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# CALL TO ACTION

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A strategic plan to improve organ and tissue  
donation and transplantation performance for Canadians



Developed by Canada's organ and tissue donation and transplantation communities  
in collaboration with Canadian Blood Services

## **DEDICATION**

*Call to Action* is dedicated to all Canadians whom the organ and tissue donation and transplantation system has been unable to support, including those who have died while on transplant waitlists, those who never made it to a waitlist, those who wanted to donate and could not, and those who have had to wait for cornea transplants in some parts of our country despite an adequate number of potential donors.

These are just some of the Canadians for whom outcomes might have been much different in the integrated, inter-provincial organ and tissue donation and transplantation (OTDT) system proposed in this strategic plan.

## **ACKNOWLEDGEMENTS**

Canadian Blood Services, the Organ and Tissue Donation and Transplantation (OTDT) Steering Committee, the Organ Expert Committee and the Tissue Expert Committee would like to acknowledge the more than 140 groups whose steadfast participation and valuable contributions have been indispensable in the development of this strategic plan. These groups represent the spectrum of OTDT voices in Canada, and some of the most respected organizations internationally. They include concerned citizens; health professional organizations; medical professional associations; patient groups; organ transplant programs; tissue, eye and surgical bone banks; organ procurement organizations; federal, provincial and territorial health ministers, deputy ministers of health and officials; related government health agencies, institutes and organizations; and numerous international societies.

Please see Appendix A (Stakeholder Consultation Groups) for a full list of contributors.

Canadian Blood Services would also like to thank the many patients, donors, families and medical teams who were eager to express support for an integrated OTDT system by sharing details of their experiences. Readers will encounter the personal stories of many of these Canadians throughout this plan.

## **REMEMBRANCE**

Canadian Blood Services would like to recognize the significant contribution of Sophie de Villers, Vice-President of Strategy Management, to the development of this strategic plan. Regretfully, Sophie lost her battle with cancer just before the plan's completion.

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**A NOTE ON THE TEXT** Organ and tissue donation and transplantation (OTDT) is a science, and must be examined in precise medical language. It is a matter of supply and demand, and must be explored in practical terms. Yet OTDT is also a field of care defined by supreme acts of altruism, and so deserves respectful discussion. It has been a primary goal of this plan to inscribe even the most technical passages with compassion and empathy particularly for donors and their families in respect of the gifts they bestow.

# A LETTER TO CANADIANS AND TO CANADA'S MINISTERS OF HEALTH

We are proud to present this strategic plan on behalf of Canada's organ and tissue donation and transplantation (OTDT) communities. Three years in the making, the plan meets the requirement expressed by Canada's governments to propose ways to improve OTDT performance in our country.

As *Call to Action* describes in detail, Canada can do better; despite numerous reviews in the past, and some areas of excellence across the country, performance nation-wide has remained unacceptably low and essentially unchanged for more than a decade. Canada's governments clearly recognized this shortfall and, in 2008, directed Canadian Blood Services to develop and propose a practical, achievable solution in partnership with the OTDT communities—a solution that adds value to OTDT by avoiding duplication of existing services and acknowledging and building on what works well in provinces and territories across Canada.



↑ Ms. Leah Hollins, Chair, Board of Directors and Dr. Graham Sher, CEO, Canadian Blood Services

In *Call to Action*, we set forth that solution. The plan presents an exhaustive evaluation of the challenges and opportunities in the current OTDT environment. It sets out principles that must underpin system reform. It establishes priorities for a new, integrated, inter-provincial system. It identifies roles and responsibilities for those involved in such a system. It presents sweeping, targeted recommendations to achieve breakthrough performance for Canadians—to reduce transplant waitlist times, increase domestic production of tissue products and help mitigate transplant tourism, among numerous other objectives. Finally, *Call to Action* demonstrates how these recommendations can be implemented and, where possible, what they will cost.

## Seizing the potential

The title, *Call to Action*, conveys a range of specific messages on behalf of the OTDT communities. The call is to all Canadians to commit fully to organ and tissue donation and transplantation. Well over 90 per cent of us have expressed our support for OTDT, yet only a fraction of that number have filled out an organ and tissue donation card, placed our names on registries, spoken to our families and friends about our wishes and encouraged others to do the same. The call is to OTDT professionals to seize every donation opportunity and make every effort to accommodate donation and transplantation procedures in every health care setting. The call is to industry and academia to continue and accelerate OTDT research and innovation; in an integrated environment, the need and the support for advances will be great. Most important, the call by Canada's OTDT communities is for governments to act now.

Where OTDT is concerned, we are at a tipping point in this country. This strategic plan marks a monumental effort on the part of the OTDT communities. It is an effort that has brought together dozens of agencies, groups and organizations with the sole purpose of realizing the potential of donation and transplantation to improve patient outcomes. The planning process has seen disparate groups and individuals strive and achieve remarkable consensus for the transformation of a vital component in Canada's health care system. Yet this effort to reform OTDT is the latest of many and so stretches back more than a decade. As a result, it is an effort that may be the last for many of our country's leading OTDT experts.

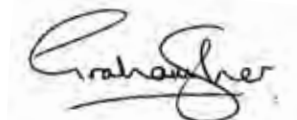
#### Heeding the call

We can do better for Canadians if we come together now. This is a time to see our differences as reason to collaborate for the greater well-being of people in need. *Call to Action* underscores the immense benefits of working together—the efficiencies, the collaboration of great minds to share and generate brilliant ideas, the saving of hundreds, perhaps thousands of lives, and dramatic improvements to thousands more.

Across Canada, patient groups, patients, donors and their families, OTDT professionals and academics, hospital administrators, health care agencies and medical professional groups, among many others, anxiously await Canada's health ministers' response to this strategic plan. Canadians from coast to coast trust this country's ultimate health care authorities, having had the foresight to request development of this plan, will be ready to heed its call to action.



Leah Hollins  
Chair, Board of Directors



Dr. Graham Sher  
CEO, Canadian Blood Services

Ottawa, April 2011



**KEN AND JOAN STEVENS** *By the time Ken Stevens was rushed to emergency in 2009, his heart was failing. Five years had passed since he'd been sidelined with a severe heart attack. Since 2004, he'd survived and waited for a transplant with "very reduced capabilities." Ken's doctors determined the only option was to fit him with a mechanical heart—a left ventricle assist device, or LVAD—until a suitable heart became available.*

*"My family's life has been on hold for the past year and a half," says Ken. While grateful for the care he receives and the technology that keeps him alive, the wish and the waiting for a new heart are forever on his mind.*

*"Each time the phone rings, especially late at night, Joan and I wonder, 'Could this be the call?' A new heart would put our lives back together and let us enjoy our family and grandchildren in our final years."*

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# EXECUTIVE SUMMARY

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## A MANDATE FOR CHANGE

Recognizing the need to improve the organ and tissue donation and transplantation system in Canada, the federal, provincial and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities. These responsibilities include assuming the activities of the former Canadian Council for Donation and Transplantation, such as those related to leading practice development and establishing three vital patient registries (See sidebar on page 8.)

Canadian Blood Services was also given responsibility to develop a plan—in collaboration with the OTDT communities—for an integrated OTDT system that would improve donation and transplantation performance in Canada. The organization had led the sweeping reform of the blood system and demonstrated the capacity to manage change and growth at the inter-provincial level. In the process, Canadian Blood Services had achieved the rigour, transparency and public awareness that would be vital to an organ and tissue donation and transplantation system. What's more, the organization had succeeded in gaining the trust of Canadians.

## A formal strategic planning process with broad stakeholder consultation

This was not the first attempt at OTDT reform. Across more than a decade, many recommendations have been made at the federal and provincial level, but meaningful and sustainable national performance improvements have not been achieved. A new approach was needed, and Canadian Blood Services drew on its experience and developed a rigorous, formal strategic planning process adapted from that used to transform the blood system.

Three committees were formed—the Steering Committee, Organ Expert Committee, and Tissue Expert Committee—to help develop recommendations. Committee members were selected for their expertise, and to ensure broad representation from across Canada.

Given the wide stakeholder group, the lack of comprehensive information about OTDT in Canada, and the diverse opinions in the OTDT communities, Canadian Blood Services also built extensive collaboration with the OTDT stakeholder community into the planning process. The public and expert engagement strategy garnered input from a wide variety of sources including members of the public; national, provincial and local patient groups; organ transplant programs; tissue,

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## GOVERNMENT PARTICIPATION

*Canadian Blood Services is funded by the provincial and territorial governments except Quebec. The government of Quebec is actively involved in the Living Donor Paired Exchange registry and has agreed to participate in other OTD patient registries; however, Héma-Québec is responsible for tissue donation and transplantation in Quebec and has its own action plan to increase TDT performance.*

*A number of the province's physicians and other stakeholders were actively involved in the development of this OTDT strategic plan, and many others in Quebec's clinical community have indicated support for broad OTDT system improvements in Canada, including Quebec.*

*The federal government considers Quebec to be an essential part of an inter-provincial strategy for OTDT. Canadian Blood Services also believes an integrated system can only be stronger with Quebec's involvement and will continue to engage and work with Quebec for the benefit of all Canadian patients.*

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## EARLY IMPROVEMENTS

Canadian Blood Services launched the first of the three patient registries—the Living Donor Paired Exchange—as a pilot just nine months after assuming its new OTDT role. All Canadian provinces and territories have signed on to the LDPE, which, as of March 31, 2011, has helped 69 patients receive kidneys. Two other registries—the National Organ Waitlist (NOW) and Highly Sensitized Patient (HSP) registry—are scheduled to launch in 2011, also with the participation of all provinces and territories. These registries mark significant steps in waitlist management, and important technological solutions for improved frontline service delivery. The registries have also fostered greater inter-provincial cooperation—a hallmark of OTDT developments to date, and vital to broader and sustained OTDT improvements.

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→ **Dr. David Grant**, Director, Transplant Centre, The Hospital for Sick Children, and **Dr. Giuseppe (Joe) Pagliarello**, Critical Care, General Surgery and Trauma, Ottawa Hospital; both members of the Organ Expert Committee.

eye, bone banks; organ procurement organizations; health professional organizations; governments; and international experts from world-leading OTDT systems.

### A principles-based approach to developing recommendations

Members of the OTDT communities gave deep consideration to a range of ethical questions during development of this strategic plan. As a vital component of Canadian health care, the OTDT system will champion the principles enshrined in the Canada Health Act—principles such as universality, portability and jurisdictional flexibility. The communities have expressed their belief that additional principles must come into play to respect the unique nature of organ and tissue donation and transplantation. Through public forums, ethics consultations and professional meetings, the community identified ten additional guiding principles, including *stewardship* as it relates to managing the gifts of human organs and tissue; *respect for human dignity* in the treatment of living and deceased donors; and *solidarity*, which is essential to build and sustain an integrated inter-provincial OTDT system.

### Focused on fixing problems and building on what currently works well

Creation of this strategic plan involved more than a clearly defined process and broad stakeholder consultation. It involved building on what works well in the current OTDT environment. It is recognized that there are pockets of excellence throughout Canada, and that many advances have been made at the provincial and regional levels. With this in mind, this strategic plan avoids duplicating existing services, concentrates on problem areas and on developing solutions to raise the performance of all provinces without restraining today's stronger performers.

### One approach, two distinct systems

Although there are areas of overlap, organ donation and transplantation (ODT) and tissue donation and transplantation (TDT) are characterized by different processes and unique challenges. As a result, ODT and TDT are envisioned as parallel but separate subsets of the broader health care system. Although ODT and TDT are addressed separately in this plan, Canadian Blood Services has built into its recommendations opportunities to share resources to address the needs of both systems in overlapping areas such as deceased donation, infectious diseases, intent-to-donate registries, public and professional awareness and education.



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# EXECUTIVE SUMMARY: ORGAN DONATION AND TRANSPLANTATION (ODT)

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*ODT presents immense life-saving and life-enhancing potential for thousands of Canadians each year, yet members of the ODT community believe only transformational change will help Canada realize the benefits of this field of care.*

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## THE CHALLENGE

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### **A CURRENT SYSTEM THAT FAILS TO MEET THE NEEDS OF CANADIANS**

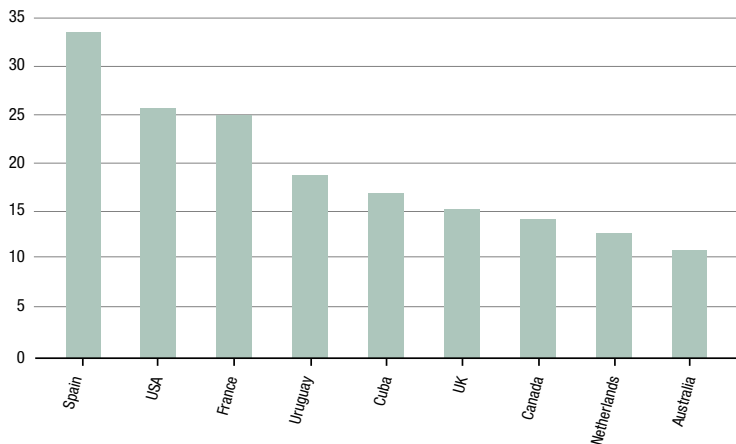
Public and professional consultations revealed a range of issues that underscore the need for change in ODT. As a country, we can do better to address these specific challenges that stand in the way of efforts to ensure patients are better served:

- Ensuring Canada realizes its potential for organ donation,
- Ensuring fairness and transparency in the ODT system,
- Increasing efficiencies associated with patient assessment and organ allocation to improve patient wait times and reduce impacts on health, and
- Strengthening measurement and accountability mechanisms to drive consistent, system-wide performance improvements.

*Challenge:***Ensure Canada realizes its potential for organ donation.**

Canada's deceased donation rate is unacceptably low—less than half that of the best-performing countries. Even provinces with the highest donation rates are far below those in comparable jurisdictions outside Canada.

*Figure 1-1. Deceased Donors PMP (2009)*



Reference: IRODaT - International Registry of Organ Donation and Transplantation website ([www.tpm.org](http://www.tpm.org)).  
At the time of publication, France and Cuba reflected 2008 data.

Donation involves numerous players and a series of complex steps, from identification of potential donors to securing hospital services necessary to recover organs. In Canada, too many donations are lost because one or more of these steps is poorly executed.

Families are not always given the chance to donate, either because individual health care professionals are not always aware of the opportunity or they are unsure about the process. Not all staff have the proper training required to ensure that families are approached in an appropriate and compassionate manner. These discussions are easier when families are aware of patients' intentions towards donation; but only a few provinces have intent-to-donate registries, and public participation in these registries is low, and information is not uniformly accessible. Even when families initiate discussions themselves, hospitals cannot always offer the expertise, resources or access to ICU and operating rooms to follow through on the donation.

Most organ donors are patients who have been declared brain dead according to neurological criteria. In other situations, however, there are patients with severe brain injury who do not meet the clinical definition of brain death, but are removed from life support because they have no chance of recovering. In certain circumstances, these patients can become organ donors. This practice, known as donation after cardio-circulatory death (DCD), is common in many countries and can result in a significant increase in the number of donors; however, DCD is in limited practice outside Ontario and Quebec in Canada.

*Challenge:***Ensure fairness and transparency in the ODT system.**

Transplants are the best long-term treatment option for patients with end-stage organ failure. To get a transplant, a patient must be identified as a potential transplant candidate, assessed for transplant suitability and placed on the appropriate waitlist. National criteria are available to help physicians identify suitable transplantation candidates, yet some professionals are unaware of the criteria and there is little consistency in the way these criteria are being applied. The result is that some patients who meet the transplantation criteria may not make it to waitlists.

The current provincial variation in transplant activity and wait times raise concerns of significant inequity in access to organ transplantation in Canada. For example, patients in some provinces are more than twice as likely to receive an organ than patients in others (see Table 1-1). Wait times for patients on kidney-transplant lists average from over one year to more than four years, depending on which province the patient is from (Table 1-2). There are groups, such as highly sensitized patients and Aboriginal patients, whose chance of receiving an organ is even lower.

**Table 1-1. PROVINCIAL TRANSPLANT RATES IN CANADA**

Patients' chances of receiving an organ vary significantly by province, and by organ type.

	Transplant Rate Range <sup>1</sup>	Wait times (range in months) <sup>2</sup>
 KIDNEY	13.4 - 27.3	19.6 - 55.8
 HEART	3.1 - 7.5	2.0 - 5.4
 LUNG	2.8 - 11.1	6.1 - 19.8
 LIVER	4.6 - 15.1	2.8 - 12.8

<sup>1</sup> (Transplants per million population, organs from deceased donors only, by province of residence CORR data, averaged from 2005-2007).

<sup>2</sup> (Average time before transplantation for patients on organ transplant waiting lists, organs from deceased donors, by province of treatment) 2008 CORR data.

Further troubling is the lack of waitlist transparency. Waitlist referral and organ-allocation criteria are, for the most part, neither public nor standardized. The criteria are difficult for many health care professionals to understand and often frustrate patients and their families.

*Challenge:***Increase efficiencies associated with patient assessment and organ allocation to improve patient wait times and reduce impacts on health.**

Some organ sharing does take place between provinces. A national waitlist is used to identify these sharing opportunities. Canada's current waitlist, maintained by the London Health Sciences Centre, identifies candidate recipients for all organs except kidney. Due to technical limitations, the current national list is challenged to ensure complete accuracy and timeliness. The list is updated by faxes to LHSC and published only weekly, again by fax distribution. This is far from ideal, and the LHSC has repeatedly requested that an appropriate agency take over and modernize the national list.

Patients with end-stage organ failure can be placed on waitlists only after extensive assessments and workups conducted by various specialists. These processes are sometimes poorly integrated, especially when different departments, hospitals and data information systems are involved.

*Challenge:***Strengthen measurement and accountability mechanisms to drive consistent, system-wide performance improvements.**

There are several over-arching ODT issues that must be addressed if transformational performance improvements are to be achieved. For example, inconsistent, incomplete data capture and the lack of mandatory centralized reporting make it difficult to achieve Canada-wide, evidence-based improvements.

There is also no coordinated approach by organ programs to develop and implement policies to respond to emerging issues. Transplant tourism poses one such policy challenge. Canada has few policies in place to respond to the disturbing numbers of patients who pay for and receive organ transplants in third-world countries—patients who often return to Canada with serious complications requiring follow-up treatment.

Transplant tourism can be reduced by increasing the domestic availability of organs, which requires higher organ donation rates. Leading practice implementation is widely considered an effective way to raise those rates, yet Canada has no requirement to implement leading practices, and no coordinating oversight body to improve training and awareness. ODT activities require highly trained hospital personnel, but few training programs exist where health care professionals can learn about this field of care and its leading practices.

Another current shortfall is the absence of supply-chain accountability, which can improve performance by delivering on agreed outcomes and targets. Individual organ programs do not necessarily coordinate performance targets with others, there are no consequences for not implementing leading practices, and no incentives or requirements to improve performance.

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**THE OPPORTUNITY:**


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**BREAKTHROUGH PERFORMANCE FOR IMPROVED PATIENT OUTCOMES**

With a clear sense of the challenges currently facing ODT, the Organ Expert Committee set out a vision for the future: *By 2017, Canadian patients will have a trusted, integrated transplant system that performs among international leaders.*

The strategy to realize this transformational vision requires focus on five ODT system priorities:

- **Increase donation to give patients the best chances to receive transplants with optimal outcomes.** Donation must become a standard part of end-of-life care—and therefore a professional responsibility—in the ODT system. This standard of care must be met through identification of all potential donors, timely referral of donors to local organ procurement organizations, proper donor management, and the effective requesting of consent from families. Carrying out these activities will ensure that the system is ready to respond to all donation opportunities.
- **Ensure fair access to transplants for all patients.** Regardless of wealth, gender, ethnicity, status or location, Canadian patients and patient groups must be treated fairly in the ODT system. There must be a consistent approach to patient identification, referral and listing. Organs must be allocated according to established principles of fairness, utility and medical need—and according to impartial rules and evidence-based criteria. Fairness also means collecting and analyzing patient-outcome information in support of all patients, and to inform long-term system improvements.
- **Earn the public's trust through transparency and accountability.** Canadians have a right to know how the system is performing. Under the new ODT system, operators must be required to report, and therefore be answerable to the Canadian public to ensure that information on decisions, processes, actions and performance is transparent.
- **Enable collaboration among all provincial stakeholders.** The ODT community believes that breakthrough performance depends on collaboration to develop, share and adopt leading practices; to maintain clearly defined roles, responsibilities and lines of accountability; to ensure stakeholders actively participate and guide system growth and evolution; and to optimize research and innovation.
- **Strengthen the system's infrastructure and capabilities.** This priority refers to the improvements in resources, skills, culture and technology that are needed to support transformation to an integrated ODT system. Strengthening the system's infrastructure and capabilities means building a commitment to ODT among senior health care administrators and professional associations. It means ensuring the right number of professionals have the right skills to ensure the right things happen. It means removing barriers to accessing ICU beds, operating rooms and follow-up care. It means providing staff with the technologies to increase efficiency and deliver the data needed to drive performance improvements.

Canadian Blood Services and the Organ Expert Committee believe that a system that meets these priorities and performs optimally for Canadians will be sure to stand strong among the ODT systems of other countries.

**Measuring progress**

At a high level, progress will be indicated within five years by growing public and health-care professional confidence in all aspects of the ODT system; an increase of 50 per cent in the number of donations from deceased donors, and in the number of transplants; a significant drop in the number of people who die while on transplant waitlists; and a decrease in the variability of wait times among provinces.

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**THE SOLUTION:**

**RECOMMENDATIONS  
FOR AN INTEGRATED  
INTER-PROVINCIAL  
ODT SYSTEM**

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*These recommendations identify the activities and processes that are required to execute the ODT strategy to improve the system for patients, families and health providers.*

### **Building on current strengths**

Hospitals that provide organ-donation services will continue to do so through their emergency departments and critical care units; organ procurement organizations will continue to work with hospital partners to promote and facilitate organ donation; other programs will continue to support living donors; and transplantation programs will continue to provide patient services. The provincial ministries of health will continue to determine the appropriate accountability and reporting relationships for these organizations (see Figure 1-2).

Canadian Blood Services will continue to provide registry services, leading-practice and policy development, and awareness and education. It will also provide leadership and coordination in areas where inter-provincial collaboration and integration are required.

Organizations that currently play a role in regulations, standards, and auditing—such as Health Canada, the Public Health Agency of Canada, the Canadian Standards Association and Accreditation Canada—will continue to do so.

### **New or expanded roles**

What is being recommended is the addition of a combination of new structures, relationships and focused initiatives that will address performance gaps and drive improvements. The system's new or expanded elements include:

- an accountability framework that includes an explicit inter-provincial governance structure,
- the availability of donation physicians who provide leadership in creating a professional and organizational culture of donation,
- a focused public awareness strategy linked to intent-to-donate registries,
- a formal education program for health care professionals linked to leading practices for donation,
- a comprehensive, inter-provincial registry system, and
- infrastructure that supports all areas of ODT, including data management and analytics, focused ODT research and innovation, and frontline funding to support increased donation and transplantation activity.

Please see Appendix B of *Call to Action* for more information on proposed ODT-system roles and responsibilities.

*Recommendations:*

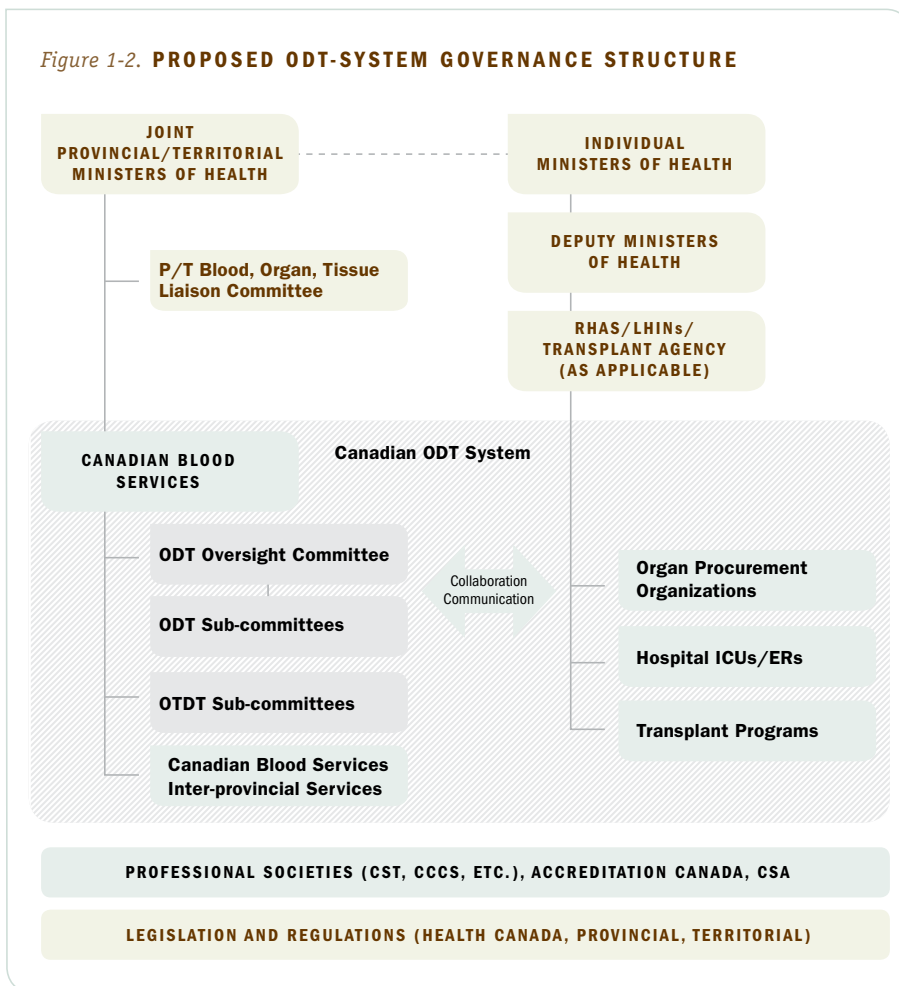
**Accountability**

1. An integrated inter-provincial ODT system involves numerous programs, organizations and jurisdictions whose shared goal is to improve performance system wide. A governance structure is essential to clarify and enable the shared accountability and respective roles and responsibilities of those participants in the integrated system.

*It is therefore recommended that the federal, provincial and territorial governments establish a formal accountability framework that outlines the structure and essential attributes of—and roles and responsibilities within—an integrated ODT system. Such a framework would enable the system as a whole to achieve and be evaluated against stated goals.*

2. *As part of the formal accountability framework, it is recommended that specific governance structures be created (see Figure 1-2). Among these is an ODT oversight committee that is broadly representative of the ODT community in all jurisdictions and is supported by a series of advisory committees. Reporting to the provincial and territorial ministers of health, through Canadian Blood Services, the governance structure would enable the development, monitoring and improvement of inter-provincial strategy and policy, and performance against stated goals.*

**Figure 1-2. PROPOSED ODT-SYSTEM GOVERNANCE STRUCTURE**





3. Transparency of system performance is essential to ensure accountability, enhance performance and drive best practice. Transparency is predicated on the availability of data to assess performance and monitor compliance.

*It is therefore recommended that the accountability framework identify mandatory data reporting and review, and system-wide audit capability, as integral components of the integrated inter-provincial system.*

#### *Recommendations:*

##### **Donation Physicians**

4. Donation physicians will provide leadership in creating a professional and organizational culture of donation. They will drive organ and tissue donation care throughout the system, including the provision or administration of clinical services such as identification and referral, consent, donor management and organ utilization. Their areas of responsibilities will also include professional education, performance measurement, accountability, quality assurance, family support, media and research.

*It is therefore recommended that donation physicians be available to all hospitals that provide donation care.*

#### *Recommendations:*

##### **Public Awareness and Intent to Donate**

5. The disconnect between support for donation and action results from the absence of a clear call to action, the absence of system mechanisms to support that call to action, the prevalence of barriers to accessing intent-to-donate information, and the many inconsistent practices within the current system.

*It is therefore recommended that an ongoing, sustainable and national public-awareness strategy be developed to increase the probability of donation. Such a strategy will focus on increased discussion with families, and will promote and improve action to support decisions to donate. It is also recommended that a robust national communications plan be developed to support the strategy, with a specific focus on promotion in the media.*

6. *It is recommended that the Canadian OTDT system be supported by intent-to-donate registries and that:*

- *existing provincial intent-to-donate registries continue to be supported and enhanced,*
- *Canadian Blood Services develop and host registries for provinces where none exist, and*
- *Canadian Blood Services work with provinces to drive a consistent call to action, a consistent mechanism through which people can register their intent to donate, and best practices for intent-to-donate registries, thereby enabling Canadians to optimize the call to action, and declare their wishes regarding donation.*

*Recommendations:*

**Leading Practice**

7. Countries with high donation rates have shown that the development, support and consistent implementation of leading practice guidelines have significant, positive impacts on system performance.

*It is recommended that OTDT leading practice guideline development continue to be the responsibility of Canadian Blood Services, and that these guidelines be appropriately communicated to the OTDT communities and supported with the tools and resources necessary to enable consistent implementation.*

*Recommendations:*

**Professional Education**

8. Although professional education on organ and tissue donation and transplantation does occur, there is no consistency in approach, leveraging of resources and evaluation of effort.

*It is recommended that Canadian Blood Services lead the establishment of a coordinated approach to professional education and awareness in medical, nursing and allied health programs to create a culture of donation and transplantation in the health care system.*

*Recommendations:*

**Patient Registries**

9. To enhance system-wide transparency, provide comprehensive standardized data, enable process and technology efficiencies, and leverage an existing shared investment, it is recommended that the scope of the patient registries that are currently being developed by Canadian Blood Services be expanded to provide a comprehensive, integrated inter-provincial service.

Figure 1-3. SCOPE OF ODT-SYSTEM PATIENT REGISTRIES



*Recommendation:***Data management and analytics**

**10.** A key factor that will improve the system's performance is the availability and analysis of accurate, timely and comprehensive data.

*It is recommended that Canadian Blood Services develop and implement an integrated data management and analytics service to support the needs of the Canadian organ and tissue donation and transplantation community.*

*Recommendation:***Research and innovation**

**11.** It is recognized that research and innovation is an essential component to optimize, advance and evolve an ODT system.

*As such, it is recommended that:*

- *Canadian Blood Services facilitate and partner with Canadian ODT research networks to leverage governments' investments,*
- *Canadian Blood Services partner with funding agencies to optimize resources and bring focus to key areas of ODT that require further research and innovation, and*
- *a research committee be created to deliver on these elements.*

*Recommendation:***Frontline financial resources**

**12.** It is conservatively estimated that implementation of the various elements of this strategy will result in breakthrough performance across Canada, as measured by a 50 per cent increase in the number of transplants over the next five years. To accommodate increased donation activity, frontline services will need more resources.

*It is recommended that governments ensure that financial resources are made available to organizations that provide ODT services—including OPOs, transplant programs, hospitals that support patients pre- and post-transplant (notably intensive care units and operating rooms), programs that support living donors, and ancillary functions (such as testing and medical diagnostics)—to support the increased activity generated as a result of increased donation and transplantation.*

## ODT TRANSFORMATION COSTS

### INVESTING IN BREAKTHROUGH PERFORMANCE

The objectives associated with the recommendations in this strategic plan are tied to new initiatives that, when implemented together over the next five years, will drive significant performance improvements in the number of donations and transplants. Table 1-3 shows the associated costs for the next ten years.

*Table 1-3. Incremental Cost of Transplantation and Patient Care (\$ Millions)*

Estimated incremental project and operating costs for implementing the recommendations, including the increase in volume-related system costs for donation and transplantation, which are over and above the estimated current state costs.

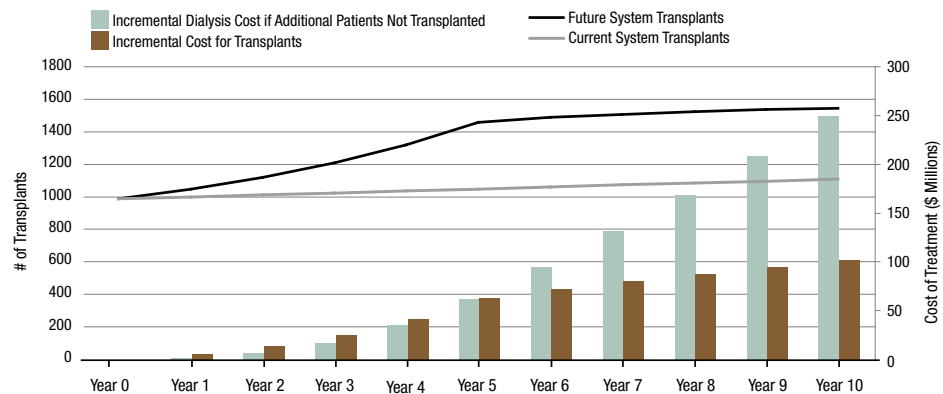
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
<b>Future System Costs</b>	\$ 507.5	\$ 564.4	\$ 624.0	\$ 698.7	\$ 790.8	\$ 847.0	\$ 901.8	\$ 958.7	\$ 1,015.7	\$ 1,072.8
<b>Current System Costs</b>	479.6	507.3	536.3	566.4	597.9	630.6	664.7	700.2	737.2	775.8
<b>Dialysis Cost Avoided in the Future System</b>	1.6	7.0	17.5	35.0	61.7	95.2	131.2	168.9	208.4	249.2
<b>Current System Costs (incl Dialysis)</b>	\$ 481.2	\$ 514.3	\$ 553.8	\$ 601.4	\$ 659.6	\$ 725.8	\$ 795.9	\$ 869.1	\$ 945.6	\$ 1,025.0
<b>Incremental System Costs</b>	\$ 26.3	\$ 50.1	\$ 70.2	\$ 97.3	\$ 131.2	\$ 121.2	\$ 105.9	\$ 89.6	\$ 70.1	\$ 47.8
<b>Incremental Transplants (All Organs)</b>	107	244	417	639	928	973	986	999	998	987

While the incremental costs are initially high during the first five years as the recommendations are being implemented, by Year 10 an incremental investment of \$47.8 million will result in almost 1,000 additional life-saving transplants annually. In addition to the increase in transplants, several other financial benefits will be realized, including:

→ **Dialysis cost avoidance.** As Figure 1-4 shows, increased costs in the future are significantly offset by the number of patients that are removed from dialysis as a result of increased kidney transplants. Kidney transplants generate significant cost avoidance to the system due to the lower cost of post-transplant care compared to dialysis, which is estimated at \$50,000 per year per patient.<sup>3</sup> With the expected 3,000 incremental kidney transplants in the proposed system, this means \$976 million of cost avoidance over a 10 year period. It also means that incremental costs to the system will level off and start dropping after five years.

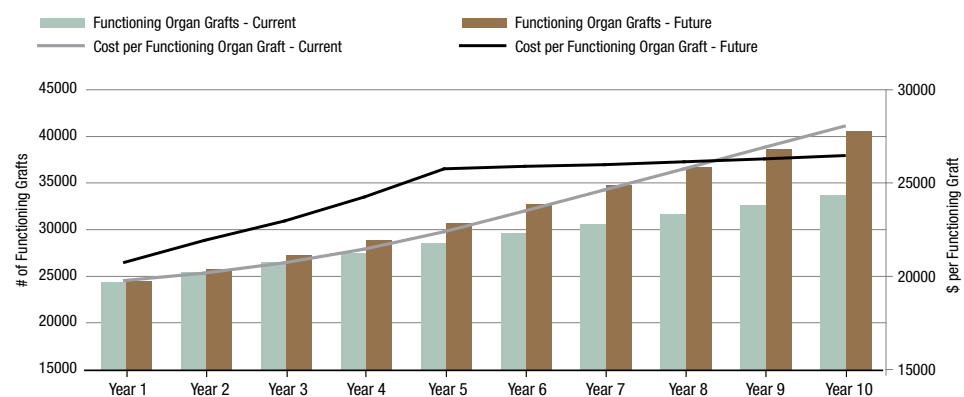
<sup>3</sup> The estimated benefit increases with inflation annually, so that by Year 10 the benefit would equal approximately \$83,000 per functioning kidney graft.

Figure 1-4. Benefit of Kidney Transplant vs. Dialysis



→ **System productivity improves** (Figure 1-5). It is estimated that the proposed investments in the system will stabilize the cost per functioning organ graft after five years, as the number of functioning organ grafts begins to increase at a faster rate, and the cost-benefit attributed to functioning kidney grafts helps to offset the cost of transplants and post-transplant care for all other organ types. As a result, approximately 7,000 additional Canadians will be living with a functioning organ graft, and at a lower cost per functioning organ graft than would be incurred in the current system.

Figure 1-5. System Productivity: Cost per Functioning Organ Graft



Numerous cost benefits stem from the proposed ODT system investments, achieved in tandem with performance improvements. The value of these investments is difficult to dispute given the immense benefits these additional transplants will mean to patients, families and society.

## FACTS ON ORGAN AND TISSUE DONATION AND TRANSPLANTATION IN CANADA

*As the Canadian population ages in the next two decades, and diseases like diabetes (which can lead to kidney disease), heart disease and Hepatitis C become more prevalent, transplant demand is projected to increase by more than 150 per cent.<sup>4</sup>*

*There are more than 2,000 Canadians on cornea-transplant wait lists that average seven months to three years in length depending on jurisdiction.*

*Due to tissue shortages, suboptimal alternatives must be used in half of all paediatric heart valve surgeries.*

*Current provincial median wait-times for patients who receive kidney transplants: 20-56 months*

*As of March 31, 2011, the Living Donor Paired Exchange registry had helped facilitate transplants for 69 patients who would not otherwise have received a kidney.*

*A single tissue donor may provide as many as 100 individual allografts that could be transplanted into patients.*

*An increase in the availability of organs for transplant in Canada will help reduce transplant tourism by reassuring Canadian patients that they can receive timely treatment and optimum care at home.*

*All demineralized bone matrix, the most commonly used tissue product, must currently be imported from the United States.*

<sup>4</sup> Baxter D and J Smerdon, Donation Matters: Demographics and Organ Transplants in Canada, 2000 to 2040, June 2000 (<http://www.urbanfutures.com/UF1%20Reports/Report%2046%20-%20Donation%20Matters%20-%20Demographics%20and%20Organ%20Transplants.pdf>)

## ORGAN DONATION AND TRANSPLANTATION

There were 3,796 patients on waitlists for organ transplants across Canada as of December 31, 2009.<sup>5</sup> In the 12 previous months, 249 people on those wait lists died before receiving transplants. In some cases, patients who could benefit from transplant are not on wait lists. For example, of the more than 22,000 patients receiving dialysis for end-stage renal disease, fewer than 13 per cent make it to the kidney transplant wait list.<sup>6</sup>

# <50%

Canada's deceased donation rate is less than half that of the best performing countries, and has remained relatively flat over the last decade.

A kidney transplant saves as much as

# \$50,000

each year in dialysis costs alone.

# 1,003

total organ donors in Canada (2009)

There were 2,035 solid-organ transplants in Canada in 2009:

-  1,224 kidneys
-  452 livers
-  170 hearts
-  189 lungs

## TISSUE DONATION AND TRANSPLANTATION

Patients in provinces and territories across Canada (excluding Quebec) were served by more than 20 tissue banks in 2008. These banks operate independently for the most part, and benefit from no formal networking that could make products that are abundant in one region available quickly in others that face shortages.

**BY THE NUMBERS** Data from a 2007 American Association of Tissue Banks (AATB) survey showed that 32 U.S. tissue facilities processed 49,207 deceased donors (an average of 1,538 donors per bank) with an average allograft production of 49 grafts per donor. In the same survey, the seven AATB-accredited Canadian tissue banks reported having processed 400 deceased donors (average of 57 donors per bank) with an average 21 grafts per donor.<sup>7</sup>

# 40,000

the approximate number of surgical and dental tissue allografts transplanted annually in Canada.

The current system does not ensure an emergency supply of skin

<sup>5</sup> 2009 CORR Data.

<sup>6</sup> 2009 CORR Data.

<sup>7</sup> Robert Rigney, Report on the 2007 Annual Survey, AATB Spring Meeting, March 29, 2009.

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# EXECUTIVE SUMMARY: TISSUE DONATION AND TRANSPLANTATION (TDT)

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*Canadians need and expect to benefit from exciting advances in TDT technology and technique—advances that are igniting new approaches to tissue recovery, processing, storage and distribution, and new ways to use tissue to improve lives. The TDT community, however, believes that nothing short of transformational change is needed to help realize the full potential of TDT.*

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## **THE CHALLENGE:**

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### **A CURRENT SYSTEM THAT FAILS TO MEET THE NEEDS OF CANADIANS**

Canadian Blood Services worked closely with the Tissue Expert Committee and members of the TDT community to understand the related challenges currently faced in Canada. This unprecedented engagement, supported by extensive research, revealed specific issues that underscore the need for change.

At the same time, there are significant achievements that challenge the community to build on the efforts of others to improve patient outcomes. The Canadian Standards Association established voluntary general requirements for cell, tissue and organ (CTO) use in 2003. Health Canada has also made important contributions, including the introduction of new CTO regulations in December 2007. In 2008, the Public Health Agency of Canada began development of a surveillance system for tissue. Additionally, performance improvements continue to accrue from ongoing TDT program refinements in many locations across Canada.



### Obstacles and opportunities

The evidence remains compelling, however, that critical TDT challenges that must be addressed if patients are to be better served. Specifically, those challenges are to:

- Enhance the quality of tissue product in Canada,
- Strengthen Canadian tissue supply practices to ensure security of supply,
- Ensure greater efficiency in tissue recovery, processing and distribution, and
- Strengthen measurement and accountability mechanisms to deliver consistent, Canada-wide performance improvements.

#### *Challenge:*

#### **Enhance the quality of tissue product in Canada.**

A lack of coordination among Canadian tissue and eye banks results in production of tissue allografts with different quality profiles and different tissue specifications. These banks interpret regulations and standards differently and, as a result, do not all implement safety and quality improvements in the same manner. In some cases budget restraints may hinder the ability to achieve consistent quality. The voluntary nature of accreditation has also been cited as a reason why not all tissue or eye bank standards have been implemented consistently across the country.

Enhancing quality means improving traceability, as a seamless record of the distribution and usage of every tissue allograft is critical to safety. While tissue and eye banks have developed systems to manage traceability as long as tissue allografts are in their control, concerns have been raised about the completeness of traceability within hospitals. Effective mechanisms have not been put into place to ensure donor and recipient information is shared between organ and tissue transplant programs when safety issues related to a donor of both organs and tissues are identified.

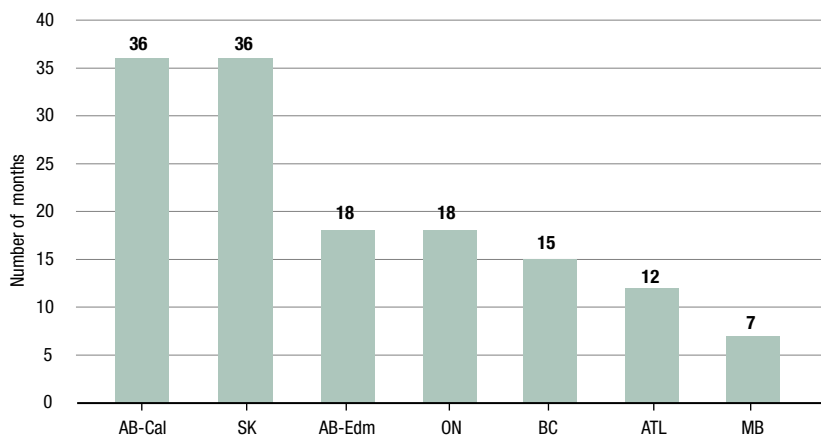
Thousands of tissue allografts are transplanted every year in Canada. Currently there is no coordinated approach to assessing the outcomes of these tissue transplants from the perspective of either effectiveness or safety. There is also no system to collect data from hospitals or clinics related to tissue transplant usage or outcomes.

The challenge to enhance tissue quality in Canada relates in part to the reliance on imports. Canada currently imports 80 per cent of its tissue product from the United States, yet there is no coordinated approach to procurement or distribution of these tissues, or to the use of supplier quality audits as part of a comprehensive quality management program.

*Challenge:***Strengthen Canadian tissue supply practices to ensure security of supply.**

Canada's tissue supply—for both domestic and imported product—is neither integrated nor coordinated. There are no processes to share inter-provincial inventory information or enable distribution across provincial borders. This shortcoming leads to provincial variation in the production of, and access to, tissue allografts. One result is that thousands of Canadians are on cornea transplantation waitlists that average seven months to three years in length depending on location (see Figure 1-6).

**Figure 1-6. Cornea Transplant Wait Times by Region**



Source: Demand for Ocular Tissue in Canada—Final Report, January 2010

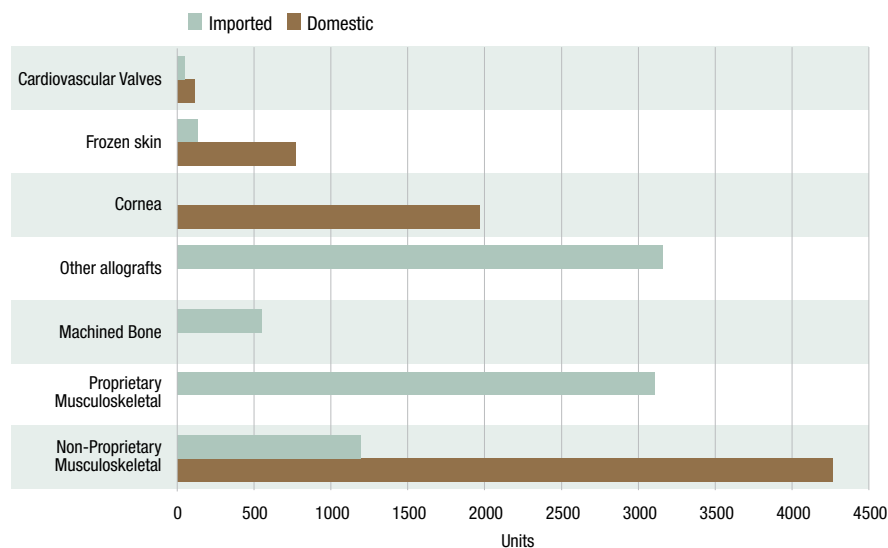
Tissue production in Canada is limited by the number of donors, the capacity to recover tissue, and the focus on meeting only local needs. As a result, end-users across Canada cannot consistently rely on their tissue banks to have the type, quantity and quality of tissue product they need. Canadian tissue banks also lack the ability to produce specialized tissue products, which must be imported from the United States.

In fact, as noted earlier, Canada imports approximately 80 per cent of its tissue product—a dependency that could pose risks to Canadian patients (see Figure 1-7). Tissue use in the United States, for example, is projected to continue increasing,<sup>8</sup> and demand could exceed supply. Such supply and demand fluctuations could limit the availability of tissue products in Canada.

<sup>8</sup> BCC Research (2008) Market Research Report – Organ and Tissue Transplantation and Alternatives, BCC Research, [www.bccresearch.com](http://www.bccresearch.com).

**Figure 1-7. Canadian Surgical Market for Tissue Allografts (2008)**

For some tissue types Canada relies on 100% importation of product.



Sources: 2010 Supply of Human Allograft Tissue in Canada; Canadian Imported Surgical and Dental Allograft, Allograft Substitute, and ADM Study 2010; Utilization and Cost of Procurement of Skin, Cardiac and Vascular Allograft Products—Final Report 2010

**Challenge:****Improve coordination among Canadian tissue banks to ensure greater efficiency in tissue recovery, processing and distribution.**

Most imported tissue purchases are made by individual medical and dental surgeons, hospitals and tissue banks. These independent and uncoordinated purchasing practices lack the buying power that could be expected from an integrated national contract system, and likely result in unnecessarily high tissue costs.

Since most tissue can be stored for extended periods and shipped safely thousands of miles, tissue banks in the United States operate according to a biological-manufacturing model. They are centralized, deal with large product volumes and are able to optimize costly investments in facilities, staff and equipment. In Canada, most tissue banks are run according to a hospital service-delivery model and deal with comparatively smaller volumes of product. The absence of a manufacturing culture makes it difficult to achieve process efficiencies.

As with organs, Canada is falling short of its potential for tissue donation. Although supply could be met for basic tissue products from Canadian donors, barriers remain. Families sometimes decline consent for donation because they are unaware of the potential donor's wishes. Families are also not always given opportunities to donate, as donation discussions in hospitals are conducted at the discretion of treating physicians in hospitals, rather than as a standard of care. In fact, a lack of specialized training means health care professionals do not always recognize potential donors.

Tissue banks also miss some opportunities for donation due to a lack of coordination with organ procurement organizations, medical examiners and coroners. Other banks simply do not have the budgets to expand or support their programs, while some hospitals do not have the capacity to recover and process tissue, even if families consent to donation.

*Challenge:*

**Strengthen measurement and accountability mechanisms to deliver consistent, Canada-wide performance improvements.**

Although many Canadian tissue banks and programs collect and analyze their own data, consolidated inter-provincial data are virtually non-existent, and there are no requirements for tissue banks to share information related to system performance. The lack of comprehensive, timely and accurate national data limits the ability to understand various aspects of performance. The lack of data also makes it difficult to identify evidence-based, system-wide improvement opportunities, including those in accountability.

In fact, there is no supply-chain accountability to improve performance by delivering on agreed outcomes and targets. Individual tissue organizations do not coordinate efforts or performance targets with others. Failure to implement leading practices is without consequences, and performance improvement incentives and requirements do not exist.

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**THE OPPORTUNITY:**


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**BREAKTHROUGH PERFORMANCE FOR IMPROVED PATIENT OUTCOMES**

Based on the challenges identified in the current TDT environment, the Tissue Expert Committee set out a clear and succinct vision for the future of TDT—*By 2017, the TDT community expects to have built a responsive and efficient Canadian system that assures a secure supply of quality tissue.*

The strategy to realize this vision requires Canadian Blood Services and the TDT community to focus on four system priorities:

- **Ensure the quality of tissue product.** The new system must strive at all times to ensure the safety and quality of the products it provides to patients. Effective quality management practices must be applied in Canadian tissue programs, and among suppliers of imported tissue. Enhanced surveillance and complete traceability are needed to quickly and accurately identify affected tissue in the event of a safety issue. Ensuring quality also means providing tissue product to standard specifications, so clinicians can trust the tissues produced in one part of the country to meet the same exacting standards as those produced in other parts of the country.
- **Ensure patients have timely and fair access to tissue products.** Unlike today, the new TDT system should be able to meet patient demand for tissues with no shortages and no waiting lists. To do this, the system must optimize donation in acute care and non-acute care settings; for example, by working with health care professionals, medical examiners and coroners to increase the number of tissue donors identified and referred. The system must also optimize recovery, processing and inventory to align supply with demand. This includes managing imports effectively and efficiently to ensure that the products patients need are imported in the right quantity at the best possible price.
- **Making TDT an efficient part of the health care system.** Ultimately, the TDT system must operate as an efficient part of the broader health care system and ensure high-quality products for the public while providing governments with value for their investments. This efficiency can be achieved in part by supporting and adopting the biomedical and technical innovations that drive change in TDT. This means partnering with industry and researchers—in Canada and around the world—to leverage innovations in product and practice. The system must also partner with clinicians to understand demand for tissue products. These partnerships will allow clear, inclusive and timely decision making to ensure the system responds swiftly when required.
- **Strengthen the system's infrastructure and capabilities.** This priority involves developing a base of trained tissue-banking professionals aligned with system goals, an information-technology network, robust tissue processing capacity, and a sustainable funding model. Strengthening system infrastructure will build the foundation for other components of the strategy.

**Measuring performance against objectives**

A systematic, evidence-based approach is vital to conduct ongoing performance analyses. Progress will be indicated by a variety of key measures including: timely and accurate reporting on tissue usage and patient outcomes, including adverse reactions; doubling the total number of allografts that are produced, and that meet the system's quality requirements; and doubling the number of tissue donors, and the number of grafts per donor.

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**THE SOLUTION:**

# **RECOMMENDATIONS FOR AN INTEGRATED INTER-PROVINCIAL TDT SYSTEM**

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*The following recommendations identify the activities, mechanisms, roles and responsibilities that are needed to operate and manage the proposed tissue donation and transplantation system.*

The intent is to build on existing expertise and capabilities throughout the country while leveraging Canadian Blood Services' successful experience transforming and managing inter-provincial blood, plasma-protein product and stem-cell services. With combined expertise, TDT in Canada can be transformed into a single, integrated system that ensures Canadian patients have equitable and timely access to tissues.

The system is based on a collaboratively developed, integrated supply plan (see Figure 1-8) that addresses the tissue needs of all patients across the country.

To drive efficiencies and improve quality and quantity, it is proposed that the number of Canadian programs that process tissue be reduced to three or four tissue processors and two or three ocular processors. These processors would be selected through a transparent selection process. For one of the tissue banks and two of the eye banks, new facilities will be built to accommodate the increased volume and range of tissues from an increased number of tissue donors, and to enable production of specialized tissue products.

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#### **VITAL CONTRIBUTORS**

*Although Canadian Blood Services will be prominent in the management of a new TDT system, organizations such as Health Canada, the Public Health Agency of Canada, the Canadian Standards Association and Accreditation Canada will continue to play essential roles in developing regulations and standards, and conducting audits and inspections.*

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Tissue or eye banks that are not selected to become ocular or tissue processors will remain important to the system as tissue recovery programs responsible for supporting the increase in tissue donation and optimizing each donor's gift. Canadian Blood Services will also establish two recovery teams and work in partnership with coroners, medical examiners and health care professionals to further increase recovery.

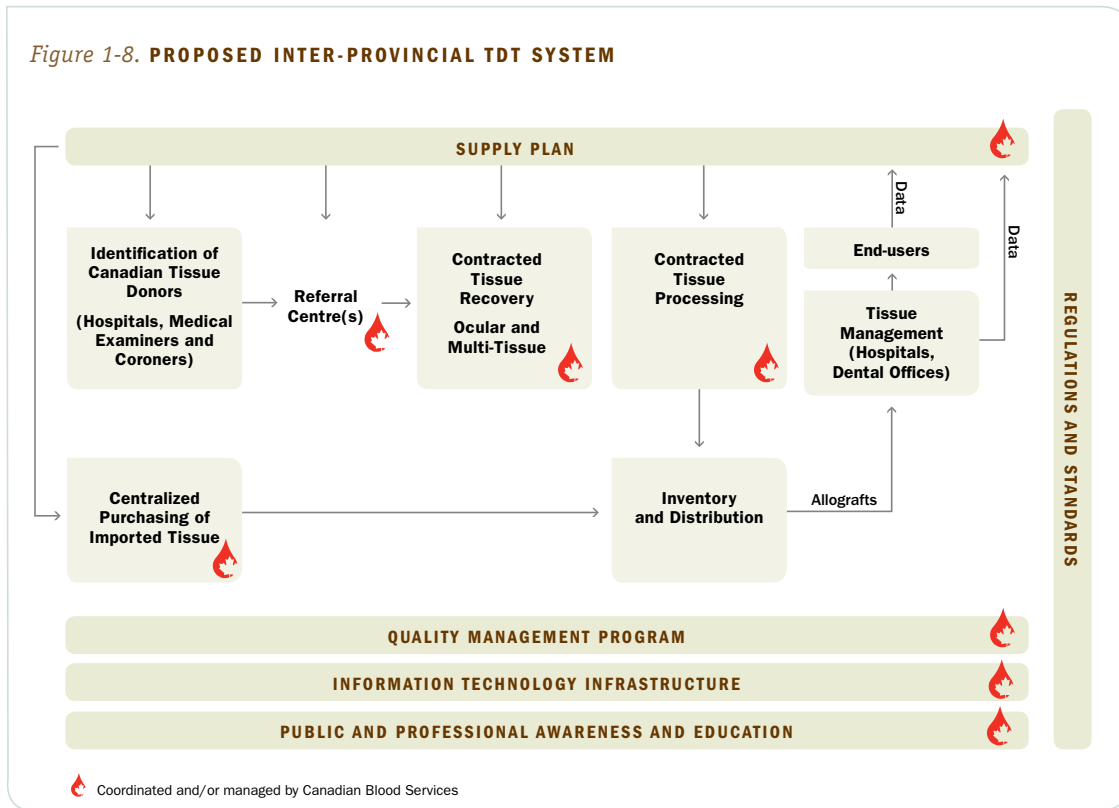
The importation of some tissue products will be centralized and managed by Canadian Blood Services to ensure not only better pricing, but also that quality specifications are met through a supplier qualification program.

Finally, Canadian Blood Services will develop a single inventory and distribution network supported by a common IT platform.

Through this network, hospitals will order the majority of their tissue products from one source, and will be required to follow standard tissue management practices to ensure the traceability of products and to report on tissue usage and outcomes.

Please see Appendix C of *Call to Action* for more information on proposed TDT-system roles and responsibilities.

Figure 1-8. PROPOSED INTER-PROVINCIAL TDT SYSTEM



**Recommendations:**

**Accountability**

1. Achieving a secure supply of high-quality tissues that provides equitable and timely access for Canadian patients requires an integrated approach to planning that aligns tissue recovery and processing with anticipated demand.

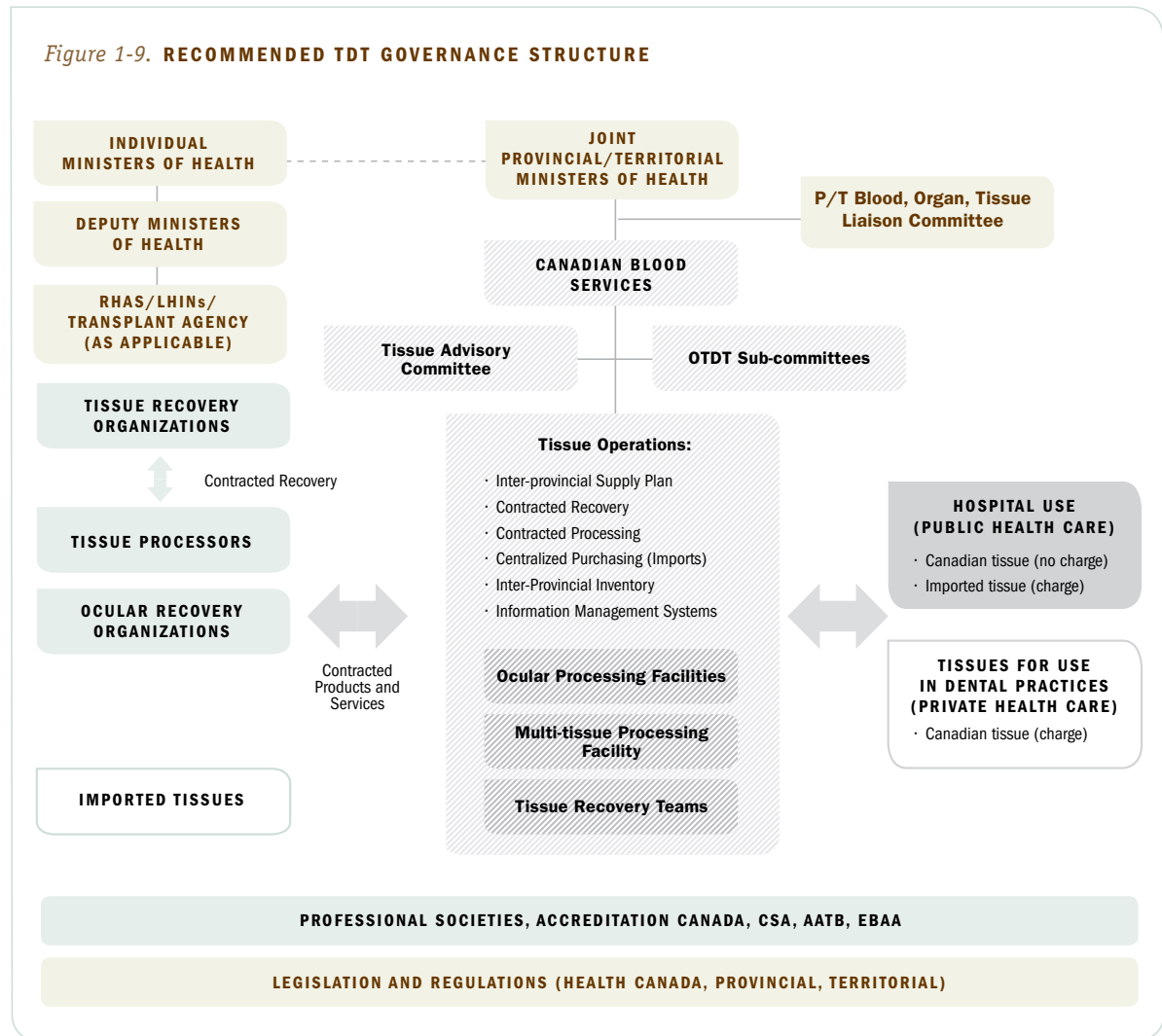
*It is recommended that the many independent and un-coordinated tissue banks that operate in the current environment transition to a system that optimizes tissue donation and recovery, consolidates tissue processing, maintains a single shared inter-provincial inventory, and is managed by one organization.*

2. Planning and managing the supply of tissue allografts as a single inter-provincial tissue system requires that a single organization manage and coordinate donation, recovery, processing and distribution activities for eye and multi-tissue.

*It is recommended that Canadian Blood Services be given the mandate and funding to assume the responsibility for managing the inter-provincial tissue system, and that provincial and territorial governments establish a formal accountability framework that outlines the structure, essential attributes of, and roles and responsibilities within an inter-provincial TDT system, thereby enabling it, as a whole, to achieve and be evaluated against stated goals.*



Figure 1-9. RECOMMENDED TDT GOVERNANCE STRUCTURE



*Recommendations:*

**QUALITY AND SAFETY**

3. A quality management program should include a set of coordinated activities to direct and control the inter-provincial tissue system and introduce a standard biological-manufacturing approach to quality.

*It is recommended that Canadian Blood Services develop and lead the implementation of a standardized quality-management program to ensure that surgeons and patients have confidence in the system’s ability to deliver tissue allografts that consistently meet their needs and expectations.*

4. Ensuring the appropriate management of tissue by hospitals and clinics—including traceability of each tissue allograft to the recipient and reporting adverse reactions—is essential to patient safety.

*It is recommended that with the implementation of a single inter-provincial tissue inventory, Canadian Blood Services partner with hospitals and clinics to establish agreements that define roles and accountabilities for hospital tissue management as well as utilization and outcomes reporting.*

#### Recommendations:

### EFFICIENT AND SECURE SUPPLY

5. The number of potential tissue donors in acute care settings, and outside of hospitals, far exceeds the number needed to meet patient demand for the types of allografts currently produced in Canada.

*It is recommended that Canadian Blood Services collaborate with medical examiners, coroners, allied health professionals, hospital donation physicians and OPO staff to develop more effective mechanisms to identify and refer potential tissue donors.*

6. Improving the rate of tissue-donor identification and referral will demand that the Canadian tissue system expand its tissue recovery capacity.

*It is recommended that Canadian Blood Services develop tissue recovery capacity by establishing its own recovery program in parts of the country where significant increased donor referral is achievable and where current recovery capacity is limited. It is also recommended that existing tissue-recovery programs maintain operations under contract to Canadian tissue processors, provided they are able to meet quality and performance requirements.*

7. Consolidating existing Canadian tissue processing activities into a smaller number of higher volume processing facilities would make the system more efficient and better able to meet the needs of Canadian patients.

*It is recommended that Canadian Blood Services conduct the selection and consolidation process for multi-tissue and ocular programs, and that the multi-tissue and new ocular facilities be operated under Canadian Blood Services management.*

8. There is currently an insufficient supply of corneas to meet the demand across the country.

*It is recommended that Canadian Blood Services coordinate the importation of corneas from the United States for three to four years to provide an immediate increase in the inter-provincial supply available for transplantation. The increased supply will reduce the number of patients currently waiting for a cornea transplant and decrease wait times for these procedures.*

9. To ensure all patients have equitable and timely access to tissues, the supply of tissue allografts must be managed as an inter-provincial resource, using a single inventory system where production is aligned with demand and supply is allocated as required.

*It is recommended that Canadian Blood Services be the organization to forecast demand, align supply and demand, and manage inventory and distribution.*

10. Imported tissue is currently purchased by individual hospitals and clinics directly from manufacturers or distributors.

*It is recommended that Canadian Blood Services implement a supplier qualification program for imported tissue vendors, and that a centralized bulk purchasing approach be used to achieve cost efficiencies and improve product tracking.*

*Recommendations:***RESPONSIVE AND FORWARD-LOOKING SYSTEM**

**11.** Approximately 80 per cent of the tissue products required for use in Canada is imported from the United States, where focused research and innovation has generated new forms of specialized tissue for use in surgical procedures.

*To reduce dependence on imported tissue products, it is recommended that Canadian Blood Services establish the facilities and capacity to produce some specialized products in Canada.*

**12.** To ensure the Canadian tissue system remains relevant to the needs of the broader health care system, tissue research activity should be coordinated to focus on priorities in areas such as product development, technological innovation, tissue donation and tissue transplant outcomes.

*It is recommended that Canadian Blood Services create linkages between tissue operations and networks of researchers with tissue-related interests, and coordinate the required tissue research by providing access to grants, directly or through collaborations with other funding agencies.*

*Recommendations:***INFRASTRUCTURE AND CAPABILITIES**

**13.** Information and data management is essential to operating in a controlled biological-manufacturing environment.

*It is recommended that Canadian Blood Services leverage its expertise and infrastructure to establish information technology systems that will support an efficient, data-driven tissue system, thereby optimizing system performance.*

## TDT TRANSFORMATION COSTS

### Investing in breakthrough performance

The objectives associated with the recommendations in this strategic plan are inexorably tied to new, shared investments that enable all provinces and territories to achieve together what no jurisdiction could do on its own.

The costs of tissue transplantation—the costs of the tissues and the surgery—are projected to rise regardless of whether or not new investments are made. Market research<sup>9</sup> indicates that the number of surgical procedures involving allografts will continue to increase at an average annual growth rate of 6.8 per cent through 2014.

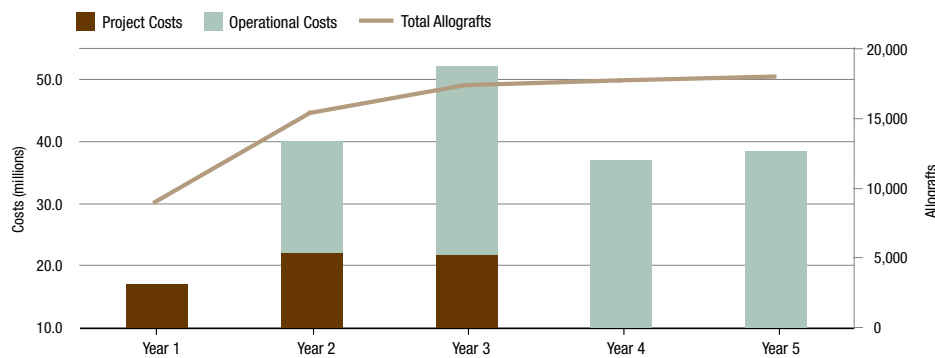
Table 1-4. Annual Estimate of Project and Operating Costs

	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Annual Estimate of Project and Operating Costs</b>					
Project Costs (\$ Millions)	\$ 17.5	\$ 22.8	\$ 22.7	\$ 1.3	\$ -
Operating Costs (\$ Millions)	\$ -	\$ 18.0	\$ 30.4	\$ 35.8	\$ 38.4
<b>Annual Estimate of Project and Operating Costs</b>					
<b>Total (\$ Millions)</b>	<b>\$ 17.5</b>	<b>\$ 40.8</b>	<b>\$ 53.1</b>	<b>\$ 37.1</b>	<b>\$ 38.4</b>

With the present TDT system unable to meet either current or rising future demand, the choices going forward are to import more tissue products or build capacity to produce a secure supply of high-quality tissue products, and more of them, here in Canada. The second option is by far the most strategically sound, since relying solely on importation to meet Canada’s tissue needs poses a higher security-of-supply risk.

Figure 1-10. Domestic Allograft Targets

With initial investments over the first three years targeting infrastructure development to sustain growth, the number of allografts is expected to increase from just over 8,700 to more than 17,700.



<sup>9</sup> Canadian Imported Surgical & Dental Allograft, Allograft Substitute, & Acellular Dermal Matrix Study 2010. Canadian Blood Services.

The target for the new TDT system is to double the volume of tissue production and deliver higher quality products (Figure 1-10). This production increase aims in part to meet tissue demand currently being fulfilled with allograft alternatives such as those for paediatric heart-valve replacement surgeries. While not the preferred clinical option, the alternatives—most of which must be imported—must be used when allograft tissue is unavailable. An increase in the supply of domestically produced tissues will reduce these imports, as well as the number of imported tissues that would otherwise be required to meet the expected increases in demand.

The benefits of an increased supply of allografts is perhaps best demonstrated with regard to cornea, where the shared investment in TDT will increase the number of Canadian donors and the supply so that approximately 1,100 additional cornea transplants—an increase of 50 per cent—can take place every year by Year 5.

The benefits of corneal transplants, while largely unmeasurable, are no less remarkable for their potential economic impact. People with vision loss experience three times as much clinical depression, a greater number of medication errors, twice the risk of falls and premature death and four times the risk of serious hip fractures.<sup>10</sup> The employment rate of working-age adults with significant vision loss is only 32 per cent. Restoring these people's vision restores them to productive lives and reduces the chance that they may further burden the health system.

Additional cost benefits in the transformed TDT system include:

- The availability of pre-processed ground and chipped bone products will reduce operating room time, as many surgeons currently extend procedures by preparing their own ground bone within the operating room.
- Sports medicine procedures that use allografts require less surgical time than autograft procedures that require a secondary surgical site.
- The availability of pre-cut corneas will eliminate the preparation step for split-thickness grafts and reduce ophthalmologists' surgical time.

Please see the full implementation and costing chapter in *Call to Action* for detailed analyses of costs related to the new TDT system.

<sup>10</sup> *The Cost of Vision Loss in Canada*. CNIB and the Canadian Ophthalmological Society, 2009.



**SUPPORTING THE FRONTLINE** *The tissue-bank team at Queen Elizabeth II Health Sciences Centre in Halifax. Left to right: **Christian Collins, Shawn Moulton, Nachia Greene, Douglas Jones, Claudia Baldaso and Max Maier.***

*If TDT-system transformation is to occur in Canada—if broad and sustainable improvements are to be achieved—the skills and experience of professionals such as these are essential. On the frontline of TDT care, they have helped shape this strategic plan, which strives to recognize their central role in hospitals and other health care settings.*

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## CONCLUSION:

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### BENEFITS FOR CANADIANS

In *Call to Action*, Canadian Blood Services, the organ and tissue donation and transplantation committees and communities have set out clear, timely, practical and achievable solutions to overcome current OTDT challenges and deliver significant performance improvements for Canadians.

The benefits of implementing this strategic plan are compelling.

A single, integrated inter-provincial ODT system will increase trust among the public and health care professionals, ensure Canadians benefit from more equitable access to the system, increase the number of organ and tissue donors and help make donation a standard part of end-of-life care.

An integrated, inter-provincial TDT system will more than double the number of donors; improve the consistency, quality and safety of allografts for all patients; be an efficient component of the broader health care system; and create a more equitable system that gives all Canadians access to domestically produced allografts and imported tissue products.

### From promise to practice

In three short years, Canadian Blood Services—in close collaboration with the OTDT communities—has helped advance organ and tissue donation and transplantation through leading practice development, broad stakeholder engagement and the launch of the living donor paired exchange registry. Yet these advances mark only the beginning of breakthrough performance. Implementing the recommendations in *Call to Action* will fundamentally transform OTDT in Canada, delivering more transplants and improved health outcomes for Canadians.



**SANDI MACPHERSON AND LEILA COWLE** Sandi was diagnosed with Idiopathic Pulmonary Fibrosis (IPF) in June 2008. IPF progressively scarred her lungs and impeded the transfer of oxygen to her circulatory system. When her left lung collapsed in August, she was transported by ambulance from her home in Ottawa to hospital in Toronto.

So began a 27-month wait for a transplant—a wait made more agonizing because Sandi and her husband were forced to leave their two teenage boys with family in Ottawa. After living separately for a year, the family was able to re-unite in a rented home in Whitby, Ontario. But more than another year would pass before Sandi was successfully matched with a donor.

Sandi gives credit to many for her recovery—family, friends and medical teams—but perhaps no one more than Leila Cowle.

Another double lung-transplant patient, Leila had been forced out of work and onto 24-hour supplemental oxygen from the day

she was diagnosed with Lymphangioliomyomatosis (LAM) in 2006. A rare lung disease that affects women, LAM plagues its victims with shortness of breath, fatigue, coughs and chest pain.

Leila and Sandi met, became friends and supported each other during treatment. After her transplant in August 2010, Leila counted on her friend's strength and encouragement while helping Sandi prepare for her double-lung procedure, the call for which finally came in November 2010.

Both women are recovering well. Sandi looks forward to returning home to Ottawa in June 2011—almost three years after her journey began. Leila finds it hard to believe how her life has turned around.

"My life before transplant was full of limitations," says Leila. "Now it's full of possibility."



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# COMMITTED TO BREAKTHROUGH PERFORMANCE

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Leila Cowle and Sandi MacPherson’s experiences demonstrate that organ and tissue donation and transplantation (OTDT) is a human story. It is a story that transcends our differences and reminds us what Canadians have in common.

OTDT is a story of potential. The potential to save and transform lives. Our potential as individual Canadians to pass on the gift of life and healing to those we love and those we will never know.

The immense promise of OTDT does not lie in some distant future. It does not hinge, like new drugs, on five or ten years more research and testing. It is not theoretical. The promise of OTDT is within reach. OTDT medicine is among the most advanced in the world. Where and when it is practiced in Canada, it is done skillfully and compassionately. Efforts by some provinces to increase donation rates and refine transplantation services have delivered some improvements; however, sustained performance increases have not been achieved, and no province is performing at world-leading levels.

Canada is at a crossroads, a convergence of key opportunities that, if seized, can lead to breakthrough performance in organ and tissue donation and transplantation—performance that will secure the greater health of Canadians.

## SPEAKING WITH ONE VOICE

*Call to Action* has been prepared by Canadian Blood Services in close collaboration with a long list of OTDT experts, health care organizations, patients, donors and concerned members of the public. During the planning process, the authors came to identify the range of stakeholders as members of either the organ donation and transplantation (ODT) community or the tissue donation and transplantation (TDT) community. In expressing the aspirations and expectations of these communities, *Call to Action* works to faithfully articulate their common needs, insights and ambitions. The ‘we’ that readers will encounter throughout the plan refers not to Canadian Blood Services, but to all Canadians committed to seizing the potential of OTDT.

→ **Ms. Maria Stranaghan**, whose child donated both organs and tissues, was one of many who participated in regional public dialogues to help shape the future of OTDT.



## BACKGROUND AND ACCOMPLISHMENTS

As the 1990s came to a close, health care experts, advocates and authorities realized there were profound shortfalls in the delivery of OTDT services in Canada:

- There was no national system, and little integration of provincial and territorial systems.
- The systems that did exist were overly complex and difficult for Canadians to understand and navigate.
- Many patients had to be moved to the United States to receive appropriate treatment.
- OTDT lacked the transparency expected of modern medicine.

The governments of the day agreed that improvements were needed. The House of Commons Standing Committee on Health held extensive hearings on OTDT, and presented a report called *Organ and Tissue Transplantation: A Canadian Approach*. The report emphasized the need for a national perspective and called for a central body to lead and take action. In fact, this was one of many reports and initiatives that attempted to reform OTDT in Canada. These attempts have led to some localized improvements in the years since, but sustained increases in nation-wide performance have not been achieved.

In response to the standing committee report, however, governments created the Canadian Council for Donation and Transplantation (CCDT). As an advisory body reporting directly to the Conference of Deputy Ministers of Health, the CCDT was tasked with studying OTDT and proposing ways to improve related care in Canada.

### Ready to collaborate

By the time the CCDT’s mandate expired in March 2008, the organization had made substantial contributions. It worked closely with the OTDT communities to develop a series of scientifically peer-reviewed leading practices. The CCDT compiled comprehensive data on OTDT in Canada and conducted rigorous and far-reaching research that revealed a field of medicine full of potential on one hand and missed opportunity on the other. At the same time, the OTDT communities were pursuing significant efforts at the provincial and regional levels, and there were pockets of excellence across Canada. In the pursuit of excellence, the range of OTDT stakeholders—professionals, advocates and governments among them—made it clear they were ready to work together to improve donation and transplantation services.

To capitalize on this spirit of collaboration and build on the achievements of both the CCDT and the OTDT communities, the deputy ministers of health approached Canadian Blood Services. The potential transformation of OTDT was comparable to that of the blood system in and after 1998. Canadian Blood Services had assumed responsibility and quickly rejuvenated and expanded the system. The organization was well organized, had demonstrated the capacity to manage change and growth at the inter-provincial level, and had delivered significant improvements. Canadian Blood Services had a well-established relationship with the provinces and the territories, and was already reporting to provincial and territorial ministers of health. What's more, the organization had achieved the scientific rigour, transparency and public awareness that would be vital to an organ and tissue donation and transplantation system. Tellingly, Canadian Blood Services had succeeded in gaining the trust of Canadians.

### **New mandate. New promise.**

On April 1, 2008, Canadian Blood Services took on a new mandate that included assuming the activities of the CCDT and setting up registries for the Living Donor Paired Exchange (LDPE) and for urgent-status and highly sensitized patients (see sidebar).

Just nine months later, in January 2009, Canadian Blood Services launched a pilot LDPE project in cooperation with three provinces. With the addition of Quebec in October 2010, all Canadian provinces and territories had signed on to the program. Two other registries—the National Organ Waitlist (NOW) and Highly Sensitized Patient (HSP) registry—are in development and expected to launch in 2011 with the participation of all provinces and territories.

These registries mark significant steps in waitlist management and important technological solutions for improved frontline service delivery. In line with leading-practice development, the registries also fostered greater inter-provincial cooperation—a hallmark of OTDT developments to date, and vital to broader and sustained OTDT improvements.

### **NEW REGISTRIES FOR ALL CANADIANS**

Carrying through on work that began with the Canadian Council for Donation and Transplantation, Canadian Blood Services was mandated to launch three patient registries: the Living Donor Paired Exchange (LDPE) registry, the Highly Sensitized Patient (HSP) registry, and the National Organ Waitlist (NOW).

The LDPE facilitates living kidney donation between those with a willing but incompatible donor and another pair in the same situation. It was launched in January of 2009 with the first surgeries taking place in June 2009. All provinces participate in the LDPE registry.

The HSP is a kidney registry for patients who are more difficult to match because they have increased antibodies, commonly because of blood transfusions, previous transplants and pregnancies.

NOW lists the most urgent-status patients and will replace the existing fax-based urgent status waitlist maintained by the London Health Sciences Centre. The registry will support non-renal patients and deliver the benefits of a real-time, web-based system.

NOW and the HSP will both launch later in 2011—each with the participation of all provinces and territories.

### A strategic plan for OTDT

The patient registries were only part of the solution. Canadian Blood Services' new mandate came with a greater responsibility. The deputy ministers directed the organization to work with the OTDT community to develop a plan for an integrated organ and tissue donation and transplantation system. In this case, *integration* means fostering connections among, and building on the strengths of, individual provincial and territorial systems while avoiding duplication of services. The goal: transformation of a vital part of Canada's health care system—transformation that improves OTDT performance, efficiency and clinical patient outcomes, and increases the quality of life for patients across Canada.

*Call to Action* details this three-year strategic planning journey and presents the OTDT community's recommendations for an integrated, inter-provincial system.

### ACCOUNTABLE TO CANADIANS

Canadian Blood Services is funded by the provincial and territorial governments except Quebec. Quebec has operated its own blood system through Héma-Québec for more than a decade. Héma-Québec and Canadian Blood Services have a cooperative working relationship and maintain regular communications between senior management groups.

Similarly, Canadian Blood Services' OTDT mandate was issued by the federal government, and all provincial and territorial governments except Quebec. This exception is due in part to the fact that the province operates its own tissue system through Héma-Québec. Quebec is actively involved with Canadian Blood Services and the rest of the ODT community in the Living Donor Paired Exchange registry, and has agreed to participate in other OTDT patient registries. Additionally, a number of the province's physicians were actively involved in developing the organ donation and transplantation strategy detailed later in this plan. These physicians are among many in Quebec's clinical community who have indicated support for broad OTDT system improvements in Canada, including Quebec.

The federal government considers Quebec to be an essential component of any Canadian health care solution, including an OTDT system. Canadian Blood Services agrees and believes an integrated system can only be stronger with Quebec's involvement. Consequently, Canadian Blood Services will continue to engage and work with Quebec for the benefit of all Canadian patients.

### Ongoing engagement

Canadian Blood Services has engaged federal, provincial and territorial governments in regular briefings and discussions throughout the OTDT planning process. In December 2010, Canadian Blood Services presented the deputy ministers of health with preliminary recommendations for the development and implementation of an integrated, inter-provincial OTDT system. Their response and direction were integrated into this strategic plan.

## EXAMINING THE PLAN

*Call to Action* is structured to recognize the differences between organ donation and transplantation (ODT) and tissue donation and transplantation (TDT). Organs, for example, are needed for life-saving treatment, can be recovered in a limited number of situations and must be transplanted immediately. Tissue products—or, more accurately, human tissue allografts—generally support life-enhancing procedures, can be recovered from a broader range of donors and be stored for extended periods of time.

Section one of *Call to Action* explains the strategic planning process and the principles that underlie the development and implementation of discrete ODT and TDT systems. Section two focuses solely on ODT; section three highlights TDT. Though structured similarly, these two sections explore the distinct aspects of the ODT and TDT environments. Each of these sections includes a chapter that examines the challenges of the current state; a strategy chapter that outlines priorities for improvement; detailed recommendations to propel improvements; and an implementation and costing chapter that examines how the recommendations can be put into action.

The conclusion summarizes many of the benefits of an integrated, inter-provincial OTDT system designed to deliver breakthrough performance for Canadians.

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# THE STRATEGIC PLANNING PROCESS

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Presented with a new OTDT mandate in April 2008, Canadian Blood Services took planning responsibility for the development of a new integrated, inter-provincial system. This new system would improve donation and transplantation performance by building on strengths in the current OTDT environment, and creating value-added and coordinated processes, programs and infrastructure. The plan required the collaboration of widely dispersed and generally uncoordinated organ and tissue communities across Canada.

As a preliminary step in the planning process, Canadian Blood Services organized and facilitated a national consultation in September 2008. Participants included more than 150 members of the Canadian OTDT community: donors and recipients, health care professionals, patient groups and other individuals committed to improving OTDT in Canada. The three-day event enabled Canadian Blood Services to engage the organ and tissue communities and gain valuable insight into their experience, expertise and expectations for a strategic plan and integrated system. Discussions revealed several key points:

- OTDT performance had been stagnant for more than a decade, despite many previous efforts to make improvements. A new approach was necessary.
- Knowledge about the current state of OTDT was incomplete. The planning process should begin with a thorough assessment of the existing model.
- Perspectives differed significantly in the communities about the best way to design a national system. Ongoing stakeholder collaboration would be vital to achieve consensus.

## **OTDT strategic planning committees**

The consultation revealed many differences in the ways organ donation and transplantation (ODT) and tissue donation and transplantation (TDT) work in Canada. Although the two systems could develop concurrently and according to the same principles and process, it became apparent that ODT and TDT strategies and designs would have to be examined separately.

To establish these principles and lead the strategic planning process, Canadian Blood Services struck three pan-Canadian OTDT committees. One expert committee addressed ODT, the other TDT. Steering-committee members provided system-level advice based on their experiences in health care policy, delivery and management, in government and in corporate strategy. Members of these expert committees included surgeons, physicians, nurses, intensivists, tissue bankers, representatives from organ procurement organizations (OPOs), hospital administrators and health care policy experts.

The three committees met individually six times during the strategic planning process. Consensus was reached on the vast majority of recommendations; however, where dissenting opinions were raised, they were discussed and recorded.

### MEET THE OTDT STEERING COMMITTEE

The OTDT steering committee brought together distinguished professionals from across Canada—academics, physicians, medical administrators, health-policy and political experts. The expert-committee members are introduced at the beginning of the organ and tissue sections of this plan.

<b>Dr. Graham D. Sher (Chair)</b>	Chief Executive Officer, Canadian Blood Services	Ottawa, Ontario
<b>Dr. Andrew Baker</b>	Chief, Department of Critical Care, St. Michael's Hospital, Toronto Professor, Departments of Anesthesia and Surgery, University of Toronto Scientist, Keenan Research Centre, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto	Toronto, Ontario
<b>Dr. John F. Hamm</b>	Former Premier of Nova Scotia Chair, Assisted Human Reproduction Canada	Stellarton, Nova Scotia
<b>Commodore Hans W. Jung</b>	Commander, Canadian Forces Health Services Group Director General Health Services Canadian Forces Surgeon General	Ottawa, Ontario
<b>Dr. Maurice McGregor</b>	Professor Emeritus at McGill University Chair, Technology Assessment Unit, McGill University Health Centre	Montreal, Quebec
<b>Honourable A. Anne McLellan P.C., O.C.</b>	Former Deputy Prime Minister and Federal Minister of Health Current member of the Royal Alexandra Hospital Foundation	Edmonton, Alberta
<b>Dr. Brian Postl</b>	Professor and Dean, Faculty of Medicine, University of Manitoba	Winnipeg, Manitoba
<b>Dr. Judith Shamian</b>	President and Chief Executive Officer, Victorian Order of Nurses (VON) Canada	Toronto, Ontario
<b>Dr. Michael Strong</b>	Former Chief Operating Officer, Puget Sound Blood Center Principle, Strong Solutions	Edmonds WA USA
<b>Dr. Simon B. Sutcliffe</b>	Chair, Board of Canadian Partnership Against Cancer Past-President, BC Cancer Agency Adjunct Professor, Faculty of Graduate Studies, UBC	Vancouver, British Columbia
<b>Dr. William J. Wall</b>	Professor of Surgery, University of Western Ontario Transplant Surgeon, University Hospital	London, Ontario

**A four-step process**

With a sound committee framework in place, Canadian Blood Services launched a formal planning process made up of four main steps:

- Assess the current state of OTDT.
- Establish strategic direction to improve performance.
- Define goals and how progress will be measured.
- Develop an implementation approach.

Used successfully by Canadian Blood Services since 2002, the planning process (Figure 3-1) has been adapted to meet the specific needs of the OTDT initiative.

**PROFESSIONAL REACH**

*OTDT expert consultations engaged respected professionals in 14 cities and eight provinces. This series of multi-disciplinary and peer group meetings, conference presentations and national conference calls ensured that Canadian Blood Services acquired the broadest perspectives and gained the deepest insight from coast to coast.*

Figure 3-1. THE STRATEGIC PLANNING PROCESS

The process comprises four phases, each accompanied by a set of key activities and deliverables, and all informed by ongoing stakeholder engagement.





### **1. Assess the current state of OTDT.**

The strategic planning process prioritizes what needs to be changed and acknowledges what works well; a thorough assessment of the current OTDT environment in Canada helped determine both. Canadian Blood Services prepared dozens of research papers and reports to ensure evidence-based analysis on subjects as varied as tissue traceability, and organ identification, referral and allocation. Supported at every step of the planning process by public and stakeholder engagement—which presented a wide range of perspectives from across Canada—this data guided the expert committees in identifying and documenting the system challenges for both ODT and TDT in Canada.

### **2. Establish strategic direction.**

With a clear sense of those areas most in need of performance improvements, the committees examined ways to build on current strengths and bridge the divide between today's OTDT approach and an integrated solution. The committees developed optional approaches to address each priority, analyzed the advantages and disadvantages of each option, and identified the best option and strategy with which to proceed.

### **3. Define goals and how progress will be measured.**

The hallmark of any effective health care system is the ability to measure its performance and ensure that investments and changes deliver their intended benefits. Targets are necessary, since performance must be measured against a baseline.

In this phase of the planning process, the expert committees:

- clarified specific objectives requiring focused attention,
- identified performance measures that would help gauge progress toward system objectives, and
- designed separate, enhanced and integrated ODT and TDT systems, a process that included the development of roles, responsibilities, mandates and accountability mechanisms to ensure successful implementation.

### **4. Develop an implementation approach.**

The final step in the strategic planning process included the establishment of clear and comprehensive guidance on how to roll out the proposed system. Canadian Blood Services and the expert committees analyzed various implementation scenarios and drafted specific recommendations including costing, where possible.

## **ENGAGING CANADIANS**

Consultations accompanied every step of the strategic planning process—to gain insight on the current OTDT state, and to ensure that both system design and the drafting of recommendations benefitted from the broad input of all interested, involved and affected participants.

These public and professional OTDT consultations were without precedent. In many cases, groups with complementary goals and mandates in either the ODT or TDT environments had the opportunity to come together for the first time. New connections were made. New excitement emerged. New potential was realized.

Consultation activities and discussions involved seven main groups:

- Canadian OTDT practitioners and experts, including tissue, eye and bone banks and OPOs,
- health care providers,
- the Canadian public,
- patient groups,
- government representatives,
- non-governmental and government agencies, and
- international OTDT experts.

The complete list of consultation groups is presented in Appendix A.

**Canadian OTDT experts**

Since the committees were necessarily limited in their scope and membership, a series of expert consultations gave voice to more than 400 other individuals, including tissue and organ donation and transplantation physicians and surgeons, and representatives from 10 provincial and regional OPOs, 50 transplant programs, 23 tissue, eye and bone banks, and 28 professional organizations, such as the Canadian Society of Transplantation, the Canadian Medical Association and the Canadian Dental Association.

**Health care providers**

Canadian Blood Services and the expert committees looked beyond donation and transplantation programs for the additional perspectives of hospital officials, health authorities and health care administrators—specifically, the professionals and organizations who may take on new roles and responsibilities in an integrated OTDT system.

**The Canadian public**

Between October 2009 and May 2010, Canadian Blood Services hosted a series of regional public dialogues to speak with and listen to Canadians about improving OTDT in Canada. The 293 participants cut across social, cultural, religious and geographic lines. These were people who had been touched directly or indirectly by organ and tissue donation and transplantation, including donors, recipients, patients awaiting transplants, and their families. They delivered clear messages about the shortcomings of the current OTDT state and their expectations for improved performance in an inter-provincial system.

**Patient groups**

In March and December 2010, Canadian Blood Services hosted OTDT roundtables that brought together a number of patient advocacy groups to discuss the guiding principles and priorities for an integrated OTDT system. The Kidney Foundation, CNIB, Canadian Diabetes Association, Juvenile Diabetes Research Foundation, David Foster Foundation, Canadian Cystic Fibrosis Foundation, Canadian Liver Foundation, Canadian Transplant Association, MedicAlert, and Crohn’s and Colitis Foundation of Canada were gracious in offering individual perspectives. Of equal value, judging by roundtable feedback, was the opportunity for these groups to expand relationships. Strengthened partnerships among these organizations and with Canadian Blood Services is vital for the future of OTDT.

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**EXCELLENT REPRESENTATION**

*Many of the larger patient groups provide vital representation at the national level, but crucial patient voices can also be heard at the provincial and local levels. To ensure the deepest possible level of patient engagement, Canadian Blood Services met with a variety of these smaller groups in towns and cities across Canada.*

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**PUBLIC FORUMS**

<i>London, ON</i>	<i>October 24, 2009</i>
<i>Vancouver, BC</i>	<i>November 14, 2009</i>
<i>Edmonton, AB</i>	<i>January 16, 2010</i>
<i>Halifax, NS</i>	<i>February 6, 2010</i>
<i>Winnipeg, MB</i>	<i>February 13, 2010</i>
<i>Regina, SK</i>	<i>March 1, 2010</i>
<i>St. John’s, NL</i>	<i>March 30, 2010</i>
<i>Moncton, NB</i>	<i>May 4, 2010</i>
<i>Toronto, ON</i>	<i>May 29, 2010</i>

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### **Government representatives**

Federal, provincial and territorial government representatives have been consulted at every stage of the planning process. Consultations with ministers, deputy ministers and senior health ministry officials have kept governments informed about progress and enabled them to voice their own ideas and requirements for an improved approach to OTDT.

### **Non-governmental and government agencies**

The OTDT initiative has benefitted significantly from the contributions of experts within non-governmental and government agencies such as the Public Health Agency of Canada, the Canadian Institute for Health Information, the Canadian Organ Replacement Register, and Accreditation Canada.

### **International experts**

It would be a disservice to Canadians not to look beyond our borders to engage with, and examine the experiences of, other countries and international bodies that face similar OTDT challenges. Working closely with international partners and programs, Canadian Blood Services has drawn immense benefit from their willingness to share best practices. Representatives from the United Kingdom, the United States, Spain and Australia are among those who have been tremendous resources during the planning of the proposed OTDT system for Canada.

#### **KEY CONSIDERATIONS**

- Canadian Blood Services formed an OTDT steering committee and two expert steering committees—one for organs, one for tissues—to guide development of this strategic plan.
- The OTDT strategic plan was developed through a proven four-phase process.
- The planning process has been fully informed by Canadian and international research, and by an unprecedented OTDT engagement process with the public, governments and non-governmental agencies, Canada's organ and tissue communities, and international experts.

# PRINCIPLES AND ETHICAL FOUNDATIONS

## of a Canadian OTDT System

The Canada Health Act of 1984 enshrines in law a number of distinct principles for health care in Canada. Long upheld as inalienable by all Canadians, these principles were reaffirmed in the Romanow report<sup>1</sup> in 2002, and by Canada's First Ministers in the 2003 Accord on Health Care Renewal and at the 2004 First Ministers' Meeting on the Future of Health Care:

- Universality, accessibility, portability, comprehensiveness, and public administration;
- Access to medically necessary health services based on need, not ability to pay;
- Reforms focused on the needs of patients to ensure that all Canadians have access to the health care services they need, when they need them;
- Collaboration among all governments, working in common purpose to meet the evolving health care needs of Canadians;
- Advancement through the sharing of best practices;
- Continued accountability and provision of information to make progress transparent to citizens; and
- Jurisdictional flexibility.

### System-specific principles

As a vital component of Canada's health care system, the OTDT system will measure up to and champion the same principles. Indeed, they underpin every aspect of the development and design of the OTDT system, and will continue to inform its implementation and evolution.

Members of the OTDT communities have given deep consideration to a range of ethical questions throughout the process of development. Through public forums, dedicated ethics consultations and professional and committee meetings, the communities have concluded that there are additional principles that are unique to OTDT and must be included among those that shape its system:

- **Stewardship**
- **Accountability**
- **Integrity**
- **Solidarity**
- **Fairness**
- **Sufficiency of supply**
- **Sustainability**
- **Respect for human dignity**
- **Inclusive, evidence-based decision-making**
- **Safety**

<sup>1</sup> Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada — Final Report*, November 2002.

## A PRINCIPLED AGREEMENT

*The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* was established in 2008 to address the growing problems of organ trafficking, transplant tourism, and transplant commercialism—practices that threaten to undermine transplantation worldwide.

Canadian Blood Services is one of the many organizations in Canada that support the declaration. The principles outlined in this chapter—indeed, the full strategic plan—are intended to guide development of a system that enhances donation and transplantation in Canada. An integrated, inter-provincial OTDT system will ensure patients can expect safe and timely transplant solutions here at home.



→ The media panel at The Transplantation Society's International Congress in Vancouver, August 16, 2010.

Left to right: **Dr. Graham Sher**, CEO, Canadian Blood Services; **Günter Kirste**, MD, President, International Society of Organ Donation and Procurement; **Frank Delmonico**, MD, President-elect, The Transplantation Society and Chair of the Istanbul Summit; and **Luc Noël**, MD, coordinator, Department of Essential Health Technologies, World Health Organization. (Credit: Wayne Leidenfrost/PNG)

### Stewardship

Donated organs and tissues are gifts from altruistic donors who wish to save and improve lives. They are gifts to society as a whole, and not the property of any program or organization. As a humanitarian gesture, donation imposes profound obligations on those involved in the OTDT system to undertake organ and tissue transplantation activities respectfully on behalf of all Canadians.

### Accountability

As both donors and shareholders in the country's health care system, Canadians have a right to know how their donation and their money are being used. Participants in the OTDT system are obligated to report and be answerable to the Canadian public. Transparency and disclosure are vital to ensure that information on decisions, processes, actions and performance is clear and readily available to all.

### Integrity

The trust of donors, patients, health care professionals and the public is essential to the success of the OTDT system. To earn and maintain that trust, the system—and those who work in it—must exemplify integrity at all levels and in all actions.

### Solidarity

Canadians have a shared social citizenship based on a mutual understanding of principles and values. An integrated OTDT system must build on this common interest, bring OTDT participants together, trigger inter-provincial collaboration and innovation, promote better and more consistent practices across Canada, and ensure Canadians benefit equally, no matter what part of the country they live in.

### Fairness

Canadian patients should be treated fairly and consistently, regardless of income, status, gender, ethnicity or location. Similar groups of patients should have similar access, and efforts should be made to improve access for currently disadvantaged patient groups. Equity should apply not only in the allocation of donated organs and tissues, but also in the benefits and responsibilities of donation. All Canadians should have the opportunity to help improve the lives of others.

### Sufficiency of Supply in Organs and Tissues

The Canadian OTDT system should provide an adequate, safe and secure supply of organs and tissues to meet the needs of Canadian patients. It should be recognized that this goal is more challenging for organs than tissues; however, if we ensure the system is making the most of every organ donation opportunity, we will meet the expectations of our population and fulfill Canada's ethical obligations to mitigate transplant tourism and organ trafficking.



↑ **Dr. John Dossetor**, Canadian physician and bioethicist, who coordinated the first kidney transplant in Canada in 1958, provided his expertise to the OTDT Ethics Review held in January 2011.

### Sustainability

Canada's OTDT system must be designed and operated in a sustainable way to meet current and future needs. It must be cost effective and efficient to address patients' needs while respecting economic and logistical realities.

### Respect for Human Dignity

The dignity and fundamental human rights of living and deceased donors must be respected at every level of, and by every participant in, the OTDT system. Specifically, the system must be committed to:

- non-commodification of organs and tissues to prevent the exploitation of vulnerable people within and outside of Canada,
- duly respecting the wishes of donors and families,
- recovering organs and tissues only when there is intention of use,
- disclosure and transparency of professional roles and actions, and
- respecting diversity of public views on organ and tissue donation and transplantation.

**Inclusive, Evidence-based Decision-making**

Decisions for the OTDT system should be based on medically, scientifically and socially sound evidence. The system must collect and analyze data, and be able to change and adapt as a result of new information. Broad stakeholder input will help ensure that decisions have democratic legitimacy, especially when conflicting perspectives exist.

**Safety**

Because organs and tissues come from living and deceased donors, there are inherent risks in their use, for patients and for living donors. However, because of the life-saving nature of transplantation, decisions to proceed are made even when risks are identified. As a result, safety-related decisions should be made based on evidence, assessments of risks and benefits, and take into account the availability of organs and tissues.

**PUTTING PRINCIPLES TO WORK**

Unquestionably, many of the additional principles examined in this chapter—integrity, fairness and safety, for example—are as applicable to the broader Canadian health care system as they are to organ and tissue donation and transplantation. But individual components of the health care system rarely, if ever, have the opportunity that was afforded to the OTDT community—the opportunity to reflect on the nature of service, on the needs of patients, on the future of their specialty. Given this opportunity, the community gave shape to a dedicated ethical framework for the efficient, sustainable and dignified conduct of integrated, inter-provincial organ and tissue donation and transplantation activities in Canada.

The next two sections of this strategic plan demonstrate how OTDT principles are being applied in the development of separate organ and tissue donation and transplantation systems.



**ROBERT (BOB) MANUEL** *For governments that face continual increases in health care costs, the integration of provincial and territorial OTDT services is partly and understandably about money. Some benefits of OTDT can be expressed as monetary savings. For example, kidney transplants save as much as \$50,000 per patient per year in dialysis costs alone.*

*But Bob Manuel demonstrates that some benefits extend beyond traditional means of calculation. Bob received his new heart more than nine years ago. His transplant enabled him to remain an active and productive taxpayer and member of his community. He's been able to watch his two grandchildren grow; in fact, last year, at age 60, Bob learned to ski with them. He and his wife have added nearly a decade to their anniversary count, and Bob has raised more than \$10,000 for his provincial OTDT program through an email and online campaign.*

*Is Bob exceptional? Perhaps only because far too many Canadians do not live long enough to receive transplants, and never get the chance to continue contributing to their families and their communities.*



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# ORGAN DONATION AND TRANSPLANTATION

## Seizing the immense opportunity of a system solution

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*Organ donation and transplantation (ODT) offer immense potential. Advances in technology and technique are prompting new ways to collect, handle and distribute organs, and new ways to use them to save and rejuvenate lives. Canadians look forward to the benefits of these exciting advances. Yet those who know ODT—including those who need transplants, and those who lobby tirelessly for more donations—unanimously believe that ODT's full potential to improve patient outcomes will be realized only through transformational changes.*

With more than three years of intense research and coast-to-coast consultations behind us, the Organ Expert Committee and Canadian Blood Services agree with the need for transformational change. In this section of the OTDT strategic plan, we explain why. The section begins with the challenges facing the system—the culmination of an extensive assessment of the current state of ODT in Canada and abroad. Based on these findings, we detail our strategy for a response, then present our recommendations for the design of an integrated, inter-provincial ODT system, including explanations of specific roles and responsibilities. Finally, we present an implementation strategy and respective cost estimates.

### EXPERT CONTRIBUTIONS

The contributions of the Organ Expert Committee have been vital to this section of the strategic plan. Brought together by Canadian Blood Services to ensure broad regional representation from across Canada, committee members included physicians, surgeons, academics and hospital surgical directors. Canadian Blood Services worked closely with these professionals and led discussions with the wider ODT stakeholder community to assess current challenges and opportunities. This broad collaboration has been instrumental in enabling Canadian Blood Services to plot a course toward an integrated inter-provincial organ donation and transplantation system.

**MEMBERS OF THE ORGAN EXPERT COMMITTEE**

<b>Dr. Peter Nickerson MD FRCP(C) (Chair)</b>	Executive Medical Director, Organs and Tissues; Medical Consultant, Platelet Immunology Laboratory, Canadian Blood Services  Medical Consultant, Transplant Immunology Laboratory, DSM  Associate Dean (Research) Faculty of Medicine; Professor of Internal Medicine and Immunology; Flynn Family Chair in Renal Transplantation, University of Manitoba	Winnipeg, Manitoba
<b>Dr. Ian P. J. Alwayn PhD</b>	Surgical Lead, Multi-Organ Transplant Program, Queen Elizabeth II Health Sciences Centre, Capital Health  Associate Professor, Department of Surgery, Dalhousie University	Halifax, Nova Scotia
<b>Dr. Stephen Beed MD, FRCP(C), Dip ABA, CCM</b>	Medical Director, Nova Scotia Organ and Tissue Donation Program  Program Director, Residency Training Critical Care Medicine – Adult, Dalhousie University/Queen Elizabeth II Health Sciences Centre, Capital Health	Halifax, Nova Scotia
<b>Dr. Tom Blydt-Hansen MD, FRCP(C)</b>	Assistant Professor of Paediatrics and Child Health, University of Manitoba  Head, Section of Paediatric Nephrology, Winnipeg Children’s Hospital	Winnipeg, Manitoba
<b>Dr. Michel Carrier MD</b>	Medical Director, Québec-Transplant	Montreal, Quebec
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**THE GAP BETWEEN SUPPORT AND INTENT**

*95 per cent of Canadians support donation, but only 51 per cent have indicated a willingness to donate their own organs—by filling out their donor card, or expressing to family members their intent to donate, for example.*

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# SYSTEM CHALLENGES

## Organ Donation and Transplantation in Canada

### OVERVIEW

This chapter is the result of a collaborative effort between Canadian Blood Services and the Organ Expert Committee with support from members of the ODT community. In 2008, Canadian Blood Services launched a series of extensive public and professional consultations across Canada to understand and assess current ODT activities. The extent of this engagement was unprecedented. The consultations, supported by available data,<sup>1</sup> revealed specific issues that underscore the need for changes.

The consultation also showed that many current ODT components perform well; the committee recognized there are pockets of excellence throughout the country. Performance improvements are ongoing thanks to ODT program refinements in many provinces, territories and regions. Some provinces have seen improvements as a result of significant efforts to improve donation rates and transplantation services; however, no province is performing at world-leading levels.

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*Current provincial average wait-times for patients who receive kidney transplants range from 20 to 56 months. Canada's deceased donation rate is less than half that of the best performing countries, and has remained relatively flat over the last decade.*

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With this chapter, the Organ Expert Committee presents a unique Canada- and stakeholder-wide perspective on the specific and critical ODT elements that must be remedied if patients are to be better served, and if a baseline is to be established to measure progress. The evidence remains compelling that Canada as a whole, and its provinces and territories individually, can perform better in many areas of ODT.

### PERSUASIVE STATISTICS

There were 3,796 patients on waitlists for organ transplants across Canada as of December 31, 2009.<sup>2</sup> In the 12 previous months, 249 people on those waitlists died before receiving transplants; many others were in advanced stages of illness and died without making it to a waitlist. In some cases, patients who could benefit from transplant are not on waitlists. For example, of the more than 22,000 patients receiving dialysis for end-stage renal disease, fewer than 13 per cent made it to the kidney transplant waitlist.<sup>3</sup>

<sup>1</sup> Some material in this chapter is based on data and information provided by the Canadian Institute for Health Information (CIHI); however, the analyses, conclusions, opinions and statements expressed herein are not necessarily those of CIHI.

<sup>2</sup> 2009 CORR Data.

<sup>3</sup> 2009 CORR Data.

### MISSING THE BENEFITS OF A COORDINATED APPROACH

Organ donation dramatically improves the health of patients with end-stage organ failure. The outcomes of organ transplant surgery in Canada are generally excellent. Indeed, many Canadian ODT programs have led the way internationally in developing and promoting leading practices in new immune-suppressive drug use, lung transplantation, and paired kidney exchange, among others.

The lack of a coordinated approach, however, restricts Canada from achieving organ transplantation's full potential. Canada needs more organ donations, more data on—and accountability for—organ allocation and outcomes, and more uniformly available leading practices.

→ A physician who knows firsthand the importance of organ donation—**Dr. Sam Shemie**, Paediatric ICU physician at Montreal Children's Hospital, McGill University Health Centre, and Medical Director, OTDT (Donation) at Canadian Blood Services.



Growing demand is expected to widen this gap. The need for organs is predicted to increase by 152 per cent over the next two decades.<sup>4</sup> Canada's aging population will consume more and donate fewer organs, medical advances will enable more patients to benefit from transplantation, and the demand for organs will increase significantly due to rising rates of Hepatitis C infection and diabetes.

The Canadian organ donation and transplantation system is unable to cope with current demand and unable to plan to meet future demand.

### OBSTACLES AND OPPORTUNITIES

This chapter describes the four most critical challenges that must be met to improve the outlook for Canadian patients waiting for organ transplants.

- Ensure Canada realizes its potential for organ donation.
- Ensure fairness and transparency in the ODT system.
- Increase efficiencies associated with patient assessment and organ allocation to improve patient wait times and reduce impacts on health.
- Strengthen measurement and accountability mechanisms to drive consistent, system-wide performance improvements.

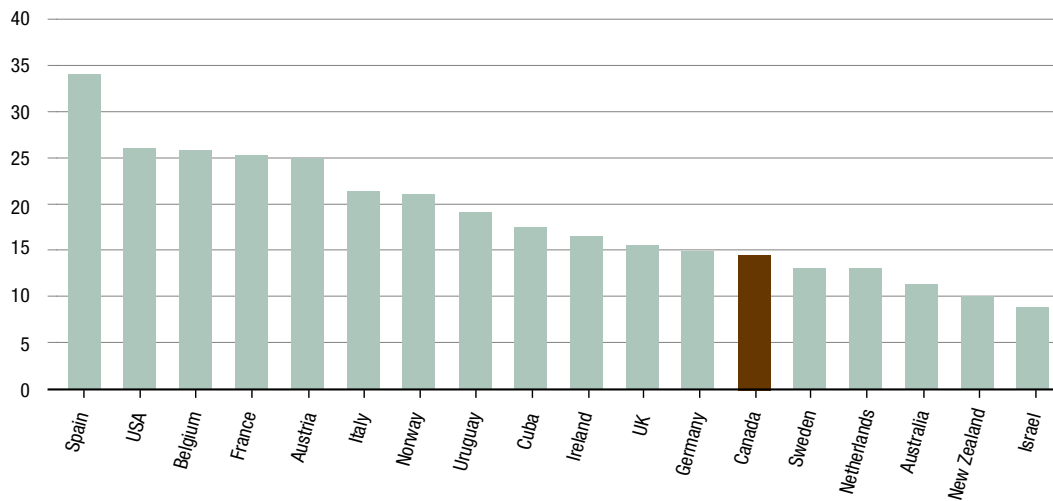
<sup>4</sup> Baxter D and J Smerdon, *Donation Matters: Demographics and Organ Transplants in Canada, 2000 to 2040*, June 2000 (<http://www.urbanfutures.com/UFI%20Reports/Report%2046%20-%20Donation%20Matters%20-%20Demographics%20and%20Organ%20Transplants.pdf>).

*Challenge:*

**ENSURE CANADA REALIZES ITS POTENTIAL FOR ORGAN DONATION.**

Compared with other countries, Canada’s deceased donation rate is unacceptably low—less than half that of the best-performing countries. Even provinces with the highest donation rates are far below those in comparable jurisdictions outside Canada.

*Figure 5-1. Deceased donors PMP (2009)*



Reference: IRODaT - International Registry of Organ Donation and Transplantation website ([www.tpm.org](http://www.tpm.org)). At the time of publication, France and Cuba reflected 2008 data.

Donation involves numerous players and a series of complex steps, from identification of potential donors to securing hospital services necessary to recover organs. In Canada, too many donations are lost because one or more of these steps is poorly executed.

**Families are not always given the opportunity to donate**

Organ donation is driven largely by the routine identification of all potential donors at hospitals, and by their subsequent referral to OPOs. Donor identifications and referrals vary across Canada. In British Columbia, Manitoba, Ontario and Alberta, referral of potential organ donors to OPOs is required by law. In other provinces, individual hospitals and health care professionals decide whether to identify and refer donors. Even when mandated, not all potential donors are referred. In smaller hospitals, where organ donation is relatively rare, health care workers may lack the experience and training to identify potential donors in a timely manner.

Some health care professionals miss organ-donation opportunities because they are unsure of the process and uncomfortable approaching families. Even when families initiate discussions with a hospital, the requests are not always supported, and the opportunity for donation may be lost.

Family members and friends are not routinely made aware of, or given the opportunity to proceed with live donation. This option, too, is put forward at the discretion of the attending physician or program, and is not a standard of care.

### **Ineffective donation requests result in lower consent rates**

It is standard practice in Canada to ask a potential donor's family for consent to donate before proceeding with organ recovery, even if the donor's intent is known. Proper training is required to ensure that families are approached in an appropriate manner. When health care professionals who have this training are not available—even in those hospitals where donor identification and referral are standard practice—donation opportunities may be missed.

Donation discussions are easier when families or health care providers are aware of donors' wishes. A few provinces have registries at which people can indicate their intent to donate. Unfortunately, these registries are hampered by relatively low public participation levels, and information that is not uniformly accessible. When crucial donation decisions must be made, a donor may not be in possession of personal identification that shows their intent. If donor intent is recorded on a database, hospitals or staff may not have timely access to the information.

Although public awareness and support for organ donation in Canada is greater than 90 per cent, only about half of all Canadians have indicated their intent to donate by telling a family member, signing a donor card or registering online.<sup>5</sup> Donation opportunities are often missed because people may not know how to register consent to donate, may not be aware of the need to talk to family members about their wishes, and because families of potential donors are sometimes unaware of all circumstances where donation is possible.

### **Low rates of donation after cardio-circulatory death (DCD)**

Most organ donors are patients who have been declared brain dead according to neurological criteria. In other situations, however, there are patients with severe brain injury who do not meet the clinical definition of brain death, but are removed from life support because they have no chance of recovering. In certain circumstances, these patients can become organ donors. This practice, known as donation after cardio-circulatory death, is common in many countries but still has limited practice in Canada. DCD has the potential to significantly increase the number of donors. In the United Kingdom, for instance, DCD accounts for 34 per cent of donations; in Canada, DCD donations accounted for approximately nine per cent in 2009.

### **Lack of hospital reimbursement for donation activities**

Donation activities in hospitals often impact and must compete with other services for access to ICU beds, operating room time and personnel, for example, as part of the overall hospital budget. Some hospitals are not reimbursed for the high costs of maintaining donors in ICU beds until organs can be recovered. With no financial reimbursement, hospitals may hesitate to undertake procedures that would lead to increased donations.

<sup>5</sup> Canadian Council for Donation and Transplantation, *Public Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation After Cardiac Death*, 2005 ([http://ccdt.ca/english/publications/surveys-pdfs/Public\\_Survey\\_Final\\_Report.pdf](http://ccdt.ca/english/publications/surveys-pdfs/Public_Survey_Final_Report.pdf)).

*Challenge:*

**ENSURE FAIRNESS AND TRANSPARENCY IN THE ODT SYSTEM.**

Transplants are the best long-term treatment option for patients with end-stage organ failure. To get a transplant, a patient must first be identified as a potential transplant candidate. He or she is then assessed for transplant suitability and placed on the appropriate waitlist. In Canada, however, it is unclear whether all patients who meet the transplantation criteria actually make it to waitlists.

Patients are referred to specialists who determine whether patients should be added to waitlists. But there is little consistency in the way these referrals are handled from province to province. National criteria are available to help physicians identify suitable transplantation candidates, yet a number of health care professionals are unaware of the criteria. Furthermore, some physicians may decide not to add a patient to a waitlist because they believe the patient’s chance of receiving an organ in time is remote.

**Varying likelihood of receiving a transplant**

Although some variation in transplant activity is to be expected from province to province, the current differences raise significant concerns in the ODT community. For example, patients in provinces with the most transplants are more than twice as likely to receive an organ than patients in provinces with the fewest number of transplants (see Table 5-1).

*Table 5-1. Provincial Transplant Rates in Canada*

Patients’ chances of receiving an organ vary significantly by province, and by organ type.

Transplant Rates <sup>1*</sup> (PMP)	BC	AB	SK	MB	ON	QC	NB	NS	NL
Kidney	13.4	22.1	20.8	16.3	20.0	26.3	24.9	27.3	24.1
Heart	5.1	7.5	5.0	3.1	4.9	4.5	5.8	5.9	5.9
Lung	3.2	8.5	5.7	2.8	5.4	3.7	3.6	5.0	11.1
Liver	9.3	15.1	7.0	6.8	11.7	12.1	10.7	14.6	4.6

<sup>1\*</sup> (Transplants per million population, organs from deceased donors only, by province of residence CORR data, averaged from 2005-2007).

Table 5-2 shows average patient wait times by province. A patient is included among these statistics only after he or she has been removed from a waitlist and received an organ transplant. The table indicates there are marked differences even among provinces with similar transplant rates. For example, wait times for patients on kidney-transplant lists average from 20 to 56 months; however, these averages do not take into account patients who are still on waitlists, and who—due to the anomaly noted above—may have waited even longer.



**Table 5-2. Organ Transplant Wait Times by Province**

Some of the greatest provincial ODT disparities exist in transplant wait times.

Wait times <sup>2*</sup> (in avg months)	BC	AB	SK	MB	ON	QC	ATL
Kidney	27.7	41.8	24.1	30.7	55.8	19.6	24.8
Heart	2.0	3.1	-	-	4.4	4.7	5.4
Lung	12.6	6.6	-	17.3	6.1	19.8	-
Liver	2.8	8.6	-	-	12.8	7.2	6.9

<sup>2\*</sup>(Average time before transplantation for patients on organ transplant waiting lists, organs from deceased donors, by province of treatment) 2008 CORR data.  
Note: Not all provinces have transplant programs for all organs.

These regional differences are caused by a number of factors, including donation rates, current waitlist sizes, and the availability of transplant programs within each province. Some provincial variation is unavoidable, yet current differences indicate a significant inequity in access to organ transplantation in Canada.

**Lack of transparency in organ allocation practices**

Patients in need of organ transplants want to know if they qualify to be on a waitlist, how likely they are to receive an organ once on a waitlist, and how long they will have to wait for their transplant. Currently, there is no easy way for patients to get answers to any of these questions. Waitlist referral and organ-allocation criteria are, for the most part, neither public nor standardized. The criteria are difficult for many health care professionals to understand. As a result, current ODT approaches are neither understood nor trusted by the public, and often constitute a source of frustration for patients and their families.

**Disproportionate sharing of available organs**

Only a small fraction of available organs are compatible with highly sensitized patients, most of whom are women. Although they make up approximately 30 per cent of kidney transplant waitlists, these patients receive less than five per cent of all deceased donor kidneys.<sup>6</sup> As a result, these patients wait longer for transplant offers and are more likely to die waiting. Their chances of receiving transplants are lowered further still because kidney allocation is limited to provincial donation pools.

Aboriginal persons are another group of disadvantaged patients in Canada. Although twice as likely as other Canadians to have end-stage renal disease, the likelihood of Aboriginal persons receiving transplants is significantly lower and they have significantly higher overall median wait times.<sup>7</sup>

<sup>6</sup> Canadian Council for Donation and Transplantation, *Canadian Highly Sensitized Patient and Living Donor Paired Exchange Registries Task force Discussion Document*, Oct 28-30, 2005.

<sup>7</sup> Yeates et al, *Indigenous people in Australia, Canada, New Zealand and the United States are Less Likely to Receive Renal Transplantation*, *Kidney International*, June 24, 2009.

*Challenge:***INCREASE EFFICIENCIES ASSOCIATED WITH PATIENT ASSESSMENT AND ORGAN ALLOCATION TO IMPROVE PATIENT WAIT TIMES AND REDUCE IMPACTS ON HEALTH.**

Organs are shared between provinces on a case-by-case basis where national sharing agreements exist for urgent status patients or when organs cannot be used within the province. A national waitlist is used to identify potential out-of-province sharing opportunities. Canada's current waitlist, maintained by the London Health Sciences Centre, identifies candidate recipients for all organs except kidney. Due to technical limitations, the current national list is challenged to ensure complete accuracy and timeliness. The list is updated by faxes to LHSC and published only weekly, again by fax distribution. This is far from ideal, and the LHSC has repeatedly requested that an appropriate agency take over and modernize the national list.

**Patient assessment for referral to waitlists can take too long**

Patients with end-stage organ failure can be placed on waitlists only after extensive assessments and workups conducted by various specialists. These processes are sometimes poorly integrated, especially when different departments, hospitals and data information systems are involved. Renal-transplantation workups typically take many months, and the duration varies significantly depending on the jurisdiction.

*Challenge:***STRENGTHEN MEASUREMENT AND ACCOUNTABILITY MECHANISMS TO DRIVE CONSISTENT, SYSTEM-WIDE PERFORMANCE IMPROVEMENTS.**

The problems discussed previously in this chapter relate to specific aspects of ODT. There are, however, over-arching ODT issues that must be addressed if transformational performance improvements are to be achieved. For example, inconsistent, incomplete data capture and the lack of mandatory centralized reporting make it difficult to achieve Canada-wide, evidence-based improvements.

Many Canadian ODT programs collect and analyze data, although standards and data definitions vary. At the national level, however, the reporting of data is limited to summary activity submitted to the Canadian Organ Replacement Registry (CORR), a national database managed by the Canadian Institute for Health Information. Data submission is voluntary, often late and lacks comprehensiveness; for example, no data is collected on donor identification, referral rates or consent rates. There is also limited auditing to verify and validate data quality.

This lack of comprehensive, timely and accurate national data imposes limits on the ability to understand current ODT performance.



↑ **Dr. Norman Kneteman**, Professor of Surgery and Regional Program Clinical Director of Transplantation, University of Alberta, and member of the Organ Expert Committee.

### Uncoordinated, inconsistent policy development and implementation

There is no coordinated approach by organ programs to develop and implement policies to respond to emerging issues. For example, when West Nile virus became an international health concern, organ programs in Canada responded in a fragmented fashion. To this day, there is a lack of standardized testing for the virus.

Transplant tourism poses another policy and safety challenge. Canada has few policies in place to respond to the disturbing numbers of patients who pay for and receive organ transplants in third-world countries. These patients often return to Canada with serious complications requiring follow-up treatment as a result of sub-standard care.

### Slow and inconsistent adoption of leading practices

Leading practice implementation is considered an effective way to improve organ donation rates. The success in Spain, which has the highest deceased donor rate in the world, is largely attributed to the way it organized and implemented organ donation processes. Both Italy and the United States have successfully implemented leading practices to help improve organ donation rates.<sup>8,9</sup> Yet Canada has no such requirement, and no coordinating oversight body to improve training and awareness. ODT activities require highly trained hospital personnel, but few training programs exist where health care professionals can learn about ODT and its leading practices.

### Vague and uncoordinated accountability

While there may be organ-program accountability to boards, professional organizations or funders, there is no supply-chain accountability to improve performance by delivering on agreed outcomes and targets. Individual organ programs do not necessarily coordinate performance targets with others. There are no consequences for not implementing leading practices, and no incentives or requirements to improve performance. Overcoming these accountability and performance shortfalls will be particularly challenging because of the fragmented and geographically dispersed nature of the organ programs and organizations involved.

#### KEY CONSIDERATIONS

The committee recognized that many current ODT components perform well, and there are pockets of excellence throughout the country. Some provinces have seen improvements as a result of significant effort to improve donation rates and transplantation services; however, the evidence remains compelling that Canada as a whole, and its provinces and territories individually, can perform better in many areas of ODT.

The Organ Expert Committee's work revealed four key opportunities to improve ODT in Canada:

- Ensure Canada realizes its potential for organ donation.
- Ensure fairness and transparency in the ODT system.
- Increase efficiencies associated with patient assessment and organ allocation to improve patient wait times and reduce impacts on health.
- Strengthen measurement and accountability mechanisms to drive consistent, system-wide performance improvements.

<sup>8</sup> International Registry of Organ Donation and Transplantation data (IRODaT), www.tpm.org, as of publication date.

<sup>9</sup> Tuttle-Newhall et al, *Organ Donation and Utilization in the United States: 1998–2007*, American Journal of Transplantation, 2009; 9(Part 2) 879–893.

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# PRIORITIES FOR THE WAY FORWARD

## Organ Donation and Transplantation Strategy

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The previous chapter identified the most critical challenges facing Canadian organ donation and transplantation (ODT) today. This chapter sets out what the ODT community must do to overcome those challenges.

### GETTING OUR PRIORITIES STRAIGHT

With a clear sense of the current ODT state, the Organ Expert Committee turned its attention to the future. Its vision—*By 2017, Canadian patients will have a trusted, integrated transplant system that performs among international leaders.*

To realize this vision, the ODT strategy must focus on five system priorities:

- Increasing donation to give patients the best chances to receive transplants, with optimal outcomes.
- Ensuring fair access to transplants for all patients.
- Earning the public's trust through transparency and accountability.
- Enabling collaboration among all provincial stakeholders.
- Strengthening the system's infrastructure and capabilities.

These priorities are inextricably linked; for example, accountability will depend in part on fair access to transplants; receiving the best possible organ will be possible only through provincial collaboration; and favourable transplant outcomes will rely on improved skills and system capabilities. Together, they define a powerful strategy to transform ODT in Canada (Figure 6-1).



↑ **Honourable A. Anne McLellan**, former Deputy Prime Minister and Federal Minister of Health, and member of the OTDT Steering Committee.

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### A SYSTEM FOR EVERY CANADIAN

*During public and professional consultations, members of the ODT community delivered a clear message: a new, integrated ODT system must inspire public and ODT-professional support and participation, and ensure fair access to organ donation and transplantation for more Canadians.*

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Figure 6-1. **ODT SYSTEM STRATEGY**

By 2017, Canadian patients will have a trusted, integrated transplant system that performs among international leaders.



Built according to specific principles and ethical foundations, the ODT system strategy identifies collaboration, and infrastructure and capabilities, as core elements through which greater accountability, donation and access to transplantation can be achieved.

*System Priority:*

**INCREASE DONATION TO GIVE PATIENTS THE BEST CHANCES TO RECEIVE TRANSPLANTS WITH OPTIMAL OUTCOMES**

With all organs currently in short supply, meeting this priority means improving organ availability without compromising organ quality. Three tasks are key to successfully fulfilling this ODT system priority. The first involves **building support for organ donation**. More organs will be needed if more lives are to be saved, and public and ODT-professional support are vital if donation rates are to rise. But support means more than simple endorsement. It means increased public commitment to donation. It also means that the ODT system and its professionals must be ready to optimize donation opportunities.

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*Donation must become a standard part of end-of-life care—and therefore a professional responsibility—in the ODT system.*

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Donation must become a standard part of end-of-life care—and therefore a professional responsibility—in the ODT system. This standard of care will be met through identification of all potential donors, timely referral of donors to local organ procurement organizations, proper donor management, and the

effective requesting of consent from families. Carrying out these activities will **ensure that the system is ready to respond to all donation opportunities**.

In addition to making the most of every donation opportunity, the system must also **make the most of every suitable organ**. Every donated organ is a precious gift. The new ODT system can maximize the supply of suitable organs by using every organ that is viable for transplant.

*System Priority:*

**ENSURE FAIR ACCESS TO TRANSPLANTS FOR ALL PATIENTS**

Regardless of wealth, gender, ethnicity, status or location, Canadian patients and patient groups must be treated fairly in the ODT system. There are three aspects to this priority.

The system must **apply a consistent approach to patient identification, referral and listing**. Fair access to transplantation means that patients with the same conditions are equally likely to be identified, referred to transplant programs and put on waitlists, no matter where they live in Canada.

Because of the shortage of organs, difficult decisions need to be made about which patients among many will receive organs. Therefore, **organs must be allocated according to established principles** of fairness, utility and medical need, according to impartial rules and evidence-based criteria.

Third, the system must **collect and analyze information as part of patient follow-up procedures**. Patient outcomes should be tracked as a matter of course. The acquired data will be valuable for the care of individual patients, to contribute to better outcomes for all patients, and to inform long-term system improvements.

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**STRIVING TO ENSURE A SUFFICIENT SUPPLY OF ORGANS**

*A strong Canadian ODT system will make its best effort to provide an adequate, safe and secure supply of organs for all patients. It will make the most of every donation opportunity to meet Canadians' needs, and to reduce transplant tourism and organ trafficking.*

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*System Priority:***EARNING THE PUBLIC'S TRUST THROUGH ACCOUNTABILITY**

As noted in the Organ Expert Committee's vision for the ODT system, public trust is vital. A trusted system must perform well, and it must be accountable. ODT authorities and practitioners will have to explain and be answerable for what they do. There are three keys to achieving public trust through accountability.

**IT'S YOUR RIGHT TO KNOW**

*Canadians have a right to know how the system is performing. Under the new ODT system, operators will be required to report—and be answerable—to the Canadian public to ensure that information on decisions, processes, actions and performance is transparent.*

First, the system must **comply with policies, standards and regulations**. A variety of oversight organizations and accountability mechanisms—such as mandatory reporting and auditing—will help monitor compliance and instill confidence that the system is operating as it should.

Second, system operators and participants must **be transparent in their policies, procedures and performance**. This transparency must be demonstrated and regularly assessed; it must also extend beyond oversight organizations to all Canadians. Members of the public are more likely to trust the system when they understand how it works and how well it is performing.

Third, the system must **collect and analyze data to continuously improve performance**. An accountable system is one that misses no opportunity to improve. Good data provides sound evidence, which enables decision making and helps set clear direction for ongoing system refinements.

*System Priority:***ENABLING COLLABORATION AMONG ALL PROVINCIAL STAKEHOLDERS**

The ODT community believes that breakthrough performance has yet to be achieved because of a lack of integration and cooperation. System improvements—sustainable improvements—depend on collaboration, because practitioners rely on each other to make the system work. The community identified four ways to promote, build and make the most of cooperation among all regional, provincial and territorial stakeholders.

The system should **develop, share and adopt leading practices** to further increase donation and improve service delivery. Merely identifying leading practices is not enough to guarantee success. The system must drive and monitor their adoption, especially as they relate to improving organ-donation performance.

*Clear roles and responsibilities will help participants take ownership of every process in—and outcome of—the system.*

Collaboration can occur only if the system **maintains clearly defined roles, responsibilities and lines of accountability**. For the many and varied organizations and individuals involved in ODT, a stake in the system depends on knowing their place in the system. Clear roles and responsibilities will help participants take ownership of every process in—and outcome of—the system.

The power of collaboration is in sharing ideas and accelerating medical advances. To make the most of collaboration, **stakeholders must actively participate in system change**. Canada needs its best ODT minds at the table to guide the system's growth and evolution. Engagement is vital to access the broadest range of viewpoints and expertise—and to ensure the system benefits from the best possible ideas.

The fourth way to capitalize on cooperation is to **optimize research and innovation**. Indeed, the collaborative efforts of Canada's provinces and territories could, for example, propel the rapid development and implementation of new and more effective organ donation and transplant practices.

*System Priority:***STRENGTHENING THE SYSTEM'S INFRASTRUCTURE AND CAPABILITIES**

This priority refers to the improvements in resources, skills, culture and technology that are needed to support transformation to an integrated ODT system.

Strengthening the system's infrastructure and capabilities means, among other things, **building a commitment to ODT among senior health care administrators and professional associations**. Support for ODT depends on the commitment of senior personnel who influence hospital priorities and resources, for example. By standing behind organ donation and transplantation, these professionals promote it as a standard of care; they influence and empower physicians, surgeons and other practitioners to do their part in identifying and referring potential donors and improving donation rates.

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*In an integrated system, a robust information-technology network is essential to ensure consistency across the provinces, and to provide the data needed to drive performance improvements.*

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To accommodate these increases and improvements, the system must **develop sufficient skills and capacity**. This means the right number of professionals with the right skills, to ensure the right things happen.

**Ensuring access to hospital infrastructure** will enable the system's professionals to carry out their work effectively. Just as important, it builds donor and patient trust in the system. When ICU beds, operating rooms and follow-up care are as accessible to ODT as to other medical disciplines, then every potential donor can be identified, every viable organ can be recovered, and every possible transplant can be carried out.

These and other efficiencies can be realized when ODT activities are better coordinated within and among provinces, and when the system can **provide enabling technologies to coordinate processes**. In an integrated system, a robust information-technology network is essential to ensure consistency across the provinces, and to provide the data needed to drive performance improvements.

Funding is a central challenge in health care, particularly amid continually rising costs and competing priorities. The proposed ODT strategy aims to **optimize current funding**, partly by removing inefficiencies, duplication and financial barriers that actively discourage donation. Making the most of current funding also means leveraging those programs and services that function well today. But more money will be needed to support the increased number of donations and transplants. The system needs to **ensure that adequate resources are available to fund all components of the donation and transplantation process**, whether they occur in the ICU, the operating room or the laboratory. Adequate resources will help ensure that Canadian patients have timely access to life-saving and life-enhancing services that are sustainable into the future.

**SOUND DECISIONS BASED ON HARD EVIDENCE**


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*ODT system officials will always make decisions based on medically, scientifically and socially sound evidence. The system will collect, evaluate and analyze data, and adapt in response to new information. Broad stakeholder input will help ensure that decisions have democratic legitimacy, especially when conflicting perspectives exist.*

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## MEASURING PROGRESS TOWARD OUR GOAL

How will we know when performance has improved? Without question, a systematic, evidence-based approach will permit detailed analysis. At a high level, however, we can tell progress is being made when we see, within five years:

- growing public and health-care professional confidence in all aspects of the ODT system;
- an increase of 50 per cent in the number of donations from deceased donors, and in the number of transplants;
- a significant drop in the number of people who die while on transplant waitlists; and
- a decrease in the variability of wait times among provinces.

## BUILDING A BETTER SYSTEM

The next chapter presents recommendations for an integrated, inter-provincial ODT system—a system that inspires public and ODT-professional support and participation, and that ensures fair access to organ donation and transplantation for more Canadians. Canadian Blood Services and the Organ Expert Committee believe that a system that does both—a system that performs optimally for Canadians and meets the priorities set out in this chapter—will be sure to stand strong among the high performing ODT systems of other countries such as Spain and the US.

### KEY CONSIDERATIONS

With a clear sense of where improvements are needed—and where we can make the most of existing strengths—the Organ Expert Committee expressed its vision for ODT in Canada. Specifically: by 2017, Canadian patients will have a trusted, integrated transplant system that performs among international leaders.

The Organ Expert Committee believes this vision can be realized through a strategy that focuses on five system priorities:

- Increase donation to give patients the best chances to receive transplants, with optimal outcomes.
- Ensure fair access to transplants for all patients.
- Earn the public's trust through transparency and accountability.
- Enable collaboration among provincial stakeholders.
- Strengthen the system's infrastructure and capabilities.

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# ODT SYSTEM RECOMMENDATIONS

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## INTRODUCTION

These recommendations identify the activities and processes that are required to execute the ODT system strategy to improve the system for patients, families and health providers. The intent of these recommendations is not to replicate efforts or roles that are already in place and working well at the local and provincial levels, but rather to build on these elements as a foundation for future success. As a result, many elements of the proposed recommendations represent a continuation of current structure and activity. In some areas, however, opportunities for improvement have been identified, both in terms of inter-provincial activities as well as those within provinces.

### Building on current strengths

Hospitals that provide organ-donation services will continue to do so through their emergency departments and critical care units; organ procurement organizations will continue to work with their hospital partners to promote and facilitate organ donation; other programs will continue to support living donors; and transplantation programs will continue to provide services to patients. The provincial ministries of health will continue to determine the appropriate accountability and reporting relationships for these organizations, through transplant agencies, regional health authorities, or local health integration networks (LHINs).

Canadian Blood Services will continue to provide registry services, leading practices, policy development, and awareness and education. It will also provide leadership and coordination in areas where inter-provincial collaboration and integration are required.

Organizations that currently play a role in regulations, standards, and auditing—such as Health Canada, the Public Health Agency of Canada, the Canadian Standards Association and Accreditation Canada—will continue to do so.



**ROBBIE THOMPSON** *One transplant would be enough stress for any individual and his family. Robbie had two by age five. His mother Sue recalls how incredibly ill he was before his first heart transplant. As an infant, he suffered several cardiac arrests, each with the potential to end his life.*

*Dr. Sam Shemie, a paediatric intensive care physician at Montreal Children's Hospital, remembers the agony he witnessed at Robbie's bedside as the boy's family waited more than 10 months for a suitable heart.*

*"Transplantation is heroic," says Shemie. "Heroic for the patient, heroic for the donor, heroic for both their families."*

*With only days to live, Robbie finally received a heart. Today, his mother thinks often of the donor and his family, and about how their loss gave her son another chance.*

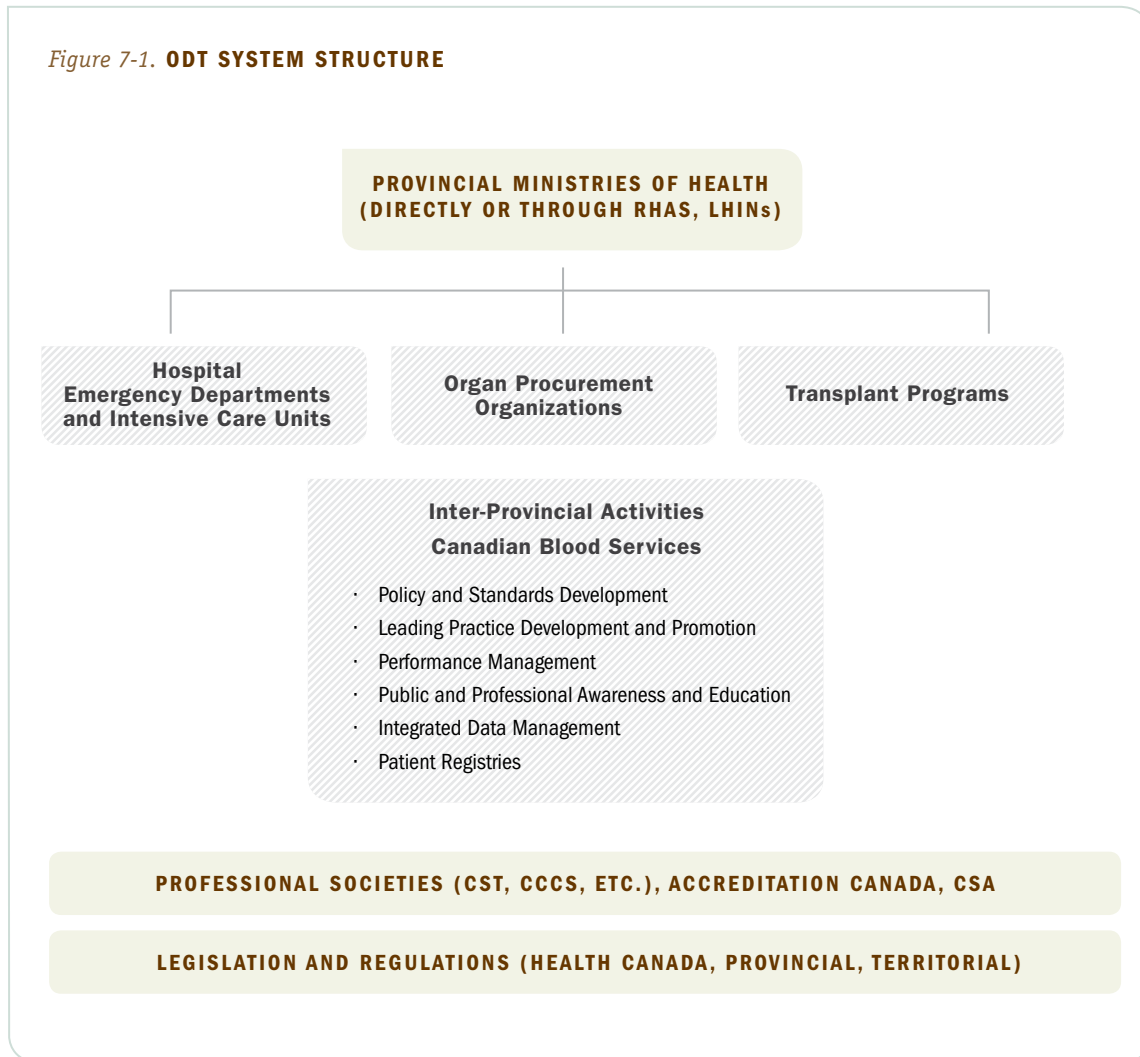
*"No form of 'thank you' could ever express the gratitude we feel."*

**New or expanded roles**

What is being recommended is the addition of a combination of new structures, relationships and focused initiatives that will provide clarity to fill in gaps and drive performance improvements. In some cases, an expansion of current activities and funding is being proposed. The system’s new or expanded elements include:

- an accountability framework that includes an explicit inter-provincial governance structure,
- the availability of donation physicians who provide leadership in creating a professional and organizational culture of donation,
- a focused public awareness strategy that is linked to intent-to-donate registries,
- a formal education program for health care professionals that is linked to leading practices for donation,
- a comprehensive, inter-provincial registry system, and
- infrastructure that supports all areas of ODT, including data management and analytics, focused ODT research and innovation, and frontline funding to support increased donation and transplantation activity.

Figure 7-1. ODT SYSTEM STRUCTURE



## RECOMMENDATIONS – ACCOUNTABILITY

**1. An integrated inter-provincial ODT system involves numerous programs, organizations and jurisdictions whose shared goal is to improve performance system wide. A governance structure is essential to clarify and enable the shared accountability and respective roles and responsibilities of those participants in the integrated system. It is therefore recommended that the federal, provincial and territorial governments establish a formal accountability framework that outlines the structure and essential attributes of—and roles and responsibilities within—an integrated ODT system. Such a framework would enable the system as a whole to achieve and be evaluated against stated goals.**

Inter-provincial cooperation is a necessity in the ODT system. The acute shortage of organs means provinces and programs must share organs to minimize the number of deaths of critically ill patients on waitlists, and to optimize benefits for Canadian patients with end-stage organ failure. Because some regions of the country are centres of excellence for particular types of transplants, not all provinces maintain transplant programs for all organs, and patients must move across provincial borders to access transplantation services. Sharing resources, knowledge and tools for leading practices and standard policies decreases the cost of development and improves quality of practices, policies and tools.

The current system lacks a formal, recognized governance structure in which to coordinate ODT activities. While there are existing, traditional organizational accountabilities, there is a lack of shared accountability, not only between provinces but also between programs. There are few consequences for poor performance, missed donation opportunities, or wastage of organs. With few documented processes, and limited communication associated with these activities, service providers have expressed confusion and a lack of trust in the system. There is no common strategy that can align and drive all parts of the system collectively to breakthrough performance improvements.

International experience has shown that leading ODT performers such as Spain, the United States and the United Kingdom have strong accountability frameworks that are supported through legislation and formal recognitions of mandate. This approach provides the ability to drive performance improvement and adherence to standards and guidelines, and offers a consistent forum for decision making. It also removes arbitrariness and improves trust among partners.

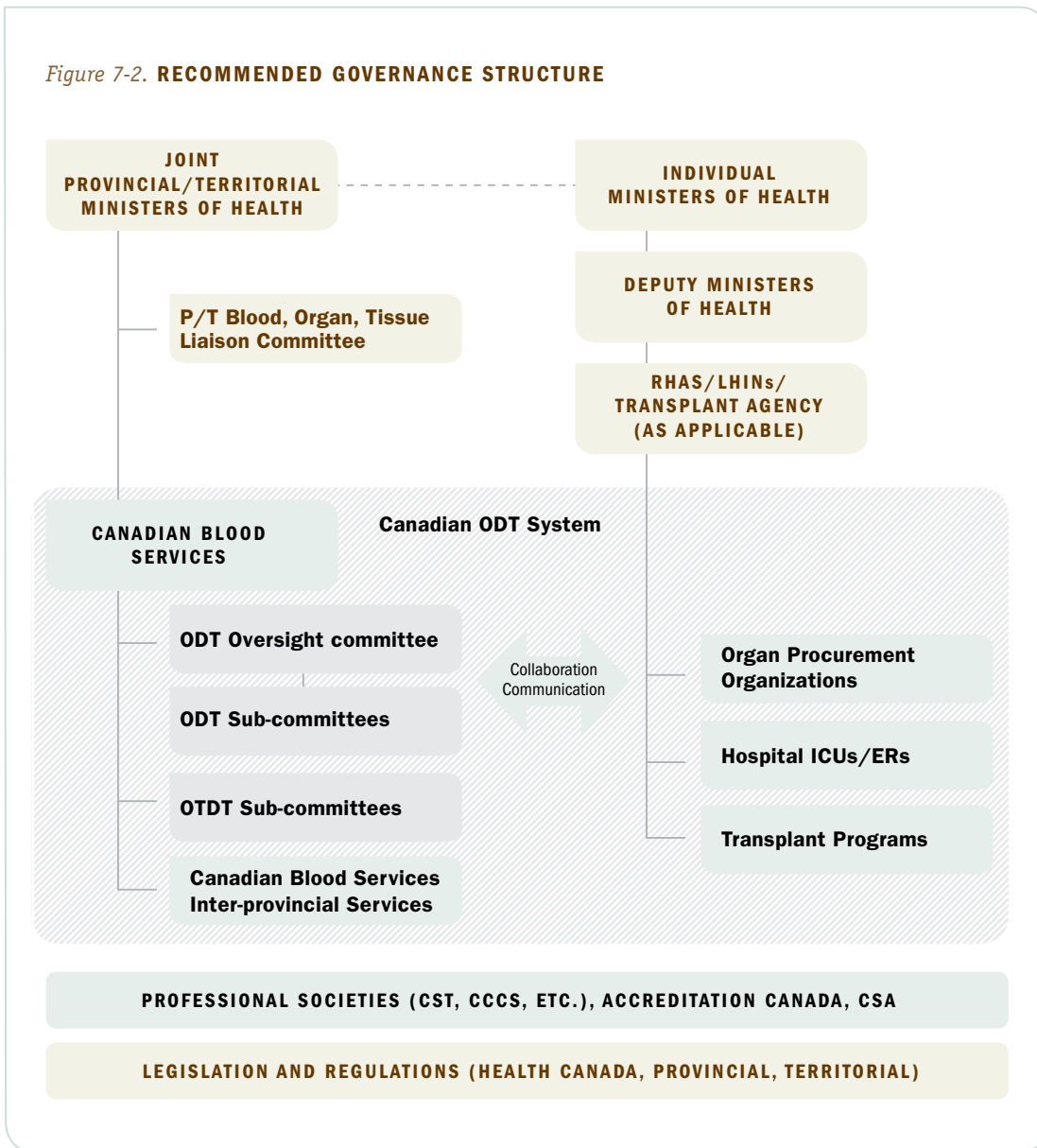
In the countries listed above, strong frameworks that enable cooperation, collaboration and shared accountability have been proven to increase system performance. Applied in Canada, such a framework—which could be supported by a memorandum of understanding or a similar mechanism—would produce better, consistent policies that improve fairness and access for patients. It would deliver better data and focused research and analysis to improve processes and provide better outcomes for transplant patients. By encouraging all system partners to work together to increase the number of donors—and the number of transplants by extension—the Spanish, American and British systems realized breakthrough results. The same can be expected of the Canadian system.

The following recommendations describe the proposed governance structure and the enablers required to make the ODT system function as an integrated entity. It is essential that roles and responsibilities be clearly defined, and that the federal, provincial and territorial governments provide the mandates and resources to organizations to enable execution of these roles. It is equally important that these roles are transparent and endorsed by all system stakeholders.

2. As part of the formal accountability framework, it is recommended that specific governance structures be created (Figure 7-2). Among these is an ODT oversight committee that is broadly representative of the ODT community in all jurisdictions and is supported by a series of advisory committees. Reporting to the provincial and territorial ministers of health, through Canadian Blood Services, the governance structure would enable the development, monitoring and improvement of inter-provincial strategy and policy, and performance against stated goals.

One of the key principles in developing a governance structure for ODT is the requirement for broad base participation in decision making by key stakeholders. The community has called for strong leadership of a comprehensive coordinated system and shared ownership and governance in the inter-provincial system.

Figure 7-2. **RECOMMENDED GOVERNANCE STRUCTURE**



To achieve this goal, it is proposed that a series of committees—reporting to and supported by Canadian Blood Services—be created to ensure oversight for inter-provincial policy and strategy development, and to monitor performance and compliance. The structure would include an ODT oversight committee and supporting sub-committees with broad representation across all jurisdictions, professions and parts of the system.

### **ODT Oversight Committee**

The oversight committee would oversee the development and adoption of inter-provincial policies and monitor overall system performance. The committee would:

- set inter-provincial performance targets and expectations,
- review system performance and make recommendations for change,
- develop an overarching inter-provincial policy framework,
- develop (or initiate the development of) policies or responses to address system issues,
- review policies from sub-committees to ensure prioritization, integration and consistency among policies and groups,
- develop (or initiate the development of) policies or responses to challenges related to international issues or questions on behalf of the Canadian OTDT community,
- ensure that structures and mechanisms are in place for reporting and reviewing system performance and compliance,
- ensure that structures and mechanisms are in place to ensure transparency of system performance and compliance,
- liaise with provincial organizations and governments, through individual committee members, to influence, inform and ensure positive change in provincial systems, and
- guide program development for inter-provincial registries and information management services.

### **Sub-committees**

The sub-committees would report to and support the work of the ODT oversight committee. They would provide expertise and advice in the following areas: living donation, deceased donation, kidney, pancreas and islet transplantation, liver and small bowel transplantation, heart transplantation, lung transplantation, paediatrics, analytics, HLA, research and audit.

Specifically, these sub-committees would:

- identify requirements for policy development,
- develop (or initiate the development of) these policies,
- monitor and review the impact of policies to effect evidence-based improvements to the ODT system,
- monitor and review international ODT developments to effect evidence-based improvements to the ODT system,
- review performance and make recommendations to the ODT oversight committee, and
- liaise and report back to the broader ODT medical community, including professional societies such as the Canadian Society of Transplantation.

Because there is overlap between organ and tissue donation and transplantation in areas such as deceased donation, infectious diseases, public and professional awareness and education, specific committees may be formed to address the need for common policy for both these groups.

It was noted throughout the public and expert engagements that public input—including the views of patients, donor families and the public at large—into the system is essential. Because of the special nature of human tissues and organs, it has also been recommended that ethics review and consultation be integrated into the decision-making process. Representation from the public, patients and ethics experts will be incorporated into the governance structure.

**3. Transparency of system performance is essential to ensure accountability, enhance performance and drive best practices. Transparency is predicated on the availability of data to assess performance and monitor compliance. It is therefore recommended that the accountability framework identify mandatory data reporting and review and system-wide audit capability as integral components of the integrated inter-provincial system.**

In the proposed accountability framework, transparency of system performance is the key mechanism that drives accountability. Improved transparency at the program and system levels will enable evidence-based system evaluation and improvements. It will also increase trust by both the public and health care professionals.

In addition to their roles in developing policies in transparent and collaborative ways, committees will ensure that information on the ODT system is available to the public in an understandable and easily accessible fashion. Canadian Blood Services will support the committees by developing and implementing mechanisms (such as websites) to allow easy public access to information. The public and patients will have the ability to provide input into policy and participate in the system through the committees. Public awareness and education of the system will be another mechanism used to improve transparency.

By themselves, however, these efforts will not be enough to ensure transparency. Two other key enablers have been identified as critical in improving transparency and driving accountability: mandatory data reporting and auditing.

### **Mandatory data reporting**

The ODT community, as well as organizations involved in treatment of end-stage organ failure (ESOF), using technologies such as dialysis and mechanical heart devices, have consistently identified the need for timely, accurate and comprehensive data to evaluate system performance. The current environment is plagued by too many gaps that result in an incomplete view of system performance: not all the required information is collected, not all information is received or analyzed in a timely manner, there is little verification of the quality of the data, and data reporting is not conducted in a timely fashion. The current environment also suffers from the lack of a responsive, modern information-technology system to manage data. As a result, it is difficult to evaluate the system and make evidence-based improvements.

Given the essential role data plays in the system, it is recommended that data collection and reporting be mandated activities for all ODT organizations. It is also important that the system's data-reporting structures support improvements to the continuum of care for patients with end-stage organ failure, given the tremendous impact this type of care places on the health care system. It is critical that organ transplantation data be linked to other data points along the continuum, from end-stage organ failure, through bridges (e.g., dialysis and artificial assist devices), and to transplantation outcomes. As such, it is also recommended that data reporting be mandated for ESOF programs.

Through the committee structure, Canadian Blood Services would work with the Canadian Institute for Health Information (CIHI), the Canadian Organ Replacement Register (CORR) and other key stakeholders to develop mandatory data-reporting requirements and processes for ODT organizations. (For more information, please see recommendation 10 on data management.)

### **Auditing**

Given the recommendations for data reporting and policy and practice compliance, it is also recommended that auditing be a mandated activity in the inter-provincial ODT system. Independent auditing of ODT processes would reinforce compliance to inter-provincial policies, reporting requirements and sharing agreements. It would also ensure that the data being provided is accurate and meets requirements. The ODT committees would establish the framework, rules and scope for audits.



The following areas were noted as being required for inclusion in the scope of the proposed audits:

- **Data provided to patient registries:** Allocation and offer-acceptance decisions are based on data entered into the patient registries. Given the criticality of this information, it is recommended that Canadian Blood Services perform regular auditing of data being provided to the registries.
- **Compliance with clinical policies:** An independent peer group should audit transplant programs to ensure that clinical policies are being followed. For example, since allocation decisions are based on the assignment of urgency status for patients on waitlists, it is critical to verify that status levels are being properly applied.
- **Supplemental data provided for information management:** In addition to required registry data, supplemental data may be required to be reported to Canadian Blood Services or CIHI for information management purposes. Periodic audits for reporting compliance and quality should be conducted by Canadian Blood Services.
- **Compliance with inter-provincial policies (non-clinical):** Service-delivery organizations should be audited against compliance with inter-provincial policies. Canadian Blood Services should be responsible for these audits, given that the organization is not responsible for frontline service delivery (other than registries), and given its experience in performing audits of both its internal operations and of external suppliers in its blood, plasma and stem cell activities. Canadian Blood Services could also manage data-reporting audits.
- **Registries audits:** It is recommended that a regular independent audit be performed on Canadian Blood Services' operation of the registries to ensure that it is fulfilling its mandate and is responsive to the ODT community.
- **Death audits:** It is recommended that audits of deaths be made at the case level (by hospitals and OPOs) and system level (by Canadian Blood Services) to ensure that all potential donors were identified and referred to OPOs.

Audit information would be submitted to the appropriate committees for review and recommended action. Where non-compliance with targets or policies is identified, the information would be made available to the programs involved. Performance and compliance would also be reported on a regular basis to the provincial and territorial governments. Each government would be required to act on non-compliance data with respect to the programs and organizations in their jurisdictions.

While the above audit areas have been identified as new requirements, it should be noted that several regulations and pieces of legislation for ODT have already effected positive change in the system, especially in defining the safety, ethical and legal frameworks in which to operate. The following organizations will continue to play an important role in driving system improvements:

- **Health Canada** regulates cells, tissues and organs, through the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* with the objective of assuring that biologics available to Canadians are safe, effective and of a high quality. Health Canada will continue to establish and maintain these regulations and audit for compliance.
- The **Canadian Standards Association** develops standards for cells, tissues and organs that are principally related to safety and effectiveness. Specific sections of these standards have been referenced by Health Canada's *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*.
- **Accreditation Canada** provides Canadian health care organizations with an external peer review process to assess and improve the services they provide to their patients and clients based on standards of excellence. Accreditation Canada has recently developed new standards for OTDT covering living donation, deceased donation and transplant services. The organization is also responsible for assessing accredited hospital against these standards.

- **Public Health Agency of Canada (PHAC)** has developed and is piloting the Cell, Tissue and Organ Surveillance System to track adverse events related to transplantation.
- Provinces and territories will continue to maintain **human tissue gift acts** in their jurisdictions, which regulate specific practices related to OTDT, such as consent, determination of death, definition of death, privacy, non-commodification of organs and tissues, liability and mandatory referral. Where possible, these practices should be aligned to ensure they are not barriers to national leading practices to optimize donation and transplantation in Canada.

## RECOMMENDATIONS – DONATION PHYSICIANS

**4. It is recommended that donation physicians be available to all hospitals that provide donation care. They will provide leadership in creating a professional and organizational culture of donation. They will drive organ and tissue donation care throughout the system, including the provision or administration of clinical services such as donor identification, referral, consent, donor management and organ utilization. Their areas of responsibilities will also include professional education, performance measurement, accountability, quality assurance, family support, media relations and research.**

The presence of donation physicians (generally critical care specialists) who are funded and have responsibility and accountability for organ and tissue donation in hospitals is one of the key contributors to increased and sustained donation performance internationally. In Spain, for example, the donation physician role is credited with increasing that country’s donation rate to more than 30 donors per million population—one of the highest in the world. In Australia and the United Kingdom, increases in donation performance have been attributed to recent reforms that included the introduction of donation physicians at local levels and with links to the respective national ODT coordinating bodies. Since the system-wide introduction of donation physicians, there has been an increase in the number of deceased organ donors by 56 per cent in Australia<sup>1</sup> and 28 per cent in the United Kingdom.<sup>2</sup>

Currently in Canada, the responsibility for donation in hospitals is generally left to physicians in ICUs who may not have the necessary time, training or commitment to make donation a standard part of end-of-life care. Accountability for donation at the hospital, senior leader and individual levels is lacking. Consequences for missing potential donors are minimal to non-existent. As a result, many donation opportunities are missed or ignored.

ODT system stakeholders agreed that the integration of donation physicians with donor coordinators and hospital donation teams will drive increases in all forms of deceased donation in Canada. The donation physician should assume a leadership role in donation care, education, quality assurance and performance management that is separate and distinct from attending physicians providing care in intensive care units. Specifically, the donation physician will:

- promote a culture of organ and tissue donation,
- facilitate the donation discussion with families to ensure that donors’ expressed wishes are acted upon,
- provide clinical leadership within the hospital and broader community on organ and tissue donation,



↑ International experts **Dr. Dale Gardiner** (U.K.), **Dr. Xavier Guasch** (Spain), **Dr. Raghavan Muragan** (U.S.) and **Dr. Gerry O’Callaghan** (Australia) addressed Canadian critical care physicians on the value of donation physicians.

<sup>1</sup> DonateLife Australia, News Release, January 18, 2011 [www.donatelife.gov.au/News-and-Events/News/Media-Releases/2010-Organ-donation-figures-show-record-high.html](http://www.donatelife.gov.au/News-and-Events/News/Media-Releases/2010-Organ-donation-figures-show-record-high.html)

<sup>2</sup> NHS Blood and Transplant News Release, January 23, 2011. <http://www.nhsbt.nhs.uk/news/2011/newsrelease210111.html>

- serve as a clinical resource, educator and champion to improve all aspects of deceased donation (e.g., identification, referral, ICU access, consent, donor management, recovery and utilization),
- provide consultation and support to ICU teams and assist in bedside donor care as required,
- lead performance management, quality improvement and quality-assurance activities for donation,
- facilitate donation opportunities in regions that are challenged by geographic disparities through telephone consultations, advocacy for transport, facilitation of operational issues and web-based education,
- serve as a source of knowledge and advice regarding the ethical and legal aspects of organ and tissue donation and manage disagreements that may arise,
- provide consultation to referral hospitals in the identification, management and transfer of potential donors through use of technology (such as telemedicine and remote monitoring) and existing infrastructure (such as ICU bed-allocation systems),
- facilitate or provide education and training to physician colleagues, physician trainees, other health care professionals on organ and tissue donation and ensure the development of local educational and training opportunities in collaboration with Canadian Critical Care Society, Royal College of Physicians and Surgeons, universities and other professional societies, and
- facilitate research on organ and tissue donation.

The domain of the donation physician should encompass the entire hospital and extend to the pre-hospital and emergency medical-services environment. It is recognized that factors such as geography, system capacity and the availability of qualified physicians will impact how the role will be implemented across the country.

Internationally, donor coordinators work in close collaboration with donation physicians. In Canada, donor coordinators are integral members of donation teams. Collaboration among donation physicians and coordinators must occur to realize improvements in organ and tissue donation activities and develop the donation culture.

Benefits for the system include:

- clear leadership and advocacy for organ and tissue donation processes and practices.
- recognized oversight of, and responsibility for, donation performance measurement and quality assurance.
- access to trained physicians who are knowledgeable about, and capable of supporting, potential donation opportunities—for attending ICU physicians, ICU teams and donor coordinators.
- access to expert consultation, support and education and training—for organ and tissue donation for hospital and OPO staff.
- access to physicians who can advise hospitals and OPOs in the implementation of donation leading practices.
- availability of knowledgeable physicians who can support or discuss donation with the families of potential donors or otherwise support consent conversations as needed.
- a resource to support the discussion of ethical issues and manage potential conflicts.
- a resource to facilitate research on organ and tissue donation.
- an increase in the number of organ and tissue donors.
- hospital donation practices will be informed by death-related data from the emergency department to the intensive care unit including clinical triggers, which should translate into improved transplant outcomes.
- death related data and transplant outcomes will inform critical care decisions on resource allocation.

### Implementation strategy

Implementation of the donation physician role will require time—to establish the roles and responsibilities and align with, and support, existing donation personnel and practices across the country. Building on the Donation Physician Consultation report, further work with the Canadian Critical Care Society and consultation with the ODT community and governments is required to develop all aspects of the role, including structure, number and distribution, reporting relationships, accountability and performance requirements, and remuneration. Inter-provincial coordination and leadership through a national donation physician's network is required to support development of this new role. Such a network will enable planning and development as well as ongoing sharing of leading practices, addressing system-level issues of accountability and performance, and further work to support creation of a culture of organ and tissue donation. Canadian Blood Services will lead this network in partnership with the CCCS, OPOs and OTD stakeholders. The development work will take approximately one year to complete.

It should be noted that Manitoba and Ontario have established, or are in the process of establishing, donation physician roles, with greatly differing models. The leadership and experiences of these provinces will be leveraged during the development phase.

## RECOMMENDATIONS - PUBLIC AWARENESS AND INTENT TO DONATE

**5. The disconnect between support for donation and action results from the absence of a clear call to action, the absence of system mechanisms to support that call to action, the prevalence of barriers to accessing intent-to-donate information, and the many inconsistent practices within the current system. It is therefore recommended that an ongoing, sustainable and national public-awareness strategy be developed to increase the probability of donation. Such a strategy will focus on increased discussion with families, and will promote and improve action to support decisions to donate. It is also recommended that a robust national communications plan be developed to support the strategy, with a specific focus on promotion in the media.**

A variety of Canadian organizations currently support OTDT public education and awareness activities. However, because they are funded differently, and often do not collaborate with one another, these activities are characterized by very different sets of messages whose effectiveness often goes unmeasured. In contrast, OTDT systems in countries that have high donation rates, such as the United States and Spain, feature a number of commonalities. They offer dedicated and consistent funding for education and public-awareness activities. They deliver consistent messages about the importance of donation at the local, regional and national levels; direct and clear calls to action that encourage people to register their intent to donate or to speak with others about their donation wishes; and audience-specific campaigns targeted at, for example, youth, ethnic and faith groups. All these tools are incorporated in comprehensive communications approaches that span direct media, social marketing, print media and others. A similar approach should be taken in Canada.

Although Canadian Blood Services has recently focused its efforts on conducting research and understanding how to move from intent to action, it is well positioned to build and implement an inter-provincial public-awareness campaign. It has a history of building national marketing programs related to blood and stem cells with a sophisticated strategy-development capability and can leverage partnerships with marketing agencies and patient-group partners. Furthermore, the organization will be able to leverage the wealth of research and community input collected by the former Canadian Council for Donation and Transplantation (CCDT) to develop an effective public awareness strategy that marries a strong call to action with mechanisms that track intent-to-donate.

Organizations and provincial programs would be able to use an inter-provincial public-awareness campaign to bolster their existing strategies. Although these organizations will incur some cost to implement this program at the regional and local levels, they would pay far less to use this approach than they would if no

centralized strategy existed. In addition, consistent national messages are more effective at building public awareness than localized efforts. It is important to the success of this recommendation that organizations leverage nationally produced tools to support their local efforts.

**6. It is recommended that the Canadian OTDT system be supported by intent-to-donate registries and that:**

- existing provincial intent-to-donate registries continue to be supported and enhanced,
- Canadian Blood Services develop and host registries for provinces where none exist, and
- Canadian Blood Services work with provinces to drive a consistent call to action, a consistent mechanism through which people can register their intent to donate, and best practices for intent-to-donate registries, thereby enabling Canadians to optimize the call to action, and declare their wishes regarding donation.

OTDT stakeholders indicated that they expect the system will support the expressed intent of people who wish to donate. There is clear evidence that families are much more likely to consent to organ or tissue donation if they are aware that loved ones have previously indicated their wishes to donate.<sup>3,4</sup> Moreover, it is largely recognized that attending physicians are more likely to take the necessary steps to enact organ- and tissue-recovery processes if they are aware of patients' wishes to be donors. Both of these points underscore the need for Canadians to make their wishes known with respect to donation, and for mechanisms to be created to capture and document this intent, and make it available whenever donation opportunities arise.

The ways to register commitments to donation differ among provinces. They include: consent on provincial health care cards, mail-in forms, online registration, driver's licenses and organ donor cards. In some provinces, registration automatically adds names to donation databases that are accessible to organ procurement organizations. In other provinces, registration is indicated on health cards or wallet cards. As a result of these inconsistencies, intent-to-donate information is not always made available to health care professionals in a direct and timely way.

The public has consistently indicated that the current process for indicating consent is confusing. Canadians want simple and clear directions that are reinforced by public-awareness campaigns.

Although many of the world's top-performing international systems use intent-to-donate registries, there is insufficient evidence to prove that these registries increase donation by themselves. Expert opinion indicates, however, that when registries are designed and used in optimal ways, they enable frontline staff to access registry information, enable the public to document and view personal wishes, and enable programs to monitor the impacts of public-awareness campaigns.

Members of the Canadian OTDT community expressed their support for intent-to-donate registries. It was agreed that the registries should be implemented in all programs. In those jurisdictions where significant investments in registries have already been made, planned developments and improvements should not only continue, but also be leveraged. Where provinces do not have intent-to-donate registries, Canadian Blood Services should develop and host these registries.

<sup>3</sup> Rodrigue, J. R., D. L. Cornell and R. J. Howard, "Organ Donation Decision: Comparison of Donor and Nondonor Families," *American Journal of Transplantation* 2006; 6: 190–198.

<sup>4</sup> Unpublished data from Trillium Gift of Life Network, Ontario.

Canadian Blood Services should continue to work with the OTDT community to review leading practices and the experiences of other intent-to-donate registries. The organization should establish guidelines that will inform the development and construction of new registries, as well as improvements to existing registries. Under this approach, provincial registries should be encouraged to align messaging around organ and tissue donation and strive toward consistent approaches for registering intent-to-donate wishes.

## RECOMMENDATIONS - LEADING PRACTICES

**7. Countries with high donation rates have shown that the development, support and consistent implementation of leading practice guidelines have significant, positive impacts on system performance. It is recommended that OTDT leading practice guideline development continue to be the responsibility of Canadian Blood Services, and that these guidelines be appropriately communicated to the OTDT communities and supported with the tools and resources necessary to enable consistent implementation.**

Canadian Blood Services has a successful history of developing and supporting leading practice guidelines in OTDT. In fact, the CCDT, and now Canadian Blood Services, have developed a number of specific leading practice guidelines that have significantly improved OTDT in this country.

In Canada, leading practice guidelines have enabled improvement in a number of areas including medical management to optimize organ potential, enhancing living donation, neurological determination of death, and donation after cardio-circulatory death (DCD). Leading practice guidelines can have a substantial impact on system performance. For example, following the development of the leading practice guideline for DCD the Canadian Critical Care Society lifted its moratorium on DCD. As a result, six provinces have established DCD programs and more than 300 transplants have since occurred.<sup>5</sup> In addition, leading practice work related to kidney transplantation was the first step toward the implementation of the patient registries now in place or being developed, including the Living Donor Paired Exchange Registry and the Highly Sensitized Patient Registry.

OTDT leading practices in Canada are developed through broad consultations with experts and the OTDT community. As background for these discussions, there is extensive material and data reviewed and prepared: national and international legislation, policies and practices related to the issue, commissioned surveys, background papers, and consultations with national and international experts. Once established, leading practice guidelines are communicated to the community and supported with appropriate tools to enable consistent implementation. Leading practice guidelines also are regularly reviewed to ensure evolution as knowledge and practices change.

Although leading practices can often be implemented by organizations—and at minimal costs—significant resources are needed to develop and support leading practice guidelines. For this reason, Canadian Blood Services should continue to provide this service for both organs and tissues and in the areas of donation and transplantation.

Canadian Blood Services will focus initially on developing leading practices in two areas: required referral and family support. These are areas where improvement is needed and where leading practices are considered to have value. Required referral of potential donors ensures that every hospital death or imminent death



↑ **Dr. Shaf Keshavjee**, Director, Toronto Lung Transplant Program, and member of the Organ Expert Committee.

<sup>5</sup> CIHI/CORR 2010 data

is referred to the local organ procurement organization for consideration for potential organ and/or tissue donation. By implementing such a policy, opportunities for donation are less likely to be overlooked. Generally, referral is linked to a set of clinical triggers and clinical inclusion and exclusion criteria that are readily available and agreed to by the clinical community. Canadian Blood Services and the former CCDT have previously worked with communities in New Brunswick and Cape Breton to develop clinical triggers. Both initiatives increased referrals for those locations and, in the case of New Brunswick's protocol, provided the basis on which other countries have established clinical triggers for required referral. This work will continue to drive toward higher uptake and consistent performance in other areas of the country.

Donor families are of necessity provided with a high level of support from organ and tissue donation organizations in each province; however, the programs and the resources applied differ greatly from province to province. The OTDT community has expressed the desire for Canadian Blood Services to develop a nationally coordinated and consistent approach to support and honour families that would be delivered locally, and for programs to share best practices. The community has also indicated its desire to see leading practices for bereavement and family support services identified, developed and disseminated so that they can be delivered through provincial programs.

## RECOMMENDATIONS - PROFESSIONAL EDUCATION

**8. Although professional education on organ and tissue donation and transplantation does occur, there is no consistency in approach, leveraging of resources or evaluation of effort. Thus it is difficult to measure the value that accrues to system performance from the programs undertaken. The infrequency of donation opportunities in all but the largest intensive care units means that many health care professionals complete their training with little exposure to donation. It is recommended that Canadian Blood Services lead the establishment of a coordinated approach to professional education and awareness in medical, nursing and allied health programs with a view to creating a culture of donation and transplantation in the health care system.**

Organ and tissue donation occurs infrequently in all but the largest ICUs and tertiary care centres. As a result, health care professionals may have limited knowledge of the OTDT system. Many, including critical care staff, complete their training without being exposed to donation. It is therefore not surprising that there is a lack of awareness of donation and of the criteria, procedures and practices of donor referral and donor management that are appropriate and effective. This translates into a lack of professional commitment and support.

Health professionals must also be aware of the resources available for end-stage organ failure and transplantation services. Many of the leading practices associated with patient support and referral are poorly disseminated and could be aligned with existing programs. Poor access to information results in inconsistent management and referral practices for patients that could potentially benefit from transplantation.

Successful international organizations rely on programs that have been specifically developed to address organ and tissue donation. In Spain, for example, a formal training program has been expressly developed for donation physicians and health care professionals. The program was created with the support of the Institute for Life Long Learning at the University of Barcelona and the European Training Program on Organ Donation. This group offers an International Masters in Organs, Tissues and Cells Donation and Transplantation, with certification through the University of Barcelona. In the United Kingdom, donor services training for physicians and the health care professionals who work with them is provided through a professional development program commissioned by the National Health Service Blood and Transplant.

Currently in Canada, professional education on organ and tissue donation is delivered by regional OPOs, professional societies, tissue banks and transplant programs (e.g., in-services, grand rounds, conferences). There is, however, no consistency in approach, leveraging of resources and evaluation of effort among these organizations. It is therefore difficult to measure the value that accrues to system performance. Professional education is currently provided as opportunities and resources allow. The Canadian OTDT community has expressed a desire for more consistent, standardized professional education and awareness programs to promote a culture of donation among professionals and ultimately, increase organ and tissue donation. The Organ Expert Committee and Donation Physician Consultation recommended that Canadian Blood Services develop and integrate organ and tissue donation education into medical, nursing and allied health training curricula, and support continued education and awareness regionally.

The nature of professional education development, combined with the resources and expertise required to launch effective programs, make it essential that this initiative be a coordinated, inter-provincial effort. The OTDT community has expressed a desire for Canadian Blood Services to pursue this initiative by coordinating an ongoing nationally consistent and targeted program of recognized professional development and training. The organization's expertise in formalized training of health care professionals in transfusion medicine (including partnerships with the Royal College of Physicians and Surgeons of Canada) supports this recommendation. These programs will be delivered in consultation with relevant professional bodies and will build on and enhance existing programs offered through OPOs, transplant programs and professional societies.

## RECOMMENDATIONS - PATIENT REGISTRIES

**9. To enhance system-wide transparency, provide comprehensive standardized data, enable process and technology efficiencies, and leverage an existing shared investment, it is recommended that the scope of the patient registries that are currently being developed by Canadian Blood Services be expanded to provide a comprehensive, integrated inter-provincial service.**

A comprehensive registry system would include:

- a listing of all patients with end-stage organ failure who are waiting for organs,
- a listing of all deceased donors (potential, referred, consented),
- donor case management functionality to support OPOs in their management of donation activities, with more comprehensive donor data available,
- functionality to support provincial allocation policies in addition to inter-provincial urgent status allocation,
- tracking of patient outcomes, and
- the consolidation of comprehensive donation, transplantation and outcome data for reporting and analytics for all ODT stakeholders.

Building on the work conducted to date by Canadian Blood Services and the ODT community, an integrated inter-provincial registry system provides enhanced, shared-cost registry services for all donation and transplantation programs. A comprehensive registry management system will enable operational improvements and improved transplant utilization and outcomes. Its key features include:

- standardized donor and recipient information, virtual crossmatch and clarity of policies for optimal allocation of organs,
- electronic sharing of comprehensive donor clinical information for timely evaluation of organ offers,
- elimination, or significant reduction, of duplicate data entry to patient registries and CIHI,
- tracking and transparency of all listings, offers, and acceptances and declinations,



- reporting of inter-provincial sharing of organs,
- essential patient outcome data to inform improved medical practices, and
- tracking of inter-provincial organ sharing and balancing mechanisms to prevent net-export or import situations beyond agreed upon thresholds.

The registries will be one of the mechanisms that support and enable overall system accountability. The comprehensive system-wide data provided will allow for transparency into performance, allow for auditing, and provide consistent application of policies. It will also support analysis and research to support policy development to further improve patient outcomes. A shared inter-provincial registry will meet privacy requirements of all jurisdictions.

Cost savings can be realized by developing a system that can be shared by all provinces, as opposed to having each province develop or buy and maintain individual allocation and donor management systems.



↑ **Dr. Peter Nickerson**, Executive Medical Director, Organs and Tissues, Canadian Blood Services, and Organ Expert Committee member.

### Current system

There are many reasons why provinces share organs. Because of the shortage of organs, there is a need for inter-provincial and inter-program sharing, especially for patients who are critically ill and urgently need organs, and for patients who are difficult to match and need access to a large pool of donors. There are also opportunities to share when organs are available but local matches cannot be found. Provinces also collaborate on transplant patient care. Not every province has a transplant program for every organ type, and many patients receive their transplants and post-transplant care in different provinces. As a result, there is a requirement for inter-provincial data tracking and sharing.

Canadian stakeholders have long recognized the need for integrated patient registries. Studies in 1999, (by the House of Commons Standing Committee on Health), in 2005 (by the CCDT Highly Sensitized Patient and Living Donor Paired Exchange Task Force), in 2007 (in the House of Commons Information Management Blueprint) all recommended a Canadian ODT information management system to improve the situation.

In 2008, as part of its OTDT mandate, Canadian Blood Services was given the responsibility to develop three inter-provincial patient registries: a Living Donor Paired Exchange (LDPE) registry, a Highly Sensitized Patient (HSP) registry, and a National Organ Waitlist (NOW). These registries were created to meet immediate needs.

The experience of the last two years of registry development, combined with input from the ODT strategic planning process, has demonstrated that there is an opportunity and a need to expand the registries to ensure a comprehensive, integrated inter-provincial system that includes patient listing, allocation and donor case management. The recommendation from the Organ Expert Committee, which was echoed during the expert engagements, was for a single registry system that listed all patient and deceased donors, that supported both inter- and intra-provincial allocation, and that supported OPOs in their management of daily donation activities.

The ODT community did express concerns about rules for sharing of organs. Although community members recognized the necessity to share, some provinces and programs that have made significant investments and

efforts in their donation programs—and realized higher donation rates as a result—expressed a desire to create agreements that ensure there is not a large imbalance in the number of organs shared. It was agreed that inter-provincial sharing arrangements should be formalized through a broad consensus process, with the involvement of stakeholders.

There were also various opinions on allocation rules within a province. Some stakeholders felt strongly that provinces should all follow the same allocation rules when allocating organs within their provinces, to ensure consistency and fairness for patients across the country. Ultimately it was determined that provinces should have latitude in determining their own allocation rules, to take into account regional differences in donation activity, in medical practice and in patient population. The proposal is to develop national guidelines for organ allocation together. Each province will then apply these guidelines within its jurisdiction and set its own intra-provincial allocation rules.

### Current system components

The components of the current system that have been developed, or are in the process of being developed, are listed below.

#### 1. Living Donor Paired Exchange (Implemented)

Some patients who need kidney transplants have a spouse, a family member or a friend who is willing to donate a kidney to them. Many times, however, the patient and potential donor are not a compatible match—often because of ABO blood group or HLA tissue typing. These patient-donor pairs can sign up with the Living Donor Paired Exchange (LDPE) registry. The registry will then identify potential donor exchange opportunities for recipients anywhere in Canada. Should anonymous donors offer kidneys through the LDPE program, the registry will also identify donation chains that significantly increase transplants. The LDPE registry not only helps transplant recipients but also helps others on the kidney waitlist by removing recipients from the deceased donation waitlist.

The LDPE registry, developed by Canadian Blood Services in partnership with the kidney transplant community, was originally piloted in British Columbia, Alberta and Ontario. Today, all provinces participate. As of March 31, 2011, 69 LDPE transplants were completed.

#### 2. Highly Sensitized Patient Registry – Implementation targeted for 2011

There are some patients with end-stage kidney failure for whom kidneys can be very difficult to find. This is because these patients have developed HLA antibodies—through previous pregnancies, previous transplants or previous blood transfusions. As a result, the potential for organ rejection in these patients is very high. Sensitized patients, as they are known, comprise approximately 30 per cent of the population of Canadian kidney transplant waitlists, but receive less than five per cent of all deceased donor kidneys. Approximately 75 per cent of highly sensitized patients are women who have had children and who are waiting for their first organ transplants.<sup>6</sup> In 2005, a Task Force for the Highly Sensitized Patient registry recommended that a list of these highly sensitized patients be maintained, and that if a deceased donor kidney anywhere in the country matched a patient on this list, one of the available kidneys should be given to that patient.

Canadian Blood Services is now working with the transplant community to implement this registry. Once in operation, all deceased donors across the country who have kidneys to donate will be entered into the system. The registry will then determine if these donors are matches for highly sensitized kidney patients. Although this registry is being built for highly sensitized kidney patients, one of its important benefits will be the availability of extensive donor information that can also be shared with non-renal transplant programs when other organs are being offered.

<sup>6</sup> *Canadian Highly Sensitized Patient and Living Donor Paired Exchange Registries Task force Discussion Document*, Canadian Council for Donation and Transplantation, Oct 28-30, 2005.

### 3. National Organ Waitlist – Implementation targeted for 2011

The National Organ Waitlist (NOW) will be a patient registry that includes all non-renal patients across Canada who have end-stage organ failure and are waiting for transplants. It will replace the fax-based list maintained by London Health Sciences Centre. In the current system, updates are made weekly, and patient data and status are often outdated. The NOW registry will provide real-time, web-based access to address concerns with accuracy, completeness, security, privacy, transparency and traceability. Using the NOW registry, whenever organs are available, transplant programs and OPOs will consult the list on behalf of urgent status patients. The programs and OPOs will also be able to use the list for allocation to other patients.

### 4. Inter-provincial allocation for urgent status patients

Implementation of NOW is the first step to completing the registry for urgent status patients. It will be upgraded to automate the processes for allocation for urgent status patients. This functionality will be initiated once an interim governance structure is in place and stakeholders are engaged to review and confirm inter-provincial allocation policies for each type of organ. Establishment of the governance structure is underway, and will include representation from all provinces.

## Comprehensive registry system

The architecture of the registries was designed so that all components—current and future—would integrate and work together. A solid foundation is in place thanks to the development of:

- information technology servers, networks and communications,
- common data elements and standardized definitions,
- expert staff and established relationships in the ODT community,
- an advanced business intelligence platform and complex modeling and simulation tools, and
- allocation engines.

This infrastructure and data can be leveraged to complete the remaining components of the system described below.

#### 1. Donor case management

Many OPOs have expressed interest in a donor case management program that tracks the details of the donation process, including potential donor identification, bed-side donor management, test requisitions, offer management, and recovery and shipping logistics. These programs can guide workflow and activities during donor management. Because much of the information is needed for both the inter-provincial registry and for donor case management, it makes sense to integrate this functionality into a single platform. Development of this module will leverage the work already available in the Highly Sensitized Patient donor management module. A common system would also alleviate the need for each OPO to develop or buy and support its own system. Donor case management should therefore be considered an integral part of the registry.

#### 2. Provincial allocation and offer management

The same functionality that will allow automated allocation and offer management for inter-provincial organ sharing will also be made available for individual provinces. Provinces continue to be responsible to set and enforce rules for intra-provincial organ allocation and individual donor case management. Once provinces have developed their own allocation rules for allocating organs within their provinces, Canadian Blood Services will program the system individually for each province.

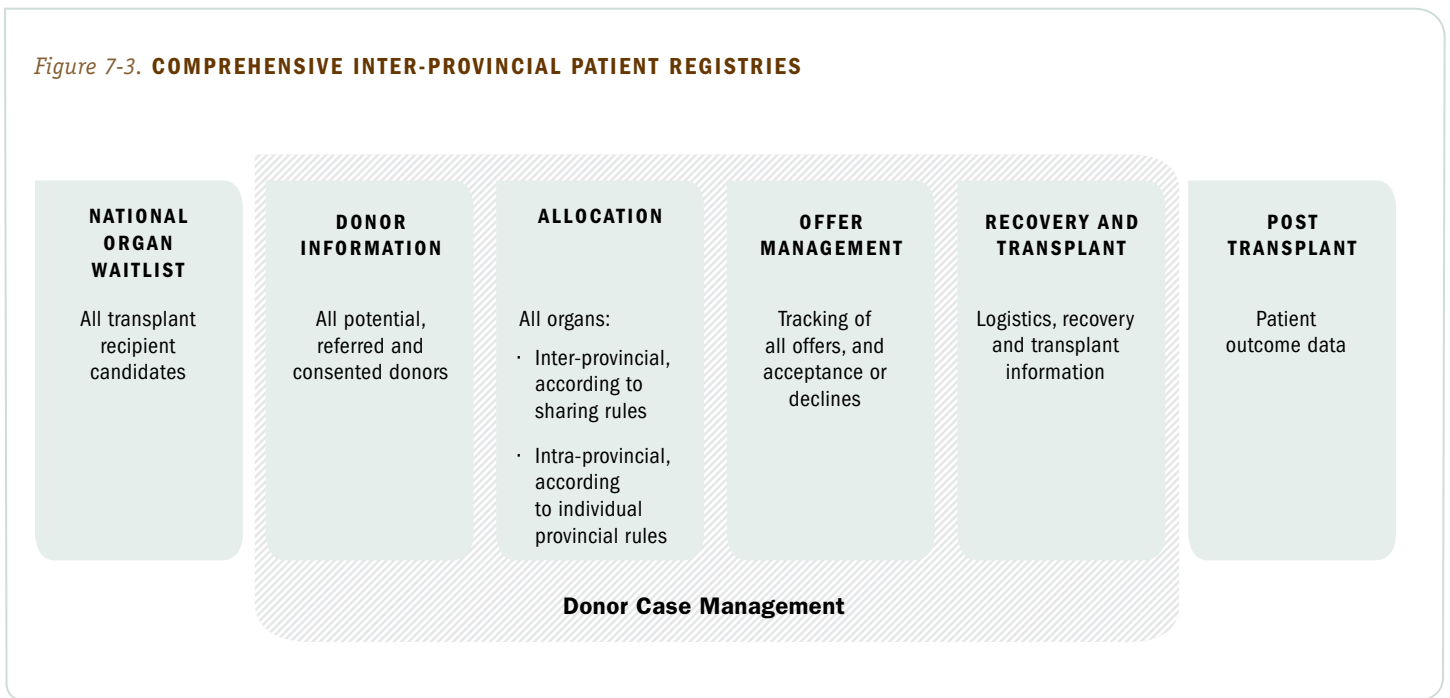
Canadian Blood Service will act as the registry operator to the programs. It will develop and maintain the registries and coordinate the development of common policies and algorithms that enable the registries. This approach alleviates the need for each province to develop or buy and support duplicate systems. It also takes advantage of investments that have already been made in the registries, provides data integrity and integration, and mitigates the requirement for data feeds and duplicate data entry.

**Implementation and transition**

It is recognized that there is a large gap between the current environment and the goal of a comprehensive, integrated inter-provincial system. Because of the number of organizations and systems involved, transition will be complex, and must evolve according to a step-by-step process. It is important to ensure that, as much as possible, programs are not asked to give up functionality before the new system provides that functionality. This consideration may also include accommodation for bi-directional data feeds to minimize duplicate data entry during and, as required, after transition, recognizing that other systems may already contain required data, such as hospital patient health record systems.

Canadian Blood Services will work with individual programs and provinces to ensure that change is managed in a coordinated, negotiated manner. The implementation will also be guided by the proposed ODT governance structure (Figure 7-2). The interim governance for registries that is being established will transition into the overall governance structure and provide shared ownership and governance of registries.

Figure 7-3. **COMPREHENSIVE INTER-PROVINCIAL PATIENT REGISTRIES**



## RECOMMENDATIONS – DATA MANAGEMENT AND ANALYTICS

**10. A key factor that will improve the system's performance is the availability and analysis of accurate, timely and comprehensive data. It is recommended that Canadian Blood Services develop and implement an integrated data management and analytics service to support the needs of the Canadian organ and tissue donation and transplantation community.**

As noted earlier, timely and accurate data is critical to deliver accountability and transparency in the system. It is used to measure, benchmark and monitor system performance, and develop policies and evaluate their effectiveness. Working with the community, the ODT committees, CIHI/CORR and others, Canadian Blood Services will ensure the standardization of data, develop the expertise for data analytics, and create the tools to enable electronic data collection, exchange, reporting auditing, modeling and research. Through data, Canadian Blood Services and its partners can provide insight and recommendations to improve donation and transplantation and optimize care for patients.

### Organ donation and transplantation

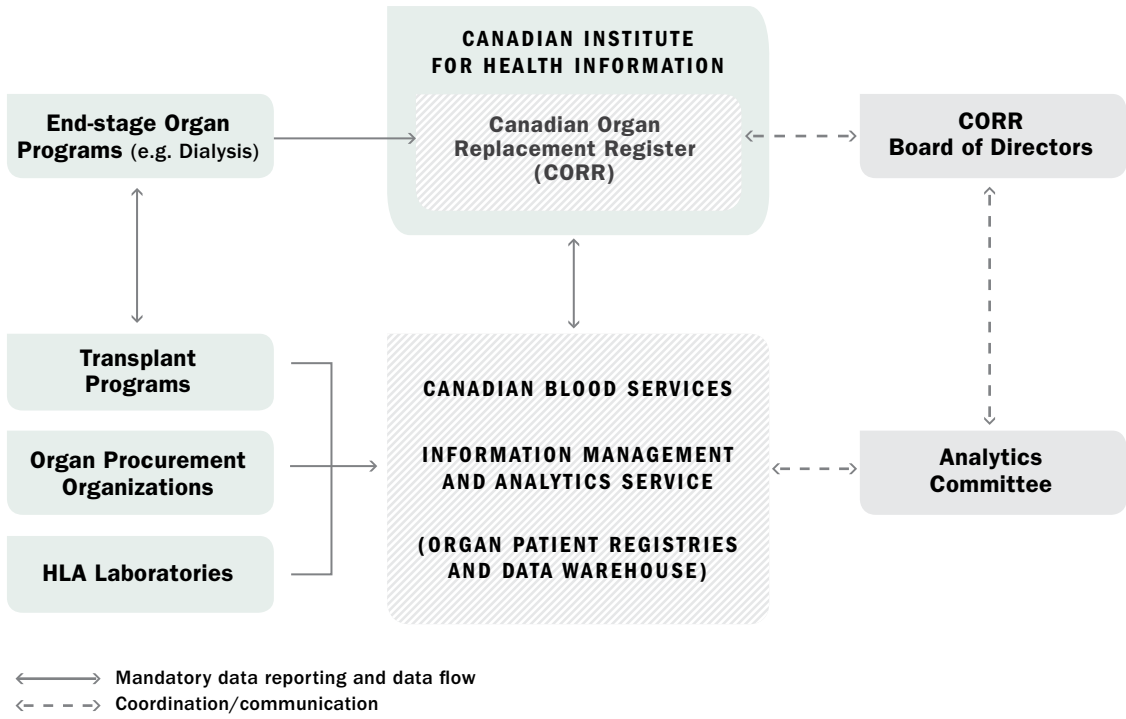
The ODT system can leverage extensive donor, recipient and transplant-event data from the patient organ registries to create a central data repository for analytics and reporting purposes that spans the continuum of end-stage organ disease. The registry initiatives that are already underway include the development of a separate data warehouse and business intelligence software tools that are specifically designed to enable advanced analytics. CIHI provides important informational insight into donation and transplantation through the CORR. Canadian Blood Services will partner with CIHI/CORR to optimize mandatory-data collection and improve information management services for all stakeholders. It is anticipated that much of the annual data reported to CIHI from transplant programs and OPOs can be provided directly from the Canadian Blood Services data warehouse, thereby removing duplication of data entry.

With the evolution of data management services, it will be important to preserve and improve existing national reporting services, including linking patient data from other sources that provide important information for optimized care or research related to patients with end-stage organ failure.

### Tissue donation and transplantation

Comprehensive, accurate national data regarding tissue donation, collection, processing and usage is extremely limited today. To address this gap, data management and analytics services will include tissue. Unlike organ donation and transplantation—where patient registries will provide an immediate and significant leap in data availability—mandatory tissue data collection will be a more measured, evolutionary undertaking.

Figure 7-4. PROPOSED INFORMATION MANAGEMENT AND ANALYTICS STRUCTURE



**RECOMMENDATIONS - RESEARCH AND INNOVATION**

**11.** It is recognized that research and innovation is an essential component to optimize, advance and evolve an ODT system. As such, it is recommended that:

- Canadian Blood Services facilitate and partner with Canadian ODT research networks to leverage governments' investments,
- Canadian Blood Services partner with funding agencies to optimize resources and bring focus to key areas of ODT that require further research and innovation, and
- a research committee be created to deliver on these elements.

Through its Strategy on Patient Oriented Research (SPOR), the Canadian Institutes of Health Research (CIHR) has identified a number of factors that complicate the translation of research into clinical practice. They include the decentralized authority and priority setting; a lack of clinical investigators and methodologists; underfunding of patient oriented research; a lack of standardized data and technology platforms; delays in the approval of large, multi-site clinical studies; deficiencies in guideline development, dissemination and uptake into practice; and the limited role of patients in patient oriented research.<sup>7</sup>

CIHR is making a significant investment in the creation of patient oriented research networks in Canada. In particular the CIHR hosted an ODT workshop in February 2011, where the steering committee identified the need for a research network in ODT. The workshop also identified that the national ODT system design and the central role that Canadian Blood Services would play in such a system presents a unique opportunity for the national ODT system to partner with a research network in ODT.

<sup>7</sup> CIHR Strategy on Patient Oriented Research



↑ At the OTDT research roundtable, February 2011: **Dr. Lee Ann Tibbles**, Associate Professor, Division of Nephrology, Departments of Medicine & Physiology and Pharmacology at the University of Calgary; **Dr. Lori West**, Acting Scientific Director, CIHR Institute of Circulatory and Respiratory Health; and **Dr. Dana Devine**, Vice-President of Medical, Scientific and Research Affairs at Canadian Blood Services.

At a subsequent Canadian Blood Services consultation with ODT research stakeholders, a number of priorities were identified that relate to research and innovation within the coordinated system design. It was felt that research and innovation should be central to the mission of the ODT system and that it should be supported by a research advisory committee to inform the research agenda on an ongoing basis. It was recognized that Canadian Blood Services is already, under its current mandate, uniquely positioned to support research and innovation through the dissemination of leading practices and policy development to address some of the key gaps identified in the CIHR/SPOR report. This mandate would be further built upon with the proposed system design to address major gaps in knowledge translation, especially as they relate to guideline development, dissemination and uptake into practice. Moreover, the proposed integrated, inter-provincial data management system would greatly accelerate the ability to effect both knowledge creation and its translation into practice. Finally, it should be noted that the proposed ODT system design ensures that patients and the public, in addition to the ODT community, are engaged in directing the research agenda, thereby addressing a key recommendation of the CIHR/SPOR report.

Canadian Blood Services has extensive experience in research and innovation in the blood system. This experience should be leveraged to support research and innovation in ODT. It is recommended that Canadian Blood Services work with the ODT community to optimize research and innovation for ODT in Canada.

## RECOMMENDATIONS - FRONTLINE FINANCIAL RESOURCES

**12.** It is conservatively estimated that implementation of the various elements of this strategy will result in breakthrough performance across Canada, as measured by a 50 per cent increase in the number of transplants over the next five years. To accommodate increased donation activity, frontline services will need more resources. It is recommended that governments ensure that financial resources are made available to organizations that provide ODT services—including OPOs, transplant programs, hospitals that support patients pre- and post-transplant (notably intensive care units and operating rooms), programs that support living donors, and ancillary functions (such as testing and medical diagnostics)—to support the increased activity generated as a result of increased donation and transplantation.

Approximately 2,100 transplants occurred in Canada in 2009. During that same year, more than 1,000 people donated organs. If the recommendations described in this strategy are adopted, within five years, it is projected that more than 1,500 people will donate organs, and the system will conduct more than 3,400 transplants. These increases will have a large impact on ODT services that will be challenged with keeping up with growth while maintaining high levels of patient care. To ensure the strategy achieves the goal of improving performance in organ donation and transplantation nationally, it is imperative that increased funding for frontline services be made available.

Offsetting the requirement for additional financial resources is the benefit the health care system will incur as a result of increased transplants. As the number of kidney increases, for example, there will be a substantial long-term benefit to the system through the reduced dependence on dialysis treatment for renal failure.

The savings in dialysis could be redirected to provide some of the additional resources required for ODT programs and organizations.

It is important to note that there was discussion at the Organ Expert Committee to improve the ways in which funds are delivered to programs (i.e., through a performance or activity based funding model). It is recognized that this cannot be done apart from the broader health care environment. It must be done with the support of, and in collaboration with, provincial and territorial governments. No matter the funding model, it is essential that adequate financial resources be available to support the increased volume of activity that derives from a concerted effort by all participants in the integrated inter-provincial system to drive to higher performance levels in Canada for donation and transplantation.

*Figure 7-5. RECOMMENDATIONS*

**By 2017, Canadian patients will have a trusted, integrated transplant system that performs among international leaders.**





# IMPLEMENTATION AND COSTING

## Organ Donation and Transplantation

Implementation of the twelve recommendations in this strategic plan has the potential to achieve transformational change and deliver breakthrough performance across Canada: an increase of 50 per cent in the number of deceased donors, as well as transplants; a decrease in the variability of wait times among provinces; a significant drop in the number of people who die while on waitlists; and a marked increase in public and health-care professional confidence in all aspects of the ODT system.

The implementation plan presented in Figure 8-1 aims to achieve these performance improvements within five years. Alternate strategy-implementation approaches do exist, and may be required if constraints delay implementation of certain recommendations; however, the performance targets envisioned in *Call to Action* are directly linked to the rapid adoption of all recommendations at the specified investment. As international experience shows, performance improvements happen when multiple, interwoven initiatives, collaboration and national leadership converge.

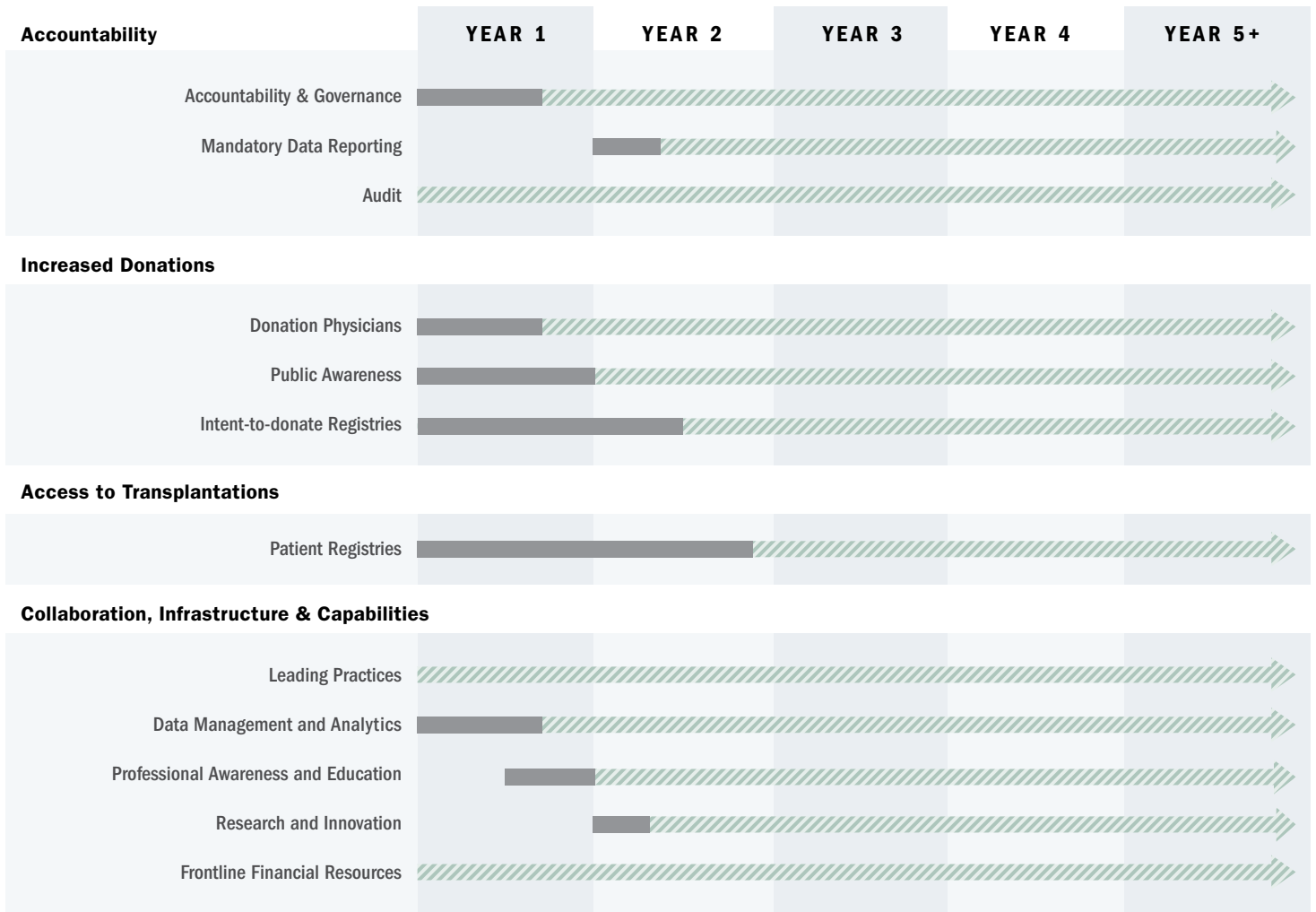


↑ **Kimberly Young**, Executive Director, Organs and Tissues, Canadian Blood Services and CEO of the former CCDT

### SUPPORTING THE FRONTLINES OF ODT

Implementation of various elements in this strategy will deliver breakthrough performance, including a 50 per cent increase in the number of transplants over five years. This increase will directly impact frontline ODT services, such as OPOs and hospitals. For example, hospital ICU capacity may be challenged to support the additional number of donors, as well as the resulting transplants recipients who require ICU stays. Adequate ongoing funding for these services is essential so they can maintain a high level of patient care, remain compliant with new policies (such as mandatory data reporting), and contribute to reaching system performance targets. Funding may include capital investments in infrastructure—including equipment, ICU beds, and operating rooms—to support anticipated performance increases.

Figure 8-1. ORGAN DONATION & TRANSPLANTATION STRATEGY IMPLEMENTATION



Note: For the purposes of this plan, Year 1 is presumed to be 2012-2013 with baseline Year 0 being 2011-2012.

■ Planning & development    ▨ Implementation & ongoing operation

## ODT SYSTEM IMPLEMENTATION HIGHLIGHTS

### Year 1

- Several key activities help establish a culture of accountability and transparency in the future OTDT system. The ODT oversight committee, and several sub-committees, are struck early in Year 1. The accountability framework is formalized among the federal, provincial and territorial governments by way of a mechanism such as a memorandum of understanding.
- The data-management analytics team goes operational toward the end of the first year. Working with ODT committees, the team prepares reports to help analyze current performance.
- Development of an integrated inter-provincial registry system is ongoing, with donor case management going operational in the first year.
- Ongoing leading practice development includes forums and a collaborative learning series, and supports implementation of donation physicians and professional education. Donation physician implementation is recommended for all regions during Year 1 to ensure targeted donation and transplantation rates are met by Year 5.
- Professional education training begins in the second half of Year 1 and targets donation physicians to support their early activation.
- Stakeholder consultations and creation of a messaging strategy mark the launch of the public awareness campaign. The current media communications strategy continues.
- In support of provinces that do not have intent-to-donate registries, Canadian Blood Services engages them in design discussions to determine requirements, opportunities for collaboration and cost implications.

### Year 2

- The primary focus is now to increase donation. The national media campaign launches, and messaging content is made available to help regions customize delivery. Intent-to-donate registries go operational during the latter half of the year.
- Mandatory data reporting begins, with all regions expected to be compliant by mid-year.
- A research committee is established to develop partnerships and build ODT research networks to leverage government investments.

### Years 3 to 5

- All recommendations are implemented by the start of Year 3. The foundation established in Years 1 and 2 begin to deliver gains in the numbers of donations and transplantations.
- Increased system transparency enables ongoing performance evaluation to ensure strategy implementation achieves targets by the Year 5, including increasing the number of donors and improving both access to transplantation and patient outcomes.

### Year Five+

- As performance improvement targets are met by Year 5, expenditures level off and new infrastructure enables continuous system evaluation and improvement.

## CURRENT SYSTEM COSTS AND PERFORMANCE

Table 8-1 presents high-level current cost estimates for ODT in Canada. These estimates were developed from data shared by provincial health ministries, OPOs and transplant programs, and supplemented with published data and literature; however, the availability of comprehensive data on ODT operating costs is limited, and therefore limiting on governments’ abilities to understand current system performance.

Many hospital ODT costs are embedded within program budgets and indistinguishable from those for operative and surgical services, and laboratory and diagnostic services, among others. The ability to isolate costs is further challenged by variations in the way provinces and territories fund and undertake ODT activities.

Improvements to ODT cost data collection and analysis are essential to achieve the insight and accuracy stakeholders require. This strategic plan aims to build the accountability and performance-measurement platform necessary for Canada’s provinces and territories to achieve clarity, insight and precision—and from which to pursue greater efficiencies.

### Cost of donation

Estimates include direct operating costs for hospital organ-donation services (for living and deceased donors), OPOs and physicians for donor identification, referral, testing, consent, donor management, transportation, recovery, and post-donation care for living donors. Estimates do not include investments for public and professional awareness, program overhead, capital infrastructure costs (equipment, ICU beds, operating rooms, etc.) or for development and operation of intent-to-donate registries.

### Cost of transplants

Estimates include direct operating costs for services provided by either hospitals, physicians or provincial drug programs for recipient identification, testing, waitlisting, transplantation and post-transplant care (including cost of immunosuppressants). Estimates do not include costs of professional awareness and education, or program overhead.

### Canadian Blood Services project costs

Estimates include funding for the development and implementation of various registries, such as HSP and NOW.

### Canadian Blood Services operating costs

Includes annual costs for Canadian Blood Services to fulfill roles and responsibilities related to public awareness, patient registries and leading practices.

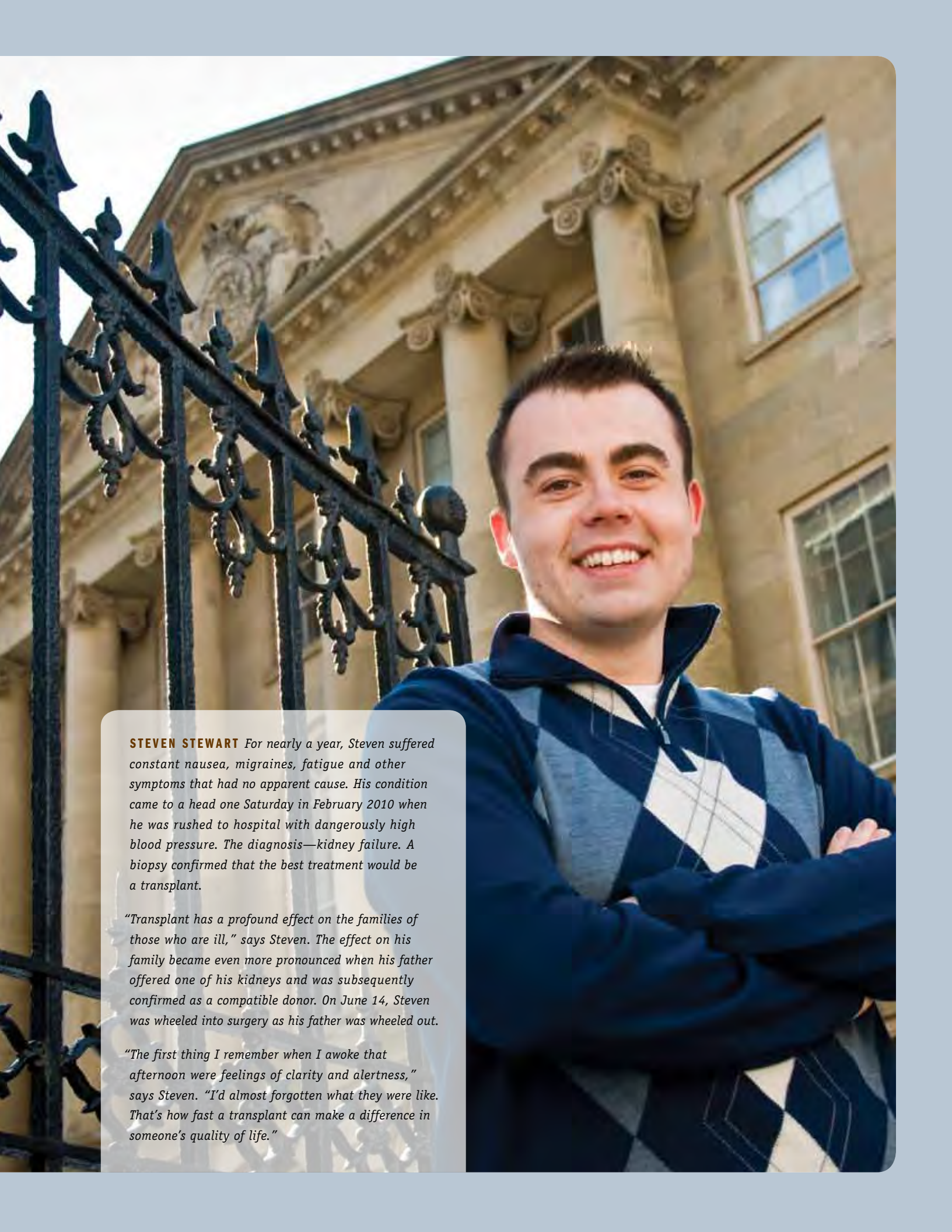
Table 8-1. Current annual system costs (\$ millions)

	Year 0*
<b>Frontline Costs</b>	
Cost of Donation	\$ 30.1
Cost of Transplants	414.3
<b>Canadian Blood Services Costs</b>	
Project Costs	3.4
Operating Costs	5.1
<b>Total Canadian Blood Services Costs</b>	<b>8.5</b>
<b>Total Current System Costs</b>	<b>\$ 452.9</b>

\* Year 0 – 2011-2012. Note: all calculations—cost and performance data—exclude Quebec.

### SYNERGIES FOR GREATER EFFICIENCY

*There are several areas where costs in the future system support both the ODT and TDT systems; for example, with respect to governance, public and professional education and awareness, and information management. These synergies increase efficiencies overall and, under the guidance of a single organization (Canadian Blood Services), avoid duplication of investment.*



**STEVEN STEWART** For nearly a year, Steven suffered constant nausea, migraines, fatigue and other symptoms that had no apparent cause. His condition came to a head one Saturday in February 2010 when he was rushed to hospital with dangerously high blood pressure. The diagnosis—kidney failure. A biopsy confirmed that the best treatment would be a transplant.

*“Transplant has a profound effect on the families of those who are ill,” says Steven. The effect on his family became even more pronounced when his father offered one of his kidneys and was subsequently confirmed as a compatible donor. On June 14, Steven was wheeled into surgery as his father was wheeled out.*

*“The first thing I remember when I awoke that afternoon were feelings of clarity and alertness,” says Steven. “I’d almost forgotten what they were like. That’s how fast a transplant can make a difference in someone’s quality of life.”*

Table 8-2. Current System Performance

	Year 0
<b>Current System Performance</b>	
Number of Deceased Donors	360
Number of Living Donors	489
<b>Total Number of Donors</b>	<b>849</b>
Number of Transplants	1,698
Number of Functioning Organ Grafts	23,362

## FUTURE SYSTEM = HEIGHTENED PERFORMANCE

Table 8-3. Future System Costs (\$ millions)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
<b>Frontline Costs</b>										
Cost of Donation	\$ 33.3	\$ 36.6	\$ 40.8	\$ 45.8	\$ 52.1	\$ 55.0	\$ 58.1	\$ 61.4	\$ 64.8	\$ 68.3
Cost of Transplants	455.2	502.9	559.4	628.3	713.5	766.1	817.0	869.8	922.5	975.3
<b>Costs of Recommendations</b>										
Donation Physicians Costs	6.1	8.3	8.5	8.8	9.1	9.3	9.6	9.9	10.2	10.5
Canadian Blood Services Project Costs	2.8	0.8	-	-	-	-	-	-	-	-
Canadian Blood Services Operating Costs	10.1	15.8	15.3	15.8	16.1	16.6	17.1	17.6	18.2	18.7
<b>Total Project and Operating Costs</b>	<b>19.0</b>	<b>24.9</b>	<b>23.8</b>	<b>24.6</b>	<b>25.2</b>	<b>25.9</b>	<b>26.7</b>	<b>27.5</b>	<b>28.4</b>	<b>29.2</b>
<b>Total Future System Costs</b>	<b>\$ 507.5</b>	<b>\$ 564.4</b>	<b>\$ 624.0</b>	<b>\$ 698.7</b>	<b>\$ 790.8</b>	<b>\$ 847.0</b>	<b>\$ 901.8</b>	<b>\$ 958.7</b>	<b>\$ 1,015.7</b>	<b>\$ 1,072.8</b>
<b>System Performance</b>										
Number of Deceased Donors	392	432	481	543	622	642	664	686	709	731
Number of Living Donors	503	517	536	556	580	588	594	601	608	613
<b>Total Number of Donors</b>	<b>895</b>	<b>949</b>	<b>1,017</b>	<b>1,099</b>	<b>1,202</b>	<b>1,230</b>	<b>1,258</b>	<b>1,287</b>	<b>1,317</b>	<b>1,344</b>
Number of Transplants	1,827	1,985	2,179	2,422	2,732	2,798	2,832	2,865	2,886	2,895
Number of Functioning Organ Grafts	24,516	25,796	27,233	28,870	30,768	32,784	34,781	36,760	38,708	40,615

### Cost of donation and transplants

During the first five years, the volume of donation and transplants will increase at a rapid pace as the recommendations are implemented. The number of living and deceased donors will rise from 895 in Year 1 to more than 1,200 by Year 5. This growth will moderate after Year 5 to reach more than 1,300 by Year 10. The growth in transplants will also be steeper until Year 5, when more than 900 additional transplants will be performed annually. By Year 10, the volume of annual transplants will have increased to nearly 2,900 transplants.

The cost for these donation and transplantation services is directly linked to the growth in the number of both donors and transplants. Although growth due to improved performance will increase these costs, they would rise even without new investment as a result of inflation and demographic changes, including population growth.

### Donation physicians cost

Estimates include the costs of staffing 20.25 full-time equivalent donation physicians across nine provinces which may be filled by multiple physicians working part-time.

### Canadian Blood Services project and operating costs

Project costs include funding for the development and implementation of recommendations related to patient registries, governance structure, public awareness strategy and professional education.

After the ramp up in activity between Years 1 and 5, Canadian Blood Services' annual operating costs to support the integrated, inter-provincial system are estimated at two per cent of total system costs (approximately \$18 million on average for Years 6 to 10). These operating costs include annual costs for Canadian Blood Services to fulfill responsibilities related to accountability and governance, public and professional awareness and education, patient registries, data management and analytics, and leading practices.

## INCREMENTAL SYSTEM COSTS

**Table 8-4. Incremental Cost of Transplantation and Patient Care (\$ Millions)**

Estimated incremental project and operating costs for implementing the recommendations, including the increase in volume-related system costs for donation and transplantation, which are over and above the estimated current state costs.

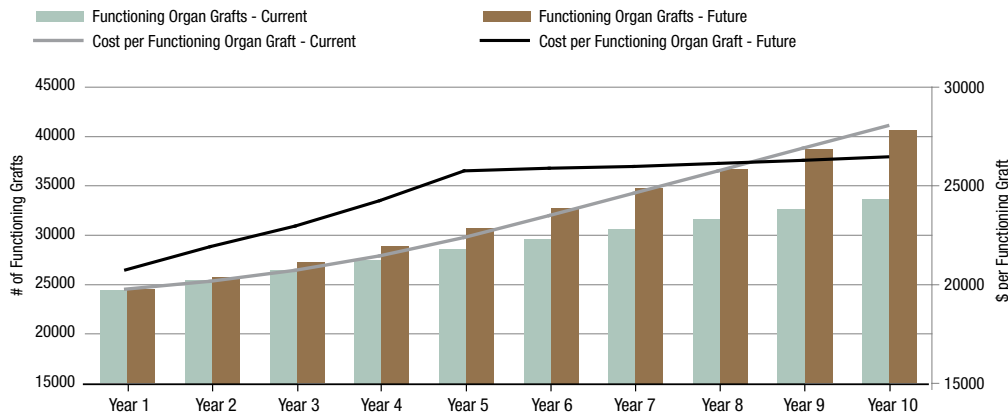
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Future System Costs	\$ 507.5	\$ 564.4	\$ 624.0	\$ 698.7	\$ 790.8	\$ 847.0	\$ 901.8	\$ 958.7	\$ 1,015.7	\$ 1,072.8
Current System Costs	479.6	507.3	536.3	566.4	597.9	630.6	664.7	700.2	737.2	775.8
Dialysis Cost Avoided in the Future System	1.6	7.0	17.5	35.0	61.7	95.2	131.2	168.9	208.4	249.2
<b>Current System Costs (incl Dialysis)</b>	<b>\$ 481.2</b>	<b>\$ 514.3</b>	<b>\$ 553.8</b>	<b>\$ 601.4</b>	<b>\$ 659.6</b>	<b>\$ 725.8</b>	<b>\$ 795.9</b>	<b>\$ 869.1</b>	<b>\$ 945.6</b>	<b>\$ 1,025.0</b>
<b>Incremental System Costs</b>	<b>\$ 26.3</b>	<b>\$ 50.1</b>	<b>\$ 70.2</b>	<b>\$ 97.3</b>	<b>\$ 131.2</b>	<b>\$ 121.2</b>	<b>\$ 105.9</b>	<b>\$ 89.6</b>	<b>\$ 70.1</b>	<b>\$ 47.8</b>
Incremental Transplants (All Organs)	107	244	417	639	928	973	986	999	998	987
Incremental Functioning Kidney Grafts in the Future System	47	153	333	607	1,002	1,410	1,814	2,216	2,610	2,991

As Table 8-4 shows, increased costs in the future system are significantly offset by the rising number of kidney transplants, which generate a significant cost avoidance to the system due to the lower cost of post-transplant care compared to dialysis. As a result, by Year 10, an annual additional investment of \$47.8 million will deliver substantial performance improvements in terms of number of donors and transplants and cost per functioning organ graft.

**PERFORMANCE-COST COMPARISON**

**Figure 8-2. System Productivity: Cost per Functioning Organ Graft**

The future system stabilizes the cost per functioning graft by Year 5. In the current system, this cost will rise continuously and unchecked through and beyond the next 10 years.



**Delivering greater cost-effectiveness**

As Figure 8-2 shows, the future system is characterized by greater cost-effectiveness due largely to dialysis cost avoidance and its impact on the Cost per Functioning Organ Graft, which is a gross productivity measure of system cost efficiency.

The measure is calculated by dividing the system’s total cost of treatment by the number of functioning organ grafts (Table 8-5).

**Table 8-5. Calculation For Cost Per Functioning Organ Graft**

	Year 10	
ODT System Costs (\$ Millions)	Future	Current
Cost of Donation	\$ 68.3	\$ 45.4
Cost of Transplants	975.3	719.0
Canadian Blood Services/Recommendations Cost	29.2	11.4
Dialysis Costs Avoided in the Future System	-	249.2
<b>Total System Costs</b>	<b>\$ 1,072.8</b>	<b>\$ 1,025.0</b>
<b>Number of Functioning Organ Grafts</b>		
Functioning Organ Grafts	40,615	33,665
Incremental Functioning Kidney Grafts in the Future System	-	2,991
<b>Total Number of Functioning Organ Grafts</b>	<b>40,615</b>	<b>36,656</b>
<b>Cost per Functioning Organ Graft</b>	<b>\$ 26,412</b>	<b>\$ 27,961</b>



**Table 8-6. Cost per Functioning Organ Graft**

Current system performance estimates are based on 2011–2012 estimates of graft survival rates, and donation and transplant rates per million population.<sup>1</sup>

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
<b>Future System</b>										
Functioning Organ Grafts	24,516	25,796	27,233	28,870	30,768	32,784	34,781	36,760	38,708	40,615
Cost per Functioning Organ Graft	\$ 20,702	\$ 21,881	\$ 22,915	\$ 24,200	\$ 25,701	\$ 25,838	\$ 25,929	\$ 26,079	\$ 26,238	\$ 26,412
<b>Current System</b>										
Functioning Organ Grafts	24,411	25,457	26,498	27,534	28,566	29,594	30,618	31,638	32,653	33,665
Incremental Functioning Kidney Grafts in the Future System	47	153	333	607	1,002	1,410	1,814	2,216	2,610	2,991
<b>Total Number of Functioning Organ Grafts</b>	<b>24,458</b>	<b>25,610</b>	<b>26,831</b>	<b>28,141</b>	<b>29,568</b>	<b>31,004</b>	<b>32,432</b>	<b>33,854</b>	<b>35,263</b>	<b>36,656</b>
<b>Cost per Organ Graft</b>	<b>\$ 19,673</b>	<b>\$ 20,083</b>	<b>\$ 20,641</b>	<b>\$ 21,371</b>	<b>\$ 22,306</b>	<b>\$ 23,412</b>	<b>\$ 25,541</b>	<b>\$ 25,675</b>	<b>\$ 26,817</b>	<b>\$ 27,961</b>

The financial impact of the future ODT system cannot be captured without considering the cost of dialysis<sup>2</sup> it avoids. This cost is associated with the Incremental Functioning Kidney Grafts in the Future System (Tables 8-5 and 8-6), which represents the incremental patients in the future system who are living with a functioning kidney graft and would have required dialysis treatment in the current system. The number of, and cost to care for, these patients must be included in the current system calculation of the gross productivity measure to ensure an equal comparison between the current and future systems.

As Table 8-6 shows, in Year 1 of both the current and future systems there is little difference between the costs per functioning graft. As recommendations are implemented over the first five years, the cost per functioning graft remains lower in the current system. The relatively higher cost in the new system is due to the rising number of kidney transplants, the costs of which are significantly higher than the cost of dialysis in the first year of transplant treatment. In subsequent years, however, post-transplant treatment will deliver an estimated \$50,000 annual benefit<sup>3</sup> over dialysis for each kidney graft.

This benefit accrues most notably in Year 6 of the new system, when the cost per functioning graft begins to stabilize, the number of functioning kidney grafts begins to increase, and the cost-benefit attributed to kidney grafts helps reduce the overall cost of post-transplant care for all organs types.

As a result, the cost per functioning organ graft is \$26,412 in Year 10 of the future system, compared to \$27,961 if the system continues in its current state (see Figure 8-2). Over that same ten year period, the number of functioning organ grafts will increase from 24,500 to 40,600. This means approximately 7,000 more Canadians alive with a functioning transplant—compared to the 33,600 who would receive transplants in ten years of the current system. Almost 3,000 of these 7,000, transplants will be functioning kidney grafts that avoid incremental dialysis costs of \$976 million over the 10 years.

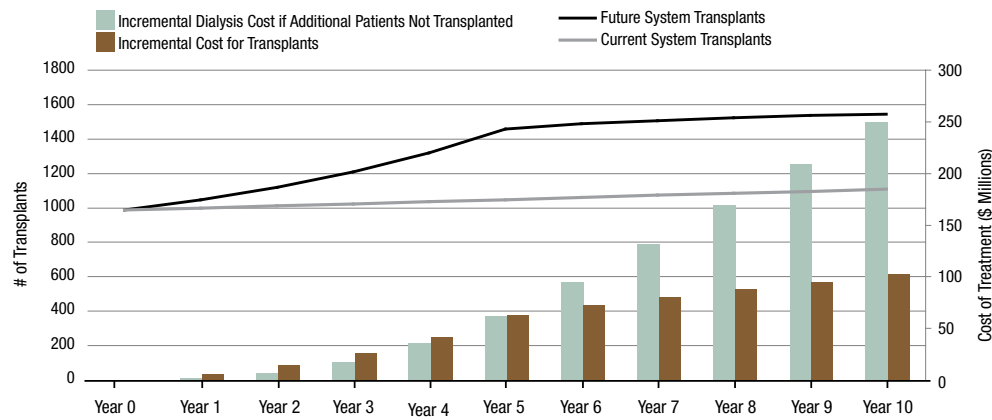
<sup>1</sup> Canadian Organ Replacement Register (CORR) Annual Report: *Treatment of End-stage Organ Failure in Canada 2000–2009*, January 2011.

<sup>2</sup> The cost of dialysis, as estimated by Transplant Manitoba - Gift of Life Program, includes the operating costs of delivering outpatient dialysis, in-hospital hemodialysis (HD), peritoneal dialysis, local centre HD and physician fees billed to Manitoba Health. The cost estimate excludes costs for hospital admissions, emergency room visits, and other hospital resources and health care. Overhead allocation has not been added to these direct cost estimates.

<sup>3</sup> The estimated benefit increases with inflation annually, so that by Year 10 the benefit would equal approximately \$83,000 per functioning kidney graft.

**Figure 8-3. Benefit of Kidney Transplant vs Dialysis**

Based on the incremental number of proposed kidney transplants, Figure 8-3 compares the cost of care if patients do not get a transplant and stay on dialysis with the cost related to patients who receive a transplant and are removed from dialysis.



### NEW SYSTEM, NEW VALUE.

Numerous cost benefits stem from the proposed ODT system in terms of marked efficiencies achieved in tandem with performance improvements. The cost per patient with a functioning organ graft—a gross productivity measure—will be lower in the future system than if the current system were to continue. Most compelling, however, is that a shared provincial and territorial investment of \$47.8 million will, in Year 10, fund nearly 1,000 more life-saving transplants annually. The value of this investment is difficult to dispute given the immense benefits these additional transplants will mean to patients, families and society.

Shared provincial and territorial investments will yield other benefits. Investment in recommendations related to shared accountability, mandatory reporting and information management will enhance transparency and provide reliable and timely data for policy development, planning, performance management, as well inter-provincial and international benchmarking. Ministries of health, transplant programs, OPOs and Canadian Blood Services will benefit from access to these data in a shared, cost-effective approach that enhances trust and avoids duplication expertise and systems.

Investment in an integrated, inter-provincial approach to OTDT public awareness, communications and marketing ensure a singular, powerful call to action, and delivers efficiencies by creating national strategies that can be customized locally. Further efficiencies flow from leveraging Canadian Blood Services’ public awareness and marketing experience and infrastructure, and from potential savings in bulk media buys.

The development and implementation of inter-provincial patient registries avoids duplication of development costs by each province and streamlines data entry to patient registries and to the Canadian Institute for Health Information (CIHI). Clinical and financial data could be linked through CIHI to enable further insight into and support for planning and economic analysis.

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## MEASURING UP

*When benchmarking performance improvements internationally, the recommendations and associated costs outlined in this plan compare well with other jurisdictions. In 2008, Australia allocated new funding of \$136.4 million over four years to implement national ODT recommendations. The United Kingdom spent £56.3 million in 2009–2010 on project and operating costs to implement recommendations aimed at increasing organ donation by 50 per cent. Since implementation of their respective national recommendations, the number of organ donors has increased by 56 per cent in Australia<sup>4</sup> and 28 per cent in the United Kingdom.<sup>5</sup>*

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Multiple benefits contribute to improved patient outcomes and transparency. These benefits include:

- standardized donor and recipient information, virtual crossmatch, and policy clarity for optimal organ allocation,
- secure electronic sharing of comprehensive donor clinical information for timely offer evaluation,
- tracking and transparency of all listings, offers and accepts/declines, as well as reporting of inter-provincial organ sharing, and
- providing essential patient outcome data to improve clinical practice.


### Harnessing the power of collaboration

Sound economic rationale underlies the collaboration-related recommendations in this strategic plan. Collaboration means cost sharing. It reduces duplication of investment. And it ensures Canada makes the best use of the time and availability of its limited number of ODT experts.

The value of collaboration and shared investment has been clearly demonstrated and recognized in the current Canadian Blood Services mandate, the previous CCDT mandate, and in successful international efforts such as the Breakthrough Collaboratives for organ donation in Australia and the United States.

<sup>4</sup> DonateLife Australia, News Release, January 18, 2011 [www.donatelife.gov.au/News-and-Events/News/Media-Releases/2010-Organ-donation-figures-show-record-high.html](http://www.donatelife.gov.au/News-and-Events/News/Media-Releases/2010-Organ-donation-figures-show-record-high.html)

<sup>5</sup> NHS Blood and Transplant News Release, January 23, 2011. <http://www.nhsbt.nhs.uk/news/2011/newsrelease210111.html>



**GARY AND JANE SMITH** *"I remember trying to understand what the medical staff was telling me," says Jane about learning that a car accident had taken the life of her youngest son Brandon and left her eldest, Jared, in critical condition with a major head injury.*

*"Then the thought came very clearly to me—Brandon told us he'd signed his donor card."*

*The circumstances of Brandon's death meant doctors could recover only his tissues. But even this enabled Jane and Gary to focus instantly on two vital and tragically related tasks: working closely with ER staff to save Jared's life and ensure the most could be made of Brandon's.*

*The couple believes every family should talk openly about and commit to organ and tissue donation. Carrying through on Brandon's wishes gave Jane and Gary an "overwhelming feeling of comfort and strength" that sustained them as they grieved for one son and helped heal the other in the ensuing months.*

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# TISSUE DONATION AND TRANSPLANTATION

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## Seizing the immense opportunity of a system solution

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*There is immense opportunity in tissue donation and transplantation (TDT). Canadians need and expect to benefit from exciting advances in technology and technique—advances that are igniting new approaches to tissue recovery, processing, storage and distribution, and new ways to use tissue to improve lives. Yet those who need tissue transplants, the surgeons who treat them, those who supply the tissues, and those who encourage Canadians to become tissue and organ donors, all indicate that transformational changes are needed to help realize the full potential of TDT to improve patient outcomes.*

The Tissue Expert Committee and Canadian Blood Services understand the changes that are necessary, and possible. This section of the OTDT strategic plan presents the culmination of years of intense research and coast-to-coast consultations. We begin with a review of system challenges—the result of an extensive assessment of the current state of TDT. Based on these, we set out our strategic response, then present recommendations for the design of an integrated, inter-provincial TDT system—including explanations of specific roles and responsibilities. The section closes with the implementation strategy and respective cost estimates.

### **EXPERT CONTRIBUTIONS**

The contributions of Tissue Expert Committee members—among them surgeons, researchers, tissue bankers, policy experts and academics selected to ensure broad regional representation from across Canada—have been vital to the development of this section of the strategic plan. Committee members worked closely with Canadian Blood Services, which coordinated the wider TDT stakeholder community not just to assess current challenges and opportunities, but also to plot a course toward an integrated inter-provincial tissue donation and transplantation system.

**MEMBERS OF THE TISSUE EXPERT COMMITTEE**

<b>Dr. Locksley McGann PhD (Chair)</b>	Professor, Department of Laboratory Medicine and Pathology, University of Alberta	Edmonton, Alberta
<b>Mr. Michael Bentley BSc(MLS), MBA</b>	Patient Care Manager, Transplantation Services, Alberta Health Sciences	Edmonton, Alberta
<b>Dr. Brian Berry BSc, MD, FRCPC</b>	Director of Hematopathology, Vancouver Island Health Authority	Victoria, British Columbia
<b>Mr. Scott A. Brubaker CTBS</b>	Chief Policy Officer, American Association of Tissue Banks	McLean VA USA
<b>Ms. Mary Gatten RN, BN, CEBT, CTBS</b>	Director, New Brunswick Eye and Tissue Bank President, Canadian Association of Eye and Tissue Banks	Saint John, New Brunswick
<b>Professor Michael Gross MD, FRCS(C&amp;LOND)</b>	Professor of Orthopaedic Surgery, Dalhousie University Medical Director, Regional Tissue Bank	Halifax, Nova Scotia
<b>Dr. Frank I. Hohn DDSC</b>	Head, Department of Dentistry/Oral and Maxillofacial Surgery, Saskatoon Health Region President, College of Dental Surgeons of Saskatchewan	Saskatoon, Saskatchewan
<b>Dr. David Howarth MD, FRCP(C)</b>	Staff Pathologist, Mount Sinai Hospital	Toronto, Ontario
<b>Mr. Dermot J. Kelly MSc, CEBT</b>	Director, Quality & Patient Safety/Infection Prevention & Control, Vancouver Coastal Health Authority	Vancouver, British Columbia
<b>Dr. Sarvesh Logsetty MD, FRCSC, FACS</b>	Medical Director, Tissue Bank Manitoba Director of Manitoba Firefighters' Burn Unit Associate Professor Department of Surgery, University of Manitoba	Winnipeg, Manitoba
<b>Ms. Janet MacLean MBA</b>	Vice President, Clinical Affairs, Trillium Gift of Life Network	Toronto, Ontario
<b>Mr. Sean Margueratt MAsc, PEng, CTBS</b>	Director, Nova Scotia Medical Examiner Service	Halifax, Nova Scotia
<b>Dr. Hassan Moghadam DDS, M.Sc, FRCD(C)</b>	Oral and Maxillofacial Surgeon	Ottawa, Ontario
<b>Dr. Jutta Preiksaitis MD, FRCP(C)</b>	Professor of Medicine, Division of Infectious Diseases, Transplant Infectious Diseases, Department of Medicine, University of Alberta	Edmonton, Alberta
<b>Mr. Christopher Snow MSc, CTBS</b>	Director, Tissue Bank Manitoba	Winnipeg, Manitoba

**WE CAN DO BETTER**

*There are approximately 40,000 surgical and dental tissue allografts transplanted each year in Canada. Roughly 80 per cent of all allografts are imported.*

# SYSTEM CHALLENGES

## Tissue Donation and Transplantation in Canada

### OVERVIEW

Canadian Blood Services worked closely with the Tissue Expert Committee and members of the tissue donation and transplantation (TDT) community to understand the related challenges currently faced in Canada. One of the first tasks was to undertake wide-ranging public and professional consultations across Canada to assess the state of TDT activities. The extent of this engagement was unprecedented. The consultations, supported by extensive research, revealed specific issues that underscore the need for change.

There are, however, significant achievements that challenge us to do our part—and to build on the efforts of others—in pursuit of improved patient outcomes. For example, the Canadian Standards Association (CSA) established voluntary general requirements for cells, tissues and organs (CTO) in 2003. Health Canada made important contributions with the introduction of new CTO regulations in December 2007, followed by increased regulatory oversight in activities such as establishment registrations and tissue bank inspections. In 2008, the Public Health Agency of Canada began development of a surveillance system for tissue. Additionally, performance improvements continue to accrue from ongoing TDT program refinements in many locations across Canada.

The evidence remains compelling, however, that Canada as a whole, and its provinces and territories individually, can significantly perform better in many areas of TDT. This chapter presents a unique Canada- and stakeholder-wide perspective on the specific and critical TDT elements that must be addressed if patients are to be better served, and if a baseline is to be established for the measure of progress.



### A FRAGMENTED APPROACH

Patients in provinces and territories across Canada (excluding Quebec) were served by more than 20 tissue banks in 2008. Among them are eye, tissue and surgical bone banks that recover, process, store and distribute tissue allografts for use in their regions. Some import and distribute tissue products, mainly from the United States.

These banks operate independently for the most part. They benefit from no formal networking that could, for instance, make products that are abundant in one region available quickly in others that face shortages. A fragmented TDT environment could scarcely be expected to meet the baseline measure of a well functioning TDT system.

← **Dr. Jutta Preiksaitis**, Professor of Medicine, University of Alberta, and Tissue Expert Committee member

## OBSTACLES AND OPPORTUNITIES

The assessment of TDT in Canada revealed four specific challenges to be addressed if improvements in tissue donation and transplantation are to be achieved:

- Enhance the quality of tissue product in Canada.
- Strengthen Canadian tissue supply practices to ensure security of supply.
- Ensure greater efficiency in tissue recovery, processing and distribution.
- Strengthen measurement and accountability mechanisms to deliver consistent, Canada-wide performance improvements.

### Challenge:

#### ENHANCE THE QUALITY OF TISSUE PRODUCT IN CANADA.

The TDT community identified several priority areas that require attention to ensure consistently high quality tissue allografts are available to patients in Canada.

##### Inconsistent approaches to quality

A lack of coordination among Canadian tissue and eye banks, reflected in varying processes and product specifications, results in production of tissue allografts with different quality profiles. In some cases budget restraints may hinder the ability to achieve consistent quality, while in other instances the absence of standardized professional education and training may result in slower adoption of leading practices that would improve tissue quality. The voluntary nature of accreditation and the absence of any consequences for not maintaining accreditation have also been cited as reasons why not all tissue or eye bank standards have been implemented consistently across the country.

Another inconsistency relates to the fact that tissue programs interpret regulations and standards differently and, as a result, do not all implement safety and quality improvements in the same manner. For example, nucleic acid testing for West Nile Virus was not implemented consistently—some banks tested seasonally, some year-round, and others not at all. More recently, there has also been no common policy developed by Canadian tissue and eye banks on testing donors for Chagas disease, which has already prompted changes to how blood is being tested for this infectious agent in Canada and the United States.

##### The importance of traceability

The TDT community recognizes that a seamless record of the distribution and usage of every tissue allograft provided by each donor is critical to safety. In some instances a single donor may provide up to 100 individual allografts that could be transplanted into patients. Should a safety or quality issue be identified after those allografts have been distributed, the ability to quickly and accurately quarantine remaining inventory, and to notify clinicians and patients, is essential. Investigations in the United States have demonstrated that severe infections and even deaths have occurred as a result of tissue-transplantation transmission of various viral and bacterial agents such as Clostridia, Group A Streptococcus as well as some viruses. While tissue and eye banks have developed systems to manage traceability as long as tissue allografts are in their control, concerns have been raised about the completeness of traceability within hospitals. Effective mechanisms have not been put into place to ensure donor and recipient information is shared between organ and tissue transplant programs when safety issues related to a donor of both organs and tissues are identified.

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#### INFORMED CONSENT

*Effective traceability depends in part on an informed patient. Currently, however, patients may not be informed of, or consent to, the potential risks associated with human tissue transplantation.*

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### Lacking the benefit of surveillance

Thousands of tissue allografts are transplanted every year in Canada. Currently there is no coordinated approach to assessing the outcomes of these tissue transplants from the perspective of either effectiveness or safety (e.g., disease transmission). There is also no system to collect data from hospitals or clinics related to tissue transplant usage or outcomes.

Better surveillance is needed, including adverse-event reporting, and robust data collection systems. Such improvements would enable health care professionals to analyze surveillance data to identify potential safety risks and emerging issues, inform medical-practice and health care policy development, and support supply planning.

### Imports and quality management

Canada imports 80 per cent of its tissue product from the United States, yet there is no coordinated approach to procurement or distribution of these tissues, or to the use of supplier quality audits as part of a comprehensive quality management program. As a mechanism to observe and examine a vendor's quality systems and overall approach to quality management, these audits provide opportunities to recommend improvements and provide additional assurance that products being purchased from that vendor are meeting expectations.

#### Challenge:

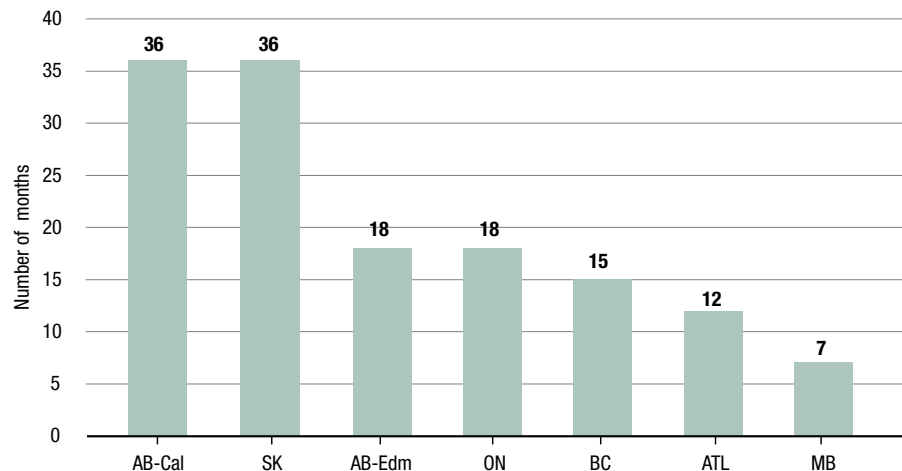
### STRENGTHEN CANADIAN TISSUE SUPPLY PRACTICES TO ENSURE SECURITY OF SUPPLY.

Canada's tissue supply—for both domestic and imported product—is neither integrated nor coordinated. As a result, the needs of Canadian patients are not being met in terms of either type or volume of product.

There are no processes nationally to share inventory information or enable distribution across provincial borders. This shortcoming leads to provincial variation in the production of, and access to, tissue allografts. One result is that thousands of Canadians are on cornea transplantation waitlists that average seven months to three years in length depending on location (see Figure 9-1).

**Figure 9-1. Cornea Transplant Wait Times By Region (2008)**

Average wait times for cornea transplant—presented here by region and eye bank—range from seven months to three years.



Source: Demand for Ocular Tissue in Canada—Final Report, January 2010

**Misalignment of supply and demand**

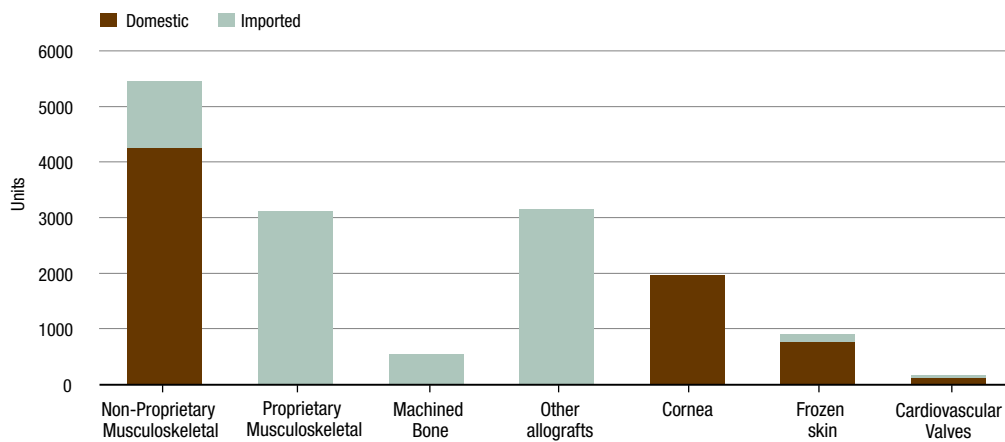
Tissue production in Canada is limited by the number of donors, the capacity to recover tissue, and the focus on meeting only local needs. As a result, end-users across Canada cannot consistently rely on their tissue banks to have the type, quantity and quality of tissue product they need. Canadian tissue banks also lack the ability to produce specialized tissue products. All demineralized bone matrix, the most commonly used tissue product, must be imported from processors in the United States.

**Relying on imports**

As indicated earlier, Canada imports approximately 80 per cent of its tissue product from the United States (see Figure 9-2). This dependency on imported products could pose risks to Canadian patients. Fluctuations in supply and demand, for example, could limit the availability of tissue products. Tissue use in the United States is projected to continue increasing,<sup>1</sup> and demand could exceed supply. A viral outbreak or emerging viral pathogen in the United States could decrease the number of donors and make importation into Canada difficult or expensive.

**Figure 9-2. Canadian Surgical Market for Tissue Allografts (2008)**

For some tissue types, Canada relies on 100% importation of product.



Sources: 2010 Supply of Human Allograft Tissue in Canada; Canadian Imported Surgical and Dental Allograft, Allograft Substitute, and ADM Study 2010; Utilization and Cost of Procurement of Skin, Cardiac and Vascular Allograft Products—Final Report 2010.

<sup>1</sup> BCC Research (2008). *Market Research Report – Organ and Tissue Transplantation and Alternatives*, BCC Research, www.bccresearch.com.

*Challenge:***IMPROVE COORDINATION AMONG CANADIAN TISSUE BANKS TO ENSURE GREATER EFFICIENCY IN TISSUE RECOVERY, PROCESSING AND DISTRIBUTION.**

Some Canadian hospitals and health authorities use centralized purchasing practices in dealing with international suppliers and processors; however, most tissue purchases are made by individual medical and dental surgeons, hospitals and tissue banks. These independent and uncoordinated purchasing practices lack the buying power that could be expected from an integrated national contract system, and likely result in unnecessarily high tissue costs.

**The benefit of a biological manufacturing approach**

Since most eye and tissue banks can be stored for extended periods and shipped safely thousands of miles, eye and tissue banks in the United States have come to operate according to a biological-manufacturing model. They are centralized, deal with large product volumes, maintain well-established distribution channels, and are able to optimize costly investments in facilities and equipment, inventory management information systems, and specialized staff.

In Canada, most eye and tissue banks are run according to a hospital service-delivery model and deal with comparatively smaller volumes of product. The absence of a manufacturing culture, however, makes it difficult to achieve process efficiencies, expand operations, and implement and maintain a biological-manufacturing approach.

**BY THE NUMBERS**

*Data from a 2007 American Association of Tissue Banks (AATB) survey showed that 32 U.S. tissue facilities processed 49,207 deceased donors (an average of 1,538 donors per bank) with an average allograft production of 49 grafts per donor. In the same survey, the seven AATB-accredited Canadian tissue banks reported having processed an average of 57 donors per bank with an average 21 grafts per donor.<sup>2</sup>*

**Falling short of our potential for tissue donation**

Although higher tissue-donation rates should be easier to achieve than those for organs, barriers remain.<sup>3,4</sup> Families sometimes decline consent for donation because they are unaware of the potential donor's wishes or are not approached properly. Families are also not always given opportunities to donate, as donation discussions in hospitals are conducted at the discretion of treating physicians, rather than as a standard of care. In fact, a lack of specialized training means health care professionals do not always recognize potential donors.

Eye and tissue banks also miss some opportunities for donation due to a lack of coordination with organ procurement organizations, medical examiners and coroners. Some simply do not have the budgets to expand or support their programs, while others do not have the capacity to recover and process tissue, even if families consent to donation.

<sup>2</sup> Robert Rigney, Report on the 2007 Annual Survey, AATB Spring Meeting, March 29, 2009.

<sup>3</sup> *Tissue Donation Potential Beyond Acute Care*, Canadian Council for Donation and Transplantation, August 2006.

<sup>4</sup> *Estimating Potential Tissue Donors in Canada from 1995 – 2000: An Exploratory Analysis Based on Acute Care Hospital Admissions Data, Final Report*, Canadian Council for Donation and Transplantation, January 2004.

*Challenge:***STRENGTHEN MEASUREMENT AND ACCOUNTABILITY MECHANISMS TO DELIVER CONSISTENT, CANADA-WIDE PERFORMANCE IMPROVEMENTS.**

Many Canadian tissue banks and programs collect and analyze their own data, although to varying standards and according to different data definitions. At the national level, however, consolidated data are virtually non-existent, and there are no requirements for tissue banks and programs to share information related to system performance.

The lack of comprehensive, timely and accurate national data limits the ability to understand various aspects of performance, including number of tissue donors per year, waitlist lengths and government expenditures on imported tissue. The lack of data also makes it difficult to identify evidence-based, system-wide improvement opportunities, including those in accountability.

**Vague and uncoordinated accountability**

There is no supply-chain accountability to improve performance by delivering on agreed outcomes and targets. Individual tissue and eye banks do not coordinate efforts or performance targets with others. Failure to implement leading practices is without consequences, and performance improvement incentives and requirements do not exist. Overcoming these accountability and performance shortfalls is particularly challenging because of the fragmented and geographically dispersed nature of tissue programs and organizations.




↑ **Sean Margueratt**, Director of the Nova Scotia Medical Examiner Service, and member of the Tissue Expert Committee.

**KEY CONSIDERATIONS**

The findings in this chapter suggest strongly that all efforts to improve TDT in Canada should be conducted with four overarching goals in mind:

- Enhance the quality of tissue,
- Provide an efficient and secure supply of tissues,
- Build a responsive and forward-looking system, and
- Ensure accountability for performance.



**Theresa Rath** *Twenty years ago, Theresa's father Glyn was declared brain dead after suffering an aneurysm at age 46. Physicians immediately approached the family and asked if they would be willing to donate his organs.*

*"While we had never discussed organ donation as a family," says Theresa, "we agreed without hesitation. My dad would have wanted to go on giving in death as he had in life."*

*The next day, the hospital called Theresa's mother to let her know that the family's decision had, within hours, given four people a chance at an improved quality of life. "In our staggering grief," recalls Theresa, "organ donation represented hope."*

*Theresa has been a powerful advocate for organ donation ever since. Looking back, she admits to one oversight. "If I knew then what I know now, I'd have donated my father's tissues to help even more people."*

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# PRIORITIES FOR THE WAY FORWARD

## Tissue Donation and Transplantation Strategy

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The previous chapter identified and described the greatest challenges facing tissue donation and transplantation (TDT) practices in Canada today. This chapter sets forth priorities for overcoming those challenges, capitalizing on current strengths and building a trusted, integrated TDT system.

### GETTING OUR PRIORITIES STRAIGHT

Looking to the future, the Tissue Expert Committee expressed a clear and succinct vision for the TDT system—*By 2017, the TDT community expects to have built a responsive and efficient Canadian system that assures a secure supply of quality tissue.*

The committee believes this vision can be realized if Canadian Blood Services and the TDT community focus on four system priorities:

- Ensuring the safety and quality of tissue product.
- Ensuring patients have timely and fair access to tissue products.
- Making TDT an efficient part of the health care system.
- Strengthening the system's infrastructure and capabilities.

These priorities are firmly interwoven; for example, high-quality tissues will help build trust in the system and enable it to become an efficient component of health care in Canada; strengthened infrastructure and capabilities will not only help ensure timely and equitable access to tissue products, but also contribute to the safety and quality of tissue product.

Individually and collectively, these priorities define a powerful strategy to transform TDT in Canada (Figure 10-1).

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*Safety and quality—including the system's capacity to quickly and accurately trace tissues from donor to patient—are essential if the system is to become a trusted component of the health care system.*

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↑ **Sophie de Villers**, Vice-President of Strategy Management, Canadian Blood Services, worked closely with the OTDT communities to develop a strategic plan for overcoming today's system challenges.

Figure 10-1. TDT SYSTEM STRATEGY

**A responsive and efficient Canadian system that assures a secure supply of quality tissues by 2017.**

**ENSURE QUALITY AND SAFETY**

*Enhance the safety and quality of tissue product*

- Operate an effective quality management program
- Enhance surveillance and ensure complete traceability
- Provide tissue product consistent with standard specifications

**PROVIDE A SECURE SUPPLY IN AN EFFICIENT MANNER**

*Ensure patients have timely and fair access to tissue products*

- Increase donation in acute and non-acute care settings
- Optimize tissue recovery and processing to align supply with demand
- Manage imported tissue effectively and efficiently

**BUILD A RESPONSIVE, FORWARD-LOOKING SYSTEM**

*Make TDT an efficient part of the health care system*

- Partner with researchers and industry to leverage innovations
- Partner with physicians to understand patient requirements
- Ensure clear, inclusive and timely decision making

**IMPROVE INFRASTRUCTURE AND CAPABILITIES**

- Build a sustainable workforce
- Establish effective data and information management practices
- Optimize facilities

**PRINCIPLES AND ETHICAL FOUNDATIONS**

Built according to specific principles and ethical foundations, the TDT system strategy identifies infrastructure and capabilities as a core element on which system operators can pursue the goals of ensuring quality and safety, providing a secure supply of tissue products in an efficient manner, and building a responsive, forward-looking system.

*System Priority:***ENSURE THE SAFETY AND QUALITY OF TISSUE PRODUCT**

Although there is inherent risk in the practice of transplanting human tissue, the new system will strive at all times to ensure the safety and quality of the products it provides to patients. Safety and quality—including the system’s capacity to quickly and accurately trace tissues from donor to patient—are essential if the system is to become a trusted component of the health care system.

There are three aspects to fulfilling this priority. For one, the TDT system must **use an effective quality management program**. This program will apply a set of coordinated activities to ensure consistently high-quality tissue products are produced in Canada. Suppliers of imported tissue will also be evaluated according to quality principles to further strengthen the quality objectives of the TDT system.

Second, the system must **enhance surveillance and ensure complete traceability**. Surveillance means collecting and monitoring data about tissue transplantation; traceability means being able to track each tissue product from donor to recipient. These functions are necessary to quickly and accurately identify affected tissue in the event of a safety issue.

Finally, ensuring safety and quality also means **providing tissue product to standard specifications**. This means that clinicians can trust the tissues produced in one part of the country to meet the same exacting standards as those produced in other parts of the country.

**MINIMIZING RISKS**

*Every tissue transplant comes with potential benefits and risks. Transplant decisions in the new system need to be based on clinical evidence to maximize outcomes and minimize risks for patients.*

*System Priority:***ENSURE PATIENTS HAVE TIMELY AND FAIR ACCESS TO TISSUE PRODUCTS**

Unlike today, the new TDT system should be able to meet patient demand for tissues with no shortages and no waitlists.

The system will meet this priority in three ways. It will **optimize donation in acute care and non-acute care settings**. This means working with healthcare professionals, medical examiners and coroners to increase the number of tissue donors identified and referred. Professional requestors will be trained to seek consent from potential donors’ families and make the most of every donation opportunity.

Timely and fair access to tissue products means that the system must **optimize recovery, processing and inventory to align supply with demand**. If donation increases, the recovery, processing and inventory capacity must also be increased to handle new volumes—and ensure an efficient, cost-effective, secure and reliable supply of tissue.

**FAIRNESS FOR ALL**

*Corneal transplants help restore vision for Canadians suffering from corneal blindness. Currently, patients may wait months or even years for transplants. With greater awareness, healthcare professionals, medical examiners, and coroners could identify and refer more eligible donors and significantly increase the availability of many tissues.*



Because Canada is dependent upon tissue imports from the United States, the system must **manage imports effectively and efficiently** to ensure that the products patients need are imported in the right quantity at the best possible price.

*System Priority:*

**MAKE TDT AN EFFICIENT PART OF THE HEALTH CARE SYSTEM**

Ultimately, the TDT system must operate as an efficient part of the broader health care system. TDT must ensure high-quality products for the public while providing governments with value for their investments. The TDT community believes there are three aspects to this priority.

First, the system must anticipate and respond to the biomedical and technical innovations that drive change in the TDT field. This means **partnering with researchers and industry—in Canada and around the world—to leverage innovations in product and practice**. This collaboration will help ensure the system remains up to date, and is able to streamline the adoption of effective new tissue products, substitutes and practices for the benefit of Canadians.

While universities, industry and research organizations are an important collaborative focus, the system must also **partner with clinicians to understand demand for tissue products**. No other group is better placed to forecast the types and specifications of tissue products that will be needed, to inform the creation of an inter-provincial supply-and-demand structure, and to monitor post-transplant patient outcomes.

Another key to making TDT an efficient part of the health care system is **ensuring clear, inclusive and timely decision making**. With the upgraded data and information capabilities discussed under the next priority (“Strengthen the system’s infrastructure and capabilities”), and the collaborative partnerships noted above, the system will be on its way to securing much of the clarity and inclusion demanded here.

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**A SYSTEM FOR TODAY—  
AND TOMORROW**

*Canada’s TDT system must be designed and operated sustainably so that it meets current and future needs. It must be cost effective and efficient to address patients’ needs while respecting economic and logistical realities.*

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Collaboration should include professional and industry ranks as well as patient groups. Well-established and effective lines of communication with all stakeholders will help inform timely decision making, and enable the system to respond swiftly when required.

*System Priority:***STRENGTHEN THE SYSTEM'S INFRASTRUCTURE AND CAPABILITIES**

Essentially, this priority involves developing a base of trained tissue banking professionals, an effective information-technology network and robust tissue processing capacity.

To **build a sustainable workforce that is aligned with system goals**, investments must be made in specialized training to ensure that professional capabilities are carefully tuned to TDT system design and implementation, and to ensure the ongoing, timely availability of the right people with the right skills.

Strengthening the system's infrastructure and capabilities means, in part, **establishing effective data and information management practices**. With the right technologies and processes, an integrated TDT system can compile comprehensive and accurate data. This data enables the research and planning that are essential for continuous system improvement, supply management and advancing clinical practice.

TDT infrastructure will also be strengthened by **optimizing facilities**. This involves leveraging and enhancing existing tissue recovery capacity and consolidating processing capacity to support growth, efficiency and improvements in the tissue system. Facility optimization also means providing new recovery and processing infrastructure to help increase domestic production of tissues and to build capacity to produce additional types of tissue products, reducing Canada's reliance on importation.

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**SOUND DECISIONS BASED ON HARD EVIDENCE**

*TDT decisions must always be based on medically, scientifically and socially sound evidence.*

*The system will collect, evaluate and analyze data, and adapt in response to new information.*

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**MEASURING PERFORMANCE AGAINST OBJECTIVES**

A systematic, evidence-based approach is vital if TDT authorities and participants are to conduct detailed, ongoing performance analyses. A variety of key measures will be used to determine when progress is being made. For example:

- Timely and accurate reporting on tissue usage and patient outcomes, including adverse reactions, will help measure success in enhancing surveillance.
- Doubling the total number of allografts that are produced, and that meet the system's quality requirements, will ensure patients get timely and fair access to effective tissue product.
- Doubling the number of tissue donors will indicate success and optimize the benefits to Canadians waiting for tissue transplants.

But there are other ways of knowing when TDT goals are being achieved. Among the most important will be a rise in the trust that the public and health care providers express in the system—trust that patients will be treated well and fairly, trust in the capacity to meet patients' needs, and trust in the availability of high-quality tissue products.

## BUILDING A BETTER SYSTEM

The next chapter explores the design of an integrated, inter-provincial TDT system. Canadian Blood Services and the Tissue Expert Committee believe that a system that meets the priorities set out in this chapter will perform optimally for Canadians and deliver excellent return on government investments.

### KEY CONSIDERATIONS

Looking to the future, the Tissue Expert Committee expressed a clear and succinct vision for the TDT system—*By 2017, the TDT community expects to have built a responsive and efficient Canadian system that assures a secure supply of quality tissue.*

The committee believes this vision can be realized if Canadian Blood Services and the TDT community focus on four system priorities:

- Ensuring the safety and quality of tissue product.
- Ensuring patients have timely and fair access to tissue products.
- Making TDT an efficient part of the health care system.
- Strengthening the system's infrastructure and capabilities.

# TDT SYSTEM RECOMMENDATIONS

## INTRODUCTION

The following recommendations identify the activities, systems, roles and responsibilities that are needed for operating and managing tissue donation and transplantation in a way that supports the proposed system strategy. The intent is to leverage the existing expertise and capabilities that currently exist, and build on them as a foundation. Throughout the country there are programs that have experience in donor referral, and tissue recovery, processing and distribution. For its part, Canadian Blood Services has successfully transformed the blood system, and has experience in managing inter-provincial blood, plasma protein products, and stem cell services. By applying these skills, the TDT system can be transformed from a collection of independent, uncoordinated tissue and eye programs, into a single, integrated system that ensures equitable and timely access to tissues by Canadian patients.

The system starts with an integrated supply plan (Figure 11-1) that takes into consideration tissue needs of all patients across the country. This would be developed by Canadian Blood Services with input from hospitals across the country.

To drive efficiencies, improve quality and quantity, and increase the system's capability for making specialized tissue products, there will be a significant reduction in the number of programs that process tissue across the country. More than 20 eye and tissue banks exist in Canada today. In the new system model, it is proposed that this number be reduced to three or four tissue processors and two or three ocular processors. Tissue and ocular processors would be chosen from existing tissue and eye banks through a transparent selection process, based on the processors' ability to meet predetermined criteria related to quality, experience, capacity, cost and other factors. For one of the tissue banks and two of the eye banks, new facilities will be built to accommodate the increased volume and range of tissues from an increased number of tissue donors. These new facilities would be capable of producing specialized tissue products and pre-cut cornea, for example. Tissue processors in the new facilities would be integrated into Canadian Blood Services' operations, while the other selected programs would be contracted by Canadian Blood Services for their services.

Also critical to the new system will be increased tissue donation by Canadians. To support this increase in donation, tissue recovery will need to be optimized to realize each donor's gift. Those tissue or eye banks that are not selected to become ocular or tissue processors will remain an important part of the tissue system by continuing their tissue recovery programs. To increase recovery further, Canadian Blood Services will also establish two recovery teams, and work in partnership with coroners, medical examiners and health care professionals whose role in increasing donor referrals will be essential. All tissue recovery activities will be linked to a single, inter-provincial supply plan, and be contracted by Canadian Blood Services directly or by one of the selected tissue processors.

**Note:** In Quebec, Héma-Québec is responsible for tissue donation and transplantation and has its own action plan to increase tissue donation and transplantation. Therefore Quebec is not included in the following descriptions and recommendations.



**OLIVIA AND SOFIA** Sofia suffers from aniridia, which is the absence of irises in the eyes. Because aniridia can be an indication of a genetic condition called WAGR syndrome, Sofia and her identical twin Olivia (pictured here with their mom, Maria) are tested regularly for another WAGR indicator—Wilms tumour, which threaten kidneys.

Sofia also suffers from glaucoma. One eye is particularly unhealthy and, during the transplant of a synthetic cornea in the fall 2010, doctors discovered she had suffered a partially detached retina. As a result, her vision is severely compromised.

Doctors are encouraged that her retina appears to be healing, but Sofia's long-term prognosis is difficult to predict. Her ability to see her world may well depend on new advances in tissue-transplantation medicine—advances propelled by targeted research and innovation investments in an integrated, inter-provincial TDT system.

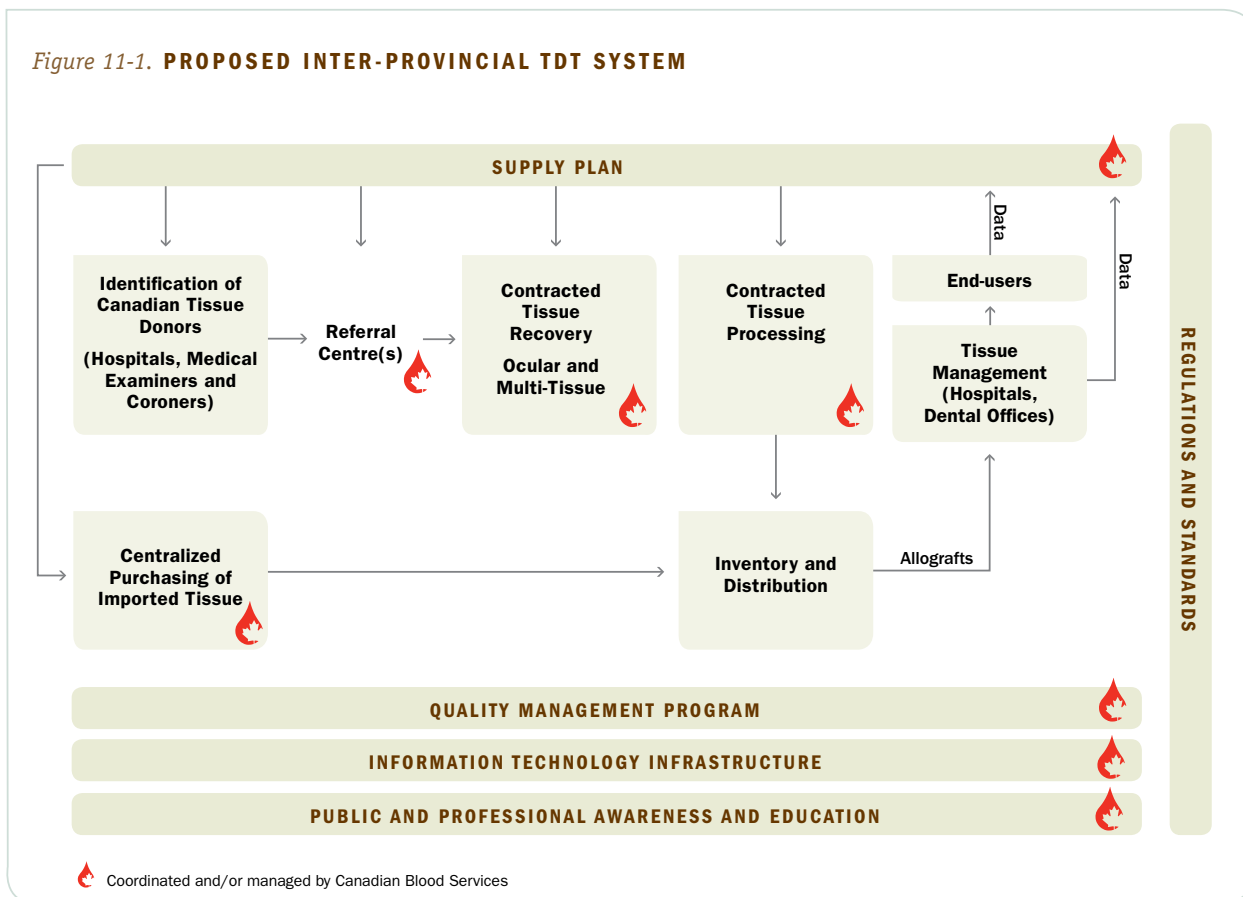
The importation of some tissue products will be centralized and managed by Canadian Blood Services. This will ensure better pricing, as well as ensuring quality specifications have been met through a supplier qualification program.

Finally, Canadian Blood Services will develop a single inventory and distribution network that will be supported by a common IT platform. Through such a network, hospitals will be able to order the majority of their tissue products from one source. Before they can access tissues from the inter-provincial inventory, hospitals will be required to follow standard tissue management practices—to ensure the traceability of products and to report on tissue usage and outcomes.

It should be noted that although Canadian Blood Services will play a prominent role in the operation and management of a new TDT system, organizations such as Health Canada, the Public Health Agency of Canada, the Canadian Standards Association and Accreditation Canada will continue to play essential roles in developing regulations and standards, and conducting audits and inspections.

The following recommendations provide the details and rationales for these changes.

Figure 11-1. PROPOSED INTER-PROVINCIAL TDT SYSTEM



## RECOMMENDATIONS—ACCOUNTABILITY

**1. Tissue recovery, processing and distribution activities are part of a complex biological manufacturing process that benefits from a standardized approach to quality, specialized training and facilities, efficient use of resources and a culture of innovation. Achieving a secure supply of high quality tissues that provides equitable and timely access for Canadian patients requires an integrated approach to planning that aligns tissue recovery and processing with anticipated demand. It is recommended that the many independent and un-coordinated tissue banks that operate in the current environment transition to a system that optimizes tissue donation and recovery, consolidates tissue processing, maintains a single shared inter-provincial inventory, and is managed by one organization.**

### Value to Canadians

A single inter-provincial tissue inventory that is supplied by Canadian tissue processing facilities that maintain a standardized approach to quality, and that is supported by increased tissue donation and recovery efforts, will ensure that patients have fair and timely access to transplants. It will also ensure that appropriate tissues are available as required to best serve patients. Corneas, for example, will be directed where and when they are needed for transplant, restoring the vision of Canadians while eliminating excessive wait times. Also, an emergency stock of skin will be maintained so that it can be deployed to burn units when disaster results in multiple patients urgently requiring treatment.

Tissue processing facilities operated by Canadian Blood Services will apply more advanced techniques to provide surgeons with a wider range of tissues donated by Canadians. In some instances this will allow treatment of patients with preferred tissues that produce better clinical outcomes. This will also reduce Canada's dependence on imported tissues, protecting it from supply disruptions.

Finally, operating a single integrated tissue system will permit collection and analysis of collated inter-provincial data to measure performance, monitor tissue use and inform planning and policy development.

### Description

The successful transition to an effective inter-provincial tissue system design will require creating and maintaining a tissue supply plan that will detail the expected demand, optimal inventory level and planned production of each type of domestically produced tissue allograft. As recommended by the Tissue Expert Committee, a single organization will be responsible for the supply plan to ensure security of supply, improve the ability of the system to meet demand and respond to supply problems. The supply plan will reduce the risk of tissue shortages, ensure equitable access to tissues across the provinces and enable the development of a cost-effective system.

To operate an effective and efficient inter-provincial tissue system, an information system will be required that integrates inventory and distribution functions with data capture for adverse events, utilization and outcomes reporting. From a patient-safety perspective, an information system that also ensures traceability of tissue products is required to ensure that traceability is handled in a consistent fashion, through to the patient at the hospital. It is recommended that an appropriate information system be implemented, and that hospitals commit to tissue management practices that ensure traceability and robust adverse-reaction reporting, and to reporting on utilization and tissue transplant outcomes. This data can be shared with end-users to inform usage decisions and with governments to inform policy decisions.

The tissue community has frequently requested that a standardized quality management program be developed. Such a program would ensure consistently high quality in all aspects of tissue donation: recovery, processing and distribution. It was recommended that a single organization with biologics manufacturing experience and an inter-provincial scope engage the tissue community to define criteria and processes from a quality perspective, developing common best practices and product specifications. This standardized approach to quality will also be a key enabler to the creation of a single inter-provincial inventory supplied by different tissue processors across the country.

For most types of tissue, the current rate of tissue donation in Canada is one-fifth or less of that in the United States. Surgeons have indicated that they must wait for tissue to schedule some orthopaedic surgeries, that they reserve skin allografts for only the most critical burn patients, or that they use sub-optimal alternative materials for paediatric cardiac surgeries because there is an insufficient supply of human heart valves. Patients must wait between seven and 36 months for cornea transplants, depending on where they live, due to a shortage of corneas.

There is a pressing need to improve the identification and referral of tissue donors, to realize the full benefit of each donor's gift, and to ensure there is a robust supply of basic bone, tendon, skin, cardiac and ocular tissues produced in Canada. Working closely with organ procurement organizations, providing educational support for hospital donation physicians, and building linkages with the medical examiner and coroner communities are essential steps to improving the rates of tissue donation. Ensuring that these tissue donation-related efforts are aligned with tissue recovery and processing activities is a pivotal role that directly links to the inter-provincial supply plan. The Tissue Expert Committee recognized that tissue donation, recovery and processing are all directly linked to planning and managing an inter-provincial supply of tissue allografts. The committee therefore recommended that the responsibility for managing all of these activities be assigned to a single organization.

Recognizing that increasing the number of tissue donors in Canada will require additional capacity to recover tissue, a prudent strategy is required to optimize the existing tissue recovery capacity while adding new capacity to align with improved tissue donation rates. The Tissue Expert Committee—with support from the broader tissue community—advised that the organization tasked with managing tissue recovery should build its own capacity and could also contract existing tissue banks to recover tissue.



↑ **Dr. Locksley McGann PhD**, Department of Laboratory Medicine and Pathology, University of Alberta, and Chair of the Tissue Expert Committee that brought together surgeons, researchers, tissue bankers, policy experts and academics from across Canada to address the challenges related to TDT performance in this country.



The processing of tissue recovered from Canadian donors is conducted by numerous independent eye and tissue banks across the country. Tissue experts have recommended that this activity be consolidated into a more efficient model. For comparison, the total number of allografts produced by the more than 20 Canadian eye and tissue banks in 2008 was well below the number of allografts produced by a typical tissue bank in the United States that year. To balance consolidation with the need for a level of redundancy over a large geography, it is recommended that the existing tissue processing activity be consolidated into three or four existing tissue banks and one new facility. Ocular tissue processing would be consolidated into two or three new facilities. These facilities would have the capacity to carry out more complex processing activities. It should be noted that although tissue processing would be consolidated, tissue recovery practices would continue where tissue banks are currently located, provided quality and performance criteria are met.

Imported tissue currently accounts for approximately 80 per cent of the tissue allografts used in Canada. However, these imported tissues are nearly all specialized tissue products—they have been subjected to processing technologies not used in Canada. The tissue community has recognized there is an opportunity to produce some of these specialized tissue products in Canada, provided the tissue system is equipped with the required technology, facilities and trained staff. Moreover, because the large volumes of imported tissues are also generally purchased in small amounts by individual hospitals, another opportunity exists to centralize some of this purchasing activity to realize some cost efficiencies. It is recommended that the organization responsible for managing tissue processing activities also pursue the production of some specialized tissue products for use in Canada, and that bulk purchasing also be pursued to achieve a more cost-effective approach to importing tissues from the United States.

The organization that operates an adaptive and responsive inter-provincial tissue system will need to build linkages with the tissue research community, attracting researchers to solve problems and answer questions. The outcomes of this research would be an input to the tissue donation and transplantation system and support evidence-based decision making. Providing access to grant funding will create the interface between tissue operations and the expertise available in research networks in academia and other institutes.

**2. Planning and managing the supply of tissue allografts as a single inter-provincial tissue system requires that a single organization manage and coordinate donation, recovery, processing and distribution activities. It is recommended that Canadian Blood Services be given the mandate and funding to assume the responsibility for managing the inter-provincial tissue system, and that provincial and territorial governments establish a formal accountability framework that outlines the structure and essential attributes of—and roles and responsibilities within—an inter-provincial TDT system, thereby enabling it, as a whole, to achieve and be evaluated against stated goals.**

Canada's tissue system currently comprises more than 20 independent, un-coordinated tissue and eye programs. Because of the fragmented nature of the system, there are a number of serious gaps that affect patient health in Canada. There are shortages of certain types of tissues in most parts of the country. Donation rates are low. There is no accurate forecast of patient demand for tissue products. There is no coordinated supply plan to ensure tissue supply is aligned with demand. The small volumes of tissues recovered and processed in many locations make the system inefficient. There are varying quality and specifications of tissue across the country, and there is no capacity to make specialized tissue products.

Internationally, the trend has been towards consolidation of tissue programs to improve efficiencies at the same time as improving quality and standardization of tissue allografts. In the United States, an average tissue processor has three to four times the output of all Canadian tissue and eye banks combined. In the U.K., one tissue bank provides almost the entire national tissue supply.

If Canada is to move forward and develop a tissue donation and transplantation system that is responsive and capable, its tissue operations must be integrated under a single organization that is responsible for ensuring the safe, secure supply of tissue for Canadian patients. In doing so, clinicians would have the tissue products they need when they need them, and the tissue system would operate efficiently and sustainably.

Recognizing the need for coordination and consolidation, the Tissue Expert Committee and the OTDT Steering Committee recommended that Canadian Blood Services be the organization to manage the inter-provincial tissue program. Canadian Blood Services currently manages inter-provincial blood, plasma protein products and stem cell services for the provincial and territorial governments. By leveraging its expertise and infrastructure, and working with the tissue community, Canadian Blood Services can transform the tissue system.

In a transformed tissue system, Canadian Blood Services' mandate would include:

- developing an integrated inter-provincial supply plan to ensure that demand for tissue by Canadian clinicians is met. This includes working with hospitals and clinicians to understand current and future requirements.
- ensuring that tissue donation and recovery is sufficient to meet the supply plan, through its own tissue recovery activities and through contracts with other tissue recovery partners.
- ensuring that tissue is processed to quality standards in an efficient, cost-effective manner by establishing its own processing sites and contracting other tissue processors.
- establishing contracts with international suppliers for imported tissue, to be made available to hospitals and clinicians through a single inventory and distribution network.
- operating a single inter-provincial inventory and distribution system that provides equitable and timely access to tissues for hospitals and clinicians across the country.

In addition to clarifying roles and responsibilities, several key enablers are critical success factors for an integrated tissue system. These include:

- formal service-level agreements that define data reporting and tissue management requirements between Canadian Blood Services and hospitals that access the inter-provincial tissue inventory, to improve tissue traceability and reporting of adverse reactions and outcomes,
- auditing of recovery organizations, tissue processors and hospitals to ensure adherence to contracts for quality standards, and
- data reporting to measure, benchmark and monitor system performance.

### **Governance and funding structure**

To ensure that Canadian Blood Services has the authority for the proposed activities, it is essential that the organization receive a clear mandate through a memorandum of understanding or similar mechanism. Such an agreement would also outline expectations with respect to key enablers. It is also proposed that Canadian Blood Services would report on progress through its board of directors to the provincial and territorial ministers of health (Figure 11-2).

The provincial and territorial ministries of health would be provided with an annual tissue forecast and budget. As it does for the blood system, Canadian Blood Services would submit a yearly budget request based on a three-year plan, which would be reviewed and approved by ministers of health. At the same time as it submits its strategic plan, Canadian Blood Services would also deliver performance data.

Under this proposed governance structure, other organizations, such as tissue recovery or processing partners, would be accountable to Canadian Blood Services through contracts for meeting quality and performance targets. These organizations would be contracted by—and receive their funding from—Canadian Blood Services as part of the budget approved by the ministers of health.

Hospitals and end-users would have access to tissues in the following ways:

- Tissues donated by Canadians and processed in Canada as a shared inter-provincial service would be made available to Canadian hospitals and clinicians at no direct cost to the hospital (similar to blood products).
- Tissue allografts processed in the United States and imported into Canada (mainly specialized products not currently processed in Canada) would continue to be purchased by hospitals and paid for out of their budgets, either directly from US suppliers or from Canadian medical products distributors. However, Canadian Blood Services would be responsible for negotiating contracts and performing supplier qualification. At a later stage, Canadian Blood Services would directly purchase inventory and distribute imported tissues to hospitals at cost.
- Dentists and dental surgeons—who use specialized tissues that are currently all imported—could be provided access to domestically produced specialized tissues when production is implemented. Access would be on a cost-recovery basis.

Detailed funding and costing mechanisms will be determined by the provincial and territorial ministers of health (who are also the members of Canadian Blood Services); however, it is expected that cost sharing between provinces would be based on usage of tissue products.

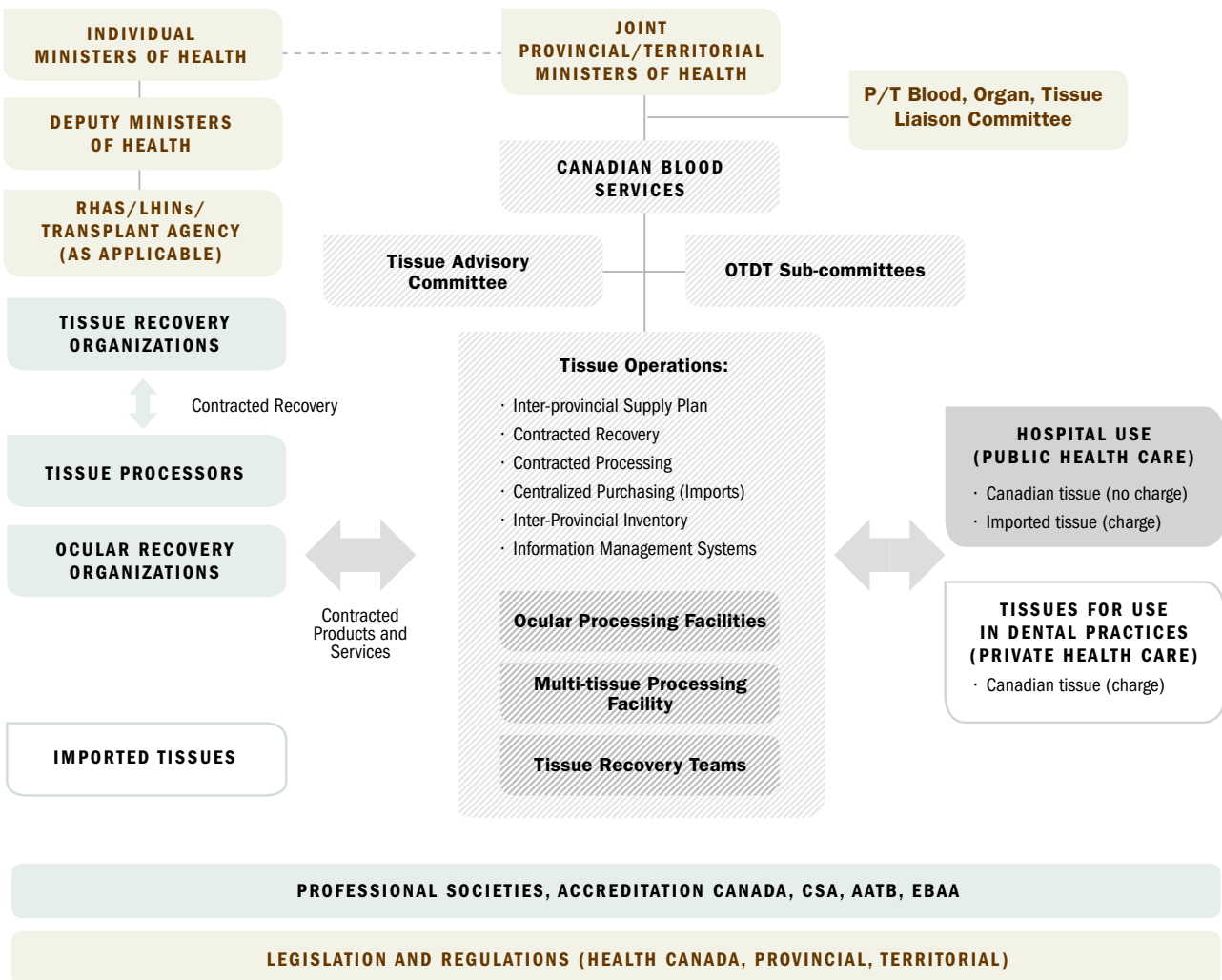
### **Advisory committees**

One key element of the inter-provincial tissue system is the requirement for continuous input by the public and by the tissue community. To achieve this, a number of committees will be created to provide advice and guidance. A tissue advisory committee will be established to discuss matters related to tissue and eye banking.

In areas where the needs of the tissue and organ communities overlap—infectious diseases, donation, public awareness and education, for example—specific OTDT sub-committees will be formed to address the need for common policy. (The structures and role of these committees are more completely described in the organ donation and transplantation recommendations.)

It was also noted throughout the public and expert engagements that public input into the system is essential. The views of patients, donor families and members of the general public must be captured at all times. Because of the special nature of human tissues and organs, it has also been recommended that ethics reviews and consultations be integrated into decision-making processes. Representatives from patient groups, donor families and members of the public will also be include in the sub-committee structure to advise on matters that have ethical implications.

Figure 11-2. RECOMMENDED TDT GOVERNANCE STRUCTURE



## RECOMMENDATIONS—QUALITY AND SAFETY

**3. Through broad consultations with the tissue community, the need for a systematic and comprehensive approach to quality and safety was identified. A quality management program should establish a set of coordinated activities to direct and control the inter-provincial tissue system and should introduce an approach to quality that is standard in biological manufacturing environments. It is recommended that Canadian Blood Services develop and lead the implementation of a standardized quality management program to ensure that surgeons and patients have confidence in the system's ability to deliver tissue allografts that consistently meet their needs and expectations.**

### Value to Canadians

A standardized, systematic and comprehensive tissue quality management program will improve the consistency, quality and safety of tissue allografts for all patients. Such an approach will also harmonize product specifications for tissue allografts, standardize response procedures for emerging risks, and establish a framework for continuous process improvements.

Canadian Blood Services will leverage its own expertise, experience and structures to ensure the tissue quality management program is developed and deployed in ways that deliver high quality tissue allografts.

### Description

The scope and effectiveness of quality management programs at tissue and eye banks across the country vary. Although a number of factors contribute to these discrepancies—including the participation of banks in voluntary accreditation standards, and their quality management resources and expertise—they result in products whose characteristics vary considerably. This variation has been identified as one of the factors that currently limits inter-provincial tissue sharing.

The proposed solution is the development and implementation of a comprehensive quality program that is standard in biological manufacturing environments. The program will support consistent processes and the introduction of closely defined product specifications. The quality program will apply to all system processes from donor identification through to the processing and distribution of the tissue allografts. Elements of the program include:

- training
- validation
- deviation management
- supplier qualification
- quality control
- corrective action and preventive action
- process control
- internal and supplier audits
- change control
- document management
- records management
- equipment management
- reporting
- management review

Standardized product specifications are essential to ensuring the tissue allografts produced for a single inter-provincial inventory have consistent characteristics and meet the needs of surgeons and patients. Product specifications will govern donor-suitability criteria, tissue-processing methods, transmissible-disease testing, tissue-allograft characteristics, and packaging and labelling specifications. A related objective will be to phase in ISBT 128 labelling on domestically produced tissues, in support of standardization and traceability. ISBT 128 is a global standard for the identification, labelling and information transfer of human blood, cell, tissue and organ products, that is used in 30 countries. ISBT 128 labelling was implemented for blood products by Canadian Blood Services in 2009.

Canadian Blood Services already maintains a comprehensive quality management program for blood, plasma protein products and stem cells. Elements of the existing quality management program will be directly leveraged in those tissue-system activities in which Canadian Blood Services plays an operational role.

Processing and recovery organizations that are contracted to supply the inter-provincial inventory will be required to meet defined quality and product requirements. Canadian Blood Services will use a supplier quality-management program to help contracted eye and tissue recovery programs and processors implement the requirements.

**4. Hospitals and clinics routinely use tissue allografts, but each adopts a different approach to tissue storage, records maintenance for traceability purposes, and adverse-reactions reporting. Ensuring the appropriate management of tissue—including traceability of each tissue allograft to the recipient and reporting adverse reactions—is essential to patient safety. It is recommended that, with the implementation of a single inter-provincial tissue inventory, Canadian Blood Services partner with hospitals and clinics to establish agreements that define roles and accountabilities for hospital tissue management as well as utilization and outcomes reporting.**

#### Value to Canadians

A standardized approach to hospital tissue-management practices will improve tissue traceability, and underscore the importance of surveillance activities and adverse-reaction reporting. Such an approach will also harmonize hospitals' and clinics' approaches to reporting tissue-usage and outcome data, inform supply plans and transplant-risk studies, and make reporting data available to all system stakeholders.

#### Description

Hospitals and clinics are vital partners in optimizing the performance of an inter-provincial tissue system. In the current environment, however, tissue management practices and surveillance and reporting activities vary among hospitals and clinics. Tissue donation and transplantation experts have also identified challenges and inconsistencies in tissue traceability within hospitals and clinics.

The elements of tissue management are described in *Hospital Tissue Management – A Practitioner's Handbook*, a joint publication of the American Association of Blood Banks (AABB), the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA). It is proposed that mechanisms be introduced to ensure the types of effective tissue management practices described in this joint publication are introduced in hospitals and clinics where tissue allografts are used. With the implementation of a single inter-provincial inventory and distribution system, Canadian Blood Services will establish service-level agreements with hospitals and clinics that outline the essential requirements for effective tissue management, including:

- tissue storage,
- record keeping and traceability,
- tissue allograft usage reporting (including indication and patient outcomes), and
- investigation of adverse reactions.

Service level agreements with hospitals would also include a provision that enables Canadian Blood Services to perform periodic assessments of hospitals or clinics as part of monitoring overall tissue system performance related to reporting and traceability. The agreement could also provide recommendations on improving recipient-informed consent practices in tissue transplantation and enhancing surveillance activities. A role similar to a transfusion safety officer could enable these and other hospital tissue management practices.

Hospital reporting would be facilitated through a web-based point of access that would also provide the link to tissue ordering from the inter-provincial inventory (see recommendation 9 on single inventory).

The inclusion of specific requirements for tissue management in hospital accreditation standards will support improved practices within hospitals. Canadian Blood Services will collaborate with Accreditation Canada to define requirements for tissue-service oversight, tissue management, traceability and the investigation of adverse reactions, and will encourage the inclusion of these requirements into standards.

## RECOMMENDATIONS—EFFICIENT AND SECURE SUPPLY

**5. A primary limitation of the current Canadian tissue and eye bank environment is the number of tissue donors identified and referred to recovery programs. Although there are examples of successful initiatives in some regions of the country, Canada's overall tissue donation rate has not changed significantly, and the gap between tissue demand and supply continues to grow. The number of potential tissue donors in acute care settings, and outside of hospitals, far exceeds the number needed to meet patient demand for the types of allografts currently produced in Canada. It is recommended that Canadian Blood Services collaborate with medical examiners, coroners, allied health professionals, hospital donation physicians and OPO staff to develop more effective mechanisms to identify and refer potential tissue donors.**

### Value to Canadians

Donor-identification initiatives will help increase the supply of tissues available to Canadian patients. An inter-provincial approach will leverage the support of professionals and professional groups—such as medical examiners, coroners and donation physicians—to increase the number of tissue donation opportunities and improve the availability of tissue for all Canadian patients. Increasing the number of tissue donations will improve the availability of some tissue allografts that are currently in short supply, such as paediatric heart valves.

Compared with the current TDT environment, an inter-provincial approach offers a number of benefits. For example, it will significantly increase the number of families that are offered the option of donation. It will align donor identification and referral activity with tissue recovery and processing activities, ensuring that increased donation translates into improved availability of tissues for patients across the country. Finally—led by Canadian Blood Services, an inter-provincial organization that has demonstrated experience and expertise in the health care sector—it will also ensure a consistent approach to quality and safety, standardizing donor criteria inter-provincially and applying best practices.



↑ **Mary Gatien** Director, New Brunswick Eye and Tissue Bank, and Tissue Expert Committee member

## Description

The Canadian supply of tissue does not meet demand. More than 2,000 Canadians are waiting for cornea transplants to restore their vision. In half of the paediatric cardiac valve procedures performed in Canada, surgeons are required to use alternate implants due to the shortage of the preferred allograft heart valve. Plastic surgeons have indicated that the shortage of skin allografts means they are used in only the most critical cases, even when other patients would benefit as well. The need for an emergency stock of skin to deal with sudden demand for treatment of a large number of burn patients has also been identified. Fresh joint allografts are considered the ideal graft for a number of surgical procedures, but the timing and logistics are a challenge to manage, making the supply of these allografts very limited. An inter-provincial approach would improve the likelihood of identifying a donor allograft best-suited to a specific patient by enlarging the base of potential donors and facilitating the transfer of the allograft to the patient's location.

In 2008, Canadian tissue banks recovered tissue from 278 multi-tissue and 2,679 ocular donors for a total of 2,957 cadaveric donors. Recent analysis indicates that the potential exists to recover tissue from 44 per cent of patient deaths that occur within the acute care environment. This figure is conservatively estimated to be approximately 4,000 potential multi-tissue donors and 8,000 potential ocular donors. Also in 2008, tissue was recovered from 135 (or 40 per cent) of the 335 organ donors in the acute care environment. This last figure can be compared with programs in Spain, where more than 90 per cent of organ donors are also tissue donors. The gap between potential and realized tissue donors in Canada's acute care environment is attributed to a lack of awareness and focus on tissue donation, as well as to a lack of capacity to recover tissue from donors.

It is estimated that half of the otherwise healthy individuals who die outside the acute care environment are potential tissue donors. Medical examiners and coroners are responsible to investigate these unexpected deaths, and can therefore play a major role in identifying and referring these potential tissue donors. Currently only a small number of referrals are received from medical examiners and coroners offices, indicating there is a significant opportunity to collaborate with this professional community to increase tissue donation.

The strategy to increase tissue donation will leverage existing structures to optimize the identification and referral of potential donors both within and outside acute care. Emphasis will be placed on collaboration with medical examiners and coroners and the existing support from this professional community. Funeral home professionals are also very influential in the tissue donation process. This community will therefore be encouraged to foster and increase support for donation. A small team of tissue donation specialists will be established by Canadian Blood Services to support the medical examiner and coroner communities and to provide subject matter expertise and support to hospital donation physicians, funeral home professionals and organ procurement organization communities.



↑ Professor of Orthopaedic Surgery at Dalhousie University, **Dr. Michael Gross** was also a member of the Tissue Expert Committee.



A number of recommendations for improving organ donation and transplantation in Canada also apply to tissue donation and transplantation. Recommendations that pertain to donation physicians, public awareness, intent-to-donate registries, required referral and professional education (detailed in the organ donation and transplantation recommendations) are designed to increase the number of organ and tissue donors. Implementation of these recommendations is fundamental to improving the number of tissue donors and the system's ability to optimize donation in acute and non-acute care settings. Existing referral centres or systems that support current donor identification and referral activities may require incremental resources to support increased activity.

As outlined, donation of organs and tissues will be encouraged in public awareness and marketing campaigns to ensure consistent messaging. However, only those donors whose tissues can be used in a timely manner and in a cost-effective fashion will be recovered. This is an acknowledgement of the reality that Canada's tissue requirements can likely be met with recovery focused in some, but not all geographic areas, and that it is not always cost-effective to send recovery teams to all outlying or remote areas.

**6. Improving the rate of tissue-donor identification and referral will demand that the Canadian tissue system expand its tissue recovery capacity. Currently Canadian tissue banks recover tissue from relatively few donors when compared to other, international tissue banking systems. There are a number of high-population regions in Canada with significant donation potential, but these areas are served by limited or non-existent tissue recovery capacity. Operating tissue-recovery teams that support a new tissue processing facility will permit greater control of product quality over all elements of the TDT system. It is therefore recommended that Canadian Blood Services develop tissue recovery capacity by establishing its own recovery program in parts of the country where significant increased donor referral is achievable and where current recovery capacity is limited. It is also recommended that existing tissue-recovery programs maintain operations under contract to Canadian tissue processors, provided they are able to meet quality and performance requirements.**

### **Value to Canadians**

The addition of two fully operational multi-tissue recovery teams will play a major role in achieving the system's target of doubling the number of multi-tissue donors and increasing the number of ocular-only donors. These teams will be established in jurisdictions that can support higher-volume donor identification and referral activity. Such an approach will ensure that the recovery teams are used efficiently.

By recovering tissue in this manner—and subsequently processing it via contracted tissue processors (and later in a new processing facility owned and operated by Canadian Blood Services)—the system will significantly increase the supply of tissue allografts in Canada. And because the supply of tissues from the donors recovered by the Canadian Blood Services teams will be managed through a shared inter-provincial inventory, surgeons and patients across all regions of the country will benefit from equitable access to an improved supply of high-quality tissues.

A coordinated approach to recovery will yield a number of benefits. It will:

- align tissue-recovery capacity with donor-identification and referral activities,
- align tissue-recovery activities with changes in demand,
- ensure standardization in recovery activities, and
- ensure best practices are applied inter-provincially.

## Description

Tissue recovery is generally conducted by skilled technicians, or in some cases physicians, who may recover only a single type of tissue from a donor, or who may recover multiple tissues. Within the current system, the tissues recovered may be limited by the type of recovery teams available in a region (e.g., there may only be ocular recovery staff available and therefore other suitable tissues are not recovered). It is essential, therefore, that improved donor identification and referral efforts be linked to adequate tissue recovery capacity to ensure each donor's gift is realized and optimized. Furthermore, increased tissue recovery must be aligned with tissue processing capacity and the overall inter-provincial supply plan (see recommendation 9 on single inventory and recommendation 7 on tissue processing).

Multi-tissue recovery is currently limited to a small number of regions that are supported by multi-tissue banks and generally takes place after-hours in hospital operating rooms. Ocular-only recoveries are simpler. They can be carried out in other locations (such as morgues) and are supported in a larger number of regions. Most often, ocular-only recoveries are performed by one person such as a staff member from an eye or tissue bank, or a nurse or physician who recovers ocular tissue on behalf of the eye bank.

Existing tissue-recovery capacity will be aligned to the contracted Canadian tissue processors through direct arrangements. Tissue processors will be expected to secure the supply of donor tissue required to meet their tissue processing targets as defined in the contracts with Canadian Blood Services. As described in recommendation 3 on the standard quality program, the tissue processors contracted to provide allografts to an inter-provincial inventory will be required to ensure that their quality requirements are met by any tissue recovery programs with which they partner for tissue recovery. The tissue recovery programs would also be subject to quality audits by Canadian Blood Services.

Consistent with the advice of the Tissue Expert Committee, Canadian Blood Services will establish two tissue recovery programs to add to the existing capacity in Canada. These programs will be focused on high volume multi-tissue recovery in different regions, and will align their tissue-recovery activities with the supply plan. They will also support ocular-only recoveries as required, with a focus on best practices for recovering corneas. The tissue recovered by the Canadian Blood Services' recovery teams will be forwarded to tissue processors that are contracted to supply tissue allografts to an inter-provincial inventory. Cornea recovered by Canadian Blood Services' recovery teams would be provided to an ocular processing program that is selected by Canadian Blood Services and that has the capability to process corneas into the advanced pre-cut form now required for many cornea transplants.

During the first two years after system implementation, the tissue allografts and pre-cut cornea produced from the tissue recovered by Canadian Blood Services' teams would be managed separately by Canadian Blood Services as an inter-provincial inventory, and allocated equitably across all jurisdictions. Tissue and corneas recovered by existing recovery programs and tissue banks would continue to be managed locally.

By year three, when the inventory and distribution information system platform becomes available, and Canadian tissue processors are funded through contracts with Canadian Blood Services, the transition to a single inter-provincial tissue inventory managed by Canadian Blood Services would take place.

Once Canadian Blood Services has established its own new tissue processing capacity, tissue recovered by Canadian Blood Services would be directed to this facility. Contracted tissue processors would continue to process tissue recovered by their own and by partnered recovery programs.

Canadian Blood Services will be responsible for recruiting, training and managing the two multi-tissue recovery teams, achieving recovery targets, and managing the processing of recovered tissue through a contractual agreement with an established multi-tissue processor and eventually through Canadian Blood Service's new processing facility. Canadian Blood Services will also be responsible for managing the inventory of tissue allografts produced from its tissue recovery teams. Tissue processors selected by Canadian Blood Services for contract processing will be responsible for managing their own recovery activities or those of their partner recovery programs, to ensure quality requirements and recovery performance targets are met.

The donation and recovery of islet cells is not considered to be in the scope of the tissue activities described here.

**7. Consolidating existing Canadian tissue processing activities into a smaller number of higher volume processing facilities would make the system more efficient and better able to meet the needs of Canadian patients. An open and transparent selection process will be conducted to select the multi-tissue and ocular processing programs that will be contracted to supply tissues to a single inter-provincial inventory. There will be opportunities for some of these programs to transition to new facilities where specialized expertise and technology can be effectively utilized. It is recommended that Canadian Blood Services conduct the selection and consolidation process for multi-tissue and ocular programs, and that the multi-tissue and new ocular facilities be operated under Canadian Blood Services management.**

#### **Value to Canadians**

The act of consolidating the number of multi-tissue and ocular processing programs into fewer, higher-volume programs—and operating them under the direction of Canadian Blood Services—will yield a number of important benefits for patients.

Firstly, supply can be adjusted to meet demand. Establishing supply targets and quality requirements through contractual agreements with tissue processors will provide the number and type of allografts required to improve the supply of tissue for patients. By concentrating tissue processing in a smaller number of programs, enabling their quality management systems with Canadian Blood Services' expertise and resources, and equipping new facilities with leading-edge technologies, a consistent, high-quality supply of tissue for patients will be realized.

The contractual agreements established with processors will clearly define roles and responsibilities and establish accountability. This approach will provide visibility to performance, enable the system to respond to changes in supply and demand, and will provide the ability to respond quickly and consistently to safety and quality issues.

Secondly, consistent and expanded processing capabilities will maximize each donor's gift and decrease surgeon time in the operating room by providing the appropriate type of processed tissue when required.

## Description

As the organization that manages the supply plan and the single inter-provincial inventory, Canadian Blood Services will implement supply contracts with the best-performing Canadian multi-tissue and ocular processors, through an open and transparent selection process. Three or four multi-tissue processors and two or three ocular processors will be selected on the basis of criteria such as demonstrated capacity and capability, range of tissues processed, quality management system, end-users' advice and cost. The selected processors will be contracted to provide tissue allografts according to set specifications and quality requirements, in accordance with the supply plan. They will also be engaged by Canadian Blood Services in a supplier quality management program. This partnership will leverage Canadian Blood Services' expertise and resources to implement or develop the processors' quality management systems and improve operational processes in alignment with best practices in biologics manufacturing and tissue specifications determined by the tissue community (see recommendation 3 on standard quality management program).

Canadian Blood Services will build and manage one multi-tissue processing facility and two or three ocular processing facilities that

operate in a biologic manufacturing environment specific for tissue processing. The selected multi-tissue and ocular processors will have the opportunity to transfer their activities into these three new processing facilities, as part of the open selection process. These facilities will be operated fully under Canadian Blood Services' management. A core competency of these facilities will be the production of some specialized tissue and ocular products required in Canada such as demineralised bone matrix, acellular dermal matrix and split-thickness corneal grafts.

Those tissue banks that are not selected to be contracted processors will be requested to focus their activities on tissue recovery. They will establish contractual linkages with the Canadian tissue processors and Canadian Blood Services. These recovery programs will be supported by Canadian Blood Services' tissue recovery supplier quality management program.

Ocular tissue programs that participate in the processor selection process, but are not selected to transfer their activities to the two new facilities will be requested to continue recovering ocular tissue. As ocular recovery programs, they will be responsible for meeting their recovery targets as defined in their contracts with Canadian Blood Services, engaging in the supplier quality management program with Canadian Blood Services, and distributing corneas to hospitals from the inter-provincial inventory.

As was recommended by the Tissue Expert Committee, living donor surgical bone banks will not be a priority during the transformation of the tissue system. It is acknowledged that these programs currently play an important role in providing bone tissue for surgical use, but it is expected that as tissue donation, recovery and processing activity increases, the supply of bone allografts from cadaveric donors will meet demand.



↑ **Kimberly Young**, Executive Director, Organs and Tissues, Canadian Blood Services, and **Janet MacLean**, Vice-president, Clinical Affairs, Trillium Gift of Life Network (both Tissue Expert Committee members), with **Paul Derksen**, Program Manager, Organs and Tissues, Canadian Blood Services.

As part of the overall transition to standardized tissue processing, a coordinated approach to tissue donor transmissible disease testing will be implemented. This will be accomplished by selecting a third-party testing facility—or leveraging Canadian Blood Services' expertise in this area—and establishing this testing program at a Canadian Blood Services facility. The testing program would be aligned with the introduction of inter-provincial tissue inventory in the third year of the plan.

It should be noted that an invitation to supply tissue allografts to an inter-provincial inventory managed by Canadian Blood Services could be extended to Héma-Québec. Should Héma-Québec express an interest in this role and choose to participate, its proposal would be evaluated in the same manner as other potential Canadian tissue processors, through the competitive selection process.

**8. There is currently an insufficient supply of corneas to meet the demand across the country. Corneal transplant wait times for patients vary from province to province and range from several months to years. It is recommended that Canadian Blood Services coordinate the importation of corneas from the United States for three to four years to provide an immediate increase in the inter-provincial supply available for transplantation. The increased supply will reduce the number of patients currently waiting for a cornea transplant and decrease wait times for these procedures.**

Canadian Blood Services will manage the process of selecting US-based cornea suppliers and ensure that the defined quality requirements and allograft specifications are met. The initial yearly importation target will be 500 corneas, beginning in the first year of the program. As corneal donations from Canadian sources increase, annual importation targets are expected to decrease. Importation of corneas therefore is expected to last between three and four years. Canadian Blood Services will manage imported corneas as an inter-provincial inventory supported by formalized allocation protocols developed with the eye bank and ophthalmological community.

Canadian Blood Services will leverage the proposed information-technology infrastructure (see recommendation 13 on information management systems) to manage the additional corneas as an inter-provincial inventory and, because some imported corneas may be pre-cut—avoiding the need for manual manipulation by surgeons in the operating room—all regions of Canada will have access to these specialized cornea grafts.

**9. To ensure all patients have equitable and timely access to tissues, the supply of tissue allografts must be managed as an inter-provincial resource, using a single inventory system where production is aligned with demand and supply is allocated as required. It is recommended that Canadian Blood Services be the organization to forecast demand, align supply and demand, and manage inventory and distribution.**

### **Value to Canadians**

A single inter-provincial tissue inventory system would allow for movement of tissues across the country, creating a more equitable system that gives all Canadians access to domestically produced allografts, and imported tissue products.

In addition to supporting more effective notification of recalls, a single tissue inventory system would be leveraged to improve hospital reporting of adverse reactions and tissue utilization and outcomes. Such an approach would enable changing demand and use patterns to be tracked. This data would be shared with end-users to inform their usage decisions and with governments to inform policy decisions.

Canadian Blood Services has expertise in forecasting demand for blood and plasma protein products, and ensuring supply is sufficient to meet the needs of Canadian patients. As an organization that delivers these products to hundreds of hospitals across the country, Canadian Blood Services also has experience with inter-provincial logistics that can be leveraged to distribute tissues.

### **Description**

A single inventory and distribution information system is essential to ensure the effective management of an inter-provincial supply plan, and to monitor demand trends, inventory levels and supplier performance. Such an information system would also be a repository for the data elements associated with the transplantation of each allograft, entered by hospitals as part of tissue management reporting (see recommendation 4 on hospital tissue management).

The different tissues recovered from donors have different processing and storage requirements. Generally, all tissues must be recovered from donors within 24 hours of donor death. Corneas must be transplanted within seven to nine days after recovery; fresh joint grafts must be transplanted two to four weeks after recovery; bone, skin and heart valves can be stored frozen for several years. The inventory management and logistics for an inter-provincial system will therefore vary by tissue type.

The transformation to a smaller number of higher-performing tissue processing sites (see recommendation 7 on tissue processing) would also streamline the number of inventory and distribution sites to an optimal number that can serve the needs of Canadian hospitals over a large geographical area. For any given allograft product, the inventory may be stored in any number of locations, but accessed through a single ordering and distribution system.

The transition to a single inter-provincial inventory represents a significant but vital change to current practice. To ensure this change evolves smoothly and efficiently, and is fully understood and supported by the end-user community, a communications strategy will be implemented.

Canadian Blood Services will be responsible for developing and managing the inter-provincial supply plan. Hospital tissue liaisons will be established to engage end-users and support the demand forecast model. Canadian Blood Services will also be responsible for managing some imported tissue products through the same supply planning process, and with the same inventory and distribution system (see recommendation 10 on centralized importation).

Tissue processors contracted by Canadian Blood Services would be accountable for meeting the performance targets as defined in supply agreements, to ensure a stable and reliable supply of each type of tissue allograft for Canadian hospitals.

**10. Imported tissue is currently purchased by individual hospitals and clinics directly from manufacturers or distributors. The use of bulk purchasing or vendor qualification processes is limited. Through a supplier qualification program, however, potential vendors can be audited to assess their capabilities, strengths and weaknesses. Supply agreements that define preferred product pricing, supply guarantees, traceability requirements and information-sharing obligations can be established with qualified vendors. It is recommended that Canadian Blood Services implement a supplier qualification program for imported tissue vendors, and that a centralized bulk purchasing approach be used to achieve cost efficiencies and improve product tracking.**

#### **Value to Canadians**

Through its experience managing plasma-protein product imports, Canadian Blood Services brings significant expertise and demonstrated capabilities in managing importation strategies. This expertise will be leveraged to support effective allograft importation strategies that ensure safety and quality for Canadian patients and provide a more cost-effective delivery of imported tissue products.

By centralizing the purchasing of targeted imported tissue products—and supporting this practice with contracts with tissue vendors—the system will increase traceability and enhance its ability to respond to safety issues through greater control of imported tissues. Centralized purchasing should also achieve cost savings through vendor agreements and with better pricing than many small-volume purchases made by individual hospitals and clinics. Supply guarantees will be included in vendor agreements, securing the supply of imported allografts for Canadian surgeons and patients. This approach will help align importation strategies with current and future demand changes. Canadian Blood Services can also leverage its experience hedging exchange rate activity for plasma protein products to obtain favourable rates for imported tissues.

Introducing a supplier qualification program will provide visibility into supplier capabilities and performance, and will provide surgeons and patients with a degree of assurance that suppliers comply with quality expectations, are cost competitive, and are reliable and responsive.

## Description

Imported products account for approximately 80 per cent of the tissue allografts used in Canada for surgical and dental purposes. The imports are generally specialized tissue allografts that are produced using manufacturing processes not currently in place in Canadian tissue banks. Importation is currently conducted independently by individual surgeons, hospitals and clinics, and is used generally for small volumes at higher per-unit costs. There is very limited application of vendor qualification processes or centralized purchasing of these tissues.

Recombinant bone morphogenetic proteins are estimated to account for more than half of the current imported tissue product expenditures. Demineralized bone matrix is the most widely imported bone product. These products will be considered for a pilot importation project. Vendors of the selected products will be required to participate in a supplier qualification program, which would include an audit for quality compliance, and an assessment of criteria such as relevant ethical guidelines related to donation and stewardship of donated tissue. Preferential pricing for a combined larger volume (representing all hospitals) will be negotiated, as would other terms and conditions such as supply guarantees and quality requirements.

The imported products included in the pilot project would be tracked through an inventory system managed by Canadian Blood Services. Participating hospitals would be required to adhere to the terms of the pilot project, which would include traceability of all tissue products to the patient recipient and reporting on usage and adverse reactions. The pilot project is expected to last two years.

The longer-term scope of the specialized tissue products managed through the bulk purchasing arrangements would be assessed based on the outcome of the pilot.

## RECOMMENDATIONS—RESPONSIVE AND FORWARD LOOKING SYSTEM

**11. Approximately 80 per cent of the tissue products required for use in Canada are imported from the United States, where focused research and innovation has generated new forms of specialized tissue for use in surgical procedures. Canada's tissue banks have not developed a similar capacity to develop and produce these products. To reduce dependence on imported tissue products, it is recommended that Canadian Blood Services establish the facilities and capacity to produce some specialized products in Canada.**

### Value to Canadians

Currently, Canadian tissue processors produce only basic tissue products. By developing the ability to produce some specialized allografts—thereby expanding the types of tissues processed from Canadian donors—the Canadian tissue system will rely less on tissue imports.

Identifying tissue research practices that yield new tissue types with surgical applications will also provide Canadian researchers with an opportunity to bring new products into the health care marketplace. The Canadian tissue system would benefit by making these products directly available to Canadian surgeons and patients, rather than importing the products from US-based processors at a higher cost.

Proposed new facilities that are managed by Canadian Blood Services will have dedicated facility space with appropriate specifications and standards for required product development and production.





↑ **Dermot Kelly**, Director, Quality and Patient Safety/ Infection Prevention and Control, Vancouver Coastal Health Authority, and Tissue Expert Committee member

### Description

A wide spectrum of tissue products is generally categorized as specialized. These products are manufactured using biochemical and physical processing steps, including technologies that have introduced the use of stem cells to create tissue forms specific for certain applications. The research and development that has led to the introduction of these products has been carried out by tissue processors in the United States, in a competitive market environment involving both for-profit and not-for-profit organizations. Many of the specialized products have been patented by these organizations.

Canada's tissue system should have the ability to manufacture some specialized tissue products. In so doing, the system would contribute to the supply of specialized tissue products in Canada and reduce demand for imported tissue. Given the large gap between the current Canadian capacity to manufacture these products and the relatively sophisticated processing capacity in the United States, a practical approach to developing Canadian capacity would likely require licensing some technology from commercial processors. This approach will require further analysis to define a cost-effective solution.

An essential enabling factor for the production of some specialized tissue products is the supply of the basic tissue needed as starting material (bone, for example, is required to produce demineralized bone matrix (DBM), skin is needed for acellular dermal matrix (ADM), and corneas are needed for pre-cutting). Aligning the recovery of tissue to meet development and production needs within the over-arching tissue supply plan will be necessary. Furthermore, product and process development for these expanded tissue types will require dedicated facility space with appropriate specifications and standards. DBM and ADM could be considered for production in Canada's tissue system. DBM is used in orthopaedic surgical procedures and dental procedures. ADM is a new tissue product that is expected to become widely used in hernia repairs.

Although very few corneas are imported for use in Canada, the supply of corneas remains insufficient to meet demand across the country. Recent consultations with ophthalmologists who transplant corneas have indicated that between 60 and 70 per cent of cornea should be pre-cut into split-thickness corneal grafts to facilitate surgical procedures with superior outcomes for patients. However, given the limited capacity of existing eye banks to produce these pre-cut corneas, the tissue must be manipulated by the surgeons in the operating room prior to the surgical procedure. This practice consumes time and resources unnecessarily. In contrast, high-performing eye banks in other countries routinely pre-cut cornea with standardized processes and trained staff, and deliver these corneas to surgeons. It is a priority to develop the capacity in a Canadian tissue system to produce a large volume of pre-cut corneas that consistently meet the standards and specifications requested by ophthalmologists, and optimized use of operating room and surgeon time.

**12. Research and innovation has not previously been a focus of Canadian eye and tissue banks. As a result, tissue research has been carried out in organizations and institutes that have minimal linkages to these banks. To ensure the Canadian tissue system remains relevant to the needs of the broader health care system, tissue research activity should be coordinated to focus on priorities such as product development, technological innovation, tissue donation and tissue transplant outcomes. It is recommended that Canadian Blood Services create linkages between tissue operations and networks of researchers with tissue-related interests, and coordinate the required tissue research by providing access to grants, directly or through collaborations with other funding agencies.**

### **Value to Canadians**

Tissue donation and transplantation are rapidly evolving fields. Effective linkages with researchers and access to research funding will ensure that the Canadian TDT system is prepared to meet emerging challenges, support evidence-based decisions and remain relevant.

The proposed inter-provincial tissue system will track outcome data that can be leveraged by clinicians and researchers to evaluate specific research questions. The system will have the capacity to manufacture new tissue or process developments that can support the work of researchers. Increasing the overall availability of tissues for transplantation will also permit a supply of other forms of tissue to be available to support research initiatives.

### **Description**

An adaptive and responsive tissue system will continuously improve its performance by anticipating the needs of the surgeons who use tissue allografts, and by examining and improving its own processes and systems. A robust and efficient system will generate research questions that can span a wide range of subjects, from cell biology to mechanical engineering to sociology. Establishing in-house expertise in all of these areas is not realistic, and attracting researchers to solve specific problems will be required. In its role as the organization responsible for managing the inter-provincial tissue supply, Canadian Blood Services will provide opportunities for researchers to apply for grant funding. The outcomes of this research will be inputs to the tissue donation and transplantation system, and support for evidence-based decision making.

The Canadian tissue system can contribute to the development of new tissue types and tissue-related processing and technologies by providing researchers with access to donor tissue and to a controlled tissue processing environment that is equivalent to a production setting. This type of controlled environment will be part of a new multi-tissue or ocular processing facility and will support new product development and process evaluation.

Canadian Blood Services can leverage its approach to coordinating research in the area of transfusion medicine and develop a similar model for tissue research. The organization will administer government-supplied research funds through an open and transparent peer-reviewed process to attract Canadian researchers to study and solve the problems relevant to Canada's tissue system. Canadian Blood Services will collaborate or partner with other funding agencies (such as the Canadian Institutes of Health Research) to leverage its own research funds to attract additional researchers.

## RECOMMENDATIONS—INFRASTRUCTURE AND CAPABILITIES

**13. Information and data management is essential to operating in a controlled biological manufacturing environment. To be complete, data must include all aspects of tissue donation, recovery and processing. A comprehensive approach to data management facilitates complete traceability, effective inventory management and tissue allograft supply and demand monitoring, and supplies timely information on utilization, adverse reactions and outcomes. It is recommended that Canadian Blood Services leverage its expertise and infrastructure to establish information technology systems that will support an efficient and data-driven tissue system, thereby optimizing system performance.**

### Value to Canadians

A comprehensive inventory and distribution information-management system is essential to measure and augment tissue-system performance. A tissue-management IT system will collect and aggregate data in a timely, accurate and comprehensive fashion to monitor performance and identify required process changes. It will also ensure that all hospital consignees are rapidly identified and notified in the event of a tissue recall.

To ensure performance data is collected in the best manner possible, the tissue donation and transplantation IT system will draw and expand on Canadian Blood Services' existing data analytics capabilities to derive information from a variety of sources, such as operational IT systems and service delivery organizations. System-performance data will be regularly reported to the ministers of health and the public.

### Description

Operating a single inter-provincial tissue inventory system will require an inventory and distribution information management platform that tracks the location of, and records the transactions specific to, each tissue. This practice is necessary to ensure effective inventory management, traceability, and tissue allograft supply and demand monitoring. A web-based portal through which hospitals and end-users order and enter data elements such as allograft utilization, adverse reactions and outcomes will help maintain a complete record for each tissue allograft.

Capturing data related to each tissue donor, and on tissues recovered and processed from donors, is essential to developing a controlled biological manufacturing system and ensuring complete traceability. A tissue management system that stores all the data related to donation, recovery and processing activities also ensures that performance metrics can regularly be evaluated. The tissue management system will link to the inventory and distribution system as packaged and labelled allografts are released into inventory.

Data from the inventory and distribution system and from the tissue management system will be exported into a data warehouse to support a robust data analytics capacity. The development of these tools will enable data analysis by, and reporting to, stakeholders and to governments.

As manager of the inter-provincial supply plan, Canadian Blood Services will leverage its existing IT infrastructure and capabilities to establish and operate the information systems required for proper functioning and ongoing monitoring of the tissue system. The enterprise resource planning platform currently used by Canadian Blood Services to manage the procurement, inventory and distribution of plasma protein products will be adapted to support an inter-provincial tissue inventory and distribution system. This platform will interface with a commercially available tissue management system that will function as the operating system for all tissue recovery and processing activity conducted by Canadian Blood Services. A competitive selection process will be used to purchase the most suitable tissue management system.

The infrastructure model now used for organ registries will be leveraged to provide data analytics capabilities for tissue data exported to a data warehouse. This approach will enable the ongoing analysis of system performance and reporting, providing accurate and timely data to operators and to governments. This is described in more detail in the organ donation and transplantation recommendations.

### TISSUE SYSTEM RECOMMENDATIONS

A responsive and efficient Canadian system that assures a secure supply of quality tissue by 2017.

#### QUALITY AND SAFETY

- Standardized quality management program
- Standardized product specifications
- Standardized hospital tissue management practices
- Supplier qualification program

#### EFFICIENT AND SECURE SUPPLY

- National public awareness strategy
- Increased donor referral by medical examiners, coroners, allied health professionals, donation physicians and OPOs
- Increased tissue recovery by contracted tissue programs and Canadian Blood Services
- Consolidated tissue processing activity
- Single inter-provincial inventory
- Cornea importation
- Centralized bulk purchasing of imported tissue

#### A RESPONSIVE FORWARD LOOKING SYSTEM

- Establish capacity to produce specialized tissue products in Canada
- Create linkages between tissue operations and researchers and coordinate tissue research

#### INFRASTRUCTURE AND CAPABILITIES

- Single inter-provincial tissue system, managed by Canadian Blood Services
- Canadian Blood Services to forecast demand, align supply and demand and manage inventory and distribution
- Increase capacity by establishing new ocular and multi-tissue processing facilities managed by Canadian Blood Services
- Establish information technology systems to optimize system performance

#### PRINCIPLES, VALUES AND ETHICAL FOUNDATION

# IMPLEMENTATION AND COSTING

## Tissue Donation and Transplantation

Analysis of the challenges and potential solutions associated with the current TDT system indicated that the implementation strategy would have to acknowledge the many interdependencies characteristic of the tissue supply chain. For example, initiatives to significantly improve tissue donation must be coupled to increase tissue recovery capacity. In turn, tissue processing would have to be consolidated to increase the supply of recovered tissue more efficiently. New facilities for both ocular and multi-tissue processing would enable production of some of the specialized tissues that are required.

The changes to the tissue system are fundamental, and the proposed investment in new infrastructure in the first three years of the implementation plan will double the output of allografts for patients. Other implementation approaches were considered and would have deferred some of the investments in tissue-system structural changes, but those approaches would delay improvements to the supply of higher quality tissue.

### Current costs for comparison

There is no current comprehensive collection and analysis of tissue cost data in Canada and, therefore, no clear insight into the cost of the system. High-level estimates of the current costs of tissue donation and cornea transplantation activity prepared by Canadian Blood Services suggest direct annual operating costs for domestic tissue banking to be between approximately \$8.7 million and \$16.4 million.<sup>1</sup> This figure, which does not include Quebec, is likely significantly underestimated as it does not take into account many related but unknown costs, such as those for capital and infrastructure, and support services provided by hospitals in which the eye and tissue banks are located.

The only realistic baseline estimate is that for cornea transplantation which, at \$10.9 million in 2009, does not include the costs of cornea recovery, processing and distribution, and would increase to an estimated \$11.9 million in year one of implementation, as transplantation costs are adjusted for inflation (see Table 12-2).

The scarcity of reliable data shows that greater insight is essential to determine such costs with the clarity and precision stakeholders require. It is a central aim of this strategic plan to build the accountability and performance-measurement platform necessary for Canada's provinces and territories to achieve this clarity, insight and precision—and from which to pursue greater efficiencies.

<sup>1</sup> The estimates are derived from analysis of direct operating costs in available data shared by some tissue banks and eye banks, focused research, and interviews with international tissue and eye banks. These funds are currently directed through the budgets of hospitals where eye and tissue banks are located. This is based on a 2009 estimate and has been adjusted for inflation.

Figure 12-1. TDT SYSTEM IMPLEMENTATION

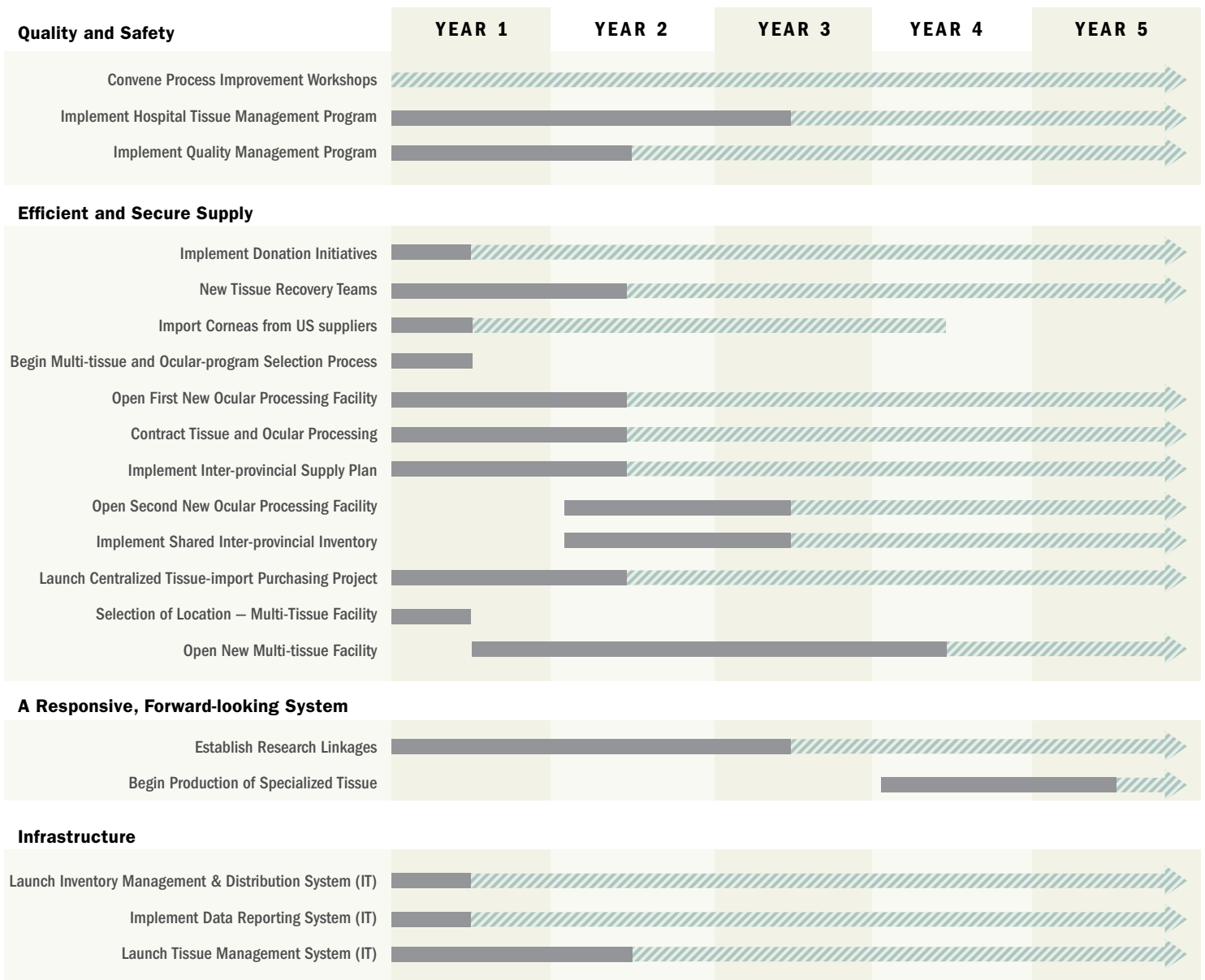


Table 12-1. Annual Estimate of TDT Project and Operating Costs

	Year 1	Year 2	Year 3	Year 4	Year 5
Project Costs (\$ Millions)	\$ 17.5	\$ 22.8	\$ 22.7	\$ 1.3	\$ -
Operating Costs (\$ Millions)	\$ -	\$ 18.0	\$ 30.4	\$ 35.8	\$ 38.4
<b>Annual Estimate of Project and Operating Costs</b>					
<b>Total (\$ Millions)</b>	<b>\$ 17.5</b>	<b>\$ 40.8</b>	<b>\$ 53.1</b>	<b>\$ 37.1</b>	<b>\$ 38.4</b>

Planning & development
  Implementation & ongoing operation

**TDT SYSTEM IMPLEMENTATION HIGHLIGHTS**

*Year 1*

- Launch an open, competitive selection process for multi-tissue and eye banks.
- Identify locations for two new ocular processing facilities and a new multi-tissue processing facility.
- Determine sites for the two multi-tissue recovery teams with potential alignment to jurisdictions where medical examiner or coroner services have expressed interest in an expanded tissue-donor identification and referral role.
- Begin recruitment and training of tissue recovery staff for Year 2 launch.
- Develop communication ties with hospitals and surgeons to better understand tissue demand.
- Implement data collection tool for ongoing reporting of donation, recovery, processing and distribution activity by existing eye and tissue banks. Regular tissue-system performance updates enable demand-forecast modelling and provide visibility into TDT system activity.
- Launch selection process for US cornea suppliers. Inventory and distribution system goes live to permit importation management and allocate equitably across all jurisdictions.
- Implement quality management program in all recovery programs and selected multi-tissue and ocular processing programs. The quality program builds on standardized specifications and supports ongoing supply-system activities.
- Implement public-awareness and professional-education donation initiatives for organs and tissues.
- Convene workshop to determine hospital tissue-management best practices.
- Begin work with Accreditation Canada to build tissue management requirements into hospital accreditation standards.

*Year 2*

- Open first new ocular processing facility, supported by an IT tissue management system, to initially maintain regional inventory and an inter-provincial inventory for additional corneas processed in the facility. All other ocular processing and recovery programs are contracted but continue cornea distribution according to current practice. Imported corneas are distributed through the new ocular processing facility and continue as part of inter-provincial inventory.
- Direct tissue provided by two new recovery teams to the new ocular facility and to one of the selected multi-tissue processors. Distribute processed product from tissue recovered by the two teams as a shared inter-provincial inventory.
- Begin construction of new multi-tissue processing facility.
- Select products and vendors for pilot project on centralized purchasing of imported tissues.
- Formalize tissue management agreements with hospitals for provision of tissues from shared inter-provincial inventory.
- Convene TDT best practices workshop with health care professionals and tissue banking experts.

*Year 3*

- Open second new ocular processing facility. All ocular tissue and all tissue produced by all selected multi-tissue processors enters the shared inter-provincial inventory. All tissue is now managed in a single inventory and distribution system.
- Hospitals receiving tissue from the inter-provincial inventory now report on usage, outcomes and adverse reactions according to formal hospital tissue-management agreements.
- Complete construction of new multi-tissue processing facility.

*Year 4*

- Open new multi-tissue processing facility, which includes a third ocular processing site.
- Importation pilot-project results establish the range of imported tissues to be centrally purchased, warehoused and distributed to hospitals.

*Year 5*

- Continue ongoing TDT-system operation and performance monitoring.
- Begin production of some specialized tissues in the new tissue facility.

**SHORT- AND LONG-TERM SOLUTIONS**

*The implementation strategy aims to quickly increase the availability of tissue from Canadian donors without compromising safety or supply. As a result, cornea importation will diminish only as domestic supply increases. The system will focus in the short term on increasing tissue donations from Canadian donors; the long-term focus is on new facilities.*

Costs outlined in Table 12-1 pertain to tissues and corneas donated and processed in Canada, and to the limited importation of corneas during Years 1 to 4. The costs of any other imported tissues are not included here.

Project costs capture the recommended investments in new ocular and multi-tissue processing facilities, establishing new tissue recovery capacity, building information systems and embedding quality throughout the tissue supply chain. These project costs do not include any costs associated with cornea or other tissue transplantation.

Operating costs include staff, supplies, purchased services, utilities, and equipment maintenance (including IT). These costs are directly related to tissue recovery, processing and distribution. As such, they include contract tissue recovery and processing. The operating costs in Years 1 to 4 reflect the projects implemented during those years. Year 5 is the first in which operating costs are based on the full implementation of all projects. These operating costs do not include any costs associated with cornea or other tissue transplantation.

As described above, the current costs of tissue and eye banking have been estimated at \$8.7 to \$16.4 million (adjusted for inflation from 2009). These funds are currently directed to eye and tissue banks through the budgets of hospitals where the banks are located. By Year 3, these banks will be contracted as processing or recovery programs and funded directly by Canadian Blood Services. At that time, the funds currently allocated for tissue and eye banking could be redirected by governments to offset the cost of the shared inter-provincial TDT system. The extent to which governments will be able to identify and redirect these funds is not known at this time.

The estimated costs of imported tissue are \$29.6 million (2009 estimate adjusted for projected growth), and are currently borne by hospitals that purchase the imports. This cost is not included in Table 12-1 and does not include the costs of the limited importation of corneas during Years 1 to 4. A pilot project is planned, in which the purchase of selected imported tissues (other than corneas) will be centralized. The estimated savings to hospitals that continue to purchase these imported tissues are \$1.2 million over the two-year pilot project. The costs of administering the centralized purchasing of pilot project are included in the operating costs in Table 12-1. The costs of all imported tissues (other than corneas) will continue to be borne by hospitals that purchase them.

## INVESTING IN BREAKTHROUGH PERFORMANCE

The improved quality, safety and security of tissue supply—and the more equitable patient access to the TDT system—associated with the recommendations in this strategic plan are inexorably tied to new investment. This is a shared investment that enables all provinces and territories to achieve together what no jurisdiction could do on its own. It is an investment that avoids duplication of costs and leverages not only the expertise and infrastructure of Canadian Blood Services, but also current provincial and territorial TDT investments.

The costs of tissue transplantation—the costs of the tissues and the surgery—are projected to rise regardless of whether or not investments are made to implement the recommendations in this plan. Market research<sup>2</sup> indicates that the number of surgical procedures routinely involving allografts will continue to increase at an average annual growth rate of 6.8 per cent through 2014. This increase is due primarily to the aging population that often requires use of these materials, and to the trend away from the use of autografts, which require a secondary surgical site with associated morbidity.

<sup>2</sup> Canadian Imported Surgical & Dental Allograft, Allograft Substitute, & Acellular Dermal Matrix Study 2010. Canadian Blood Services.

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### SYNERGY = EFFICIENCY

*Several elements of the strategy and its associated costs apply to both TDT and ODT, including public awareness and professional education. The strategic plan leverages this synergy to ensure investments are efficient and effective. Other recommendations in the TDT and ODT plans would leverage the structures and inter-provincial systems already in place at Canadian Blood Services, such as information management, quality management, supply chain planning and logistics, as well as elements of accountability and governance.*

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**KYM RADA** *Kym was diagnosed with Fuchs' dystrophy 15 years ago; five years later, he began to notice degeneration caused by the slowly progressing corneal disease.*

*"It's like looking through progressively thicker layers of waxed paper," says Kym. "You lose depth perception and the ability to see colour."*

*Facing eventual blindness, Kym had one cornea transplant in 2010, and a second in February 2011. His vision is now excellent.*

*"I've been overwhelmed," says Kym. "As my vision deteriorated, I stopped looking for the details in my life. Now the world is this fabulous sea of colour."*

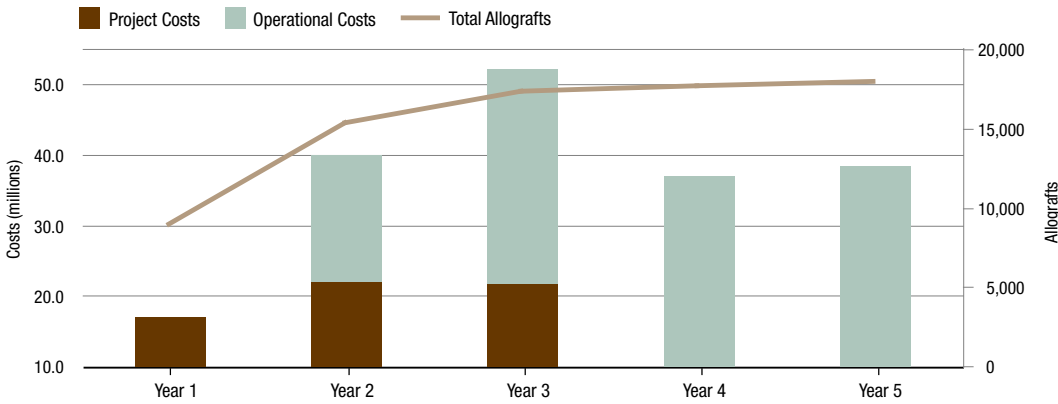
*Kym's corneal transplants have helped him see with more than his eyes. "My doctors told me that if I lived elsewhere in Canada, I would have had to wait for my transplants. I had no idea there were province-to-province differences in cornea availability. What if I needed a heart transplant?" he asks. "Why shouldn't all Canadians have the same access?"*

With the present TDT system unable to meet either current or rising future demand, there are two options going forward: import more tissue products or build capacity to produce a secure supply of high-quality tissue products, and more of them, here in Canada.

The Tissue Expert Committee was clear in its selection of the second option, recognizing that tissue-production expertise exists in Canada, and that relying solely on importation to meet Canada’s tissue needs constituted a higher risk from a security-of-supply perspective. In fact, the target for the new TDT system is to double the volume of tissue production and deliver higher quality products (See Figure 12-2).

**Figure 12-2. Domestic Allograft Targets**

With initial investments over the first three years targeting infrastructure development to sustain growth, the number of allografts is expected to increase from just over 8,700 to more than 17,700.

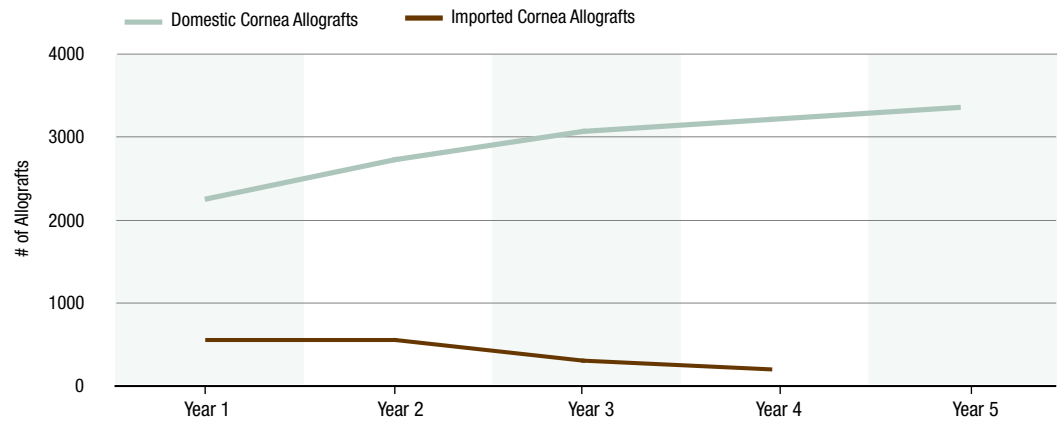


In part, this production increase aims to meet tissue demand currently being fulfilled with allograft alternatives that, while not the preferred clinical option, must be used when allograft tissue is unavailable. For example, bio-prosthetic valves are used for paediatric heart-valve replacement surgeries even though allograft heart valves are preferred. Matrix product alternatives are commonly used for burn patients even though allograft skin is the first choice as a wound covering. Since these allograft alternatives must be imported, an increase in the supply of domestically produced tissues will reduce imports, as well as the number of imported tissues that would otherwise be required to meet the expected increases in demand.

The benefits of an increased supply of allografts is perhaps best demonstrated with regard to cornea, where the shared investment in TDT will increase the number of donors and the supply so that approximately 1,100 additional cornea transplants—an increase of 50 per cent—can take place every year by Year 5.

**Figure 12-3. Corneas Available for Transplantation**

There is a two-pronged strategy to increase the supply of corneas for Canadians by importing corneas from the United States while increasing domestic supply of corneas to more than 3,000 annually. In the short-term, importing as many as 500 corneas per year will help close the gap between supply and demand.



**Table 12-2. Incremental Costs of Cornea Transplantation**

	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Incremental costs (\$ Millions)</b>					
Number of donors	1,833	2,233	2,511	2,631	2,751
1.2 corneas/donor	2,200	2,680	3,014	3,158	3,302
Imported corneas	500	500	250	150	-
<b>Total number of corneas</b>	<b>2,700</b>	<b>3,180</b>	<b>3,264</b>	<b>3,308</b>	<b>3,302</b>
Cost per Transplant*	\$ 5,429	\$ 5,591	\$ 5,759	\$ 5,932	\$ 6,110
<b>Cost of cornea transplant</b>	<b>\$ 14.7</b>	<b>\$ 17.8</b>	<b>\$ 18.8</b>	<b>\$ 19.6</b>	<b>\$ 20.2</b>
Baseline costs	\$ 11.9	\$ 12.3	\$ 12.7	\$ 13.1	\$ 13.4
<b>Incremental costs of cornea transplantation</b>	<b>\$ 2.7</b>	<b>\$ 5.5</b>	<b>\$ 6.1</b>	<b>\$ 6.6</b>	<b>\$ 6.7</b>

\* Based on estimate transplant costs of 2010+3 per cent annual inflation rate for 2 years for year 1

### The cost benefit of cornea transplantation

Table 12-2 presents an estimate of the costs related directly to an improved supply of corneas and subsequent, projected increases in cornea transplantation. The estimate of \$2.7 million in Year 1 increases to \$6.7 million in Year 5. The incremental costs for cornea transplantation are associated with implementation of recommendations to improve the performance of TDT in Canada, and with increasing the supply of corneas. These figures do not include the cost of recovery, processing and distribution of the corneas, which are included in Table 12-1.

The total number of corneas is the sum of corneas realized from Canadian donors—at an average yield of 1.2 corneas per donor—plus the number of corneas imported from the United States. The cost of cornea transplantation is the product of the total number of corneas multiplied by the cost per transplant for one cornea. The cost of per transplant is adjusted for an annual inflation rate of 3 per cent.

Baseline costs assume there would be only 2,200 cornea transplants in Years 1 to 5 and assumes no other growth in the supply of cornea from Canadian donors and no cornea importation from the United States.

Incremental costs of cornea transplantation are the estimated additional costs resulting from increased cornea transplantation as the supply of cornea increases, as compared to the baseline costs. The increased numbers of corneas for transplantation derive from achieving the target of a 50 per cent increase in the number of corneas from Canadian donors (from 2,200 in Year 1 to 3,302 in Year 5), and the temporary supplemental supply of corneas imported from the United States (1,400 corneas over four years).

A recent cost benefit analysis conducted by Canadian Blood Services compared the cost of corneal transplantation to the cost of not receiving a transplant. The analysis—based on numerous conservative assumptions—concluded that transplantation would have a payback period of approximately four years, after which point considerable cost avoidance would be achieved. Key assumptions included:

- Average cost of \$5,117 per transplant and average cost of a cornea of \$2,300 in 2010.
- Transplantation occurred halfway through the first year of the analysis period, with medical management being required for the initial six-month period.
- Second and third year post-transplant costs were estimated at 20 per cent of pre-transplant costs as the transplant cost estimates include follow-up care costs for three years.
- Post-transplants costs from the fourth year onwards were estimated to be 50 per cent of pre-transplant costs.
- Graft failure rates were not factored into the calculations.<sup>4</sup>

<sup>3</sup> <http://www.cnib.ca/en/your-eyes/ask-expert/corneal-transplant/>

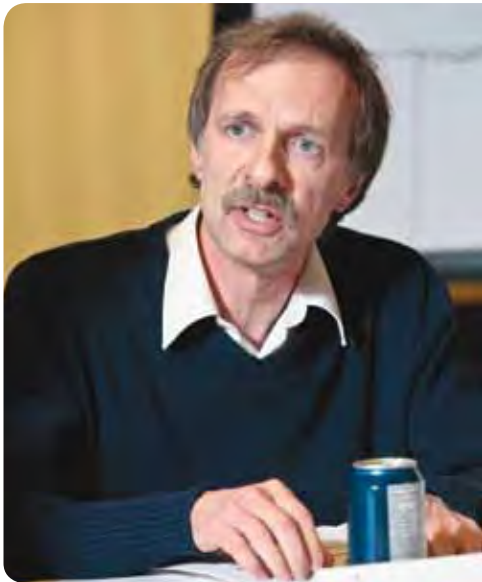
<sup>4</sup> A longitudinal review of 4000 PK procedures from 1982 to 1996 found survival of first time grafts to be 90% at five years and 82% at 10 years (Thompson RW, MO Price et al, "Long-term Graft Survival after Penetrating Keratoplasty." *Ophthalmology* (July 2003) 110(7): 1396-1402. More recent advancements in surgical techniques (e.g. lamellar keratoplasty) and medical management may have resulted in even higher graft survival rates.

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### UNNECESSARY SUFFERING

*Corneal damage and disease adversely impact quality of life. According to the CNIB, those waiting for a corneal transplant are generally suffering from vision loss or pain that "interferes with daily activities such as driving, reading or working at a computer."<sup>3</sup> Corneal transplantation is widely used across Canada to restore a patient's vision. While transplant candidates generally do receive a transplant, there is evidence of waitlist backlogs of between seven months and three years.*

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**ADDITIONAL BENEFITS**

The transformed TDT system will deliver valuable cost savings. For example:

- Cost savings will accrue as a result of centralized purchasing of imported tissue products. The scope and full potential of centralized purchasing will be evaluated on completion of the two-year pilot project.
  - The availability of pre-processed ground and chipped bone products will reduce operating room time, as many surgeons currently extend procedures by preparing their own ground bone within the operating room.
  - Sports medicine procedures that use allografts require less surgical time than autograft procedures that require a secondary surgical site.
  - The availability of pre-cut corneas will eliminate the preparation step for split-thickness grafts and reduce ophthalmologists' surgical time.
- .....

← **Dr. David Howarth**, Staff Pathologist, Mount Sinai Hospital, Toronto, and Tissue Expert Committee member

In Canada, a health intervention is considered to be cost-effective if it costs less than approximately \$40,000–\$50,000/quality adjusted life year<sup>5</sup> (QALY). According to Hirneiss et al (2006), a cost utility of \$11,557 USD was gained over ten years after penetrating keratoplasty surgery, taking into account graft survival. This is well within the acceptable limits for cost effectiveness in Canada and can be attributed to the substantial gain in quality of life relative to the cost and maintenance of a transplant.

It is helpful to express quality of life in pure monetary terms, yet the benefits of corneal transplants, while largely unmeasurable, are no less remarkable for their potential economic impact. People with vision loss experience three times as much clinical depression, a greater number of medication errors, twice the risk of falls and premature death and four times the risk of serious hip fractures.<sup>6</sup> The employment rate of working-age adults with significant vision loss is only 32 per cent. Restoring these people's vision restores them to productive lives and reduces the chance that they may further burden the health system.

<sup>5</sup> The QALY is a measure of burden disease used in assessing the value for money of a medical treatment. It is based on the number of years of life that would be added by the intervention and a ranking of the quality of life the intervention affords.

<sup>6</sup> *The Cost of Vision Loss in Canada*. CNIB and the Canadian Ophthalmological Society, 2009.

# TRANSFORMING OTDT FOR THE BENEFIT OF CANADIANS

In *Call to Action*, Canadian Blood Services and the OTDT committees and communities have clearly set out timely, practical and achievable solutions to overcome current OTDT challenges and deliver significant performance improvements for Canadians. Propelled by unprecedented levels of engagement and consensus, this strategic plan has captured the community's aims and expectations, and secured support for Canadian Blood Services as lead organization in new integrated, inter-provincial ODT and TDT systems.

The benefits of implementing this strategic plan are numerous and compelling.

## ODT-system benefits for Canadians

A single, integrated inter-provincial ODT system will feature a strong accountability framework to enable cooperation and collaboration, and produce better, consistent policies that improve fairness and access for patients. Improved transparency will increase trust among the public and health care professionals. The introduction of donation physicians will increase the number of organ and tissue donors and help make donation a standard part of end-of-life care.

An effective public awareness strategy will deliver clear, coordinated and consistent messages about the importance of donation. New intent-to-donate registries will give more Canadians the chance to make their wishes known quickly and easily—and ensure rapid access to registry information by qualified frontline staff.

An integrated inter-provincial registry system will provide enhanced, shared-cost registry services for all donation and transplantation programs, while consistent, standardized professional education and awareness programs will promote a culture of donation among professionals.

## TDT-system benefits for Canadians

An integrated, inter-provincial TDT system will more than double the number of tissue donors and significantly increase the amount of tissue available from Canadian donors.

A standardized, systematic and comprehensive tissue quality management program will harmonize tissue specifications and improve the consistency, quality and safety of allografts for all patients.

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*“As a stakeholder and partner, the Association appreciates the opportunities for consultation provided by the Canadian Blood Services and strongly supports its work to date. The Association looks forward to future opportunities for consultation and collaboration with Canadian Blood Services and other stakeholder groups to work towards the establishment of a strong and equitable, pan-Canadian OTDT system.”*

— **Michael Cloutier**, President and CEO, Canadian Diabetes Association

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*“CNIB has been an active participant with Canadian Blood Services in various consultations, both individually and together with other stakeholder organizations. We are convinced that the plan laid out by Canadian Blood Services for a national eye banking system is not only the right thing to do, but should be feasible in both the short and long run.”*

— **Keith Gordon**, Vice President Research and Service Quality, CNIB

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**ROB AND KATE PATTISON** *Diagnosed with polycystic kidney disease in 2008, Rob was told to expect an eight-year wait for a transplant. Until then, he would spend every second night on dialysis. His wife Kate offered one of her kidneys, but their blood types did not match. Instead, the couple registered in the Living Donor Paired Exchange program—the first nation-wide organ registry in Canada. Operated by Canadian Blood Services, the LDPE facilitates kidney donations between a Canadian patient with a willing but incompatible donor and another pair in the same situation. The program enabled Kate to donate one of her kidneys to someone she would never know so that Rob could receive the organ he needed.*

*The LDPE cut Rob's wait to two-and-a-half years. His recovery has been excellent, his quality of life dramatically improved. Kate is also doing well. A recreational runner, she has since gone on to record her personal best time.*

## DOING OUR PART

In better serving Canadians, the recommendations in this strategic plan also benefit others around the world.

The shortage of human organs has helped make organ trafficking and transplant tourism global problems that threaten to undermine legitimate transplantation worldwide. *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism* was established in 2008 to address these growing problems.

*Call to Action* supports the declaration by proposing an integrated, inter-provincial OTDT system to improve the availability of organs in Canada and thereby reduce waitlist times. The goal of the system with respect to transplant tourism is to ensure patients can expect safe and timely transplant solutions here at home, and to prevent the exploitation of vulnerable people outside Canada.

A key element of the new system will be a robust tissue-management IT solution to collect and aggregate the valuable data needed to inform an effective accountability framework, measure performance, monitor tissue use and inform planning and policy development. A single inter-provincial tissue inventory system will enable movement of tissues across the country, creating a more equitable system that gives all Canadians access to domestically produced allografts and imported tissue products. Concurrently, the TDT system will develop the ability to produce some specialized allografts to reduce Canada's reliance on tissue imports.

### From promise to practice

In three short years, Canadian Blood Services—in close collaboration with the OTDT communities—has helped advance OTDT through leading practice development, broad stakeholder engagement and the creation of the living donor paired exchange registry, the first national organ registry in Canada. Two more registries will soon come online.

Yet these registries mark only the beginning of breakthrough performance. *Call to Action* describes precisely the immense advances that can be achieved in years to come as more transplants and improved health outcomes for Canadians help write many more inspiring success stories like Rob Pattison's (previous page).

### Substantial and sustained performance improvements are within reach

This strategic plan will be presented to Canada's deputy ministers of health in April 2011, setting into motion a ministerial review of OTDT. *Call to Action* will enable Canada's ultimate health care authorities to see what genuine OTDT transformation will deliver: fairness, accountability, transparency, collaboration, trust, efficiency, cost-effectiveness, consistency, innovation, responsiveness, compassion and inter-provincial integration.

Canadians have asked for, and deserve, no less.

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*"...the CCFC is strongly in favour of measures to improve registry development, research facilitation, system integration and system performance in organ and tissue donation and transplantation. Canadian Blood Services is well positioned from a leadership role in this regard, and we encourage the deputy ministers to support Canadian Blood Services' efforts to create a better system for all Canadians."*

— **Kevin W. Glasgow**, MD, MBA, MHSc, FCFP, FRCPC,  
Chief Executive Officer, Crohn's and Colitis Foundation of Canada

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# APPENDICES

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# STAKEHOLDER CONSULTATION GROUPS

Canadian Blood Services consulted the spectrum of OTDT stakeholders listed here to gain broad input for the system design of integrated, inter-provincial organ and tissue donation and transplantation systems. These consultations included group presentations, one-on-one meetings and conference calls. Canadian Blood Services is grateful to those who took the time to share their expertise and experience.

## PUBLIC FORUMS

London	October 24, 2009
Vancouver	November 14, 2009
Edmonton	January 16, 2010
Halifax	February 6, 2010
Winnipeg	February 13, 2010
Regina	March 1, 2010
St. John's	March 30, 2010
Moncton	May 4, 2010
Toronto	May 29, 2010

## NATIONAL PATIENT GROUPS

Cystic Fibrosis Canada  
 Canadian Diabetes Association  
 Canadian Liver Foundation  
 CNIB  
 Canadian Transplant Association  
 Crohn's and Colitis Foundation of Canada  
 David Foster Foundation  
 Juvenile Diabetes Research Foundation  
 The Kidney Foundation of Canada  
 (national and most provincial chapters)  
 MedicAlert  
 The Lung Association

## OTHER GROUPS

Canadian Transplant Support  
 Good Hearts Mentoring Foundation  
 Heart Transplant Home Society  
 Kin Canada  
 Lions Clubs (various local and provincial chapters)  
 Merv Sheppard Transplant Network  
 Ontario East Transplant Support Group  
 Sarnia Organ Donor Awareness Group  
 Saskatchewan Coalition for Organ Donation Awareness  
 Sport Fest Windsor  
 Toronto Lung Transplant Civitan Club  
 Vancouver Island Kidney Patients Association

## ORGAN TRANSPLANT PROGRAMS

### British Columbia

BC Children's Provincial Renal Program, BC Children's Hospital  
 Renal Program, St. Paul's Hospital, Providence Health Care  
 Heart Transplant Program, Providence Health Care  
 Renal and Pancreas Transplant Program, Vancouver General Hospital  
 Liver Transplant Program, Vancouver General Hospital  
 Lung Transplant Program, Vancouver General Hospital

### Alberta

Kidney Transplant Program, University of Alberta Hospital  
 Liver Transplant Program, University of Alberta Hospital  
 Heart and Lung Transplant Programs, University of Alberta Hospital

Clinical Islet Transplant Program, Pancreas Transplant,  
University of Alberta Hospital  
Pediatric Cardiac Surgery, Stollery Children's Hospital, Calgary  
Pediatric Kidney Transplant Program, Alberta Children's Hospital  
Heart Transplant Program, Foothills Medical Centre  
Kidney Transplant Program, Foothills Medical Centre

### **Saskatchewan**

Saskatchewan Transplant Program

### **Manitoba**

Lung Transplant Program, Transplant Manitoba  
Adult Kidney Transplant Program, Transplant Manitoba  
Pediatric Kidney Transplant Program, Transplant Manitoba  
Adult Heart Transplant Program, Cardiac Sciences Program,  
Transplant Manitoba  
Liver Transplant Program, Transplant Manitoba

### **Ontario**

Kidney Transplant Program, Kingston General Hospital  
Kidney Transplant Program, St. Joseph's Health Care, London  
Kidney Transplant Program, Multi-organ Transplant Program,  
London Health Sciences Centre, University Hospital  
Heart Transplant Program, Multi-organ Transplant Program,  
London Health Sciences Centre, University Hospital  
Liver Transplant Program, Multi-organ Transplant Program,  
London Health Sciences Centre, University Hospital  
Heart Transplant Program, The Ottawa Heart Institute  
Kidney Transplant Program, The Ottawa Hospital - Civic Campus  
Kidney Transplant Program, Hospital for Sick Children, Toronto  
Liver and Bowel Transplant, Hospital for Sick Children, Toronto  
Heart Transplant Program, Hospital for Sick Children, Toronto  
Lung Transplant Program, Hospital for Sick Children, Toronto  
Kidney Transplant Program, St. Michael's Hospital, Toronto  
Kidney Transplant Program, Multi Organ Transplant Program,  
University Health Network, Toronto  
Kidney-Pancreas Transplant Program, Multi Organ Transplant  
Program, University Health Network, Toronto  
Heart Transplant Program, Multi Organ Transplant Program,  
University Health Network, Toronto  
Lung Transplant Program, Multi Organ Transplant Program,  
University Health Network, Toronto  
Liver Transplant Program, Multi Organ Transplant Program,  
University Health Network, Toronto  
Small Bowel Transplant Program, Multi Organ Transplant Program,  
University Health Network, Toronto

### **Nova Scotia**

The kidney, kidney-pancreas, liver and heart transplant programs,  
Multi Organ Transplant Program, QEII HSC  
Pediatric Kidney Program, IWK Health Centre, Halifax

## **TISSUE, EYE AND BONE BANKS**

### **British Columbia**

BC Tissue Bank, Vancouver Coastal Health Authority  
Eye Bank of British Columbia  
Vancouver Island Health Authority Bone Bank

### **Alberta**

Comprehensive Tissue Centre, Edmonton  
Southern Alberta Tissue Program (includes the Alberta Lions Eye  
Bank), Calgary

### **Saskatchewan**

Regina Qu'Appelle Health Region Bone Bank  
Saskatoon Health Region Bone and Tissue Bank  
Lions Eye Bank of Saskatchewan, Saskatoon

### **Manitoba**

Tissue Bank Manitoba, Winnipeg  
Lions Eye Bank of Manitoba and Northwest Ontario, Winnipeg

### **Ontario**

London Health Sciences Centre Tissue Bank  
St. Michael's Hospital Bone Bank, Toronto  
RegenMed, Lake Superior Centre for Regenerative Medicine,  
Thunder Bay  
St. Joseph's Healthcare, Hamilton  
Hamilton Health Sciences Centre Bone Bank  
Mount Sinai Allograft Technologies, Toronto  
National Capital Region Bone Bank, Ottawa  
The Eye Bank of Canada, Toronto  
Sunnybrook Health Sciences Centre Blood and Tissue Bank, Toronto  
The Hospital for Sick Children Tissue Laboratory, Toronto  
Trillium Gift of Life Network, Toronto

### **New Brunswick**

Dr. Donald MacLellan Tissue Bank, Moncton  
New Brunswick Eye and Tissue Bank, Saint John

### **Nova Scotia**

Regional Tissue Bank, Halifax

**ORGAN PROCUREMENT ORGANIZATIONS**

BC Transplant, British Columbia  
 HOPE Program North, Alberta  
 Southern Alberta Organ and Tissue Donation Program  
 Saskatchewan Transplant Program  
 Transplant Manitoba, Gift of Life  
 Trillium Gift of Life Network, Ontario  
 Organ Procurement Exchange Network, Newfoundland  
 New Brunswick Organ and Tissue Procurement Program  
 Critical Care Organ Donation Program, QE II Health Sciences  
 Centre, Halifax  
 Québec-Transplant

**CANADIAN HEALTH PROFESSIONAL ORGANIZATIONS**

Accreditation Canada  
 Aboriginal Nurses Association of Canada  
 Canadian Academy of Sport and Exercise Medicine  
 Canadian Association of Critical Care Nurses  
 Canadian Association of Emergency Physicians  
 Canadian Association of Eye and Tissue Banks  
 Canadian Association of Oral and Maxillofacial Surgeons  
 Canadian Association of Pathologists  
 Canadian Conference of Chief Coroners and Medical Examiners  
 Canadian Critical Care Conference  
 Canadian Critical Care Society  
 Canadian Dental Association  
 Canadian Institute for Health Information  
 Canadian Medical Association (Ottawa)  
 Canadian Ophthalmological Society (Ottawa)  
 Canadian Organ Replacement Register  
 Canadian Orthopaedic Association  
 Canadian Spine Society  
 Canadian Society of Transplantation  
 Canadian Society of Transfusion Medicine  
 Canadian Society of Nephrology  
 Canadian Society of Plastic Surgeons  
 Cardiac Care Transplant Network  
 Conference of Chief Coroners and Chief Medical Examiners of  
 Canada

Indigenous Physicians Association of Canada  
 Legacy of Life, Nova Scotia  
 Royal College of Physicians and Surgeons  
 Trauma Association of Canada

**CANADIAN GOVERNMENT DEPARTMENTS AND NATIONAL AGENCIES**

Health Canada  
 Provincial and territorial ministries of health  
 Federal, provincial and territorial health ministers  
 and/or deputy ministers  
 Public Health Agency of Canada  
 Canadian Institute for Health Information  
 Canadian Organ Replacement Registry  
 Accreditation Canada  
 Canadian Standards Association

**INTERNATIONAL AGENCIES**

American Association of Tissue Banks, USA  
 Australian Organ and Tissue Donation and Transplantation Authority  
 EuroTransplant, Netherlands  
 European Association of Tissue Banks, Germany  
 German Foundation of Organ Donation  
 Health Resources and Service Administration USA  
 Iowa Lions Eye Bank, USA  
 Musculoskeletal Transplant Foundation, USA  
 National Health Service, National Tissue Service, United Kingdom  
 National Health Service, UK Transplant, United Kingdom  
 New England Organ Bank, USA  
 Organización Nacional de Transplantes, Spain  
 Philadelphia Gift of Life, USA  
 SightLife, USA  
 The Eye Bank Association of America, USA  
 The Transplantation Society, Canada  
 United Network for Organ Sharing, USA  
 World Health Organization, Switzerland

# SUMMARY OF ROLES AND RESPONSIBILITIES

## Organ Donation and Transplantation

The following table lists the ODT system's key stakeholders and the roles and responsibilities entrusted to each. Readers should be aware that each stakeholder's roles and responsibilities relate only to ODT; stakeholders will likely perform other duties outside of the ODT system. Also, ODT service-provider roles and responsibilities may vary among provinces. Where roles vary, general roles have been listed and not all exceptions have been identified. Some roles are shared among multiple stakeholders.

Group/Organization	Roles and responsibilities
<b>Provincial and territorial ministers of health</b>	<ul style="list-style-type: none"> <li>· Determine the roles, responsibilities and reporting structures of the public organizations that provide ODT services</li> <li>· Formalize the ODT accountability framework through Memorandum of Understanding or another mechanism</li> <li>· Monitor ODT performance and act on compliance and performance issues with respect to programs and organizations in their jurisdictions</li> <li>· Appropriately resource ODT activities</li> <li>· Provide support through policy and legislation</li> </ul>
<b>Hospital emergency rooms and ICUs</b>	<ul style="list-style-type: none"> <li>· Provide organ and tissue donation services through donor identification, referral, and clinical management</li> <li>· Assist OPOs in donation activities such as donor screening, family consent and support, and logistics</li> <li>· Provide OTDT training for health care professionals</li> <li>· Participate in the development of national policies, standards and leading practices</li> <li>· Implement national policies, standards and leading practices</li> <li>· Collect and deliver data required for national consolidation</li> </ul>
<b>Organ procurement organizations (OPOs)</b>	<ul style="list-style-type: none"> <li>· Provide organ and tissue donation services in collaboration with hospital partners</li> <li>· Manage donation activities such as donor screening, family consent and support, donor testing, logistics, and assist in recovery</li> <li>· Provide OTDT training for health care professionals</li> <li>· Participate in the development of national policies, standards and leading practices</li> <li>· Implement national policies, standards and leading practices</li> <li>· Collect and deliver data required for national consolidation</li> <li>· As per individual provincial structure, manage intent-to-donate registries</li> <li>· As per individual provincial structure, allocate according to intra-provincial rules for organs</li> <li>· Manage local public-awareness efforts in alignment with national messaging and in partnership with national efforts</li> </ul>

**Donation physicians**

- Provide clinical leadership within the hospital and broader community on organ and tissue donation to promote a culture of organ and tissue donation and improve all aspects of deceased donation
- Provide consultation and support to ICU teams and assist in bedside donor care
- Provide OTDT training to physicians and other health care professionals
- Participate in the development of national policies, standards and leading practices
- Implement national policies, standards and leading practices
- Collect and deliver data required for national consolidation

**Transplant programs**

- Assess and care for transplant candidates and recipients
- Recover and transplant organs
- Provide OTDT training for health care professionals
- Participate in the development of national policies, standards and leading practices
- Implement national policies, standards and leading practices
- Collect and deliver data required for national consolidation
- As per individual provincial structure, manage living donor programs
- As per individual provincial structure, develop intra-provincial allocation rules

**Canadian Blood Services**

- Lead the establishment of the ODT accountability framework, including governance structure and accountability mechanisms
- Support committees through performance and strategy management, compliance monitoring, auditing and policy development
- Develop and promote adoption of leading practice guidelines
- Establish a coordinated OTDT public awareness campaign in partnership with relevant professional bodies, OPOs, tissue banks and transplant programs
- Establish a coordinated program for ODT professional education in partnership with relevant professional bodies, OPOs tissue banks and transplant programs
- Develop, implement and operate a comprehensive, integrated inter-provincial organ registry
- Develop and implement an integrated data management and analytics service for the ODT community
- Develop and host registries for provinces in which registries do not currently exist
- Develop leading practices for intent-to-donate registries
- Create a research committee to facilitate and optimize government investments for Canadian ODT research

**ODT Oversight Committee**

- Develop inter-provincial policies and monitor overall system performance by:
- establishing inter-provincial performance targets and expectations,
  - reviewing system performance and making recommendations for change,
  - developing an inter-provincial policy framework,
  - developing policies to address system issues and international issues,
  - reviewing policies from sub-committees to ensure prioritization, integration and consistency among policies and groups,
  - ensuring that structures and mechanisms are in place for reporting and reviewing system performance, compliance and transparency,
  - liaising with provincial organizations and governments, through individual committee members, to influence, inform and ensure positive change in provincial systems, and
  - guiding program development for inter-provincial registries and information management services.

<b>OTDT Sub-committees</b>	<ul style="list-style-type: none"> <li>· Provide advice to the ODT Oversight Committee</li> <li>· Identify requirements for policy development and develop these policies</li> <li>· Monitor and review the impact of policies to effect evidence-based improvements in the ODT system</li> <li>· Monitor and review international ODT developments to effect evidence-based improvements in Canada's ODT system</li> <li>· Review performance and make recommendations to the ODT Oversight Committee</li> <li>· Liaise and report back to the broader ODT medical community and professional societies</li> </ul>
<b>Canadian Institute for Health Information (CIHI)</b>	<ul style="list-style-type: none"> <li>· Provide data analysis and modeling services to inform policy and system improvements for the end-stage organ failure (ESOF) community</li> <li>· Work with Canadian Blood Services and the ODT community to develop mandatory data-reporting requirements and processes for ODT and ESOF organizations</li> </ul>
<b>End-stage organ failure programs</b>	<ul style="list-style-type: none"> <li>· Participate in the development of standards for mandatory data requirements</li> <li>· Collect and deliver data required for national consolidation</li> </ul>
<b>Professional organizations and societies</b>	<ul style="list-style-type: none"> <li>· Establish a coordinated program for ODT professional education in partnership with Canadian Blood Services, OPOs and transplant programs</li> <li>· Provide OTDT training for health care professionals</li> <li>· Participate in the development of national policies, standards and leading practices</li> <li>· Promote the implementation of national policies, standards and leading practices</li> </ul>
<b>Health Canada</b>	<ul style="list-style-type: none"> <li>· Establish and maintain regulations for organ donation and transplantation, and monitor and enforce compliance</li> </ul>
<b>Public Health Agency of Canada</b>	<ul style="list-style-type: none"> <li>· Continue the development of a surveillance system for adverse events that result from transplantation</li> </ul>
<b>Accreditation Canada</b>	<ul style="list-style-type: none"> <li>· Develop and maintain national standards for the accreditation of hospitals in organ donation and transplantation in collaboration with ODT stakeholders from across Canada</li> </ul>
<b>Canadian Standards Association</b>	<ul style="list-style-type: none"> <li>· Develop and maintain national standards for safety and effectiveness in organ donation and transplantation in collaboration with ODT stakeholders from across Canada</li> </ul>

# SUMMARY OF ROLES AND RESPONSIBILITIES

## Tissue Donation and Transplantation

The following table lists the TDT system's key stakeholders and the roles and responsibilities entrusted to each. Readers should be aware that each stakeholder's roles and responsibilities relate only to TDT; stakeholders will likely perform other duties outside of the TDT system. Also, TDT service-provider roles and responsibilities may vary among provinces. Where roles vary, general roles have been listed and not all exceptions have been identified. Some roles are shared among multiple stakeholders.

Group/Organization	Roles and responsibilities
<b>Provincial and territorial ministers of health</b>	<ul style="list-style-type: none"> <li>· Determine roles, responsibilities and reporting structures of the public organizations that provide TDT services</li> <li>· Formalize the TDT accountability framework through memorandum of understanding or another mechanism</li> <li>· Appropriately resource TDT activities</li> <li>· Provide support through policy and legislation</li> </ul>
<b>Canadian Blood Services</b>	<ul style="list-style-type: none"> <li>· Maintain an inter-provincial supply plan</li> <li>· Support tissue-donor identification and referral activities to meet performance targets</li> <li>· Operate tissue-recovery activity to meet performance targets</li> <li>· Operate ocular-processing facilities to meet performance targets</li> <li>· Operate multi-tissue processing facility to meet performance targets</li> <li>· Contract selected tissue processors to supply the inter-provincial inventory</li> <li>· Contract selected eye banks to recover ocular tissue</li> <li>· Maintain a robust supply chain for domestically produced tissues and selected imported tissues</li> <li>· Provide training and education for Canadian tissue bank staff</li> <li>· Direct tissue-related research to meet the needs of the tissue system</li> <li>· Provide tissues to hospitals</li> <li>· Maintain compliance with regulations and standards</li> <li>· Provide accurate data reporting to governments</li> <li>· Establish a coordinated public awareness campaign for OTDT in partnership with relevant professional bodies, OPOs, tissue banks and transplant programs</li> <li>· Establish a coordinated program for OTDT professional education, in partnership with relevant professional bodies, OPOs, tissue and transplant programs</li> <li>· Develop and implement an integrated data management and analytics service for the TDT community</li> </ul>



<b>Tissue recovery organizations</b>	<ul style="list-style-type: none"> <li>· Recover tissue as per contracted specifications, volumes and schedules</li> <li>· Provide performance metrics data as contracted</li> <li>· Maintain compliance with regulations and standards</li> </ul>
<b>Tissue processors</b>	<ul style="list-style-type: none"> <li>· Deliver tissue allografts to contracted specifications, volumes and schedule</li> <li>· Establish and maintain agreements with tissue recovery organizations</li> <li>· Provide performance metrics data as contracted</li> <li>· Maintain compliance with regulations and standards</li> </ul>
<b>Coroners and medical examiners</b>	<ul style="list-style-type: none"> <li>· Ensure effective identification and referral of potential tissue donors to OPOs or recovery organizations</li> </ul>
<b>Donation physicians</b>	<ul style="list-style-type: none"> <li>· Provide clinical leadership within the hospital and broader OTDT community to promote a culture of organ and tissue donation and improve all aspects of deceased donation</li> <li>· Provide OTDT training to physicians and other health care professionals</li> <li>· Participate in the development of national policies, standards and leading practices</li> <li>· Implement national policies, standards and leading practices</li> <li>· Collect and deliver data required for national consolidation</li> </ul>
<b>Hospitals</b>	<ul style="list-style-type: none"> <li>· Identify and refer potential tissue donors</li> <li>· Work collaboratively with OPOs and tissue recovery organizations in donation activities such as screening donors, obtaining family consent and supporting families</li> <li>· Provide OTDT training for health care professionals</li> </ul>
<b>Organ procurement organizations (OPOs)</b>	<ul style="list-style-type: none"> <li>· Support tissue donation services in collaboration with hospital partners and tissue recovery organizations.</li> <li>· As per individual provincial structure, manage donation activities or refer donors to tissue recovery organizations.</li> <li>· Provide OTDT training for health care professionals</li> <li>· As per individual provincial structures and responsibilities, manage intent-to-donate registries</li> <li>· Participate in the development of national policies, standards and leading practices</li> <li>· Implement national policies, standards and leading practices</li> <li>· Collect and deliver data required for national consolidation</li> <li>· Manage local public awareness efforts in alignment with national messaging and in partnership with national efforts</li> </ul>
<b>American tissue vendors</b>	<ul style="list-style-type: none"> <li>· Deliver tissue allografts to contracted specifications, quantities and schedules</li> <li>· Comply with regulations and standards</li> </ul>
<b>Hospitals that obtain tissues through the inter-provincial system</b>	<ul style="list-style-type: none"> <li>· Adhere to tissue-management agreements including traceability, utilization and outcomes reporting, and adverse reaction reporting</li> </ul>

<b>Dentists and dental surgeons that obtain tissue through the inter-provincial system</b>	<ul style="list-style-type: none"><li>· Comply with regulations and standards</li><li>· Comply with applicable tissue management agreements, including traceability, utilization and outcomes reporting, adverse and reaction reporting</li></ul>
<b>Health Canada</b>	<ul style="list-style-type: none"><li>· Establish and maintain regulations for tissue donation and transplantation, and monitor and enforce compliance</li></ul>
<b>Public Health Agency of Canada</b>	<ul style="list-style-type: none"><li>· Continue the development of a surveillance system for adverse events that result from transplantation</li></ul>
<b>Accreditation Canada</b>	<ul style="list-style-type: none"><li>· Develop and maintain national standards for the accreditation of hospitals in tissue donation and transplantation in collaboration with TDT stakeholders from across Canada</li></ul>
<b>Canadian Standards Association</b>	<ul style="list-style-type: none"><li>· Develop and maintain national standards for safety and effectiveness in tissue donation and transplantation in collaboration with TDT stakeholders from across Canada</li></ul>

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# GLOSSARY

## of Organ and Tissue Donation and Transplantation Terminology

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### DEFINITIONS

*Note: The following terms are not regulatory or standards-based definitions but rather provide clarity on terms used in this report.*

**Accountability** The obligation to report, explain and be answerable for acknowledged and assumed responsibilities.

**Accreditation** The process by which an organization recognizes a program or an institution as meeting predetermined standards.

**Adverse reaction** An undesirable response in the recipient to transplanted cells, tissues or organs, including the transmission of a disease or disease agent.

**Allograft** Any cells, tissues or organs from one human being intended for transplantation into another human being. In this report the term is used to mean processed human tissue.

**Audit** A documented review of personnel functions, facilities, procedures, records, equipment, materials, and contract-service facilities or suppliers to evaluate adherence to written standard operating procedures, standards, and applicable laws and regulations.

**Autograft** Any cells, tissues, or organs transplanted into the same person from whom they were recovered.

**Brain death** The irreversible loss of capacity for consciousness combined with the irreversible loss of all brainstem functions including the capacity to breathe.

**Donation after Cardiocirculatory Death (DCD)** The procurement of organs for transplantation from individuals who are declared dead according to circulatory-respiratory criteria, as opposed to brain death criteria (also known as non-heart-beating donation or NHBD).

**Deceased donor** An individual from whom at least one solid organ is recovered for the purpose of transplantation after suffering brain death or cardiac death.

**Donor** A person (either living or deceased) who provides cells, tissues or organs for transplantation.

**Donor screening** The process for determining the suitability of a specific individual for cell, tissue or organ donation based on age; medical, social, and sexual history; physical examination; and autopsy finding (if performed).

**Donor testing** The laboratory tests and measurements done on a donor or donor specimen to determine:

- if the donor has or ever had a transmissible disease or is or ever was infected with a transmissible disease agent,
- donor compatibility, and
- the degree of functionality of the cell, tissue or organ that is to be retrieved.

**End-user** The physicians/surgeons or dentists who transplant tissues and organs for the benefit of recipients.

**Eye bank** An establishment that recovers, processes and/or distributes ocular tissue.

**Histocompatibility laboratory (or HLA or Tissue Typing Laboratory)** A laboratory that performs HLA tissue typing of donors and recipients, and cross-match testing to determine the degree of compatibility between donor and recipient.

**Human Leukocyte Antigen (HLA)** The major antigen compatibility complex in humans that is genetically determined and is involved in cell self-identification. These protein molecules can provoke an immune response and the development of antibodies. If the recipient has preformed antibodies to the donor's HLA type, there is a risk of rejection of the graft or organ.

**Highly Sensitized Patient (HSP)** A patient who has been exposed to foreign tissue either through previous transfusions, transplantation or pregnancy, and who has developed antibodies against many common Human Leukocyte Antigen (HLA) molecules. As a result, the majority of organs that become available are incompatible and cannot be transplanted to these patients.

**Intensivist** A physician with training in critical-care medicine.

**Leading practices** Methods and techniques that have consistently shown results superior to those achieved with other means. Leading practices are used to guide medical practice and decision-making in the absence of evidence based research; for example, effective procedures requesting consent for donation.

**Listing** The process for placing an individual on a waitlist to receive an organ or tissue transplant, and for managing that individual's rank and status on the waitlist.

**Living Donor Paired Exchange (LDPE)** Frequently, healthy and motivated people are unable to be living kidney donors for their spouses, relatives or friends because their blood group or tissue type is incompatible with the intended recipient. In a paired exchange, these live donors—healthy people who donate one of their two kidneys—are matched with other compatible recipients. Once an acceptable match is made, transplantations can occur between two sets of kidney donors and recipients.

**Neurological Determination of Death (NDD)** The process and procedure for determining death of the individual based on neurological or brain-based criteria.

**Organ procurement organization (OPO)** An organization that is responsible for the facilitation of cell, tissue or organ donation (procurement), retrieval and distribution. This includes:

- receiving referrals for donation,
- collecting the information necessary to determine the suitability of the donor and their cells, tissues or organs,
- offering the cells, tissues or organs to the appropriate transplant program,
- coordinating the retrieval of cells, tissues or organs,
- preserving, storing, transporting, releasing and delivering the cells, tissues or organs to the transplant program, and
- documenting this process.

**Policy** A guiding principle or plan of action used to set direction and influence and determine the operational framework within which an organization functions.

**Potential donor** Someone who has died and for whom consent for donation has been obtained, or someone who is alive and has been approved for donation.

**Processing** In respect to tissues, any of the following activities:

- Donor screening
- Donor testing
- Donor suitability assessment
- Testing and measurements after retrieval
- Preparation for use in transplantation
- Preservation
- Storing
- Packaging and labeling

**Quality Management Program** A program that defines the policies and environment that are required to meet standards of quality and safety and that provides confidence that the processes and tissue consistently conform to requirements for quality.

**Recipient** A person who receives a transplant.

**Regulations** Laws, rules or orders prescribed by authorities to govern the behaviour of its citizens and organizations.

**Recovery** The dissection and surgical removal of cells, tissues or organs from a living or deceased donor.

**Specialized Tissue Products** Tissue allografts that are more extensively processed than the allografts currently processed in Canada.

**Standard** An established norm or requirement, described in a formal document, that sets out technical specification or other criteria that a product, process or service must meet; for example, CSA standards, and Accreditation Canada standards.

**Surgical bone bank** An establishment that processes and/or distributes femoral heads obtained from living donors.

**Surveillance** Monitoring of cell, tissue and organ recipients for undesirable responses or outcomes related to the transplant including the transmission of a disease or disease agent.

**Tissue** A functional group of cells. Tissues may be transplanted as viable cells or otherwise preserved or fixed. Examples include ocular, musculoskeletal, cardiac, connective tissue (fascia), skin and amniotic membrane. Tissues do not include perfusable organs for transplantation.

**Tissue bank** An establishment that recovers, processes and/or distributes musculoskeletal, cardiac, vascular, skin, amniotic membrane and/or soft tissue.

**Traceability** The ability to locate tissues or organs at all stages in the process, from initial recovery from a donor through to either transplantation or disposal.

**Transplant follow-up** The process of monitoring and evaluating the ongoing health and organ or tissue function of transplant recipients.

**ACRONYMS**

<b>AATB</b>	American Association of Tissue Banks
<b>ADM</b>	Acellular Dermal Matrix
<b>CCDT</b>	Canadian Council for Donation and Transplantation
<b>CIHI</b>	The Canadian Institute for Health Information
<b>CORR</b>	Canadian Organ Replacement Register
<b>CSA</b>	Canadian Standards Association
<b>CTO</b>	Cells, tissues, organs
<b>DBM</b>	Demineralized bone matrix
<b>DCD</b>	Donation after cardiocirculatory death
<b>EBAA</b>	Eye Bank Association of America
<b>ER</b>	Emergency room
<b>HLA</b>	Human Leukocyte Antigen
<b>HSC</b>	Health Science Centre
<b>HSP</b>	Highly sensitized patient
<b>ICU</b>	Intensive care unit
<b>LDPE</b>	Living donor paired exchange
<b>LHIN</b>	Local health integration networks
<b>NDD</b>	Neurological determination of death
<b>ODT</b>	Organ donation and transplantation
<b>OPO</b>	Organ procurement organization
<b>OR</b>	Operating room
<b>OTDT</b>	Organ and tissue donation and transplantation
<b>PHAC</b>	Public Health Agency of Canada
<b>TDT</b>	Tissue donation and transplantation
<b>UNOS</b>	United Network for Organ Sharing

**Canada's Organ Donation and Transplantation Community**

**Canada's Tissue Donation and Transplantation Community**

**Canadian Blood Services**

For more information please contact:

**Canadian Blood Services  
Organs and Tissues Donation and Transplantation**

1800 Alta Vista Drive  
Ottawa, ON K1G 4J5  
Phone: 613 739-2300

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