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Application of the concepts of Authority and Consent in the Transplantation
of Human Organs and Tissues Act, 1994: An analytical Study

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Abstract

Transplantation of Human Organs and Tissues Act, 1994 is passed with an object to regulate the removal, storage and transplantation of human organs and tissues for therapeutic purposes and for the prevention of commercial dealing in human organs and tissues. The whole operation of the law is based on two major concepts i.e. authority and consent. Every donor or legal representatives of the deceased are allowed to authorize human organ donation. The fundamental issue involved in the process the real application of the authority and consent in the legal procedure laid down under the Transplantation of Human Organs and Tissues Act, 1994. Researcher has tried to study and analyze the legal procedure applied under the Act how core concepts authority and consent are deviated from it as well as researcher suggested legal solutions to address these issues. Researcher mainly relied upon the doctrinal method.

Words: Human organ donation, consent, authority, law, legal procedure etc.

Introduction:
Medical technology has been proved to be a reliable source for the physicians to determine the accurate diagnosis of medical disease and also beneficial to the patients for medical treatment which resulted into the quality of health and life of human beings. Without medical technological assistance, it would not be possible to transplant the organ. It is a boon and proved to be a successful alternative to the life ending in some of the cases. Recent advances in medical technology, together with the successful use of human tissues and organs for a wide range of therapeutic treatments and research, have enhanced the potential for commercial exploitation of those tissues and organs. This has resulted in the human body, its tissues and organs being viewed from a different legal perspective. One potential change is the extent to which and in what context a priority can be afforded to human tissues and organs.¹ The organ donation and transplantation system strives to ensure that the gift of donated organs by fully using those organs to save and improve the quality of the lives of their recipient. Organ transplantation has become the optimal treatment for many end-stage organ-specific diseases.² Organ Transplantation is predominantly a socio-cultural activity, made possible medically by virtue of this quality.³ Transplantation is one of the most visible and influential medical accomplishments of the twentieth century.⁴

History:
Tales of successful magical replacement of lost tissues are found in the themes of folklore from all part of the ancient world. The tales of restoration of lost limbs or eyes, and even replacement of decapitated heads, are hardly less popular in present lore than the raising of the dead or magical cures for paralysis or blindness. These transplant claims are found in the legends of all nations since ancient times⁵ in the different nations Greece⁶, India⁷ etc. Ancient human harbored a lively belief in the centaur (half man, half horse) and in other fusions that resulted in dragons, griffins, mermaids, Pegasus the winged horse, the Minotaur and the Sphinx. Hittite temple carvings depict some fierce creatures with the head of a man, body of lion, and wings of an eagle.⁸ History recorded several stories of the power of magic such as Cosmas and Damiana which showed miracle into leg transplant etc.

Assistant Professor, Marathwada Mitra Mandal's Shanikarrao Chavan Law College, Pune (Maharashtra).
1. Medical and Legal Essentials in Healthcare, Jason Payne-James, Peter Dean and Ian Wall, Cambridge University Press, Cambridge, 2004. Pg. 1.
2. Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation, National Academies of Sciences, Engineering, and Medicine, et al. Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation, edited by Catharyn T. Liverman, et al., National Academies Press, 2013. Available from infolibnet-ebooks on 2021-08-31 09:24:44.
3. Dr. Braver Ben-David, Organ Donation and Transplantation: body organs as an exchangeable socio-cultural resource, Preger Publishers, Westport, CT, ISBN:0-275-97918-0, 2015, 1st Publication, Pg. 14.
4. Handbook of Organ Transplantation, Allan D. Kirk, Stuart Knechtle, Christian Larsen, Joren Madson, Thomas Pearson and Steven Webber, Wiley Blackwell Publishing, Chichester UK, Pg. 5.
5. History of Organ Transplantation, David Hamilton, University of Pittsburgh, Pittsburgh, Pg. 1, 2012.
6. In ancient Greece, the fire-breathing Chimera (part lion, part goat and part serpent) was the alarming creature of the liad that terrorized the coast of Lycia in Turkey before the hero Bellerophon destroyed it. The unpleasant lamia was a female who was part snake, and the harpies were ugly, winged birdwomen who stole food and abducted humans; while the manticores had a man's head, the body of a lion and a scorpion's tail. The myths about these creatures suggest that most were aggressive and unpleasant, but others were more kindly, notably the centaur, the wisest of the centaurs, who was teacher and mentor to the young Asclepius, Greco-Roman god of medicine.
7. The young Hindu god Ganesha, son of Shiva and Parvati, gained a new animal head after decapitation by his angry father. Repenting of his deed, the father told his servants to obtain the head of the first living being they could find, which was an elephant.
8. History of Organ Transplantation, David Hamilton, University of Pittsburgh, Pittsburgh, Pg. 3 to 4, 2012.

Afterwards, particularly, after the establishment of legal system across globe and progression in medical science transplantation movement extended rapidly. Continued growth in organ transplantation led to the numerous ethical issues. Human body was considered as property. The assumption that there was 'no property in a dead body', was merely 'a gift of flesh for the worms', dated back to the 17th century. This view was upheld in *Williams v Williams* in which it was held that, as there is no property in a dead body, any direction made by the deceased during his lifetime binding upon his executors. Consent to autopsy was regarded as a professional courtesy, not a necessary interpretation had been reinforced in the 20th century by the decision in *Dondward v Spence* (1998). Because the body of itself worthless, the court held that any human material became the property of the person who gave it and preserving it.⁹ After the recognition, several scandals appeared on record such as Alder Hey Children's Hospital in Liverpool and at Bristol Royal Infirmary¹⁰ which ultimately forced law makers to address these issues and laid down procedure for it. Accordingly, in India, The Transplantation of Human Organs and Tissues Act, 1994 was passed by Parliament of India. The legal procedure is based on the two fundamental concepts 'Authority and Consent'. This paper intends to study the application of the concept of 'authority and consent' in the legal procedure mentioned in Act, lacunas exists in the Act and the concrete solution to redress the identified issues.

III. Need of Transplant Donation:

There is a relentlessly increasing need for organs for patients with life threatening organ failure that requires the help of donors and timely intervention to obtain the donated organs in the best possible transplantable condition. Many transplants because an organ that they need to continue living is failing to function. Many diseases and conditions lead to end-stage organ failure.¹² Right to life is at stake due to the failure of an organ which can be easily transplanted. It is estimated around 1.8 lakh persons suffer from renal failure every year, however the number of renal transplants performed in India is around 6000 only. An estimated 2 lac patients die of liver failure or liver cancer annually in India, about 10,000 can be saved with a timely liver transplant. Hence about 25-30 thousand liver transplants are needed annually but only about one thousand five hundred are being performed. Similarly, about 50000 persons suffer from Heart failure annually but only about 10 to 15 heart transplants are performed every year in India. In case of Cornea transplants are done every year against a requirement of 1 lakh.¹³ Shortage of Organs, critical and complex procedure, awareness among the people, religious misunderstanding etc. are the foremost reasons for this issue.

IV. Concept of Organ Transplantation: Organ Donation is the process of retrieving or procuring an organ from a deceased person and transplanted into the recipient who requires that organ.¹⁴ It becomes necessary due to the failure of the functioning of such organs to live life healthy.

V. Kinds of Human Organ Transplantation: Human Organ Transplantation are classified into the following manner:

- a) Living Donor Organ Donation: "Living organ donors" are the persons who can donate certain organs while they are still living.¹⁵ An organ is taken from a live person and given to another. A popular example is kidney. Living Organ Donation Means a person during his life can donate one kidney (one kidney is capable for maintaining body functions), a portion of pancreas (half of the pancreas is adequate for sustaining pancreatic functions), a part of the liver (the segments of liver will regenerate after a period of time).¹⁷
- b) Cadaver Organ Donation: Cadaver Organs are the organs which are retrieved from brain dead declared deceased individual and transplanted into the body of a living recipient who requires it.¹⁸
- c) Xeno Transplantation: An organ is taken from another animal and used in a human.¹⁹
- d) Genetically Created Organ; Scientists are presently working on this technology. The hope is that at some point of time an organ can be created in a laboratory, from a person's own generic material, that can be used and transplanted into a person.

9 Dealing with Death: a handbook of practices, procedures and law, Jennifer Green and Michael Green, Jessica Kingsley Publishers, London, First Publication, 2006. ISBN: 10-1-84310-381-8P. 122

10 Alder Hey Children's Hospital in Liverpool and at Bristol came into limelight after the allegations made for the preserving church organs in the hospital. After inquires it was found that thousands of human body parts and samples of tissues were preserved in the hospital without the parents or relatives consent. And this was continuously operated against the name of research by the college administration.

11 Institute of Medicine, et al. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement, National Academic Press, 1998. ProQuest Ebook Central, <http://ebookcentral.proquest.com/lib/inflibnet-ebooks/detail.action?docID=3376365>

12 Created from inflibnet-ebooks on 2021-08-31 09:14:14. Page 8

13 Understanding Organ Donation Applied Behavioral Science Perspectives, Edited by Jason T. Siegel and Eusebio M. Alvarez, Blackwell Publishing Ltd, Chichester, UK, 2010, First Publication, Pg. No. 14

14 <https://dghs.gov.in/content/1353131/NationalOrganTransplantProgramme.aspx> (Last accessed on 09th May, 2022 at 10:15am)

15 Srivastava A, Mittal A. A Deceased organ transplantation in India: Promises and Challenges. *Neuro India*.

16 Organ donation in India and Nurses as a change to lead in organ donation: scoping review of organ donation, Mahendra Kumar, et al. *Indian Journal of Nursing Education and Research* 2021; 11(3): 321-325. 2021 Pg. 322

17 Medical Law and Ethics, Jonathan Herring, Oxford University Press, 2012, Fourth Edition ISBN 978-0-19-964640-1. Pg. 431

18 <https://netto.gov.in/funq.htm>

19 Srivastava A, Mittal A. A Deceased organ donation and transplantation in India: Promises and Challenges. *Neuro India* (serial online). Cited 2020 Aug 25; 66: 316-322. Available from: <https://www.neurologyindia.com/text.asp?2018/66/2/316/27259>

20 Medical Law and Ethics, Jonathan Herring, Oxford University Press, 2012, Fourth Edition ISBN 978-0-19-964640-1. Pg. 432

e) Artificial Organs: Some work is being done to create robotic/mechanical organs for transplantation with some success.²⁰

Legal Framework for the Organ Transplantation:

The Transplantation of Human Organs and Tissues Act, 1994 (herein after Act) is enacted with an object to regulate removal, storage and transplantation of human organs and tissues for therapeutic purposes and for the prevention of commercial dealing in human organs and tissues.²¹ The object of the Act is to regulate removal and transplantation of human organs with a view to prohibit commercial dealings in such transactions. A legislation of this nature was necessitated on account of the exploitation of humans for financial benefits in the dealings of organs.²² Selling and purchasing of organs is absolutely prohibited and only method adopted for human organ transplantation is donation. To achieve this objective, the Act constituted several authorities for the regulation of the organ transplantation in India. India is the second largest transplanting country in the world.²³ Several attempts have been made by the Government to promote people to donate their organs still demand and supply ratio could not be achieved after the implementation of legislation. 'Authorization and consent' are essential factors for living organ donation as well as for deceased organ donation.

The central idea behind the regulation of the human organ is authority or transfer of power from the donor to the recipient. The key concept applied in The Transplantation of Organs and Tissues Act, 1994. The bedrock of the Act is the 'Authority and Consent'. Authority means the moral or legal right or ability to control.²⁴ Authority is a specific justification or justification of a prescription precisely when the prescription does not follow with inferential clarity from other prescription we already accept.²⁵ Subsumptive, Institutional Authority and Personal Authority are the well-known categories of authority. Personal authority means individual transferred power upon the others. In simple words, authority means to confer power. Under this Act, donor is vested a power and right to donate human organ or tissues to the recipient. The entire procedure involves several fundamental issues which are discussed below:

Authority for removal of human organs or tissues:

- **Living Organ Donation:**
Section 3 of the Act, legalizes the living organ donation and provides procedure for the removal before his death of any human organ or tissue or both of his body for therapeutic purpose.²⁷ The donor and recipient shall make jointly an application for approval for removal and transplantation of a human organ to the competent authority or authorization committee specified in Form No. 11 with requisites documents in case of 'near relatives donation'.

- **Deceased Organ Donation:**
In the absence of such authority granted by the donor, the person lawfully having possession of the dead body of the donor for the human organs, (issues or both) donation for therapeutic purposes.²⁸ Sub-section (4) of section 3 states that authority given under sub-section (1) or sub-section (2) would be sufficient warrant for the removal of any human organ or tissues for therapeutic purposes. The detailed procedure is laid down under Rule 3 of the Transplantation of Human Organs and Tissues Rules, 2014 and Form No. 1, 2 and 3. Form No. 1 contains the authority and consent for donation of human organ or tissue to near relatives and added further declaration that the living donor is understood about the nature of organ donation, non-transaction of payment, free will for removal of donor, explanation of medical procedure and risks involved in the same. It is also mentioned that Form No. 1, should be notarized. Registered Medical Practitioner is duty bound merely to verify the unequivocal and unrevoked authorization by the donor.²⁹ Further, Rule 7 deals with the powers and functions of the authorization committee. Express obligation is imposed upon the Authorization Committee to evaluate and verify that any commercial transaction or transfer of payment made between the donor and recipient also to examine the reasons why the donor wishes to donate the organs or tissues.³⁰ But, there is no mention about the duty to verify the validity of authority given by the donor which is rather very crucial unaddressed issue.

Non-application of the Core concept of Consent in the procedure and conditions laid down in the Form No. 1, 2 and 3. Consent is an essential element in the entire procedure of human organ donation. Donor authorizes with his/her consent for organ donation for therapeutic purposes. Section 2, 9 and 19 of the Act as well as Form No. 1, 2 and 3 of the Transplantation of Human Organs and Tissues Rules, 2014 provides legal procedure to delegate the powers from donor to recipient.

Human Organs and Tissues Rules, 2014 provides legal procedure to delegate the powers from donor to recipient. Pg 432

Medical Law and Ethics, Jonathan Herring, Oxford University Press, 2012, Fourth Edition ISBN 978-0-19-964640-1 Pg 432
The Transplantation of Human Organs and Tissues Act, 1994-Object of the Act
Shree K. M. V. State of Kerala, 2018 AIR CC.1936 (KRR) (2017) 3 Ker LJ 876
<http://www.transplant-observatory.org> : GODT
<https://dictionary.cambridge.org/dictionary/english/authority>
Harris, J. W. "Kelsen's Concept of Authority." The Cambridge Law Journal, vol. 36, no. 2, 1977, pp. 353-63. Pg 353
<http://www.jstor.org/stable/4506020>: Accessed 16 May 2022.
Harris, J. W. "Kelsen's Concept of Authority." The Cambridge Law Journal, vol. 36, no. 2, 1977, pp. 353-63. Pg 353
<http://www.jstor.org/stable/4506020>: Accessed 16 May 2022.

Section 3 of the Act
Section 3(3) of the Act
The Transplantation of Human Organs and Tissues Rules, 2014 Rule 5
The Transplantation of Human Organs and Tissues Rules, 2014 Rule 7(3)

'Authority and consent' are the essence of the whole legal procedure. The legal procedure laid down under Transplantation of Human Organs and Tissues Act, 1994 emphasizes on written form of authority. Surprisingly, despite ease of 'near relatives' it is presumed that 'written authority on paper' would be sufficient evidence for the transplant of human organ.

The major concern for the consideration is the validity of the authority and consent which is the most essential and categorically ignored aspect in the Act. Form No. 1, 2 and 3 states the delegation of written authority from the donor to recipient and medical practitioner.

Unfortunately, careful study of the Transplantation of Human Organs and Tissues Act, 1994 and 2014 Rules thereunder, indicates the inappropriate attention is accorded towards this issue. Hence, whole of the process of giving authority by donor is in question and major loophole is still exists.

The essentials of consent are understanding of the subject matter, adequate information to be provided to the donor, voluntariness and competency of the donor. The phrase consent is used especially in the Form No. 1, 2 and 3. In order to understand the application of concept of consent, major alarming question remain unanswered is the verification and confirmation of the consent. In order to accord consent, Form No. 1 is to be attested by Notary Public.³¹ Form No. 1 contains affirmation and declaration to be given by the prospective donor in respect of non-receipt of payment, giving consent for the removal of human organ, understanding the nature of medical procedure and risks and consent etc.³² Form No. 2 and Form No. 3 covers the authority and consent given by the prospective donor with address proof.

The Act has laid down a procedure for the validity of authority and consent. A Notary is obligatory to verify and authenticate the authority and consent given by the prospective donor at his office. Unfortunately, adequate procedure is not laid down regarding how the verification of authority and consent to be done. Merely signature of the prospective donor on the forms is sufficient to indicate that the prospective donor has given an authority and consent for the removal of human organ. In *Karanjit Kaur v. State of Punjab*³³ Punjab and Haryana High Court has raised a doubt about the validity of authority and consent in case of 'near relatives' procedure for organ transplantation and passed direction to validate the authority in life.

Further, notary is not a god who has a detailed knowledge about all illness as well as pros and cons of organ donation in a situation, if medical practitioner has given wrong or inadequate information to the donor about the risk or loss involved in the donation and eventually, based on the information provided by the medical practitioner, if donor has given an authority and consent for the donation. Still, is it a valid authority or consent or just a legal formality?

Application of essentials of the concept of consent provides additional effective support to the above discussed issues. Surprisingly, definition of consent is not laid down under the Act. The roots of the consent are found in the right to individual autonomy.³⁴ For the valid consent, adequate information regarding the medical risk involved in the procedure, probable impact upon the health and demerits of the removal organs etc must be provided by the competent medical practitioner to the prospective donor.

Also, understanding of the information, voluntariness as well as competency of the prospective donor are the most prominent aspects of consent. The Act has not defined the procedure to get the consent after the observation of the core concepts of consent in the entire procedure. Signature on the Forms is just a formality and evidence for the authority and consent. However, Notary is bound to take signature on the Forms and entry into the register. Though express duty is imposed under the Notaries Act, 1952 but unanswered questions appears in the mind such as how notary verifies the consent when he is supposed to take signature and make entry in the register. It seems most inappropriate and irrational when notary is supposed to verify the competency of the prospective donor at the time of taking signature on Forms. Regarding voluntariness of the consent, how notary would verify and ascertain that the prospective donor is well informed about probable consequences of the human organ donation and now such person with free consent is ready to accord consent.

Additionally, majority of the Indian societal members are not fully literate to understand the meaning of the word 'authority' in the Act. Moreover, the practice usually observed in the real life is just to put the signature on the form without reading the terms and conditions or contents of the form. Several instances happened in the medical history which confirm this fact as well. Giving an authority to transfer living organ or deceased organ to another is very crucial and emotional

31 Sec. 8 deals with the Functions of the Notaries. Sec. (1)(a) provides that a notary may verify, authenticate, certify or at least the execution of any instrument.

32 Sec. 8 deals with the Functions of the Notaries. Sec. (1)(a) provides that a notary may verify, authenticate, certify or at least the execution of any instrument.

33 2010 (4) RCR (Civil) 760; Punjab and Haryana High Court directed that where the proposed transplant is between a married couple, the competent authority or Authorization Committee (in case donor or recipient is a foreigner) must evaluate the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph etc. are kept for records along with the information on the number and age of children and a family photograph depicting the entire family; birth certificate of children containing the names of parents and issue a certificate in Form 6 (for deceased donor).

34 Autonomy is the concept understood in the reference with to think, decide and act. It means individual persons particular kind of decision or action based on rationality.

35
right
well

ch is related with the donor's right to health. Hence, considering this issue, there should be a clear process that donor's authority or consent could be affected due to the present of coercion, undue influence, or manipulation. A common person or uneducated person could be trapped easily in the process.

on, the most structured and determined process to get the authority for organ donation is to be used in the process of leading information. Donor may be convinced or authority could be based on many things like the doctor's opinion or medical practitioner. In these cases, whether it is legally appropriate to say that the authority or consent is legally valid? Without any express power granted under the Act, the authority or consent is not valid.

By authority granted is it legally correct and valid. Hence, taking into consideration the practical aspects of the societal structure, behavioral pattern and the process of the layman, it is always indispensable and advantageous to protect the interest of the prospective donor by the state organs and it is the legitimate sphere of decision making process of the donor.

Therefore, the entire procedure laid down under the Act of giving authority and consent is frustrated. If the defined procedure is just a legal formality and documentary evidence, the purpose of the Transplantation of Human Organs and Tissues Act, 1994, Authority and Consent should be a legal procedure. The procedure is in a big question.

Conclusion:
To conclude the discussion, the Act has laid down the detailed procedure for human organ donation. The object of the Act is to regulate, storage and transplantation of human organs and tissues for medical purposes, to achieve this objectives and prevent commercial transactions, human trafficking, and other illegal activities. The Act has considered 'authority and consent' as a foundation of the entire legal procedure for organ donation. The individual autonomy is to take appropriate decision for human organ donation voluntarily.

The purpose of legally valid and binding 'authority and consent' under the Act, following suggestions should be appropriate to resolve ambiguities and the real object of the Act could be achieved.
1. Upon Authorization Committee: Researcher suggests that express duty must be imposed upon the Authorization Committee to verify the validity of authority and consent as well. Such committees should ensure that prospective donor is fully informed about his authority to donate human organ. During the entire procedure, focus should be on the donor's consent to be used for organ transplantation, validating the competency of the donor, and the procedure to be observed in the organ donation, without any undue influence or any coercion free and voluntary consent as well as pros and cons of the granting authority upon the donor's interest etc. The entire procedure should be recorded in audio and video system.

2. Upon the Medical Practitioner: To establish the legally valid system in the organ donation under the Act, it is suggested that the medical practitioner under whose supervision and control or authority, human organ donation is done should be duty bound to inform the prospective donor about the detailed medical procedure to remove the organ from his body as well as after the removal what will be the impact upon his body in the future as well. This entire procedure should be happened before the authorization committee. After the intimation of detailed information, sufficient time should be given to the prospective donor to take appropriate decision regarding human organ donation. Further, the entire procedure should be recorded in audio-video format. Afterwards, authorization committee will verify the authority and consent.
In any case, if it is found that, authorization committee or medical practitioner fail to perform their duties, stringent penal action should be initiated against them and Act should prescribe imprisonment upto seven years in such cases.
In nutshell, merely prescribing granting of authority and consent is not sufficient also to avoid the issues discussed above. It is the responsibility upon the medical practitioner as well as authorization committee to accord the real legal concept of authority and consent in human organ donation.

As per WHO Constitution (1946) health means "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being." Also the preamble of the Constitution defines health as: "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."