

## Law Relating To Human Organ Transplantation In India: An Analysis

### Abstract

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With the development of science, life expectancy rate also grows. People want to live more than their natural organs allowed to them. With the help of Science dead or damaged organ of a patient could be replaced with the healthy ones and patient can play one more inning of his life. Earlier no need of organ transplantation because people lead healthy life style and life expectancy rate is much greater in comparison of today. But with advancement of scientific technology life style of people also affected due to which cases of organ failure increasing day by day which increased the demand of organs. To prevent the commercialization of human organs Transplantation of Human Organs Act came into force in 1994.

### A. Introduction

Organ 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 evolutionary history of transplants has witnessed a different facet of transplant emerging in each decade. The first ten years were spent mastering the surgical techniques and immune-suppression. Its success resulted in a rise of numbers of transplants in the next 10 years which increased the demand of human organs due to which unrelated kidney donation from economically weaker sections started taking place.<sup>2</sup> It is the duty of the State to protect life of its citizens and the physician's duty is to provide care and not to harm patients.<sup>3</sup> It has been well established that right to life does not include right to die.<sup>4</sup>

Before the enactment of The Transplantation of Human Organs Act, 1994, there is no law to regulate the human organ transplantation. Any person who needs an organ can easily access it from relative donor as well as from non-relative donor without any legal formality. But with the change of time this noble act turns into black market in human organs. People

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<sup>2</sup> Sunil shroff, "legal and ethical aspects of organ donation". Indian Journal of Urology 25(3) 348-355 at 348 (July-September 2009).

<sup>3</sup> Suresh Bada Math and Santosh K. Chaturvedi, "Euthanasia: Right to life Versus Right to Die." Indian J Med Res. 2012 Dec; 136(6): 899–902. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612319/>

<sup>4</sup> *Gyan Kaur v State of Punjab*, AIR 1996 SC

have started business in human organs and sale and purchase of human organs came into rise. In January 1995, the kidney scandal came into limelight through a series of incidents which received wide media coverage and prompted public outrage causing the Indian Govt to pass legislation banning kidney trade.

### **B. Transplantation of Human Organs and Tissues Act, 1994**

The Act came into force on 1994 for the purpose of removal, storage and transplantation of human organs. It regulates the removal, storage and transplantation of human organs for therapeutic purposes and prohibits commercial trade in human organs. The Act was initiated at the request of Maharashtra, Himachal Pradesh and Goa. After some time this Act was adopted by all states except Andhra Pradesh and Jammu and Kashmir, which enacted their own laws.<sup>5</sup> Organ transplant law does not allow exchange of money between the donor and the recipient. Further this Act limits the living transplantation to three categories: relative by blood, spouse, and those who donated out of love and affection. State Authorisation Committees are meant to scrutinize all applications for unrelated transplants. Hospitals conducting transplants are supposed to be registered with committees which are also supposed to monitor their functioning.<sup>6</sup>

Procedure for organ transplantation has been mentioned under the Rules which were enacted in 1995 to give enforcement to the provisions of the Act. From time to time these provisions have been interpreted by parliament and where the provisions of the Act and Rules are not clear or could not properly applied, then Court can interpret those provisions and give direction to change and modify them. In 2008 transplantation of Human Organs (Amendment), Act passed and many changes takes place in the Act. Again it was felt that the law had not made the desired impact on the growth of transplantation in India. In order to correct some problems with the original Act and to keep up with further progress in transplantation, amendment to the Act was proposed in 2009 and enacted in 2011. It prescribes the major changes. Originally this Act covers only the Human organs but now tissues are also included under the Act.

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<sup>5</sup> Since “public health” is a State List subject, under Article 252 of the Constitution of India, Parliament may enact a law for two or more states if legislatures of two or more states pass resolutions empowering the Parliament to enact a law on their behalf. The Act may be applicable only in these states and other states may adopt it by a legislation passed in those states.

<sup>6</sup> “Law and medicine: An Analysis of the Organ Transplantation Law in India”. Available at <http://www.legalserviceindia.com/article/l224-Organ-Transplantation-Law-In-India.html> (accessed on October 2, 2015)

**(i) Regulation of Removal and Transplant Proceedings**

Activities of organ transplantation are regulated by various authorities in its different phases. Appropriate authority and Authorisation Committees are two important authorities which deals with the transplant and removal proceedings and keep a check upon transplant proceedings. We cannot discuss the provisions of transplantation of human organs Act, without discussing these two authorities because the provisions of the Act revolve around these authorities. Both have their important role to play.

**(ii) Role of Appropriate Authority**

Appropriate Authority has been defined under section 13 of the Transplantation Act. According to section 13 Central Govt<sup>7</sup> and State Government<sup>8</sup> shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union Territories as well as State respectively. Role of Appropriate Authority is very important as it granted registration or renewal certificate to hospitals for conducting transplantation in human organs and tissues. It is the duty of the authority to take strict action against those institutions which are carried on transplantations without any registration or whose registration has been expired. It has been seen in Punjab that the hospital which is under the scanning of kidney trade were conducting transplantations without any authority.

**(iii) Constitution of Advisory Committee<sup>9</sup>**

Transplantation of Human Organs Act, 1994 does not contain any provision of Advisory Committee. Appropriate Committee was discharging their functions on their own. In the wake of the various media reports about commercial transactions in organs transplantation and the recent Amritsar and Gurgaon kidney scams, it has been felt that the Appropriate Authority's function rather mechanically. It has often been said that the poor conviction rate under the Act is mainly due to the fact that the officer of the Department of Health, who is designated as the appropriate authority in most States takes on this responsibility in addition to other administrative functions. He is unable to find time for a methodical and systematic discharge of the duties assigned to the Appropriate Authority

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<sup>7</sup> Section 13 (1)

<sup>8</sup> Section 13 (2)

<sup>9</sup> New section 13A has been inserted by the Amendment Act, 2011. Under this Section an Advisory Committee shall be constituted.

under the Act.<sup>10</sup> To implement the Act properly and to do proper justice, in 2011 an amendment has been made into the Act under which a provision regarding the appointment of Advisory Committee has been provided. Advisory Committee shall advise to the Appropriate Committee for discharge of their functions. It shall be appointed by the Central as well as State Government for the period of two years to aid and advise the Appropriate Committee.<sup>11</sup>

#### (iv) **Role of Authorisation Committee**

Authorisation Committee is the main body under the transplantation of human organs act which performs the removal and transplantation activities. It grants no-objection certificate to the parties for the removal and transplantation. The duty of this authority is to check that there is no commercial transaction between the parties and nothing illegal is going on under the shield of affection and attachment. Whether the Act is achieving its goal and objectives, it depends upon the impartial working of the Committee.

The Central Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the Central or State Governments on such terms and conditions as may be specified in the notification for each of the Union Territories for the purposes of this section. In 2014 new rules have been framed for the purpose of transplants. According to these rules there shall be one state level authorisation committee. In districts or institutions or hospitals additional authorisation committees may be set up based on the fulfilment of certain conditions. No member from transplant team of the institution should be a member of the respective authorisation committees. By the Transplantation of Human Organs (Amendment) Rules, 2008 certain changes have been brought. Rule 6A has been inserted according to which one authorisation committee shall be on State level. Authorisation Committee should be Hospital based in Metro and big cities if the number of transplants exceed 25 in a year at the respective transplantation centres. In smaller towns if transplants are less than 25 in a year in the respective districts there will be State or District level committees.<sup>12</sup>

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<sup>10</sup> Available at

<http://www.prsindia.org/uploads/media/Organ%20transplantation/Note%20on%20the%20Amendments%20proposed%20to%20the%20Act.pdf> (accessed on December 27, 2015)

<sup>11</sup> Section 13A (1)

<sup>12</sup> Rule 6A of the Transplantation of Human Organ (Amendment) Rules, 2008.

Authorisation Committee's role is of very important in the point of view of organ trafficking. The committee is responsible to prevent and increase trafficking in human organs. Cases on organ trafficking are evident that in most circumstances these committees are responsible in the commission of this crime. In Amritsar kidney it had been seen that in most of the cases authorisation committee granted approvals for organ transplantation between non relatives on the ground of affection and attachment but in reality there was no affection or attachment. Donor and recipients are belonged to different states and communities. It is the duty of authorisation committee to inspect the true relationship between donor and recipient but if committee perform their duty negligently or if it became a part of illegal activities then no law or regulations can save the country from this crime.

Where the transplant is between individuals who are not near relatives, the authorisation committee shall evaluate that there is no commercial transaction between the recipient and the donor and there is no payment of money or money worth has been made to the donor or promised to be made to the donor or any other person. The authorisation committee shall consider certain facts between the donor and the recipient likewise documentary evidence that they have lived together; there is no middleman involved; financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two, must be evaluated in the backdrop of the objective of preventing commercial dealing. When the proposed donor and the recipient or both are foreigners then a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient. Earlier the authorisation committee shall examine the cases of Indian donors consenting to donate organs to a foreign national, including a foreign national of Indian origin, with greater caution. Such cases were considered rarely on case to case basis. But by the new organ transplantation rules 2014, organ donation to foreigners who are non-relative totally rejected.<sup>13</sup> Now no living person in India can donate their organs to foreigners.

After analysing all the relevant factors, it is the decision of the Authorisation committee either to approve or reject the application of the proposed living donor. In case committee decide to approve then it has to check whether the required criteria is being

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<sup>13</sup> Rule 20 of 2014

fulfilled or not. Where situation of patient is critical and required transplantation urgently, then the Authorisation Committee shall take its decision as soon as possible. Committee shall use its discretion judiciously and pragmatically. Authorisation committee must have its own website and shall take its final decision within twenty four hours of holding the meeting of approving or disproving the transplantation. Apart from it decision should also be display on the notice board of the Hospital or institution immediately and should reflect on the website of the hospital or institution within twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden.<sup>14</sup>

#### **(v) Removal of Human Organs from Living Beings**

The basic object as enshrined under the preamble of the Act is that organ can be removed only for therapeutic purposes. It is the donor's wish whether he want to donate his organs or not and when and to whom they want to donate. Consent is the main legal question related to living organ donations. If donor's decisions are not autonomous or self-determined this leads to treating a person without respect. Respect for autonomy requires that the donor must be able to exercise the power of free choice.<sup>15</sup> Donor has been defined in section 2 (f) of the Transplantation of Human Organs Act, 1994, as: "any person not less than 18 years of age, who voluntarily authorises, the removal of any of his human organs for therapeutic purposes under sub-section i or sub-section ii of section 3."

Donor may authorise the removal of any human organs of his body for therapeutic purposes before his death as prescribed under the Transplantation of Human Organs Act, 1994. According to the section a living adult person can donate his organ or gives the permission for the removal of human organs but these organs can be used for therapeutic purpose only<sup>16</sup> because section 11 prohibits the removal of transplantation of human organs for any purpose other than therapeutic purpose.

#### **(vi) Removal and Transplantation of Human Organs between Near-Relatives**

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<sup>14</sup> Rule 24 of 2014

<sup>15</sup> Scaria Kanniyakonil, *Living Organ Donation and Transplantation: A Medical, Legal, and Moral Theological Appraisal* at 88 (2005)

<sup>16</sup> Section 3(1) reads as "any donor may, in such manner and in subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ of his body for therapeutic purposes."

While most solid organ and tissue donation occurred after the donor has died, some organs and tissues can be donated while the donor is alive. Section 9 prohibits the removal of human organs from living beings but further it relax the restriction allowing that the organ removed from living beings can only be transplanted to the near-relatives of the donor. Section 9 (1) says, “save as otherwise provided in sub-section (3), no human organ 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.” The term “near relative” has been defined in section 2(i) which includes spouse, son, daughter, father, mother, brother, sister, [grandfather, grandmother, grandson, and grand-daughter]<sup>17</sup>

In 2011 an amendment has been made to the Transplantation of Human Organs Act, 1994 to prevent the commercial activities in organ transplantation. Earlier Act grants permission to transplantation between near relatives but amendment of 2011 explain the position of near relatives and lays down that where the donor or the recipient being near relative is a foreign national, prior approval of the authorisation committee shall be required before removing or transplanting human organ or tissue or both. In case the recipient is foreign national and donor is an Indian national and both are not near relative then the authorisation committee shall not grant approval for the transplantation.<sup>18</sup> Similar provision has been laid down by the new organ transplantation rules 2014, whereby organ donation to foreigners who are non-relative totally rejected.<sup>19</sup> Now no living person in India can donate their organs to foreigners.

Provision of donation by living beings to near relative shows that where our legislation considering the need of transplantation for ill and sick persons, there they equally conscious to prevent the misuse of the provisions of the Act. A person will donate his organ to the near relatives only if such type of need arises and there is no chance of harassment of human beings. So, when a person wants to donate human organ to his or her near relative, no rigid procedure followed is to be followed as in case of non relatives.

The important feature of 2011 Amendment is that first time it established the provision of swap transplantation under the Indian transplantation Act. Swap transplantation

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<sup>17</sup> Inserted by the Transplantation of Human Organs (Amendment) Act, 2011.

<sup>18</sup> Section 9 (1) (1A) Instituted by the Amendment Act, 2011.

<sup>19</sup> Rule 20 of 2014

means when a donor and recipient are mismatched with each other, either by blood group or by tissue type, it may be possible for them to be matched with another donor and recipient pair in the same situation.

**(vii) Removal and Transplantation between Non-Relative Donor and Recipient**

On the one hand Transplantation of Human Organs Act restricts the donation of human organs by living beings only to the near relative and on the other hand it allows the transplantation between the non-relatives on the ground of affection and attachment.<sup>20</sup> Removal of organs from living beings for transplantation into non relatives on the ground of affection and attachment needs prior approval from the authorisation committee. The provision has been established to prevent the misuse of Act. An application shall be filed before the authorisation committee by the proposed donor and the recipient jointly for the approval of removal and transplantation. After presenting the application it is the duty of the authorisation committee to conduct inquiry regarding the dealings between the donor and the recipient.<sup>21</sup> Authorisation committee must check that there has not been any commercial transaction between the donor and the recipient.

**(viii) National or Regional or State Human Organs and Tissues Removal and Storage Networks**

Indian government made amendment to the transplantation of human organs and tissues act, 1994 and new rules have been substituted in 2014. According to new provisions criteria of organ sharing and allocation has been laid down under the Indian Act. In order to regulate the removal of organs from living as well as deceased persons and transplantation of such organs in the country, an apex National Network Organisation at the centre has been formed in accordance with rule<sup>22</sup> 31 of the Transplantation of

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<sup>20</sup> Section 9 (3): “If any donor authorises the removal of any of his human organs before his death under sub section (1) of section 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 shall not be removed and transplanted without the prior approval of the authorisation committee.”

<sup>21</sup> Section 9 (5): “on an application jointly made, in such form and in such manner as may be prescribed, by the donor and the recipient, the authorisation committee shall, after holding an inquiry and after satisfying itself that the applicants have complied with the requirements of this Act and the rules made there under, grant to the applicants approval for the removal and transplantation of the human organ.”

<sup>22</sup> Transplantation of human organs and tissues rules 1995 replaced by 2014 rules. According to new rules there shall be national transplantation organization at national level.

human Organs and Tissues Rules, 2014. This removal and storage network has been divided into three stages i.e., national level, regional level and state level popularly known as NOTTO (National organ and tissue transplantation organisation), ROTTO (Regional organ and tissue transplant organisation) and SOTTO (State organ and tissue transplant organisation). According to rules there shall be an apex national networking organisation at the centre and there shall also be regional and state level networking organisations where large number of transplantation of organs and tissues are performed. The State units are linked to hospitals, organ or tissue matching laboratories and tissue banks within their area and also to regional and national networking organisations. The broad principles of organ allocation and sharing shall be online. The website of the transplantation centre shall be linked to State or Regional cum State or National networks through an online system for organ procurement, sharing and transplantation. Patient or recipient may get registered through any transplant centre, but at only one centre of a state, if there is no centre in the state then in the region he can register himself. Details of registration shall be made available online to the networking organisations, who shall allocate the registration number, which shall remain same even if patient changes hospital. The criteria of allocation of the organ to be shared, is to be decided by the State networking organization and by the National networking organization in case of Delhi. All recipients are to be listed for requests of organs from deceased donors, however priority is to be given to be those: (i) who do not have any suitable living donor among near relatives; (ii) who have a suitable living donor available among near relatives but the donor has refused in writing to donate; and (iii) who have a suitable living donor available and who has also not refused to donate in writing. Organ shall be allocated first to persons who are on state level waiting list, after that regional level waiting list and last national level waiting list. If available organs do not match to person of state waiting list than immediately regional level organisation has been contacted regarding organ allocation. If no match is found at regional level too then contact has been made to national level organisation and organs are allocated to that organisation. Likewise preference of recipient shall also lay down under the rules. As per criteria Person of Indian origin shall be preferred over foreigners. The online system of networking and framework and formats of national registry as mentioned under rule 32 shall be developed by the apex networking organisation which shall be followed by the States Governments or Union territory Administrations and the allocation criteria may be State specific which shall be finalised and determined by the State

Government, in consultation with the State level networking organisation, wherever such organisation exists. The organ sharing and networking policy of States or locations of hospitals shall not be binding on the Armed Forces Medical Services (AFMS) and the armed forces shall be free to have their own policy of organ or tissue allocation and sharing, and the Director General Armed Forces Medical Services shall have its own networking between the Armed Forces Medical Services hospitals, who shall be permitted to accept organs when available from hospitals within their State jurisdiction. Reference or allocation criteria would be developed and updated regularly by networking organisations in consultation with the Central or State Government, as the case may be. The networking organisations shall maintain and update organ or tissue Donation and Transplant Registry at respective level. National Registry shall be based on the organ transplant registry, organ donation registry and tissue registry.

**(ix) Penalties for Violation of Organ Transplantation Act and Rules**

Section 18, 19 and 20 of Transplantation of Human Organs Act deals with punishments for offences covered under this Act. After the amendment Act of 2008 and 2011 changes have been made in the punishments and attempt has been made to tight the provisions so that no one can take the undue advantage under the garb of legal provisions.

Section 18 provides that any person, who renders his services to or at any hospital and who, for purposes of transplantation, conducts or associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with ten year imprisonment and with fine up to twenty lakh rupees.<sup>23</sup> Where any person convicted under this sub-section is a registered medical practitioner, his name shall be reported by the appropriate authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the council for a period of two years for the first offence and permanently for the subsequent offence.<sup>24</sup> Any person who renders his services to or at any hospital and who conducts or helps in any manner in the removal of

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<sup>23</sup> Section 18(1)

<sup>24</sup> Section 18(2)

human tissues without authority, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees.<sup>25</sup>

Section 19 prohibits use of human organs for commercialization. In 2011 amendment has been made with a view to impose harsh punishments and which increased the term of punishment and fine. According to section whoever makes or received any payment for the supply of, or for an offer to supply, any human organ or initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ; shall be punished with imprisonment for a term which shall not be less five years but which may extend to ten years and shall be liable to fine which shall not be less than twenty lakh rupees but may extend to one crore rupees; provided that the court may, for any adequate and special reason to be mentioned in the judgement, impose a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees. With the amendment of 2011 tissue has been included under the Organ Transplant Act and whoever makes or receives any payment for the supply of, or for an offer to supply, any human tissue; or Initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human tissue; Shall be punishable with imprisonment for a term which shall be liable to fine which shall not be less than five lakh rupees but which may extend to twenty-five lakh rupees.<sup>26</sup>

### **(C) Conclusion**

Transplantation of human organs Act, 1994 came into force after the incidence of organ trade. It includes various provisions to prohibit the sale and purchase of human organs. But in the presence of these provisions trafficking in organs has not been completely stopped. Again amendments have been made in 2008 and in 2011 to make the provisions harsh to deal with this crime. In 2014 new rules have been framed to prescribe the procedure of organ removal and transplantation. But despite of these provisions incidents of sale and purchase of human organs are happening in one or the other corners of the country. This crime is flourishing under the shield of law and it is very difficult to identify the wrongdoers who are responsible for this. Bare provisions cannot prevent the violation of legal provisions unless the enforcement agencies do their duties honestly. So the need of time demands that

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<sup>25</sup> Section 18(3) Inserted by amendment Act, 2011.

<sup>26</sup> Section 19A, Inserted by Amendment Act, 2011.

provisions of Organ Transplantation Act and Rules should be strictly implemented if we really want to save the precious organs of our country.