Domain Summary

TISSUE & CELL DONATION

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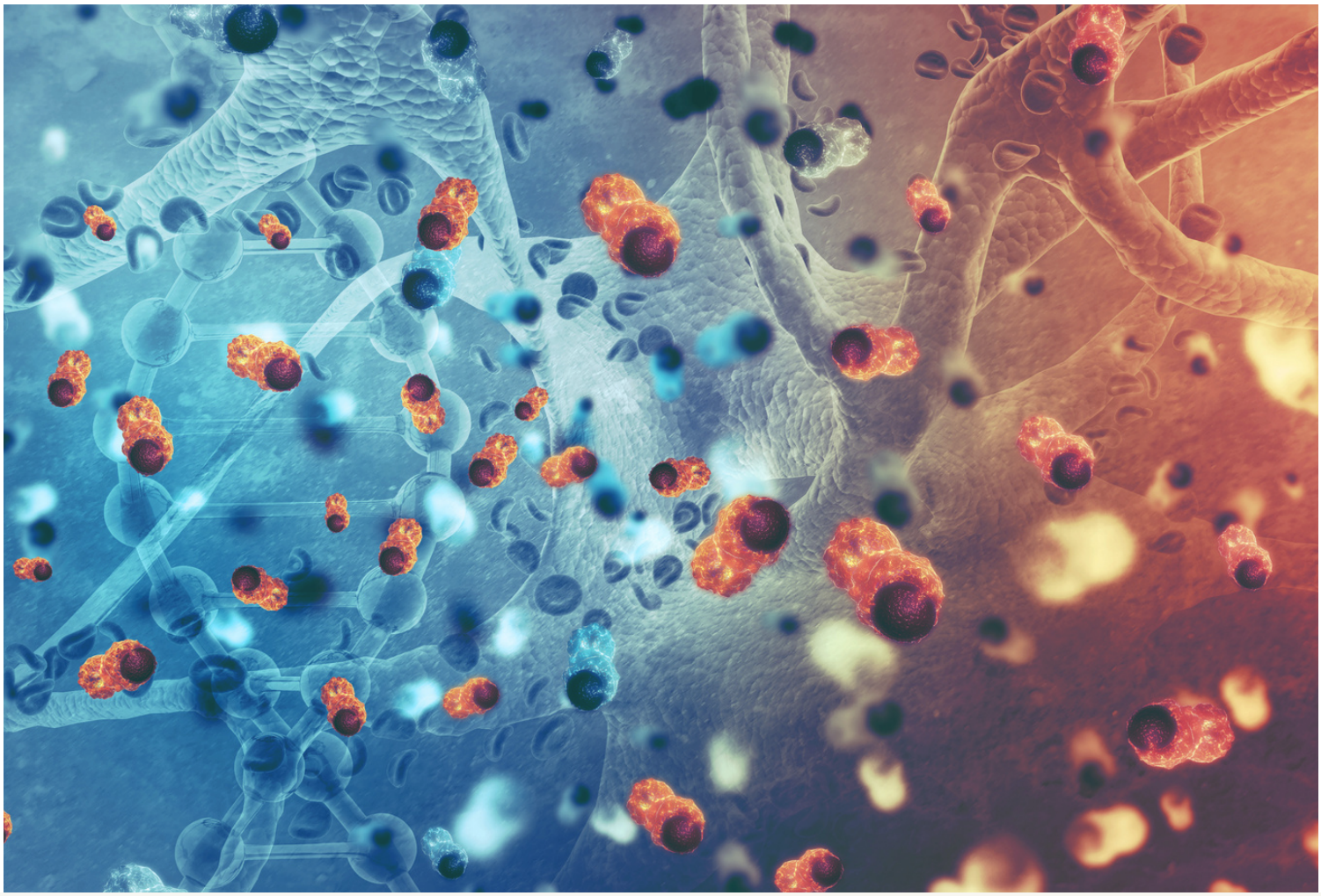

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TRANSPLANT QUÉBEC

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.

Tissue and Cell Donation, one of seven domains developed through the Forum, provides expert guidance for legislative and policy reform. The 13 recommendations outlined in the chapter focus on (1) self-sufficiency of supply, (2) ethics, (3) quality and safety, and (4) innovation for non-profit organizations.

Given that legislation and policies impacting tissue and cell donation and transplantation vary significantly across jurisdictions, the issues surrounding this field warrant separate considerations from other issues affecting OTDT systems. The recommendations are not intended to provide a prescriptive pathway for implementation. Rather, the recommendations provide a general framework for developing a fair, ethical, safe, and accessible system supporting patient outcomes and self-sufficiency.

The complete scholarly publication and this accompanying summary report will assist those making and implementing legislative and policy changes in an OTDT system. The publication can be accessed here.

CURRENT GAPS IN TISSUE AND CELL DONATION SYSTEMS

A significant limitation to improving tissue and cell donation systems includes a lack of data, including the number of tissue donors, grafts procured, transplants, recipients, and patients on waiting lists. This gap is for several reasons:

- The wide range of processing methods used for different tissues and cells does not allow for consistent data, making it difficult for researchers to publish studies.
- Cells and tissues used range from unaltered materials donated to patients to processed products for commercialized use.
- The role of for-profit organizations involved in processing cells and tissues results in therapies adhering to regulatory frameworks outside of transplantation regulation and policy.

These factors make it difficult for OTDT systems to collect data and create unclear lines between cell and tissue donation for medical treatment and commercialization. As a result, concerns and risks remain between the role of financial profit and the ethical and policy frameworks prohibiting financial gain for altruistic donations.

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

ENSURING NATIONAL SELF-SUFFICIENCY IN TISSUE AND, WHERE RELEVANT, CELLS FOR HUMAN APPLICATION

RECOMMENDATION #1

Governments and policymakers aim to achieve national and regional self-sufficiency in the supply of tissues and, where relevant, cells of human origin.

The sustainability and security of tissue products for transplant require a systematic and long-term perspective. [1] To do this, decision-makers should develop appropriate legislative and regulatory frameworks, allocate resources to carry out policy effectively and regulate exports and imports to diminish the impact of market-driven flows of tissues and cells.

Importation should be a temporary strategy executed in conjunction with, not as a substitute for, developing tissue banking programs. [2] Although imported tissue can be essential for addressing shortages, creating an adequate domestic supply offers greater security against fluctuations in global tissue supply.

Where self-sufficiency for specific tissues and cells may not be a feasible long-term solution (i.e., because of the size or characteristics of the country), international collaborations based on solidarity or reciprocity may be sought to attain regional self-sufficiency. [3] The provision of exported tissue by countries with a surplus should be conditional on a regional or national plan to develop the infrastructure and resources needed to provide long-term services.

RECOMMENDATION #2

Governments, policymakers, and donation and transplantation services regularly collect activity data related to the availability and use of tissues and cells of human origin to evaluate demand and supply, ideally using harmonized and common datasets.

Systems should strive to understand production and demand volumes for each tissue and cell type to support fair, timely, and equitable access to safe transplantation services. Systems should collect data related to imported and exported tissues, tissue type, volumes, and origin to understand the level of dependency on imported tissues and progress on self-sufficiency. [4]

Timely data collection allows continuous system improvements, and understanding of system capacity is essential to avoid overreliance on third parties and help prepare for scenarios that may impact supply. [5,6]

ENSURING ROBUST ETHICAL PRINCIPLES

RECOMMENDATION #3

Free, informed, and specific consent is central to the donation process. Donated tissues and cells should not be used in a manner not explicitly acknowledged and accepted by the person providing consent—including their use for nontherapeutic purposes, research, and/or profit.

Governments are responsible for determining the process of obtaining and recording consent for cell, tissue, and organ donation in line with international ethical standards. [7-9] To maintain public trust and support for donation programs, tissues must not be removed from the body of a deceased person unless consent or authorization has been obtained.

Concerns include the terms of consent being abused (by using the donated material in a manner not explicitly agreed), the fact that additional material may be taken without knowledge, or third parties obtaining financial gain from altruistically donated material. Therefore, it is vital that public confidence is maintained by standards of good practice and that the limits of consent are clearly established, made explicit, and scrupulously respected.

RECOMMENDATION #4

When patients receive treatments involving human tissues and cells, they are given accurate and balanced information about their origin and the need to report any complications after the treatment. In the case of innovative/experimental therapies, patients should receive all the necessary information so they can provide informed consent to treatment and have realistic expectations about the results.

This applies to procedures involving human tissues or cells, such as corneal or hematopoietic progenitor cell transplants, and products such as skin or bone powder. The use of human tissues and cells is not exempt from risk, and this should be communicated to prospective recipients.

Regulations should require that patients are fully informed about the risks of innovative/experimental treatments, therapeutic alternatives based on robust clinical evidence from sources free of commercial bias, and the authorization status of these treatments.

RECOMMENDATION #5

The principle of voluntary unpaid donation has a central role in the donation process. Compensation to donors should cover only justifiable expenses and loss of income and should not act as a direct or indirect inducement.

Non-altruistic-focused interventions targeting potential donors with incentives to donate (e.g., payment) must be strictly prohibited. Acceptable financial exchanges could include compensation of living donors for lost earnings or where damage results from removing tissues and cells from a living person. These financial interventions should achieve financial neutrality for the donors or their families.

Promotional activities may be acceptable if the measures involved are altruism-focused, such as general donation promotion campaigns and campaigns recognizing altruistic donations. [10]

RECOMMENDATION #6

Governments and policymakers develop measures and interventions to avoid the commodification of altruistically donated tissues and cells.

Commodification breaches the fundamental ethical principle that the human body should not give rise to financial gain or equivalent advantage and also endangers patient access to therapies. Given the demand for tissue, procurement organizations, tissue banks, and numerous brokers and distributors charge 'reasonable fees' for their services.

The term 'reasonable fees' has never been defined, creating a loophole where altruistic donations are exploited for profit. [11-15] This conflict between altruistic donations and industry risks technology development taking precedence over patient outcomes and research. The Council of Europe recently evaluated the risk of commodifying substances of human origin and set out a series of recommendations. [16]

RECOMMENDATION #7

Governments and policymakers implement measures and interventions to ensure that clinical criteria and ethical principles guide the allocation of tissues and cells. Financial considerations (such as distribution to the highest bidder) should not be weighted in the allocation process.

Tissues and cells must be allocated on transparent, objective, equitable, and duly justified clinical criteria conforming to internationally accepted ethical standards. [17] This includes advanced therapies derived from human tissues and cells, in which there is a real risk that unjustified pricing schemes may restrict access to therapies derived from altruistically donated bodily material.

RECOMMENDATION #8

Governments, policymakers, and healthcare professionals implement appropriate measures and safeguards to ensure the utmost protection of living tissue or cell donors.

Living persons can only donate specific tissues and cells. Therefore, developing a living donation program requires robust legislative and operational measures to safeguard donors' health and individual rights and freedoms. Adequate medical and psychosocial selection criteria, proper informed consent, a limit on the number of times a donor can donate based on robust clinical data, a guarantee of follow-up care, and appropriate follow-up of the donor's health status in the short- and long-term should be assured.

ENSURING THE QUALITY AND SAFETY OF TISSUES AND CELLS FOR HUMAN USE

RECOMMENDATION #9

Governments and policymakers take all necessary measures to protect donors and recipients by ensuring the application of internationally accepted quality and safety standards for the donation, preparation, and clinical application of tissues and cells that consider evidence-based best practices.

There is a need to provide tissue banks, professionals, and stakeholders with strict, comprehensive, and evidence-based international guidelines and standards to ensure the quality and safety of tissues and cells for human application. [18-22] These standards would support the evaluation of the safety, quality, and efficacy of practices and should be regularly updated according to developments in the field.

RECOMMENDATION #10

Governments and policymakers take all necessary measures to ensure systems of surveillance and biovigilance for tissues and cells are in place and coordinated with other vigilance systems (organs, pharmaceuticals, medical devices, etc.)

Using human tissues and cells risks disease transmission and other potential adverse effects on the recipient. Policymakers must ensure that tissue systems have traceability and biovigilance infrastructure in place so risk can be monitored and controlled. This infrastructure should have processes to detect risks and investigate their causes. When risks are detected, all parties (donor and recipient) must be notified, and preventative measures be implemented to reduce future risks.

FOSTERING THE DEVELOPMENT OF SAFE AND EFFECTIVE INNOVATIVE THERAPEUTIC OPTIONS IN NOT-FOR-PROFIT SETTINGS

RECOMMENDATION #11

Regulatory agencies require and evaluate clinical efficacy and safety studies before authorizing any novel therapy for clinical application.

An objective evaluation founded on structured clinical studies should be part of the authorization process for new therapies. Most developed countries have adequate regulations for cell and tissue therapies; however, to ensure public safety, governments must deploy appropriate resources to enforce these regulations. [23]

RECOMMENDATION #12

The decision to fund innovative therapies should be based on independent and objective cost-effectiveness analyses. The resources (human, financial, and material) of donation and transplantation programs of tissues and cells should be adjusted, taking into account these cost-effectiveness studies.

A formal cost-effectiveness assessment should be part of the authorization process for new therapies. Given that more than 70% of health spending across Organization for Economic Co-operation and Development countries is funded from public sources, [24] an adequate balance between innovation, cost, and safety is required. Many countries have established a health technology assessment agency with the necessary expertise to assess the clinical benefits and costs of therapies. [23] The experience and expertise of these groups should be applied when assessing the relevance of new therapies derived from human tissues and cells.

RECOMMENDATION #13

Non-profit and predominantly publicly funded organizations consider collaborations and partnerships to have access to complementary resources, technologies, and expertise to make the development of innovative processing methods and treatments financially possible and sustainable.

As tissues and cells become more than minimally manipulated and treatments involve more sophisticated processes, regulatory requirements become increasingly complex. As a result, compliance costs related to development and production increase, making innovation financially unsustainable in non-profit and predominantly publicly funded organizations. Organizations must therefore explore alternatives to the traditional management and development innovative model through public-private collaborations. [25-27] However, transparent, public oversight is critical to ensure that public funds are not used to bolster the profits of companies that benefit from the altruistic donation of materials from human sources.

CONCLUSION

Global tissue systems experience infrastructure gaps that affect the donation and use of human tissues and cells and need to be addressed internationally to protect all potential donors and patients. These include respecting internationally accepted ethical principles, pursuing self-sufficiency, and protecting donors and recipients.

Incorporating these recommendations, in total or in part, would benefit most tissue donation and transplantation systems in the world, and to ensure the needs of patients are met, it is the role of legislators and governments to implement the measures resulting in the necessary system improvements.

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