Domain Summary

CONSENT MODELS

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TRANSPLANT QUÉBEC
Organ donation, together for life for 50 years

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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 61 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.

Organ and Tissue Donation Consent Model and Intent to Donate Registries, one of the seven domains developed through the Forum, provide expert guidance for jurisdictions implementing or reforming their consent model. The consent model working group does not recommend one type of consent model over another. Instead, the 11 recommendations outlined in this domain cover the main factors influencing the success of a consent model. These factors include the type of consent model (opt-in vs opt-out), donor registry, marketing campaigns/public education, and the education of health care professionals.

CONSENT MODELS IN OTDT SYSTEMS

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 prior to a person becoming a potential donor.

Accordingly, each country with an OTDT system has enacted and implemented a consent model for deceased donation. While there are numerous differences between 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.

Below is a summary of the recommendations from the working group and some of their justifications which are explained in detail in the full manuscript.

RECOMMENDATION #1

The choice of consent model for a jurisdiction should be guided by a broad public consultation between donation stakeholders and the public that includes consideration of the:

- Prevailing values and culture of that jurisdiction.
- Existing donation and health laws.
- Existing organ and tissue donation and transplantation infrastructure.
- Commitment to supporting a model with the needed resources.
- Development and maintenance of public trust in the donation and transplantation system.

Current evidence on the benefits of the opt-out and opt-in models is varied and contradictory. Experts cannot state that one model will significantly impact donation and transplantation rates more than another. As such, jurisdictions must address four fundamental aspects of consent models when designing their policy and legislation:

- The capacity of the OTDT system to directly solicit and respond to the deceased person's (or next-of-kin) willingness to donate.
- The default option stated by law, applicable when the deceased's decision is unknown, must be defined.
- The role of relatives in consenting or denying organ recovery must be clearly stipulated.
- The role of HCPs, including when and how donation decisions should be discussed with families.

The success of the model, both in terms of increasing donation and transplantation activity as well as protecting the rights of people who are potential donors, depends on a careful understanding of the laws, OTDT infrastructure, and the culture of the jurisdiction.

RECOMMENDATION #2

A consent model must provide a written regulatory framework on safeguards for vulnerable populations to assure that their donation decision satisfies the ethical and legal standards.

Jurisdictions must have a framework to ensure the validity of consent and protection for their population. At a minimum, this must include the legal criteria for determining competency for people allowed to register a donation decision. OTDT systems should clearly define hierarchies of who has legal standing to become the formal next-of-kin regarding consent decisions. [1,2,3] These hierarchies should include definitions of when, if ever, the state is allowed to consent for donation if no person is identified who meets the legal criteria to become the next-of-kin decision maker.

RECOMMENDATION #3

Donation registry choices should reflect the decision architecture as recognized in law and aligned in practice. Registries should allow citizens to express their deceased donation intent while minimizing barriers to registering a decision.

Registration methods should be universally accessible to the population. Preferably, multiple pathways should exist to allow for registration and changing of registration. This will permit people with varying preferred modes of registering a decision to engage. If multiple pathways for registration exist, processes should be created to ensure that the OTDT system has access to a web-based centralized system, is easily searchable on a continuous basis at the time of a referral of a potential donor and includes the most recent decision. In addition, the donation registration text must align with the legal framework.

RECOMMENDATION #4

The legal and policy implications of a registered donation decision must be consistent with the social and legal norms of each jurisdiction. At a minimum:

- Jurisdictions with opt-out consent models should include the option to register a refusal to donate.
- Jurisdictions with opt-in systems should include the ability to remove oneself from the registry at a future date.

When designing a donation registry, stakeholders must consider the prevailing consent model and that the registry is developed according to existing privacy and consent laws. Jurisdictions considering a consent model change must ensure that their donation registry is updated to allow choices appropriate to the new consent regime.

Laws and policy should define to what extent registration is legally binding in the event of death with clinical potential for donation and what role the next-of-kin has in finalizing a donation decision. Laws and policy must also define what organization is responsible for safeguarding registered information, who has access, and under what circumstances this information can be accessed.

Decision makers should also consider the role of registries in attaining consent for medical interventions before donation (see the full publication for further details).

RECOMMENDATION #5

Law, policies, and procedures should clarify resolutions to situations where surrogate decision makers' decisions conflict with the registered decision of a patient who is a potential donor.

Situations where the next-of-kin disputes the registered intent of a person who is a potential donor represent some of the most difficult challenges to the alignment between law, policy, and societal values. Certain jurisdictions have implemented soft opt-out models allowing families to override the registered decision of the potential donor. [4,5] These soft opt-out systems strongly emphasize respecting cultural values and maintaining public trust in the OTDT system.

What is clear is that public trust is enhanced through transparent policies that remain consistent throughout the authorizing consent process, from the level of legislation down to conversations with individual families. OTDT policy should ensure that their laws, policies, and procedures regarding this situation are clearly worded, consistent with societal values, and fairly applied.

RECOMMENDATION #6

In jurisdictions with developing donation systems, the time, energy & resources required to establish and maintain a registry may outweigh potential benefits in the short-term, while recognizing that strategies to increase intent to donate registrations remain a valuable outcome in more resourced OTDT systems.

The rates of recovering organs among potential donors who have previously registered are consistently higher than among non-registered potential donors. [6,7] However, the association between increasing the total number of registered donors in a jurisdiction and actual transplants is poorly defined. [8] Further research into the links between changes in the number of registrations and actual transplantations is needed.

While a mature system with an established donation registry can justify costs associated with building a registry, less developed systems could reasonably focus on developing other aspects of OTDT activity that are more likely to increase consent rates and deceased donation. [8,9]

RECOMMENDATION #7

In cases of a consent model change, any methods used to promote the changes be sufficient to fully communicate details of the new model to the public.

A change in a consent model requires an effective communication strategy to not harm the public or professional trust in the OTDT system.

Awareness and education campaigns serve two primary functions. The first is to ensure that people understand how to register a decision, either for or against donation. In an opt-out model, if the public does not know how to register a refusal to donate, consent cannot be considered truly informed. The second function is that organ donation organizations (ODO) and other stakeholders often desire to increase registrations to increase donation and transplantation opportunities.

Mass media campaigns can produce positive changes and prevent negative changes in health-related behaviours across large populations. [10] Media campaigns should understand factors influencing consent to donation and adjust their message accordingly. How the request to register and donate is made and by whom affects consent rates. [6]

RECOMMENDATION #8

In cases of a consent model change, culturally and religiously sensitive outreach before, during, and after should be performed in collaboration with historically underrepresented populations and communities with low donation rates.

Any OTDT system considering a change in consent model, particularly towards an opt-out system, should pay particular attention to groups that may have tendencies to distrust the healthcare system in general or the OTDT system in particular.

A comprehensive review of studies [11], conducted primarily with groups with historically low donation rates, highlighted eight major themes regarding community attitudes that influence decision making: relational ties, religious beliefs, cultural beliefs, family influence, body integrity, interaction with the health care system, knowledge of donation, and reservations in donation itself.

With careful engagement, even groups with historically low donation rates could develop positive attitudes towards OTDT systems. Understanding the concerns of people, especially those communities with lower donation rates, is required to implement outreach strategies.

RECOMMENDATION #9

Public and professional outreach should be integrated into information sources that are most trusted by the target community.

Communication strategies of consent models must broadly reach the population, particularly during a system change. While accessing health information online is increasing globally, it is not always preferred or accessible to all. [12] Communication is particularly challenging for historically marginalized groups (i.e., First Nations, immigrants, religious minorities, illiterate, and rural). As demonstrated in reviews of effective strategies to seek new donor registrations, engagement methods must be credible and connected with those groups, optimally delivered by individuals trusted by the community. [13]

RECOMMENDATION #10

The implementation of a change to a consent model should be preceded by adequate time to:

- Build, test and deliver training to clinicians who approach families and surrogate decision makers to frame the conversation in compliance with the laws and policy;
- Create and publish guidance documentation for clinicians;
- Engage and involve stakeholders across the donation system to garner support for the changes;
- Develop necessary informational technology changes;
- Increase the public's awareness of the changes to the law.

An important factor to consider is the time required to safely deliver the change at an operational level. Most recent examples of jurisdictions changing their consent model have allowed a minimum of 12 months [14,15,16,17]. Where technology infrastructure changes are required, more time should be allowed for development. HCPs delivering clinical care must be trained sufficiently to apply consent policies and procedures appropriately.

RECOMMENDATION #11

Measuring the impact of a consent model change should be a high priority.

Outcomes must be carefully defined, and the tools to measure them must be implemented. In general, changes in consent models would be expected to impact consent rates, donor identification and referral rates, and the public's attitudes towards donation. Many of these outcomes are best measured through donor audits, which should be equipped to capture quantitative data and compare results pre- and post-change.

While looking at the impacts on quantifiable donation and transplantation outcomes, these programs should also evaluate public and professional opinions and explore the lived experiences of the people impacted by the donation and transplantation process.

CONCLUSION

This summary report and its publication identify the critical areas for consideration by OTDT stakeholders and decision-makers when contemplating a consent model change. The organ and tissue consent mode working group highlights the factors influencing the implementation of a consent model and should be used by decision-makers and other stakeholders as a guide to effectively develop, plan, and implement or reform their consent model.

FURTHER READING

Download the CDTRP Fact Sheet on Consent Models

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