

# Background Paper for the Tissue Expert Committee:

For recovery and processing, what is the best balance  
between domestic and imported tissue?

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# 1. Introduction

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## A. Background

Recognizing the need to improve the organ and tissue donation and transplantation (OTDT) system in Canada, the federal, provincial (except Quebec) and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities related to OTDT. This included the development of a strategic plan for an integrated OTDT system, in collaboration with the OTDT community. As part of this work, three committees were formed – the Steering Committee, Organ Expert Committee and Tissue expert Committee – to help develop the recommendations through a formal, structured planning process.

This document is one of a series of background documents developed to help the committees in their discussions. These documents focused on the critical issues within the system, describing the current state and examining potential options and solutions. Conclusions from the committee discussions were consolidated and incorporated in the final recommendations of the final report. The full report, ***Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians***, can be found at [organsandtissues.ca](http://organsandtissues.ca), along with the other background documents in this series.

### Limitations of these documents:

- These documents were intended for an audience familiar with the subject matter and contain terms and acronyms that may not be in common usage outside the field.
- In some cases, original documents referenced draft materials which have now been finalized. In these cases, where possible, references have been updated. These situations are clearly marked.

- These documents provided an overview of the issue for further discussion by experts in the field of OTDT. The findings and evaluations contained in these documents are not comprehensive—they reflect what was considered to be most applicable to the issue at the time.
- Information in these documents presents knowledge available at the time of the OTDT committee meetings. These documents have been edited for consistency in style and format, but have not been updated to reflect new information or knowledge. References and web links also remain unchanged and may no longer be accurate or available.
- As these are background documents to the ***Call to Action*** report which is available in both English and French, they are available in English only. Requests for translation can be made to Canadian Blood Services using the contact information below.

*Note: Production of this document has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of the federal, provincial or territorial governments.*

For more information on these documents or the ***Call to Action*** report, please contact:

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## 2. Scope

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**For recovery and processing, what is the best balance between domestic and imported tissue?**

This paper reviews the current state, data and options in regards to domestic and international sourcing and processing of tissue. It also examines the related risks associated with each option. The scope includes the following tissue types: skin, cardiac, eye, musculoskeletal, and dental.

This document does not examine in the various mechanisms for achieving different states of balance between imported and domestic tissue; nor does it discuss how to ensure alignment between supply and demand in practice or safety matters, which are typically in the purview of a good quality management program. These topics are discussed in separate papers.

## 3. Current State

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### A. Current State

A variety of tissue products are used in Canada each year to save lives (e.g., heart valves), improve quality of life (e.g., corneas and musculoskeletal grafts) and improve surgery outcomes (e.g., demineralized bone matrix). Tissue grafts and specialized bone products are available through a number of channels:

- Tissue banks recover and process tissue locally or send it to another Canadian or American tissue bank for processing. Grafts are made available to end-users, either free of charge or on a cost-recovery basis. Distribution can be restricted to the affiliated hospital, or can extend to hospitals in other provinces.
- End-users can order tissue grafts directly from foreign tissue banks, or indirectly through local distributors.
- Hospital tissue banks, blood banks and health authorities can also act as local distributors for imported tissue.

Generally, provincial governments pay for tissue grafts used in hospitals, either through medicare or through a hospital or tissue bank budget. Tissue products used for dental procedures are generally paid for through private insurance or by patients.

While the actual amount of tissue imported into Canada is unknown, it has been estimated that imports account for more than 80 per cent of the tissue products used by Canadian patients.<sup>1</sup> The amount of importation varies depending on tissue type (recent estimates are provided in Table 1). In spite of the current availability of tissue product from international markets, there are certain tissues types that consistently are in short supply and for which waitlists exist. These products include heart valves, skin, corneas and tendons.

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<sup>1</sup> *Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand, Final Report*, Canadian Council for Donation and Transplantation and Canadian Institute for Health Information, September 2003

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**Table 1: Summary of Estimated Canadian Supply and Demand<sup>2</sup>**

	Number of Allografts				Canadian Supply
	Canadian Supply	Estimated Surgical Demand	Estimated Dental Demand	Total Estimated Demand	
Corneas	3,577	4,001	0	4,001	89%
Bone	5,248	33,476	116	33,592	16%
Tendons	764	2,131	0	2,131	36%
Soft tissue	224	1,637	4,833	6,470	3%
Cardiovascular	231	1,122	0	1,122	21%
Skin	654	1,775	8,073	9,848	7%
<b>Sub-Total</b>	<b>10,698</b>	<b>44,142</b>	<b>13,022</b>	<b>57,164</b>	<b>19%</b>
Demineralized and mineralized bone matrix	0	16,293	58,688	74,981	0%
<b>Total</b>	<b>10,698</b>	<b>60,435</b>	<b>71,710</b>	<b>132,145</b>	<b>14%</b>

<sup>2</sup> Data, with the exception of Canadian supply data, was taken from *Table 40 Summary of extrapolated predicted demand versus known supply across ranges (medium range), Demand for Human Allograft Tissue in Canada: Integrating Dental Industry Demand, Final Report September 2003*. (Canadian Council for Donation and Transplantation, Canadian Institute for Health Information) Canadian supply data was estimated from the 2008 Canadian Blood Services Tissue Survey, 2007/08 Hema-Quebec data, and historic 2002 data from Quebec eye banks and non-respondent bone banks.

### Security of supply

The current dependency on imported tissue product presents risks that could significantly affect the health of Canadian patients:

#### Availability

Currently, sufficient tissue supply exists internationally to meet Canadian requirements; however, Canadians have few alternatives with which to deal with the disruption of this supply, should shortages occur due to:

- **Increased demand:** Tissue use in the United States is projected to increase by 5.4 per cent from 2008 to 2013<sup>3</sup>, and demand could potentially exceed supply. As well, in case of

natural or manmade disasters, it may be difficult to quickly obtain the amount and type of tissue graft required (e.g., allograft skin to treat burn victims of wildfires or manufacturing facility fires).

- **Decreased supply:** An epidemic could decrease the number of tissue donors or result in restrictions at international borders, making importation difficult and expensive.

#### Cost

The volatility of the exchange rate makes it difficult to plan financial budgets for the importation of tissue product. As experienced by Canadian Blood Services with the importation of plasma protein products, an increase in the rate from 1.09 to 1.30 in a two-month time frame resulted in a \$41 million increase in cost.

<sup>3</sup> BCC Research (2008) Market Research Report – Organ and Tissue Transplantation and Alternatives, BCC Research [www.bccresearch.com](http://www.bccresearch.com)

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## B. Current Community Thinking

### **National Consultation: Organ and Tissue Donation and Transplantation (Canadian Blood Services) September 22 to 24, 2008—Gatineau, Quebec**

More than 130 experts came together to discuss this question: "Given the need for national, integrated services in tissue donation and transplantation, how do we establish the system that best meets the needs of Canadian patients?"

The following recommendations related to self-sufficiency:

- Develop an integrated national strategy and targets for sufficiency.
- Focus on developing tissue specific targets and objectives:
  - Target scarce tissues that are not difficult to procure and process.
  - Build on the East Coast and Manitoba practice of having donor tissue exported for processing and then returned to Canada for use.
  - Consider converting excess domestic tissues into structured allografts.
  - Target tissues that are locally produced at better cost and with equal efficacy than through other sources.
  - Engage end-users to ensure their needs are met.

### **Enhancing Tissue Banking in Canada, Phase I: Sustainability (Canadian Council for Donation and Transplantation, Task Force on Enhancing Tissue Banking) November 23 to 24, 2006—Montreal, Quebec**

This event brought together 30 experts from across Canada to discuss key issues related to sustainability in tissue banking. The following recommendations relate to self-sufficiency and security of supply:

- Define reasonable and appropriate self-sufficiency for Canada in collaboration with end-users.
- Define a sustainable funding model(s) in collaboration with end-users.
- Develop a national processing strategy, taking into account regional variations.
- Develop a national strategy for managing the long-term demand and processing of advanced tissue products, and assign oversight responsibility and accountability.
- Establish a mechanism for the bulk purchase of external products, starting regionally and then expanding to national procurement.

## C. Other Models

### **United States**

The US tissue industry, based on a manufacturing business model, is a mix of for-profit and not-for-profit tissue banks that generate revenue from tissue product they provide to customers. These tissue banks provide basic and sophisticated specialized product for the American and international market. Market and business factors dictate the level of American sufficiency. Because of the surplus of tissue the US is currently experiencing, American companies are exporting product to over 40 countries. American tissue

banks also have the option of procuring tissue from donors from other countries.

### **National Health Service Blood and Transplant (NHSBT) - Tissue Services**

Like Canada, the UK has a mix of domestic tissue banks that recover, process, import and distribute tissue products. There are also distributors that sell imported tissue product through sales forces in hospitals. While there are approximately 150 tissue establishments in the UK, NHSBT Tissue Services is the UK's major provider of tissue. They provide 100

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per cent of the UK's skin requirements, 70 to 80 per cent of basic bone, and are the primary provider of tendons. The amount of importation is unknown, although some importation-related decisions that have been made based on safety risk. For example, because of the potential prevalence of vCJD in the population, there is a preference to import dura mater, rather than produce it internally.

### Canadian Blood Services

One of those principles in the Memorandum of Understanding between Canadian Blood Services and the Deputy Ministers of Health states that national self-sufficiency in blood and plasma collections should be encouraged. Canadian Blood Services has managed to achieve this goal for blood and blood components; however, it has not been able to become self-sufficient in plasma protein products, because of the large plasma volumes required, as well as the cost. In 2004, Canadian Blood Services revised its strategic plan with respect to plasma protein products. Canadian sufficiency in plasma products was analyzed based on a risk management framework, balancing cost, benefit, and risks.

The analysis concluded, in part, that:

- target sufficiency levels should be based on the risk of mitigating supply disruption for intravenous immunoglobulin (IVIG);
- self-sufficiency, defined as 100 per cent of IVIG needs met from Canadian plasma, would be hugely expensive and require a significant program expansion from current levels, and therefore was not practical; and
- the goal should be to ensure a three-month reserve in the event of a supply disruption. Based on target inventory levels, critical inventory levels, reasonable time to respond to supply disruption, cost and level of albumin sufficiency, the recommended IVIG sufficiency target was established at 40 per cent.

### Héma-Québec

In Québec, tissue banking is moving towards a centralized provincial model, for both tissue processing and tissue purchasing and distribution. Based on a discussion with Héma-Québec representatives in 2008, they produce approximately 15 per cent of Québec's tissue needs.

## 4. Analysis

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### A. Analysis Approach

Strengths and weaknesses of proposed options were evaluated based on risk and benefit. Note that insufficient financial data was available to evaluate options with respect to cost increases or savings. In evaluation of the options, the following assumptions were made:

- Security of supply, including mitigation of supply disruption, is required to ensure the health and safety of Canadians.
- Canada has enough potential tissue donors to supply all its tissue requirements.
- Choice of product must be maintained for patients and physician stakeholders.
- Over the next 20 years, new technologies will not generate products that will replace the requirement for tissues.

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## B. Analysis Findings

As mentioned above, certain data was difficult to obtain and is lacking in many areas. There are, for example, no accurate supply and demand forecasts. Consolidated, complete national financial data is non-existent. Current and potential capacity of

Canadian tissue banks is unknown. More detailed information is required on international models for comparison. Further data collection and analysis is needed to determine the financial impacts and feasibility of each option.

# 5. Options and Considerations

## A. Options

### Status Quo

Individual tissue banks and end-users continue to procure, process, source and supply tissue product independently with little to no coordination. Imported product continues to account for a significant portion of total volume of allografts used by Canadian patients.

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>A diverse supply base, wide range of choice in products for end-users, including latest innovative products.</li> <li>Access to an open market that is responsive to dramatic changes in end-user product preferences.</li> <li>Allows purchasing from alternate suppliers in the event of a problem with any one supplier.</li> </ul>	<ul style="list-style-type: none"> <li>Uncoordinated response to supply disruption or supply shortages at national level.</li> <li>No long-term contingency planning or mitigation at national level.</li> <li>Slow and uncoordinated system response to emerging safety issues.</li> <li>No optimization of cost savings nationally by leveraging purchasing power.</li> <li>Continued risks related to availability and costs.</li> </ul>
Barriers	
<ul style="list-style-type: none"> <li>None</li> </ul>	

### Move to 100 per cent self-sufficiency in tissue products

All tissue products used in Canada are derived from Canadian donors, and processed and distributed by Canadian tissue banks, including advanced tissue graft (e.g., demineralized bone matrix).

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>Complete control of donor selection criteria and testing.</li> <li>Provides more opportunities for Canadians who wish to donate.</li> </ul>	<ul style="list-style-type: none"> <li>May jeopardize ability to meet product demand for certain types of tissue.</li> <li>May limit product diversity, especially for advanced tissue graft (e.g., demineralized bone matrix) and innovative new products.</li> </ul>

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<ul style="list-style-type: none"> <li>• Will strengthen tissue banking industry in Canada, increasing Canadian jobs and expertise.</li> <li>• Potential to generate profits, as surplus inventory could be sold internationally.</li> </ul>	<ul style="list-style-type: none"> <li>• Slow response to disruptions or persistent shortages in Canadian supply as ongoing relationships with external suppliers would be diminished or non-existent.</li> </ul>
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**Barriers**

<ul style="list-style-type: none"> <li>• Canada currently lacks capacity, expertise and infrastructure to be totally self-sufficient. It would require time and investment to meet full demand.</li> <li>• Resistance from some end-users to lack of access to imported products.</li> </ul>
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**Move to 100 per cent importation of tissue product**

All Canadian tissue requirements are supplied from international sources. No tissue is recovered from Canadian donors. Sourcing, purchasing, and distribution of tissue product are coordinated nationally. No processing is performed in Canadian tissue banks.

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• No need for additional investment in tissue recovery and processing.</li> <li>• A diverse supply base, wide range of choice in products for end-users, including latest innovative products.</li> <li>• Access to an open market that is responsive to dramatic changes in end-user product preferences.</li> <li>• Potential to optimize cost savings nationally by leveraging purchasing power.</li> <li>• Permits purchasing from alternate suppliers in the event of a problem with current sources of supply.</li> <li>• National coordination ensures consistent management of risks associated with supply disruption and emerging safety issues.</li> </ul>	<ul style="list-style-type: none"> <li>• Little control of donor selection criteria and testing.</li> <li>• Does not promote tissue banking industry in Canada; jobs and expertise are lost to other countries.</li> <li>• Does not give Canadians the opportunity to donate tissue.</li> </ul>

**Barriers**

<ul style="list-style-type: none"> <li>• Potential resistance from tissue programs operating in Canada, from governments who have tissue programs, and from the Canadian public.</li> </ul>
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**Move to 100 per cent self-sufficiency in tissue donation**

Canadian donors provide 100 per cent of tissue product used in Canada. Tissue is processed by Canadian tissue banks and American processors through coordinated, national contract agreements, depending on the capacity of Canadian tissue banks, the type of tissue, and the complexity of processing required.

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• More control of donor selection criteria and testing.</li> <li>• International purchasing would provide contingency in the event of donation shortages.</li> <li>• Provides more opportunities for Canadians who wish to donate.</li> </ul>	<ul style="list-style-type: none"> <li>• May jeopardize ability to meet product demand for certain types of tissue.</li> <li>• May limit product diversity, especially for advanced tissue graft (e.g., demineralized bone matrix) and innovative new products.</li> </ul>

**Barriers**

- Will require improvements and investments in tissue donation programs across the country.
- Will need to establish or expand relationships and agreements with international tissue processors.

**Increase number of Canadian donors, as well as Canadian processing capacity and capability**

Increase the number of tissue donations from Canadian donors, the capacity of Canadian tissue banks to process Canadian tissue, and the types of products being produced. Continue to import tissue products, as required, based on a risk analysis that considers costing and possible disruption of supply.

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• Access to an open market that provides a wide range of choice and is responsive to dramatic changes in end-user product preferences, including latest innovative products.</li> <li>• Allows purchasing from alternate suppliers in the event of a problem with any one supplier, or in the event of a donor shortage.</li> <li>• Will strengthen tissue banking industry in Canada, increasing Canadian jobs and expertise.</li> <li>• Potential to generate profits, as surplus inventory could be sold internationally.</li> <li>• Allows more Canadians the opportunity to donate.</li> </ul>	<ul style="list-style-type: none"> <li>• None identified</li> </ul>

**Barriers**

- Investment and time will be required to increase donation opportunities and processing capacity and capabilities,
- National coordination would be required to propel production and inventory management

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## **B. Considerations**

Different strategies can be considered for different tissue products; for example, 100 per cent self-sufficiency in cornea and skin may be desirable and feasible while, in the short term, Canada continues to import 100 per cent of specialized bone material.