

Domain Summary

ORGAN DONATION ORGANIZATION ARCHITECTURE

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PREPARED BY



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Programme de recherche en
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**TRANSPLANT
QUÉBEC**

*Organ donation,
together for life
for **50 years***

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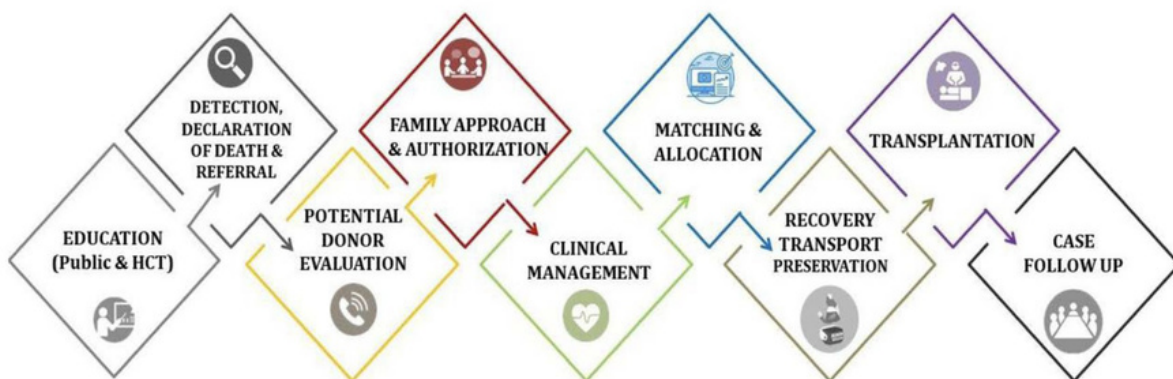
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INTRODUCTION

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 Donation Organization Architecture, one of the seven domains of the Forum, provides expert guidance on the required components of an effective organ donation organization (ODO), its relationship with OTDT stakeholders, and markers of best practices that support an effective donation and transplantation care pathway and continuous improvement.

The 33 recommendations summarized below represent the foundational markers of a safe, fair, and transparent system that maximizes the number of organs available for transplantation and maintains public trust across all stages of the care pathway.



(Image: courtesy Gift of Life Donor Program)

FIGURE 1. The donation and transplantation care pathway.

[THE PUBLICATION CAN BE ACCESSED HERE.](#)

SUPPORTING INFRASTRUCTURE

RECOMMENDATION #1

Establish a clear pathway for the organ and tissue donation and transplantation processes, with clear roles and accountabilities for actions to be taken at all stages and supporting governance to monitor adherence to best practices.

When setting roles, consideration should be given to potential conflicts of interest. Accountability includes safety, quality assurance, quality improvement, and regulations. Data collection and reporting support the creation of an accountable and transparent system.

RECOMMENDATION #2

Establish detailed legislation, guidance, information, and support to clarify the donation pathway and actions required at each stage, tailored to different audiences (e.g., public, patients, families, critical care teams, ODOs, etc.), as well as monitoring systems to ensure alignment with innovation and best national/ international practice.

Given that donation is a low-frequency and high-impact event, clinical, legal, and ethical guidelines should be publicly available to inform clinical decision-making. These guidance frameworks inform actions throughout the ODO.

RECOMMENDATION #3

Establish open and transparent systems to support clinical and public confidence in OTDT.

Transparency can be achieved by publishing guidelines, and developing policies and processes with input and collaboration with patients, families, donors, and donor families. These processes should include regular, public-facing reports that detail the ODO's adherence to its stated goals and policies.

RECOMMENDATION #4

Establish methods and processes for timely, standardized data collection and sharing to inform improvements in successful clinical outcomes, safety, and performance.

Standardized datasets should be available across the care pathway to drive decision-making and continuous improvements. Implementing a national data system to report timely and accurate metrics can be used to compare systems, and identify high-performing centres and their processes.

RECOMMENDATION #5

Invest in research and innovation at all stages of the care pathway, including continuous improvement of practices and processes.

Opportunities to identify and deliver innovation and research should be provided throughout the care pathway to support continuous improvements in patient care and the number and quality of organs available for transplant. Innovations should always be evaluated to ensure efficacy and adherence to ethical standards.

RECOMMENDATION #6

Provide the necessary resources to support all stages of the care pathway to effectively operate at any time, on any day of the year.

An effective donation system relies on various supporting infrastructure measures and resources. Given that organ donation and transplantation are unpredictable, prioritizing timely access to the right resources is critical to ensuring no missed donor opportunities.



PUBLIC EDUCATION AND AWARENESS

RECOMMENDATION #7

Establish effective governance of the care pathway to support public confidence in the system.

Transparent systems will have resources available so that the public can be confident that any safety or ethical principles violations will be quickly identified, and the system modified to respond to underlying factors.

RECOMMENDATION #8

An organ donor registry (opt-in or opt-out or a hybrid thereof) will enable individuals to record their donation decision formally and informs the donation team before the discussion with the family. However, although the registry supports public awareness, it is not essential.

Registries encourage people to register their decision and inform their families of their organ and tissue donor wishes. [1] Ensuring families are aware of the possibility of organ donation during end-of-life care discussions can decrease feelings of surprise and shock when asked about organ donation. [2]

RECOMMENDATION #9

Providing communications strategies, aligned to national campaigns and tailored to different audiences (e.g., faith/ beliefs; cultural; age), will support messaging to different communities. Campaigns that promote individuals sharing their decision with their families are effective, as families will always be approached and are more likely to support donation if they knew their loved ones' decision.

When developing public awareness campaigns, consideration should be given to dispelling myths and misconceptions, encouraging people to register their decision, and informing their families of their organ and tissue donor wishes. [3,4] Campaigns should inform the public of the possibility of being approached to discuss donation as part of a loved one's end-of-life care.

POTENTIAL DONOR IDENTIFICATION, REFERRAL, AND THE DETERMINATION OF DEATH

RECOMMENDATION #10

Establish systems to identify and support the early referral of potential donors.

OTDT legislation should include mandatory referral, an obligation of hospital systems to refer all potential organ donors to the ODO. A referral must occur early to facilitate donation, which includes obtaining consent, undertaking donor assessment, and coordinating donation logistics. [5,6,7,8]

RECOMMENDATION #11

Establish a potential donor audit of all deaths, which monitors adherence to best practices and identifies missed opportunities, with continuous improvement supported through feedback to hospital clinicians.

Adherence to mandatory referral can be audited through a recurring retrospective medical record audit of all deaths. [9] Regular and timely feedback to hospital clinicians in the form of case reviews of “missed donors” or late referrals, along with reporting of key performance indicators, helps support learning and adherence to best practices. [9]

RECOMMENDATION #12

Ensure that the determination of death using neurological or circulatory criteria accords with established national/regional/jurisdictional professional standards complies with legal frameworks, and is reliably performed so that health professionals and the public have trust and confidence in the process.

The process for death determination must be reliable, transparent, and performed to the highest standard. [10] Tests required to diagnose death should be based on established criteria that comply with local legal frameworks. Although legal definitions of death vary worldwide, medical professionals must define the specific clinical or paraclinical exams and tests used to determine death in compliance with local law.

RECOMMENDATION #13

The healthcare professional(s) who perform(s) the death determination of a specific patient cannot be involved in allocation, recovery, and transplantation procedures of the donated organs from that donor.

Roles and accountability must be clear to maintain confidence in the donation system and remove any perceived conflicts of interest.

POTENTIAL DONOR EVALUATION

RECOMMENDATION #14

Critical care, organ donation, and transplant teams collaborate to explore the potential donor's medical history, evaluate the risk of disease transmission, and determine whether organs are safe for transplantation.

OTDT systems are required to provide clinical guidance regarding medical suitability for donation, ensuring the safety and viability of donated organs.^{11,12,13,14} This ensures that families are not inappropriately offered donation where absolute contraindications exist. [9]

Consultation with donation services regarding donation feasibility and medical suitability also reduces the effect of clinician bias or lack of knowledge regarding particular forms of donation, which has been reported in surveys to be a leading cause of physician non-referral. [14,15,16]

RECOMMENDATION #15

Privacy laws and regulations allow for the exchange of patient information within the critical care and organ donation teams and administrators before consent for donation is obtained to enable potential donor evaluation.

Donation teams must be allowed to explore the potential donor's medical history and to identify any potential issues with the safety or efficacy of any donated organs.

FAMILY APPROACH AND AUTHORIZATION

Families have a vital role in the donation process. When a potential donor meets the criteria to be a potential donor, families must always be involved in the donation discussion. [17,18,19,20,21] Effective systems establish clear roles, accountability structures, and processes to ensure that families of potential donors are approached in a timely way by professionals with the necessary training and insights. [22] Healthcare professionals responsible for approaching families are provided regular training and resources (e.g. video, coaching, and role-plays) and best practice guidance. [23] Below is the recommended communication pathway with families and caregivers.

RECOMMENDATION #16-21

- The physician caring for the patient informs the family of the grave prognosis and/or declaration of death by neurological criteria (brain death), before approaching for organ donation.
- Organ donation is not raised at the same time as the discussion of the patient's prognosis, and the request is ideally "decoupled" from the news of the patient's demise.
- Before approaching a family, the patient's donor registry status is checked. If the patient is on the registry as an intended organ donor, the conversation informs the family of the individual's decision to donate, rather than ask permission.
- Families are approached by someone with the training and skills in the donation discussion, adhering to their jurisdiction's agreed-upon guidelines and best practices.
- Discussion with the family needs to include the options for organ and tissue donation and research to maximize the potential benefit from every donation.
- Families are given sufficient information, support, and time to reach a decision.



CLINICAL MANAGEMENT OF THE DONOR

RECOMMENDATION #22

Establish national or regional guidelines with clear algorithms to manage the potential organ donor in critical care (after death determination or decision for withdrawal of life-sustaining measures and consent for donation).

Effective donor management will optimize the number and quality of organs for transplantation. Guidelines should be established for the medical management of neurologically deceased potential donors and donation after a circulatory determination of death from the time of consent for donation to the transfer of the potential donor to the retrieval team. [24]

RECOMMENDATION #23

Access to guidance/advice on individual cases 24 hours a day, 7 days a week, regarding donor management will support optimizing donation potential. Maximizing organ function requires specialized knowledge and resources, and the hospital and/or ODOs support this process.

Local donor management guidelines should be current and evidence based. Regular reviews and benchmarking against national and international practices, guidelines, and policies are required. [25]



MATCHING AND ALLOCATION OF ORGANS

RECOMMENDATION #24

Provide clear rules and guidance regarding the safe, fair, and equitable allocation of donated organs and tissues, including roles, responsibilities, accountabilities, and governance structures for each action.

Allocation balances multiple competing priorities, including medical efficacy, equity, and respect for human rights. Effective matching and allocation systems are vital to support stronger post-transplant outcomes and ensure the safe and equitable distribution of organs. [26] Clear roles, responsibilities, and accountability should be defined in legislation, where appropriate, along with the matching and allocation care pathway.

RECOMMENDATION #25

Ensure timely access to diagnostic services to support donor assessment and inform the organ offering and allocation processes.

Sufficient investments in infrastructure and resources for OTDT support timely matching and allocation.

RECOMMENDATION #26

Establish legislation and guidance to support the secure sharing of data between organ donation, recovery, and transplant teams to support prompt decision-making.

Before transplantation, patients and their caregivers should be provided with information about the health status of the organ, the donor, and assess the level of risk a patient will accept regarding an offered organ. These decisions should be captured as part of the patient record and shared securely, as appropriate, to inform the offering and allocation processes. [27]

ORGAN RECOVERY, PRESERVATION, AND TRANSPORTATION

RECOMMENDATION #27

Establish recovery, transport, transplant teams, and hospital services that are available 24 hours a day, 7 days a week to support the timely recovery and transplantation of donated organs, and that liaise closely with the donation teams to ensure that organ donation potential can be maximized, and any issues/risks are identified, shared, and managed.

Organ recovery can only begin once it is confirmed that the donor has died and consent for donation is in place. Close cooperation between the ODO, transplant center, retrieval teams, transport teams, and the donor hospital should be established, with a central point of command (usually the ODO or donor coordinator) to ensure the timeliness and efficacy of the process. [28]

RECOMMENDATION #28

Machine perfusion may be used to improve organ quality and organ recipient outcomes and assess organ performance.

Clear guidance and protocols should be available regarding the clinical retrieval and organ preservation processes, and these documents should form the basis of retrieval teams' training. [29]



ALTERNATIVES TO DECEASED DONATION AND TRANSPLANTATION QUALITY ASSURANCE

RECOMMENDATION #29

Establishment of living donor programs will maximize the potential for transplantation. Active research programs may be developed to identify alternative approaches in the long term (e.g., stem-cell therapies, regenerative medicine, xenotransplantation, etc.)

While international guidance and recommendations strongly support attempts by jurisdictions to meet their goals of self-sufficiency through deceased donation, OTDT systems cannot meet their needs without supplementation from living donations. [30]

Ongoing research and innovation suggest that other alternative sources of transplantable organs currently being developed and tested include xenotransplantation or laboratory-grown organs. [31,32] OTDT systems should anticipate these changes and create regulatory frameworks that include consideration of access and equity before implementing these developing technologies.

RECOMMENDATION #30

Short-term and long-term recipient follow-up is essential for the health of the recipient to monitor the efficacy and outcomes of the organ transplant and identify areas for improvement.

ODOs and health systems should collaborate to establish a comprehensive data system tracking short, medium, and long-term recipient outcomes linked to the donor. Such a system will allow for improvements in post-transplant care and research into donor selection and management and lead to improved donor management and expanded donor pools. [33]

POST-DONATION FOLLOW-UP AND FAMILY CARE

RECOMMENDATION #31

Communication of case outcomes to relevant stakeholders, including donor family and donor hospital care teams, enables ongoing improvements in care and supports public and clinical confidence in the system.

Proper case follow-ups are essential to ensure the efficacy and safety of the donation and transplantation service. This includes monitoring the outcomes of the transplanted organs and providing care and support to the donor family.

RECOMMENDATION #32

Establish ongoing support for donor families, transplant recipients, and caregivers, recognizing that caregiver support is a component of the post-transplant outcome and supports improved patient outcomes.

Proper stewardship of the donated organs should be a founding principle that protects and honours the donors and their gifts of life. This includes ongoing support of caregivers, and donor families. [34]

RECOMMENDATION #33

Establish policies for communications between donor families and organ recipients' communications, including a confidentiality clause, based upon local legal requirements and cultural values.

Consistent ODO practices, policies, and guidelines will ensure consistency and safety in communication between all parties involved during and after donation. This will establish trust and provide a transparent base to advance donation.

CONCLUSION

Establishing a safe and effective organ donation and transplantation system is complex. This requires close collaborations across multiple teams, with the proper resources in place to ensure that an individual's wish to be a donor is honoured, and no opportunity for a safe transplant is missed.

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