the same. So they donate what the twin needs to save one of the twins' illness and the other's life. Because twins share genetic information, there is very little chance of a donated organ being rejected. There is always the possibility that the body will reject the organ and fail to deal with it properly. However, this is a very small percentage and is not something that usually happens.

Allotransplant; There are completely different donors and recipients within the type of transplant. They do not share genetics. They do not belong to the same family. This is the most known type of transplant and the most risky. This is because a thorough study of the compatibility between the donor and the recipient must be done.

Xenotransplant; the final type in this transplant is not only about two genetically different individuals, but also about the species. For example, if a patient wants a heart valve transplant and for some reason there is nothing compatible or does not come from a human, it can be obtained from a donor. However, the risk of rejection is slightly higher.

## **Brain- stem death**

In Sri Lanka, section 15 of The Transplantation of Human Tissues Act No 48 of 1987 the brain death is defined as irreversible and complete cessation of the functions or loss of all functions of the brain and brain stem. Also in the United States, The Uniform Determination of Death Act 1981 has defined death as either irreversible cessation of respiratory function or all functions of the entire brain, including the brain stem. In some law books, this described

as a 'physiological decapitation' which used for legal purposes. Here, can give support to live through a machine to such diseased person to continue respiration of the brain and the heartbeat which could allow the other tissues to live. However, there are three important findings in brain death namely coma, absence of brainstem reflexes, and apnoea. But in many countries, brain death has been recognized as the death of an individual.

Brain- stem death should be diagnosed in situations such as switching off the supporting machine and organ transplantation. In Sri Lanka, clinical diagnosis of brain death should be done by two different doctors separately by examining the patient at two different time intervals and one of them should ideally be the specialist in charge of the patient and neither of them should be interested in organ transplantation with reference to the concerned patient. In India for the clinical diagnosis of brain death should be done by two different doctors and they have to be nominated by the relevant authority of the country and also one of them should be an expert in the field of neurology. In the UK clinical diagnosis of brain death should be done by two medical practitioners who holding full GMC registration for more than 5 years and one of them should be a consultant for diagnosis of brain stem death and also should be independent of the transplantation party.

So the concept of brain death has a key role in organ transplantation and donation. The Certificate of Death is also an important factor not only in organ transplantation but also in many other legal matters such as money transactions and cases of properties. Therefore all the death has to be registered in Civil Registration and Vital Statistics (CRVS). However, the awareness of brain death and organ transplantation is still questionable among the society in some countries including Sri Lanka because of the lack of knowledge regarding this concept.

Although donations of organs and tissues upon death are rare, it is to some extent practices in Sri Lanka and most road traffic accidents, suicides and homicides lead to brain death of many individuals in Sri Lanka. The majority of them are younger and middles ages that potential kidney, bowel, pancreas and liver donors.

### **Living donation**

A living donation takes place when a person donates an organ to another while he is alive. Most living donations happen between family members/ relatives or close friends. The paired organs such as kidneys or regenerative tissue such as liver, lung, pancreas and intestine can be donated during life. However, in instances where the living organ donors are related to the recipient genetically, there is a susceptibility risk of organ failure later in life due to shared inheritance of genetic variants or common environmental exposure. Although related living kidney donors are at higher risk compared to unrelated living kidney donors at the end-stage. Therefore the surgeon who transplants the organs has to be more careful because there is endanger to the life of a healthy living person. As a consequence, some argue that organ donation from living persons should be abandoned. However, in the USA lots of living organ donations are being reported each year. Living donation can be considered as the backbone of organ transplantation in many countries and as a result of that, it occurs lots of unacceptable transplantation practices and processes. Nevertheless, according to the statements of the World Health Organization (WHO), the majority of organs for the transplanting process are from living donors. In most of the developing countries including Sri Lanka, almost all kidney transplantations are from living donors. However while some are having successful kidney transplantations, some had to die due to renal failure while waiting for transplantation.

In Sri Lanka, organ transplantation is limited to transplantation of kidneys and liver at present. Also, the supply of organs is mainly received by living donors. However, there is a shortage of organs for transplantation because of a significant wastage of potentially transplantable deceased donor organs. Although deceased donor organ transplantation programs, well established in some countries, it is still in the early stage in Sri Lanka.

According to WHO specifically mentioned that sales of organs are a violation of the Universal Declaration of Human Rights and as well as the human body and its parts cannot be subject to commercial transactions and giving and receiving money for organs should be prohibited. Because there are lots of organ trafficking happening in many countries by way of kidnapping lots of living people, especially middle ages and children. Therefore the WHO had advised the physicians or surgeons not to transplant the organs if they are any reason to believe that such organs have been obtained by commercial transactions. However, commercial trade or sale of human organs is illegal in all countries except Iran.

In the USA in the court decision on Scheloendorff Justice Benjamin Cardozo declared that "every human being of adult years and sound mind has a right to determine what shall be done with her own body". According to that decision, it can be identified that in most democratic countries there is an implied ethical right to decide what to do to your own body.

### **Medico - legal aspect and ethics**

Country to country the legal validity of the transplantation concept might be different and may also have other medical circulars as well. Some countries allow the donors to agree or refuse donation or give that choice to the relatives. So here the consent is very important because when giving consent, to transplant the organs there are two types of consent knowingly explicit consent and presumed consent. Explicit consent consists of the donor giving direct consent through proper registration depending on the country and in the presumed consent it is assumed that individuals do intend to donate their organs to medical use when they died.

#### *Sri Lanka*

In Sri Lanka the concept of transplantation of the organs govern by the Transplantation of Human Tissues Act No 48 of 1987 and the Directorate General of Health Services' (DHHS) Circulars of Ministry of Health on Organ Transplantation which describe procedures for the donation and removal of organs, tissues or any part of the body for the purpose of scientific, educational and research purposes. However, there are differences between the currently practiced laws in Sri Lanka and the laws practice in other countries. According to the current relevant procedures in Sri Lanka, Section 2 of the Transplantation Act stipulated that, any person who is above the age of 21, can give consent to the donation of the body or any part of the body or any tissues after his or her death for the purpose of medical education, researches or for the use on any living person. Section 5 of the Transplantation Act stated that, in situations where, any person who has not given the consent for a donation prior to the death, the law allows to the next of kin of such diseased person who is above the age of 21 to give prior consent for such donation. So here the age is an essential factor that influences the success of transplantations. In this section it is also mentioned that, on the death of any child, both parents or in the absence or incapacity of one parent, the other parent or in the absence or incapacity of both parents the guardian of the diseased child can give consent for removal of the body or any part of the body or any tissues in writing.

Under Section 4 of the Transplantation Act a donation effective upon death may be made to,

- Any government hospital
- Any medical practitioner
- Any dentist
- Any prescribed institution

Also in situations where the donor has not specified the donee or where such donee is not available, the nearest government hospital or any prescribed institution to the place where the donor died shall be considered as the donee.

In accordance with the Part 8 Special Proceedings Chapter 30 "Inquests of Death" in Criminal Procedure Code No 15 of 1979 in Sri Lanka, the dead body in a medico-legal investigation is release subject to an inquest followed by autopsy examination. After the confirmation of brain death and when the consent for transplantation has been obtained from the next of kin, the Judicial Medical Officer (JMO) and the coroner will be informed as such in writing and also the coroner should authorize the retrieval of the organs by the transplantation group before the JMO who is part of that group and then JMO should prepare a report and submit to the nearest Magistrate Court (MC). Furthermore the surgeon who conducts the organ retrieving should provide a comprehensive report specially, about the procedure carried out, findings, and the condition of the organs. In the medical report on the retrieval of the organs from a diseased donor for transplantation, it should include the followings,

- Details of the decease person- Name/Age/gender/ address/Bed Head Ticket number
- Name of the next of kin consenting for organ donation/ address and the relationship
- Name of this hospital/ date/time (brain death)
- Name of the surgeon/s who retrieval the organs (Prof./ Dr.)
- Date, time and place of the procedure (retrieval of organs)
- Name of the organ/s (e.g. lungs/ kidney/heart)
- Side of the organ ( e.g. Left /Right)
- Weight of the organ/s
- Size of the organ retrieved
- Macroscopic appearance
- Surgical procedure with details of the incisions and date/time and name/s of the transplant group
- Colour photographs of the organ with a scale (more desirable)

Those included details should be by means of the guidelines stipulated in the DHHS, which is necessary for subsequent medico-legal procedures.

In relation to the current relevant laws and practices in Sri Lanka, to conduct the retrieval of organs from a victim who is deemed brain dead, should obtain a court order from Magistrate Court for removal of such organs by forwarding a declaration of death which is known as B-33 Form (not the death certificate) through investigating police officer or through a lawyer of the transplantation group. Nevertheless, at some instances the removal and transplantation take place with the compliance of the JMO and inquirer with the support from the investigating police officers.

In accordance with the Section 17 of the Transplantation Act, any person shall not buy, sell or deal directly or indirectly, body or any part of the body or any tissues for dental and medical education, researchers, for advancement of medical science or for use on any living person for a valuable consideration, without the prior approval of the Minister and if any person acts in the violation of this section he shall be guilty of an offence under the relevant laws in Sri Lanka.

#### *United Kingdom*

In the United Kingdom, legal provisions governing the medical and scientific practice of the corpse have largely emerged from statute law. It goes back to the Human Tissues Act of 1961 and the Corneal Grafting Act of 1952 for

organ transplantation. These original criteria controlled the removal and use of tissue and organs obtained from dead bodies. Current laws govern the removal, storage and use of corpses and parts for transplantation. These legal origins vary throughout the United Kingdom after devolution, and the Human Tissues Act 2004 applies to England, Wales and Northern Ireland, and the Human Tissues Act 2006 applies to Scotland. The 2004 Act is a comprehensive law that applies to many uses and materials obtained from the living and the dead. The Scottish Constitution applies only to items obtained from the deceased. Thus, unlike the 2004 Act, it is not a comprehensive legislative framework, but as a result of an agreement reached with the Scottish Executive, many other frameworks and processes of that Act also operate in Scotland in the manner of the Human Tissue Authority.

The Human Tissue Act 2004 implements a legal framework for organ donation in England, Wales and Northern Ireland. The Human Tissue Act also sets out a licensing framework for the storage and use of human organs and tissues from living things and the removal, storage and use of human organs and tissues from the dead. According to Section 33 of the Human Tissue Act, a person is guilty of removing or using an organ from a living person for transplantation if the conditions set out in the regulations are not met. And also Section 32 of the Human Tissue Act generates errors related to the commercial transactions of human organs, namely the awarding or receiving of a gift for the provision of an organ or a semi-organ. For these offences, the penalty is up to three years imprisonment, a fine or both.

The legal frame for Scotland is stated in section 17 of the Human Tissue Act 2006. The role of the Human Tissue Authority in living organ donation is to ensure that no gift is requested or submitted for organ donation and that there is a valid agreement for the removal and use of organs or partial organs for transplantation.

The Human Tissue Act agrees with the basic principle of the legal storage and use of human bodies, body parts, organs and tissues and the removal of fluid from the bodies of the dead. The Human Tissue Act needs the acquiescence of patient to use organs or parts obtained from a living or deceased person for transplantation.

#### *India*

Organ donation is legal under Indian law. The Government of India enacted the Human Organ Transplantation Act in 1994, which allows organ donation. The Human Organ Transplantation Act governs the removal, storage and transplantation of human organs for therapeutic purposes and prevents commercial transactions of human organs. This act is now adopted by all States besides Andhra Pradesh, Jammu and Kashmir, who have their own comparable legislation. And also the Human Organ Transplantation Act was amended in 2009 to regulate the transplantation of body tissues with human organs.

By law, dead and living donors are allowed to donate their organs. According to Transplantation of Human Organs and Tissues Act 1994, living donors are allowed to donate the following:

- One of their kidneys
- Part of the pancreas
- A portion of the liver
- Living donors must be over 18 years of age.

And also recognizes brain death as a form of death. According to the Act, brain stem death is identified as a legal death in India. In India, dead donors can donate six life-saving organs, such as the pancreas, liver, lungs, heart, kidneys, and intestines. Organ donation from a person who is not a "close relative" wants the permission of the State Authorization Committee. If found guilty of trafficking in human organs, the donor and recipient will be

punished. The Human Organ Transplantation Act of 2009 expands the definition of "close relative" to include grandparents and grandchildren in addition to parents, children, brother, sister and spouse.

In India, a panel of four doctors must declare your brain dead before you can harvest your organs. This is done after a series of thorough tests - corneal reflex examination, ear reflex examination, gag reflex examination and Aphenia reflex test within a six-hour time frame. The committee should include - the medical administrator in charge of the hospital, an authorized specialist, a neurologist/neurosurgeon and the medical officer treating a patient. In many parts of the world, these tests are performed only once.

### *South Africa*

In South African law, the National Health Act does not specify who can agree to donate human tissue to living persons. Nevertheless, the regulations do not remove tissue, blood, or gametes from another organism's unless the donor himself is over 18 years of age or with the written consent of the donor's parents or guardians under 18 years of age. According to the law, individuals under the age of 18 cannot donate tissue that cannot be replaced by natural processes, nor can they donate gametes.

The law defines death as 'brain death', but it does not say who should decide this. In organ transplants, the death of the deceased must be determined by two physicians, one of whom must have been qualified for at least 5 years and none of them must be members of the transplant team.

Under South African law, the provisions of the Human Tissue Act, which have been removed from the National Health Act, are incorporated into its regulations. Nonetheless, the new provisions of the Second Amendment provide strict control over organ transplants for non-South African citizens or non-permanent residents and make it illegal to charge for human organs.

Some aspects of the Human Tissues Act, which were not covered by the National Health Act, are included in the regulations.

- The parties are responsible for determining the death of a person whose organs have to be removed for transplant purposes.
- The need to obtain a tissue harvest within 24 hours from the donated bodies.
- Removal of eye tissue
- The uniqueness of the rights regarding tissue donation.
- Confidentiality and publicity of tissue and organ transplantation.

### *Common Legal, Social and Ethical Issues in Organ Transplantation*

Organ transplants are numerous help to the medical industry and can save the lives of those who would have died otherwise.

Ethical issues: When discussing ethical issues, the ethical requirements of transplantation can be stated in three ways: The first is medical integrity. Accordingly, the trust of patients and the general public in physicians should not be compromised for the benefit of another. If the person cannot make that donation, it is not their doctor. The second is scientific validity. Basic biology and technology must be adequately guaranteed to provide the potential for beneficial returns in each case. The final ethical requirement is Consent. Consent based simultaneous information adequately performed, unforced and weighed and understood.

Legal and social issues: Kidney trade is a global phenomenon. It is found in both the developing and the developed world. Demand for this speciality has grown significantly as a result of recent corporate scandals. Brokers have taken steps to sell the kidneys to cover the shortfall. Two central issues need to be addressed in organ trafficking: the effectiveness of current law enforcement, and the elimination of financial incentives which have for people to donate their organs. Furthermore, organ transplants from one person to another also have rising religious and social issues.

## CONCLUSION

In developing countries including Sri Lanka there is a clear necessity to strengthen and develop organ transplantation and donation programs because of lack of knowledge and awareness among the society. Through conducting effective awareness programs and through media, regarding organ donation and transplantation at national and local level under the guidelines and supervision of the relevant authorities we can give advices and knowledge to the general public by explaining the importance of this concept and overcome future barriers that impact to effective and acceptable organ transplantation process. Also the government should actively engage with this area with the support of the Minister of Health and the respective authorities to ban organ trafficking which result to lots of illegal transplantations and introduce new health circulars and legal framework and also manage existing legal framework. Most of developing countries including Sri Lanka, India and Philippines has to face this organ trafficking and selling organs in illegal way. As well as some people are voluntarily sell their organs because of poverty and pay off their debts. As a consequence there are lots of kidneys transplantations are happening throughout the world since human beings are born with two kidneys but need only one to survive. Therefore living donors are willing to donate one kidney to another person who may ask for. Therefore in every country the health circulars and legal validity for the organ donation and transplantation process has to be in good standard, because it is very crucial process which may result to save a life or otherwise put it in to danger. As a developing country Sri Lanka should enforce more reliable health circulars and legal framework to organ transplantation process and for its development.

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