

## Chapter 4

### Section 4.10

Ministry of Health and Long-Term Care

# Organ and Tissue Donation and Transplantation

Follow-up to VFM Section 3.10, *2010 Annual Report*

## Background

In the 2011/12 fiscal year, almost 1,000 organs were transplanted from almost 550 donors at the eight Ontario hospitals that perform transplants. As of March 31, 2012, more than 1,500 Ontarians were waiting for organs, most of them for a kidney or a liver. As well as saving or enhancing lives, transplants can save money. For example, each kidney transplant surgery cost about \$25,000 at the time of our 2010 audit. The same year, however, the cost of dialysis—a mechanical procedure carried out frequently to cleanse the blood of a person whose kidneys have failed—was about \$70,000 a year.

The Trillium Gift of Life Network (Network), which has a staff of about 130, was established in 2002 as an agency of the Ministry of Health and Long-Term Care (Ministry) to co-ordinate the donation of organs and tissue, which includes eyes and bones. Funding to the Network and the eight hospitals for transplants in the 2009/10 fiscal year was about \$100 million. Our 2010 audit assessed whether there were adequate policies, procedures and systems in place to meet the organ and tissue needs of Ontarians in an efficient and fair manner.

As we reported in our *2010 Annual Report*, initiatives by the Network, the Ministry and the transplant hospitals had improved the province's

ability to meet organ- and tissue-transplant needs. As demand exceeds availability for many organs, the willingness of families of deceased people to donate organs is critical. Since the Network's establishment, the number of deceased donors has increased from 11.3 to 16.7 donors per million people. Nevertheless, our 2010 audit suggested certain changes that could be made to reduce wait times for organs, thus saving lives and improving patients' quality of life.

Our findings included the following:

- There was no periodic independent review of the Network's allocation of organs. Oversight of transplant activities on a province-wide basis needed to be enhanced to help ensure that patients were consistently prioritized on wait lists and that the highest-priority patient received the first available compatible organ. In more than 40% of the cases we reviewed, the highest-priority patient did not get the organ, and no reason for this decision was documented.
- Forty hospitals generally did not refer potential donors to the Network even though they had the medical equipment necessary to maintain organs until transplant.
- For years, many Ontarians signed the donation-consent part of their driver's licence and kept it in their wallet. However,

this type of consent was not included in the Ministry's consent registry, which the Network uses to determine if a potential donor has given consent.

- There was a lack of consistent clinical criteria regarding the time when hospitals should refer potential donors to the Network, resulting in many referrals being made too late or not at all.
- Only 15,000 of the 4 million Ontarians who still have red-and-white OHIP cards had their consent registered with the Ministry (almost certainly because this required mailing in a separate form to ServiceOntario), while 1.9 million people with photo OHIP cards had registered (because people are specifically asked during the application/renewal process if they want to register). Consent-registration rates also varied significantly among regions, from less than 10% in Toronto to more than 40% in Sudbury.
- Hospitals indicated that patients requiring organs were not always referred so that the transplant hospital could determine whether the patient was eligible to be placed on a transplant wait list. For example, only 13% of dialysis patients were on a kidney wait list, and rates varied from only 3% in the South East Local Health Integration Network (LHIN) to 16% in the Champlain LHIN.
- Instead of being allocated to the highest-priority patient province-wide, kidneys and livers generally stayed in the same region in which they were donated. As a result, for example, 90% of kidney recipients received the organ within four years in one area of the province, while those in two other regions waited about nine years. Wait times by organ type were generally not publicly available.
- Transplant hospitals did not have electronic access to donor information such as medical history and laboratory results, which is necessary to determine organ viability for potential recipients. Instead, they generally relied on

the Network to verbally communicate this information, increasing the risk of decisions being based on incomplete or inaccurate information.

- Less than 8% of tissue needed for transplant in Ontario actually came from Ontario donors because of a lack of resources to recover, process and store it. Instead, Ontario hospitals purchased tissue primarily from the United States and Quebec.
- One Ontario hospital performed only six transplants in a year, and although Ontario does not stipulate a minimum yearly number of transplants to ensure a hospital remains proficient, the U.S. minimum requirement is generally 10.

We made a number of recommendations for improvement and received commitments from the Network and the Ministry that they would take action to address our concerns.

## Status of Actions Taken on Recommendations

The Network and the Ministry provided us with information in the spring and summer of 2012 on the current status of our recommendations. According to this information, some progress was made in implementing all of the recommendations in our *2010 Annual Report*, with significant progress in areas such as simplifying the consent registration process and using kidney pumps to increase the viability of kidneys from deceased donors. While more hospitals are now required to report potential organ and tissue donors to the Network, it will take additional time to fully address and implement this and several of our other recommendations. Some actions depend on the interprovincial-territorial response to the national organ and tissue donation and transplantation plan released in April 2011 by Canadian Blood Services.

The current status of the actions taken by the Network and the Ministry is summarized following each recommendation.

## ORGANS

### Identifying and Referring Donors

#### Recommendation 1

*To increase the number of organs available to individuals waiting for a transplant, the Trillium Gift of Life Network (Network) could enhance the identification of potential organ donors through such means as:*

- *determining whether all 61 hospitals with advanced ventilator capacity (necessary to maintain the viability of organs for transplant), rather than just the current 21 hospitals, should be required to notify the Network of potential organ donors, in accordance with the recommendation of the Ministry of Health and Long-Term Care's Organ and Tissue Transplantation Wait Times Expert Panel;*
- *developing and implementing consistent, appropriate clinical criteria, in conjunction with hospitals, to assist physicians in knowing when to notify the Network of potential donors;*
- *using existing provincial systems, such as CritiCall, a referral service for critically ill patients, and the Emergency Neurosurgery Image Transfer System, used to remotely view the computed tomography (CT) images that can confirm brain death, to help identify potential donors; and*
- *working with all stakeholders—including the Ministry, hospitals, and physicians—to ensure that there are sufficient financial incentives to encourage more widespread identification and reporting of potential donors.*

#### Status

At the time of our follow-up, the Network said that the requirement to report potential organ donors was being expanded to all hospitals that have

advanced ventilator capacity. As of summer 2012, 18 more hospitals were notifying the Network of potential organ donors, and another 10 were expected to start by the end of the 2012/13 fiscal year. The remaining hospitals with ventilator capacity were expected to begin notifying the Network in the 2013/14 fiscal year.

The Network indicated that updated clinical triggers, which assist physicians in identifying when to notify the Network of potential donors, were reviewed and endorsed by the Network's Donation Steering Committee in fall 2011. The Network noted that the revised triggers were being incorporated into the policies of all hospitals required to report potential organ donors to the Network. The Network also planned broader consultations to ensure acceptance of the criteria, and indicated that it may further revise the triggers after the consultations end in December 2012.

The Network said it planned to review opportunities to integrate organ donation and end-of-life care, including ways to leverage the Emergency Neurosurgery Image Transfer System and CritiCall, during the 2012/13 fiscal year. The Network noted that the Executive Director of CritiCall was a member of the Network's Donation Steering Committee.

The Network said it worked with the Ontario Medical Association and physicians, in consultation with the Ministry, to identify gaps and opportunities in the current physician fee schedule to encourage doctors to identify and report potential organ donors. The Ministry determined that the physician fee schedule already includes fees covering this area—but that physicians may not be aware that it does because they seldom bill for it. The Ministry expected the Network to clarify with physicians when these fees can be billed and further indicated that it will monitor the implementation of the Health System Funding Strategy for hospital funding opportunities related to the identification and reporting of potential donors.

## CONSENT

### Recommendation 2

To help improve consent rates for potential organ donation, the Trillium Gift of Life Network (Network) should:

- work with the Ministry of Health and Long-Term Care, the Ministry of Transportation, and ServiceOntario to change the system of obtaining consent at the time of driver's licence renewal to enable persons to be added to the donor registry, because neither the Network nor hospitals have access to the donor card previously sent with licence renewals that many people sign and keep in their wallet;
- determine, in conjunction with the hospitals, the best approaches to increasing consent rates at the hospitals, especially in those areas of the province where consent rates are low—for example, by identifying specific individuals who have an aptitude for or training in successfully requesting consent; and
- consider implementing a “mandatory ask” policy, along the lines of a policy used in the United States, which would require that the next of kin of every potential organ donor be asked for consent before the removal of life support.

Further, the Ministry of Health and Long-Term Care should simplify the process by which people register consent to be an organ donor, such as by implementing an on-line consent registry similar to those available in British Columbia and other jurisdictions.

### Status

In fall 2010, the Network, in collaboration with ServiceOntario and the ministries of Transportation and Health and Long-Term Care, began mailing donor-registration forms with prepaid return envelopes to persons renewing their driver's licence. The Network indicated that the response rate has been much higher, with 4.3% of people signing their consent and returning the forms to ServiceOntario between December 2010 and March 2012. The Ministry further noted that the Network and

ServiceOntario launched a pilot project in which ServiceOntario counter staff ask people who renew a driver's licence or obtain an Ontario photo health card if they wish to register as potential donors. The Network and ServiceOntario were planning to expand this practice province-wide by March 2013.

In May 2011, the Network began to monitor the effectiveness of all staff involved in obtaining consent from families of potential donors, and found that staff with Network training and experience were more successful at obtaining consent than health-care professionals with no training in this area. The Network's policy endorses its staff approaching families for consent, but also says that a discussion is required between Network staff and the health-care team of a potential donor to determine who should approach the family, and how best to do it. The Network provides quarterly training sessions for staff, and monitors all staff involved in obtaining consent to identify areas where additional follow-up training is necessary. The Network also noted that it held a workshop in March 2012 to help ensure staff have the appropriate knowledge and understanding to deal with families and health-care professionals from diverse cultural backgrounds.

To improve consent rates, the Network's Donation Steering Committee endorsed a “mandatory ask” policy in summer 2012 whereby consent to donation must be requested of all potential donors before the withdrawal of life-sustaining therapy. The Network also indicated that it was reviewing situations where organ donations do not proceed because a potential donor's family does not support the person's previously registered consent decision, to see if it can devise strategies for ensuring that decisions are fully informed while the family's rights are still respected.

The Ministry said an online donor registration system was implemented in spring 2011, and that more than 44,000 people used it to register their consent between June 2011 and April 2012. Also, the Ministry, working with the Ministry of Government Services and ServiceOntario, made online

registration accessible through mobile telephone and computing devices in April 2012. As well, the Network is working on an electronic “grass roots” social media campaign, whereby interested individuals can encourage others to register their consent to be organ and tissue donors.

## ORGAN WAIT-LISTS

### Recommendation 3

*To enhance its management of the wait-lists for organ transplants, the Trillium Gift of Life Network (Network), in conjunction with transplant hospitals and physicians, should:*

- *develop target time frames for provincial priority rating scales for organ transplants, as recommended by the Ministry of Health and Long-Term Care’s Organ and Tissue Transplantation Wait Times Expert Panel;*
- *determine the best way to communicate referral criteria to non-transplant physicians, so that individuals who would benefit from a transplant (including from a quality-of-life perspective) are added to the wait-list; and*
- *require hospitals to enter on the Network’s system the reason for taking a patient off the wait-list, and periodically review, by hospital, the number of patients removed from the wait-list because they die or become too ill for a transplant, to determine whether actions can be taken to minimize the incidence of such cases.*

### Status

At the time of our follow-up, the Network said it had initiated a review of national and global practices for establishing target wait times for organ transplants. In conjunction with clinical experts, the Network plans to use this information to help determine by fall 2013 the appropriate use of wait-time information for transplant patients. The Network noted that the development of target wait times also requires standardized organ-transplant listing criteria and organ-allocation practices.

The Network indicated that its organ-specific working groups identified consistent practices for adding patients to transplant wait lists, and are working on standardized referral criteria. Once referral criteria are developed for all organs, the Network plans to develop a communication and implementation strategy, and expects to begin communicating with referring physicians by the end of the 2012/13 fiscal year.

The Network noted that its organ-specific working groups were developing standardized processes to remove patients from wait lists, including documentation of the reasons for removal, and it expected to have the processes for all organ wait lists in place by the end of the 2012/13 fiscal year. Once that is done, the Network said it plans to periodically review on a hospital-by-hospital basis the number of patients removed from wait lists because they die or become too ill for a transplant to see if there are any ways to minimize the incidence of such cases.

## ALLOCATION OF ORGANS

### Recommendation 4

*To better ensure that organs are allocated in an efficient and equitable manner, the Trillium Gift of Life Network (Network) should:*

- *in conjunction with the transplant hospitals, review kidney and liver allocations, with a view to having one province-wide wait-list (rather than up to five regional wait-lists) for each organ, so that the highest-priority patient in the province, based on clinical evidence, receives the first suitable organ available, and transplant program sustainability is maintained;*
- *have periodic independent reviews conducted of organ allocations, to ensure that either the highest-priority compatible patient received the organ or there was a valid reason for allocating the organ to another patient; and*
- *provide information to the eight transplant hospitals on organs made available but not accepted by them, so that the Network and the*

*hospitals can monitor the acceptance rates and determine whether any changes are needed to the process for offering and accepting organs.*

### Status

At the time of our follow-up, the Network indicated that a single wait list for liver transplants was being developed and would likely be implemented by the end of summer 2012. With respect to persons waiting for kidney transplants, a working group was evaluating the effect of sharing kidneys among the five regions and had agreed in principal to move toward a single province-wide wait list. The Network expected to have in place by winter 2013 a system that alternates between allocating one kidney locally and one provincially.

With respect to conducting independent reviews to ensure that either the highest-priority patient receives the organ, or a valid reason is identified for allocating it to another patient, the Network noted that a quality committee would be formed to consider a system for periodically reviewing organ allocation. The Network expected this process to be established by the end of the 2012/13 fiscal year. In the interim, the Network stated that it has improved its chart documentation to better identify the rationale for allocating an organ to a patient who does not have the highest priority, and is conducting internal audits of organ allocations.

The Network expected that changes to its current database to track the number of organs accepted and declined by the eight transplant hospitals would be in place in the 2013/14 fiscal year. The Network indicated that, once available, it planned to share this information with all transplant hospitals.

## EFFICIENCY OF THE ORGAN DONATION PROCESS

### Recommendation 5

*To improve the efficiency of the organ donation process and avoid delays that may harm the viability of donated organs, the Trillium Gift of Life Network (Network) should:*

- *determine the feasibility of providing transplant hospitals with simultaneous electronic access to information required to facilitate the physician's assessment of the compatibility of the donor and a potential recipient, such as the donor's laboratory test results;*
- *review the costs and benefits of implementing a system capable of tracking the information required to oversee the organ donation process, including the time taken for each stage of the donation process from identification of the potential donor to the time of transplant (compared against target times), and the reasons for any delays; and*
- *review research on current best practices with respect to the use of kidney pumps when transporting donated kidneys to transplant hospitals and track the use of such pumps.*

*Further, the Ministry of Health and Long-Term Care should review its agreement with the air ambulance provider, Ornge, and, in conjunction with the Network, clarify Ornge's transportation responsibilities with respect to organ transplantation.*

### Status

At the time of our follow-up, the Network indicated that it had conducted a competitive process and expected to have a more comprehensive donor-management system in place by the end of the 2012/13 fiscal year. Once implemented, the system will enable the sharing of donor data via email with transplant hospitals, which helps assess the medical suitability of a donor organ. The Network anticipated that further work will be done in the 2013/14 fiscal year to electronically share donor information with the transplant programs at subsequent stages of the organ donation process.

The Network expected that the new donor-management system would also facilitate the measurement and reporting of more indicators, including time spent on each stage of the donation process, from identification of a potential donor to the time of transplant, and reasons for any delays.

The Network said that it completed its review of best practices for kidney-pump use and as of March 31, 2012, all transplant hospitals have agreed to use the pumps to preserve kidneys from deceased donors. The Network has also begun tracking use of the devices, and has identified preliminary measures for monitoring and evaluating their use, which will be discussed at future meetings of its Kidney/Pancreas Working Group.

The Ministry stated that the Network and Ornge air ambulance are developing a formal service agreement to standardize processes for organ transport. The Ministry expected a draft agreement would be ready for its review in January 2013.

## TISSUE

### Recommendation 6

*To help ensure that there is an adequate supply of quality tissue, such as bones and eyes, to meet the needs of Ontarians and reduce reliance on tissue purchased from other jurisdictions, the Trillium Gift of Life Network (Network) should:*

- *increase the number of hospitals required to report potential tissue donors to the Network and, in conjunction with the hospitals, develop more specific clinical triggers (such as age criteria) to help hospitals determine which patients should be referred to the Network as potential tissue donors;*
- *review the process of obtaining consent for tissue donation, in conjunction with the hospitals, with a view to increasing consent rates; and*
- *reassess, in conjunction with the tissue banks, the screening processes used to determine tissue viability so that non-viable tissue is identified as quickly as possible.*

*Further, the Ministry of Health and Long-Term Care, in conjunction with the Network and the tissue banks, should:*

- *assess the costs and benefits of implementing a centralized tissue bank, which would help ensure that, after consent is received, tissue*

*is recovered, processed, and stored safely and efficiently; and*

- *consider whether specific funding should be provided to offset the costs incurred by hospitals and to compensate physicians for their time with respect to tissue donation and banking.*

### Status

At the time of our follow-up, the Network said that the additional hospitals required to refer potential organ donors to the Network also have to refer potential tissue donors to the Network. As well, the Network stated that it requires reporting of all deaths occurring at designated hospitals, but that it would consider in the 2012/13 fiscal year the implications of moving to more specific clinical triggers for reporting potential tissue donors. The Network planned to establish a Tissue Working Group, which would begin meeting in fall 2012, to increase tissue donation through effective donation, recovery and banking practices.

With respect to obtaining consent for tissue donation, the Network tracked the consent rates for its staff and hospital staff in 2011, and found that Network staff obtained an average consent rate of 50% while untrained hospital staff obtained 4%. The Network said it shared this information with the hospitals to emphasize the importance of having the Network approach families for consent. The Network indicated that in the 2011/12 fiscal year, it approached almost 75% of potential tissue donors, while hospitals spoke to the rest.

At the time of our follow-up, the Network noted that it was working with various Ontario tissue banks to define and implement “exclusion criteria” to help identify tissue that is not viable and therefore should not be referred for tissue donation. The Network anticipates that this will streamline workload and ensure that only relevant referrals are made to the tissue banks.

The Ministry indicated that it was reviewing, in conjunction with the Network and other provinces and territories, the April 2011 national plan of the Canadian Blood Services for organ and tissue

donation and transplantation. The plan recommends a restructured tissue system, including nationally centralized tissue banking. At the time of our follow-up, the Ministry expected that an interprovincial–territorial response to this plan would be completed by fall 2012, and therefore it was not planning to otherwise assess the costs and benefits of a centralized tissue bank.

The Ministry said it met with the Network and physicians who recover tissue donations to discuss reimbursements to physicians performing tissue recovery. The Ministry concluded that the current physician payment schedule included sufficient fees for tissue recovery and that it, the Network and the Ontario Medical Association had to be more proactive in making physicians aware of these fees. The Ministry indicated that hospital funding for tissue recovery may need to be considered in future as the Health System Funding Strategy is implemented.

## PERFORMANCE MONITORING

### Recommendation 7

*To provide additional assurance that organ and tissue transplantation in Ontario is meeting the needs of patients safely and efficiently, the Ministry of Health and Long-Term Care (Ministry), in conjunction with key stakeholders, including the Trillium Gift of Life Network, transplant hospitals, and transplant physicians, should determine the best structure for providing effective oversight for organ and tissue transplantation in Ontario, as recommended in the 2009 report of the Ministry's Organ and Tissue Transplantation Wait Times Expert Panel. As well, performance indicators for transplant activity in Ontario—such as wait times for transplant by organ, number of transplants performed by hospital and patient survival rates by hospital—should be established and made publicly available.*

### Status

At the time of our follow-up, the Ministry stated that oversight of transplant activities in Ontario was a collaborative effort between the Ministry and the Network. In this regard, the Network established donation and transplant steering committees, as well as organ-specific working groups, to help implement an integrated structure for effective management of organ and tissue donation and transplantation in Ontario. The Ministry also indicated that, in conjunction with the Network, it is reviewing the April 2011 national plan of the Canadian Blood Services for organ and tissue donation and transplantation. The plan includes recommendations related to the oversight of donation and transplantation, and the Ministry expected that an interprovincial–territorial response to this plan would be completed by fall 2012.

At the time of our follow-up, the Network's website had data on organ transplant wait lists as well as on the number of patients who received a transplant, broken down by categories such as age and gender. The Ministry noted that the Network is consulting with transplant hospitals to establish the means and timelines for publicly reporting hospital-based transplant statistics, including the number of transplants performed by each hospital. However, the Ministry indicated that public reporting of other data, such as wait time for transplant by organ type and life expectancy after transplant, would require more time because of factors that included the need to develop consistent data definitions and implement information technology changes. In this regard, the Ministry noted that the Network's Transplant Steering Committee and its organ-specific working groups were developing standard definitions for wait times that it expected would be drafted by spring 2013.