



ORGAN DONATION AND TRANSPLANTATION IN CANADA

System Progress Report 2006–2015

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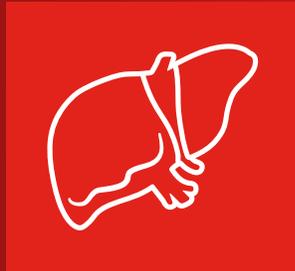
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EXECUTIVE SUMMARY



CANADA HAS SEEN INCREMENTAL PROGRESS IN ITS ORGAN DONATION AND TRANSPLANTATION SYSTEM SINCE 2006.

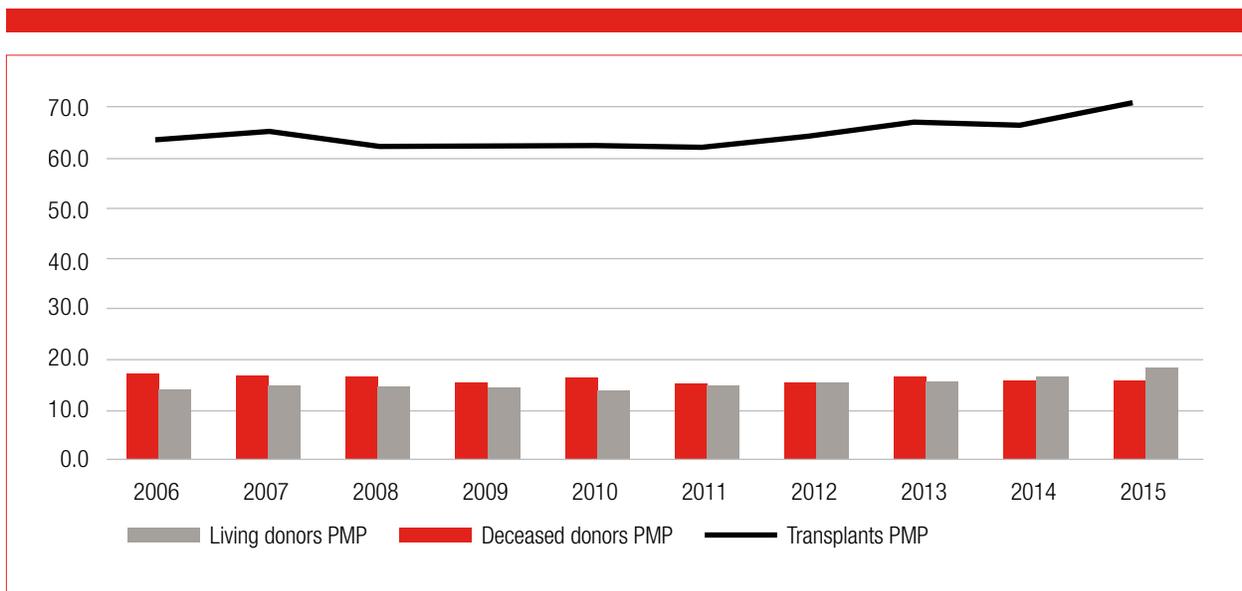
Our deceased donation rate has increased from 14.1 donors per million population (DPMP) to 18.2 DPMP in 10 years. While this is encouraging, organ donation and transplantation in our country is simply not improving fast enough to help the thousands of Canadians waiting for lifesaving or life-improving transplants.

Drawing on data obtained from the Canadian Transplant Registry, the Canadian Organ Replacement Register, and the various transplant programs and provincial organ donation organizations (ODOs) across the country, this report presents an overview of the state of Canada's organ donation and transplantation system today. It charts the areas in which the system has performed well over the past 10 years, and those in which further focus and investments may yield the greatest outcomes for patients.

Burden and outcomes

In 2015, 2,559 lifesaving or life-enhancing transplants were performed in Canada. Of those, over 57 per cent (1,473) were kidney transplants. Yet, as of the end of 2015, there were 4,631 people on Canada's organ transplant wait-lists. That same year, 262 patients on wait-lists died before receiving transplants. Many others who were in advanced stages of their illnesses died without ever making it to wait-lists, or after being removed from wait-lists after they were considered no longer suitable for transplant.

Donors and transplants per million population in Canada



Benefits of transplantation

Transplantation leads to significant personal benefits for patients and to economic benefits for governments. Transplantation is the best therapy for patients with end-stage kidney disease, and the only treatment for patients suffering from end-stage liver, heart and lung disease. Compared to dialysis, a kidney transplant can more than double a patient's life expectancy. It is also the most cost-effective method of treatment for patients with end-stage kidney disease. Starting in the second year after transplant, the health-care system avoids between

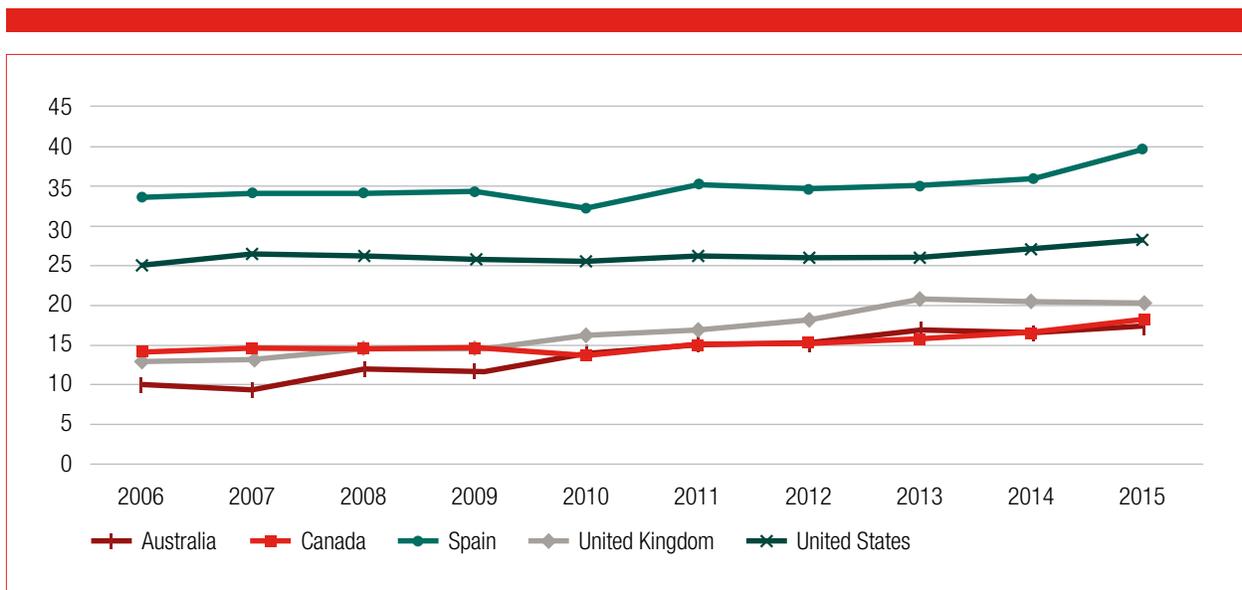
\$33,000 and \$84,000 per transplant patient per year of dialysis, while at the same time providing better outcomes for patients.¹

A study conducted by the Kidney Foundation of Canada² showed that if 1,000 patients who were unable to work because of kidney failure were to receive kidney transplants and return to work full-time, their combined annual contribution to Canada's gross domestic product would be \$50 million. The study also estimated that the Government of Canada would collect about \$8 million in additional tax revenue each year.

Deceased donation performance results

Although Canada's national deceased donation rate has increased by 29 per cent since 2006 — from 14.1 to 18.2 DPMP in 2015 — the system is underperforming. The national deceased donation rate is still well below the proposed target of 22 DPMP* and well below those of leading countries internationally.

International deceased donation rates, 2006–2015 (DPMP**)



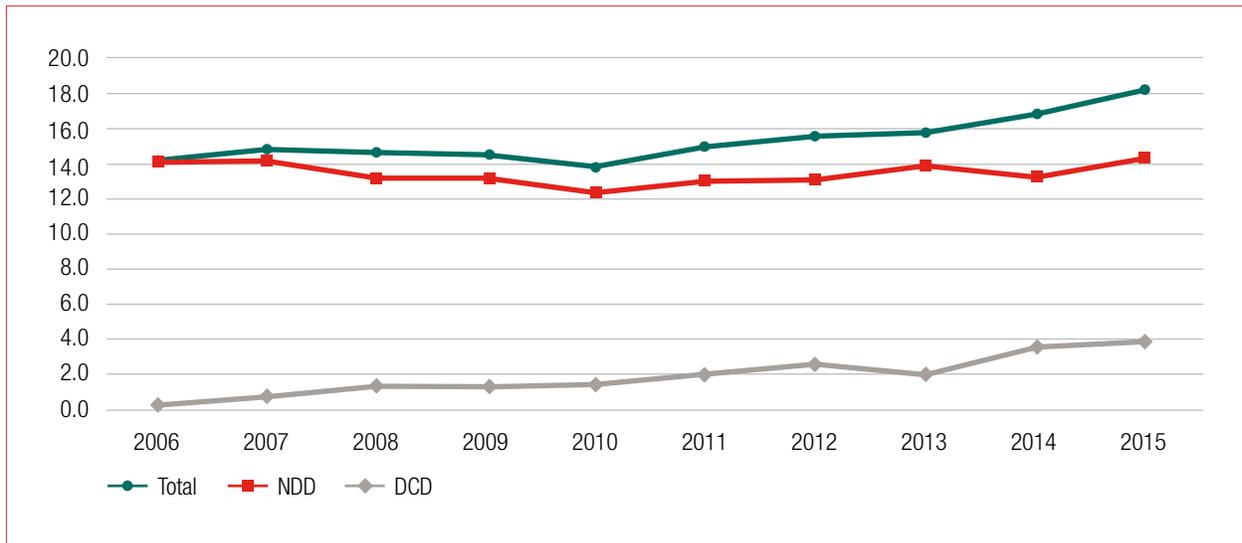
* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

** Although the DPMP measure has been criticized as not being an accurate indication of donation performance, it is still widely used for comparative purposes. For this metric, most countries report actual donors, a figure that only requires an organ to be removed or an incision made in the operating room for the purposes of transplantation. Canada, however, reports utilized donors, a metric that requires at least one organ to have been transplanted into a patient. Annual reports on organ donation and transplantation activity issued by the National Health Service in the United Kingdom (2012–2015) estimate differences of between four to eight per cent when comparing actual donors and utilized donors.

National performance: Continued success hinges on donation after circulatory death

If Canada is to continue improving its deceased donation rate, it must increase the number of donors making donations after circulatory death (DCD). Donations made in 2015 by DCD donors represent 21 per cent of the total number of donations made by deceased donors — and the area of the organ donation and transplantation system with the greatest potential for growth.

Deceased donors in Canada, 2006–2015 (DPMP)



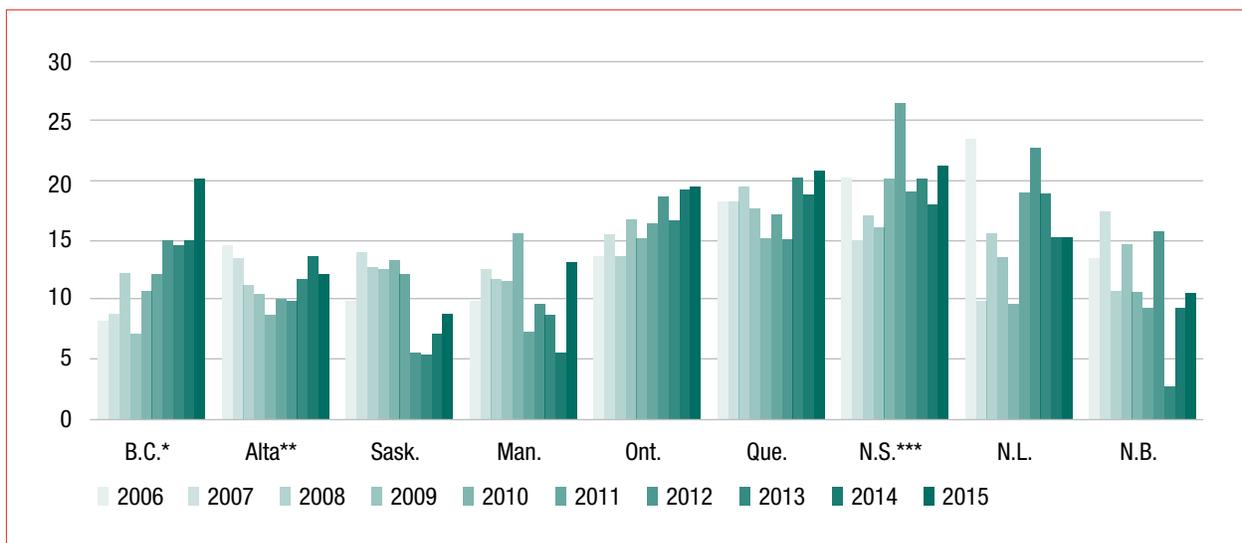
Performance among provinces varies

The systems of those countries with the highest deceased donation rates share similar features, including the presence of in-hospital donation specialist teams who are accountable for performance and quality; optimized programs for both types of donation (DCD and donation

after neurological determination of death); highly developed and consistently implemented leading practices; and public and professional awareness and education.

These features have been applied to differing degrees across Canada's provinces and territories.

Deceased donors per million population by province and year, 2006–2015



* The population of Yukon is included in the calculation of these rates, as per Canadian Institute of Health Information standards.

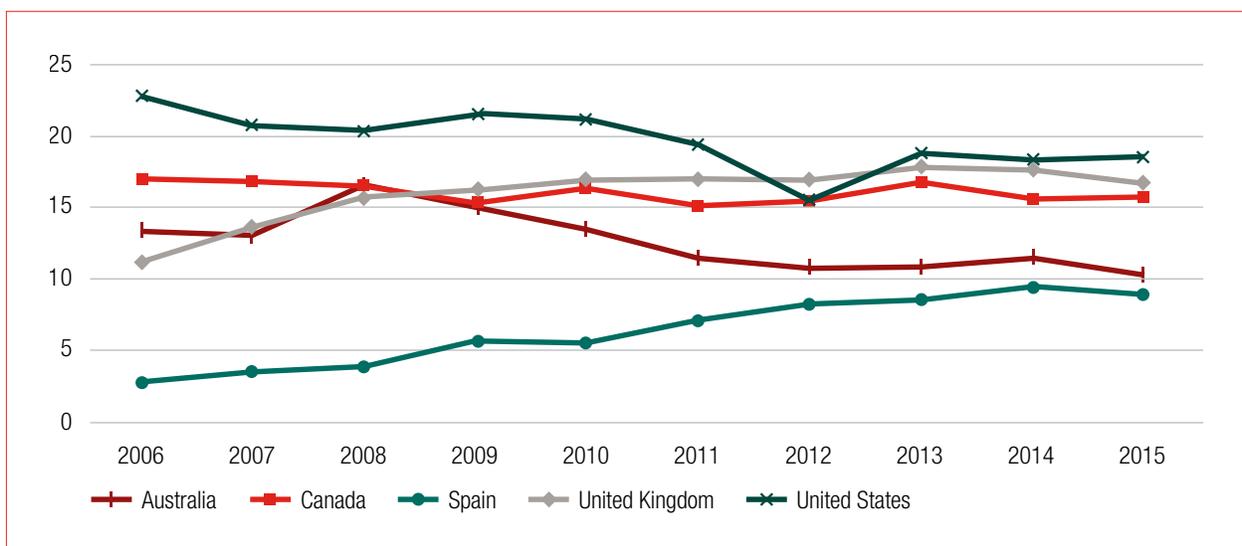
** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates, as per CIHI standards.

*** Donors from Prince Edward Island are included in the calculation of these rates.

Living donation performance results

Canada's living donation rate (i.e., organ donation rate by living donors) in 2015 was 15.7 DPMP. This rate — which is primarily made up of kidney donors, but also includes liver and lung donors — has decreased by eight per cent over the last 10 years.

International living donation rates, 2006–2015 (DPMP)

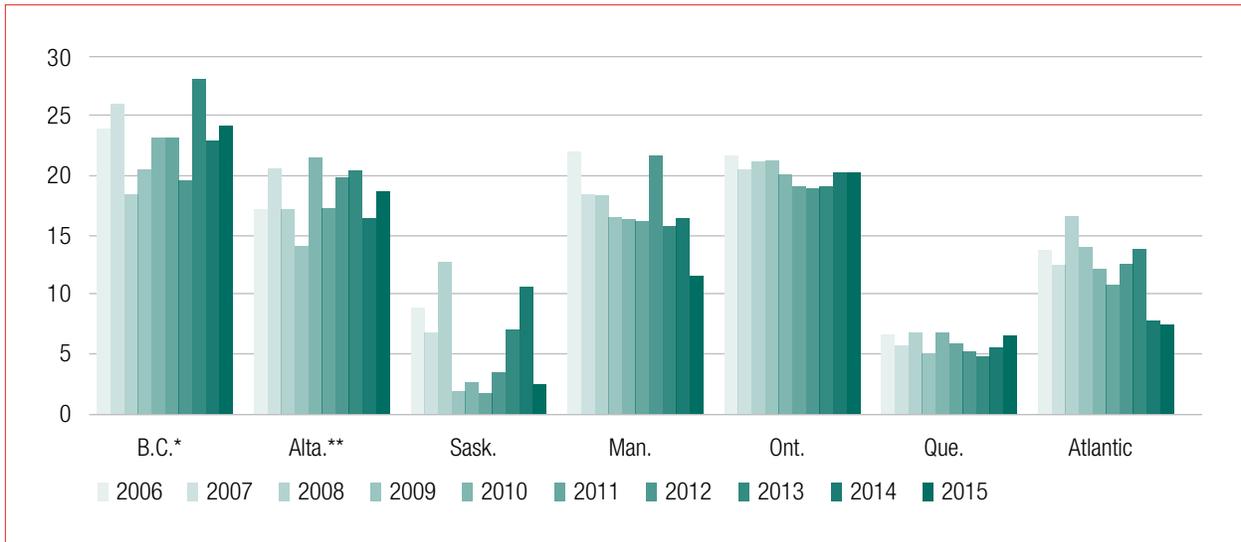


Despite this, positive indicators remain. Our rate compares well internationally, and outcomes for kidney transplant recipients and their living donors compare to the best in the world. The Kidney Paired Donation (KPD) program has facilitated 391 kidney transplants from living donors from 2009 to 2015 — transplants that may otherwise have not occurred. Canada has also shown increased performance in liver donation rates by living donors.

While the national rate decreased, living donation performance among provinces varies significantly.

Those provinces that perform best stress the importance of donations by living donors, and have efficient programs and professional education systems that teach hospital staff and patients about benefits of living donations. They also provide access to timely pre-transplant testing for both donors and patients, and to operating rooms reserved for transplant surgeries. Living donation rates and patient wait times for a transplant from a living donor vary significantly among provinces and territories.

Number of living kidney, liver and lung donors per million population by province, 2006–2015



* The population of Yukon is included in the calculation of this rate.

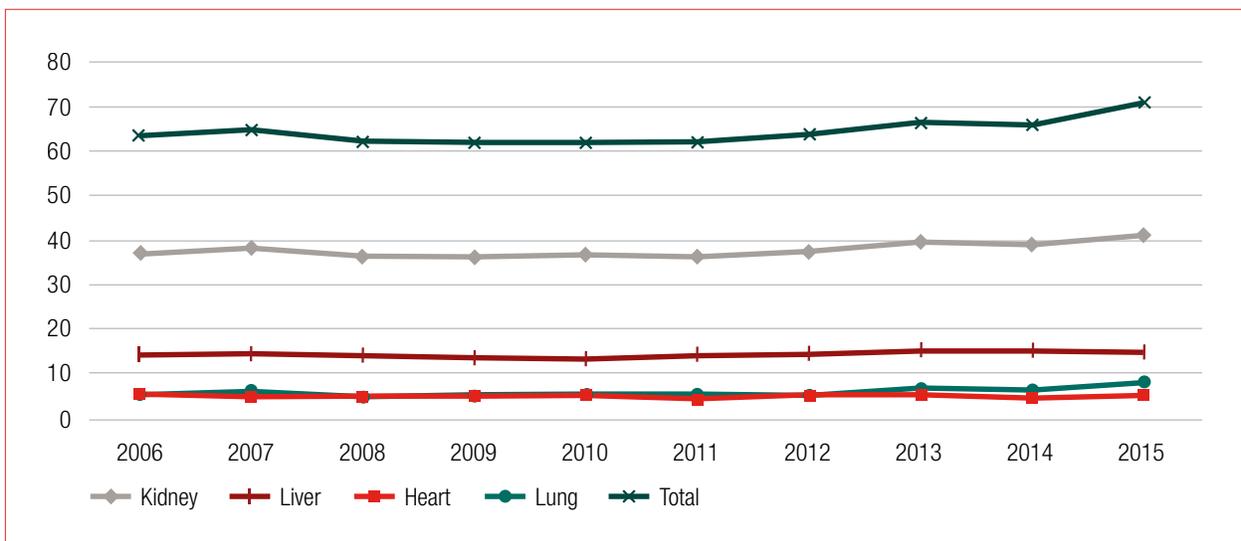
** The populations of Nunavut and the Northwest Territories are included in the calculation of this rate.

Transplantation performance results

Between 2006 and 2015, Canada's transplant rate (which includes organs from both deceased and living donors) increased by 12 per cent from 63.7 to

71.4 transplants per million population. Over the same period, the actual number of transplants increased by 23 per cent from 2,074 to 2,559.

Transplants per million population in Canada by organ type, 2006–2015



In spite of the modest increases in transplant numbers, Canada still has a shortage of organs. More than 4,600 patients are waiting for transplants. Given that Canada will continue to have a shortage of organs into the future, there is a need to provide equitable access to the limited number of donated organs for all potential recipients.

Organ listing and allocation criteria and access to transplants varies from province to province. In many cases, these criteria are not readily available to the public and patients. Kidney sharing among provinces is largely limited to those transplants done through the KPD program (i.e., living donation) and the Highly Sensitized Patient (HSP) program (i.e., deceased donation).

Key national system improvement initiatives

Several initiatives have guided system development, and have been undertaken through the efforts of individual programs and provinces, and collective efforts at a national level. Others require greater focus. Some of the key national initiatives are listed below.

A coordinated systems approach

An integrated organ donation and transplantation system involves numerous programs, organizations and jurisdictions, the shared goal of which is to improve national donation and transplantation performance. Countries such as the United States, the United Kingdom and Australia have benefited by enhancing coordination and changing structures. These countries also have legislation to guide all programs and services. While the optimal donation and transplantation system in Canada has been developing, national and provincial programs and services, though foundational, are not formally coordinated and aligned. This includes necessary

alignment for the purpose of strategic planning and annual reporting to funding governments and the public. Without a formal process, there is a constant risk of duplication of resources and investment and lost opportunities to leverage established successes to enhance donation and transplantation within the country as a whole. The system would benefit from enhanced legislation, in particular for pan-Canadian collection and reporting of health data, integrated planning, and formalized annual reporting that links the work of all government-supported programs contributing to donation and transplantation.

A clinical governance model to advance national programs and services

While national programs and services for organ donation and transplantation were launched in 2008, an important final step to optimize national programs and services is to formalize the clinical governance. Clinical governance takes a patient-centred approach to implementing a number of key elements of quality management, including processes to report on clinical effectiveness, risk management, national program audits and training. It defines responsibilities and accountabilities for the quality and continuous improvement of care specific to national programs and services.

In the absence of a formal structure, an interim clinical governance committee structure has been established out of necessity by Canadian Blood Services for national programs and services. This informal structure brings together stakeholders to develop interprovincial policies, to guide strategic direction, to advise on the operations of the Canadian Transplant Registry (including interprovincial listing, organ-sharing programs, responses to emerging issues), and to review and report on system performance, including deceased and living donation. It is composed of the Organ Donation and Transplantation Expert Advisory

Committee and its subcommittees and working groups. While this group has contributed to the progress seen in recent years, its informal participation and relationship-based model has a limited threshold of influence.

A formal, integrated clinical governance structure for national ODT programs and services could bring a greater clarity of roles and responsibilities for all users of the system, as well as a catalyst for system performance improvements while advancing higher-quality care, greater efficiency and reduced costs.

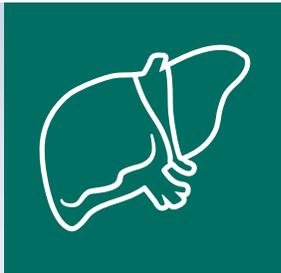
Implementation of donation specialists

Donation physicians have key responsibilities for donation leadership, education, consultation, clinical support, and performance and quality improvements. In partnership with coordinators, they are acknowledged to be the cornerstone of successful organ donation and transplantation programs in other countries. Canadian provinces have begun the implementation of donation physicians in their programs. To date, British Columbia, Alberta, Manitoba, Ontario, Quebec and Nova Scotia have intro-

duced donation physicians. The model by which each has done so varies according to factors such as geography, system capacity and resourcing, as well as the structure and organization of the province's donation and transplantation services.

Improved public awareness and education

There are many organizations working to increase awareness of organ donation among Canadians. Patient advocacy groups and health charities continue to work diligently to promote the social and economic benefits of organ donation and transplantation. Provincial organ donation organizations have introduced a number of campaigns to increase public awareness and decisions to donate. They have also worked with Canadian Blood Services to align messaging and develop common marketing for traditional and new media. Efforts are focused on a clear call to Canadians to register their intent to donate and discuss donation wishes with family members to ensure expressed wishes are understood.



Reg Parker, double-lung and liver recipient

Intent-to-donate registries enable Canadians to formally declare their expressed wishes to donate their organs. Health-care staff and physicians report that registry information can inform discussions with family members and bring families some relief and comfort when loved ones' wishes are known. Several provinces have either implemented new registries or improved their existing registries to ensure Canadians have effective ways to record their decisions about organ and tissue donation. To date, the number of registered Canadians remains low. In most provinces, only about a third of residents are registered, despite recent public polling data that indicates over 91 per cent of Canadians support organ donation.³

Leading practices development and knowledge translation

Leading practices are developed through rigorous evidence-based processes. These processes include literature reviews, systematic evidence reviews, environmental scans, evidence synthesis, and the evaluation and development of recommendations by subject-matter experts. Once these practices are completed, their implementation is supported through knowledge mobilization tools and educational activities. Leading practices have been shown to significantly improve system performance when implemented consistently across the country. Several leading practices relating to deceased donation, living donation, human leukocyte antigen antibody testing and organ-sharing protocols have been developed to improve practices and outcomes for patients.

Professional education

Formal training in organ donation and transplantation for health-care professionals varies considerably across the country. Work has progressed on a national, coordinated approach to professional development to not only support knowledge translation of leading practices, but also increase the commitment and support of health-care professionals to create a culture of donation. Programs will continue to focus on work in this area.

The Canadian Society of Transplantation worked with the Royal College of Physicians and Surgeons of Canada to develop a diploma program focusing on competency in solid organ transplantation for transplantation physicians. This program provides postgraduate medical education in transplantation compliant with national standards of excellence. The program will help standardize organ transplantation practices and attract surgeons to this specialty.

Canadian Transplant Registry

A significant achievement of the past 10 years is the development of interprovincial patient programs. These programs include the KPD program, the National Organ Waitlist, the HSP program, the Canadian Transplant Registry (CTR), and the services developed to support each. These programs have improved access to transplants for highly sensitized patients and increased the effectiveness and efficiency of national organ-sharing programs for living donors and critically ill patients. While the early development of the CTR programs and services was focused on the development of new listing and allocation practices, the service is now in place to support and advance national sharing for all organ groups.

The CTR has also established a platform for improved data standardization, a development that will move the system toward a better, more comprehensive framework for data analytics and management. Timely access to comprehensive and accurate data is critical for planning and managing organ donation and transplantation programs, improving patient outcomes, assessing system performance and satisfying research needs. Progress has been made in developing business intelligence capabilities, data warehousing tools, and establishing minimum data sets for deceased and living donation, and for heart, liver, lung and kidney transplants. Once a major information technology upgrade has been completed in 2017 and the CTR is fully functional, a large portion of the minimum data sets will be available in the CTR as a result of the

data required to perform the national listing and matching services. Other options for collecting outcome data must be explored and implemented to allow for the full scope of reporting required in the minimal data sets.

Research and innovation

Research is foundational to system improvement and innovation. Canada has a history of world-class transplantation research thanks to the efforts of a number of investigators and institutions that contribute at the national and international levels. Through the contributions of the Canadian Institutes of Health Research, new initiatives such as the Canadian National Transplant Research Program (for organ donation and transplantation and stem cell research), and ongoing national and international research, efforts have become better aligned and coordinated with excellent outputs. Ongoing investments will support further momentum in research and knowledge mobilization.

Conclusion

This report shows there is much evidence to support continued movement forward in a focused and collaborative manner to advance transplantation where possible. Programs across Canada have seen consistent improvements, and those strategies that have been proven successful both in Canada and around the world have been highlighted in this report. Programs are encouraged to focus on building the foundational elements of successful donation and transplantation practices to improve access to transplants for current and future patients.



Sherry, kidney donor through the Kidney Paired Donation program and her father, Peter, kidney recipient



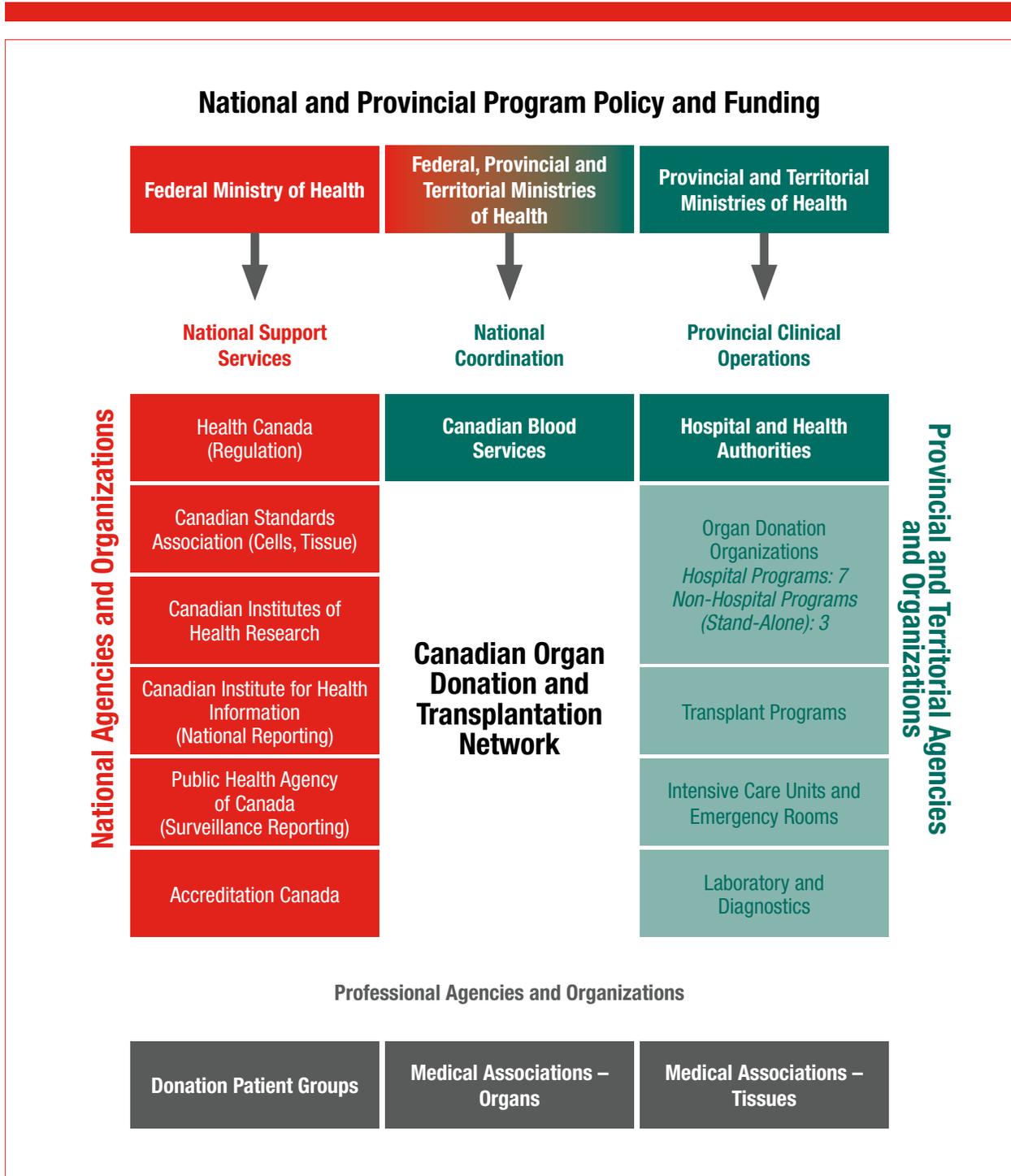
ABOUT THE ORGAN DONATION AND TRANSPLANTATION SYSTEM IN CANADA



PROVINCIAL AND TERRITORIAL GOVERNMENTS ARE RESPONSIBLE FOR HEALTH CARE IN CANADA. As such, they manage their own programs and laboratories to provide organ donation and transplantation services in their jurisdictions. Canadian Blood Services provides national programs and services to advance the practice of organ and tissue donation and transplantation. Professional societies provide support and focused education for health-care professionals. A variety of organizations and institutions provide direction through legislation, regulation and accreditation, and contribute to research efforts to improve the system.

The system relies on clinical, administrative and allied health professionals to work together to maximize donation and transplantation opportunities. These contributors include physicians, surgeons, nurses, intensive care unit personnel, laboratory medicine professionals, transplant coordinators, donor coordinators, donation-focused physicians, hospital administrators, social workers, administrators, information management specialists, policy analysts and other allied health workers. Without focused alignment, clear roles and responsibilities, and performance targets, the system remains vulnerable and could fail to meet the expectations and targets that are recognized as performance drivers in other national systems.

Canada's organ donation and transplantation system



ABOUT THIS REPORT

THE ORGAN DONATION AND TRANSPLANTATION IN CANADA: SYSTEM PROGRESS REPORT 2006–2015 PROVIDES THE MOST CURRENT AVAILABLE NATIONAL DATA ON DECEASED AND LIVING DONATION AND TRANSPLANTATION PERFORMANCE. THIS CRITICAL DATA PRESENTS GOVERNMENTS AND NATIONAL AND PROVINCIAL ORGAN DONATION AND TRANSPLANTATION PROGRAMS WITH THE CURRENT STATE OF CANADA'S DONATION AND TRANSPLANTATION SYSTEM. AS A RESULT, IT ENABLES AN ASSESSMENT OF THE RETURN ON THEIR INVESTMENTS, AND INFORMS RESPONSIBLE DECISION-MAKING.

This report acknowledges the generosity of organ donors and their families, and those patients with end-stage organ failure who depend on all organizations involved to improve opportunities for donation and transplantation.

Why was this report prepared?

In fulfilment of its stewardship role in system performance reporting, Canadian Blood Services, together with organ donation and transplantation advisory committees, developed this report to:

- Inform organ donation and transplantation programs, governments and Canadians on the progress of system improvements.
- Improve the accuracy and timeliness of system-level performance data to inform progress and guide future investments in shared national initiatives, provincial clinical operations and research priorities.
- Increase accountability and transparency through data collection and analysis.
- Identify gaps in information and data.
- Develop a framework for future system progress reporting.

How was this report developed?

Canadian Blood Services produced this document in close collaboration with its partners at the national, provincial and territorial levels. The content of this report was further informed by consultations with clinical experts and knowledge leaders in the organ donation and transplantation community.

Data for the report was collected from the Canadian Institute for Health Information (the Canadian Organ Replacement Register), the Canadian Transplant Registry and the Canadian Institutes of Health Research. Leaders from provincial organ donation and transplantation programs provided further information, analysis and context to support this data. (Refer to the Data Sources and References section for more information.)

The report also includes data from the Organs and Tissues Donation General Public Survey conducted by Ipsos Reid on behalf of Canadian Blood Services in 2015. This data provides insight and opinions from Canadians regarding donation and their expectations of the people and processes in Canada's health-care system.

This report was made possible through the dedicated efforts of the members of the Organ Donation and Transplantation Expert Advisory Committee. It includes input from the Canadian Institutes of Health Research, the Canadian National Transplant Research Program, the Canadian Institute for Health Information, the Deceased Donation Advisory Committee, the Donation and Transplant Administrators Advisory Committee, the Kidney Transplant Advisory Committee and the Living Donation Advisory Committee.

Overarching considerations

This report covers key areas of Canada's organ donation and transplantation system. Each section considers relevant data and its context, and, where appropriate and possible, national and international benchmark data. Data limitations and system challenges and opportunities are also highlighted.

Readers should consider the following:

- In collaboration with the organ and tissue donation and transplantation community, Canadian Blood Services led the development of a strategic plan for organ and tissue donation and transplantation in Canada. This plan was presented to governments in May 2011. While it is acknowledged that provincial governments did not fully endorse or implement all of the recommendations, the fundamental components of system improvement for organ donation and transplantation identified in *Call to Action* were largely implemented. These components continue to inform and guide national and provincial efforts to improve the organ donation and transplantation system in Canada. (Note: The tissue donation and transplantation system described in *Call to Action* is not described, discussed or analyzed in this report.)
- Canada's progress to date is the result of the collective work undertaken by the programs and organizations across the country that support organ donation and transplantation activities and provide related services. It confirms the leadership and successes of partnerships among its constituent organizations. Experience from leading international partners has demonstrated that coordinating a national effort to support provincial activities improves system performance and increases the efficiency of an organ donation and transplantation strategy.
- Deceased donation activities are primarily driven by organ donation organizations' clinical operations, whereas living donation activities reflect variable contributions by hospital transplant programs and some organ donation organizations.
- Donation comes from deceased donors — both through donation after neurological determination of death (NDD) and donation after circulatory death (DCD) — and living donors. Deceased donors provide organs for the vast majority of transplants (approximately 77 per cent), since living donors can provide only one organ. More organs per donor are provided by NDD donors than DCD donors.
- Variations in population density, demographics, funding for organ donation and transplantation, and differing priorities affect provincial organ donation and transplantation performance. Since Quebec, Ontario and British Columbia together comprise 75 per cent of Canada's population, performance in these provinces significantly influences the country's overall results.
- Data sharing on organ donation and transplantation performance, data reporting, data transparency and data analysis are fundamental to system improvement.
- Organ donation and transplantation is predicated on system integrity and trust among patients, families, the Canadian public, individual health-care providers, health-care teams, institutions and organizations, and funders, including various levels of government. Accountability and transparency are critical to maintaining this trust.
- Transplantation and organ utilization remains a provincial responsibility. Performance targets for utilization, reporting and comparability and audit are fundamental to future improvements.
- Research is at the heart of system improvement and innovation. The best available evidence should be used to improve clinical practices and health policy for Canadian donors and recipients. Research is broadly defined and includes basic sciences, clinical studies, clinical trials, data analysis, systematic reviews and assembly of evidence to inform health policy.

BURDEN AND OUTCOMES



IN 2015, 2,559 LIFESAVING OR LIFE-ENHANCING TRANSPLANTS WERE PERFORMED IN CANADA. Of those, over 57 per cent (1,473) were kidney transplants (481 kidneys transplanted came from living donors).

Figure 1: Donors and transplants per million population (PMP) in Canada

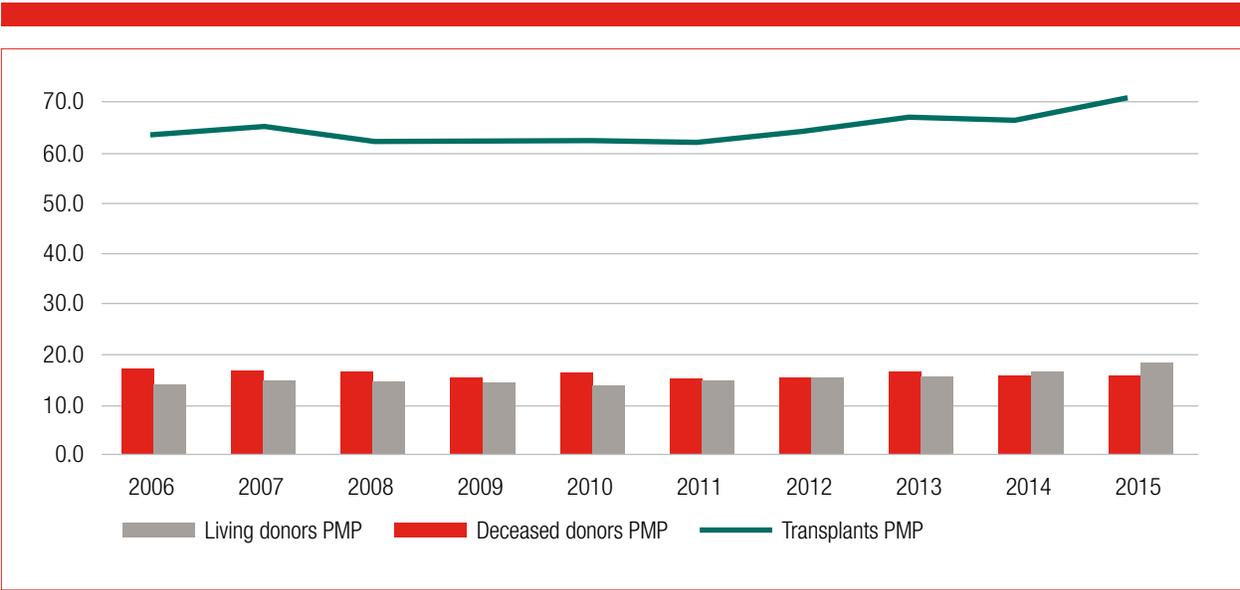
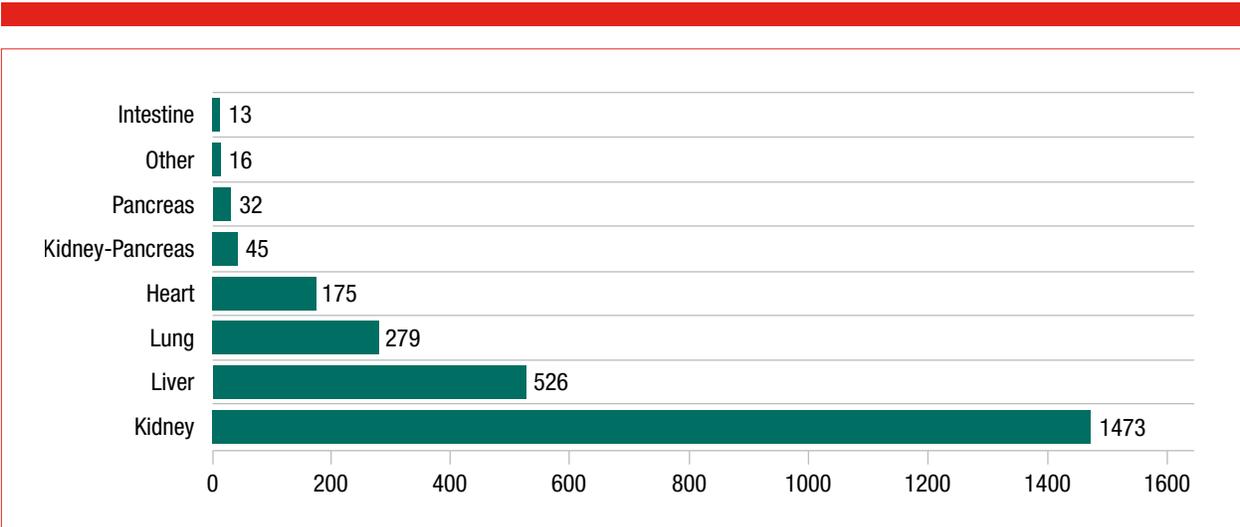


Figure 2: Transplants by organ type in 2015



As of Dec. 31, 2015, there were 4,631 people on organ transplant wait-lists in Canada. In 2015, 262 patients on wait-lists died before receiving transplants. Many others who were in advanced stages of their illnesses died without ever making it to wait-lists or after being removed from wait-lists.

End-stage organ failure also has a significant impact on Canada’s health-care system. The number of Canadians (excluding those in Quebec) with end-stage kidney disease increased by approximately 38 per cent from 2005 to 2014. By the end of 2014, at least 35,281 Canadians were living with end-stage kidney disease, creating unprecedented demand for regular dialysis and kidney transplants.

Benefits of transplantation

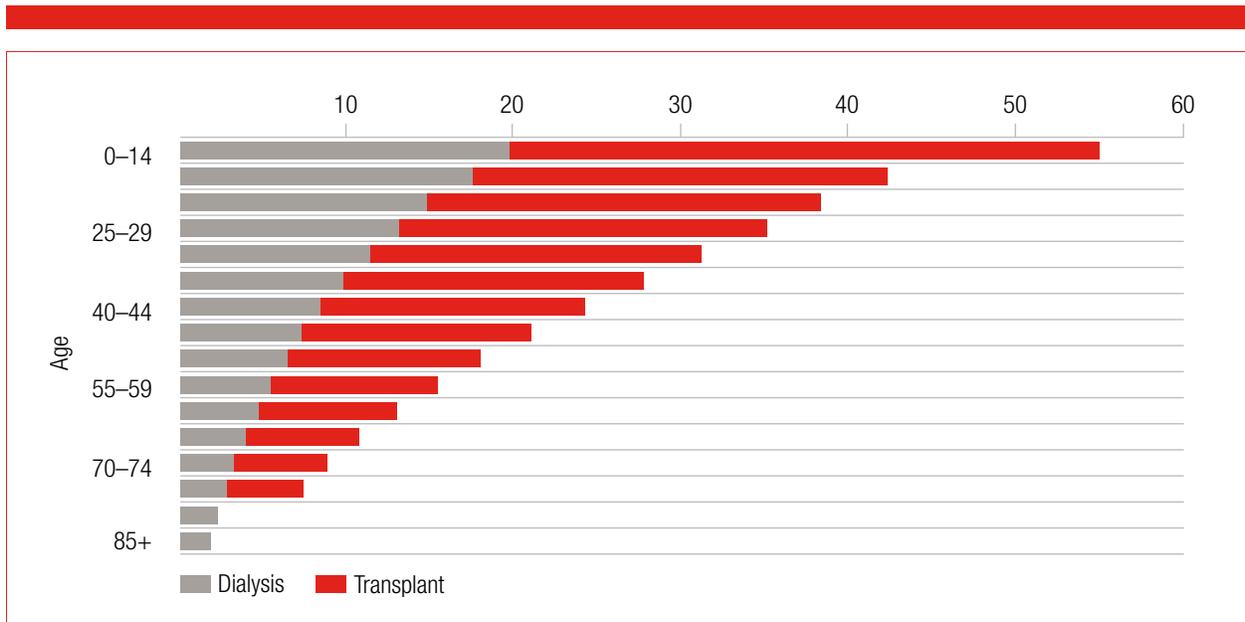
Transplantation leads to significant personal benefits for patients and economic benefits for provincial health

services. Kidney transplantation is the best therapy for patients with end-stage kidney disease. Compared to dialysis, it can more than double a patient’s life expectancy. Although the data in this section speaks primarily to the benefits of kidney transplantation, other types of transplantations, such as lung, heart and liver, are also beneficial.

A kidney transplant significantly increases the number of years a patient is expected to live compared to dialysis.

In spite of dialysis treatment, end-stage kidney failure can be fatal. Twenty per cent of patients on kidney transplantation wait-lists either die or are removed from wait-lists after three years because they are too sick to receive transplants. The five-year mortality rate for these patients (excluding those in Quebec) is very similar to the five-year death rates in common cancers diagnosed after they have begun to spread, including breast cancer and adenocarcinoma of the colon.⁴

Figure 3: Additional patient life years — remaining on dialysis versus receiving a transplant (based on age of onset of end-stage kidney disease)⁵



Transplantation is the most cost-effective treatment for end-stage kidney disease.

On average, most patients receiving dialysis need treatment three times per week, often for four hours per session. The total annual cost per patient for dialysis care can range from \$56,000 to \$107,000⁶, depending on the type of treatment (in-patient versus out-patient, hemodialysis versus peritoneal dialysis). Health-care costs for a patient who has had a kidney transplant are about \$66,400 in the first post-transplant year, and about \$23,000 per year after that. (Anti-rejection drugs account for approximately half of these costs.⁷) This means that, starting in the second year after transplant, the health-care system avoids between \$33,000 and \$84,000 per transplant patient per year of dialysis, while at the same time providing better outcomes for patients.

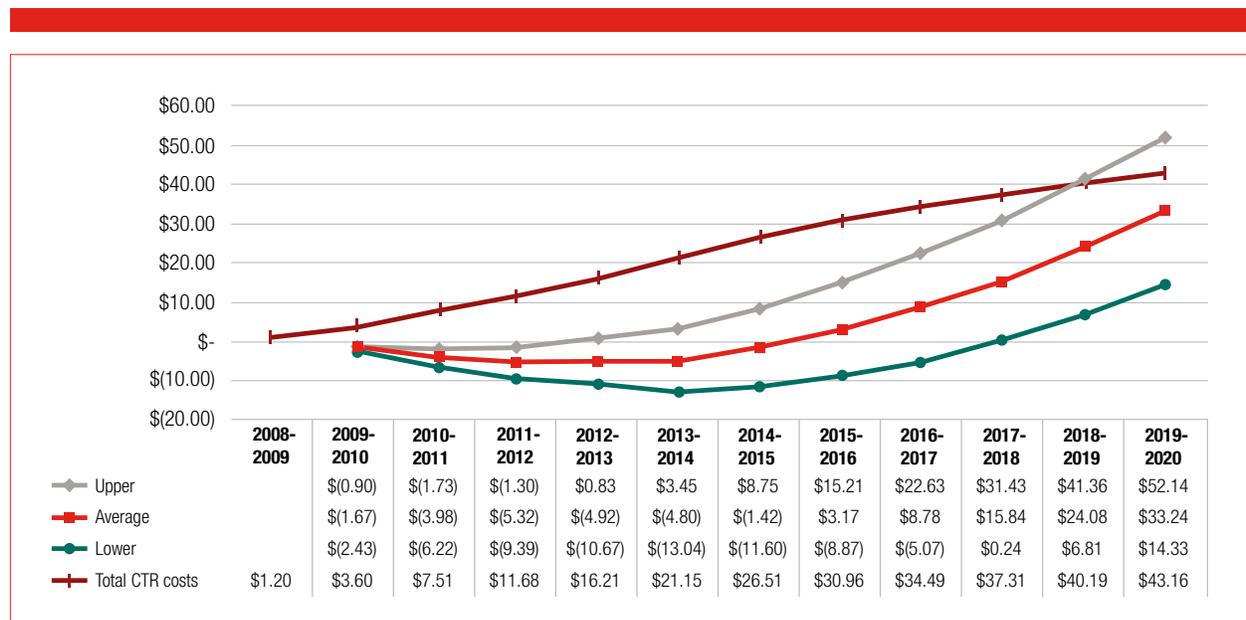
Liver, heart and lung transplants may also reduce costs for governments.

Although there is limited information on the cost avoidance associated with the transplantation of organs other than kidneys, a U.K. report states, “there is some evidence that the care of patients with life-threatening organ

failure — e.g., liver failure — may involve many days or weeks of in-hospital care, including significant time in intensive care (which is very expensive), that would be avoided if transplantation had taken place.”⁸

National initiatives such as the KPD program demonstrate quickly that the investment pays off. With the bigger integrated pool of donors, matching becomes statistically more probable. When patients are matched and transplanted they not only have the best treatment possible but the most cost-effective. Costs associated with transplantation are less than ongoing dialysis. Investments to date in the Kidney Paired Donation program not only supported hundreds of transplants that would likely not have occurred without the bigger pool to match from, as well, the infrastructure or registry built to facilitate the match has much more capacity to support all organ sharing. Simply said, based on the number of transplants, the estimated costs avoided without dialysis will have covered the full cost of building and operating the Canadian Transplant Registry by 2018, the program’s tenth year of operation. (See the upper estimate trend line in Figure 4.)⁹

Figure 4: Estimated economic benefits of the Kidney Paired Donation program (\$ millions)



Transplantation lets patients return to work and be productive.

The Economics of Kidney Failure, an analysis undertaken for the Kidney Foundation of Canada, found “approximately 50% of patients who received a transplant were working again within two years. If 1,000 patients unable to work because of kidney failure were to receive a kidney transplant and subsequently return to work full-time, the additional contribution to the GDP related to these jobs would be \$50 million. These gains would extend over the 18- to 19-year lifespan of a transplanted kidney from a living donor, this in comparison to 12 years for a deceased donor kidney.”¹⁰ The study also predicted that, based on these estimates, the Government of Canada would collect about \$8 million in additional tax revenue each year. Transplant Québec has estimated that in the past decade, that province’s health-care system has saved more than \$100 million due to efficiencies realized from kidney transplants alone.¹¹ In 2015, Quebec’s health-care system saved \$13.5 million, mainly through kidney transplants from deceased and living donors.¹²



Erin Taylor, kidney donor through the Kidney Paired Donation program

DECEASED DONATION PERFORMANCE RESULTS



National results

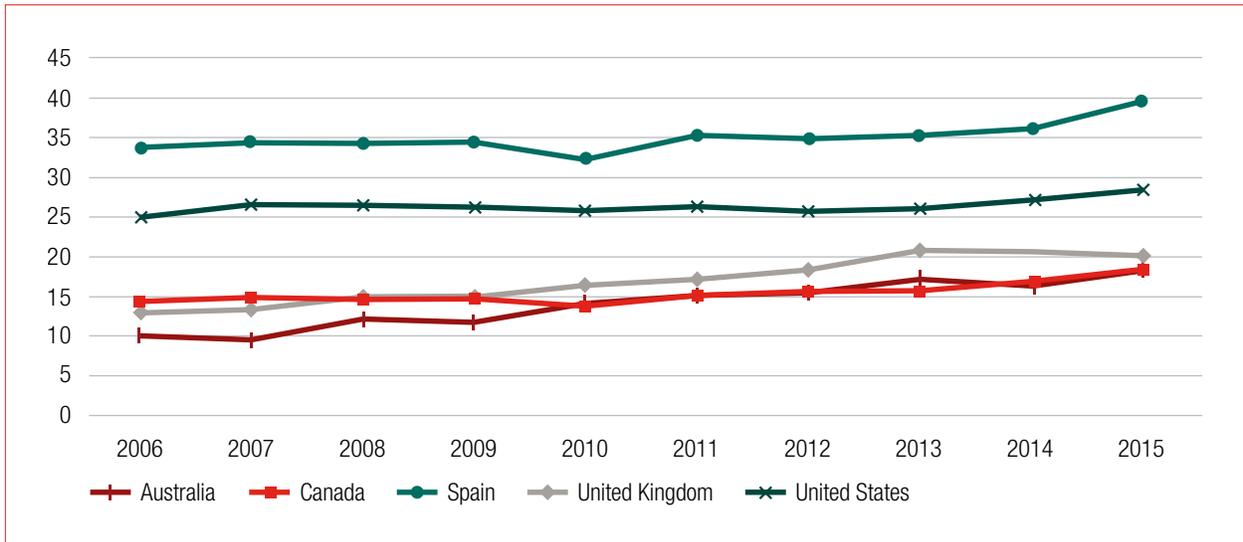
ALTHOUGH CANADA'S NATIONAL DECEASED DONATION RATE HAS INCREASED BY 29 PER CENT SINCE 2006 — FROM 14.1 TO 18.2 DONORS PER MILLION POPULATION (DPMP) IN 2015 — THE SYSTEM IS UNDERPERFORMING.

The national deceased donation rate is still well below the proposed national target of 22 DPMP*, and well below those of leading countries. Performance rates among Canada's provinces and territories vary significantly.

The number of deceased donors has increased by 42 per cent from 460 in 2006 to 651 in 2015. Donation after circulatory death (DCD) accounts for the largest increase in the number of deceased donors over time. There were 138 DCD donors in 2015. Donations made in 2015 by DCD donors represent 21 per cent of total donations made by deceased donors. DCD has the greatest potential for future increases in donations.

* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

Figure 5: International deceased donation rates, 2006–2015 (DPMP)



Although the DPMP measure has been criticized as not being an accurate indicator of donation performance, it is still widely used for comparative purposes. For this metric, most countries report actual donors, a figure that only requires an organ to be removed or an incision to have been made in the operating room for the purposes of transplantation. However, Canada reports utilized donors, a metric that requires at least one organ to have been transplanted into a patient. Annual reports on organ donation and transplantation activity issued by the National Health Service (2012–2015) from the United Kingdom estimate differences of between four to eight per cent when comparing actual donors and utilized donors.

Figure 6: Deceased donors in Canada, 2006–2015 (DPMP)

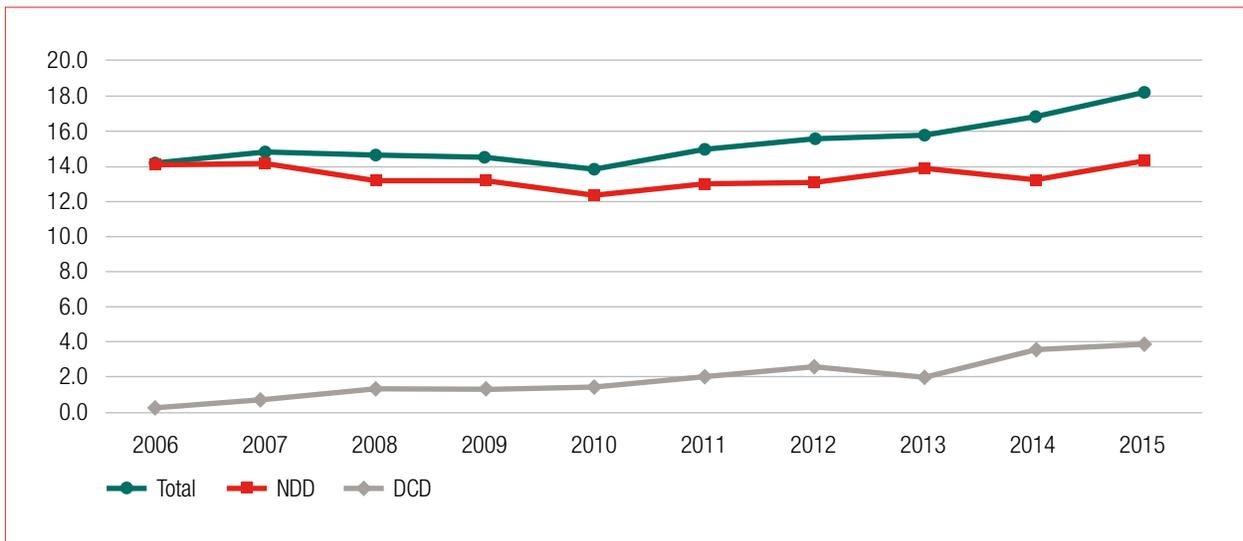
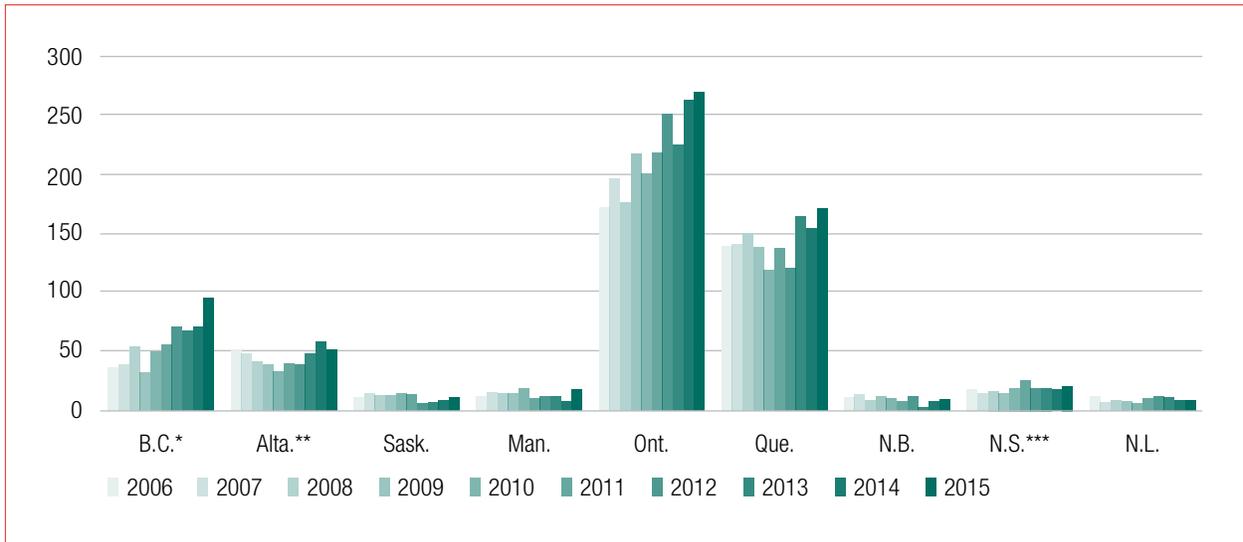
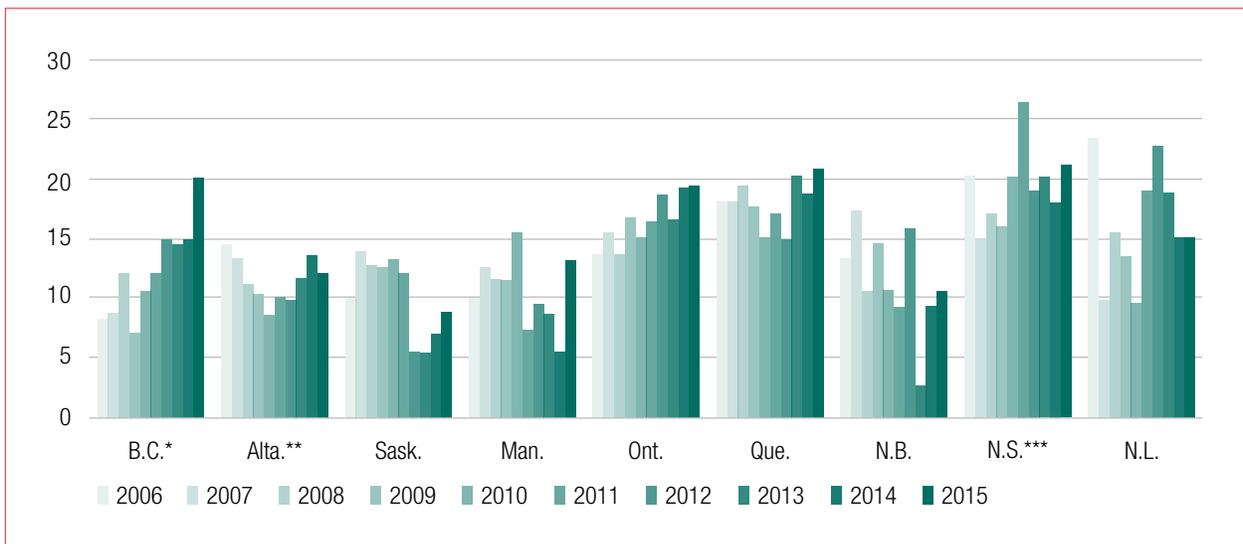


Figure 7a: Number of deceased donors by province and year, 2006–2015



* Donors from Yukon are included in B.C. numbers.
 ** Donors from Nunavut and the Northwest Territories are included in Alta. numbers.
 *** Donors from Prince Edward Island are included in N.S. numbers.

Figure 7b: Deceased donors per million population by province and year, 2006–2015



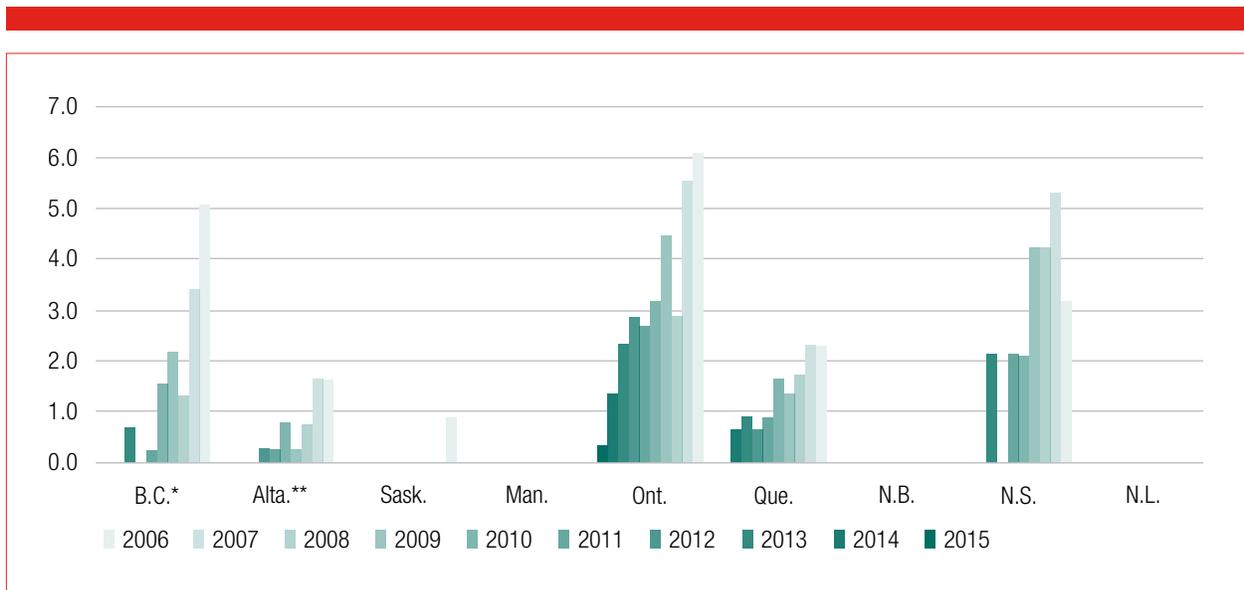
* The population of Yukon is included in the calculation of these rates, as per Canadian Institute of Health Information standards.
 ** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates, as per CIHI standards.
 *** Donors from Prince Edward Island are included in the calculation of these rates.

Donation after circulatory death is critical to increasing donation rates.

Catastrophic brain injuries are now being increasingly treated more aggressively and with new techniques. As a result, the number of donors who could donate after neurological determination of death (NDD) has stabilized or even decreased, as demonstrated in a recent Alberta study.¹³ Although NDD yields more transplants per donor than DCD, given decreasing NDD donor rates, it is now more important than ever that DCD programs be implemented to ensure donation continues to increase.

Recent increases in the national donation rate are due to increasing numbers of DCD donors. Ontario, Quebec, British Columbia, northern Alberta (Edmonton) and Nova Scotia have established DCD programs. These regions are looking to expand their programs to further increase donation rates. Meanwhile, Saskatchewan completed its first DCD transplantation in 2015, Manitoba is ready for its first DCD transplantation, and southern Alberta (Calgary) is starting its DCD program. Across Canada, there have been more than 600 DCD donors and more than 1,300 resulting transplants.

Figure 8: DCD donors per million population by province and year, 2006–2015



* The population of Yukon is included in the calculation of these rates as per CIHI standards.

** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates as per CIHI standards.

Donation physicians facilitate transplants.

The introduction of donation physicians has also helped improve Canada’s transplantation system. Donation physicians work with donor coordinators and hospitals to implement leading practices, support donor care, improve quality and provide education.

The donation physician model has been implemented to varying degrees and in different ways among the provinces. For example, Ontario has introduced five regional leads and 60 hospital leads, British Columbia has

introduced seven donation physicians, and Manitoba has introduced five. Alberta has two established donation medical leads and plans to introduce a third, while Quebec has received approval for 11 donation physicians. (Note these are not full-time positions in any province.) Nova Scotia has recently completed a pilot test of the model. An evaluation of the pilot highlighted the challenges of this role when using non-hospital-based physicians. Nova Scotia anticipates re-launching the donation physician role, and recruiting critical-care physicians as a priority.

New guidelines for holding end-of-life discussions with families of potential donors should also improve donation rates and services to families. Donor coordinator workshops for end-of-life discussions have been conducted nationally to further encourage implementation by front-line staff.

Mandatory referral and medical record review reduce missed transplant opportunities.

Establishing consistent clinical triggers for mandatory referral, also known as routine notification, is essential to high-performing deceased donation systems. Many international programs legislate and implement mandatory referral processes with clear roles, responsibilities and guidelines to support the practice. There are currently a variety of different types of mandatory referrals modelled in Canada. Provinces stand to benefit from ongoing review to determine the optimal model. Missed donors are sentinel events, and can mean the difference between life and death for up to eight people waiting for life-altering transplantations. Initiatives are underway to explore advanced processes where missed referrals can be reported and tracked with the same importance as other serious medical errors.

Mandatory referral with clinical triggers can be adjusted to promote early engagement of organ donation organizations (ODOs). Such an approach should facilitate direct links to donation specialists and ODOs to support the donation process with clinical guidance, diagnosis and prognostication of NDD and DCD. Routine early or real-time review of medical records is an important opportunity for the ODO and referring hospital teams to review cases and make quality improvements. Retrospective medical record reviews also inform annual trends, gaps and opportunities by regions, sites or individual units.

Standardization of medical record review practices nationally, and the availability of such information in real time will inform important regional variability. A national review tool is being piloted this year with the expectation of future national collaboration. Estimates of true donor potential from administrative or discharge databases vary significantly. Some range from as high as 90 DPMP¹⁴,

to 40 to 50 DPMP^{15,16,17}, to as low as 33 DPMP¹⁸. At a minimum, national retrospective reviews are required to better estimate donor potential and identify performance gaps. However, real-time reviews provide significantly more accurate and timely data, and introduce immediate information for future quality improvement. Going forward, national comparisons could also inform performance opportunities.

Progress has been made, but there is still room for improvement.

As a result of ODOs' efforts, there has been a modest, yet sustained increase in the national donation rate. However, consistency among referral patterns remains elusive.

Provincial results

The systems of those countries with the highest deceased donation rates share similar features:

- The presence of in-hospital donation specialists who are accountable for performance and quality.
- Optimized NDD and DCD programs.
- Highly developed and consistently implemented leading practices.

Those provinces that have implemented these elements show higher donation rates than those that have not, or show upward donation trends. Conversely, those provinces that lack these elements generally show low donation rates. (See Figure 9.) For some of these elements, results are not achieved right away. Additionally, data for some contributors to high donation rates — such as public awareness, death audits, ODO funding, professional education, intensive care unit (ICU) and operating room (OR) capacity, and availability of surgical recovery teams — is not yet available for analysis. Nonetheless, these factors are considered important for future comparative analysis.

Figure 9: Factors contributing to higher donation rates

	B.C.	ALTA.	SASK.	MAN.	ONT.	QUE.	N.B.	N.S.	N.L.
Mandatory referral	●	●*	■	●	●	●	●	▲	■
Donation physicians	●	▲	■	●	●	▲	■	▲	■
NDD leading practices	●	●	●	●	●	●	●	●	●
DCD programs	●	▲	▲	▲	●	●	■	●	■
% DCD donors, 2015	25	13	10	0	31	11	0	15	0
Leading practices in donor management	●	●	●	●	●	●	●	●	●
Deceased donors, 2015 (DPMP)	20.1**	12.2***	8.8	13.1	19.5	20.8	10.6	21.2****	15.2
Number of donors, 2015	95	52	10	17	269	172	8	20	8
2011–2015 % change in DPMP	76	33	-17	89	22	26	14	-20	-20

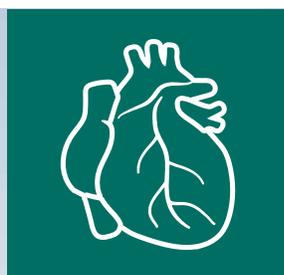
* Mandatory consideration

** The population of Yukon is included in the calculation of this rate.

*** The populations of Nunavut and the Northwest Territories are included in the calculation of this rate.

**** Donors from Prince Edward Island are included in the calculation of these rates.

- Implementation complete or near completion
- ▲ Implementation in progress
- Implementation not started

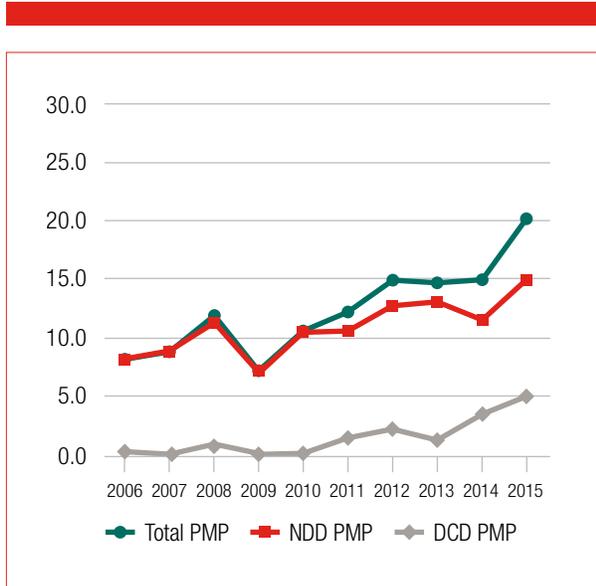


Jennifer Woolfsmith and her son, Owen; Jennifer's late daughter, Mackenzy, was a pediatric organ donor

British Columbia

British Columbia has one of the most improved and highest donation rates in the country. It has made a significant financial investment in its deceased donation program. Funding has been allocated to the implementation of donation physicians, and ODO and in-hospital donation coordinators. The province has also focused on deceased donation education for front-line ICU and OR staff. Significant work has been done to adopt a deceased donation strategy that offers greater support to smaller hospitals. The province has successfully implemented DCD programs in all health authorities in its larger hospitals and is now looking at opportunities to expand into smaller and remote hospitals.

Figure 10: Donation performance in B.C., 2006–2015*

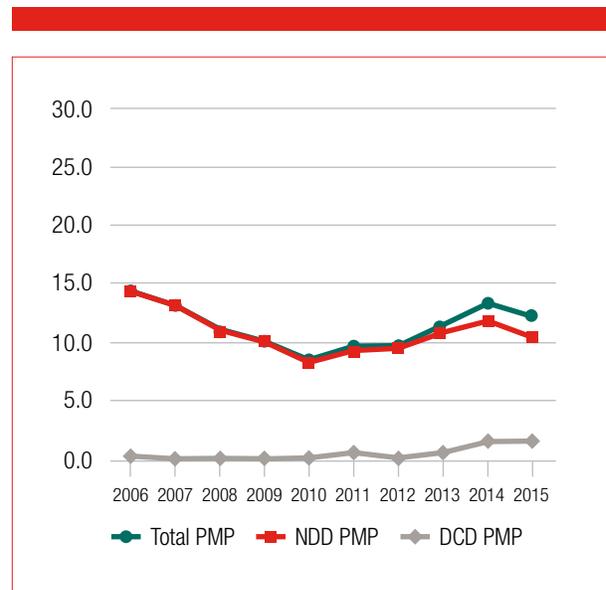


* The population of Yukon is included in the calculation of these rates, as per CIHI standards.

Alberta

Donation rates in Alberta had been on the rise in previous years, although they dropped slightly in 2015 (corresponding to a drop in NDD donations). There have been ongoing efforts to advance leading practices in organ donor identification and referral, and death audits and medical record reviews. Edmonton has recently implemented a DCD program and Calgary will follow suit in early 2016. The recently created Alberta Organ and Tissue Donation Program is also anticipated to improve provincial coordination and performance. To date, Alberta has focused on public awareness and professional education, with the implementation of a new web-based registry.

Figure 11: Donation performance in Alta., 2006–2015**

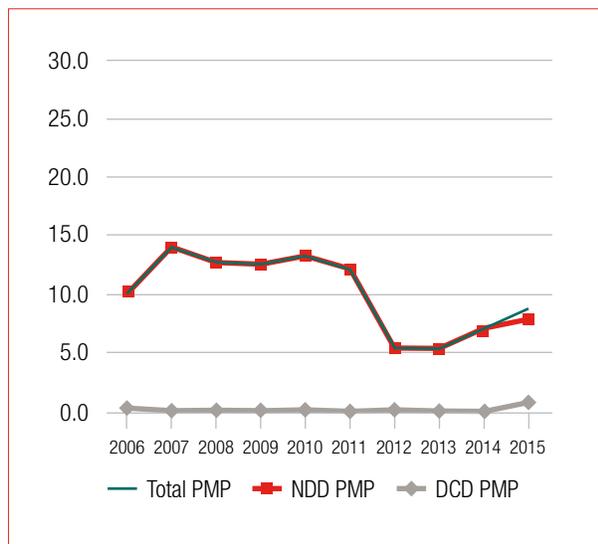


** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates, as per CIHI standards.

Saskatchewan

Saskatchewan's deceased donation rates increased modestly in 2014 and 2015. The province has yet to introduce three of the most important system improvements: mandatory referral, DCD and donation specialists. This fact may be limiting the province's potential to increase deceased donations.

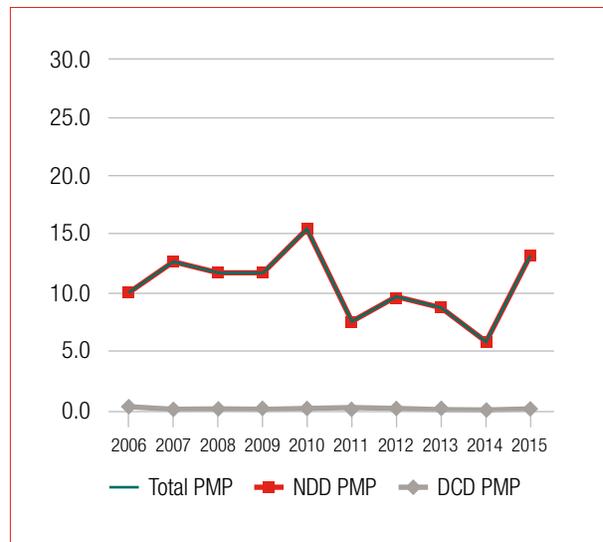
Figure 12: Donation performance in Sask., 2006–2015



Manitoba

The province has renewed its focus on donation specialists and professional education, including identifying and referring potential donors. The Health Sciences Centre has implemented an ICU bed for donation and has increased its efforts to secure funding for a second OR to improve access for donation cases. These efforts seem to have had an impact as there was a significant increase in the donation rate in 2015. Manitoba implemented a DCD protocol in 2015, but has not yet had a DCD case progress to donation. This will likely increase rates in the future.

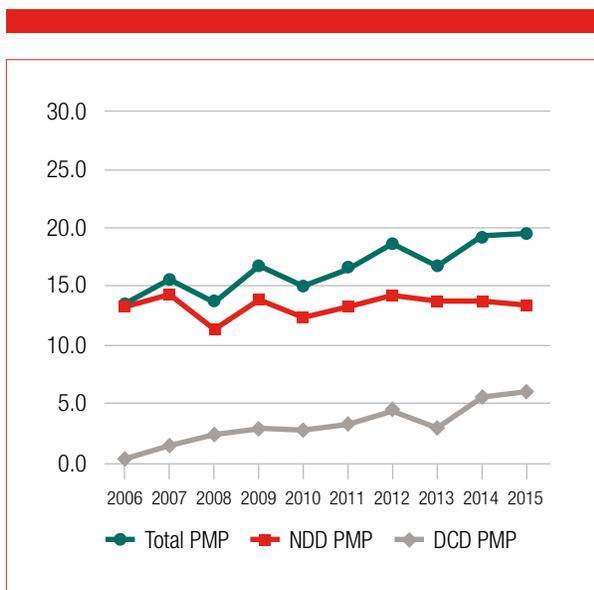
Figure 13: Donation performance in Man., 2006–2015



Ontario

Ontario has one of the highest donation rates in the country, and leads Canada in the implementation of DCD programs and the broad implementation of donation physicians (across more than 60 hospitals). Especially in the last few years, the province's higher deceased donation rate can be attributed to its DCD program and sustained performance in NDD. The ODO has expanded its focus from 21 Level 3 ICU hospitals to 67 (56 with Level 3 ICUs and 11 with Level 2 ICUs). The number of Ontarians committed to organ donation has continued to rise via the province's online intent-to-donate registry.¹⁹ In addition to implementing other components of high-performing systems, Ontario has formed strong relationships with hospital administrative and physician leaders and initiated donation committees within hospitals. The introduction of publicly available hospital performance metrics further expanded awareness of the importance of deceased donation performance and helped evolve accountability for performance. These efforts are expected to further increase donation rates.

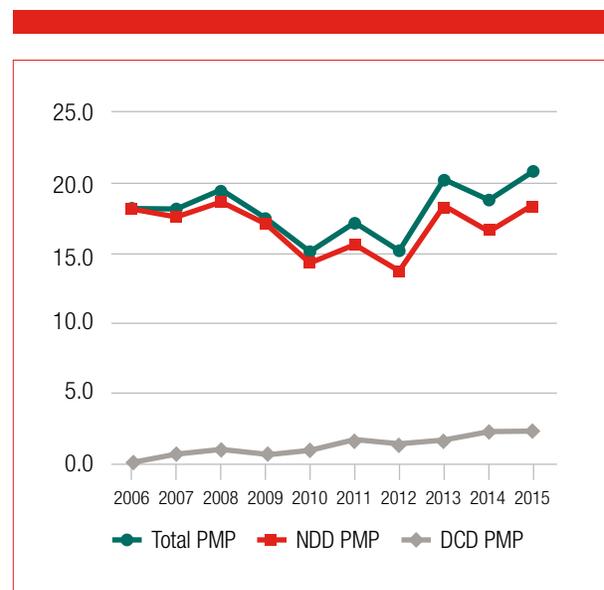
Figure 14: Donation performance in Ont., 2006–2015



Quebec

Transplant Québec continues to be a strong performer in NDD donation and is increasing its DCD donations. The organization has been recognized as a leader in deceased donation in Canada. It had one of the country's highest donation rates in 2015. In particular, Transplant Québec has taken significant steps to improve professional education in the field of organ donation, including implementing an e-learning module for hospital administrators and health professionals. To date, more than 30 Quebec hospitals have implemented audit processes. The hospitals monitor and review the outcomes and performances of these processes to make further system refinements. Transplant Québec has also put in place recruitment protocols for lung donors and clinical protocols for heart donors that, combined with other measures, have significantly improved organ utilization. Ex vivo lung perfusion practices, although just beginning (only three lungs have been used to date) are expected to improve the use of lungs in the future. The provincial government has approved funding for additional donation physicians, and these positions are expected to be implemented soon.

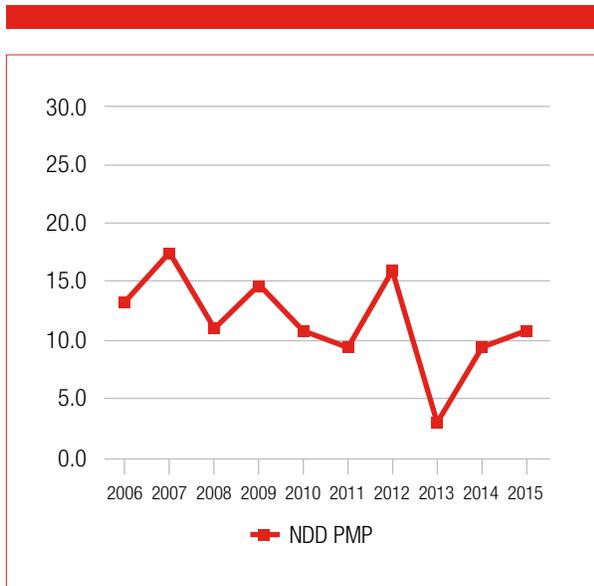
Figure 15: Donation performance in Que., 2006–2015



New Brunswick

The number of deceased donations in New Brunswick decreased significantly in 2013 to the lowest in the country, then rebounded to just slightly above the lowest performing program. The province's department of health has recently reorganized its organ program and transferred it to Horizon Health Network, the province's largest regional health authority. Horizon Health then merged the organ program with the New Brunswick Eye and Tissue Bank to create the NB Organ and Tissue Program. The new program has one director and three distinct divisions: the ocular program, the tissue program and the organ program. Each division has its own medical director and staff. The province is not considering DCD programs at this time. Funding is available for two donation physicians. Both are expected to be filled by the end of June 2016.

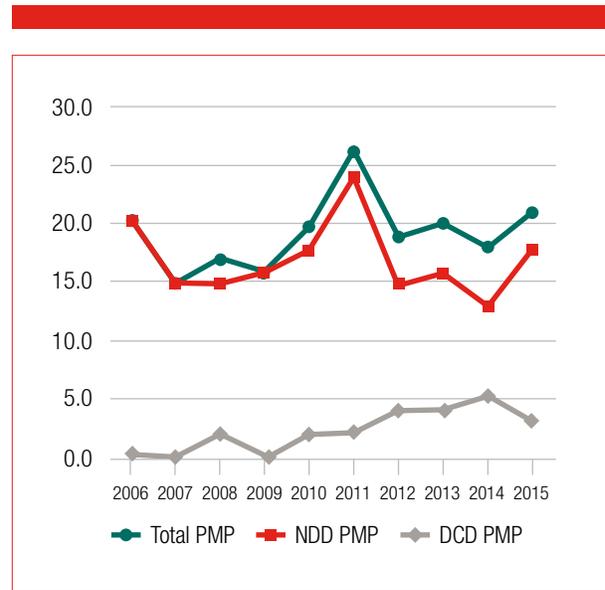
Figure 16: Donation performance in N.B., 2006–2015



Nova Scotia

Nova Scotia has historically been a strong performer in deceased donation. Thanks to its strong province-wide referral network, it had the highest donor rate in the country in 2015. A pilot project for donation physicians has ended. Nova Scotia anticipates re-launching the donation physician role, focusing on the recruitment of critical-care physicians as a priority.

Figure 17: Donation performance in N.S., 2006–2015*



* Donors from Prince Edward Island are included in the calculation of these rates.

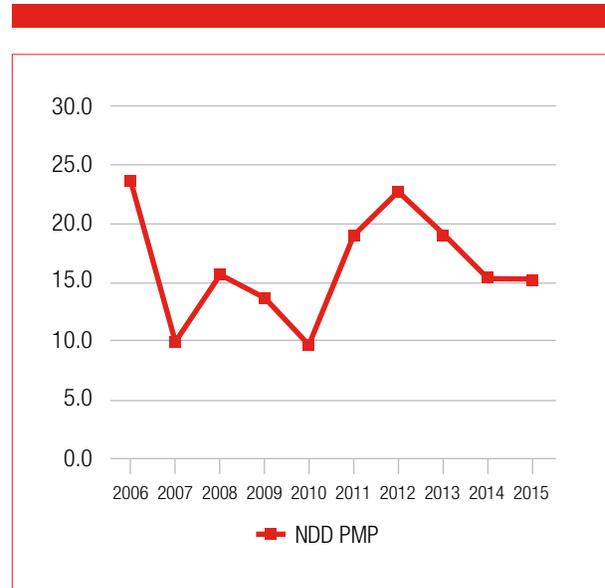
Prince Edward Island

Between 2006 and 2015, there was an average of between one and two deceased donors annually in Prince Edward Island. These donors were managed in Nova Scotia (and included in Nova Scotia's statistics). Prince Edward Island has implemented a referral policy, an online intent-to-donate registry, and education and awareness campaigns that have increased screening and referrals of potential deceased donors.

Newfoundland and Labrador

Newfoundland and Labrador has been a strong performer, but has seen a decline in donation since 2012. Implementation of required referral and a DCD program may help to increase donation rates, but the province faces many logistic and geographic challenges to implementation, as well as a lack of organ-retrieval teams. There are currently no donation physicians to drive implementation of a DCD program.

Figure 18: Donation performance in N.L., 2006–2015



LIVING DONATION PERFORMANCE RESULTS



National results

CANADA'S LIVING DONATION RATE IN 2015 WAS 15.7 DONORS PER MILLION POPULATION (DPMP). This rate is less than the proposed target rate of 20 DPMP*. The national living donation rate (which is primarily made up of kidney donors, but also includes liver and lung donors) decreased by eight per cent over the last 10 years. Performance among provinces varies significantly, as do historical rates within individual provinces.

Despite this, positive indicators remain. For example, patient, graft and donor outcomes for kidney transplants from living donors continue to compare to the best in the world. The Kidney Paired Donation (KPD) program has also facilitated 391 kidney transplants from living donors from 2009 to 2015 — transplants that may otherwise have not occurred. The program can increase kidney donation and transplants from living donors, but its uptake across the country has varied.

* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

Figure 19: International living donation rates, 2006–2015 (DPMP)

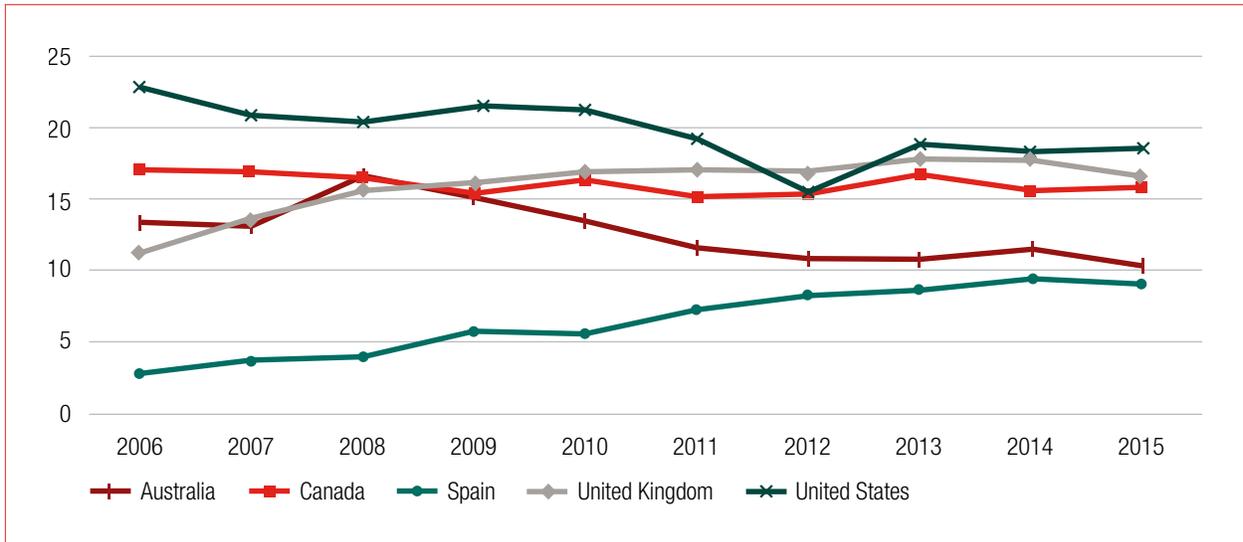
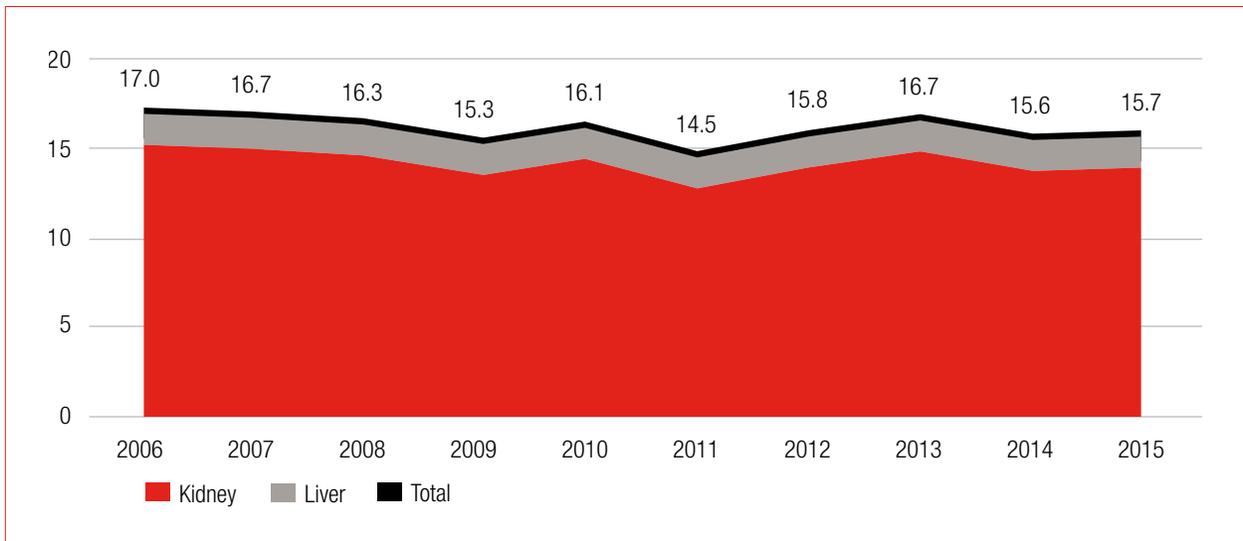


Figure 20: Living donor transplants in Canada, 2006–2015 (DPMP)



Kidney donation by living donors

Kidney transplantation is the best therapy for people with kidney failure. It gives patients the best chance at survival, improves quality of life for patients, and costs the health-care system less compared to dialysis. Unfortunately, the number of Canadians who need kidney transplants continues to rise, and there are too few deceased donors to meet demand. Compared with a kidney from a deceased donor, a kidney from a living donor offers several advantages:

- Kidneys from living donors last more than 25 per cent longer, and recipients live longer.
- The transplant reduces or avoids health-care costs to the system.
- Patients do not need to wait for a deceased donor kidney to become available.
- Patients progressing to kidney failure can avoid dialysis altogether.
- It is the best and most cost effective treatment for chronic kidney disease.
- The transplant can be scheduled at a time when the patient is fully ready to undergo surgery.
- It makes transplantation possible for some patients who are immunologically complex.

Canada's national rate of kidney donation by living donors has stagnated since 2006. Even allowing for increased non-directed anonymous donation and the KPD program, Canada's rate has not increased. The number of pairs referred to the KPD program has been static for three years.

Living kidney donor rates vary significantly across the provinces. Barriers to kidney donation by living donors include the following:

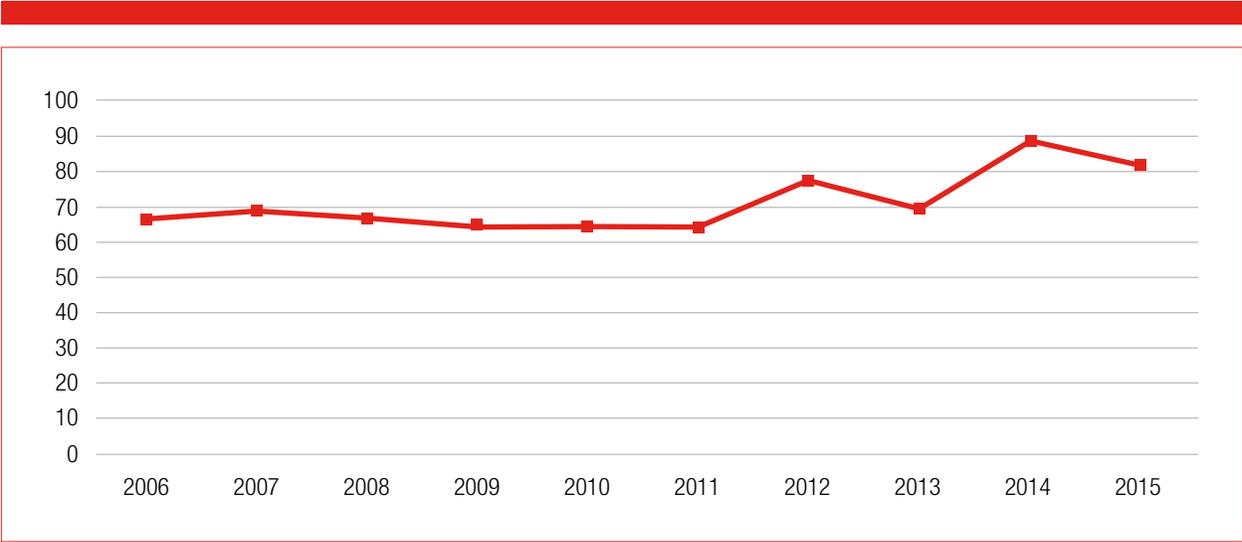
- Inconsistencies for accommodating the number of donors and recipients who wish to participate either directly at the program level or through the KPD program.
- Donors state that the long evaluation time is a disincentive to donation. Assessments for kidney patients can last for months or years. In contrast, donor assessments for living liver donors can be completed in days.
- Enhanced education about living donation is needed for patients and potential donors in some areas. For example, many patients struggle to discuss living donation with people in their communities. Consensus-driven, evidence-based public messaging about the option of kidney donor transplantation from living donors is also needed, including non-directed anonymous kidney donations by living donors.
- Expenses incurred by donors are not always covered through existing expense-reimbursement programs, and some variation exists among provinces. Shipping kidneys (as opposed to patients) between transplant centres would ease the financial and physical strain on patients and donors but does have program impacts which are being explored.

In contrast to comparable international programs, such as those in the United States and the United Kingdom, there is no public availability of centre and program level donation and transplant activity and outcomes. In any system, publicly accountable data is a foundational prerequisite to describing, quantifying and improving system performance.

Liver donation by living donors

Growing demand for liver transplants and stagnating supply from deceased donors has forced programs in the developed world to re-evaluate the need for liver donations by living donors. As rates of death and withdrawal from Canada’s liver transplant wait-list hover between 20 and 30 per cent, several Canadian programs have established robust living donor programs. To date, Canadian programs have conducted several hundred living donor liver transplants without donor mortality.

Figure 21: Total liver transplants from living donors in Canada, 2006–2015



As with kidney donation by living donors, the main advantage of liver donation by living donors is the opportunity to offer a transplant before the patient's condition deteriorates to the point of risk of death or withdrawal from the wait-list. However, since there is a very high threshold to reach the top of the priority list, the risk of death is still high.

As patients benefit from liver donations by living donors, those without potential living donors also benefit from shorter wait-lists. Liver transplantation in children may see the greatest advantages from liver donations by living donors. This field has demonstrated high rates of success, reduced donor risk among patients with segment 2,3 hepatectomy, and greater acceptance of donation from parents or close relatives of children in need.

The growing demand for liver transplants in recent years has been mainly due to increasing rates of treatable hepatocellular carcinoma driven by diseases such as hepatitis C, hepatitis B, non-alcoholic steatohepatitis and other forms of cirrhosis. Although the growth of deceased liver donation has modestly increased Canadian donation rates, it has not kept pace with need.

Rates of liver donation by living donors in Canada have increased slowly in recent years, and have been driven largely by activity in Toronto, Edmonton and Vancouver. Liver donation by living donors is currently not offered in Halifax and is practised sparingly in Montreal and London. Barriers to greater activity in this area include insufficient program resources (including costs for evaluation and access to operating room time) and a lack of public and professional education (which leads to under-referral of potential donors). Attitudes to the risk/benefit analysis of liver donation by living donors and transplant vary among the public and medical professionals.

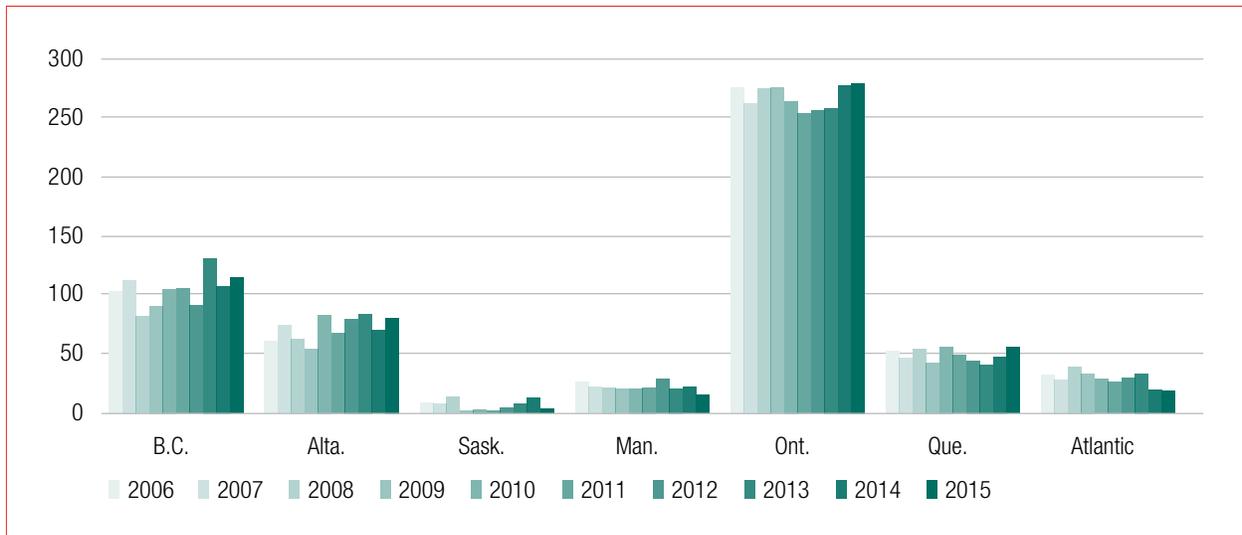
Substantial numbers of Canadians are dying on liver transplant wait-lists. Expanding liver donation by living donors — with attention to maximizing donor safety and minimizing the risk for undue coercion — will help to alleviate this problem.



David Presley, kidney recipient,
and his wife, Lyn Presley

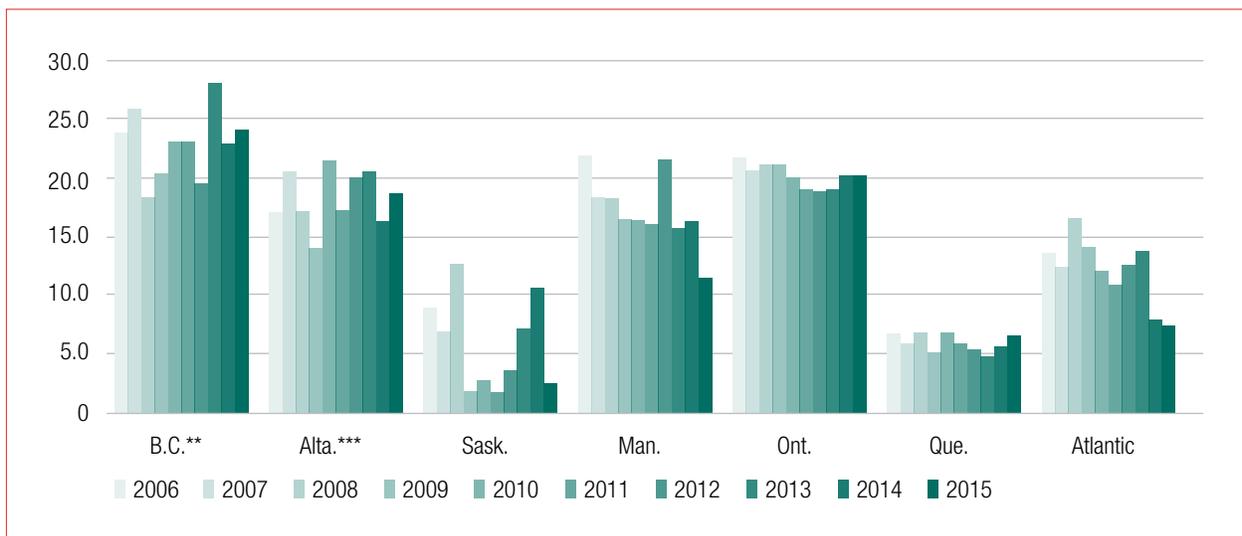
Provincial results

Figure 22a: Number of living donors* by province, 2006–2015



* These numbers primarily include living kidney donors, but also include liver and lung donations by living donors.

Figure 22b: Living donors* per million population by province, 2006–2015



* These rates primarily include living kidney donors, but also include liver and lung donations by living donors.

** The population of Yukon is included in the calculation of these rates, as per Canadian Institute of Health Information (CIHI) standards.

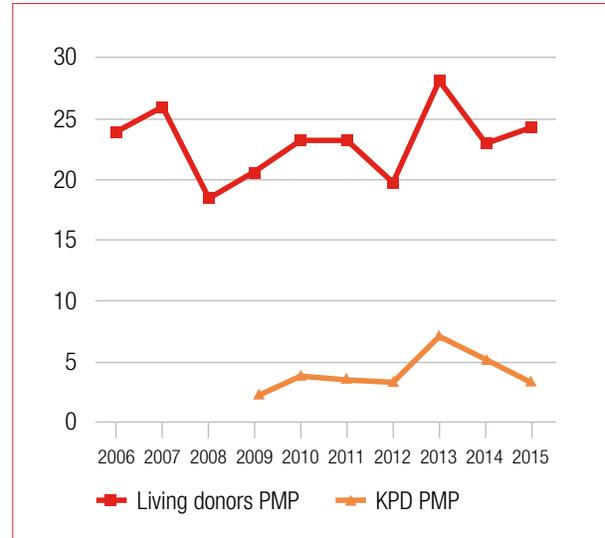
*** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates, as per CIHI standards.

British Columbia

British Columbia has the highest living donation rate in Canada and has implemented a number of changes that have contributed to this rate:

- All transplant activity is coordinated and resourced by BC Transplant. Living donation is part of BC Transplant's mandate and therefore a priority.
- The programs operate under an activity-based funding model. As living donation increases, so does program funding.
- There is enhanced funding for living donor evaluations, as well as for follow-up activities that may also be supported at regional health authority-based transplant clinics throughout the province.
- Professional education has been expanded to non-transplant nephrologists and nurses to increase their knowledge of living donation. Consequently, health-care professionals act quickly to teach dialysis patients about the benefits of living donation and how to identify potential living donors within their social networks.
- Operating rooms and staff are made available to handle the increasing number of transplant surgeries to allow donations to occur within a reasonable amount of time.
- KPD is a priority program. As a result, pairs are consistently put into the program and a high percentage of B.C.-enrolled patients have been matched.

Figure 23: Living donation performance in B.C. *, 2006–2015

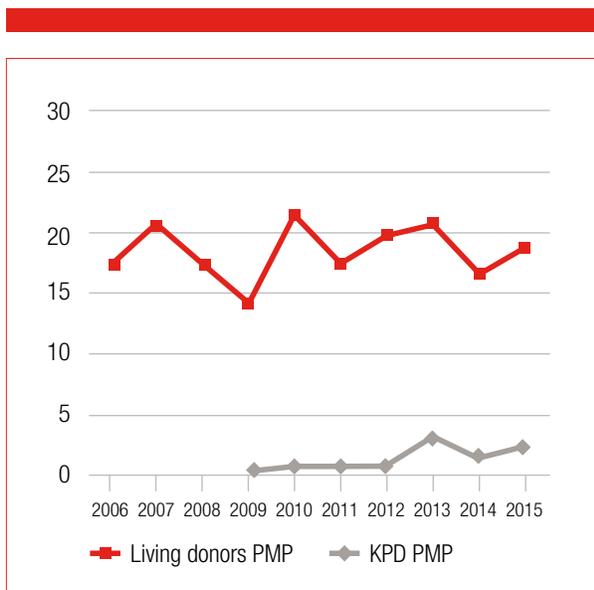


* The population of Yukon is included in the calculation of these rates, as per CIHI standards.

Alberta

Although Alberta's living donation rate has been inconsistent in the past 10 years, it is usually at or close to the proposed national target of 20 DPMP*. Provincial programs have experienced logistical challenges assessing pairs for the KPD program. Insufficient numbers of potential donors also contributed to Alberta's recent decline in living donation rates. Access to operating rooms has also been identified as a barrier by some programs. A workshop with broad internal representation was held in the winter of 2015 to further identify ways to increase living donation in Alberta.

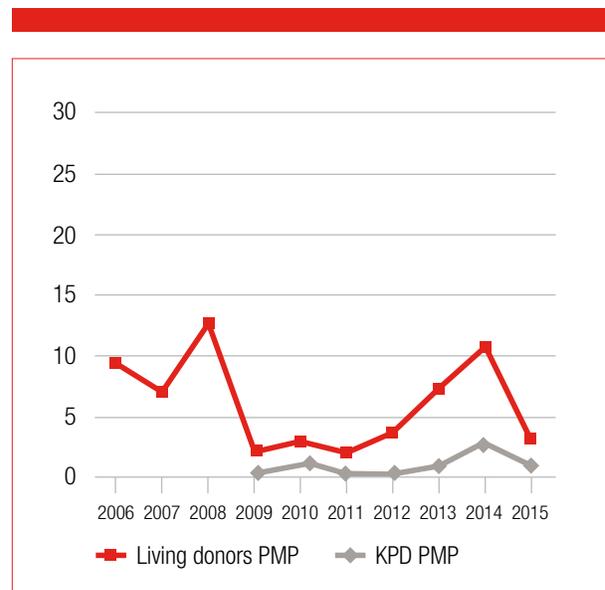
Figure 24: Living donation performance in Alta.**, 2006–2015



Saskatchewan

Saskatchewan's ODO and transplant program is run out of the Saskatoon Health Region and a satellite office in Regina. Advancing provincial initiatives has proved to be challenging without an authority for provincial processes. Saskatchewan lacked a transplant surgeon for a few years, but its program continued to evaluate living donors for directed donation and for the KPD program. The pairs were sent to Edmonton for the surgeries. (Between 2009 and 2012, 11 Saskatchewan-resident transplants were counted among Alberta's numbers). A lack of sufficient resources has hampered efficient and timely access to testing and consults for donor evaluation.

Figure 25: Living donation performance in Sask., 2006–2015



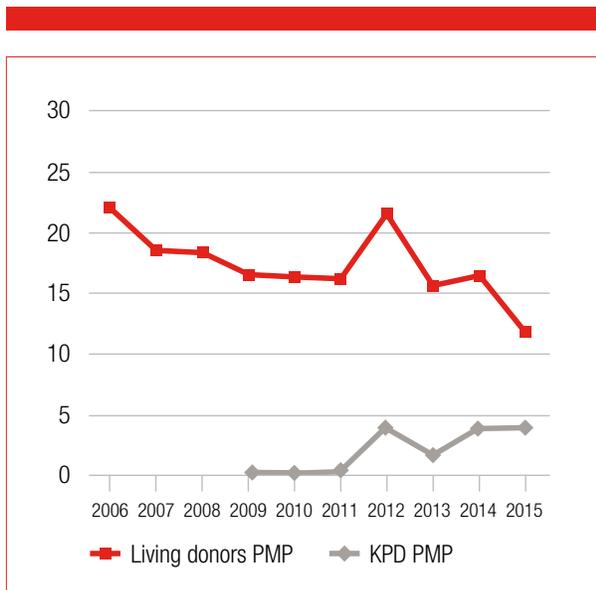
* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates, as per CIHI standards.

Manitoba

Manitoba's living donation program has seen a decline in recent years, although it has been successful in getting candidates and donors to participate in the KPD program. The program indicates it could do more to increase living donation rates and maximize the use of the KPD program with additional resources for donor evaluation and operating room availability, and if it were given the ability to receive shipped kidneys rather than asking donors to travel to their centre to donate.

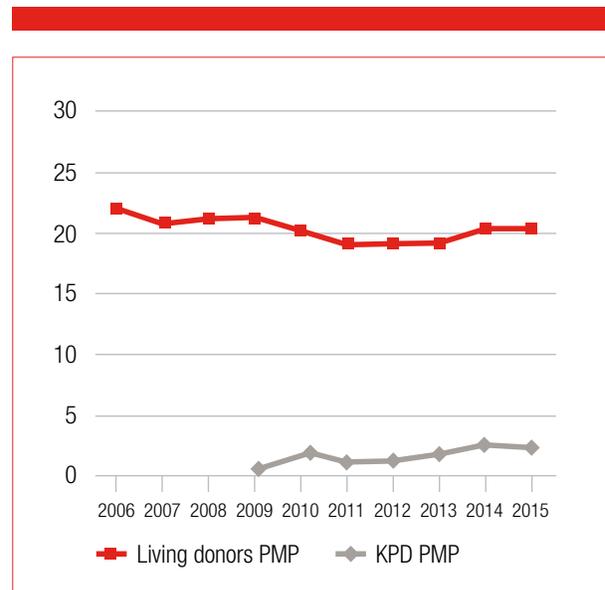
Figure 26: Living donation performance in Man., 2006–2015



Ontario

Living donation rates in Ontario have been consistent over the past 10 years and have generally met the proposed national target of 20 DPMP*. Overall, the province has provided transplants to 41 per cent of its enrolled patients. For the KPD program, Ontario ranks eighth among the 10 provinces in enrolment of candidates per million population and sixth in the number of transplants achieved through the KPD program. This last fact is largely due to the participation of two programs in Toronto and one in Ottawa. Because of Ontario's large numbers, its increased participation in living donation could help people in other provinces find matches without disadvantaging its own patients.

Figure 27: Living donation performance in Ont., 2006–2015

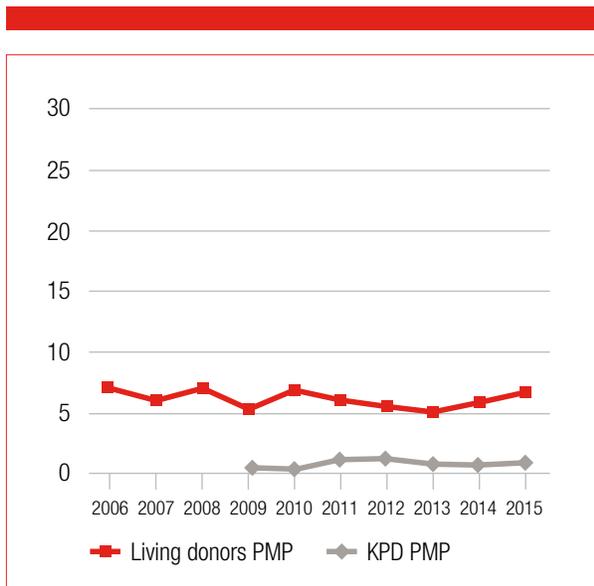


* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

Quebec

Living donation rates in Quebec have remained steady at about six DPMP, well below the proposed national target of 20 DPMP*. Although Transplant Québec operates the province's expense-reimbursement program for living donors and brings stakeholders together for discussions, the transplant programs themselves are responsible for living donation. Some of the factors that contribute to Quebec's low donation rate include a lack of dedicated living donor coordinators; a lack of time from other health-care professionals, such as physicians, surgeons, social workers, psychologists and psychiatrists; a lack of access to operating rooms; non-optimization of the KPD program; and the need for more efficient and timely testing and consults to evaluate donors. Most Quebec transplant centres indicated that the ability to ship kidneys would improve participation in the KPD program. They also identified the need for better awareness of the living donation opportunity with both the public and the health care community including outreach by referring centres.

Figure 28: Living donation performance in Que., 2006–2015

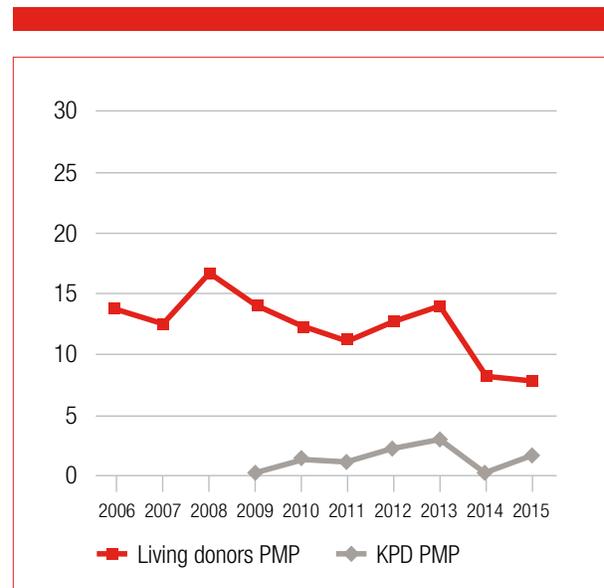


* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

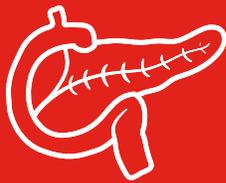
Atlantic Canada

Living donation rates in Atlantic Canada peaked at 16.7 DPMP in 2008 and have declined almost steadily since. The provinces act as a single region. Newfoundland and Labrador and New Brunswick evaluate their donors and transplant candidates via the Multi-Organ Transplant Program, which performs the surgeries. The decrease in living donation transplants appears to be the result of a combination of factors: lower enrolment in the KPD program, a lack of living donation coordinators proportional to the donor volume, region-specific challenges related to remuneration for nephrologists, and the lack of a centralized IT system for real-time chart communication for joint evaluation and decision-making. The ability to ship kidneys, supported by robust expense-reimbursement programs for living donors that include companion coverage, may also increase living donation.

Figure 29: Living donation performance in Atlantic Canada, 2006–2015



TRANSPLANTATION PERFORMANCE RESULTS



BETWEEN 2006 AND 2015, CANADA'S TRANSPLANT RATE (FROM BOTH DECEASED AND LIVING DONOR ORGANS) INCREASED BY 12 PER CENT TO 71.4 TRANSPLANTS PER MILLION POPULATION (TPMP) FROM 63.7. This figure still falls short of the national target of 95 TPMP*. Over the same period, the actual number of transplants increased by 23 per cent from 2,074 to 2,559.

Although the Kidney Paired Donation (KPD) program and the Highly Sensitized Patient (HSP) program have improved access to transplants nationally, and the National Organ Waitlist (NOW) ensures real-time listing of all high-status patients for national visibility, access to transplants nonetheless varies depending on a patient's province of residence.

Data on all donations, all transplants and all outcomes is not currently collected. This fact limits the ability to analyze performance and identify gaps and solutions.

* This target was proposed in *Call to Action*, a strategic plan to improve organ and tissue donation and transplantation performance for Canadians. This document can be found at blood.ca.

National results

Figure 30: Transplants per million population in Canada by organ type, 2006–2015

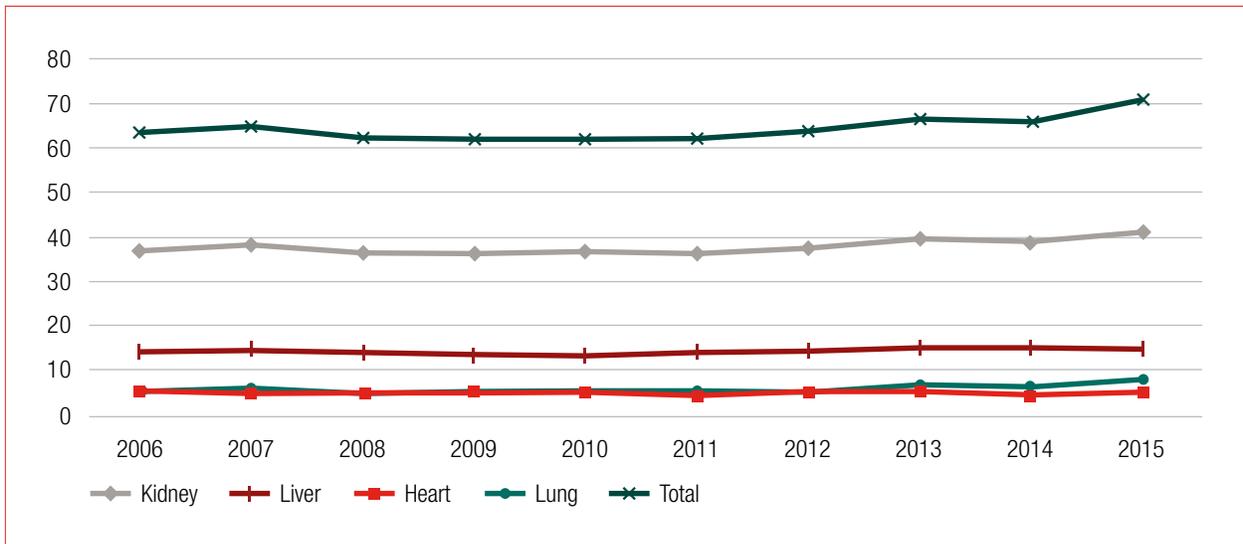


Figure 31: Number of solid organ transplants in Canada by donor type, 2006–2015

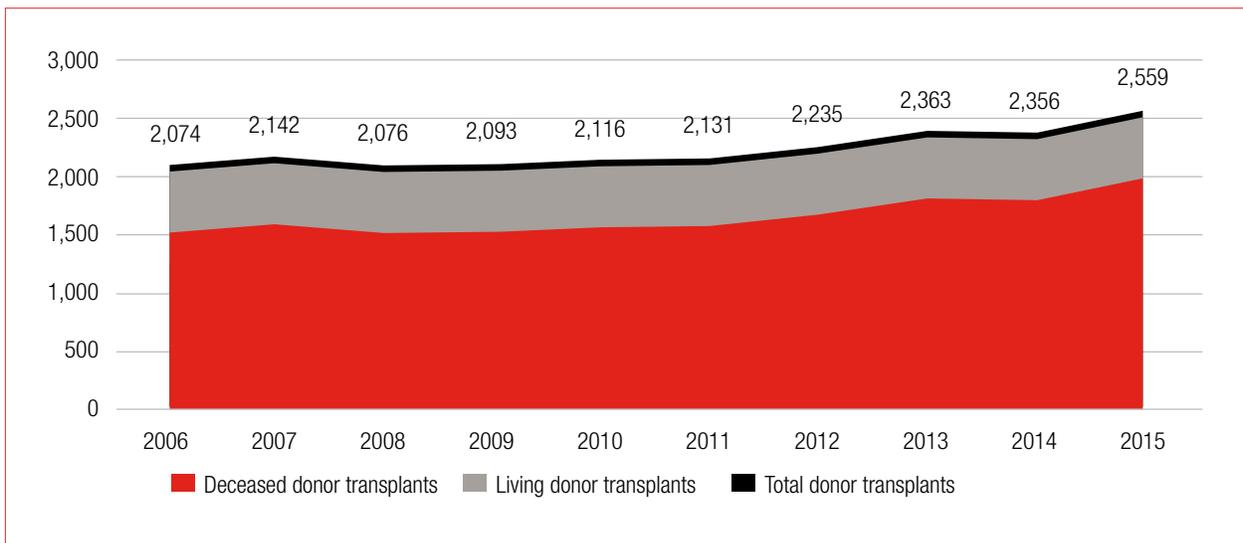


Figure 32: International kidney transplant rates, per million population and by donor type, 2015

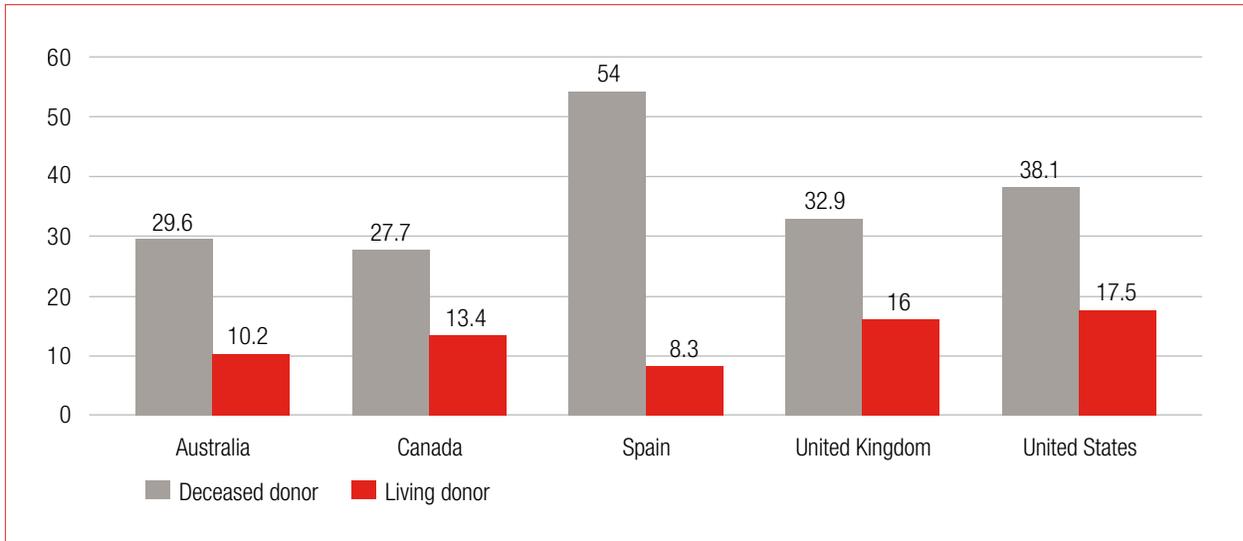


Figure 33: International liver transplant rates, per million population and by donor type, 2015

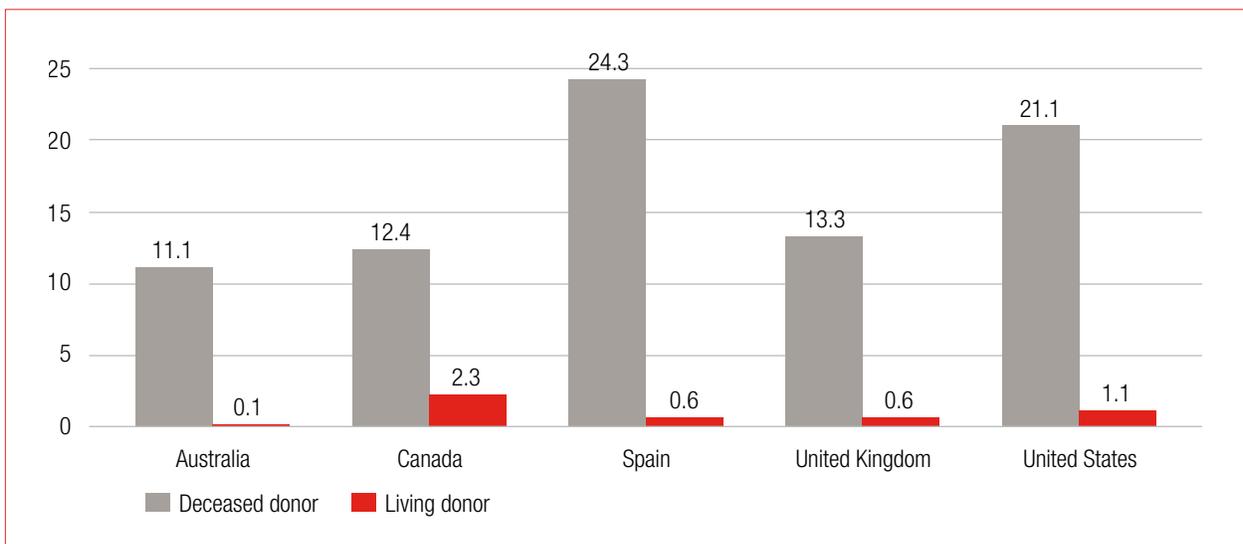


Figure 34: International heart transplant rates, per million population and by donor type, 2015

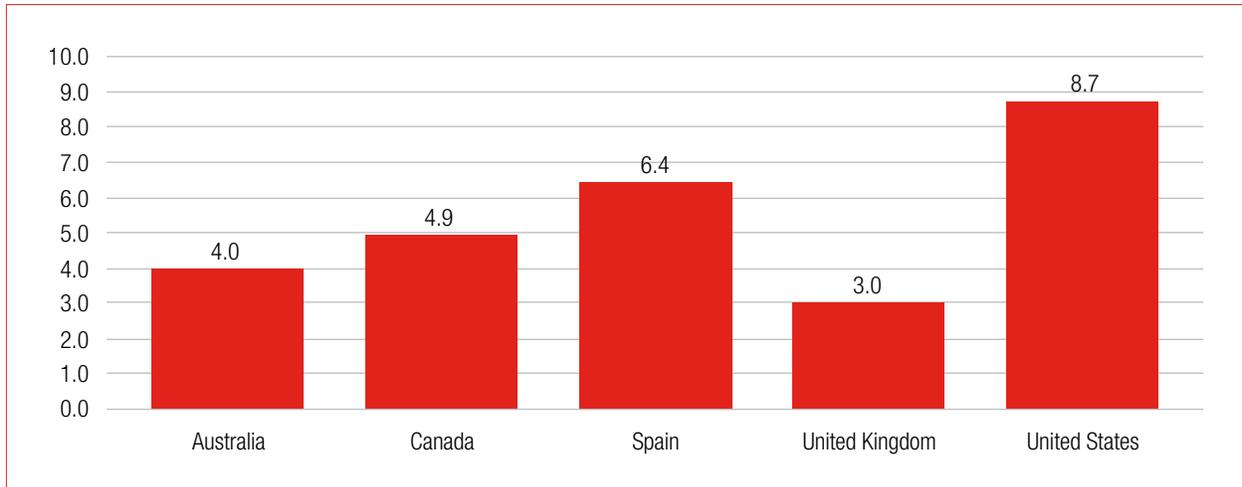


Figure 35: International lung transplant rates, per million population and by donor type, 2015

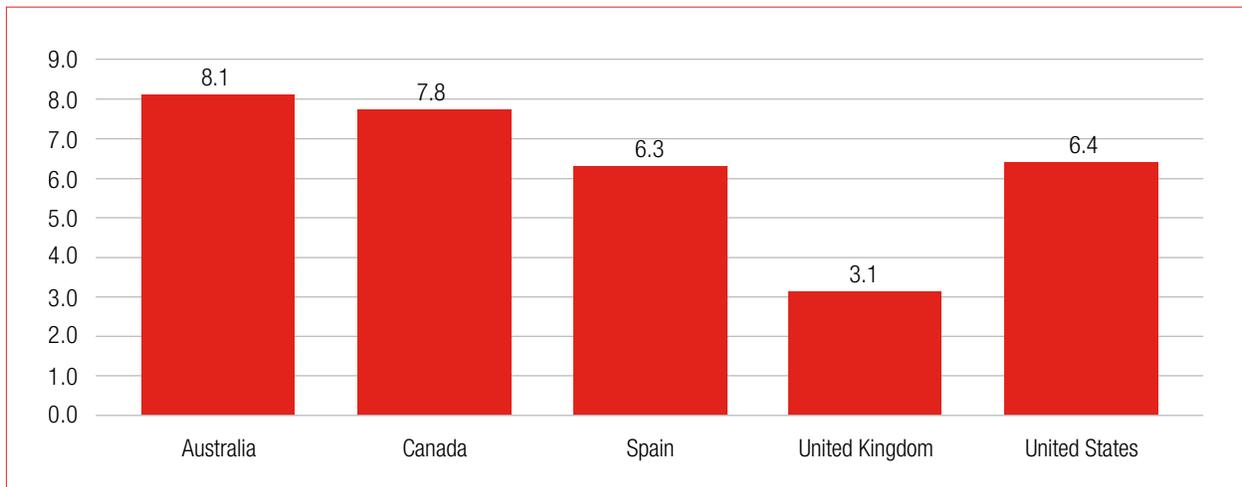


Figure 36: Kidney transplant survival rates for recipients of a first kidney only; transplant from a deceased donor for selected countries²⁰

COUNTRY	FIVE-YEAR SURVIVAL RATE (%)	TEN-YEAR SURVIVAL RATE (%)
Australia	81	59
Canada	80	58
United Kingdom	78	56
United States	69	43

Figure 37: Increases in transplants in Canada, 2006 versus 2015

		DECEASED DONORS (DD)	TRANSPLANTS FROM DD	LIVING DONORS (LD)	TRANSPLANTS FROM LD	TOTAL DONORS	TOTAL TRANSPLANTS
2006	No.	461	1,519	556	555	1,017	2,074
	PMP	12.7	46.6	15.6	17.0	28.3	57.8
2015	No.	651	1,996	564	563	1,215	2,559
	PMP	18.2	55.7	15.7	15.7	33.9	71.4
Increase	No.	41%	31%	1%	1%	19%	23%
	PMP	43%	19%	1%	-8%	20%	23%

Figure 38: Organs transplanted* by province of retrieval, 2014²¹

PROVINCE OF RETRIEVAL	EXPORTED TO/ UTILIZED IN OTHER PROVINCE	TRANSPLANT FROM LOCALLY RECOVERED ORGAN	TRANSPLANT FROM IMPORTED ORGAN (CANADA)	TRANSPLANT FROM IMPORTED ORGAN (U.S.)	% OF TRANSPLANTS FROM IMPORTED ORGANS
British Columbia	26	197	15	4	9
Alberta	16	178	41	10	22
Saskatchewan	9	14	3	0	18
Manitoba	17	11	4	0	27
Ontario	29	787	40	12	6
Quebec**	–	–	–	–	–
New Brunswick	21	0	0	0	N/A
Newfoundland and Labrador	19	0	0	0	N/A
Nova Scotia	14	43	33	0	43
Total	151	1,230	136	26	–

* Transplant recipient may be from a different province. Only organs from deceased donors with identified recipients and donors are included. Islet cell transplants excluded.

** No data available for Quebec.

Increasing the number of transplants

The national trend in transplantation rates has followed the trend in donation rates closely, although it has not increased as quickly (accounting for population growth). Increases are largely attributed to the rise in donation after circulatory death (DCD). A number of strategies may help to raise the number of transplants.

- The transplant community continues to explore the idea of increased organ utilization, including using organs from expanded-criteria donors (i.e., people who, due to age or other circumstances, were traditionally turned down as viable donors). The Canadian Society of Transplantation/Canadian National Transplant Research Program Working Group²² recently provided guidelines on the use of increased infectious risk donors for organ transplantation.
- As a result of successes from ex vivo organ repair used by the liver and lung transplant programs, surgeons are exploring ex vivo organ repair for heart transplant patients.
- As experience grows in DCD kidney, liver and lung transplantation, the potential for DCD heart transplants is being considered internationally.

Barriers to fairness in the system

In spite of increasing transplant numbers, Canada still has a shortage of organs. More than 4,000 patients are waiting for transplants. Given that Canada will continue to have a shortage of organs into the future, there is a need to provide equitable access to the limited resource of donated organs for all potential recipients. At the moment, patient access to transplants varies depending on where they live. Many complex factors have created these conditions. Different criteria used by provinces to list patients, allocate organs and accept organs may contribute to these variances, yet Canada's system is based on longest time waiting or urgent need —

criteria that require resource sharing across jurisdictions. Creating common listing practices and drafting national allocation agreements will help to facilitate resource sharing. Additionally, practices of not disclosing organ listing and allocation criteria to patients and the public erodes transparency, which is an essential element of public trust.

The transplantation community has worked with Canadian Blood Services to develop leading practices and revised interprovincial policies, and to implement national programs such as the KPD program, the National Organ Waitlist and the HSP kidney sharing program. Canada's organ groups are using the Canadian Transplant Registry to different degrees to further local and interprovincial operational activities and to collect and report data. National listing and allocation practices require national policy and ongoing audit and evaluation to further strengthen system improvements to date. Such requirements could be built into a clinical governance model to guide national programs and services.

The lack of data makes it difficult to analyze variances in transplant rates. The number of patients in Canada who are in various stages of assessment for listing and transplantation is unknown. Also unknown is the number of patients who have been diagnosed with end-stage organ failure who are not being evaluated or considered for transplantation. One province estimated that only about one-third of its patients who are eligible for transplant are placed on wait-lists at any given time. The ability to measure and monitor such information nationally would help stakeholders better understand the burden of disease on their respective patient groups.

Information on the number of patients and deaths on wait-lists is also questionable. As a result, the data is not very useful as a measure of system performance. The practice of adding a patient to a wait-list appears

to depend on subjective criteria in some cases. The practice differs among organ groups and across provinces. Not all patients eligible for transplants are added to, or kept active on, wait-lists. As well, reasons for removing patients from wait-lists are not captured systematically. Some are removed or put on hold from wait-lists when they become too sick to receive transplants. Also, those who die soon after being removed are not recorded as having died on wait-lists. Therefore, the number of deaths as a result of not getting a transplant is underestimated. Through the Canadian Transplant Registry, the technology now exists to ensure all patients in Canada are listed, evaluated and reported in a similar manner.

Further analysis at all stages of the referral path — initial diagnosis and referral, listing and allocation, and transplantation — is required.

Interprovincial organ sharing

In 2010, 17 per cent of transplants occurred as the result of interprovincial organ sharing.²³ Of those transplants

facilitated in 2014 by the KPD program, 51 per cent occurred between donors and recipients who were registered through transplant centres in different provinces. Similarly, 56 per cent of the transplants provided to highly sensitized kidney patients as a result of the HSP program in 2014 involved donors and recipients who came from different provinces.

Although interprovincial organ sharing for high-status liver and high-status or sensitized heart transplant patients occurs, system-level accounting is not currently available. (It is, however, under development by liver and heart working groups.) There is still tremendous need to improve trust and accountability so that the right patients get access to wait-lists, and ultimately get transplants. All participants in the system continue to strive to ensure no organs are lost, that previously unusable organs are assessed and rehabilitated where possible, and that Canada has agreed-upon standards to ensure those patients in greatest need of transplants are considered first.

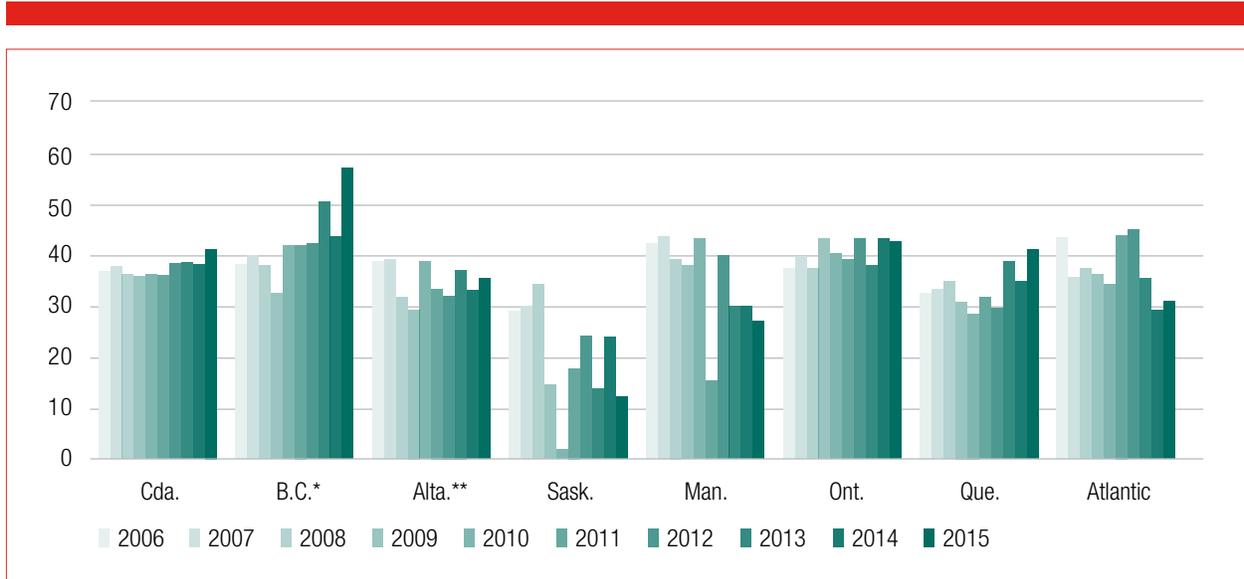


Arnold Dysart, kidney recipient

Provincial results

Kidney transplants

Figure 39: Kidney transplants by province per million population, 2006–2015



* The population of Yukon is included in the calculation of these rates to align with Canadian Institute for Health Information standards.

** The populations of Nunavut and the Northwest Territories are included in the calculation of these rates to align with CIHI standards.



Nathalie Randall, kidney donor through the Kidney Paired Donation program

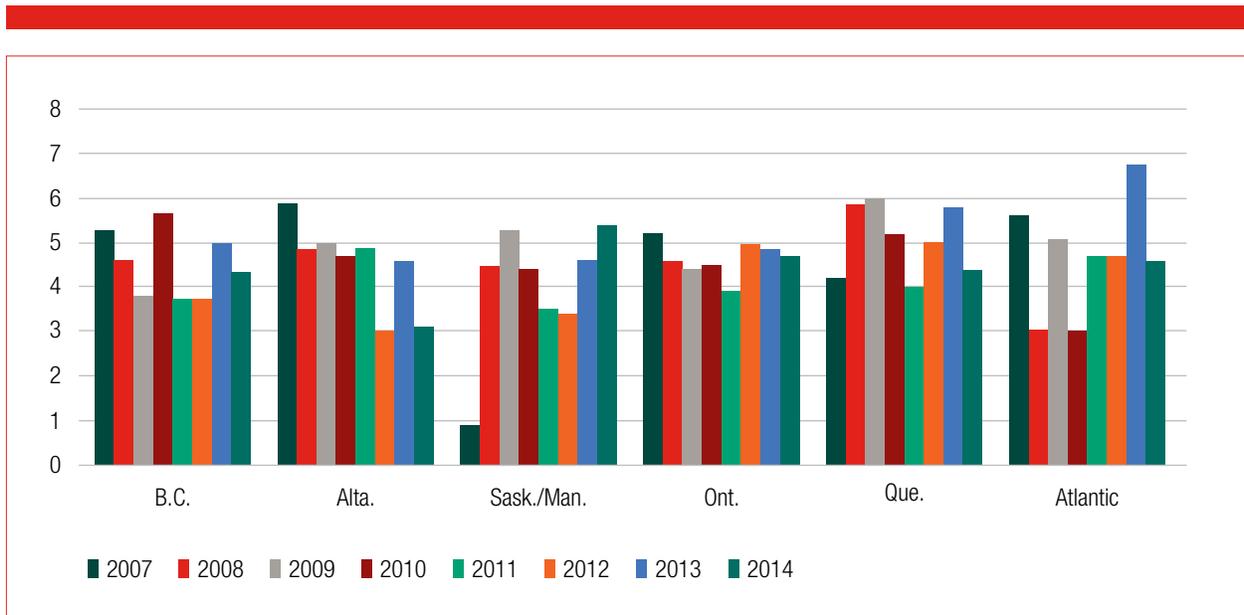
Heart transplants

Because heart transplant surgical programs exist in only a limited number of provinces, national community members must work together to ensure equitable access to these lifesaving interventions. Unfortunately, available data is limited, and meaningful analysis of chronic and emerging barriers to access is difficult to perform.

Annual heart transplant figures vary due to the relatively low number of transplants performed and due to variances in provincial populations. Detailed analyses of these figures will become possible only when data resulting from all listings, offers, acceptances and declines, and outcomes becomes available.

Canadian Blood Services and the Heart Data Working Group have developed a minimum data set for heart transplantation which, if implemented, will begin to close important data gaps. Meanwhile, the Heart Transplant Advisory Committee is modelling and drafting policy that will channel all interprovincial heart offers through the Canadian Transplant Registry, using the same virtual crossmatching services that have expedited kidney sharing in Canada through the HSP program. This development is expected to improve heart allocation and transplantation.

Figure 40: Heart transplants by province, per million population, 2007–2014

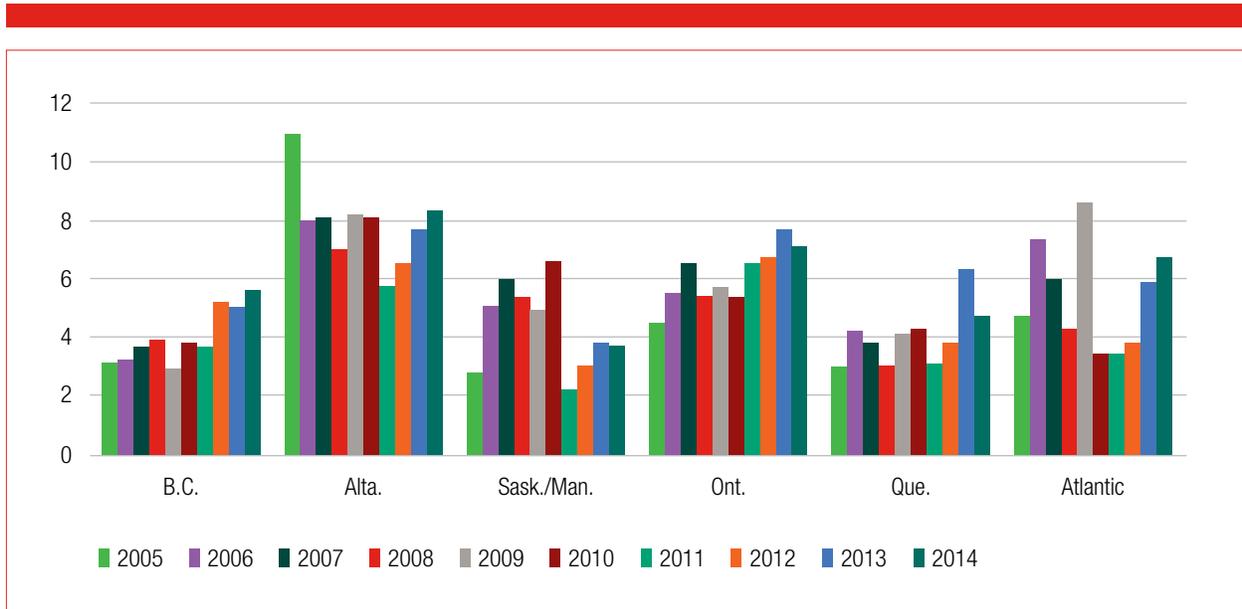


Lung transplants

The low number of lung transplants tends to create high variability at the provincial and regional levels. Key changes in lung transplantation over the past few years have included new ex vivo organ resuscitation and preservation devices. Such technologies were first pioneered in Canada by the Toronto General Hospital, and judging by the gradual increase in the number of transplants in Ontario, may have helped add previously unusable lungs into the pool of viable organs available for transplant. Other lung programs have also begun using these technologies more recently. They are eager to see the potential benefits for their patients.

For many reasons, but especially due to surgical volumes and staffing, in 2015 Transplant Manitoba decided to stop providing surgeries via its lung transplant program. It now lists its patients in Edmonton. Canada's lung groups have drafted a comprehensive proposal for detailed and validated data collection through the Canadian Transplant Registry. Such information will help the community monitor system performance nationally, and study the effects of provincial changes, like those put in place by Transplant Manitoba.

Figure 41: Lung transplants by province, per million population, 2005–2014

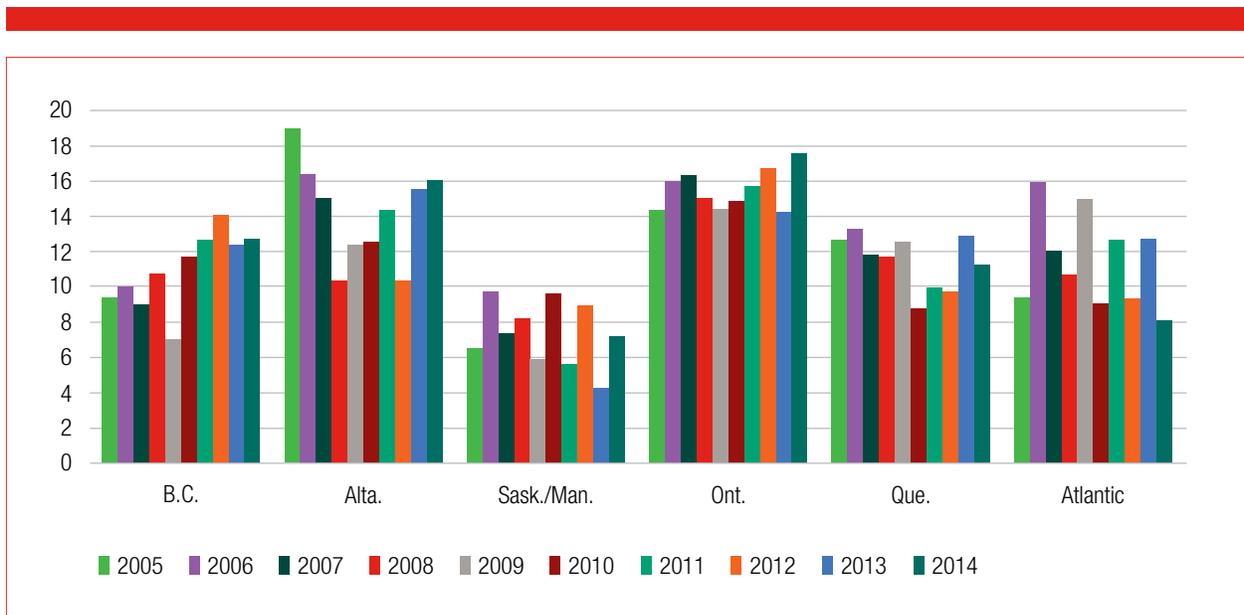


Liver transplants

With a long history of interprovincial sharing, the liver community actively tries to monitor its legacy sharing policies and revise agreements to accommodate opportunities and trends. Unfortunately, a lack of valid national data hinders the community's ability to monitor overall performance and the ways in which agreements are followed.

The liver community was the first organ group to develop a proposal for a minimum data set that would help to close data gaps. It will also soon convene a leading-practice forum on the standardized use of end-stage liver disease and pediatric end-stage liver disease scores, and hepatocellular carcinoma, to ensure patients across Canada are assessed and prioritized in a similar manner. This change will represent a significant milestone in data and clinical standardization for a key cohort of liver patients. It will also improve trust and communication across all liver programs when examining patient data in a consistent manner.

Figure 42: Liver transplants by province, per million population, 2005–2014



PROGRESS OF NATIONAL ORGAN DONATION AND TRANSPLANTATION SYSTEM IMPROVEMENT INITIATIVES

SEVERAL IMPROVEMENT INITIATIVES HAVE GUIDED SYSTEM DEVELOPMENT. THESE INITIATIVES HAVE BEEN UNDERTAKEN THROUGH THE EFFORTS OF INDIVIDUAL PROGRAMS AND PROVINCES, AND COLLECTIVE EFFORTS AT A NATIONAL LEVEL. SOME ARE WELL INTO IMPLEMENTATION; OTHERS ARE JUST BEGINNING. THE STATUS AND PROGRESS OF IMPLEMENTATION OF EACH IS DESCRIBED IN THE FOLLOWING SECTIONS.

A coordinated national approach

An integrated organ donation and transplantation system involves numerous programs, organizations and jurisdictions, the shared goal of which is to improve national donation and transplantation performance. Countries such as the United States, the United Kingdom and Australia have benefited by enhancing coordination and changing structures. These countries also have legislation to guide all programs and services. While the optimal donation and transplantation system in Canada has been developing, national and provincial programs and services, though foundational, are not formally coordinated and aligned. This includes necessary alignment for the purpose of strategic planning and annual reporting to funding governments and the public. Without a formal process, there is a constant risk of duplication of resources and investment and of lost opportunities to leverage established successes to enhance donation and transplantation within the country as a whole. The system would benefit from enhanced legislation, in particular for pan-Canadian collection and reporting of health data, integrated planning, and formalized annual reporting that links the work of all government-supported programs contributing to donation and transplantation.

A clinical governance model to advance national programs and services

While national programs and services for organ donation and transplantation were launched in 2008, an important final step to optimize the national programs and services in ODT is to formalize the clinical governance. Clinical governance takes a patient-centred approach to implementing a number of key elements of quality management, including processes to report on: clinical effectiveness; risk management; national program audit and training. It defines responsibilities and accountabilities for the quality and continuous improvement of care specific to national programs and services.

In the absence of a formal structure, an interim clinical governance committee structure has been established out of necessity by Canadian Blood Services for national programs and services. This informal structure brings together stakeholders to develop interprovincial policies, to guide strategic direction, to advise on the operations of the Canadian Transplant Registry (including interprovincial listing, organ-sharing programs, responding to emerging issues), and to review and report on system performance, including deceased and living donation. It is composed of the Organ Donation and Transplantation Expert Advisory Committee and its subcommittees and working groups. While this group has contributed to the progress seen in recent years, its informal participation and relationship-based model has a limited threshold of influence.

A formal, integrated clinical governance structure for national ODT programs and services will bring a greater clarity of roles and responsibilities for all users of the system, and will be a catalyst for system performance improvements while advancing higher quality care, greater efficiency and reduced costs.

Implementation of donation physicians

Donation physicians are acknowledged to be the cornerstone of the well documented and world-leading success of Spain's national organ donation and transplantation program. The model has been adopted with demonstrated success in other countries, such as the United Kingdom, Italy, Croatia and Australia. Donation physicians, working with donor coordinators, nurses and other hospital physicians, are responsible for donation leadership, education, consultation, clinical support, and performance and quality improvements.

Canadian applications vary

In February 2011, Canadian Blood Services and the Canadian Critical Care Society co-hosted a forum to review different models for donation physicians and develop recommendations for implementation in Canada.²⁴ Since then, two national guideline

documents — *Donation Physicians in a Coordinated OTDT System and Ethics Guide for Donation Physicians* — have been published. Each helps to clarify the roles and responsibilities of donation physicians before, during and after donation.

To date, British Columbia, Alberta, Manitoba, Ontario, Quebec and Nova Scotia have introduced donation physicians. The model by which each has done so varies according to factors such as geography, system capacity and resourcing, as well as the structure and organization of the province's donation and transplantation services.

Varying roles and responsibilities of donation-focused physicians have emerged, including front-line intensive care unit staff, regional hospital donation champions, and ODO medical directors and advisors. Those provinces that have moved forward with donation physicians (Ontario, British Columbia and Manitoba) continue to improve and adjust their models to work within the context of their hospital systems. Nova Scotia has recently completed a donation-physician pilot project, while Quebec and New Brunswick have recently approved funding for donation physician positions. For its part, Alberta has implemented two donation physicians that lead regional donation activities. It anticipates receiving funding for a third to help lead the developing Alberta Organ and Tissue Donation Program.

There are a variety of donation physician models and varying degrees of implementation in Canada. Further work and analysis needs to be done in completing implementation and supporting donation physicians nationally through a formal network and training program.

Improved public awareness and education

There are many organizations involved in public awareness for organ donation in Canada. Patient advocacy groups and health charities work diligently to promote the social and economic benefits of donation. ODOs and Canadian Blood Services work together to align messaging and develop common strategies and

marketing campaign materials for traditional and new media platforms. These efforts focus on a clear call to Canadians to register their intent to donate and discuss donation wishes with family members. Provincial ODOs have a number of campaigns on public awareness and decisions to donate.

Consent for organ donation

Despite many efforts, there is still a significant gap between intent to donate and action. In a recent poll, 91 per cent of Canadians indicated their support for organ donation, but only 51 per cent indicated they have made the decision to donate their organs when they die. Of those decided, almost all have registered or signed up. However, one in three people does not know how to confirm his or her intention to donate.²⁵ When the time comes to make donation decisions, a large number of families still do not consent to donation and override the potential donor's wishes.

■ Recent public opinion polling indicates that 59 per cent of Canadians believe the wishes of a deceased person who has signed a donor card or registry takes precedence over the wish of his or her family members

Currently, family members may override the previously expressed consent of a potential donor. The Canadian National Transplant Research Program and Canadian Blood Services are collaborating to explore health-care policy with regard to the legally binding decision of potential donors, when applicable. This work includes evaluation of legal implications and possible impacts on hospitals when honouring patient wishes in spite of family objections. The groups are currently gathering input from affected stakeholders to develop leading practices and policies.

Presumed consent to donate

Several countries have enacted legislation that presumes consent to donate absent any indications to the contrary. Recent polls indicate that Canadians are split on whether presumed consent laws should be introduced in Canada,

although support has been slowly growing. Sixty-two per cent of respondents supported presumed consent, up from 54 per cent in 2010.²⁶ Some provincial governments have expressed interest in exploring presumed consent laws, although the subject remains open for discussion.

Donation ethics

There is growing recognition of the importance of ethics discussions and public input into policy development in this field. For example, the Canadian Society for Transplantation held a forum to explore aspects of public solicitation for living organ donors. Canadian Blood Services is working to create mechanisms by which ethics and public feedback can be formally and regularly obtained through creation of public and patient groups and a bioethics committee.

Intent-to-donate registries

Although it is difficult to link registries directly with higher donation rates, almost all respondents to the 2015 Canadian Blood Services Ipsos Reid survey felt that registries increase awareness of donation issues and contribute to overall marketing activities. Registries

provide a call to action for marketing messages and allow individuals to support donations. Further, registry activity can be used to measure the success of marketing initiatives.

Registries allow for formal declarations of expressed wishes. Health-care staff and physicians report that registry information can inform discussions with family members and bring families some relief and comfort when loved ones' wishes are known.

In consultation with the public, Canadian Blood Services heard that a single, national online registry was the preferred way to provide a consistent mechanism through which people can register their intent to donate. Currently, registries are provincially run and vary significantly. Some (such as those in British Columbia, Alberta, Manitoba, Ontario and Nova Scotia) are web-based, and some are linked to health-card or driver's-licence databases. Many draw on both approaches. All would benefit from greater registration rates and alignment. Consultations with health professionals indicated a number of foundational system improvements in hospitals should take priority over an integrated national registry, but that this should be further explored going forward.

Figure 43: Provincial intent-to-donate registration mechanisms²⁷

	WEB-BASED REGISTRATION	LINKED TO HEALTH-CARD DATABASE OR DRIVER'S-LICENCE DATABASE	PERCENTAGE OF POPULATION REGISTERED*	NOTES
B.C.	✓	✓	20	Yes/No registry, long-standing
Alta.	✓	✓	7	Online registry launched in 2014
Sask.	X	X	X	Orange sticker for health card
Man.	✓	✓	1	Yes/No registry launched 2014
Ont.	✓	✓	29	Yes-only registry. People are removed from the registry upon death.
Que.	X	✓	32	Régie de l'assurance maladie du Québec registries plus notary registration. Paper forms required.
N.B.	X	✓	N/A	0
N.S.	X	✓	52	0
P.E.I.	X	✓	N/A	Red sticker for health card
N.L.	X	✓	N/A	0

* Registration rates are current up to Dec. 31, 2015.

Leading practices development and knowledge translation

Leading practices are developed through rigorous evidence-based processes: literature reviews, evidence reviews, environmental scans, evidence synthesis and evaluation, and development of recommendations by subject-matter experts. Once these practices are completed, their implementation is supported through knowledge-mobilization tools and educational activities. Leading practices have been shown to significantly improve system performance when implemented consistently across the country.

Completed and in-progress initiatives

To date, Canadian Blood Services and its partners have developed leading practices in several key areas: national guidelines for controlled donation after circulatory death (DCD), guidelines for determination of death, end-of-life conversations with the families of potential donors, ethics guides for donation physicians, human leukocyte antigen standardization for virtual crossmatching, a protocol for donors participating in the KPD program, a panel reactive antibody calculator, and a standard for allocation of organs for combined transplantation.

Further work is required on the following critical issues: system-wide DCD implementation, protocols for pediatric DCD, death audits and reviews of medical records for missed potential donors, uncontrolled DCD potential, liver listing and allocation, and harmonizing provincial living donor expense-reimbursement programs.

Deceased donation

A number of leading practices related to deceased donation either have been developed or are being implemented.

Donation after circulatory death

Canadian guidelines for DCD were developed in 2005. Since that time, DCD programs have become firmly established in many parts of the country, with ongoing efforts to expand DCD into more hospitals. Given that DCD represents the future for increases in donation and transplantation rates, it is critical that all appropriate hospitals implement DCD.

Determination of death by neurological criteria

In 2015, 79 per cent of the donations in Canada came from donors who were declared dead through neurological criteria. For many families, it is difficult to reconcile the diagnosis of brain death with the patient's seemingly alive condition. In 2012, Canadian Blood Services and the World Health Organization co-sponsored an invitational forum in Montreal as a first step to develop international guidelines for death determination.²⁸ Such standardization will promote safe practices, protect patients and health-care professionals, and improve public and professional confidence in the deceased donation process.

End-of-life conversations with families of potential donors: Offering the opportunity for donation

Holding conversations about donations with families who have just experienced, or are about to experience, the death of a loved one is difficult. It must be done with sensitivity to each family's unique situation, values and beliefs. International and national leaders in this area have demonstrated that conversations with families can be done in a way that leads to better family decision-making and support, and can increase donation rates.

In February 2014, Canadian Blood Services sponsored an invitational forum for the development of leading practices for donation conversations with families of potential donors. This was followed up with a professional education workshop in 2015 for donor coordinators and medical directors from ODOs from across the country.

Ethics Guide for Donation Physicians

Donation physicians, who are generally intensive-care physicians, must manage the dual obligation of caring for dying patients and their families while providing donation services. Because of the potential for conflict of interest between these obligations, clearer rules for behaviour were required.

Canadian Blood Services held a forum in Whistler, B.C., in February 2015 to develop an ethics guide that would support donation physicians in managing issues of actual, potential or perceived conflicts of interest, and in protecting the interests of dying patients who might become donors. The report has been completed and distributed to participants, and will be published in 2016.

Living donation

A number of leading practices have been developed to further improve living donation processes and outcomes.

Kidney Paired Donation Protocol for Participating Donors²⁹

Assessment and acceptance criteria for living kidney donors vary among programs across Canada. The Living Donation Advisory Committee developed the KPD Protocol for Participating Donors to reduce the number of matches declined, speed up the donor-review process, and assess all those participating using the same safety-testing requirements. The protocol is the first of its kind developed by a national paired donation program after consultation with all kidney donation programs for living donors in the country.

Review of Canadian expense-reimbursement programs for living donors

At the request of the provincial and territorial ministries of health, Canadian Blood Services developed a report comparing policies of, and client satisfaction with, provincial expense-reimbursement programs for living donors. The report concluded that while the programs help donors financially, they vary considerably with respect to eligibility policies and reimbursement amounts. The Living Donation Advisory Committee is developing recommendations for harmonizing the programs to better serve all Canadians. Those recommendations will be ready in 2016.

Evaluation and follow-up care of donors

Members of the kidney donation and transplantation community are working with Kidney Disease Improving Global Outcomes to develop clinical practice guidelines on the evaluation and follow-up care of living kidney donors. When the guidelines are available for public consultation, the Living Donation Advisory Committee will review and comment on them and incorporate changes into Canadian standards.

Human leukocyte antigen

The National Human Leukocyte Antigen Advisory Committee has been working on standardizing antibody testing. In particular, it has focused on the accuracy of virtual crossmatches to improve interprovincial organ sharing. The committee worked directly with Canadian Blood Services to design and execute the most comprehensive and accurate human leukocyte antigen (HLA) data collection system in the world. This system has resulted in very low rates of unexpected positive actual crossmatches at the national and regional levels. It has also played a key role in reducing the number of positive actual crossmatches for highly sensitized patients who are more likely to have allele-specific antibodies.

The committee has also overseen development of a Canadian calculated Panel Reactive Antibody (cPRA) calculator by Canadian Blood Services. The cPRA can measure a patient's level of sensitization to HLA proteins. It is the most comprehensive publicly available calculator for estimating a recipient's antibody burden. It provides a significantly more accurate estimation of cPRA, which in turn translates into better matching for organ transplantation³⁰.

Transplantation

The work of the organ-specific communities has been focused on developing protocols that build and optimize national organ-sharing programs linked to the Canadian Transplant Registry (CTR). Those protocols are built on leading practices that are either in development or have previously been completed.

Leading practices for kidney allocation and living donation

Foundational to the establishment of the first national kidney transplantation allocation programs in Canada was a leading practice forum in which participants considered factors contributing to the equitable and transparent access to kidney transplantation, the development of allocation models based upon these factors and the identification of best practices to advance the science of kidney transplantation. The forum made recommendations regarding HLA matching and sensitization that inform current KPD and HSP programs as well as many regional allocation algorithms, and clearly defined recommendations regarding age-matching and priority consideration for patient groups with reduced access to transplants. It also ranked factors for consideration in local and regional kidney allocation. A leading practice

forum on living donation for kidney, liver and lung transplantation was held at the same time. It made recommendations for improving practices in the identification, evaluation, selection and follow-up of living donors, for removing barriers to living donation and for supporting an increase in living donor transplant activity in a safe and ethical environment. Canadian Blood Services continues this work today.

Leading practices for the allocation of organs for combined transplantation

The high demand for transplantable organs is complicated by the needs of those patients who require more than one type of organ — such as those with end-stage heart, lung or liver disease who also have advanced chronic kidney disease. The Canadian Society of Transplantation and Canadian Blood Services held a forum in March 2012 to evaluate current evidence and practices, and make recommendations on listing and allocation for combined transplantation. Each province will evaluate the recommendations to understand how they will affect their various patient groups.

Liver listing and allocation

Liver listing and allocation practices vary among provinces. Surgical and medical representatives from the liver transplant programs in Canada identified the need to develop national consensus on patient listing criteria and prioritization to ensure fair access, develop agreements on organ sharing and examine graft and patient survival rates. A liver listing and allocation forum is planned for 2016 to identify, review and build on current listing and allocation strategies using end-stage liver disease and pediatric end-stage liver disease scores and hepatocellular carcinoma to develop interprovincial liver listing and allocation policies for Canada.

Figure 44: Status of organ listing and allocation criteria

	NATIONAL STANDARDS AVAILABLE	LOCAL IMPLEMENTATION OF NATIONAL STANDARDS	INTERPROVINCIAL ORGAN SHARING*	
			INTERPROVINCIAL AGREEMENTS	USE OF CANADIAN TRANSPLANT REGISTRY
HLA testing	Yes	Yes	Yes	HLA typing, calculated panel reactive antibody, antibody specification, and virtual crossmatch for kidney programs (virtual crossmatch rules for heart programs are in progress)
Kidney	Yes	Variable	7	Listing and allocation
Liver	In progress	Variable	KPD HSP	Listing available currently; allocation planned for 2017
Heart	Yes	Variable	Urgent status	
Lung	Yes	Variable	No	
Pancreas	No	No	Regional	
Small bowel**	No	No	No	
Multi-organ	Yes	Variable	In development	

* Interprovincial sharing occurs when an organ cannot be utilized locally.

** Programs exist in Toronto and Edmonton only.

Professional education

International practice has demonstrated that formal organ donation and transplantation training for health-care professionals is effective in converting leading practices into actual adoption at the bedside. Currently, Canadian health-care professionals receive limited, inconsistent training on donation and transplantation. A national, coordinated approach to professional development will not only support knowledge translation of leading practices, but also increase the commitment and support of health-care professionals to create a culture of donation.

ODOs, Canadian Blood Services, the Canadian National Transplant Research Program, the Canadian Critical Care Society and the Canadian Society for Transplantation have a variety of initiatives aimed at health-care professionals who are engaged in donation and transplantation.

Deceased donation

Provincial ODOs have numerous education initiatives directed at their own staff and hospital-based health-care professionals. For example, the British Columbia Transplant Society holds annual provincial education days and provides in-service talks to staff from ICUs, ERs and ORs throughout the year. Donor coordinators with Trillium Gift of Life Network provide professional education and support in hospitals. Transplant Québec has recently developed a provincial training program for hospital administrators and staff that has been widely implemented. In-hospital ODOs hold regular in-services and education for hospitals across the region.

In collaboration with ODOs, Canadian Blood Services is developing a national program that will focus on those individuals who have the greatest impact on identifying, referring and managing donors, and those who hold discussions about donation with families. The plan for the next two years includes finalizing a national donation curriculum, developing training tools, modules and materials, and piloting and implementing the program.

ODOs and Canadian Blood Services continue to partner with groups such as the Canadian Society for Transplantation, the Canadian Critical Care Society, the Canadian Association of Critical Care Nurses and the Critical Care Canada Forum to host annual symposia and plenary sessions. A number of workshops have been held to increase awareness in individuals who may encounter donation and transplantation in their work and promote the uptake of leading practices:

- DCD workshops (Saskatchewan and Manitoba, 2014).
- End-of-Life Conversations with Families of Potential Donors: Leading Practices in Offering the Opportunity for Donation (Toronto, 2015).
- Deceased Organ Donation Symposium — Toronto Critical Care Canada forum (Toronto, 2015).

Kidney donation by living donors

A *transplant from a living kidney donor is the best treatment for patients with end-stage renal disease. Living donation in Canada has yet to be optimized and multiple potential barriers have been identified, including patient and donor access to necessary information, health-care provider awareness of donor opportunities and health-system resource allocation to living donation. Addressing these and other barriers offers a great opportunity to increase this critical transplant option.*

Transplantation

T *he Canadian Society of Transplantation worked with the Royal College of Physician and Surgeons of Canada to develop a diploma program in the area of focused competency in solid organ transplantation. This program provides postgraduate medical education in the transplantation specialty area with national standards of excellence. Members will typically require one to two additional years of training to receive their diplomas as a result. The program will help standardize organ transplantation practices and attract surgeons to this specialty.*

Canadian Blood Services has also worked with committees and associations to support professional education activities. For example, Canadian Blood Services worked with the National HLA Advisory Committee to support professional education in the area of proficiency testing for HLA laboratories across the country. A formal professional education system is also being planned to educate health-care professionals on leading practices, policies and protocols related to the clinical programs associated with the Canadian Transplant Registry.

Canadian Transplant Registry

A significant achievement in the past eight years is the development of interprovincial patient programs, including the KPD program, the National Organ Waitlist, the HSP program, and the Canadian Transplant Registry (CTR) infrastructure and services developed to support each. While this is a major accomplishment, the full scope and potential of the CTR and other interprovincial programs has yet to be realized. More work remains to support provincial organ-allocation policies, build a calculator to support listing patients with end-stage liver disease, align the CTR with minimum data sets, integrate and align provincial IT systems, and capture data for all donors, transplants and outcomes.

CTR infrastructure

The CTR is a foundational component that supports the programs and services administered by Canadian Blood Services. The web-based registry provides real-time access to information, and transactional and point-of-service data any time.

It includes:

- Data for all candidates and associated donors enrolled in the KPD program.
- Data for patients enrolled in the HSP program.
- Data for all donors with viable kidneys for potential offer within the HSP program.
- Algorithms and programs for generating proposed matches and offers for the KPD and HSP programs.
- Data for all non-renal patients that ODOs may use to generate complete lists of active patients waiting for transplants.
- A publicly available cPRA calculator for virtual cross-matching between potential donors and recipients.

- Facilities for automated data exchange with participating ODOs.
- Reporting and business intelligence functionality.

Although not currently fully utilized for these functions, the CTR is already able to manage data for the following:

- Living lung and liver donors.
- Living kidney donors not enrolled in the KPD program.
- Patients waiting for kidney transplants on provincial wait-lists (these people represent 90 per cent of all kidney transplant patients).
- Transplants that occur outside the KPD and HSP programs.

Additionally, all outcome data for all transplants from deceased and living donors can be easily optimized to facilitate local allocation.

Canadian Transplant Registry 2.0

In 2014, the final phase of completion for the Canadian Transplant Registry began. This phase included optimization and the integration of the KPD program. The CTR 2.0 is scheduled to be completed in early 2017.

To date, through the collaborative efforts of all provinces, the KPD program, the HSP program and the National Organ Waitlist have been developed and launched using CTR technology. While most provinces are using the CTR directly, some have opted to build direct data feeds between the CTR and their local IT systems. Benefits to this adjusted approach include the ability to reduce duplication of data entry. It is noted, however, this approach has resulted in some production delays and increased costs, and means there is not a single, national source for daily modifications. Despite technical differences with local systems and alignment to the national program, Canadian Blood Services and its provincial partners have enjoyed a significant number of successes.

Building on completed work and investments already made in the CTR, and the successful implementation of CTR-based kidney programs, Canadian Blood Services is working with the organ donation and transplantation community to explore and expand use of the CTR to its full potential. A common repository for data related to all donors, transplants and outcomes continues to be the community's objective.

Canadian Blood Services has leveraged a number of highly trained professional service providers who also support a number of other national IT services for blood and stem cell transplantation. These resources have specialized skillsets and the capability to advance the national system rapidly. The CTR technology and architecture have been built to allow for flexibility and the swift application of system changes, while adhering to the highest possible quality standards. The skillset of the team, coupled with the technology solution, has provided a strong foundation for the national programs and services. Canadian Blood Services has also provided significant support for provincial partners in the alignment of existing infrastructure.

As collaborative provincial efforts continue to advance, in the near future the CTR will be used for all desirable activities for listing, allocation of all organs and data recovery. The CTR will reduce delays in listing, illustrate wait-list trends, provide access to national data, and quickly apply adjustments for matching algorithm improvements.

KPD program

The Living Donor Paired Exchange program was launched in 2008 to find and facilitate kidney transplant opportunities for patients who have willing but medically incompatible living donors and for non-directed anonymous donors who wish to donate kidneys to anyone in need. The program was renamed the KPD program in June 2014 to better align with international terminology. The KPD program was developed and is operated by Canadian Blood Services in conjunction with the living donation and transplantation programs.

As of Dec. 31, 2015, the KPD program facilitated 391 kidney transplants from living donors. The transplants are considered immunologically low risk for rejection. Without the KPD program, it is highly unlikely that such a large number of compatible transplant opportunities would have been found.

The program has also been successful in increasing transplants for blood-group O patients — those who can accept donations from only group O kidney donors. The program has coordinated transplants for 140 of the 427 blood-group O patients who participated in the KPD program.

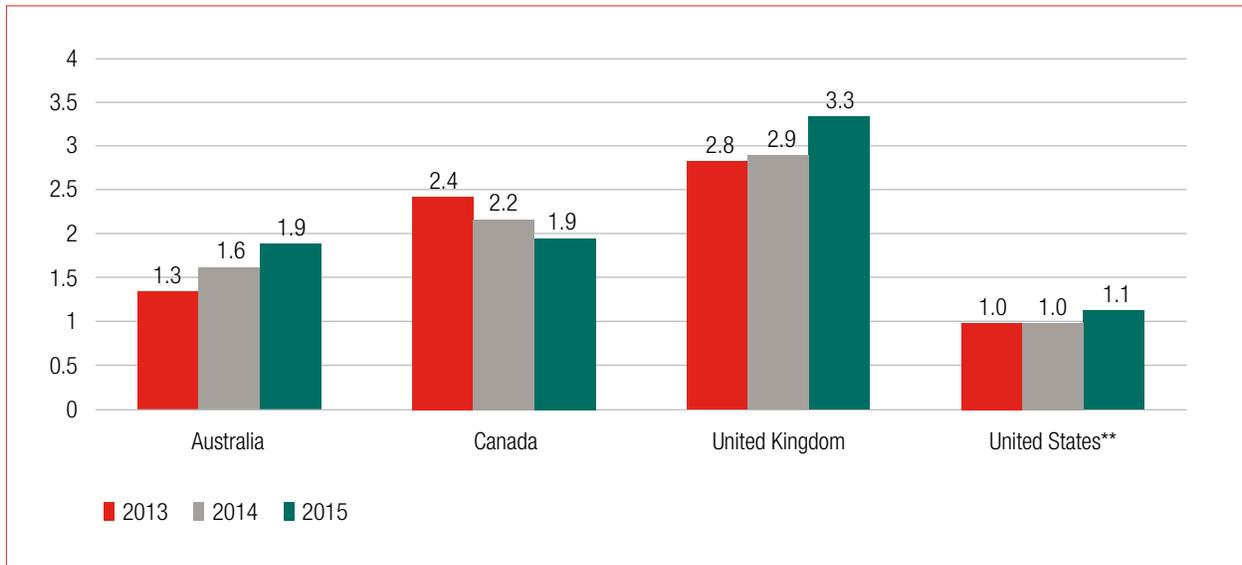
Figure 45a: KPD program activity, 2009–2015

CANDIDATES REGISTERED	741
Pairs registered*	812
Non-directed anonymous donors registered	102
TRANSPLANTS COMPLETED	391
Candidates transplanted	319
Transplants of wait-list recipients	72
Donations by non-directed anonymous donors	74

*Candidates may register with more than one potential donor.

Between 2013 and 2015, the KPD program facilitated up to 2.4 transplants per million population (TPMP) compared with 1.1 TPMP in the United States, 1.9 TPMP in Australia and 3.3 TPMP in the United Kingdom — all of which are single national programs.

Figure 45b: International comparisons of KPD programs, TPMP*, 2013–2015



* Transplants facilitated (by year of surgery) per million population of the country in which the program operates.

** The U.S. data is representative of the National Kidney Registry network, which includes 76 transplant centres in 28 states, and which represents approximately 30 per cent of U.S. transplant centres currently in operation.

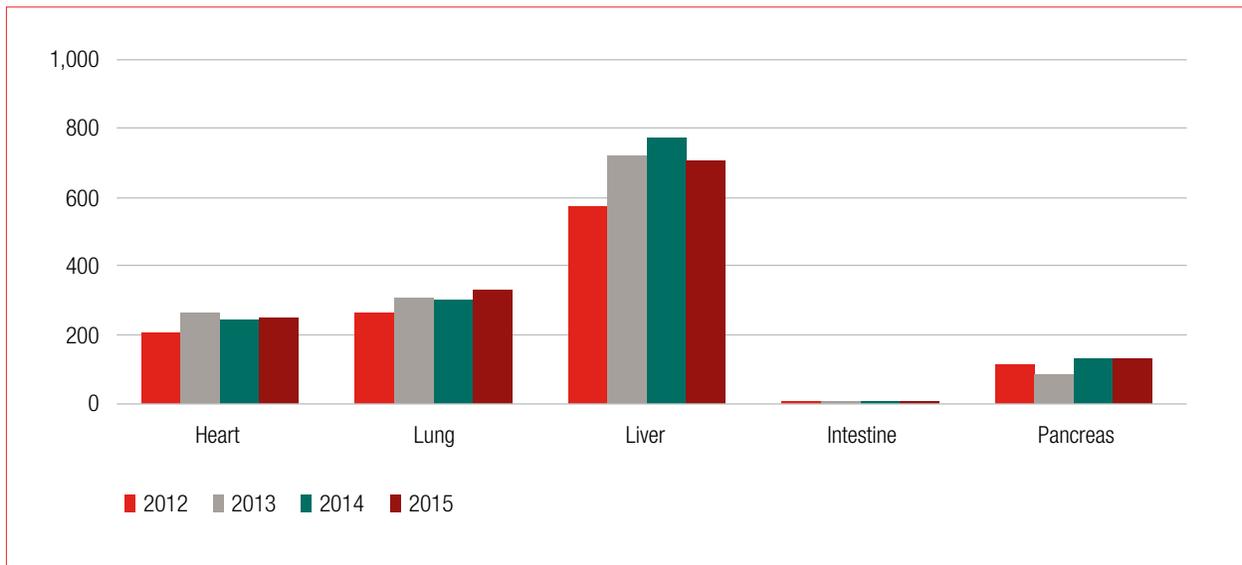
National Organ Waitlist

The National Organ Waitlist (NOW) is a shared, secure, web-based system for listing Canadians who need organ transplants other than kidneys by level of urgency. In June 2012, the NOW replaced the previous wait-list system in which data was shared among national programs via weekly faxes. Under the current system, when a deceased donor is identified by an ODO, the agency can check the NOW to see whether the donor is a match to a patient anywhere in the country who is in urgent need of an organ. The NOW allows transplant programs to keep their wait-lists current by adding

and removing patients and increasing or lowering patient priority in real time. In this way, programs can be sure they offer organs to Canadians who need them the most.

The NOW is not being fully utilized. Transplant programs today register only non-renal transplant candidates for high-status matching, and informal national agreements are in place only for high-status sharing of heart and liver organs. Considerations for national sharing with lung and pancreas also need to be addressed, as does tracking and sharing for non-utilized national organ allocation. Canadian Blood Services is facilitating discussions with the transplant programs with the intent of standardizing all patients' listing statuses and providing transparency with respect to organ wait times.

Figure 46: Patients listed on the NOW*, 2012–2015



* Counts are based on patients' list dates.

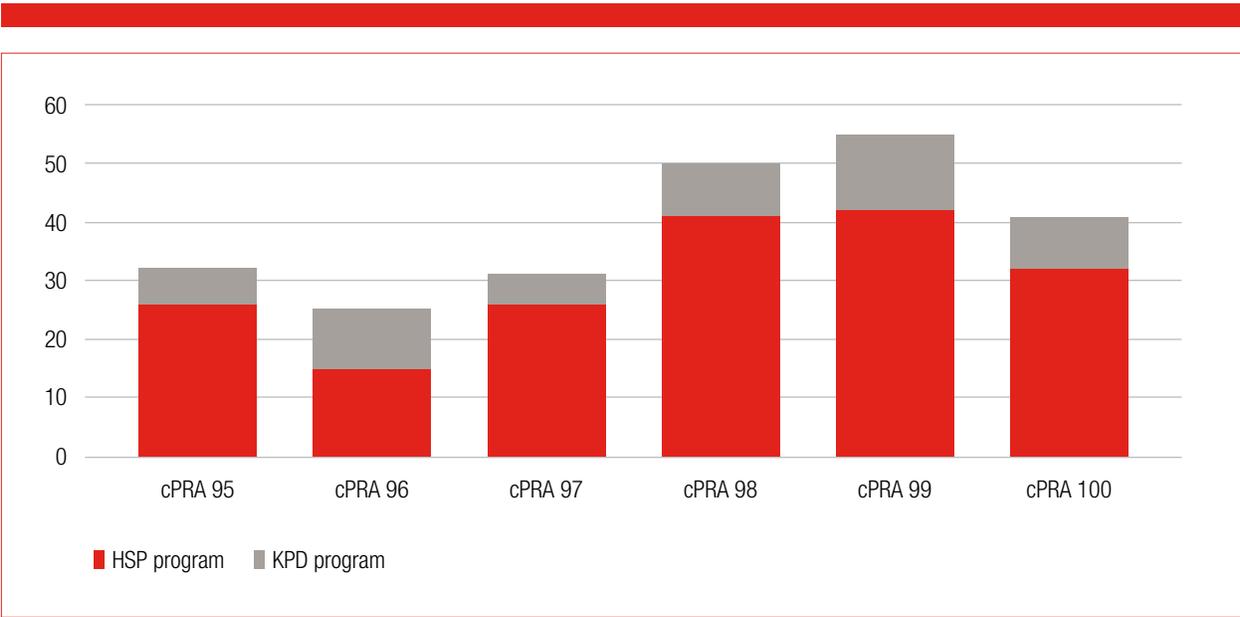
Patients who are re-listed for the same organ in a given year are counted as a single listing for that organ and year category.

HSP program

Some patients have high levels of antibodies as a result of past exposures to foreign tissues through pregnancy, past transplants and blood transfusions. As a result, they are difficult to match for transplantation. Before the KPD and HSP programs, these patients made up as much as 25 per cent of the names on national wait-lists and received fewer than five per cent of the transplants. With the introduction of the KPD and HSP programs, as well as standardized provincial

allocation policies that prioritize highly sensitized patients, the number of transplants for this group has gradually increased.³¹ The HSP program provides access to the entire national pool of donors. This access, along with rapid and accurate HLA matching in the CTR, significantly increases the likelihood of finding matches for these patients. The HSP registry went live in January 2013, and all provinces participated by October 2014.

Figure 47: Number of transplants for highly sensitized patients facilitated by the KPD and HSP programs as of Dec. 31, 2015



Data management and analytics

Timely, comprehensive and accurate data is critical for planning and managing health services, improving patient outcomes, reporting on performance and enabling research and development. Currently, Canadian organ donation and transplantation data is dispersed among many provincial and national organizations. Provincial ODOs, for example, report individually to their respective ministries. Also, the quality of data among these sources varies. Many key pieces of information, such as the number of patients on wait-lists and the number of deaths on wait-lists are not completely or accurately collected. The organ donation and transplantation community has requested that data be collected and presented in a format that is comparable interprovincially and internationally.

Achievements to date

Canadian Blood Services hosted a workshop in Toronto in June 2013 to begin the development of a national integrated framework for data analytics and reporting. Stakeholders agreed on the vision, guidelines and model for the framework.³² They noted the data collected and

reported should include system-wide information generated throughout the donation and transplantation process. The data would capture:

- All donors and recipients.
- All transactions (e.g., organ allocation, offers and accepts/declines).
- All transplants (e.g., related and unrelated living donation, donation after neurological determination of death or donation after circulatory death).
- All outcomes.
- All provinces and territories (where donation data begins from the time a potential donor is identified, to the time of donation [or beyond for living donors] and transplantation data begins from the point of referral of a patient to an organ replacement program, and is followed until the death of the patient).

Participants also agreed that the Canadian Organ Replacement Register, which is operated by the Canadian Institute for Health Information, should focus on kidneys and that all donation and transplantation data should be collected and reported through the CTR. The participants

indicated that governance would be a major success factor — and a key challenge — in moving forward with this work.

Progress has been made in several areas. There has been agreement on the data elements to be collected and their definitions (i.e., the minimum data sets for heart, liver, lung and kidney transplants). Data sets for pancreas/islet transplants and living and deceased donations are being developed. Business intelligence capabilities and data warehousing tools and infrastructure (through the CTR) are being implemented, and an advisory committee was created to guide the strategic development and implementation of the data system and to work on operational issues.

Barriers remain

However, a number of key barriers and challenges remain in achieving the scope and intent identified by participants.

National data reporting remains voluntary and as such is not trusted by the international community to reflect reported patient outcomes accurately. Such a practice has failed to produce timely, accurate, comparable and transparent data sets at the national level and in most provinces. Although there are now nationally standardized data elements and definitions, national advisory committees have no formal authority to implement mandatory data reporting of these elements, or to audit practices to ensure data quality and compliance.

In other national systems, data transparency has led to widespread impetus for improvement. In the United States, for example, there is legislative authority to collect data. The reimbursement paid to clinics, transplant programs and ODOs is linked to data collection. As a result, compliance with data reporting requirements is excellent.

Ontario's Trillium Gift of Life Network has introduced its own hospital-based donation performance data and metrics that it provides to the hospitals. The group reports that this procedure has been extremely influential in changing practices and increasing support of the initiatives and best practice changes that result in improved system performance.

Further advancement on data reporting could be tied into a proposed clinical governance and accountability framework, including mechanisms for national reporting and auditing for compliance. Additional resources will be needed at a national level and in front-line programs to support this work.

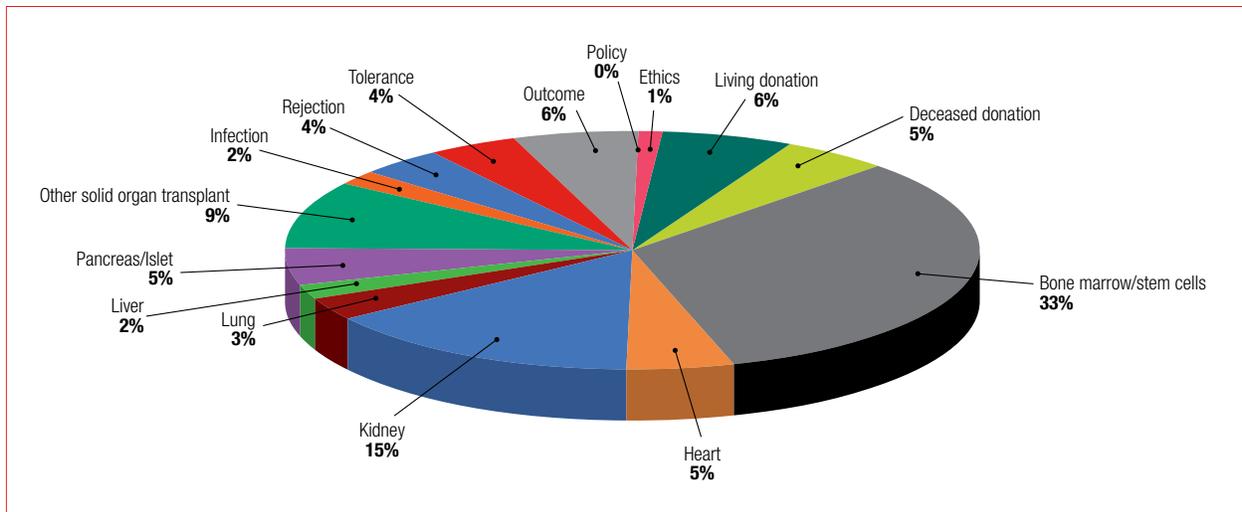
Research and innovation

Research is foundational to system improvement and innovation. Canada has a history of world-class transplantation research thanks to the efforts of a number of investigators and institutions that contribute at the national and international levels. Deceased donation research is evolving. Relative to transplantation, however, it has only just begun and requires further development. Ongoing collaborative research is needed in this area.

Organ donation and transplantation research in Canada

Research on donation and transplantation is part of the Canadian Institutes of Health Research's strategic priorities on "enhanced patient experiences and outcomes through health innovation" and "improved quality of life for persons living with chronic conditions." Research funded by CIHR is organized under four themes: biomedical research; clinical research; health services research; and social, cultural, environmental and population health research. Most funding for donation and transplantation research is found in the biomedical theme, followed by investments in clinical research, health-system research and population health research. From 2008 to 2015, through individual investigator-initiated research applications, CIHR invested \$98.9 million in transplantation and donation research. (Of that total, \$76.5 million was dedicated to research grants, and \$22.4 million to training, including new investigator salaries).

Figure 48: CIHR investments in transplantation and donation according to research areas, 2008–2015



The Canadian National Transplant Research Program

The Canadian National Transplant Research Program (CNTRP) was established in 2013 following a successful CIHR funding application. In addition to the funding described above, CIHR also supports the CNTRP at a rate of \$2.25 million per year over five years. The CNTRP is a coalition of more than 300 scientists, students, collaborators, patient partners and knowledge users at 29 sites throughout Canada. Its members are actively engaged in the science of solid organ transplant, hematopoietic cell transplant and organ donation. The CNTRP's goals are to increase access to transplantation while improving outcomes and quality of life for transplant recipients through innovative research strategies. These research strategies cross the full spectrum of health research including biomedical, clinical, health systems and policy, and population health.

Since it launched, the CNTRP focused on six national projects, each tackling major challenges faced by transplantation and donation communities. These projects included:

- Developing and testing ex vivo organ-perfusion strategies to enhance the number and quality of organs available for transplantation.
- Increasing the pool of organ, tissue and stem cell donors.
- Understanding and predicting rejection and graft-versus-host disease.
- Inducing and maintaining immune tolerance.
- Predicting and preventing infectious complications.
- Addressing specific needs of pediatric transplant patients.

A seventh project focusing on chronic complications of transplantation and a new patient-researcher partnership platform is embedded within the CNTRP framework.

Collectively, these projects include more than 35 conceptually linked subprojects that cross-fertilize, and link to other projects. This matrix-type structure aims to help research groups working collaboratively around research questions by providing a multi-faceted, yet integrated approach to knowledge generation.^{33,34}

Further funding and support

Many academic institutions support further research into organ donation and transplantation. The Canadian Society for Transplantation and the Kidney Foundation of Canada, for example, provide research and fellowship grants and collaborate with national and international organizations to support a robust research network.³⁵

The Canadian Critical Care Trials Group, which promotes and helps implement investigator-initiated, patient-oriented, multi-centre research, has a number of donation and transplantation studies underway. Provincial ODOs and transplant programs are key partners in research, providing support in this area.

Canadian Blood Services has also been working to make CTR data available to scientists for research purposes. With the implementation of the various clinical registries and the resulting data collected in the system, there is an opportunity to share this data with researchers to improve patient outcomes and inform health-care policy. The necessary procedures to ensure compliance with privacy regulations and research ethics standards are being created, along with the infrastructure to support data extraction and analytic tools. This area will be supported by Canadian Blood Services' Information System Advisory Committee and Research Ethics Board.

IN CONCLUSION



CANADA HAS SEEN INCREMENTAL PROGRESS IN ITS ORGAN DONATION AND TRANSPLANTATION SYSTEM SINCE 2006.

The national deceased donation rate has risen from 14.1 to 18.2 donors per million population in 10 years, with a related rise in the transplant rate (63.7 to 71.4 transplants per million population). There have also been significant improvements to access to transplant, especially for highly sensitized patients who previously had difficulties accessing transplantation. However, organ donation and transplantation is not yet improving quickly enough to help the thousands of Canadians waiting for lifesaving or life-improving transplants. Donation rates are still below potential in most provinces. Variation in access to transplants remains high with potential consequences for patients. There has been consistent progress in improving donations after circulatory death, optimizing donations after neurological determination of death, introducing donation physicians and implementing national organ sharing programs. There is now better alignment and coordination among researchers.

Figure 49: Transplants versus people waiting for transplants in Canada, 2006–2015



While national programs and services are evolving as important system contributors, national and provincial programs aligned with shared strategic priorities and targets will foster and focus the potential. For example, mandatory data reporting at all levels of the system would help optimize programs and services, and prevent donation rates from plateauing.

Similarly, living donation, which has decreased over the last 10 years, requires national and provincial considerations to support donors and decrease lengthy workup times for donors and recipients.

In addition, strategic program reviews are encouraged – for organ donation organizations, transplant programs, hospitals that support patients pre- and post-transplant (notably intensive care units and operating rooms), national programs, programs that support living donors, and ancillary functions, such as testing and medical diagnostics – to help ensure that donation and transplant opportunities are realized.

Looking forward, other areas that require further analysis to inform the prioritization and alignment of work include:

- Understanding and contrasting provincial investments and funding models for donation and transplantation.
- Capacity of intensive care units.
- Consent rates and their relationships to provincial intent-to-donate registries.
- Organ utilization.
- Surgical organ recovery service.
- Extended-criteria donors.

Given the proven health benefits for patients and the economic benefits for governments, there is much evidence to support continued movement forward in a focused and collaborative manner to advance transplantation where possible. Programs across Canada have seen consistent improvements, and those strategies that have been proven successful both in Canada and around the world have been highlighted in this report. Programs are encouraged to focus on building the foundational elements of successful donation and transplantation practices to improve access to transplants for current and future patients.

ABBREVIATIONS

CIHI	Canadian Institute for Health Information
CIHR	Canadian Institutes of Health Research
CNTRP	Canadian National Transplant Research Program
cPRA	calculated panel reactive antibody: a measurement of a patient's level of sensitization to human leukocyte antigens
CST	Canadian Society of Transplantation
CTR	Canadian Transplant Registry
DCD	donation after circulatory death: a diagnosis and confirmation of death based on circulatory criteria
DPMP	donors per million population
HLA	human leukocyte antigen
HSP	Highly Sensitized Patient
KPD	Kidney Paired Donation
NDD	neurological determination of death: a diagnosis and confirmation of death based on neurological criteria
ODO	organ donation organization
ODT	organ donation and transplantation
OTDT	organ and tissue donation and transplantation
TPMP	transplants per million population

DATA SOURCES

A note on data sources

The Canadian data collected for this report was compiled from a number of sources and standardized and validated to the greatest degree possible by experts from Canadian Blood Services. Unless indicated otherwise, source material was derived from figures compiled from the Canadian Transplant Registry, and materials published by the Canadian Institute for Health Information and the Canadian Organ Replacement Register, including e-stats, quick stats and annual reports. Demographic data was taken from Statistics Canada reports, *Annual Estimates of Population for Canada, Provinces and Territories, from July 1, 1971, to July 1, 2015*.

Also, to make the document as valuable as possible to readers, Canadian Blood Services' personnel collected and validated 2015 data from the various provincial organ donation organizations.

The international donation and transplantation data collected for this report was compiled from a number of sources and standardized and validated to the greatest degree possible by experts from Canadian Blood Services. Source material was derived from figures compiled from the International Registry on Organ Donation and Transplantation, the Organ Procurement and Transplantation Network in the United States, and the Organizacion Nacional de Trasplantes in Spain.

The international data for the kidney paired donation comparisons was obtained from: the Australian Paired Kidney Exchange Programme Biannual Report #6; the United States Paired Exchange Results Quarterly Report, December 31, 2015. The United Kingdom data was taken from a presentation delivered by R. Johnson at the British Transplant Society Congress, February 2016, entitled "Overview of Organ Donation and Transplantation." Population estimates were obtained from the World Bank mid-year population estimates (2015 extrapolated). This data is based on published results from each program but has not been reviewed by program representatives, except for the Canadian program.

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