

## IMPACT OF TRANSPLANTATION OF HUMAN ORGANS ACT, 1994 ON HEALTHCARE SERVICES IN STATE OF MAHARASHTRA

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### **Abstract**

*Transplantation of Human Organs and Tissues Act, 1994 is only to prevent commercial dealings in human organs and tissues. World Health Organization (WHO) has developed a set of guidelines on human organ transplantation. National human rights commission was very much concerned about the illegal trade/business in human organs especially trading kidneys which involved human rights. Family members of a deceased person can decide to donate the organs of a deceased. Decision can be taken by deceased's spouse, adult children, parents, adult siblings or guardian. Doctor has to obtain free consent from the family members before removing organs. The illegal trading of human organs is unethical and serious violation of human rights and hence there was a need for law to provide for the regulation of removal, storage and transplantation of the human organs for therapeutic purposes and for the prevention of commercial dealings in human organs. For this reason Government of India has enacted the Transplantation of Human Organ Act, 1994.*

**Key Words :** *Transplantation, Human Organs, Tissues, Deceased, Brain Stem Death, Kidney, Heterotransplantation, Autotransplantation, Homotransplantations.*

### **1. Introduction**

In the past there was no laws to prevent the illegal removal and donation of human organs. National human rights commission was very much concerned about the illegal trade/business in human organs especially trading kidneys which involved human rights. Many doctors were involved in organ trafficking especially trading kidney. National human rights commission has noticed that many organ transplant donors were abused in kidney donations with minimal price or amount. In many cases the kidney donor unrelated and unacquainted with the person who requires the kidney. There were many commission agents in this racket, used amount for the kidney was collected from the recipient and very minimal amount was paid to kidney donor. Many times patient comes to the surgeon for appendix operation for acute appendix. During appendix operation surgeon uses to remove one of the kidneys of the patient without prior consent of the patient and keeping the patient in dark of removal of kidney. In future when patient goes for investigation like sonography for some or other reason he gets aware of removal of one of his kidneys. This is against the principle of human rights such cases are reported earlier in Karnataka, Tamil Nadu, Andhra Pradesh and number of other states. This illegal trading of human organs is unethical and serious violation of human rights thus, there was a need for law to provide for the regulation of removal, storage and transplantation of the human organs for therapeutic purposes and for the prevention of commercial dealings in human organs for this reason Government of India has enacted the transplantation of human organ Act, 1994.

### **2. Literature Review**

Transplantation of Human Organs and Tissues Act, 1994 is only to prevent commercial dealings in human organs and tissues.  
..... **Bombay High Court**

World Health Organization (WHO) has developed a set of guidelines on human organ transplantation, it was resolved that human organ or tissues may be removed from living persons or from the bodies of the deceased for the purposes of transplantation in accordance with the following principles;

1. Valid information/ consent required by the law should be obtained.
2. Physician involving organ removal from the donor and subsequent transplant should not be involved in declaring brain death of the person.
3. The donor should be genetically related to the recipient except in the bone marrow, skin, blood, etc.
4. There should be a free consent from any undue pressure or misrepresentation.
5. The donor should be told about the risk and side effects of the donation.
6. There should be no commercial transplantation or removal in donation of the organs or tissues.
7. The professional should not be engaged in such transplantation where such illegal methods take place.
8. The physician can charge nominal fee for the procedure or operation of transplantation of organs or tissues.
9. Any advertisement stating the availability of the organ with a view of earning money should be prohibited.
10. Donated organs should be made available to patient on their medical need and not on the basis of any financial or other consideration.
11. Human organs or tissues are of two types,

- a. **Regenerative** : It means the tissues or organs in the body have a capacity to replicate or reproduce itself if removed within the body on its own accord e.g. blood, bone marrow, skin, semen, etc.
- b. **Non-Generative**: It means if tissues or organs are removed from the body it does not have capacity to reproduce or replicate itself . Here, a man or woman loses a vital organ or its function, it results in partial disablement, permanent disablement or death. eg. kidney, liver, heart,etc.

**Donor:** Donor means a person who donates his/her organs or tissues for the benefits of others. The donation can be from a living person or a cadaver.

**Brain Death:** Brain death means a person is living with a medical support and drugs keeping his hearts and lungs alive but the brain is irreversibly dead. Human organs like kidney, hearts, liver or tissues like human cornea, skin, bone can be transplanted without much difficulties because of innovative surcharge material, antibiotic. Blind person and chronic renal failure have hope of new life.

### Who Can Donate the Organs

1. Family members of a deceased person can decide to donate the organs of a deceased.
2. Decision can be taken by deceased's spouse, adult children, parents, adults siblings or guardian.
3. Doctor has to obtain very consent from the family members before removing organs even though deceased person have completed the donor form.
4. Minors as donor : Minors even can donate his/her organs but signature of a parents or guardian is required.

### Medical Screening before Used as a Donor

1. Donated organs and tissues are screened for infectious diseases like HIV/AIDS, Hepatitis etc.
2. Its a crime to donate organ or tissue if you know that you are a HIV Positive because the viruses can be transmitted by the donation.

### Important Definition Under the Act

1. **Brain stem Death:** It is defined in section 2(d) means the stage at which all the functions of brain stem has ceased or stopped it is certified by the Doctor called urologist.
2. **Deceased Person:** It is defined in section 2(d) means a person all evidences of life are permanently absent due to cardio respiratory arrest or brain storm death.
3. **Donor:** It is defined in section 2(f),it means any person who is not less than 18 years of age and who voluntarily authorises the removal of any human organ for the thearapatic purposes under sub section (1) or sub section (2) of section 3 of transplantation of human organ Act 1994.
4. **Human Organ:** It is defined in section 2(h) it means any part of human body consisting of a structural arrangement of tissue if wholly removed cannot be replaced by the body.
5. **Near Relative:** It is defined in section 2(i) means spouse, son, daughter, father, mother or sister.
6. **Receipient:** It is defined in section 2(m) means a person to whom the human organ is proposed to be transplanted.
7. **Therapeutic Purposes:** It is defined in section 2(o) means systematic treatment of any diseases to improve the health according to any particular method or modality.
8. **Transplantation:** It is defined in section 2(p) means the drafting of any human organ from living person or deceased person to living person for theropathic purposes.

### Types of Transplantation

- a. **Heterotranplantation or Xenografting:** Transplant of organs from one species to other, it currently appears not possible.
- b. **Autotransplantation:** Transplant of one portion of a body to the same body elsewhere-limited to skin grating, but easy and highly successful.
- c. **Homotransplantation:** The transfer of viable tissue from one human being (dead / alive) to another. For homotransplantation, organ can be taken from a cadaver or a living body. Transplantation of liver or heart is naturally restricted to cadaver transplants. Kidney transplants are most commonly done procedures for both, cadaver or living donor.

## 3. Research Methodology

### 3.1 Objectives of the Study

1. To study the medicolegal cases of transplantation of human organs in state of Maharashtra.
2. To study the impact of transplantation of human organs act on the healthcare services in the state of Maharashtra.

### 3.2. Type of Research

This is an applied research or action research. Applied research aims at finding a solution or certain conclusion for an immediate problem facing a society. The researcher will discover a solution for some pressing practical problem.

### 3.3. Hypothesis

There is an impact of Transplantation of Human Organs Act on the healthcare services in the state of Maharashtra.

### 3.4. Sources of Data Collection

a) It is a **Desk Research or Secondary Research** which involves the summary, collation and/or synthesis of existing research where data is collected from the orders or judgments in transplantation of human organs cases by Consumer Courts, session courts, Bombay High Court and the Supreme Court of India.

#### b) Secondary Data

The researcher has collected the secondary data from

1. Information gathered from medico legal cases decided by the competent courts of law in Maharashtra & medicolegal & forensic books, medical magazines, newspapers, Published data from various research journals, law journals & internet from <http://indiankanoon.org>.
2. Availability of previous statistical data of medico legal cases on transplantation of human organs.
3. Data collected, will be analyzed and produced scientifically.

### 3.5. Limitations of the Study

The study is restricted only to four case studies or case laws decided by the Consumer Courts, Session Courts, Bombay High Court in State of Maharashtra. It covers only those medicolegal cases related to the Transplantation of Human Organs Act, 1994.

## 4. Research Data / Materials

Following four Medicolegal cases on The Transplantation of Human Organs in state of Maharashtra have been studied and analyzed by the Research Scholar.

### 4.1. Vijaykumar Hariram Sahu Vs The State of Maharashtra<sup>i</sup> on 27<sup>th</sup> September, 2012 in the High Court of Judicature at Bombay, ordinary Original Civil Jurisdiction.

The Petitioners have in these proceedings under Article 226 of the Constitution of India challenged orders passed by the Authorization Committee constituted under the Transplantation of Human Organs and Tissues Act, 1994 ('the Act') and an order passed in appeal by the Appellate Authority of the State Government. The Second Petitioner is stated to be suffering from end stage renal disease and is being treated at Jaslok Hospital, Mumbai. The Second Petitioner was advised renal transplantation. The First Petitioner has agreed to donate a kidney to the Second Petitioner. The Petitioners claim to be cousins. The First and Second Petitioner do not fall within the definition of the expression "near relatives" as defined in Section 2(i) of the Act. Justice Dr.D.Y. Chandrachud held that there is a need to save the life of the donee which is a significant consideration and ordered the Authorization Committee to reconsider the matter on humanitarian ground in order to save the life of a donee.

### 4.2. Miss. Sonia Ajit Vayklip and Anr. Vs Hospital Committee<sup>ii</sup> on 18<sup>th</sup> January, 2012 in the High Court of Judicature at Bombay, Ordinary Original Civil Jurisdiction.

Miss. Sonia Ajit Vayklip, a tribal lady from Chhattisgarh, has challenged the decision of the hospital committee herein refusing to grant approval for transplantation of her kidney to the body of her younger brother Deekap Ajeet Vayklip. Chief Justice Smt. Roshan Dalvi held that since petitioner No.1 Miss. Sonia Ajit Vayklip is the elder sister of petitioner No.2 (recipient), no approval of the authorization committee is required as contemplated under Section 9 of the Transplantation of Human Organs and Tissues Act, 1994. Thus, Transplantation of kidney from donor sister to donee brother was permitted.

### 4.3. Master. Siddhant Vikram Pal Vs The Authorization Committee<sup>iii</sup> on 21<sup>st</sup> June, 2013 in the High Court of Judicature at Bombay, Civil Appellate Jurisdiction.

The present Petitions have been filed essentially in view of the delay in disposal of the applications made before the Authorization Committee for grant of approval to the proposal of a donor for removal of kidney before his death for transplantation into the body of a recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient. These are the cases of the persons who are suffering from renal failure and who are in need to undergo kidney transplantation.

Bombay High Court held that if certificate of medical practitioner having requisite super specialization in the concerned subject is submitted recording that the recipient is immediately required to undergo transplantation of human organ and if the Authorization Committee is satisfied about the genuineness of certificate, the Committees shall proceed to decide such Application by giving utmost priority and preferably within a period of four weeks from the date of submitting the Applications. Such certificate of medical practitioner shall contain reasons in brief as to why urgent transplantation is necessary.

#### **4.4. Dr. Ajay Tejraj Oswal Vs Secretary, The state of Maharashtra<sup>iv</sup> on 21<sup>st</sup> July, 2011 in The High Court of Judicature at Bombay, Appellate Side, Bench at Aurangabad.**

This writ petition filed under Articles 226 and 227 of Constitution of India, takes exception to the two orders dated 01/04/2011 and 11/04/2011 passed by competent authority established under the provisions of "The Transplantation Of Human Organs Act, 1994" (Henceforth referred to as "the Act"), preventing and affecting the petitioner's right to practice medicine. The petitioner is Medical Practitioner. He is a Surgeon. Since 1999 he has been performing kidney transplantation surgeries. He has been providing his services to various hospitals as free lance surgeon. He used to visit and perform surgeries at Aditya Birla Hospital, Pune and "Suretech Hospital", Nagpur prior to the impugned orders.

On 26th November, 2010 a team comprised of Dr. Bhavani the head of the department of urology & Department of Surgery, Bombay and Dr. Mohan Jadhav, who is a Govt. Officer who is appointed as "the appropriate authority" under the Act, visited Aditya Birla Hospital, Pune. They found that the petitioner had been visiting this hospital for performing the surgeries. They noticed that the petitioner's name as a surgeon of the hospital was not mentioned when the hospital sought registration under the Act. They therefore, issued a show cause notice to the hospital as to why its registration should not be cancelled. Similar show cause notice was given to Suretech hospital, Nagpur on the same ground that the petitioner and one more Surgeon were allowed to perform surgeries in that hospital. After submission of explanations etc the impugned orders mentioned above were passed.

Justice A.V. Nirgude allowed the writ petition and ordered that the directions contained in the impugned order that the petitioner shall not carry on transplantation operations in a registered hospital is set aside. The appropriate authority shall not prohibit the petitioner from performing transplantation operation in any registered hospital of his choice.

#### **5. Data Analysis**

This is a qualitative research where the research scholar has studied about four case studies or case laws of medicolegal nature related to Transplantation of Human Organs in state of Maharashtra. All the secondary data and necessary information for the research is provided by indiankanoon.org. The judgments or orders given by different courts namely Session Courts, Bombay High Court in the state of Maharashtra related to Transplantation of Human Organs those four case laws or case studies have been analyzed keeping in the mind the main objectives of the study.

Thus, this desk research is based on secondary data available till date from the Session courts, and Bombay High Court in the state of Maharashtra.

Data is analyzed by studying the various judgments given by the Hon'ble Judges of the different courts of law in four case laws/case studies related to Transplantation of Human Organs till date in state of Maharashtra. For analyzing the case studies, the Research Scholar has used "Within Case Analysis and Between Case Analysis or Across Case Analysis."

#### **6. Results and Discussion**

Research scholar has viewed and studied four case studies on the transplantation of human organs in details in Maharashtra state with reference to its impact on healthcare services and found that there is an illegal removal and donation of human organs. There is an illegal trade or business in human organs especially trading kidneys which involved violation of human rights. Many doctors are involved in organ trafficking especially trading kidney. Many organ transplant donors were abused in kidney donations with minimal price or amount. In many cases the kidney donor is unrelated and unacquainted with the person who requires the kidney. There were many commission agents were involved in this kidney rackets. Huge or large amount for the kidney was collected from the recipient and very minimal amount was paid to kidney donor.

Many times patient comes to the surgeon for appendix operation for acute appendicitis. But during appendix operation surgeon uses to remove one of the kidneys of the patient without prior consent of the patient and keeping the patient in dark of removal of kidney. In future when patient goes for investigation like sonography for some or other reason he gets aware of removal of one of his kidney. This is against the principle of human rights. Such cases are reported earlier in Karnataka, Tamil Nadu, Andhra Pradesh and number of others states. This illegal trading of human organs is unethical and serious

violation of human rights. Thus, there is a need for law to provide for the regulation of removal, storage and transplantation of the human organs for therapeutic purposes and for the prevention of commercial dealing in human organs. For this reason Government of India has enacted "The Transplantation of Human Organ Act, 1994".

Further, in 2009 Govt. of India passed a bill called The Transplantation of Human Organs (Amendment Bill), 2009 to curb the instances of illegal dealings in the transplantation of human tissue along with the transplantation of organs. It makes it mandatory for the medical staff treating a patient at the ICU/medical unit to request relatives of brain dead patients for organ donation and requires that all organ donation cases go through an Authorization Committee.

#### **Highlights of the Transplantation of Human Organs (Amendment Bill), 2009**

1. The Bill amends the Transplantation of Human Organs Act, 1994, which regulates removal, storage and transplantation of human organs.
2. In addition to human organs, the Bill seeks to regulate transplantation of tissues of the human body.
3. The Act permits donations from living persons who are near relatives. The Bill expands the definition of "near relative" to include grandparents and grand children in addition to parents, children, brother, sister and spouse.
4. The doctor in an Intensive Care Unit has to inform the patient or relatives of patient about the option of organ donation and ascertain whether they would consent to the donation.
5. A pair of donor and recipient who are near relatives but whose organs do not medically match for transplantation are permitted by the Bill to swap organs with another pair of such persons.
6. The Bill enhances the penalty for unauthorized removal of human organs and for receiving or making payment for human organs.

This act was further amended for the regulation of removal, storage and transplantation of human organ for therapeutic purposes and for the prevention of commercial dealings in human organs in 2013 as "Transplantation of Human Organs and Tissues Rules 2013".

#### **7. Conclusion**

Research Scholar has viewed, studied and analyzed four case studies/case laws on The Transplantation of Human Organs Act, 1994 and arrived on the following conclusions:

Kidney transplants in India first started in the 1970s and since that time, India has been a leading country in this field on the Asian sub-continent.

The legislation called the Transplantation of Human Organ Act (THO) was passed in India in 1994 to streamline organ donation and transplantation activities.

Even though the Transplantation of Human Organs Act, 1994 has been enacted by the parliament for the regulation of removal, storage and transplantation of human organ for therapeutic purposes and for the prevention of commercial dealings in human organs, still there a trafficking of human organs especially of the kidney, retina, liver and heart etc. is going on.

Thus, the research scholar further conclude that,

1. The physicians are charging very high fees for the operation of transplantation of human organs or tissues especially in kidney and retina transplantation.
2. Physician involving organ removal from the donor and subsequent transplant is involved in declaring brain death of the person at the early stage even though person is not in brain death.
3. Valid information / consent required by the law is not obtained in many cases of organ transplant.
4. The donor should be genetically related to the recipient except in the bone marrow, skin, blood etc. But this is not happening in kidney transplant cases in state of Maharashtra.
5. There is a commercial dealing in the transplantation or removal in donation of the kidney or retina organs or tissues.
6. Donated organs are not made available to patient on their medical need but made available to them on the basis of their financial or other consideration.
7. The professional i.e. doctors doing kidney or retinal transplantation surgery are engaged in such transplantation where illegal and unethical methods of transplantation takes place.
8. The donors are not told about the risk and side effects of the organ donation.
9. There should be a free consent from any undue pressure or misrepresentation but this is not followed in kidney or retinal transplantation.

The legal and ethical principles that we follow universally with organ donation and transplantation are also important for the future as these may be used to resolve our conflicts related to emerging sciences such as cloning, tissue engineering, and stem cells.



Thus, there is a definite impact of Transplantation of Human Organs Act on the healthcare services in the state of Maharashtra.

Thus, a hypothesis “There is an impact of Transplantation of Human Organs Act on the healthcare services in the state of Maharashtra.” is thereby proved.

### Scope for Future Work

There is a lot of scope for future work on impact of Transplantation of Human Organs Act, 1994 on healthcare services in other states of India. The study could be initiated with the help of primary data to reflect the latest situation.

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<sup>i</sup> <http://indiankanoon.org/doc/13673523/>

<sup>ii</sup> <http://indiankanoon.org/doc/113917983/>

<sup>iii</sup> <http://indiankanoon.org/doc/36717777/>

<sup>iv</sup> <http://indiankanoon.org/doc/167763941/>