PREPARED BY

The Canadian DONATION and TRANSPLANTATION Research Program
Programme de recherche en DON et TRANSPLANTATION du Canada

TRANSPLANT QUÉBEC
Organ donation, together for life for 50 years

CONSENT MODELS

CONTENT: SEPTEMBER 2022

INTRODUCTION

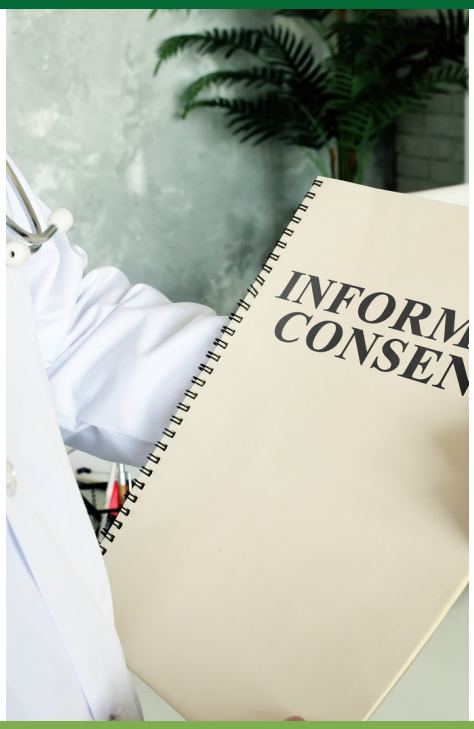
Transplant Québec and the Canadian Donation and Transplantation Research Program (CDTRP) collaborated to co-host The International Donation and Transplantation Legislative and Policy Forum (the Forum). The Forum assembled 57 national and international experts in donation and transplantation, including patient, family, and donor partners, to provide consensus guidelines on the structure of an ideal organ and tissue donation and transplantation (OTDT) system.

The Forum does not recommend one type of consent model, given the need for further evidence to understand the impact of consent models on deceased donation rates. Rather, the Forum recommends collaboration with donation and transplantation stakeholders and the public when implementing or reviewing a consent model to create and maintain trust, transparency, and accountability in the OTDT system.

WHAT ARE CONSENT MODELS?

A consent model is a system for obtaining consent for deceased organ donation. Because deceased donation becomes possible at a moment where the patient who is a potential donor is almost uniformly incapable of expressing consent themselves – due to catastrophic injury or illness – most systems have a way to communicate and register intent to donate.

The methods used to register this intent or refusal to donate should be structured according to the World Health Organization's (WHO) guiding principles for donation, which define the conditions for consent for deceased donation as follows: "Organs may be removed from the bodies of deceased persons for transplantation if a) any consent required by law is obtained, and b) there is no reason to believe that the deceased person objected to such removal."[1]



Accordingly, each country with an OTDT system has enacted and implemented a consent model for deceased donation. While there are numerous subtle differences defining consent models, they can broadly be categorized into explicit (opt-in) or presumed consent (opt-out) models where:

- Explicit Consent allows individuals to opt-in and become a donor after their death but presumes that the default position is refusal.
- Presumed Consent presumes individuals have consented to organ donation after their death unless the person has expressed their choice not to donate.

In most iterations of the above consent models, the individual's next-of-kin are involved in the consent process and may influence the organ procurement process to varying degrees.[2]

EVALUATING THE IMPACT OF CONSENT MODELS

Public policy discussions in OTDT systems often focus on the role of consent models, and specifically the presumed consent model, as a tool to increase deceased donation and transplantation rates. However, there is no global consensus on the benefits of one model over another, and the relative impact on organ donation rates is controversial.[3] Some evidence indicates that consent, donation, and transplantation rates can be higher under presumed consent policies than explicit consent policies and such a consent model is a component of a high-performing system.[4,5] However, the impact of presumed consent itself remains unclear,[6] and evidence suggests that presumed consent is one of many factors impacting donation rates.

Despite the incomplete evidence guiding decision-making, there has been a trend toward presumed consent legislation.[7,8] Supporters of presumed consent point to the experience of many top-performing jurisdictions, primarily in Western Europe, and includes Spain, Croatia, Portugal, France, Belgium, and Finland.[9] However, countries including Poland, Luxembourg, Chile, Latvia, and Bulgaria also have presumed consent, and low deceased donation rates.[10,11]

When Brazil introduced presumed consent legislation in 1997, it had a negative effect on their donation rates and was repealed. This was primarily because there was an increase of individuals actively opting out due to fear of organ removal prior to death, and a lack of infrastructure to support donor identification.[12]

Nova Scotia, Canada, became the first jurisdiction in North America to introduce this policy (2018). The Legislative Evaluation – Assessment of Deceased Donation Reform (LEADDR) Program will evaluate the impacts of legislative changes on deceased donation rates and will help inform other stakeholders.[13]

THE SPANISH EXPERIENCE

Spain introduced presumed consent in 1979 and, as a global leader in deceased donation rates, is cited as a successful case study in presumed consent. However, ten years after implementing presumed consent, Spain had 14.3 donors per million population (DPMP). Spanish OTDT leaders attribute their current success to an overhaul of its OTDT system that occurred more than ten years after presumed consent[11], including the establishment of the National Organization of Transplants, which prioritized early identification and referral of potential organ donors, broadened eligibility criteria of usable organs, adopted the framework for organ donation after circulatory death, and enhanced training in communication with family members of potential organ donors.[4,14] The Spanish system also included investment in public education and ensured each hospital in Spain had a donor coordinator.[15] Ten years after overhauling its system, their rate increased to 33.6 DPMP. Today, Spain remains a global leader in deceased donation rates.

POLICY CONSIDERATIONS WHEN IMPLEMENTING CONSENT MODELS

Policy makers should balance other policy options when implementing a presumed consent system to improve donation and transplantation rates.[16] These policy options and local considerations include, but are not limited to, legislation, donor availability, organ donation organization, public education and acceptance of presumed consent, quality of data collection and reporting, and funding.[5,17]

The Forum's experts recommend broad public consultation with adequate time when jurisdictions introduce or reform their consent models. These consultations should reflect prevailing social values and culture, existing donation and health laws, and the OTDT infrastructure. When implementing or reforming a consent model, jurisdictions need funding commitments, and they should be guided with a focus on the ongoing development and maintenance of public trust in the system.[18]

Identifying and addressing the public's views towards the consent system for organ procurement is key to developing effective and ethical organ donation policies.[19] In developing or reforming a consent model, policymakers must also consider:

- Legislation should provide safeguards for vulnerable populations.
- Outreach for underrepresented populations should be sensitive to culture and religion.
- Registries should allow individuals to express their intent while minimizing barriers to registering a decision.
- Legislation and policy should clarify resolutions to situations where a next-of-kin decision conflicts with the registered decision of a person.
- Public and professional education should be integrated into the information sources most trusted by the target community.
- There should be professional training and guidance documents for clinicians who approach families.
- Development and implementation of information technology changes should be integrated into the donor registry to reflect the chosen consent model.
- Incentive programs, such as prioritization of registered donors for transplantation, could be considered in a local context, but not enough data supports their widespread use.
- To ensure long-term sustainability, measuring the impact of the consent model should be a high priority through well structured research programs.[13]

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REFERENCES

[1] WHO-HTP-EHT-CPR-2010.01-eng.pdf. Accessed July 11, 2022. https://apps.who.int/iris/bitstream/handle/10665/341814/WHO-HTP-EHT-CPR-2010.01-eng.pdf?sequence=1

[2] Rosenblum AM, Horvat LD, Siminoff LA, Prakash V, Beitel J, Garg AX. The authority of next-of-kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations. Nephrol Dial Transplant. 2012;27(6):2533-2546. doi:10.1093/ndt/gfr619

[3] Clavien C. [An ethical evaluation of presumed consent for organ donation in Switzerland]. Rev Med Suisse. 2020;16(682):370-373.

[4] Matesanz R, Domínguez-Gil B, Coll E, Mahíllo B, Marazuela R. How Spain Reached 40 Deceased Organ Donors per Million Population. Am J Transplant. 2017;17(6):1447-1454. doi:10.1111/ajt.14104

[5] Rithalia A, McDaid C, Suekarran S, Myers L, Sowden A. Impact of presumed consent for organ donation on donation rates: a systematic review. BMJ. 2009;338:a3162. doi:10.1136/bmj.a3162

[6] Chandler J. Opt in Model.

[7] Welsh Government. Opt-out Systems of Organ Donation: International Evidence Review. Number 44/2012. 2012.; :91. https://gov.wales/sites/default/files/statistics-and-research/2018-12/121203optoutorgandonationen.pdf

[8] Scottish Government. Opt out Organ Donation: A Rapid Evidence Review. Accessed July 8, 2022. http://www.gov.scot/publications/opt-out-organ-donation-rapid-evidence-review/

[9] chart. GODT. Accessed July 11, 2022. http://www.transplant-observatory.org/data-charts-and-tables/chart/

[10] loprespub. Consent for Organ Donation in Canada. HillNotes. Published October 25, 2021. Accessed July 13, 2022. https://hillnotes.ca/2021/10/25/consent-for-organ-donation-in-canada/

[11] Willis BH, Quigley M. Opt-out organ donation: on evidence and public policy. J R Soc Med. 2014;107(2):56-60. doi:10.1177/0141076813507707

[12] Tennankore KK, Klarenbach S, Goldberg A. Perspectives on Opt-Out Versus Opt-In Legislation for Deceased Organ Donation: An Opinion Piece. Can J Kidney Health Dis. 2021;8:20543581211022150. doi:10.1177/20543581211022151

[13] Weiss MJ, Krmpotic K, Cyr T, et al. A Program of Research to Evaluate the Impact of Deceased Organ Donation Legislative Reform in Nova Scotia: The LEADDR Program. Transplant Direct. 2020;7(1):e641. doi:10.1097/TXD.0000000000001093

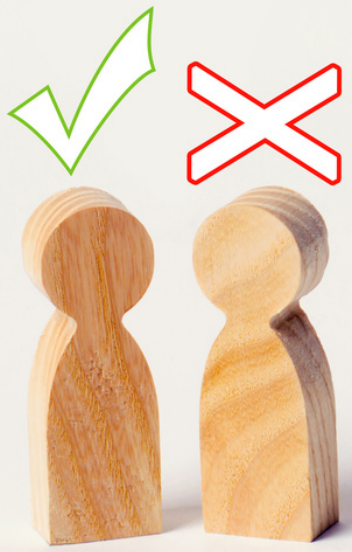
REFERENCES
CONTINUED

[14] Lewis A, Koukoura A, Tsianos GI, Gargavanis AA, Nielsen AA, Vassiliadis E. Organ donation in the US and Europe: The supply vs demand imbalance. Transplantation Reviews. 2021;35(2):100585. doi:10.1016/j.trre.2020.100585

[15] Bramhall S. Presumed consent for organ donation: a case against. Ann R Coll Surg Engl. 2011;93(4):270-272. doi:10.1308/147870811X571136b

[16] Steffel M, Williams EF, Tannenbaum D. Does changing defaults save lives? Effects of presumed consent organ donation policies. Behavioral Science & Policy. 2019;5(1):68-88. doi:10.1353/bsp.2019.0005

[17] Key Policy Issues in Organ Donation & Transplantation – Panel 4. Opt-Out Systems of Organ Donation.; 2021. Accessed July 11, 2022. https://www.youtube.com/watch?v=bVZIWDlbP1Y

[18] Walton P. Consent Models and Emerging Legal Issues.

[19] Molina-Pérez A, Rodríguez-Arias D, Delgado-Rodríguez J, et al. Public knowledge and attitudes towards consent policies for organ donation in Europe: A systematic review. Transplant Rev. Published online September 22, 2018. doi:10.1016/j.trre.2018.09.001