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UNEARTHING THE VICES IN PRESUMED CONSENT LAW IN LIGHT OF RECENT AMENDMENTS TO TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT

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ABSTRACT

To streamline the process of organ donations in India, the Parliament enacted Transplantation of Human Organs and Tissues Act. Since the first Kidney Transplantation in 1954, Organ donation has been viewed as a critical medical advancement which has potential to save lives, however, its effectiveness is questioned due to mismatch in its demand supply rates, though the donation is somewhat able to match the number of recipients, but that itself fails to resolve the problem of prolonged delays while ascertaining the consent of deceased. The recent amendment brought by the central govt to the Act aims to tackle the administrative inefficiency by introducing presumed consent for donations that will eventually streamline consent process. However, it has certain concerns as it suppresses the patient's autonomy and family's authority over deceased's decision which has the potential to reduce even the existing donation rates. The research article brings into light foreign jurisprudence by mentioning countries such as Wales and Spain having high organ donation rates and how they have reacted to the presumed consent law taking a balanced approach while accounting the interests of the parties. In light of the same, the research article brings to the fore suggestions that can be implemented having less harsher consequences than presumed consent law. Moreover, it critically examines the issue from the lens of cultural and moral rights of patients and attempts to support the arguments using relevant facts and figures.

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1. INTRODUCTION – THE RELEVANCE OF ORGAN TRANSPLANTATION IN LIGHT OF "SURVIVAL LOTTERY THEORY" PROPOUNDED BY JOHN HARRIS

The concept behind organ donation lies in the "Survival lottery" (based on utilitarian view) which states that till the time living being stands to gain from the removal of deceased's organ the latter cannot be harmed by such removal[1]. Deontological branch asserts that right to receive a transplant when in need creates a corresponding duty towards the donor.[2]

Culminating the 2 theories it can be concluded that organ donations have been a major live saver for patients suffering from irreversible organ failure since inception of its surgical techniques and the stage for it was first set when a groundbreaking kidney transplantation occurred between identical twins in 1954.

2. MISMATCH IN DEMAND SUPPLY FOR ORGAN DONATIONS

However, in recent times there exist a demand supply gap in organ donors and recipient despite increase in number of deceased donors resulting in high morbidity and increased mortality. For instance, 185,000 kidneys, 33,000 livers, and 50,000 hearts are among the 258,000 organs that India needs each year, but in comparison to it only 6000 kidneys, 1200 livers, and 15 hearts are transplanted annually.[3] Furthermore, India has a very low rate of deceased organ donation (0.34) per million people (PMP) compared to Spain, which has a 36 PMP donation rate.[4] This led to a shortage of organ donors in India. Several reasons can be attributed to such lower rates and even after its resolution their lied certain administrative difficulty.

Even though donations reach an equilibrium with the number of recipients still the efficacy

1 Peter Singer, Utility and the Survival Lottery: Philosophy Cambridge Core (2009), https://www.cambridge.org/core/journals/philosophy/article/utility-and-the-survival-lottery/B5A7A1F0AF344BD1EA8C1FC55C557819 (last visited Dec 2, 2024).

2 Sunil Shroff, *Legal and Ethical Aspects of Organ Donation and Transplantation,* Indian J. Urol., 25(3), at 348, 348-355 (2009).

3 Deepak Saxena et al., *Challenges and Motivators to Organ Donation: A Qualitative Exploratory Study in Gujarat, India,* Int'l J. Gen. Med., 16, at 151, 151-159 (2023).

4 R.P. Tamuli, S. Sarmah & B. Saikia, *Organ Donation: Attitude and Awareness Among Undergraduates and Postgraduates of North-East India,* J. Fam. Med. Primary Care, 8(1), at 130, 130-136 (2019).

of donation programme lacks because of prolonged delay to ascertain the consent of donor which is not clear before his death so the administration is forced to approach his family to rectify the standpoint. The administration further faces ethical legal dilemma as the family members already are in remorse and sometimes refuse to donate the organs, moreover, the physicians are often reluctant to intrude into familial affairs during such times.

Living donors were considered as one of the potential solutions to reduce the gap b/w demand and supply of organs[5], however, it is seen from a contentious lens and is discouraged due to the possibility that someone might donate in exchange of price which is lower thereby rendering injustice to those who are uneducated and with little bargaining power. So, preference was given to cadaveric donors but that is further plagued with certain consent related issues.

Now the potential solution to solve it is to either expand the donor pool or improve the existing consent prevailing mechanisms for pacing the process of transplantation.

In the light of same, the Govt recently introduced amendments to the Transplantation of Human Organs and Tissues Act (THOTA), 1994 to include the concept of presumed consent (also known as default donation) for facilitating cornea donation from the Indian Patients who dies without giving consent to their family and in such cases their consent to donate will be presumed unless they withdraw while they are alive.[6]

The theme sounds a progressive one improving cornea donations in the country and to majorly to assist those in need. However, it carries with it certain implications such as patient's autonomy, which will be discussed in the article and addressed further.

3. EARLIER NOTIONS

The concept of explicit consent (as the case was) mandated the individuals to actively register as organ donors affirming their willingness to donate organs posthumously, this was usually done by an act of signing into donor register and relies much on his awareness and proactive decision-making process. For instance, S. 3(1) of THOTA mentions about explicit consent as a pre-condition to utilise the donor's organs as may be determined by

5 T. Morris, H. Maple, S. Norton, J. Chilcot, L. Burnapp, H. Draper & P. McCrone, *Challenges and Opportunities in the Supply of Living Kidney Donation in the UK National Health Service: An Economic Perspective,* TRANSPLANTATION, 106(11), at 2137, 2137-2142 (2022).

6 S. Vijay Kumar, *Centre Eyes Presumed Consent for Cornea Retrieval in Hospital Deaths,* THE HINDU (Oct. 22, 2024), https://www.thehindu.com/news/national/centre-eyes-presumed-consent-for-cornea-retrieval-in-hospital-deaths/article68783423.ece.

him after he dies.[7] In case of untimely death where there is lack of evidence to ascertain the consent the decision to donate rests on his family. Hence, through this a safeguard is granted against unauthorised Organ Retrieval.

It is asserted that one who is the owner is the sole decider about disposal of his property but law has been flexible to take the inputs from the closest family members as they are the best known to be aware of donor's desires and will act accordingly.

In certain countries family members have been given veto over the consent of the donor based on the ground that a person may change his mind after opting in, and in case he forgets to withdraw or in case of unforeseen circumstances then irrespective of the nature of his consent the family's decision has to be given a priority[8].

Later, the administration was faced with several obstruction from the family because the former was unable to utilise the organs against the wishes of the latter – hence causing ethical dilemma and cause negative effect on social solidarity which is essential to transplantation process.

4. WHAT THE CENTRE AIMS TO CHANGE: HARMS PATIENT'S AUTONOMY

It was evident from the data that patient autonomy was not leading sufficient registration on donor registers as majority of donors lacked awareness on the legislation or they understand that donation works more often on the institutional framework[9] (the society in which they belong and how the regulations are imposed) rather than individual consent. The aim of centre to work on consent related issues might not give a desired output as donation has certain pre-conception bias in the society.[10]

Even though an individual is granted a consent autonomy to donate he might not be aware of the procedures and risks associated to it. Centre should first target more on improving public awareness and subsequently introduce the reforms. Wales for instance implemented presumed consent in 2015 and studies showed that 60% of the Welsh adults were first

7 Transplantation of Human Organs and Tissues Act, No. 42 of 1994, § 3 (India).

8 Mikayla Toews & Timothy Caulfield, Evaluating the "Family Veto" of Consent for Organ Donation, 188(17–18) CMAJ E436, E436–37 (2016).

9 Vivek Shrivastav et al., *Knowledge, Attitudes, and Practices Regarding Organ Donation Among Medical Students in India: A Mixed Methods Study,* 16(3) Cureus e56136 (2024), https://doi.org/10.7759/cureus.56136.

10 Greg Moorlock et al., *Should We Reject Donated Organs on Moral Grounds or Permit Allocation Using Non-Medical Criteria?: A Qualitative Study,* 30(4) Bioethics 282, 282–92 (2016).

informed about the policy before its introduction resulting in increased donation rates[11]. Similarly, Spain's donation success can be attributed more towards family consultations and education and not just presumption of consent.[12] Hence, without such safeguards it might lead to public distrust. Brazil transitioned its position from presumed to informed consent because of widespread public opposition as many were unaware of the new policy which led to confusion.[13]

Furthermore, widening gap b/w demand and supply of organ donations can also be attributed to related illness, patients with co-morbidity such as diabetes, obesity, and renal disease, apart from reduced consent rates. Hence, focussing solely on resolving consent related issues might not bring the desired outcome instead, much emphasise needs to be placed on ancillary issues related to awareness and improving other age-related health issues.

5. "CONSENT" AS USED IN HEALTHCARE INDUSTRY

"Consent" used in healthcare industry rests on ethical notion, implying that donor analyses the potential consequences and comprehensively have a dialogue with the authorities. Therefore, the policy of presumed consent somewhat goes against the ethical notions of consent as understood in "medical field."

Further instance can be taken from, UK's Codes of Practice laid down by the Human Tissue Authority[14] which asserts that consent is not passive process it is more of a positive one. This precaution has retained the faith and confidence of public in the system. It was witnessed that switching from active to opt out consent will not improve the numbers of available organs and it may undermine the public's confidence in the system as a result of which the donation rates might worsen from the existing one.

The move adopted by the centre undermines patient autonomy, his wishes are not paid heed and might have untoward impact on the organ donations across country. Individuals having learnt about bodily integrity may protest against the centre's move by explicitly opting out for donation which will altogether reduce donations even lower than what could have been

11 D.J. Dallimore et al., Media Content Analysis of the Introduction of a "Soft Opt-Out" System of Organ Donation in Wales 2015–17, 22(3) Health Expectations 485, 485–95 (2019), https://doi.org/10.1111/hex.12872.

12 J. Fabre, Presumed Consent for Organ Donation: A Clinically Unnecessary and Corrupting Influence in Medicine and Politics, Clinical Medicine 14(6):567 (2014), https://doi.org/10.7861/clinmedicine.14-6-567.

13 N.J. Williams & S. Wilkinson, Presumed Dissent? Opt-Out Organ Donation and the Exclusion of Organs and Tissues, 30(2) Med. L. Rev. 268 (2022), https://doi.org/10.1093/medlaw/fwac001.

14 Human Tissue Authority, *Codes of Practice, Standards, and Legislation*

in the situation of informed consent. The possibility of more opt-outs as a reaction to govt interference was expressed by the Organ Donor Task Force[15]. Welsh experience has shown that since law went into effect, roughly 5% of the eligible population choose to opt out.[16]

Moreover, 54% of the individuals are registered as organ donors in US and research indicates that as a result of lack of robust consent policies 20% to 40% of potentially qualified deceased donors may not have given their organs.

Here it is important to consider Ramsey's defence of voluntary behaviour wherein he mentions that the more the state takes the more the state restricts people's ability to behave voluntarily, the less opportunity they have to be altruistic, and consequently the society will be less moral[17]. Since presumptive consent limits the ability of individual to act voluntarily, it also reduces the ability to act generously.

With its introduction organ donation will be construed more as "organ acquisition, implying that act will not be termed as gift or donation per se rather a commodity "coercively taken" from the dead. In the words of Pope Benedict – a transplantation can be categorised a gift only when it involves aspect of informed consent else will be classified is an abusive act.[18] The Catholic church was always inclined towards adopting traditional mode of organ donation and not unfair means of presumed consent. It believed in not cooperating with such means and allowed retrieving of organs in accordance with the donor's wish.

The idea of presumed consent focusses on "nudge theory" which makes the people default donors unless they opt out, the theory can be connected because it mentions that when people are unsure about what to do, they often stick to the default option.[19] Herein donors might not understand the policy properly or forget to opt out, or avoid taking action because it feels like too much effort or not have thought in depth about what organ donation means for them or their beliefs. This sometimes is referred as "status quo" bias.[20] The presumed consent supersedes over human psychology in a manner that some might be encouraged to donate but do not come forward actively to register themselves, however this concept aims

15 Prabhu, P. K., *Is Presumed Consent an Ethically Acceptable Way of Obtaining Organs for Transplant?,* 20 J. Intensive Care Soc. 92 (2018), https://doi.org/10.1177/1751143718777171.

16 Ibid

17 Mehlman, M. J., *Presumed Consent to Organ Donation: A Reevaluation,* 1 Health Matrix 31 (1991).

18 Pope Benedict XVI, Address to the Members of the Academy for Life (Nov. 7, 2008), https://www.vatican.va/content/benedict-xvi/en/speeches/2008/november/documents/hf_ben-xvi_spe_20081107_acdlife.html.

19 A.T. Schmidt & B. Engelen, The Ethics of Nudging: An Overview, 15 Phil. Compass e12658 (2020). A.T. Schmidt & B. Engelen, *The Ethics of Nudging: An Overview,* 15 Phil. Compass e12658 (2020).

20 Ibid

to increase the donors without despite their willingness. Hence, it can be concluded that donation happens because people "forget to opt out" instead of their conscious to donate.

Hence, it should be noted that as per Art. 21 of Indian Constitution[21]. right to make autonomous decision about one's own body is an integral part of right to life, the presumed consent strikes at the root of it. In Aruna Shanbaug v. UOI, the SC mentioned the significance of individual autonomy in matters related to their body[22]. Herein removal of organs without express consent amounts to a blatant violation of bodily integrity.

6. OVERRIDING FAMILIES' DECISION OVER DECEASED'S ORGAN DONATION THERAPY

Simply put, the presumptive consent would allow the authorities to put forth the questions to deceased's kin that *"do you think that donor would have objected?"* instead of *"can we go ahead with the donation?"*

Under the existing legal framework (S. 9 of THOTA), the act empowers the family members to authorise the donation on behalf of deceased in case of brain stem death making them as a surrogate decision maker.[23] The family's involvement is regarded significant and their choice is respected. In informed consent regime families can either confirm the deceased's decision or in absence of that take their own authorisation. However, the decision is generally influenced by moral values and religious beliefs, preconceived bias, non-willingness to involve in the process, lack of decision-making capacity and emotions creates an obstruction in donation process. For instance, in UK family refusal rates exceeds 40%. due to aforesaid factors.[24]

In situations where presumed consent is implemented it leads to a dilemma that should the state override the objections of family thereby upholding the presumed consent of the deceased or should wishes of family prevail.

On one hand countries such as Denmark where families retain the right to veto organ donation representing collective will of deceased and Spain where donor's consent (having donor card) is insufficient until backed written consent of family but on the other such policies of govt. In 2020 Survey was carried out in India where it was inferred that 68% of families

21 India Const. art. 21.

22 Aruna Ramchandra Shanbaug v. Union of India, (2011) 4 SCC 454.

23 Transplantation of Human Organs and Tissues Act, No. 42 of 1994, § 9 (India).

24 Bird, S. M., & Harris, J., Time to Move to Presumed Consent for Organ Donation, 340 BMJ 1 (2010).

were hesitant to approve the donation because they hadn't had any prior consultations with deceased.[25] This hesitancy might exacerbate in case families are excluded further from the process. Brazil's policy failure cannot be ignored where presumed consent led to widespread mistrust one of the reasons being exclusion of families.

Furthermore, for adults dying without being registered donors there is a trend of high refusal rates for organ donation by the relatives – data shows it as 46.7%. Consent rate reaches to 91.25 in case a donor is registered and his wishes is known to relatives.[26]

Spain enacted the law on presumed consent in 1979 however, there was no significant increase in donation as a result of which several organisational structures were introduced at the national level commonly known as "the Spanish system" which became a model for countries to emulate.[27] It focussed on alleviating the concerns and misconceptions of families to enhance their consent rates instead of focussing solely on donor specific consent law.

7. NOT ACHIEVES WHAT IT INTENDS TO - ATTENTION MUST BE PAID TO DIFFERENT THINGS

A survey conducted revealed that donations pmp increased significantly for the countries with opt-out legislation for instance in Spain, Belgium, and Austria, however, this could not be solely attributed to the opt out system, for instance in Bulgaria and Luxemburg despite the presence of such system there is lower pmp, hence other factors such as health infrastructure, education and public awareness play a crucial role[28]. The scope of opt out legislation has to be kept open for review after every 5 years.

25 Panwar, R., Pal, S., Dash, N. R., Sahni, P., Vij, A., & Misra, M. C., *Why Are We Poor Organ Donors: A Survey Focusing on Attitudes of the Lay Public from Northern India,* 6 J. Clin. & Exp. Hepatol. 81 (2016), https://doi.org/10.1016/j.jceh.2016.04.001.

26 Ibid

27 Streit, S., Johnston-Webber, C., Mah, J., Prionas, A., Wharton, G., Casanova, D., Mossialos, E., & Papalois, V., *Ten Lessons from the Spanish Model of Organ Donation and Transplantation,* 36 Transplant Int'l 11009 (2023), https://doi.org/10.3389/ti.2023.11009.

28 Rithalia A., McDaid C., Suekarran S., Norman G., Myers L., Sowden A., *A Systematic Review of Presumed Consent Systems for Deceased Organ Donation,* 13 Health Technol. Assess. 26 (2009), https://doi.org/10.3310/hta13260.

8. WAY FORWARD

To achieve the intended objective of the presumed consent a preferable strategy would be to create an efficient opt out mechanism for patients and their families to voice their objections to donation and to educate them about the operation of implied consent. A 2019 Study by MOHAN Foundation revealed that only 12% of the population was aware of organ donation procedure, introducing presumed consent without adequate public education risks exploitation of uninformed and the situation might worse for people in rural areas.

A set of special rules is required to govern the removal of organs from minors, and other class of patients who are incompetent or died without family members present.

A classic instance is of Welsh Assembly which decided to incorporate presumed consent for organ donation into a law by passing the Human Transplantation (Wales) Act 2013[29]. However, it was incorporated with certain modifications by allowing "soft opt out" system implying that the state will not override the next of kin's decision. The state did not want to portray itself as having a "right" over deceased's organs which might lead to "individual – opt outs". With this model family objections still account for 10% of refusals reflecting the significance of family consultation as a safeguard. Hence a similar model can be considered in India, presumed consent must be accompanied by family consultation to balance autonomy and cultural sensitivities. Spain also passed a legislation regarding presumed consent; however, it did not have beneficial effect on donations due to which significant changes were introduced thereby creating "organisational infrastructure" at national level for transplantation globally referred as "the Spanish system" which led to its success of being leader in organ donation in the world. This further has imposed trust of family members in the healthcare system as a result of which they easily agree to donate deceased's organs.

Another potential solution lies in emphasising on the concept of "mandated consent" where it will require people to either agree or disagree with the donation making it ethically sound policy. Furthermore, as donor choices vary over time they should be allowed to review their preferences for organ donation on frequent basis. In this regard, the case of Australian govt can be taken into account where people are obligated to indicate their preference for organ donation at the polling station while they caste their vote for federal elections.[30] So,

29 J.F. Douglas & A.J. Cronin, The Human Transplantation (Wales) Act 2013: An Act of Encouragement, Not Enforcement (2015).

30 X. Symons & B. Poulden, *An Ethical Defense of a Mandated Choice Consent Procedure for Deceased Organ Donation,* 14(3) Asian Bioethics Rev. 259, 259–70 (2022).

each time a person casts a ballot, their decision to donate should be reviewed so that any modifications are regularly monitored. Hence, without imposing any additional obligations for registration or review it allows for careful examination of the decision.

9. CONCLUSION

Though the centre has adopted a benevolent approach while bringing out recent amendments to the Act, it should be vigilant of its potential consequences. The Models of different countries can be used as an approach to bring structural changes in the proposed amendment to streamline the process and bring out the desired results.