Comparative Analysis of Opt-Out Organ Donation Laws in Developed Countries: Lessons for India

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ABSTRACT

The persistent gap between organ demand and availability has prompted many countries to reform their organ donation frameworks. It's important to mention that EU nations like Spain, Austria and France have opted for the opt-out system where all citizens start out as potential donors unless they say otherwise. The paper examines the laws of these countries, their working structures and public attitudes to assess how much presumed consent laws actually help. We examine how these systems have helped to increase the number of organ donations and adjust their viability to suit the Indian system and laws. Identifying how these systems function in terms of regulations, hospitals and clinics, info for the public and right practices is a main goal. These matters involve the hesitation welcomed by society for deceased organ donation, the lack of a national law that treats consent as presumed, concerns raised by religions and families and the possible use of organs without clear objection in a great democracy. By reviewing experiences from other nations, the document strives to offer meaningful suggestions for India to move from an opt-in to an opt-out model, stressing the importance of public faith, transparent policies and laws that fit India's diverse groups.

Keywords: *Opt-out Organ Donation, Organ Transplantation, Ethical Considerations, Deceased Organ Donation.*

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1. Introduction

In the matter of organ donation, some developed countries are adopting a policy where people do not have to actively agree for donation. At death, the concept treats people as consenting organ donors unless they have chosen not to become donors during their lifetime.[1] This idea is opposite the opt-in method, where donation takes place only after people officially registers themselves as organ donors. In Spain, Austria and France and other developed nations, using the opt-out system has increased the deceased organ donation rates. The models created in different countries show that India's low level of donated organs needs attention, even as the number of patients requiring transplants is growing.

Though India's population is largest in the world yet very few organs become available through donation. Only 0.65 persons give the gift of organ donation for every million Indians, while Spain registers more than 40 such donors per million. This proves that a big change in India's organ donation rules is essential. Because the opt-out system has grown donor pools in other places, it is now a key topic under discussion in Indian policy circles. A comparison of its use in different countries and its fitness to the India's culture, laws and society should be carried out before adopting the model.[2]

The way things are handled legally, culturally and in healthcare are not the same in developed countries. Spain and France follow a soft opt-out policy whereas Austria follows a hard opt-out approach. In a soft opt-out approach even though the citizens are deemed to be organ donors unless they have opted out from it in their life time, the consent of the aggrieved family of the deceased is also sought and respected, whereas in hard opt-out approach no such consent of the family is sought and even if the family refuses for such donation their emotions are not respected. Spain has one of the highest organ donation rates in the world, largely due to a well-organized transplant coordination system and public awareness efforts, not just the legal framework.[3] A detailed comparison of these frameworks, how they were created and what they accomplished may suggest a way for India to modify its donation rules without harming their usefulness.

2. Types of Organ Donation and Transplant Policies

Organ donation requires receiving organs from a generous donor to transplant them into people who urgently need a healthy organ. States use many different, often complicated

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[1] Rajesh Panwar, *et. al.*, “Why Are We Poor Organ Donors: A Survey Focusing on Attitudes of the Lay Public From Northern India” 6 *Journal of Clinical and Experimental Hepatology* 81 (2016).

[2] *Ibid.*

[3] R. Matesanz, *et. al.*, “How Spain Reached 40 Deceased Organ Donors per Million Population” 17 *American Journal of Transplantation* 1447–54 (2017).

guidelines to regulate donation and transplantation. Unless mentioned otherwise, the term organ donation here will refer to deceased organ donations.[4] Deceased donation refers to the donation of organs after a death is declared, and the organs will be usable if the death is either determined by brainstem or circulatory death. A great many organ transplants around the world involve these types of transplants. Living donation, on the other hand, involves a living person voluntarily donating a very limited number of organs such as one of their kidney, a portion of their liver, lung, pancreas or intestines, and the donor's condition often determines whether he can donate the organ or not. Organ transplantation refers to the process in which organs given by donors are inserted into people who need them, and there is a difference between donating and transplanting, as not all donated organs are successfully transplanted due to factors such as organ condition or chance of compatibility. Getting an organ involves finding a suitable donor, asking the family's permission and obtaining the organ, and in most cases, permission is granted for organ donations after a transplant coordinator talks with a potential donor's relatives.[5]

Organ donation rules use three main options: people must opt in, opt out, or consent through a required option. In opt-in systems, individuals must agree to become donors in order to register, and a person becomes a donor after he fills out a registration form. It is also called an "express consent" policy.[6] In an opt-out system, all citizens are presumed to be organ donors unless and until they have voluntarily made it clear during their lifetime that they do not want to be an organ donor. In these systems, people are presumed to give consent after death unless they have excluded themselves in advance.[7] Under the required option system, people must make a decision about whether they want to become an organ donor or not when applying for a new or renewed driver's license or when signing up for a donor registry, and most states have donor registries where prospective donors can register their desire to donate their organs. With this strategy, personal responsibility of individuals also comes into the picture, and everyone knows what they are working towards.

According to hard consent models, what people choose in their life time matters a lot. Only with their permission the organs be donated in hard opt-in systems, and if they did not

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[4] Kenneth W. Kizer, Rebecca A. English, *et. al.*, *Realizing the Promise of Equity in the Organ Transplantation System Realizing the Promise of Equity in the Organ Transplantation System* (National Academies Press, 2022).

[5] Katja Doerry, *et. al.*, "Religious and Cultural Aspects of Organ Donation: Narrowing The Gap Through Understanding Different Religious Beliefs" 26 *Pediatric Transplantation* (2022).

[6] Jordan Miller, *et. al.*, "'It's Like Being Conscripted, One Volunteer Is Better Than 10 Pressed Men': A Qualitative Study into the Views of People Who Plan to Opt-out of Organ Donation," 25 *British Journal of Health Psychology* 257–74 (2020).

[7] David B. Olawade, *et.al.*, "Transforming Organ Donation and Transplantation: Strategies for Increasing Donor Participation and System Efficiency" 133 *European Journal of Internal Medicine* 14–24 (2025).

have actively said no to organ donation in hard opt-out systems their organs will be donated. People who are grieving for their loved ones are more concerned about the cremation rather than on deciding about organ donation. When a person's wishes are not known for certain, families may be asked for consent to donation by the donation agency. Since the deceased's wishes are considered to be respected, the responsible families accompany these practices.[8]

The central worry about posthumous organ donation is the status of individuals in both legal and ethical terms after dying. Although there are no major rights of the deceased which are recognized by law but the customs and traditions says to treat them with lasting respect. So, normally, organs are taken only when the deceased and their family both agree to this.[9] Often, it is up to the family to make decisions about remains as well as organ donations. Legal frameworks set out how to get permission, who is allowed to approve payments and how closely donor requests need to be followed. Because there is no single rule for the rights of human remains, it is clear that laws regarding organ donation must be adjusted depending on the situation.[10]

An opt-out system means that in most countries, people become donors at death, unless they have stated somewhere that they did not wish to donate after their death. The goal of this policy is to overcome the shortage of organs for transplantation by making the process of receiving people's consent faster and easier for those dealing with their loved one's death. Whether or not it is the right choice such agreements continue to raise ethical questions, since individuals active consent is not sought by him voluntarily. A lot of countries that use this approach let families know about the process ahead of time, making sure efficiency is maintained while still thinking about personal and family wishes.[11]

3. Working of Opt-Out System at International Level

Countries around the world have implemented or tested variants of the opt-out approach, with differing levels of success. In Europe, nations like Spain, Austria, Belgium, and France have historically advocated for implied consent. In recent years, some countries, notably England (UK), the Netherlands, and Wales, have adopted opt-out frameworks, moving away from opt-in systems. Beyond Europe, nations like Singapore and Colombia

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[8] Raymond Vanholder, *et. al.*, "Organ Donation and Transplantation: A Multi-Stakeholder Call to Action" 17 *Nature Reviews Nephrology* 554–68 (2021).

[9] R. Matesanz, et al., "About the Opt-Out System, Live Transplantation, and Information to the Public on Organ Donation in Spain … Y olé!" 17 *American Journal of Transplantation* 1695–6 (2017).

[10] Sunil Shroff, "Legal and Ethical Aspects of Organ Donation and Transplantation" 25 *Indian Journal of Urology : IJU : Journal of the Urological Society of India* 348 (2009).

[11] Sunil Shroff, "Working Towards Ethical Organ Transplants" 4 *Indian Journal Of Medical Ethics* 68–9 (2007).

have adopted opt-out regimes, indicating an increasing worldwide trend towards implied consent as a strategy to mitigate organ shortages.

The justification for the opt-out mechanism is both legal and practical. From a legal perspective, assumed consent laws seek to streamline and standardise organ retrieval processes, therefore eliminating procedural obstacles that might hinder or obstruct donation. Advocates contend that these systems signify a change in society norms, positioning organ donation as a standard social benefit rather than an extraordinary act of generosity. From a public health standpoint, implied consent methods are thought to decrease family refusal rates and expand the pool of possible donors, hence enhancing transplantation results and decreasing reliance on live donors.[12]

Nonetheless, the shift to an opt-out mechanism is fraught with controversy. Critics express apprehensions over the ethical ramifications of assuming consent without specific individual approval. Enquiries about physical autonomy, informed consent, and governmental overreach persist in questioning the validity of these legislative improvements. The efficacy of opt-out legislation is heavily influenced by contextual circumstances, including public faith in healthcare institutions, the strength of administrative processes for registering disagreement, and the availability of infrastructure for organ retrieval and transplantation. Legislation alone is insufficient; the efficacy of opt-out systems requires meticulous implementation, ongoing public education, and clear legal protections.

The top three countries where the adoption of opt-out system have proved to be a great success are Spain, Austria and France. The entire working of the system in these countries becomes important to be discussed in detail, to find some viable solution to be adopted for India.

3.1 Spain

Although Spain operates under a formal assumed consent system, transplant coordinators actively seek to ascertain a patient's willingness to donate before to death, as well as the comfort level of their families or loved ones with this decision. Estébanez a transplant coordinator for 4 years stated in a paper published by World Economic Forum that around 10-15 percent of relatives decline to provide permission, a figure she aspires to reduce to zero. The impact of death is sometimes difficult to comprehend. Estébanez

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[12] Alejandra Zúñiga-Fajuri, "Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile" 93(3) *Bulletin of the World Health Organisation* 199–202 (2015).

recalled a patient who expressed a desire to become a donor. Following his death, his sister consented, although his wife did not. The medical personnel had respected the family's wishes, she said.[13] Transplant coordinators arrange matters and National Transplant Organisation (Organización Nacional de Trasplantes) (ONT) takes charge of organ allocation, cooperating with 189 facilities where organs are harvested and 44 hospitals for transfer and transplant. To coordinate, Estébanez and others rely on one database and many phone calls, often using older cell phones that keep working.[14] As soon as a donor dies, an external group acts quickly to gather the organs for distribution among the recipients. Organs take just minutes to become unusable after oxygen is cut off and hospitals are compensated by the government when a retrieval is performed.[15]

Spain introduced its presumed consent (opt-out) system for organ donation with the *Transplantation Law (Law 30/1979 of October 27)*. Article 5 of this statute presumes all citizens are organ donors unless they have expressly objected. Although the legislation for organ donation in Spain switched from consent required to opt out in 1979, the rate didn't increase immediately. It was in 1989, a decade after the law passed, that a national coordinating network *Organización Nacional de Trasplantes (ONT)* for transplants was set up. As a consequence, a major change began in the country's organ donation processes. Part of what made this change happen was that every hospital hired transplant coordinators. The specialists often chosen from critical care units know how to recognize potential donors, carry out medical aspects of the procedure and talk compassionately to families about the possibility of donation.[16] The active approach used by doctors contributed to many more organ donations, making Spain the leading country in the world. In fact, there is much misunderstanding about Spain's legal situation. Even with the opting-out law, there is no central, national system for people to indicate their choice.[17]

With this method, rates of organ donations in Spain soared rapidly. It pointed out that a rigorous system and knowledgeable employees matter, apart from making sure the laws are strong. As a result, the European Union backed a policy to help member states set up systems similar to Spain's. One of its main points is to develop national coordination and to assign professionals familiar with donation to each hospital following the Spanish

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[13] Chris Baraniuk, "Spain Has a Lesson for The Rest of The World About Organ Donation" *World Economic Forum,* June 27, 2018.

[14] *Ibid.*

[15] Rekha Lalwani, Sheetal Kotgirwar, *et.al.*, "Changing Medical Education Scenario: A Wakeup Call for Reforms in Anatomy Act," 21 *BMC Medical Ethics* (2020).

[16] Chris J. Rudge, "Organ Donation: Opting In or Opting Out?" 68 *The British Journal of General Practice* 62 (2018).

[17] A. Rithalia, *et.al.*, "A Systematic Review Of Presumed Consent Systems for Deceased Organ Donation" 13 *Health Technology Assessment* (2009).

model.[18]

Because of Spain's strong organ donation program, Croatia looked to the Spanish *National Transplant Organization (ONT)* for advice in the past. After that, Croatia apparently copied Spain's governance system almost completely.[19] Research done in 2013 showed Croatia's progress with to an increase in donors over 30 per million population. Yet, the close resemblance to parts of Spain's system suggests the basis was drawn from the Spanish approach, without any formal recognition.[20]

Although opting out is allowed, Spanish officials say that the legislation alone is not behind their high proportion of donors.[21] The implied consent statute was not very effective until major changes were made in medical practices and hospitals were better coordinated. In Spain, city planners, hospitals and families are involved to show that infrastructure, training and family help lead to more organ donations. It acts as a strong model for other nations wanting to progress in donation rules by putting into practice real advances, not only passing new laws.[22]

3.2 Austria

Austria follows a "hard" opt-out system for organ donation, since 1992, after the enactment of the *Federal Act on Transplantation (Transplantationsgesetz)* in the year 1991. As per Section 62 (Para 1) all adults are considered as organ donors unless they have explicitly refused it during their life. Section 62 (Para 2) gives the requirement for the refusal; it says that a written declaration of refusal must be recorded in the Austrian Federal Ministry of Health's registry. In cases where the deceased did not opt out, organs may be removed without consulting the family, making enforcement strict compared to the softer approaches in Spain or France. Even so, only about 0.25% of the population has chosen to do this so far. Austrians tend to be somewhat passive in signing out of donation, which has helped Austria have high donation statistics for several years.[23]

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[18] John Fabre, Paul Murphy, *et.al.*, "Presumed Consent: A Distraction In The Quest For Increasing Rates Of Organ Donation" 341 *BMJ (Online)* 922–925 (2010).

[19] M. J. Pérez-Sáez, *et.al.*, "Survival Benefit From Kidney Transplantation Using Kidneys From Deceased Donors Aged ≥75 Years: A Time-Dependent Analysis" 16 *American Journal of Transplantation* 2724–2733 (2016).

[20] *Supra* Note 3.

[21] Marie Thuong, *et.al.*, "New Classification of Donation After Circulatory Death Donors Definitions and Terminology" 29 *Transplant International* 749–759 (2016).

[22] S. D. Shemie, *et.al.*, "Lifetime Probabilities of Needing an Organ Transplant Versus Donating An Organ After Death" 11 *American Journal of Transplantation* 2085–2092 (2011).

[23] Rajvir Singh, *et.al.*, "Opt-Out Consent at Different Levels of Attitude to Organ Donation: A Household Survey in Qatar" 14 *Journal of Multidisciplinary Healthcare* 401 (2021).

Austria is part of the European Eurotransplant consortium, made up of eight countries, that makes organ sharing across borders possible. The member countries are Austria, Slovenia, Belgium, Croatia, Luxembourg, Germany, Hungary and the Netherlands. From Leiden University, the Eurotransplant Foundation supervises the lists of people waiting for organs and makes sure each member country follows its organ allocation rules. The Transplantation Advisory Board has created Austria's unique allocation rules which were then signed by the Ministry of Health. Transplant clinics generally allot organs according to medical urgency and recipient need, exercising considerable discretion. The Standing Committee Organ Transplantation of the German Medical Council enforces allocation regulations in Germany, serving as a member of the European Transplant Committee (ET).[24]

All four regional centers for organ donation in Austria are set up inside transplant centers. National transplantation would not be effective without these coordination centers. It is their job to find possible donors, give donor information to Eurotransplant and arrange the procedure for collecting organs with surgeons from the entity involved. Also, specific coordination centers in hospitals become responsible for telling the regional centers about possible donors. Affiliated with transplant centers, transplant coordinators direct and support smaller hospitals in learning how to identify donors and submit their reports. Since 2017, Austrian law requires that a second opinion from a different transplant centre is obtained before the organ of a suitable donor can be rejected. It aims to build better openness, accountability and begin strengthening medical integrity in organ procurement. The extra check is added to ensure no deserving organs are overlooked due to anyone's or an organization's healthy prejudices.[25]

Some parts of the job of the transplant coordinator are different in Austria than in Spain. In Spain, many transplant coordinators are critical care experts who help determine who should donate and how to speak with relatives. In Austria, it falls to the ICU staff to talk about organ donation with a family member. As most transplant coordinators in Austria are medical students, they tend to hold back from family matters, afraid their training may cause tension. Austrian experts believe surgeons ought to stay out of conversations about donation with families. The issue comes from worries about surgeons' personal profit from success in retrieval and transplantation. Family ethics require that no one is pressured, but all families receive complete support instead. When possible, the family should hear this news from an

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[24] A. Vincent and L. Logan, "Consent for Organ Donation," 108 *British Journal of Anaesthesia* (2012).

[25] Danyang Li, Zackary Hawley, *et.al.*, "Increasing Organ Donation via Changes in the Default Choice or Allocation Rule" 32 *Journal of Health Economics* 1117–1129 (2013).

ICU staff member they are used to and trust which is typically the patient's physician or nurse.[26]

Using this approach which values culture and ethics, reassures families and asserts that the organ donation procedure is done with great respect to the dead. It enables families to discuss these hard choices with medical staff they recognize, instead of relying on transplant coordinators or surgeons, because it might ease their stress at that time. Austria has succeeded in increasing organ donation but its credit goes to opt-out method, only partly, as it is not the only reason behind its success. Carrying out the system requires a wide range of coordination centers, detailed ways of allocation, constant medical oversight and a family-based method for starting donation talks. The close relationship among sections of the health system is behind Austria's high rates of organ donation and makes its approach unique.[27]

Nations considering or applying this type of regulation can learn a lot from Austria's experience. It explains how essential infrastructure, qualified people and morally sound rules are, as well as the requirements the law sets out. Although using implied consent encourages donations, a sound system should address the emotional, ethical and medical part of the donation process. Austria achieves an effective and caring opt-out system using strong organizational support, clear sharing practices and caring family involvement.[28]

The nation's successful opt-out system depends on much more than just its laws. Such an outcome is achieved with an organized, ethically solid and scientifically correct process applied from national planning to the hospital bedside. Europe has one of its most effective organ donation systems, which is largely possible due to Austria's joining in Euro transplant and its diligent management of responsibilities. Here, legislation defines the system, but it is only when policy, practice and empathy join together that the process leads to great results.[29]

3.3 France

France's presumed consent system is enshrined in the *Bioethics Laws*, specifically in the *French Public Health Code (Code de la Santé Publique)* as amended in 2017. Article

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[26] M. Wilkinson, "Individual and Family Decisions About Organ Donation" 24 *Journal of Applied Philosophy* 26–40 (2007).

[27] Jeremy Chapman. *et.al.*, "Follow-up After Renal Transplantation With Organs From Donors After Cardiac Death" 19 *Transplant International* 715–719 (2006).

[28] Rajvir Singh, *et.al.*, "Prevalence of Socio-demographic and Behavioral Factors About Organ Donation in Qatar: A Household Survey" 2020 *Qatar Medical Journal* (2020).

[29] "The Potential Impact of An Opt-out System for Organ Donation in the UK on JSTOR", *available at*: https://www.jstor.org/stable/20789510 (last visited on May 28, 2025).

L.1232-1 of the law states that all deceased persons are considered as potential donors unless they've registered an objection during their life in the National Register of Refusals or communicated their refusal to relatives, who can relay it to medical staff. The system is "soft" opt-out, as relatives are consulted, especially if no official refusal exists. Additional principles required by law include the anonymity of donation, prohibition of payment, and procedures to ensure informed decisions and safety of transplants. The 2021 Bioethics Law extended the obligation for broad public information about organ donation.

The reason for France's switch to an opt-out system is the ongoing gap between those who require transplants and organs that can be transplanted. The policy intends to assist transplantation by including those who may need an organ on the waiting list, unless they express other wishes. Establishing consent as a default means for most of the organs that are transplantable, so more people tend to treat donation as the expected thing.[30] On the one hand, French law supposes that agreement is not needed, but it gives people tools to ensure that their values are recognized. The people signing up on the refusal registry gets an opportunity to state clearly without any external pressure their wish to not become an organ donor. In addition, if family members keep expressing objections in conversations, it protects against anyone's silent and unspoken wishes.[31]

It is clear from France's opt-out contribution that trust from the public and good communication are crucial. Those working in medicine should speak compassionately and clearly with the family if the deceased didn't object to the procedure. As a result, although families are not able to correct the lack of registration, their interests are recognized and proper standards direct the removal of organs.[32] France and its healthcare services have chosen to educate the public to promote lasting success. Measure are in place to teach the local community about rights under the revised system and to decrease the shame often attached to organ donation. The goal is to reach youngsters as well as groups that have doubts about medical institutions. France is encouraging people to see organ donation as a responsible thing to do through open discussions about it.[33]

The introduction of the soft opt-out provision has improved donation rates in France, as the data shows. Although the legal shift alone didn't cause the rise, it has

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[30] Amanda M. Rosenblum, *et.al.*, "The Authority Of Next-of-kin In Explicit And Presumed Consent Systems For Deceased Organ Donation: An Analysis of 54 Nations" 27 *Nephrology Dialysis Transplantation* 2533–2546 (2012).

[31] Janet Delgado, *et.al.*, "The Role of the Family in Deceased Organ Procurement: A Guide for Clinicians and Policymakers" 103 *Transplantation* 112–118 (2019).

[32] Katharina Beier, *et.al.*, "Understanding Collective Agency in Bioethics" 19 *Medicine, Health Care and Philosophy* 411–422 (2016).

[33] David Shaw, *et.al.*, "Family Over Rules? an Ethical Analysis of Allowing Families to Overrule Donation Intentions" 101 *Transplantation* 482–487 (2017).

definitely changed how donation discussions take place. Health professionals say there are fewer cases now of donation being blocked due to family members unsure of the deceased's wishes.[34] But, the process of moving to the present system has not been entirely smooth. Concerns about implied consent continue, since many underprivileged groups still continue to protest against inadequate care. In reaction, France has promised to work on improving communication, making sure everyone in rural or undeveloped areas, as well as other groups, learn about their rights and new system options.[35]

World leaders should realize that good healthcare reform depends on tactics that fit a country's culture and values. The basic block is legislation and the rest such as community participation and continuous monitoring of the result, should be built on top of it. The focus of the strategy is that organ donation should be ethically, socially and medically and legally sound.[36] France's decision to make people organ donors unless they opt out is a clear and early move against the lack of organs. Although there are still problems around ethics, autonomy and reputation, the policy helped create an improved and fairer way for donations. The nation is working to improve its methods, explaining how better laws, community work and institutional support can make a big difference in public health.[37]

4. Disadvantages of Opt-Out System

Presumed consent may be seen as a violation of the individual's autonomy and bodily integrity, especially if individuals are unaware of their right to opt out.[38] Some people may not understand the law or may not know they are considered donors unless they take specific action.[39] Greece is one of the glaring example which has faced this issue it had implemented an opt-out system in 2013, but faced public backlash and mistrust due to poor public awareness, leading to suspension of the law's enforcement.[40]

The other major downside is persistent high rates of family refusal. In many of the opt-out countries, the families are often consulted, and in case if the deceased persons had

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[34] *Supra* note 6 at 3.

[35] Alberto Molina-Pérez, *et.al*., "Should the Family Have a Role in Deceased Organ Donation Decision-making? A Systematic Review of Public knowledge and Attitudes Towards Organ Procurement Policies in Europe" 36 *Transplantation Reviews* 100673 (2022).

[36] *Ibid.*

[37] *Supra* note 21 at 7.

[38] Cameron, J. & Forsythe, J. L. R., "How Can We Improve Organ Donation Rates? Research Into the Identification of Barriers and effective Policy Strategies" 322(7292) *British Medical Journal* 1114–1116 (2001).

[39] Delgado J., & Llobet G., "Presumed Consent in Organ Donation: Is It Really the Answer?" 45(3) *Journal of Medical Ethics* 191–195 (2019).

[40] Georgiadis, A., & Papalois, A., "Donation and Transplantation in Greece: Problems and Solutions" 5(2) *International Journal of Organ Transplantation Medicine* 79–84 (2014).

not made their wishes clear to their relatives, they most often block donation out of uncertainty or mistrust. The UK had reported family refusal as the biggest obstacle to donation, with rates around 39% for ethnic minorities, largely due to families not knowing their loved one's preferences.[41]

The evidence repeatedly shows that simply shifting to an opt-out default doesn't inherently raise donation rates. Longitudinal studies across countries like Argentina, Chile, Sweden, Uruguay, and Wales found no significant difference in deceased donor rates after switching from opt-in to opt-out, unless accompanied by substantial investment in healthcare infrastructure and public education.[42] Chile experienced a 29% drop in donations after implementing opt-out, due in part to widespread misunderstanding and mistrust among the population. Only later, with legislative adjustment and improved transparency, did donor rates recover.[43]

Imposing presumed consent without adequate public preparation can damage confidence in the health system. Brazil's experience is instructive: After a “hard” opt-out model was introduced in 1997, there was such public outrage that people rushed to register as non-donors, and the law was repealed just one year later.[44] In England, 15% of respondents in a government survey indicated they would opt out if presumed consent became law, thus, significantly limiting potential gains.[45]

The notion of “presumed” willingness contradicts many people's understanding of donation as a deliberate gift. Critics argue it risks commodifying the body and can be perceived as state overreach (“organ conscription”).[46] In multicultural societies, this can intensify suspicions, especially where religious or cultural attitudes to the body after death are sensitive topics. For instance, the Latin American context shows that abrupt or poorly communicated policy changes can lower trust and increase opt-outs, as initially seen in Chile.[47]

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[41] Harriet Marsden, “The Pros and Cons of 'Opt Out' Organ Donation” *The Week*, Mar. 17, 2025.

[42] Organ donation: Opt-out Defaults Do Not Increase Donation Rates, *available at:* https://www.mpg.de/23726833/1113-bild-organ-donation-opt-out-defaults-do-not-increase donation-rates-149835-x (last visited on Aug. 2, 2025).

[43] Harriet Rosanne Etheredge, “Assessing Global Organ Donation Policies: Opt-In vs Opt-Out” 14 *Risk Management and Healthcare Policy* 1985–1998 (2021).

[44] Nicola J Williams , Laura O'Donovan, *et.al.*, “Presumed Dissent? Opt-out Organ Donation and the Exclusion of Organs and Tissues” 30(2) *Medical Law Review* Spring 268–298 (2022).

[45] *Ibid.*

[46] *Ibid.*

[47] *Supra* note 43.

The opt-out donation regime is not a panacea for organ shortages. Without heavy investment in public education, family engagement, cultural sensitivity, and healthcare logistics, it can even backfire. Countries considering opt-out models must proceed cautiously, learning from the missteps and lessons of others. Countries like Chile, Greece, Brazil, and even England in some respects, highlight the pitfalls when presumed consent is implemented without adequate safeguards.

5. Laws About Organ Transplantation in India

An organ transplant gives individuals who have organ failure at its worst stage the possibility to live again. The chief legal rules for human organ transplantation in India are found in the Transplantation of Human Organs Act (THOA), 1994 which sorts out details of the organ removal, storage and transplantation process to avoid unauthorized trading of organs. It represents a key step forward in making transplantation consistent in India by complying with both ethical and legal standards.[48]

The management of health affairs in India is a state subject. That means while the THOA is central law, it does not become automatically applicable to states rather they have to adopt it by resolution passed in that behalf under Art. 252(1) of the Constitution of India. Maharashtra, Himachal Pradesh and Goa had asked for the Act, so there it was applicable from the beginning. Nearly all the states have now adopted it except Andhra Pradesh and Jammu & Kashmir. Despite the strong efforts to curb illegal trade and regulate organ donation still, there were reports of illegal organ trafficking, with the first version of the Act.[49]

In 2009, Goa, Himachal Pradesh and West Bengal had proposed amendments in the 1994 Act to the shortcomings. The upgrades were designed to focus the framework more on current needs, improve the system for governing transplantation and boost how clearly policies for organ donation and transplantation are communicated. The changes brought about the Transplantation of Human Organs (Amendment) Act, 2011, drafted by Parliament and followed by adoption of the THOA Rules, 2014. Additional steps and documentation rules were added to the regulations to make sure administration remains overseen and ethical.[50]

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[48] S. Shroff, *et. al.*, "Cadaver Organ Donation And Transplantation - An Indian Perspective," 35 *Transplantation Proceedings* 15–17 (2003).

[49] Francis L. Delmonico, *et. al.*, "Ethical Incentives — Not Payment — For Organ Donation," 346 *New England Journal of Medicine* 2002–2005 (2002).

[50] *Supra* note 10 at 348-355.

As per the THOA a donor may allow the removal of his organs or tissues, at any point prior to his death.[51] Such approval shall be executed in writing by the use of Form 7 as stipulated under the Rules, and shall be made while two or more witnesses are present, and one of such witnesses shall be a close family of the donor. If this sanction has not been withdrawn before the intended donor's death, the person in possession of the deceased's corpse is obligated to enable the donation.[52] Nonetheless, the approval of a close family or anyone who is having legal possession of the corpse is necessary for organ retrieval, regardless of the fact that the deceased had already registered himself as an organ donor.[53]

The National Organ and Tissue Transplant Organisation ("NOTTO") offers the opportunity to create a 'donor card', which allows the donation of certain organs upon an individual's death. Nonetheless, the THOA contains no provision for the establishment of such cards. The procedure followed in making of a donor card does not adhere to the guidelines given in section 3 clause 2 of the Act. The legal validity and enforcement of such cards is therefore ambiguous.

Upon the admission of a prospective donor to the ICU of any hospital, the Registered Medical Practitioner (RMP) there is obligated to verify whether the individual has prior to his death consented to the donation of their organs and to get the relevant documents of such consent.[54] If the prospective donor has not consented to donation, the RMP must inform him of his choice to give his organs posthumously.[55] Upon the individual's death, 'brain-stem death' is verified by a panel of medical experts if the person has consented to donation.[56] The hospital thereafter notifies the Human Organ Retrieval Centre in writing on the authorised donation for requisite action.[57]

In situations where the prospective donor did not provide permission for donation prior to his demise, then there could be three situations which would arise:

5.1 Permission from Family

The RMP is obligated to inform the close relatives of the possible donor on the choice to consent to or refuse the donation of organs or tissues.[58] Anyone legally in possession of the deceased's corpse has the power allow or disallow the retrieval of any

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[51] *Ibid.*

[52] The Transplantation of Human Organs and Tissues Act 1994, s. 3(2).

[53] The Transplantation of Human Organs and Tissues Rules, 2014, rules 5(4)(a) and (b).

[54] *Supra* note 25, s. 3(1A)(i).

[55] *Id.*, s. 3(1A)(ii).

[56] *Id.,* s. 3(5).

[57] *Id.*, s. 3(1A)(iii).

[58] *Id.*, s. 3(1A).

organ if a) the prospective donor had not voiced any unwillingness to organ donation before his death.[59] and b) no proximate related entities object to the contribution.[60] In case the deceased person is a minor, then his parents or guardians may consent to the extraction of his organs for medicinal reasons.[61] Prior to the excision of any organs, the 'brain-stem death' shall have to be validated by a panel of medical professionals.[62] Upon authorisation of the donation, the hospital notifies the Human Organ Retrieval Centre in writing for requisite action.[63]

5.2 Unidentified Corpses

If a deceased individual (with certified brain death) remains unclaimed in a hospital or prison, and no near relative claims the body within 48 hours post-mortem, the individual responsible for the management or oversight of the facility may authorise the extraction of any organ or tissue from the body.[64] Nevertheless, physicians should refrain from permitting the extraction of organs if they have grounds to suspect that a close family of the deceased may assert a claim to the corpse, even if such a claim has not been made within 48 hours.

5.3 Post-mortem Examination for Medico-legal Reasons

The individual authorised to permit the retrieval of organs of the deceased under the Act may give such permission even when the deceased has to undergo a post-mortem examination for medico-legal purposes (in case of death caused by an accident or unnatural causes) or even for pathological reasons. Nonetheless, the individual sanctioning the removal of organs must verify that the dead did not articulate any objections to organ or tissue donation prior to their death. Consequently, when a post-mortem is necessitated following an individual's demise, the RMP will obtain consent from the donor or their family, subsequently requesting the SHO, SP, or DIG of the region to ensure the prompt extraction of the organs from the deceased.[65]

The Delhi Anatomy Act and other state guidelines are in addition to the national THOA rules on body donation. This legislation directs the supply of bodies to medical schools and it lets THOA help in making that happen. In 2013, a study paper was commissioned by the Parashar Foundation and the MOHAN Foundation to look at how

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[59] *Id.,* s. 3(3).

[60] *Supra* note 25, s. 3(3).

[61] *Id.*, s. 3(7).

[62] *Id.*, s. 3(5).

[63] *Id.,* s. 3(1A)(iii).

[64] *Id.,* s. 5.

[65] The Transplantation of Human Organs and Tissues Rules, 2014, rule 6.

organ donation from dead donors operates in Delhi. As part of the study, "A study of the deceased donation environment in Delhi/NCR" examined trends, noted issues, researched international success stories and offered recommendations on how India and the National Capital Region (NCR) might enhance their organ donation services.[66] The research suggested that more public awareness to be provided. It called for all donor registry data to be united and for transplant coordinators to take on more important responsibilities between healthcare staff and family members of donors.[67]

6. Challenges of Organ Donation in India

"The Transplantation of Human Organs and Tissues Act of 1994" with the 2014 Rules, was enacted to stop organ trafficking and control transplants across India. No matter its original goal, there are still several problems- like a shortage of organs, murky criteria for new donors, confusing application procedures and complications over what brain-stem death exactly means under the law. If someone suffers brainstem death, usually from a stroke, or injury, they cannot be brought back to normal consciousness by mechanical life support. The Act names certain individuals as deceased for organ transplantation purposes, meaning organs may be taken if consent has been given.[68]

Even so, in India, brain-stem death becomes official for organ transplantation purposes only. Additional laws, for example, the "Registration of Births and Deaths Act, 1969" and BNS, still use irregularities in the body's circulatory or respiratory system to define death. Because of these gaps, physicians are less certain about the law. Even when a brain-stem dead patient is not having organs donated by their family, life support must be kept running by the hospital. This leaves hospitals needing to balance their duties, their responsibilities by law and their use of available resources. Also, there are very few places outside cities where brain death can be detected, through ICU beds and ventilators. For this reason, patients living in smaller facilities or rural areas often miss the opportunity to become donors, even though brain-stem death is now accurately determinable.[69]

Because of the Act's opt-in model, registering to donate organs is still very difficult. Given this principle, individuals are not expected to participate unless they have approved

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[66] Reginald Magee, "Art Macabre: Resurrectionists and Anatomists" 71 *ANZ Journal of Surgery* 377–380 (2001).

[67] Kaissar Yammine, "The Current Status of Anatomy Knowledge: Where Are We Now? Where Do We Need to Go and How Do We Get There?" 26 *Teaching and Learning in Medicine* 184–188 (2014).

[68] Surraj Susai, Mrudula Chandrupatla, *et.al.*, "Anatomy Acts Concerning Body and Organ Donations Across The Globe: Past, Present and Future With A Special Emphasis on the Indian Scenario" 56 *Anatomy & Cell Biology* 1 (2023).

[69] Sanjib Kumar Ghosh, "Human Cadaveric Dissection: A Historical Account From Ancient Greece To The Modern Era" 48 *Anatomy and Cell Biology* 153–169 (2015).

themselves. Because people are not sufficiently aware, a great many prospective donors are passed by. If there is no written permission, the Act lets authorized relatives direct organ removal; yet, problems among family members and the fear of legal fallout often keep transplants from happening. The Authorisation Committee which approves gifts that do not come from relatives or exchange gifts, is accused of causing delays in its procedures. According to the Rules, governments should judge as quickly as possible, although this speed is not clearly stated in the document. Patna High Court has recommended judges render rulings in one month, but this is not always followed.[70] These challenges require several changes to be made. It is necessary that brain-stem death be recognized in each medical statute rather than being limited only to organ transplants. Neurological changes need to be added to the agreement on death in the RBD Act and BNS.

7. Lessons For India

Instead of getting a person's permission which is what opt-in means, opt-out means adults are considered potential organ donors unless they actively choose not to. In Spain, Austria and France, the opt-out models have produced good and improved results. Such a model may assist India also which faces both organ scarcity and problems related to cultural beliefs about organ donation.[71]

Spain's system for organ donation is seen by many as the world standard. Although the law allowed for mild opt-out in 1979, the big change came when the National Transplant Organisation (ONT) began in 1989. This association is responsible for all of Spain's organ donation and transplant programs and means to professionalize the whole process. In Spain, hospitals have transplant coordinators available, who make sure likely donors are identified and referred quickly and that dialog with the families be easily ensured. Although Spain legalizes donation from those who have not opposed, families are always contacted to ensure their views are included. The approach Spain takes which is both caring and efficient, makes it the world's leader with 40 or more donors per million citizens.[72]

Implied permission in Austria takes the form of a very rigid opt-out system. If the dead hasn't objected to the procedure, the legislation doesn't require family members to be consulted. Because the state wants to safeguard lives, it is believed that a donation should

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[70] Omar Habbal, "The Science of Anatomy: A Historical Timeline" 17 *Sultan Qaboos University Medical Journal* 18–22 (2017).

[71] N. Wig, *et.al.*, "Awareness of Brain Death and Organ Transplantation Among High School Children," 66 *Indian Journal of Pediatrics* 189–192 (1999).

[72] Alberto Abadie and Sebastien Gay, "The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross-country Study" 25 *Journal of Health Economics* 599–620 (2006).

receive priority consideration. People in Austria give organs more often than in many other countries, mainly because of strong support from lawmakers and an advanced health system for quick organ procurement. Some critics believe that the method used by Austria could deny people's freedom if they are unaware of the laws or unable to show disagreement for any reason.[73]

The change to a hard opt-out system in France in 2017 represents a good example of a hybrid model. Consent to use personal data is given unless a person has their own record in the national refusal registry. Yet, families no longer enjoy the absolute right to reject the organ retrieval, but anything mentioned to relatives by a child may still get considered if it's recorded properly. Public awareness among young people was improved through supported education campaigns from the French government. The purpose was to make donating part of our sense of community responsibility. Though early numbers suggest a small rise in donations, ethical talks are still ongoing about how implications of consent work and how transparency between health organizations and the public can be upheld.[74]

To judge how relevant these models are in India, we must take account of the country's laws, culture and infrastructure. Since 1994, the Transplantation of Human Organs and Tissues Act has governed India's choice of an opt-in framework for organ donation. Even with excellent work by NOTTO and other amendments, the number of organ donors each year is low at just 0.65 donors for every million people. In addition, most European countries that do well also see between 15 and 20 donors per million. Because the gap is very wide, opt-out choices may play a part in bringing about needed reforms.[75]

At the same time, putting opt-out laws into Indian law will face many big challenges. Personal consent is given top importance by Indian law in medical ethics matters. According to Article 21 of the Constitution, the implied consent approach could go against our personal rights to life, liberties and bodily autonomy. When there are no detailed rules to protect them, public health workers might treat those of low means in ways that make implied consent unjust or exploitative.[76]

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[73] Lucy D. Horvat, *et.al.*, “Informing the Debate: Rates of Kidney Transplantation in Nations With Presumed Consent” 153 *Annals of Internal Medicine* 641–649 (2010).

[74] M. Usman Ahmad, *et.al.*, “A Systematic Review of Opt-out Versus Opt-in Consent on Deceased Organ Donation and Transplantation (2006–2016)” 43 *World Journal of Surgery* 3161–3171 (2019).

[75] Firat Bilgel, “The Impact of presumed Consent Laws and Institutions on Deceased Organ Donation” 13 *European Journal of Health Economics* 29–38 (2012).

[76] Alberto Molina-Pérez, David Rodríguez-Arias, *et.al.*, “Differential Impact of Opt-in, Opt-out Policies on Deceased Organ Donation Rates: A Mixed Conceptual and Empirical Study” 12 *BMJ Open* e057107 (2022).

Indian culture reflects many beliefs and religious practices that determine people's opinions about organ donation. The number of religious groups believe in the idea of bodily integrity after death. A number of scholars argue that performing funeral rites may stand between the dead and their spiritual fate. Skipping over these concerns might cause the public to disapprove and put more trust in the healthcare system at risk. Because dissent from the public caused Britain to reverse its similar law, Brazil's own experience underlines the risks of not involving society enough when making such decisions.[77]

In addition, India does not currently have the resources necessary to carry out a straightforward opt-out mechanism. Many hospitals do not have enough workers certified in transplantation, do not use consistent standards to declare brain death and lack adequate means of preserving and conveying the organs to recipients. Nations such as Spain, had achieved the success more from coordination and training than simply passing new laws. If we lack these basic requirements then implied consent legislations would become merely an article of aesthetics rather than actual authority.[78]

Still, India could learn much from the way the United States has dealt with the disease. Starting out, India could put some states or groups such as officially listed drivers or insured members, under the assumed permission rule, while permitting entire families to disagree by not following the requirement. It would allow the system to be tested and improved before being rolled out for the whole country. A second option which could be tried is to create a list of people who have made their wishes known and make it digitally accessible for the public awareness. India must make sure to invest in training coordinators, standardize the legal system and ensure that families receive proper and clear treatment from start to finish.[79]

Informational sessions shall be made necessary for all state governments to be imparted to public at large. A large part of Spain's success comes from the regular, varied programs that discuss organ donation and deal with related problems. To change the way organ donation is discussed, India should include people of different faiths, leaders in the community and teachers.[80] A truly effective opt-out movement requires people to be open

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[77] Aric Bendorf, *et.al.*, “Socioeconomic, Demographic and Policy Comparisons of Living and Deceased Kidney Transplantation Rates Across 53 Countries” 18 *Nephrology* 633–640 (2013).

[78] Brian J. Boyarsky, *et.al.*, “Potential Limitations of Presumed Consent Legislation” 93 *Transplantation* 136–140 (2012).

[79] Institute of Medicine (US) Committee on Assessing Genetic Risks, *et.al.*, *Social, Legal, and Ethical Implications of Genetic Testing* (National Academies Press (US), 1994).

[80] Jane Parry, “Breaches of Safety Regulations are Probable Cause of Recent SARS Outbreak, WHO Says” 328 *BMJ* 1222 (2004).

and carefully watched.[81] Be certain about how people's right to object are laid out, how objections are handled and how problems can be solved. Such a view may not properly develop in the community if this balance is missing, with those who are below the economic threshold refusing to see the policy as suitable.[82]

Even though Spain, Austria and France's opt-out measures are useful examples, they must be carefully changed to suit India's legal, social and healthcare settings.[83] A smooth shift to the new system calls for legislative changes, support from the public, better infrastructure and strong morals and ethics.[84] If foreign methods are adjusted to fit the situation in India, the nation stands a better chance of finally closing the huge gap between those needing organs and those whose lives can be saved.[85]

8. Conclusion

The success of Spain's opt-out law depends both on its law and on how the system is put together. Spain's worldwide leadership in organ donation has improved greatly due to ONT's creation, the education imparted to transplant coordinators in hospitals and new efforts made to locate more donors. Trust from the public which grows when transparency in system is improved and real time information is shared is crucial. France makes it simple for people to opt-out, and also notifies the family before retrieval of organs from deceased's body to obtain their consent and hence keeps a balance between privacy and what's good for society as a whole. In Austria, it is thought that consent has been given, so objections from the family have no effect on the law. Although this has caused more donations, opposed voices argue it weakens principles about making informed decisions and having personal freedom.[86] The opt-out model has potential advantages such as increasing the donor pool and normalizing donation but its effectiveness depends heavily on complementary factors such as public trust, transparency, healthcare infrastructure, and education. Countries like Spain, France and Austria show that opt-out works best with strong administrative and ethical

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[81] Jeanne Guillemin, "Scientists and the History of Biological Weapons: A Brief Historical Overview of the Development of Biological Weapons in the Twentieth Century" 7 *EMBO Reports* (2006).

[82] Stefan Riedel, "Biological Warfare and Bioterrorism: A Historical Review," 17 *Baylor University Medical Center Proceedings* 400–406 (2004).

[83] Thachamvally Riyesh *et. al.*, "Laboratory Acquired Buffalo Pox Virus Infection, India" 20 *Emerging Infectious Diseases* 325–326 (2014).

[84] Eva Pilot, *et. al.*, "Towards Sustainable Public Health Surveillance in India: Using Routinely Collected Electronic Emergency medical Service Data for Early Warning of Infectious Diseases" 9 *Sustainability (Switzerland)* (2017).

[85] John J. Ewel, *et. al.*, "Deliberate Introductions of Species: Research Needs" 49 *BioScience* 619–630 (1999).

[86] J. Rosel, *et.al.*, "Discriminant Variables Between Organ Donors and Nondonors, A Post Hoc Investigation" 9 *Journal of Transplant Coordination* 50–53 (1999).

frameworks. In contrast, countries like Chile, Greece, Brazil, and even England in some respects, highlight the pitfalls when presumed consent is implemented without adequate safeguards.

Meanwhile, the approach India follows now comes across a number of hurdles. There is no enough public awareness, religious and cultural hurdles, underdeveloped procedures to handle donated organs and not enough qualified doctors and proper facilities, mainly in rural locations. Common myths discouraging donation are, that someone will benefit from the donation at another person's expense or that a deceased person becomes less respected after organ donation, and some religious beliefs also disallow donation such as the concept of rebirth in hindu mythology, these are some of the reasons which often cause families to deny organ donation. It's possible that even registered donors will have their wishes abandoned by family if the family does not understand the situation or is highly emotional. Since the health system is already strained and not be able to deliver proper care to patients, it limits the effectiveness of any new legislation covering organ donation.

For adoption of an opt-out model, India needs to move forward by gradually and clearly planning its steps. Public involvement is important and it should be followed with experiments in specific locations. Consultations with healthcare workers, lawyers, religious authorities and civil society members can help produce a framework that matches the needs of India's population. When public awareness and infrastructure strengthening were carried out gradually, the nation will become ready for the transformation in all aspects. Building better transplant infrastructure is very important. There should be trained transplant coordinators in Indian hospitals to handle each stage, from searching for donors to advising and obtaining consent from the families of the deceased. Real-time systems that display organs availability at national and state level needs to be strengthened where already present and needs to be introduced where missing.

The existing framework established by the Transplantation of Human Organs and Tissues Act (THOTA), 1994, functions based on express agreement. Although THOTA establishes regulations for organ retrieval and transplantation, including punitive measures against commercial transactions, it inadequately addresses the structural obstacles that impede donations. Transitioning to an opt-out model requires not just legislative modification but also fundamental alterations in the relationship between individual rights, governmental obligations, and healthcare ethics.

Any initiative towards implied consent must comply with Article 21 of the Indian Constitution, which ensures the right to life and personal liberty. The idea of physical autonomy is fundamental to this right, and any rule assuming consent must include channels for persons to express protest readily and effectively. This entails establishing a legal duty for the state to provide extensive knowledge, accessible opt-out registers, and open protections against pressure or exploitation. Moreover, India's diversified culture, characterised by varied religious and cultural views, need a culturally attuned legal system. The legislation should be designed to provide religious exemptions and preserve the autonomy of the family unit where appropriate.

From a legal scholar's viewpoint, the implementation of an opt-out system in India is not only a legislative action but a multifaceted reconfiguration of legal standards, ethical implications, and institutional practices. While legally viable, its success hinges on meticulous legislative drafting, constitutional conformity, public trust cultivation, and administrative readiness. By using worldwide best practices and tailoring them to India's own legal and social environment, the legislation may effectively bridge the gap between demand and supply in organ transplantation, thereby reshaping India's organ donation landscape in a fair and equitable way.