

# Organ donation consent after death

Valter Duro Garcia<sup>I</sup>, José Osmar Medina de Abreu Pestana<sup>II</sup>, Paulo Manuel Pêgo-Fernandes<sup>III</sup>

*Instituto do Coração (Heart Institute), Hospital das Clínicas (HC-FMUSP), School of Medicine, Universidade de São Paulo (USP), São Paulo, SP, Brazil*

<sup>I</sup>MD, PhD. Director of the Kidney and Pancreas Transplant Department at Santa Casa de Misericórdia de Porto Alegre, Porto Alegre, Brazil. PhD in Nephrology, University of São Paulo, São Paulo, SP, BR.

 <https://orcid.org/0000-0002-7394-1501>

<sup>II</sup>MD, PhD. Full Professor of the Nephrology discipline at Escola Paulista de Medicina UNIFESP; Superintendent Director of Hospital do Rim, São Paulo, SP, Brazil.

 <http://orcid.org/0000-0002-0750-7360>

<sup>III</sup>MD, PhD. Vice-director, Faculty of Medicine, Universidade de São Paulo (USP), São Paulo (SP), Brazil; Full Professor, Department of Cardiopneumology, Faculty of Medicine, Universidade de São Paulo (USP), São Paulo (SP), Brazil; Director of the Scientific Department, Associação Paulista de Medicina (APM), São Paulo (SP), Brazil.

 <https://orcid.org/0000-0001-7243-5343>

Most countries where organ transplants are performed, defined laws exist to address different legal aspects of these procedures, particularly concerning consent for organ donation after death.<sup>1</sup>

The authorization for organ removal for transplantation purposes raises controversial debates, considering its profound ethical and moral implications. It examines core societal values and reflects on fundamental rights, such as respect for human dignity, including the right to personality and autonomy of self-determination.

Every individual possesses the freedom to decide regarding certain actions concerning their body according to their own conscience. However, these decisions must be made within certain boundaries to uphold fundamental rights. In Brazil, an individual's autonomy over their own body is included in three articles of the Constitution. Article 1 emphasizes the principle of human dignity; Article 5 outlines the right to life and the right to freedom; and Article 199 addresses the ability to waive parts of the human body.<sup>2</sup>

## Classification of consent for organ donation after death

Consent for organ donation is typically classified into four categories: informed consent, mandatory choice, presumed consent, and compulsory removal. Informed consent, mandatory choice, and presumed consent are used in a vast majority of countries, although with variations.<sup>3,4</sup> However, compulsory removal, which involves the mandatory removal of viable organs for transplantation from deceased individuals, is not legally permissible in any country. Unlike other types of consent, compulsory removal does not involve obtaining formal consent as it renders consent unnecessary.

## Informed consent

This approach requires explicit consent from individuals during their lifetime and/or from their family members after death. It is widely regarded as the most ethical approach and upholds principles of autonomy, voluntarism, and altruism. Under this system, organs are not removed without explicit consent, and individuals have the opportunity to benefit others without any personal benefit.<sup>4,5</sup>

In countries following this system, such as those that prioritize the principle of autonomy, individuals make their decision and register it through a donor registry (opting-in). When individuals have not registered, the decision lies with their family members.<sup>5,6</sup> However, in countries such as Brazil, the family has the exclusive decision-making authority immediately after death.<sup>7</sup> Other countries with greater restrictions on donation, such as Japan and South Korea, require authorization from both the individual during their lifetime and from family members after death.<sup>8</sup>

From a bioethical standpoint, many scholars advocate that a donation should only be considered valid if it was the explicit wish of the deceased individual, rather than relying solely on the family's decision. However, others argue that offering the possibility of donation to the family can provide a way to relieve their suffering by adding a noble act to the tragedy of losing a loved one.

### Mandatory choice

Mandatory choice requires that all competent adults must decide in advance whether they wish to donate their organs for transplantation after death. The decision, labeled as either “donor” or “non-donor,” is recorded on an identity document or driver’s license.<sup>4,9</sup>

Advocates of this approach argue that it can boost consent, preserve altruism values, and eliminate the need for family approval. Moreover, this approach provides the possibility to increase the pool of potential donors, by mandating that all competent adults make a decision.<sup>4</sup>

However, the chief disadvantage lies in the requirement for all adults to make the definitive decision and officially record their status as either a “donor” or “non-donor.” Not all individuals may feel adequately prepared or informed to make such a significant decision, which is considered coercive and an invasion of privacy.<sup>9,10</sup>

For instance, in Sweden, the implementation of the National Register of Donors and Non-Donors in 1996, and the first 300,000 records revealed that 52% opted to register as donors, whereas 48% selected the non-donor status.<sup>11</sup>

Similar trends were observed in Brazil from January 1998 to October 2000 when mandatory choice was implemented, although without the support of medical entities and society. A consultation by the Brazilian Association of Organ Transplants performed in the identification institutes and traffic departments from January 1998 to December 1999 found that 51.2% of people were against the donation of their organs after death.<sup>1</sup>

These results suggest that forcing people to make a decision may have adverse effects, as the majority opt not to donate. Although opinion polls consistently indicate support for donation exceeding 70%, mandatory registration records indicate that only approximately 50% opt to be donors after death.<sup>9,10</sup> Therefore, the implementation of mandatory choice did not sufficiently increase the “donors” rate, where it was used, to justify the moral, social, and financial costs.<sup>8</sup> Education and public awareness are more important than a mandatory choice system.

### Presumed consent

In presumed consent, individuals are assumed donors unless during their lifetime, they do not express opposition to the donation of their organs after death. This system operates based on non-donor registration, implying that individuals must actively opt out if they do not wish to be donors.<sup>1,2,12</sup>

Under strong presumed consent, the lack of a record indicating the individual’s refusal to donate results in their organs being removed for transplantation, regardless of the family’s wishes.

Under weak presumed consent, donation is assumed unless there is a specific objection from the individual while alive and from family members immediately after their death.

Proponents argue that presumed consent prevents family members from having to make the decision about donation at an emotionally difficult time, when they are grieving. This implies an increase in the consent rate.<sup>13</sup> However, this has been questioned, as many families feel comforted by organ donation, stating that “*the death was not in vain.*” Presumed donation removes altruism and denies this possibility for the family.<sup>14</sup>

Presumed consent is deemed ethically acceptable under certain conditions:<sup>1</sup>

1. Universal acknowledgment of the law within the population
2. Easy registration of donation denial
3. Respect for the decision made

Some bioethics experts advocate that the absence of objection cannot be considered as consent. They view organ removal without explicit consent as a violation of the autonomy over one’s body and dignity.<sup>12,14,15</sup> Others consider this system ethical, as failure to register the objection (with adequate possibilities to do so) can be interpreted as implied consent.<sup>13,16,17</sup>

Despite only approximately 5% of the eligible population opting out of donation, opinion polls indicate that 20% to 30% are against donations.<sup>18</sup> The ethical point is that a person may not register their opposition for various reasons and cannot be implied to have consented.<sup>12,14,15</sup>

There is no conclusive evidence to suggest that presumed consent increases organ donation, as indicated by the examples of the two countries with the highest donation rates:

- In Spain, which has presumed consent in legislation, the family is consulted and must authorize the removal of the organs in all situations (presumed consent in law but informed in practice). Although presumed consent has been in place since 1979, the significant increase in donation rates began in 1989, when hospital transplant coordinators became involved in the search for donors.<sup>19</sup>
- In the United States, the decision regarding organ donation is typically made by the individual during their lifetime. If no decision was made, the family decides after death. Organ procurement organizations, which are highly professional and work with goals, are a common model there.<sup>20</sup>

In Latin America, several countries have adopted presumed consent over the last 15 years and have not increased donation rates, as it does not increase organ donation alone.<sup>14</sup>

### Compulsory removal of organs from deceased people

The compulsory removal of organs from deceased individuals without requiring permission, also known as **Organ Conscriptio** or **Routine Salvaging**,<sup>21,22,23</sup> is not formally used in any country.

Proponents of this approach argue for the principle of distributive justice, asserting that all individuals who die with usable organs should contribute, and all patients who need them can benefit, without depending on altruism or voluntarism. They advocate for the perspective that human organs should be considered a societal asset with society assuming possession of them after death.<sup>23,24</sup>

The chief argument against compulsory removal is that it infringes upon individual autonomy, and society's rights override individual rights, which makes it unacceptable.

In China, thousands of prisoners sentenced to death have had, or have, their organs removed after death for transplantation purpose. This situation is absolutely unacceptable, considering that a select few individuals (prisoners sentenced to death) have their organs compulsorily removed and a minimal portion of society receives these organs (those who pay for them).<sup>8</sup>

### Evolution of consent in Brazil

The first three transplant laws in Brazil, dating back to 1963,<sup>25</sup> 1968,<sup>26</sup> and 1992<sup>27</sup> used the concept of "informed consent," considering the patient's authorization while alive or of family members after death. Over the years, subtle changes were made. In all cases the family was consulted and it decided regarding the donation, as it was not possible to register individuals' preferences for organ donation after death.

The hemodialysis tragedy in Caruaru in 1996, which resulted in numerous deaths owing to poisoning, encouraged a group of chronic kidney disease patients to ask the National Congress for measures favorable to transplantation. Senator Darcy Ribeiro worked to approve a new transplant law that would increase donations. On February 4, 1997, without any discussions with society and medical entities, Law 9,434<sup>28</sup> was approved to come into effect from 1998, changing the form of consent from *informed* to *strong presumed*. However, this law did not take effect, as the non-donor registry was not created. One month later, in March 1997, Decree n° 2,170 was approved,<sup>29</sup> using mandatory choice, and required all adults to express their choice as "donor" or "non-donor," when obtaining or renewing their identity or driver documents, with strong opposition from society and medical entities.

There were two types of consent in practice: mandatory choice for those opting to be "non-donors" and informed consent for those opting to be "donors," decided by medical professionals.

As it was highly opposed by the population, the mandatory choice was repealed in October 2000.<sup>30</sup> Subsequently, in March 2001, a new law was enacted, returning to the informed consent system, with the exclusive decision of family members. The registers of "donor" or "non-donor" in the documents lost their value.<sup>7</sup>

Large sections of the media and population and some health professionals misunderstood that presumed consent was the rule between 1998 and 2000. An opinion poll conducted by Datafolha

in January 1998, and compared with that of April 1995, revealed that the intention to donate organs decreased from 75% to 63%. It may be because of the media affirming in 1997 that presumed consent would be in force from 1998 onward, which caused fear among the population. This indicates that despite not being used, this form of consent reduced the population's positive perception of donation.<sup>1</sup>

### CONCLUSION

Although a bill advocating for presumed consent is pending in the Chamber of Deputies in Brazil, maintaining informed consent appears to be more suitable. This entails establishing a voluntary donor registry, where individuals can register in the presence of witnesses. The registry should be legally valid and under the control by the Judiciary, allowing for revocation if desired. The State Transplant Center should only access this registry after the individual's death.<sup>1</sup>

The informed consent legislation could be articulated as follows: "Unless explicitly stated during the donor's lifetime in the donor registry, the removal of organs, tissues and parts of the human body will require the authorization from family members."

These modifications aim to uphold informed consent to its fullest extent, preserving society's trust in the transplant program. Although the foundation is robust, enhancements are necessary to maximize benefits for the maximum number of patients respecting while adhering to ethical principles.<sup>6</sup>

It is noteworthy that in Brazil, states with equal legislation and financing have achieved donor rate above 40 per million people (pmp), among the highest in the world. Conversely, some states have a rate below 10 pmp.<sup>31</sup> This variance suggests that the decisive factor in the increase in donation and transplantation is not the form of consent adopted. Other important challenges, such as failure to identify potential donors, lack of logistics for evaluating potential donors and removing organs, and the limited use of removed organs, cause or increase the imbalance between demand and the number of transplants performed. Therefore, effective planning, organizational improvements, logistical enhancements, and educational initiatives can be more effective than changing the form of consent. Such measures can enhance efficiency, avoid public distrust, and reduce conflicts with family members.<sup>6</sup>

There is no universal method of consent, and the success of any transplant program cannot be attributed to legislation alone. If that were the case, all countries would follow the same. Moreover, effective laws should conform to what is accepted by society and not attempt to change society through coercion. The relation between the form of consent and donation rate is not straightforward, suggesting that the laws governing organ donation are more of a legal and philosophical challenge than a crucial factor in obtaining organs.<sup>1</sup>

## REFERENCES

1. Garcia VD, Campos HH, de Paula FJ, Panajotopoulos N, Pestana JOM. Proposta de uma Política de Transplantes para o Brasil. (*Proposal for a Transplant Policy for Brazil*.) In: Garcia VD. Por uma política de transplantes no Brasil. (*For a Transplant Policy for Brazil*.) São Paulo: Office Editora e Publicidade; 2000. p 109-62.
2. Brasil. Constituição da República Federativa do Brasil. (*Constitution of the Federative Republic of Brazil*.) Brasília: Senado Federal; 1988.
3. World Health Organization. Global glossary of terms and definitions on donation and transplantation. Geneva: World Health Organization; 2009. Available from: <https://www.who.int/publications/m/item/global-glossary-on-donation-and-transplantation>. Accessed 2024 (Feb. 7).
4. Symons X, Poulden B. An ethical defense of a mandated choice consent procedure for deceased organ donation. *Asian Bioeth Rev*. 2022;14(3):259-70. PMID: 35791333; <https://doi.org/10.1007/s41649-022-00206-5>.
5. Faden RR, Beauchamp TL. A history and theory of informed consent. Oxford: Oxford University Press; 1986.
6. Caplan A. Ethical and policy issues on organ transplantation. In: Caplan A, Coelho D. The ethics of organ transplant. New York: Prometheus Books; 1998. p. 142-6.
7. Brasil. Law nº 10,211, March 23, 2001. Changes part of Law no 9.434, from February 4, 1997, which "provides for the removal of organs, tissues and parts of the human body for the purposes of transplantation and treatment". *Diário Oficial da União*. 2021, March 24. Available from: <https://www2.camara.leg.br/legin/fed/lei/2001/lei-10211-23-marco-2001-351214-norma-pl.html>. Accessed in 2024 (Feb. 7).
8. Zhang Z, Zang Z. Ethical dilemmas, and principles in organ transplantation in China. *Acta Bioethica*. 2021;27(2):181-91. Available from: <https://acta.bioethica.uchile.cl/index.php/AB/article/view/65479>. Accessed in 2024 (Feb. 7).
9. Spital A. Mandated choice for organ donation: Time to give it a try. In: Caplan A, Coelho D. The ethics of organ transplant. New York: Prometheus Books; 1998. p. 147-53.
10. Klassen AC, Klassen DK. Who are the donors in organ donation? The family perspectives in mandated choice. In: Caplan A, Coelho D. Ethics of organ transplant. New York: Prometheus Books; 1998. p. 54-160.
11. Gäbel H, Rehnqvist N. Information on new transplant legislation: how it was received by the general public and the action that ensued. *Transplant Proc*. 1997;29(7):3093. PMID: 9365678; [https://doi.org/10.1016/s0041-1345\(97\)00794-x](https://doi.org/10.1016/s0041-1345(97)00794-x).
12. Veatch RM, Pitt JB. The myth of presumed consent: ethical problems in new organ procurement strategies. *Transplant Proc* 1995;27(2):1888-92. PMID: 7725540.
13. Kennedy I, Sellis RA, Daar AS, et al. The case for "presumed consent" in organ donation. *International Forum for Transplant Ethics*. *Lancet*. 1998;351(9116):1650-2. PMID: 9620733; [https://doi.org/10.1016/s0140-6736\(97\)08212-3](https://doi.org/10.1016/s0140-6736(97)08212-3).
14. Prabhu PK. Is presumed consent an ethically acceptable way of obtaining organs for transplant? *J Intensive Care Soc*. 2019;20(2):92-7. PMID: 31037100; <https://doi.org/10.1177/1751143718777171>.
15. Sharif A. Presumed consent will not automatically lead to increased organ donation. *Kidney Int*. 2018;94(2):249-51. PMID: 30031447; <https://doi.org/10.1016/j.kint.2018.04.020>.
16. Saunders B. Opt-out organ donation without presumptions. *J Med Ethics*. 2012;38(2):69-72. PMID: 21828226; <https://doi.org/10.1136/medethics-2011-100039>.
17. Fabre J. Presumed consent for organ donation: a clinically unnecessary and corrupting influence in medicine and politics. *Clin Med*. 2014;14(6):567-71. PMID: 25468837; <https://doi.org/10.7861/clinmedicine.14-6-567>.
18. Koffman G, Singh I, Bramhall S. Presumed consent for organ donation. *Ann R Coll Surg Engl*. 2011;93(4):268-72. <https://doi.org/10.1308/rcsann.2011.93.4.268>.
19. Rodríguez-Arias D, Wright L, Paredes D. Success factors and ethical challenges of the Spanish model of organ donation. *Lancet*. 2010;376(9746):1109-12. PMID: 20870101; [https://doi.org/10.1016/s0140-6736\(10\)61342-6](https://doi.org/10.1016/s0140-6736(10)61342-6).
20. Nathan HM, Conrad SL, Held PJ et al. Organ donation in United States. *Am J Transplant*. 2003;3(suppl 4):29-40. PMID: 12694048; <https://doi.org/10.1034/j.1600-6143.3.s4.4.x>.
21. Dukeminier J, Sanders D. Organ transplantation: a proposal for routine salvaging of cadaver organs. *N Engl J Med*. 1968;279(8):413-9. PMID: 4874207; <https://doi.org/10.1056/nejm196808222790807>.
22. Spital A, Erin CA. Conscriptio of cadaveric organs for transplantation: let's at least talk about it. *Am J Kidney Dis*. 2002;39(3):611-5. PMID: 11877582; <https://doi.org/10.1053/ajkd.2002.32164>.
23. Spital A, Taylor JS. Routine recovery of cadaveric organs for transplantation: consistent, fair and life-saving. *Clin J Am Soc Nephrol*. 2007;2(2):300-3. PMID: 17699428; <https://doi.org/10.2215/cjn.03260906>.
24. Harris J. Consent and end of life decisions. *J Med Ethics*. 2003;29(1):10-5. PMID: 12569187; <https://doi.org/10.1136/jme.29.1.10>.
25. Brasil. Law nº 4,280, November 6, 1963. Provides for the removal of organs or tissue from a deceased person. *Diário Oficial da União*. 1963, November 11. Available from: <https://www2.camara.leg.br/legin/fed/lei/1960-1969/lei-4280-6-novembro-1963-353353-publicacaooriginal-1-pl.html>. Accessed in 2024 (Feb. 7).
26. Brasil. Law nº 5,479, August 10, 1968. Provides for the removal and transplantation of tissues, organs and parts of cadavers for therapeutic and scientific purposes, and other provisions. *Diário Oficial da União*. 1968, August 14. Available from: <https://www2.camara.leg.br/legin/fed/lei/1960-1969/lei-5479-10-agosto-1968-358591-publicacaooriginal-1-pl.html>. Accessed in 2024 (Feb. 7).
27. Brasil. Law nº 8,489, November 18, 1992. Provides for the removal and transplantation of tissues, organs and parts of the human body for therapeutic and scientific purposes and other provisions. *Diário Oficial da União*. 1992, November 20. Available from: <https://www2.camara.leg.br/legin/fed/lei/1992/lei-8489-18-novembro-1992-363720-norma-pl.html>. Accessed in 2024 (Feb. 7).

28. Brasil. Law nº 9,434, February 4, 1997. Provides for the removal and transplantation of tissues, organs and parts of the human body, for transplant and therapy purposes and other provisions. *Diário Oficial da União*. 1997, February 5, p. 2191. Available from: <https://www2.camara.leg.br/legin/fed/lei/1997/lei-9434-4-fevereiro-1997-372347-norma-pl.html>. Accessed in 2024 (Feb. 7).
29. Brasil. Decree nº 2,170, March 4, 1997. Rewords article 2 of Decree No. 89,250, of December 27, 1983, which regulates Law No. 7,116, of August 29, 1983, which ensures national validity to Identity Cards, regulates their issuance, and other provisions. *Diário Oficial da União*. 1997, March 5, p. 4143. Available from: <https://www2.camara.leg.br/legin/fed/decret/1997/decreto-2170-4-marco-1997-444937-norma-pe.html>. Accessed in 2024 (Feb. 7).
30. Brasil. Provisional Measure No. 1,959, of October 24, 2000. Adds paragraph to article 4 of Law No. 9,434, of February 4, 1997, which provides for the removal of organs, tissues and parts of the human body for the purposes of transplantation and treatment. *Diário Oficial da União*. 2000, October 25, p. 3. Available from: <https://www2.camara.leg.br/legin/fed/medpro/2000/medidaprovisoria-1959-27-24-outubro-2000-376407-norma-pe.html>. Accessed in 2024 (Feb. 7).
31. Associação Brasileira de Transplante de Órgãos. Registro Brasileiro de Transplante 2023. Dados Numéricos da doação de órgãos e transplantes realizados por estado e instituição no período: janeiro/setembro – 2023. (*Figures on organ donations and transplants carried out by state and institution in the period: January/September – 2023*.) Ano XXIV, nº 3, p. 12-3. Available from: <https://site.abto.org.br/conteudo/rbt/>. Accessed in 2024 (Feb. 7).

