

Organ and Tissue Donation and Transplantation

Background

Organ and tissue donation and transplantation can save or enhance the lives of many individuals. In the 2009/10 fiscal year, almost 1,000 organ transplants (from over 550 donors) were carried out at the eight Ontario hospitals that perform transplants. Although most organs and tissue are donated by deceased donors, kidneys and livers (and, in rare cases, lungs) can also be donated by living donors. Further, the number of organs being transplanted has risen, as shown in Figure 1. As

well, donations of tissue, such as eyes and bones, can enhance lives—for example, by restoring sight or improving mobility through a hip or knee replacement. The majority of organ and tissue donations in Ontario occur at 21 hospitals. As of March 31, 2010, over 1,600 people were waiting for an organ transplant in Ontario. Most were waiting for either a kidney or a liver transplant, as shown in Figure 2.

The *Trillium Gift of Life Network Act* gives the Trillium Gift of Life Network (Network) the authority and responsibility for, among other things, co-ordinating the donation of organs and tissue, as well as co-ordinating some transplantation-related activities, such as wait-list management. The

Figure 1: Number of Organ Transplants in Ontario, 2002/03–2009/10

Source of data: Trillium Gift of Life Network

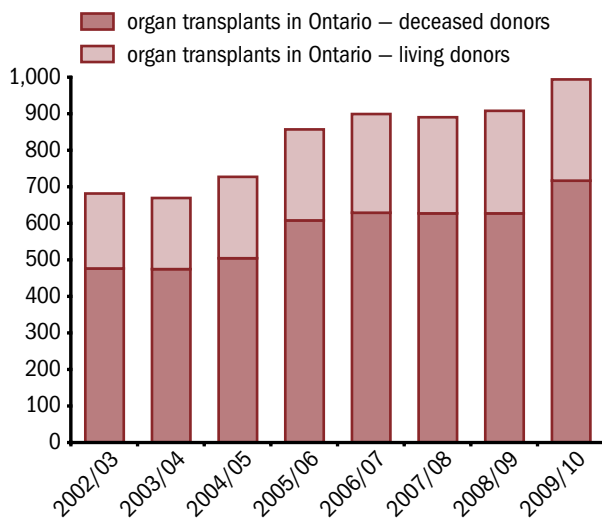
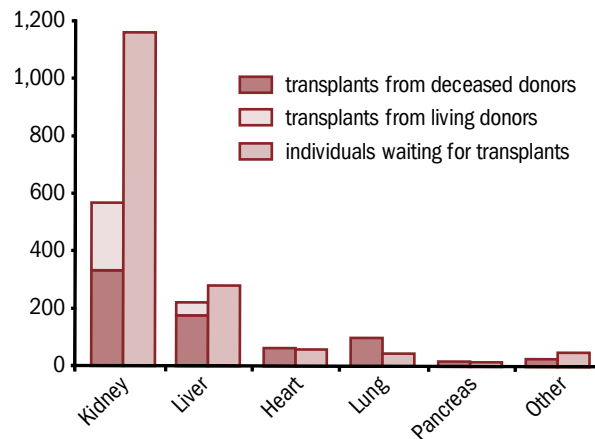


Figure 2: Number of Transplants, 2009/10, and Number of People Waiting, as of March 31, 2010

Source of data: Trillium Gift of Life Network



Network, which began operations in 2002 and is an agency of the Ministry of Health and Long-Term Care (Ministry), has a staff of about 100.

As well as enhancing lives, organ transplants can also save money. For example, although each kidney transplant surgery costs hospitals about \$25,000, dialysis costs approximately \$70,000 annually per patient. Ministry funding to the Network and transplant hospitals for co-ordinating and conducting transplants in the 2009/10 fiscal year was approximately \$100 million. The majority of this funding went to the eight hospitals that perform transplants, to help cover patient care associated with transplant surgery; hospitals use general ministry funding to cover any additional costs. The two hospitals we visited estimated that their total annual transplant program costs were about \$11 million and \$50 million, respectively. These costs exclude most physicians' services, such as surgeons' services, that are provided to hospital patients and paid for by the Ministry to physicians through the Ontario Health Insurance Plan (OHIP). The Network received \$19 million, of which \$1.6 million was paid primarily to the 21 donor hospitals to help with the costs of managing organ donors, such as operating-room costs for organ retrieval.

Ontario's six tissue banks, which are run by various institutions (primarily hospitals) to store tissue, do not receive specific ministry funding, although hospitals may use their general ministry funding to cover associated costs. Because each hospital purchases its own tissue, no provincial total for spending on tissue was available.

Audit Objective and Scope

Our audit objective was to assess whether there are adequate policies, procedures, and systems in place, including at the Trillium Gift of Life Network, to meet the organ and tissue needs of Ontarians in an efficient and fair manner. Our work did not focus on the living-donor programs in transplant hospi-

tals because the Network has limited involvement in living-donor transplants and because deceased-donor transplants are the most common type of transplant.

Our audit work was largely conducted at the Network, with visits to two transplant hospitals: the University Health Network in Toronto and the London Health Sciences Centre in London. In conducting our audit, we reviewed relevant files, systems, and administrative policies and procedures; interviewed Network, hospital, and ministry staff; and reviewed relevant research obtained from organ procurement organizations in Canadian and other jurisdictions. As well, we spoke with physicians from other transplant and donor hospitals, and with two of the tissue banks, in addition to representatives from Canadian Blood Services and from the Ministry's Organ and Tissue Transplantation Wait Times Expert Panel. We also reviewed data on transplants from the OHIP system and from the Discharge Abstract Database maintained by the Canadian Institute for Health Information. As well, we engaged independent consultants, with expert knowledge of organ and tissue donation and transplantation, to assist us.

We did not rely on the Ministry's internal audit service team to reduce the extent of our audit work, because it had not conducted any recent audit work on organ or tissue donation and transplantation. The Network does not have an internal audit function.

Summary

The establishment of the Trillium Gift of Life Network (Network) in 2002 has enhanced the province's ability to meet organ and tissue transplant needs. The Ministry and hospitals have also instituted initiatives that contributed to this enhancement. For instance, the photo health-card application process specifically asks whether the person consents to organ donation, and 27% of

people with a photo health card have made this declaration. As well, in 2009/2010, the first full fiscal year the Network had access to the Ministry's consent registry, the number of deceased organ donors reached record levels, increasing 20% over the previous year. Further, since the Network's establishment in 2002, the number of deceased donors per million people has increased from 11.3 to 16.7 donors in 2009, as shown in Figure 3.

On the other hand, we believe that certain changes could be made that, over time, could help reduce wait times for organs. Doing so would not only save lives, but also improve the quality of life for hundreds of Ontarians. For instance, there are 40 hospitals that do not routinely inform the Network when there are potential donors, even though these hospitals have the necessary medical technology to maintain organs for transplant. As well, until August 2010, many Ontarians signed the donation consent card that came with their driver's licence renewal package and kept the card in their wallet. However, signing this card was almost meaningless, because hospitals did not go into patients' personal effects to see if they had signed it. Further, this type of consent was not included in the Ministry's consent registry, which is what the Network uses to determine whether a potential organ donor has previously consented to organ and/or tissue donation.

Many people wait years for a transplant; others die while waiting. However, we noted that kidneys and livers were not always allocated to the highest-priority patient, owing to hospital concerns about decreasing the number of organ donors if organs did not remain in the same region of the province as the donor. Further, there was a lack of oversight

of organ and tissue transplantation activities in Ontario, which is needed to ensure compliance with best-practice standards, such as ensuring that patients are consistently prioritized on the wait-list, that the highest-priority patient receives the first compatible organ available, and that hospitals performing transplants are proficient at doing so.

Some of our other more significant observations include the following:

- There was a lack of consistent clinical criteria on when hospitals should refer potential donors to the Network, resulting in many referrals that were either made too late or just not done. One hospital that already did a number of transplants each year doubled its number of organ donors after implementing such clinical criteria.
- Since 2006, the Network and the transplant and donor hospitals have facilitated organ donation after cardiac death (previously done only when there was a formal determination of brain death), thus increasing the pool of potential donors.
- Only 15,000 of the 4 million Ontarians who still have red-and-white health cards had registered their consent to donate organs and/or tissue, partly because doing so requires sending a form to ServiceOntario (a process they may not be aware of) or waiting until they obtain a photo health card. In contrast, 1.9 million (or 27% of) people with photo health cards had registered their consent. Consent registration rates also vary significantly across the province, from a low of

Figure 3: Number of Deceased Donors per Million People, by Region and Canada-wide, 2002–2009

Source of data: 2002–2008 Canadian Institute for Health Information; 2009 estimated by Trillium Gift of Life Network

	2002	2003	2004	2005	2006	2007	2008	2009
Atlantic	16.8	15.0	10.9	17.2	18.7	15.1	15.5	14.1
Ontario	11.3	11.6	12.3	11.8	13.6	15.5	13.7	16.7
Quebec	16.9	19.0	18.2	18.6	18.3	18.4	19.6	17.6
West	11.5	11.2	10.8	9.5	11.4	11.8	12.6	9.4
Canada-wide	13.0	13.4	13.1	13.0	14.3	14.9	14.7	14.4

under 10% in Toronto to a high of over 40% in Sudbury.

- Hospitals indicated that eligible patients requiring a new organ were not always referred for transplantation. For example, the Canadian Society of Transplantation notes that patients with end-stage kidney disease should generally be considered for kidney transplantation, and that a kidney transplant provides a higher quality of life, can increase life expectancy, and is less expensive than dialysis; but of those Ontarians on dialysis (almost all of whom have end-stage kidney disease), only 13% were on a kidney wait-list. Further, this percentage varied from a low of only 3% in the South East LHIN to a high of 16% in the Champlain LHIN.
- There are no target maximum wait times for organ transplants, as recommended by the 2009 Organ and Tissue Transplantation Wait Times Expert Panel, and wait times by organ type were generally not publicly available. The Network indicated that individual kidney patients are generally not given high-priority status for transplants, because dialysis is a life-sustaining alternative. Although little Canadian research exists, a U.K. study found that the remaining life expectancy of dialysis patients on a kidney transplant wait-list was tripled by a successful transplant.
- Wait times for some organs varied significantly, depending on where in Ontario the patient lives. For example, in 2009/10, 90% of kidney recipients received a kidney within four years in one region, compared to about nine years in two other regions.
- There is no periodic independent review of the Network's allocation of organs to recipients. In over 40% of the cases we reviewed, organs were not allocated to the highest-priority person, and no documentation was kept to explain why. Further, transplant hospitals generally cannot identify organ misallocations, because they cannot determine where their patients stand on the wait-lists. (This restriction also prevents the hospitals from giving patients a rough idea of their wait-list position.)
- Transplant hospitals do not have electronic access to donor information, such as medical history and laboratory results, needed to determine an organ's viability for their patient. And because such decisions need to be made quickly, they generally rely on the Network to verbally communicate this information, increasing the risk that decisions may be made using incomplete or inaccurate information.
- Less than 8% of Ontario's tissue needs were met with Ontario tissue, due to a lack of resources to recover, process, and store it, which resulted in hospitals purchasing tissue elsewhere (often from the United States and Quebec). Neither the Network nor the Ministry had current information on the costs being incurred to purchase tissue, the capacity for processing and storing tissue in Ontario, or the extent of the unmet demand for tissue.
- Unlike the United States, Ontario does not require transplant hospitals or surgeons to demonstrate proficiency through a minimum number of yearly organ transplants and a minimum survival rate for recipients. One Ontario hospital performed only six transplants in the 2009/10 fiscal year, whereas the U.S. minimum requirement is generally 10 per year for a hospital to be approved to do transplants.

OVERALL NETWORK RESPONSE

The Trillium Gift of Life Network (Network), Ontario's organ and tissue donation organization, is responsible for all aspects of organ and tissue donation in the province of Ontario. Between its establishment in 2002 and 2009, the Network has led an increase in deceased organ donors within the province of 59%, a record which exceeds other Canadian jurisdictions and which the Network believes also exceeds

many American jurisdictions. With respect to tissue donation for research, teaching, and transplantation, the Network has led a 61% increase in donors in the last two years.

Yet, the Network would be the first to acknowledge how much more can be done to increase both organ and tissue donation in Ontario. For that reason, the Network welcomes the recommendations of the Auditor General, as we believe that their implementation will further strengthen our efforts. The Network is committed to implementing the Auditor General's recommendations in the coming years.

OVERALL MINISTRY RESPONSE

The Ministry of Health and Long-Term Care (Ministry) supports the findings and recommendations outlined by the Office of the Auditor General and can confirm that the key directions are being implemented.

In 2007, the Ministry announced the Organ Donation Strategy and, in 2009, established the Organ and Tissue Transplantation Wait Times Expert Panel, which submitted its report with recommendations in June 2009. In implementing the Organ Donation Strategy and responding to recommendations from the Expert Panel, the Ministry, in partnership with the Trillium Gift of Life Network (Network) and with the assistance of ServiceOntario and other ministries, has implemented a number of systemic enhancements aimed at improving the identification of potential donors, consent rates, and registration, and the availability of organs and tissue for donation. It is important to note that the number of completed transplants has grown by 11% between the 2006/07 and 2009/10 fiscal years.

The Ministry acted quickly on the Expert Panel's recommendations by establishing the Transplant Action Team comprising representatives of the transplant community, the Network, and the Ministry. The team is developing a new

model of patient care for organ and tissue donation and transplantation that will incorporate many of the recommendations. The Ministry will continue to move forward with implementation of the recommendations of the Auditor General and others, and is fully committed to improvements that will lead to more transplants for Ontarians, including improving processes related to the identification of organ and tissue donors, consent to donation, and the delivery of care to individuals both giving and receiving organs, and their families.

Detailed Audit Observations

THE DONATION PROCESS

People can have their consent to donate organs and/or tissue after they die recorded on the consent registry maintained by the Ministry when they obtain or renew their photo health card with ServiceOntario. (ServiceOntario provides access to Ontario government information and services.) If the person consents, his or her new health card indicates "donor" on the back. For people who still have a red-and-white health card, or those not wishing to wait for their photo health card to be renewed, consent can also be recorded on the Ministry's registry by completing a form and mailing it to ServiceOntario. If people have the red-and-white health-card, a sticker indicating "donor" is sent to them to put on the back of their card, while photo health-card holders will receive an updated card. Until August 2010 many other people signed the consent card that came with their driver's licence renewal and may continue to keep the card in their wallet. However, people who have only signed this card are typically not aware of the need to also fill out the consent registry form and submit it to ServiceOntario, and therefore are not included on the Ministry's consent registry (which is generally

the only source the Network uses to determine whether a person has consented to donate organs and/or tissue). Further, even if potential donors had their wallet with them when admitted to hospital, personal belongings such as wallets are often brought home by a family member. Therefore, hospital staff generally do not have access to any consent card that may be in a person's wallet when the decision to donate organs and/or tissue is being considered.

According to the *Trillium Gift of Life Network Act*, the Network must be notified of the death or imminent death of patients at all hospitals that have mechanical ventilators unless the Network specifies otherwise. Mechanical ventilators provide life support by maintaining a potential donor's breathing, enabling the donor's organs to receive oxygen and therefore preserving their viability until transplantation can be arranged. In practice, although 61 Ontario hospitals have the appropriate type of ventilator, the Network requires only 21 hospitals to report data on ventilated patients whose death is imminent or who have just died. Once such a report is received, Network staff on-site at the hospital, in conjunction with the hospital and with staff at the Network's head office, determine the patient's suitability for organ or tissue donation. This process generally involves determining which of the potential donor's organs are likely to be viable for transplant, with input from the Network's medical advisers if needed.

If there are viable organs, the Network contacts the Ministry, which has someone available around the clock to determine whether the patient had registered on the Ministry's consent registry. Regardless of whether the patient had registered or not, a Network staff person or a health-care practitioner (such as a doctor or nurse) at the hospital asks the next of kin to consent to donating the patient's organs and/or tissue. This person also lets the next of kin know whether or not the patient's consent was on the Ministry's registry.

If consent for donation is received, the Network generally identifies the next potential recipient on

the wait-list for each organ, and offers each organ to that patient's transplant hospital. If an organ is rejected (for example, because it is an inappropriate size for the patient), the Network contacts the transplant hospital where the next potential recipient on the wait-list would receive his or her transplant.

Once the organ is accepted, the transplant hospital generally sends a physician to recover the organ. The Network may make administrative arrangements for the recovery and transplantation of the organ, such as arranging to transport the organ and working with both the donor and recipient hospitals to schedule operating-room time. As well, for tissue donations, Network staff may arrange for the tissue's recovery and transfer to the appropriate tissue bank.

INITIATIVES

Since 2002, the Ministry and the Network have commenced various initiatives to increase organ and tissue donation and improve the transplantation process.

Ministry initiatives include:

- The 2007 report by the Citizens Panel on Increasing Organ Donation: This report, which reflected the views and opinions of Ontarians, made observations about ways to increase organ donation rates.
- The 2009 report by the Organ and Tissue Transplantation Wait Times Expert Panel: This report included recommendations related to increasing the number of organ and tissue donors and ensuring equitable access to organs and tissue based on clinical evidence. Subsequently, a Transplant Action Team was established to address the recommendations and work toward a provincially integrated system for donation and transplantation in Ontario.
- Assistance for living donors: In 2008, a program was implemented to reimburse expenses (such as travel costs and lost wages) incurred by living donors, with a view to increasing

the number of these individuals. Moreover, in 2009, job protection was legislated for people who take time off work to donate an organ to another person.

Network initiatives include:

- staffing 21 hospitals with medically knowledgeable individuals who manage potential organ donors, review records to identify potential donors who were missed, and provide education to hospital staff to help improve donation rates;
- facilitating, in conjunction with the donor and transplant hospitals, donation for patients after cardiac death (whereas previously, donation was done only after a formal determination of brain death), thereby increasing the pool of potential donors; and
- engaging community groups and religious leaders to raise awareness of the benefits of organ donation.

Further, individual hospitals have engaged in various projects aimed at raising local awareness of the benefits of organ donation and transplantation—for example, organizing donor-family appreciation events and initiating educational tools for use in the school system.

ORGANS

Identifying and Referring Donors

Organ Donor Hospitals

To assist in identifying potential donors, under the *Trillium Gift of Life Network Act*, the Network can require two types of hospitals to notify it as soon as possible when a patient dies or the physician is of the opinion that the patient's death is imminent:

- hospitals that provide neurosurgical or trauma services, because these hospitals have ventilators and because individuals who sustain a fatal head injury or other major trauma are often candidates for organ donation; and
- hospitals that are able to make a neurological determination of death (that is, brain death),

which is completed by conducting an assessment while the patient is on a ventilator.

As of January 2007, the Network required 21 hospitals with advanced ventilator capacity (that is, hospitals that can provide prolonged support for breathing or support for more than one organ) to report deaths or imminent deaths in their intensive-care units or emergency departments. The Network indicated that, given limited resources, it had decided to focus its efforts on these 21 hospitals, which are referred to as Tier 1 hospitals. In the 2008/09 fiscal year, these hospitals accounted for almost 90% of all organ donors in Ontario. Other hospitals can report if they choose to do so.

Because ventilated patients who are dying are the people most likely to become organ donors, one indicator of a hospital's organ donor potential is the number of patients who die while on a ventilator. We noted that 61 Ontario hospitals have advanced ventilator capacity, including the 21 Tier 1 hospitals. Using data provided by the Ministry of Health and Long-Term Care (Ministry), we reviewed the number of ventilated deaths (that is, patients who were on a ventilator at the time of their death) in the intensive-care units and emergency departments at the 40 hospitals that were not required to report to the Network. Overall, we noted that 40% of ventilated deaths province-wide occurred in the intensive-care units and emergency departments of those 40 hospitals. However, at the time of our audit, these hospitals referred to the Network only about 2% of patients who died while on a ventilator. Further, these hospitals may have additional potential donors, because we did not review deaths that occurred after patients were taken off a ventilator. Requiring these hospitals to report deaths and imminent deaths of ventilated patients to the Network, as is required of the 21 Tier 1 hospitals, might help address the long wait-lists for some organs, especially kidneys and livers (as shown in Figure 2).

The 2009 report of the Ministry's Organ and Tissue Transplantation Wait Times Expert Panel (Expert Panel) recommended that these 40 hospitals be required to notify the Network about

potential organ donors. A similar recommendation requiring more hospitals to refer potential donors was also made by Premier Harris's Advisory Board on Organ and Tissue Donation in its 2000 report.

We noted that, in September 2008, the Network submitted its 2009/10 Business Plan to the Ministry, in which it indicated that it planned to increase the number of hospitals required to report deaths or imminent deaths to the Network. Further, in 2009, in an effort to increase organ donations, the Network assessed the donation potential of three of these 40 hospitals, based on their prior referral history. However, at the time of our audit, the Network had not finalized its assessment of the three hospitals or decided whether any of the 40 hospitals would be required to report potential donors to the Network in the future.

Identifying Potential Donors

In Ontario, there are two types of deceased organ donors: donors for whom a neurological determination of death (NDD, or brain death) has been made, and donors who donate after cardiac death (DCD, or heart death). To help identify all potential organ donors for referral to the Network, hospitals may establish criteria, called clinical triggers, for staff to use in determining which patients may be potential organ donors. Such criteria may include the patient having low neurological activity, such as a score of five or less on the Glasgow Coma Scale; the patient being intubated (that is, having a tube inserted down the windpipe to facilitate breathing); the patient being ventilated (attached to a machine that assists with breathing); and the physician having had an end-of-life discussion with family and/or with other health-care providers.

In 2006, the Network noted that when clinical triggers were implemented at one large Ontario hospital that already did a number of transplants each year, the number of organ donors from this hospital doubled in comparison to the previous year. Further, the Expert Panel recommended that all Ontario hospitals with advanced ventilator

capabilities adopt standard clinical trigger policies for NDD and DCD cases. One of the hospitals we visited supported the use of standardized clinical triggers in all Tier 1 hospitals; the other indicated that it had not formalized clinical triggers, and thought these should be left to the clinical experts at each hospital. We also noted that Australia was implementing standardized clinical triggers for all intensive-care units and emergency departments in early 2010.

One challenge, particularly at hospitals in remote locations, is insufficient expertise to evaluate whether an individual is a potential organ donor. Therefore, the Expert Panel recommended that CritiCall and the Emergency Neurosurgery Image Transfer System be used to assist in identifying potential donors. CritiCall is a 24-hour medical emergency referral service that Ontario's hospital-based physicians can call when a critically ill patient requires an assessment and/or transfer to a more specialized facility. The Emergency Neurosurgery Image Transfer System enables computed tomography (CT) images, which physicians can use to declare brain death, to be viewed by neurosurgeons anywhere in the province. At the time of our audit, the Ministry's Transplant Action Team, responsible for reviewing and implementing the recommendations made by the Expert Panel, was reviewing this recommendation.

Donation after Neurological Death

People who have no brain activity and who are on a ventilator to maintain breathing are potential NDD donors. According to the Network's data, three of the 21 Tier 1 hospitals had not developed clinical triggers for helping staff identify potential NDD donors.

For the other 18, we noted differences in the clinical triggers used. For example, they used different referral cut-off levels, as measured by the Glasgow Coma Scale. Further, the hospitals' policies did not clarify whether all or only one of the clinical triggers needs to be met; nor did they clarify whether an end-of-life discussion should

be planned, actually held among health-care team members, or held between the family and the health-care team prior to referral. The absence of clear clinical triggers may result in missed referrals by hospital staff, particularly less experienced staff.

We were informed that the Network has not developed standardized NDD clinical triggers for all Tier 1 hospitals to use because hospitals that have physicians who are experienced with organ donation generally prefer less guidance than other hospitals, and physicians prefer to establish their own clinical triggers and use their own judgment.

Donation after Cardiac Death

Europe and the United States have been completing transplants with organs from DCD donors for over 30 years. A family's decision about DCD donation is made after a physician has determined that the patient will not recover. However, DCD is still considered controversial in some parts of Canada because life-sustaining therapies (such as a ventilator) have to be removed in order for the potential organ donor to die, rather than the potential donor being brain-dead before life-sustaining therapies are removed. Further, in some cases, life-sustaining therapies have to be introduced to prevent the potential DCD donor from dying before organ transplantation can be arranged. Only four provinces in Canada transplant organs from DCD donors; Ontario performed its first DCD donor transplant in 2006.

In order to be an organ donor, potential DCD donors generally must die within two hours after the withdrawal of life-sustaining therapies, because the lack of life support reduces oxygen to the organs and therefore reduces the organs' viability. To further ensure that the organs can be used, arrangements to transplant each organ must be in place before life support is withdrawn. For that reason, individuals who die from an unanticipated heart attack are generally not good organ donors. Therefore, in Ontario, the only cases considered for DCD donation occur when the patient is dependent on life-sustaining therapies and the family consents

to the withdrawal of these therapies at a time that coincides with the time organ transplantation can be arranged.

In 2006, the Canadian Council for Donation and Transplantation (a federal/provincial organization that co-ordinated discussions on donation and transplantation among various stakeholders, such as governments and organ procurement agencies, before its operations were transferred to Canadian Blood Services in April 2008) released national recommendations for DCD, including a recommendation that the "option of organ and tissue donation should be routinely provided to all potential donors and families." The 2007 Citizens Panel on Increasing Organ Donation recommended that every hospital in Ontario that refers donors should institute DCD policies consistent with these national recommendations. Although the Network's legislation enables it to require all 21 Tier 1 hospitals to comply with the national recommendations, the Network has not required these hospitals to adopt DCD policies; rather, it has encouraged them to do so and has forwarded examples for their consideration. However, at the time of our audit, almost 25% of the Tier 1 hospitals did not have a DCD policy in place. Further, two hospitals generally do not support DCD donation unless the donor's family specifically requests it. We also noted that the DCD policy at another of the hospitals was much more restrictive than the national recommendations. The 2009 report of the Organ and Tissue Transplantation Wait Times Expert Panel observed that a number of panel members "believe that opportunities for [DCD] are being missed due to lack of knowledge and clinical triggers for DCD in teaching and community hospitals."

Referring Potential Donors to the Network

When a hospital staff person identifies a potential donor, he or she is to call the Network. The Network has staff available 24 hours a day, seven days a week. Patients not on a ventilator may be considered for tissue donation, as discussed in

more detail later in this report. If the patient is on a ventilator, the Network obtains information to determine the person's suitability for organ donation. For example, the Network determines whether the individual has an infection that would prohibit donation. As well, the Network determines whether one of the co-ordinators on-site at the 21 Tier 1 hospitals should become involved.

Missed Referrals

At the 21 Tier 1 hospitals, only 12% of patients who had been on a ventilator and subsequently died were referred in the 2008/09 fiscal year. Although there was insufficient information available to explain why this rate was so low, we were informed that it could be a result of various factors. For example, various studies have indicated that physicians' lack of familiarity with the organ donation process may contribute to low referral rates. In other situations, no call is made to the Network because there would not be time to arrange for transplantation. Another reason, which was identified by the Expert Panel, could be that the \$6,000 in funding that hospitals receive to manage each donor through the donation process (from consent to organ recovery) may not cover all their costs.

The Network's hospital co-ordinators on-site at the 21 Tier 1 hospitals are generally nurses with an intensive-care background. These co-ordinators review the health records of every patient who dies in the intensive-care units and emergency departments of the 21 hospitals to identify, among other things, any potential NDD organ donors who were not referred to the Network. Potential DCD donors are not identified. Approximately 50 to 60 cases per month are reviewed. The results of these reviews are summarized monthly and annually for each hospital in a report, and forwarded to the hospitals for their information. According to the 2008/09 performance report, in cases where a formal determination of brain death had been made, virtually all were referred to the Network. However, a formal determination is not made for all brain-dead patients, and therefore these patients may not be referred to

the Network. Clinical triggers may assist hospitals in referring all potential donors, even if there has not been a formal determination of brain death.

Late Referrals

Network staff indicated that they generally need eight hours to arrange for organ donation, including screening potential donors to ensure that they are medically suitable, obtaining consent, and allocating the organs. To maintain the viability of the potential donors' organs, the potential donors need to be kept on life support during this time. A patient who is referred to the Network less than one hour before the withdrawal of life support is informally defined by the Network as a late referral, because one hour usually does not allow sufficient time to arrange for an organ transplant.

The Network gathers information on late referrals for both NDD and DCD donors, but generally does not analyze this information. Our analysis for April 1, 2009, through January 31, 2010, indicated that almost 200 cases were referred only after the patient's death, which is too late to allow for the organ donation process. With respect to DCD cases, the Network conducted a separate study for the 2008/09 fiscal year and found that 48% were not referred at least one hour before the withdrawal of life support.

The Network indicated that one reason for late DCD referrals is the practice of calling the Network after the health-care practitioners have discussed a plan for the withdrawal of life support with the patient's family. We noted that another Canadian province's policy is to refer DCD cases to the organization that co-ordinates organ donations for that province (the Network's equivalent) before such a discussion occurs. Because the timing of this other province's practice equates to reporting imminent death, which is one of the requirements in the *Trillium Gift of Life Network Act*, it is our view that the Network has the authority to require a similar reporting practice in Ontario. The Network informed us that hospitals determine when to refer the patient to the Network (that is, whether to refer

before or after informing the next of kin that a family member will not recover).

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.

NETWORK RESPONSE

Consistent with its 2009/10 fiscal year Business Plan and the recommendation of the Organ and Tissue Transplantation Wait Times Expert Panel, the Network is working with the Transplant

Action Team to implement the recommendation regarding more hospitals being required to report potential donors to the Network.

The Network's approach is to provide hospitals with a template to guide the development of their policies, procedures, and referral criteria. This approach is consistent with the best practice from the U.S. Organ Donation and Transplantation Breakthrough Collaboratives, which in 2009 indicated that clinical triggers should be mutually agreed on by both the hospital and the organ, procurement organization. Now, with five years' experience in this area, the Network believes there is an opportunity to work with hospitals to ensure a higher level of consistency. The recommendation of the Organ and Tissue Transplantation Wait Times Expert Panel is to move toward standard policies for all Ontario hospitals and, accordingly, the Network will work with members of the Transplant Action Team and its hospital partners to assess how to best move toward a more consistent practice across the province.

The Network has identified the impact that provincial systems, such as CritiCall and the Emergency Neurosurgery Image Transfer System (ENITS), can have on the referral patterns of potential donors. The Network believes that CritiCall, in particular, can be a useful vehicle for prompting referrals, and looks forward to working with the Ministry and the Transplant Action Team to determine how best to leverage these and other systems.

In 2002, the Ministry, in consultation with the Network, developed a reimbursement model to compensate hospitals for the direct costs associated with supporting an organ and tissue donor. This model does not compensate physicians for their work in donation. The Network supports a review and update of this model and, where necessary, the development of new approaches for reimbursement, including to physicians.

MINISTRY RESPONSE

The Ministry agrees with the need to continue to increase the number of organs available to individuals waiting for transplants. In this regard, the Transplant Action Team has proposed a new model of care that will enhance communication with all hospitals; develop and disseminate standardized criteria to assist clinicians in determining when to notify the Network of potential donors; and provide education and support to smaller hospitals around the issue of donation. Further, the use of CritiCall and ENITS as tools to facilitate the exchange of information between clinicians will be explored by the Transplant Action Team.

The Ministry will also review the current hospital reimbursement model for organ and tissue donation with the Network and will consult with the Ontario Medical Association regarding physician compensation as part of payment discussions related to the Ministry's 2011 investment funding under the 2008 Physician Services Agreement.

Consent

Under the *Trillium Gift of Life Network Act*, people at least 16 years of age may consent to donate their organs and tissue when they die, and can have their consent documented on a consent registry maintained by the Ministry. Consent decisions involving younger donors are not registered but can be made by these donors' next of kin or legal guardians should the opportunity for donation arise.

Increasing Awareness

The Network and transplant hospitals have developed a number of initiatives aimed at encouraging people to register their consent to donate organs and tissue. For example, the Network conducts various advertising campaigns, has a Face-

book page, and has a Religious Outreach Strategy to work with religious leaders to educate people about organ donation. As another example, one transplant hospital, in conjunction with the Kidney Foundation of Canada and the Network, developed a program called "*One Life...Many Gifts*," which was being taught in some high schools to increase awareness of organ donation and transplantation, and provide people with an opportunity to register their consent. Further, the Network holds events for families of donors, and transplant hospitals also hold events, for example, for families of donors and transplant recipients, to recognize the difference that the donated organs have made in the recipients' lives.

As of December 31, 2009, only 17% of Ontarians aged 16 and older were registered donors, compared to about 30% of the population 16 and over in the United Kingdom, and 37% of the population 18 and over in the United States. (Other Canadian provinces with a registry that we contacted do not track information in a comparable manner.) Further, the Network noted that rates of consent to donate vary considerably across the province. For example, as of December 31, 2009, less than 10% of those in Toronto aged 16 and older had registered their consent to donate, compared to over 40% in Sudbury. Furthermore, according to the Network, actual organ donation rates in 2009 varied across the province, from a low of about 8 donors per million people in Kingston to a high of over 21 donors per million people in Hamilton and London, with Toronto having about 16 donors per million people. Moreover, although Ontario's overall rate of donors per million people has improved—from 11.3 in 2002 to 16.7 in 2009—Ontario's rate has remained consistently lower than Quebec's rate (as shown in Figure 3). The Network indicated that a new advertising campaign was to be launched in 2011 to increase awareness in areas of Ontario with lower rates of registered consent, such as Toronto.

Registering Consent

As of December 2009, 27% of people with a photo health card, or 1.9 million people, had had their consent recorded on the Ministry's consent registry. However, only 15,000 (or less than 1%) of the 4 million people who still have red-and-white health cards had registered consent. And as noted in our *2008 Annual Report*, based on the conversion rate at that time, red-and-white cards will not all be converted to photo health cards until 2016.

As an alternative way to register, a consultant's report commissioned by the Network in 2006 noted that a best practice is to enable individuals to register on-line with an electronic signature, similar to the approach used in British Columbia. In 2008, the Network proposed such an on-line registry to the Ministry. Further, in 2009, the Expert Panel also recommended that the Ministry support the implementation of on-line registration.

The Ministry and the Network encourage people to let their family know about their organ donation wishes. Historically, many Ontarians indicated their consent to be an organ donor by carrying a signed organ-donor card in their wallet. At the time of our audit, the driver's licence renewal notification still included a paper card that individuals could sign to consent to organ donation. Most people probably believe that signing and carrying this card is sufficient to make their organ donation wishes known. Although the Ministry conducted some advertising in December 2008 to advise the public of the registry, it did not mention that people who just sign the donor consent card sent with their driver's licence renewal are not on the Ministry's registry. (The Ministry's registry is generally the only source that the Network refers to in order to see whether a person has consented to organ donation.) A 2009 on-line survey commissioned by the Network found that 20% of respondents mistakenly believed they were registered on the Ministry's system when they were not, and we suspect that this was due to a misunderstanding about the donor consent card sent with the driver's licence renewal.

As well, even if potential donors had their wallet with them when admitted to hospital, it is rarely still with the patient at the time organ donation is being considered. Consequently, if the person is not on the Ministry's registry, staff will not know that the patient had consented to be an organ donor. In 2008, the Network proposed to the Ministry of Health and Long-Term Care that the Ministry of Transportation be asked to change what it includes in the driver's licence mailings. Instead of the paper organ-donor card, the Network wanted the mailings to contain the consent form for registering as an organ and tissue donor, along with a postage-paid return envelope addressed to ServiceOntario (who in turn enter the person's consent on the Ministry's registry). This initiative had not, at the time of our audit fieldwork, been implemented, but we were informed by both ServiceOntario and the Ministry of Transportation that as of August 23, 2010, a donor consent form was being sent with driver's licences, and donor cards were no longer being mailed out. However, unlike the health-card renewal, the driver's licence renewal process does not specifically require people to answer a question on whether they consent to being an organ donor. In 2010, the U.S. Donate Life America report, which includes a summary of information from donor registries across the United States, noted that requiring individuals to answer a question on consent as part of their driver's licence renewal process is part of effective donor registry design.

Obtaining Consent for Organ Donation

The *Trillium Gift of Life Network Act* specifies that upon the death of a person who has given consent, consent is binding and is full authority for the use of the body or specified parts for transplant purposes, except when there is reason to believe that consent was withdrawn before death. If consent was not previously given, the deceased individual's next of kin may consent on the individual's behalf. Therefore, once a potential organ donor has been identified, the Network calls the Ministry to

determine whether the person has registered his or her consent to donate. In response, the Ministry verbally indicates and forwards the individual's consent status (either "yes" or blank) from the registry. (One of the hospitals we visited indicated that it would be advantageous for health-care practitioners to obtain this information directly rather than waiting for the information to come from the Network.) The potential donor's next of kin is then approached about organ donation, generally by Network staff at the 21 hospitals required to report potential donors or, in some cases, by other health-care practitioners at the hospital.

Authorization is not legally required from the next of kin of a person who has registered his or her consent to donate. But in practice, the next of kin are almost always asked to sign a donation consent form, regardless of whether the potential donor has registered his or her consent. The 2007 Citizens Panel on Increasing Organ Donation, commissioned by the Ministry of Health and Long-Term Care, recommended that the legislation be amended to require tangible proof that the potential donor had withdrawn his or her consent, to reduce situations in which the family overrides the deceased person's decision to donate. However, according to the Network, consent is much more likely to be obtained from the family when the potential donor has registered consent. In fact, the Network indicated that in the 2009/10 fiscal year, the family of a potential organ donor consented 89% of the time when consent was registered, compared to 52% when consent was not registered. Further, although there could be additional reasons, in 2009/10, the first full fiscal year that the Network had access to the Ministry's registry, the number of deceased organ donors reached record levels, increasing 20% over the previous year.

We were informed that all families were initially approached in a similar manner, regardless of whether the person had registered consent. However, in fall 2009, the Network initiated a new method of requesting consent in cases where the donor's consent was registered with the Ministry.

In these cases, the family was informed of the registered consent and given the consent form with the understanding that they were merely confirming the donor's consent. We were informed that in these situations very few families decided to refuse consent.

Although some health-care practitioners are very successful at obtaining consent, the Network believes that its staff are more successful than most health-care practitioners because of their training in requesting consent. Therefore, in 2006, the Network asked the 21 hospitals that are required to report potential donors to allow only Network staff to approach a potential donor's next of kin for consent. However, the Network has never compared the consent success rate obtained when next of kin are approached by health-care practitioners versus Network staff versus both collaboratively, although some U.S. studies and one of the hospitals we visited suggested that a collaborative approach is most successful. The Network has also never tracked the relative success of individual health-care practitioners or Network staff persons. Consequently, the Network has not determined who is most effective at obtaining consent or who has lower-than-normal consent rates and may require further training.

In some cases, no one approaches the next of kin about donation, especially for potential DCD cases since health-care practitioners may have little experience in identifying these patients and referring them to the Network. The Network found that in the 2008/09 fiscal year, the next of kin were not approached for 64% of potential DCD cases.

According to a 2009 information document from the Canadian Parliamentary Information and Research Service, "[s]urveys of health care professionals have revealed a high degree of reluctance to approach the families of potential donors and a low level of knowledge about organ referral." To avoid cases where a family is not approached, one Ontario hospital informed us that it was considering implementing a "mandatory ask" policy, which would require that all families of potential organ donors be asked for consent before removing life

support. A similar approach is taken in the United States, where hospitals are required, as a condition of participation in Medicare, to ensure that families of potential donors are made aware of the option to donate organs and tissues. Further, as noted by the 2000 report of Premier Harris's Advisory Board on Organ and Tissue Donation, "a decision not to provide a family with the opportunity to consider donation should be made only in very rare circumstances."

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.

NETWORK RESPONSE

The Network, in partnership with the Ministry, ServiceOntario, and the Ministry of Transportation, has now replaced the donor card in the driver's licence mailings with the organ and tissue donor registration form and a message about the importance of donor registration. In fall 2010, a prepaid return envelope was to be added. Further, the Network would welcome the expansion of the "required request" policy beyond health-card transactions, so that all Ontarians aged 16 and older would be asked about registering their consent to donate during appropriate in-person transactions occurring at ServiceOntario centres, starting with driver- and vehicle-related transactions. This approach would help broaden public access to donor registration opportunities and thereby help increase donor registration in Ontario.

Literature indicates that the most effective way to increase consent for donation is to use people who are trained in approaching families. The Network provides extensive training to its staff in having these difficult conversations with families, and has ongoing training three times a year. In exploring how to best work with more hospitals across the province, the Network is considering, and will be working with the Transplant Action Team to determine, the cost-benefit of keeping hospital staff and physicians trained to approach families for consent. The Network will work to test and evaluate the effectiveness of these approaches.

With respect to considering a "mandatory ask" policy, the Network's position is that families of all potential donors referred to the Network should be presented with the opportunity for organ and tissue donation if the donor is deemed medically suitable. We support that "required request" be part of good end-of-life care for potential donors.

The ability to register consent on-line for organ and tissue donation is best practice for

donor registries. The Network strongly supports the establishment of an on-line donor registry that is simple, easy, and convenient for the public to use.

RESPONSE FROM HOSPITALS

With respect to increasing consent rates, both of the hospitals we visited commented that they supported the involvement of trained hospital health-care practitioners in approaching patients' next of kin for consent for organ donation. In particular, one of the hospitals indicated that it had obtained a high organ-donor consent rate by having trained hospital health-care practitioners approach a patient's next of kin for consent, while the other hospital indicated that it anticipated a positive impact on consent rates by enhancing the training of its health-care practitioners.

MINISTRY RESPONSE

The Ministry concurs with the need to improve the consent rates of potential donors. Key to doing this is the implementation of systems and processes to educate and inform potential donors, their families, and clinicians about donation. Also essential is the implementation of quick and easy-to-use processes to identify potential donors and register consent. In this regard, the Transplant Action Team has proposed a model of care that would provide support and education to hospitals around a standardized approach to requesting consent, and would promote the identification of donor "champions" and the establishment of donation committees which could address issues such as low consent rates. The introduction of a "mandatory ask" policy will be considered as one potential component of a standardized approach.

With respect to simplifying the process by which people register consent to be an organ

donor, the Ministry is currently working with the Network, ServiceOntario, and the Ministry of Transportation to make improvements. These include replacing the driver's licence donor card with the organ and tissue donation consent form, and implementing a safe, secure, and easy-to-use on-line donor registration and authentication process, which has been approved and is anticipated to be in place by summer 2011.

Organ Wait-lists

Organs from a living donor, often a relative of the patient, accounted for 41% of kidney transplants and 20% of liver transplants in the 2009/10 fiscal year. Other patients must wait for an organ donated from a deceased person. All decisions regarding adding a patient to, removing a patient from, or changing a patient's status on the Network's organ wait-lists are made at the transplant hospitals, which enter this information in the Network's information system. The decision on whether or not to include a patient on an organ wait-list usually involves assessments by a multidisciplinary team of experts, with the final decision made by a medical specialist. For example, nephrologists (that is, kidney specialists) generally decide which patients should be added to the kidney wait-list. Although criteria for placing patients on organ wait-lists have been developed in Canada for most organs, no Canadian or Ontario standard criteria exist for adding most patients to the liver transplant wait-list. Where there are criteria, there is no oversight to ensure that physicians apply the criteria consistently or do not overstate how sick a patient is, to assist that patient in receiving an organ more quickly.

The Canadian Society of Transplantation (a professional organization for physicians, surgeons, scientists, and other health professionals working in the field of transplantation) has consensus guidelines on eligibility for kidney transplantation,

which the transplant hospitals we visited indicated that they generally follow. Although not all eligible patients may want a kidney transplant, these guidelines note that all patients with end-stage kidney disease should be considered for kidney transplantation provided no absolute contraindications (for example, leukemia) exist. A transplant provides patients on dialysis with an improved quality of life and can increase life expectancy. As well, the cost of a transplant is significantly less than the cost of ongoing dialysis.

However, the 2009 report of the Organ and Tissue Transplantation Wait Times Expert Panel (Expert Panel) noted that only 13% of people on dialysis in Ontario were on a kidney transplant wait-list. The report further noted that there was “some evidence to suggest that not everyone who could benefit from an organ transplant is put on an organ transplant list.” Further, the number of people on the kidney wait-list as a percentage of the total number on dialysis (almost all of whom have end-stage kidney disease) varied depending on the LHIN. For example, as of March 1, 2009, the percentage of people on dialysis who were also on a kidney transplant wait-list varied from about 3% in the South East LHIN to 16% in the Champlain LHIN. Both hospitals we visited indicated that eligible patients were not always being referred for transplantation.

When people are added to a transplant wait-list, their position on the list usually depends on how sick they are, based on a detailed set of criteria used by the Network. However, the Network’s wait-list system has very few edit checks, which help prevent obviously incorrect data from being entered, and therefore errors sometimes occur. For example, according to the wait-list, one patient had been waiting for an organ since the year 0009. Such errors can result in patients being misprioritized on the wait-list.

For the sickest individuals, transplant hospitals across Canada have agreed to maintain a national wait-list, giving these patients priority for available organs. These patients often will die within a few days if they do not receive an organ transplant. We

were informed that kidney patients are excluded from that list because dialysis is considered a life-sustaining alternative.

The national wait-list is maintained at one Ontario transplant hospital. It is a paper-based listing: transplant centres across Canada fax in the names of priority patients, and the hospital faxes back a weekly listing of all such patients across Canada. We were informed that Canadian Blood Services plans to introduce interprovincial wait-lists in 2011 for high-priority liver, heart, lung, pancreas, small-bowel, and kidney patients, which will replace the current national wait-list. Canadian Blood Services is also developing a national organ donation and transplantation strategy for review by the provinces, which is to include recommendations for one wait-list for each type of organ for most patients across Canada, and an information system to support national and provincial organ allocation.

Patients are removed from the wait-list when they receive an organ transplant. Hospitals may also remove patients from the wait-list for other reasons. Although the Network has some information on these reasons, it does not review them, because it believes that doing so is outside its mandate. Our review indicated that about 260 patients who did not receive transplants were removed from the wait-lists in the 2008/09 fiscal year. For 22% of these patients, “other” was the reason indicated for their removal. Of those with a specific reason, 52%, mostly liver patients, were removed because they died. An additional 15%, mostly kidney patients, were removed because they became too sick for a transplant, though there was no record of how many subsequently died. For the patients who died, we noted that it took an average of 32 days after their death to remove them from the wait-list, with two patients not being removed until over 500 days after death. Delays in organ allocation, which can affect organ function, could result if time must be spent trying to contact the surgeons of patients who are still on the wait-list despite having died some time previously.

For patients who received a transplant in 2009/10, Network data indicated large variances in the wait times for certain organs based on the transplant hospital that patients went to. Although some of these variances were probably a result of the regional allocation of certain organs (discussed later in this report), variations also existed for other organs. For example, 90% of heart transplant patients at one transplant hospital received their transplants within two months (50% within less than one month), compared to 22 months (50% within three months) at another transplant hospital. The Network has not analyzed these disparities, although one transplant hospital indicated that they may be due to the organ acceptance policies of the transplant hospitals (discussed later in this report, under “Allocation Review”). The Expert Panel noted similar regional variations and recommended that the Ministry’s Wait Time Information Program, part of the Wait Time Strategy, work with expert transplant clinicians to develop a provincial priority rating scale with target time frames for organ transplants. At the time of our audit, the Ministry indicated that the Transplant Action Team was reviewing the recommendations of the Expert Panel, including this recommendation.

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.

NETWORK RESPONSE

The Network supports the development and use of a priority rating scale that is consistent with its organ allocation algorithms to establish target time frames for organ transplants. In developing these time frames, it needs to be recognized that even with improved donation rates, one cannot schedule transplants due to the random pattern of donation.

The Network agrees with the importance of ensuring that physicians who provide care to patients with an organ-related disease do understand the referral criteria for patients requiring transplant assessment. The Network supports this initiative, within the limits of its mandate.

It is mandatory for hospitals to select a reason (including “other” as a valid reason) for removal of patients from the organ transplant waiting list in the Network’s clinical information database. The Network will work with transplant hospitals to review data quality issues related to recording the decision to remove patients from the transplant waiting list.

MINISTRY RESPONSE

The Ministry agrees with the need to enhance the management of organ transplant wait-lists. In this regard, the Transplant Action Team’s proposed model of care will establish provincial rating scales with target wait times for each organ, develop standardized criteria for listing patients on the wait-lists, develop pre- and post-transplant best practices, and move to a single

wait-list for each organ. The proposed model of care will link into and enhance the work that the Network and the Ministry have done in this area as noted in the Ministry's overall remarks. This will also guide the Network's and the Ministry's work in the future.

Allocation of Organs

The *Trillium Gift of Life Network Act* gives the Network responsibility for establishing and managing a system to fairly allocate organs from deceased donors. Consequently, the Network has the responsibility to determine who receives the next available organ.

In practice, when allocating organs, the Network gives the first priority to any seriously ill patient on the national wait-list. After that, Network staff follow organ allocation algorithms developed by committees consisting of physicians from transplant hospitals as well as, in some cases, Network staff. Using these algorithms generally involves the Network referring to its own wait-lists to determine which patient should receive a heart, lung, pancreas, or small bowel. In arriving at this decision, the Network considers the patient's position on the wait-list, as well as the results of tests to ensure compatibility. For example, diagnostic imaging is used to confirm that the organ is the right size, and a blood test to confirm compatible blood types. Kidneys and livers are generally allocated to the transplant hospital that is in the same region as the donor's hospital. There are five kidney regions (based out of Hamilton, Kingston, London, Ottawa, and Toronto). Since there is more than one transplant hospital in the Toronto region that performs kidney transplants, a kidney will go to the highest-priority person on that regional wait-list. However, two Toronto transplant hospitals get one kidney each if two kidneys are available from a DCD donor or certain potentially higher-risk donors. There are two liver regions, based out of London and Toronto,

which are the same as their kidney regions. All liver transplants are performed in these two regions. Livers donated from outside these regions are allocated to the liver region with the highest-priority patient.

Once a potential recipient—or, in the case of kidneys or a liver, the associated transplant hospital—is identified, the Network calls the transplant surgeon or other applicable person at the transplant hospital to offer the organ. The hospital may accept the organ, or may reject it for various reasons. For example, the organ may be rejected if the donor was over age 60 and the potential recipient is still healthy enough to wait for another organ. Each transplant hospital has its own criteria for whether or not to accept an organ.

Rejected organs are generally offered to the transplant hospital associated with the compatible patient who is next highest on the wait-list. If an organ cannot be used in Ontario, in many cases it is offered to other provinces or to the U.S. United Network for Organ Sharing.

Regional Allocation of Organs

We noted that most jurisdictions, including Quebec, British Columbia, and Manitoba, have only one wait-list for each organ. However, in Ontario, kidneys and livers are distributed on a regional basis. These regions primarily arose out of historical patterns in referrals made by physicians—for example, physicians referred their kidney patients to certain hospitals for dialysis. Under the regional allocation method, with very few exceptions, kidneys and livers are offered to a transplant hospital that is in the same region as the donor's hospital. This transplant hospital considers the organ's viability. If the hospital accepts the organ, the hospital generally chooses which of its patients will receive the organ, based on organ compatibility and the hospital's prioritizing of patients. The Network does not receive any information from two of the eight transplant hospitals on how they select which of their patients will receive a particular kidney. Further, because one

of these hospitals does not provide certain information (needed to help determine organ–patient compatibility) to the Network for about 50% of its patients, these patients cannot be allocated a kidney from a donor outside of this hospital’s region.

We noted that the transplant hospitals may prioritize liver and kidney patients somewhat differently than the Network does. For example, the transplant hospitals we visited prioritized liver patients based on specific conditions related to liver disease, whereas the Network’s liver allocation algorithm gave priority to liver patients who were in hospital rather than at home. Discussions with health-care practitioners at transplant hospitals indicated that they tried to prioritize their patients based on how sick they were.

We were informed by the transplant hospitals we visited that the main reason kidneys and livers are allocated on a regional basis is concern that in regions with a higher number of donors per capita, the number of donors would decrease if many organs were sent outside those regions. As well, transplant hospitals advised us that each transplant hospital needed to do a sufficient number of organ transplants to maintain its proficiency in conducting transplants and therefore maintain the sustainability of the transplant program. The Network indicated that it had made a strategic decision to focus on increasing organ donation province-wide, although it recognized the need to eventually move to single wait-lists for each organ.

Because of the regional allocation of kidney and livers, the patients in the province who have the greatest need for these organs—for example, those who are very ill, have a high risk of rejection, and/or have waited the longest time—do not necessarily receive the first available organ. Further, the regional allocation of these organs results in regional variations in how long recipients wait for their organ transplant. For example, Network data indicate that in 2009/10, 90% of kidney recipients received the kidney within four years in one region (50% within two years), compared to about eight years in another region (50% within three and

a half years), and almost nine years in two other regions (50% within four years and five and a half years, respectively). The variations were not as large for liver transplants: in the same year, 90% of liver recipients received a liver within about two and a half years in one region (50% within four months), compared to three and a half years in another region (50% within five months).

The Network informed us that individual kidney patients generally are not considered to have a high-priority status because dialysis is considered life-sustaining for most patients. However, for kidneys, a person’s position on the wait-list is based on when that person began dialysis, regardless of when he or she was added to the wait-list. Using the start time of dialysis to indicate a person’s position on the wait-list is consistent with Canadian Blood Services’ recommendation, and they note that a longer time on dialysis generally corresponds with poorer long-term outcomes for patients. Further, while there is little Canadian research on this topic, the Canadian Society of Transplantation also indicates that increased time on dialysis is an important determinant of the patient’s long-term outcome. As well, studies from other jurisdictions have found that longer periods of dialysis are associated with poorer transplant outcomes. Further, a 2005 study from the United Kingdom found that the remaining life expectancy of dialysis patients on a kidney transplant wait-list was tripled by a successful transplant. Unlike kidney patients, the highest-priority liver patients are placed on the national wait-list.

The 2009 report of the Organ and Tissue Transplantation Wait Times Expert Panel recommended that the Network and transplant hospitals review organ allocation and distribution and identify improvements to ensure equitable access to transplant based on clinical evidence.

Allocation Review

The 2000 report of Premier Harris’s Advisory Board on Organ and Tissue Donation noted that

it was important that organ allocation algorithms be reviewed regularly and updated when necessary, because “failure to do so, and any perception that organs are not fairly allocated, could have a negative effect on the willingness of the people of Ontario to donate their organs.” We noted that the lung algorithm was updated in 2006; the algorithms for liver, pancreas, and small bowel were updated in 2008; and the kidney and heart algorithms were updated in 2009.

In some cases, it is reasonable that the next person on the wait-list will not necessarily receive the first available organ: for example, the organ may be too small for the patient. Although the Network indicated that staff should document an explanation, such as that provided by the physician, if an organ is not allocated to the highest-priority person listed in the organ allocation system, Network staff can override the allocation system without providing such an explanation. In fact, in 40% of the donor files we reviewed, there was no documentation explaining why the person at the top of the wait-list did not receive the organ. Further, Network staff were unable to recall or provide verbal explanations for over 70% of these cases.

The Network does not have a policy on reviewing organ allocations, but indicated that since February 2009 a second staff person is to agree to all organ allocations at the time they are initially made. However, although the Network indicated that it conducts reviews to ensure that this process takes place, we found that one-third of the cases we sampled had no evidence that a second person had reviewed the organ allocation.

Senior Network staff indicated that they follow up on organ misallocations that are brought to their attention (for example, by one of the transplant hospitals). However, transplant hospitals generally cannot determine whether a misallocation has occurred, because they do not have sufficient information to do so: they do not know their patient’s position on the wait-list; they generally never know which patient received the organ or why their patient did not receive it; and only the hospital to

which the Network offers the organ is provided with test results to determine compatibility of the donor organ and the potential recipient.

We noted that the U.S. United Network for Organ Sharing reviews the allocation of every organ transplanted from a deceased donor to make sure that policies are being followed and patients are treated equitably. Senior Network staff indicated that no similar review is completed in Ontario by persons independent of the organ allocation process to ensure that organs are allocated in accordance with the Network’s organ allocation algorithms.

The Network maintains a roster of seven Chief Medical Officers (CMOs), who are on-call physicians with expertise relating to organ transplantation, including kidney and heart transplants, but not liver transplants. At least one CMO is available around the clock to respond to any questions from Network staff concerning the viability of organs from potential donors. However, the Network does not capture information on how often organs are approved by a CMO only to be subsequently refused by all the transplant hospitals or on whether a physician with expertise in liver transplants is needed on the CMO roster. Although the Network has not performed any analysis of unused organs, it does track some information on them. At our request, the Network ran a report on available organs that were not accepted for transplant, which indicated that over 1,200 organs that the Network offered to transplant hospitals were not used in 2008/09. For almost 10% of the unused organs, no specific reason was provided for not using them. “No suitable recipient” was given as a reason for not transplanting 12% of the unused organs. We also noted that about 70% were not used because none of the transplant hospitals considered them appropriate for their patients—for example, because of a donor infection or poor organ function.

In the United States, as noted in a September 2005 best-practice evaluation issued by the Health Resource and Service Administration’s Organ Transplantation Breakthrough Collaborative, organ

procurement organizations (OPOs) “provide regular, meaningful feedback to the transplant centers in their regions about the centers’ organ acceptance rates and the OPOs’ export rates. This feedback allows transplant centers to identify areas in which they may be too conservative in their acceptance of organs, and some of the centers interviewed have acted on this information.”

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.

NETWORK RESPONSE

The Network agrees with the need to have organ-specific province-wide wait-lists for kidney and liver transplantation. Presently, through its provincial kidney and liver working groups, the Network is undertaking discussions to understand the implications of transitioning

to a single organ-specific provincial waiting list, including barriers and opportunities. In particular, a transition plan for moving to a single wait-list must recognize the volume and viability issues relating to specific transplant programs.

The Network agrees with the need to audit organ allocations to ensure compliance with the established allocation rules, which support a fair and equitable allocation. Further, the Network believes that this process should be transparent, thus demonstrating accountability and ensuring confidence in the donation and transplant system in Ontario. The Network is working with the Transplant Action Team to discuss how this review of organ allocations can best be done.

The Network has begun to develop and provide organ offer and acceptance reports to transplant programs. In this regard, the Network is reviewing improvements to its clinical information database, to better collect data on organ disposition, which includes organ offer/decline/acceptance. This enhancement will require an upgrade/enhancement to the Network’s clinical information database or purchase of new donor management software.

RESPONSE FROM HOSPITALS

One of the transplant hospitals agreed with the recommendation on ensuring the highest-priority kidney and liver patient in the province receives the first suitable organ available. The other hospital commented that there should be a review of kidney and liver allocations, conducted in conjunction with the transplant hospitals, to ensure that for each organ, the highest-priority patient province-wide receives the next suitable available organ, followed by the longest-waiting patient. The hospital indicated that this review must consider the merits of a single provincial list rather than maintaining several regional wait-lists as an option to achieve this goal, as well as the impact of donor organ transportation and donor quality on

patient outcomes. Alternatively, patients could choose to receive their transplants in centres with the shortest wait times. This alternative would minimize or eliminate the differences in wait times, recognize the excellence of donation in high-performing centres, and maintain the expertise and stability of the individual transplant centres.

MINISTRY RESPONSE

The Ministry agrees with the need to enhance the management of organ transplant wait-lists. In this regard, the Transplant Action Team's proposed model of care will, through the establishment of standardized criteria, move to a single wait-list for each organ. Furthermore, performance indicators and mechanisms to monitor system performance will be developed through the committee structure and processes, in the model of care proposed by the Transplant Action Team, in order to identify opportunities for improvement within the system. The proposed model of care will link into and enhance the work that the Network and the Ministry have done in this area as noted in the overall remarks, and will guide their work in the future.

Efficiency of the Organ Donation Process

To ensure that organs are transplanted in the best possible condition, the organ donation process must be completed without undue delays that may harm organ function.

Each of the key stages in the organ donation process takes time, including the time between hospital referral and consent; consent and the offer of an organ to a transplant hospital; and the transplant hospital receiving the offer and deciding whether the organ is a good match for its patient. Time is also needed for the transplant hospital's retrieval of the organ and for transplantation of the organ into the recipient. We were informed that the

entire process generally takes about two days. However, delays can occur at any point—for example, because laboratory results are late or the donor family requests a postponement in the removal of life support.

The Network does not routinely track the time intervals in the organ donation process. However, it has undertaken two projects that gathered some information on this process. One of the projects, in 2008, extracted the times from 30 files, with results indicating that the median time from declaration of brain death to consent was about five hours, and from consent to the start of organ removal was about 22 hours. Almost seven hours of this time was used to gather information about the donor, and it took another four hours for a transplant hospital to decide whether the offered organ was a good match for its patient. The Network's second project was under way at the time of our audit, and no information was yet available. The Network indicated that it plans to use its new phone system, implemented in August 2009, to assist it in tracking this information in the future.

We also noted that there are some significant variances in the number of donor cases managed by Network staff on-site at the 21 Tier 1 hospitals. Our analysis indicated that the number of cases managed in the 2008/09 fiscal year ranged from a low of three by a Network staff person on-site at one hospital to over 40 by a Network staff person on-site at another hospital.

Communicating Donor Information

Delays in getting the critical medical and other data to the various decision-makers can also impede the organ donation and transplantation process. We noted that much of the information about potential donors is faxed to the Network, which, because decisions need to be made quickly, then verbally communicates it to the transplant hospital (although hospitals may ask for specific items to be faxed to them). Therefore, donor information—such as the donor's medical history, medications,

and past social behaviour (which may indicate a higher-risk organ), as well as laboratory results—cannot be electronically reviewed by the transplant surgeons to assist them in determining whether an organ is a good match for their patient. Further, there is generally little direct communication between the donor hospital and the transplant hospital, resulting in a risk that decisions may be made using incomplete or incorrect information.

In the United States, the system used by the United Network for Organ Sharing can electronically notify all transplant programs with a compatible recipient about an organ. Programs can then electronically view the donor information, such as laboratory results, and are given up to two hours to indicate whether they are interested in the organ for their patient. Based on this interest, the organ is offered to the program that has the highest-priority patient. This approach gives physicians all the critical information they need in order to quickly assess whether there is a high degree of compatibility between the donor and the recipient—thereby expediting the process of allocating the organ, which enhances the likelihood of achieving a successful transplant.

Recovering Organs

If the organ recipient is not located at the same hospital as the organ donor, generally a member of the recipient's transplant team and a Network staff person travel to the donor hospital to recover the organ(s). If the organs are going to recipients at more than one hospital, this process may involve recovery teams from each of the recipient hospitals. In many cases, the Network arranges the transportation for the organ recovery teams, and may also arrange for operating-room time at the donor's hospital for the organ recovery.

Ideally, the organ recovery teams should be able to start the organ recovery soon after arriving at the donor's hospital. We were informed, however, that in some cases the organ recovery teams have to wait, which could happen for a variety of reasons, such as an operating room not being available.

Once the organs are recovered, it is important to transport them without delay in order to minimize the time the organ spends outside the body (called "cold ischemic time"). The longer the organ is without oxygen, the poorer the organ's viability and therefore the poorer the transplant outcome. Transporting organs between locations that are geographically close to each other may be easily accomplished, but when the donor hospital is a significant distance from the transplant hospital, travel arrangements may be more complex. In some situations, organ recoveries rely on the air ambulance service operated by the Ministry's appointed provider, Ornge, to ensure that organs arrive at the hospital in time for transplant. We noted that the Ministry's performance agreement with Ornge does not include specific requirements related to transporting organs for transplantation. Further, our file review indicated and the Network noted that organs have been delayed many times—for example, because air transport was not available at pre-arranged times. The Network indicated at the time of our audit fieldwork that it had met with Ornge twice to review the situation but that the delays had continued.

Although information on cold ischemic time is supposed to be noted (generally by hospital staff) in a form that accompanies each organ, we noted that it was not present in 20% of the cases we reviewed. Further, the Network's information system does not track the time taken to transport organs. Therefore, the Network is not able to readily assess the frequency or potential impact of unacceptably long delays in transporting organs to transplant hospitals.

Certain types of equipment and supplies assist in decreasing the impact of cold ischemic time. For example, all organs are required to be packed in ice and transported in a solution, called a perfusion fluid, in order to preserve them. Further, kidneys may be attached to a pump that flushes the perfusion fluid through them to provide nutrients and oxygen, and to remove certain toxins.

A 2009 study in the *New England Journal of Medicine* indicated that there can be a significant benefit to using a kidney pump. The Network has informally suggested to transplant hospitals that kidney pumps be used in certain circumstances, such as for kidneys from DCD donors. But the Network has not assessed how frequently kidney pumps are actually used, either in the suggested circumstances or overall. Based on data maintained by the Network, we noted that between April 1, 2009, and February 28, 2010, more than half the kidney cases did not indicate whether a pump was used.

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.

NETWORK RESPONSE

The Network will review and analyze the feasibility of providing timely electronic access to information required to facilitate the physician's assessment of the compatibility of the donor and potential recipient. The review will assess the information required and explore options to deliver the information and safeguard privacy requirements. As well, the Network agrees with the need to improve case tracking, including establishing a time-tracking function in its clinical information database. The Network is in the process of determining the best solution to address this and other identified requirements. The Network indicated that both of these items will require an upgrade/enhancement to the Network's clinical information database or purchase of new donor management software.

The Network has been a leader in supporting the use of kidney pumps for use with kidney recovery in Ontario, having purchased pumps in 2006 and again in 2008 when we made them available to all kidney transplant programs. It is recognized that we now need to consider how to further support the province by ensuring that consistent policies and practices, and adequate resources are in place to support the use of pumps across the province. Further changes to the Network's clinical information database are needed to improve data entry and quality, and they are being considered.

MINISTRY RESPONSE

The Ministry supports the Auditor's position that the organ donation process should be as efficient as possible and that delays that have the potential to harm viable organs be avoided. In this regard, the Ministry and the Network will work together in their annual business planning process to ascertain the information and information technology needed to support the improved exchange of information and data on

donor availability, assessment, and compatibility between facilities and clinicians.

As well, the Ministry is committed to supporting discussions between the Network and Ornge to ensure rapid transport in support of organ donation, and it will amend agreements as appropriate.

TISSUE

The *Trillium Gift of Life Network Act* requires the Network “to manage the procurement, distribution and delivery of tissue.” Tissue includes skin, bones, eyes, and heart valves. The process for tissue donation has several similarities to that for organ donation: the same 21 hospitals (referred to as Tier 1 hospitals) are required to report potential donors to the Network; consent is obtained from the next of kin of suitable donors; and tissue is recovered. But unlike consent for organ donation, consent for tissue donation is often obtained by phone, and donated tissue is generally not transplanted immediately: instead, it is processed and stored at a tissue bank until needed. There are six tissue banks in Ontario: three for bone and one each for skin, eyes, and heart valves. In 2009 the Network co-ordinated for transplant purposes the recovery of eyes from 876 donors, bone from 70 donors, and heart valves from 31 donors. No skin was recovered in 2009.

Identifying Potential Tissue Donors

More patients can be tissue donors than can be organ donors, primarily because tissue is not affected as quickly by a lack of oxygen and therefore potential donors do not need to be on a ventilator. However, the Network does not have specific clinical triggers to help hospitals determine which patients should be referred to the Network as potential tissue donors. Instead, the Network requests the 21 Tier 1 hospitals to report every

death in their intensive-care units and emergency departments. Nevertheless, the Network generally does not consider tissue from people over 80 years of age to be viable. Because this age restriction has not been communicated to hospitals, we noted that the Network was receiving almost 2,300 calls a year from hospitals about patients who were not eligible for tissue donation because of their advanced age.

The Network requires Tier 1 hospitals to notify it within one hour after a potential tissue donor dies. However, based on our analysis of Network data, we noted that between April 1, 2009, and January 31, 2010, 44% of the referrals from hospitals were not made within this time. Further, if a hospital reported an expected imminent death, but did not call back within one hour after the patient died, we noted that the tissue was often not recovered because the Network did not pursue these cases. This occurred over 670 times between April 1, 2009, and January 31, 2010.

Once a potential donor is reported, Network staff use a screening form developed in conjunction with the tissue banks to identify patients who are obviously unsuitable for tissue donation. (In the case of organ viability, the Network has physicians on call to provide expertise when needed; however, no similar arrangement is in place for determining tissue viability.) Proper screening is important to ensure that tissue is viable (for example, that it carries no infection that could be transferred to a recipient) and that costs are not incurred to send health-care practitioners or others to recover non-viable tissue. Nevertheless, one bone bank indicated that the Network still referred non-viable cases (for example, people who had an infectious disease such as hepatitis C) to it.

Obtaining Consent for Tissue Donation

In September 2008, the Network started asking hospitals that refer tissue donors to permit Network staff, rather than the hospital’s health-care practitioners, to approach the patient’s next of kin for consent. However, subsequent Network data

indicated that many hospitals' health-care practitioners continued to request consent themselves. In fact, based on data from 18 referring hospitals, health-care practitioners approached next of kin for tissue consent almost 67% of the time, from September 2009 to January 2010. Further, Network data indicated that during this time, the Network staff had almost a 50% success rate when requesting consent, whereas health-care practitioners had only a 20% success rate.

The Network provides some training and generic wording to assist its staff in approaching families for tissue consent. However, the Network generally does not track how often each individual who requests tissue consent receives it. Based on June 2009 data, the Network found that individual success rates ranged from 18% to 60%. No further follow-up was completed to determine why there was such a large variance among its own staff when requesting consent.

We also noted that at the time of our audit, Network staff did not check, before requesting consent, to see whether a potential tissue donor had registered his or her consent on the Ministry's registry. Given that presenting this information to the next of kin resulted in much higher consent rates for organ donation, we believe that the same might well be true for tissue. After we completed our fieldwork, the Network advised us that it had begun checking the registry for consent.

Recovering Tissue

Tissue is generally recovered by staff from one of the six tissue banks, except for eyes, which are recovered by Network staff within the Greater Toronto Area, and by health-care practitioners elsewhere in the province. The Network indicated that starting in July 2010, it planned to have staff trained to recover skin in addition to eyes in the Greater Toronto Area.

We noted that generally only one type of tissue was recovered per donor, although more could be recovered. Further, in some cases tissue is not

recovered even though consent was received and the tissue was viable. Although the Network could not provide us with a list of all such cases, we noted that from April 1, 2009, to January 31, 2010, there were at least 200 cases of unrecovered tissue. Network information indicated that the tissue was not recovered for a variety of reasons, including a lack of staff available to recover the tissue; no operating room available to recover the tissue; and the deceased person's body being released to the funeral home too soon. Further, unlike the hospitals' costs for organ recovery, their costs for tissue recovery are not supported by specific ministry funding, so hospitals have a fiscal disincentive to promote tissue donation. The 2009 report of the Organ and Tissue Transplantation Wait Times Expert Panel (Expert Panel) recommended reviewing the payment schedule for tissue donation to ensure that hospitals are adequately compensated for these costs.

The Network indicated that doctors are not required in order to recover tissue and that the current approach to tissue recovery could be improved if everyone who performs tissue recovery were trained to retrieve multiple types of tissue (not just one type, as is generally the case now) and if people with such training were available throughout the province. However, one bone bank indicated that only medical fellows, at least one of whom has orthopaedic training, should recover bone, because this approach allows for a thorough screening for potential diseases or other conditions that might compromise bone recipients. At the time of our audit, neither the Network nor the Ministry had fully analyzed the costs and benefits of different approaches to tissue recovery.

Tissue Availability

According to the Network's 2006 Strategic Plan to Improve Tissue Donation Activities in Ontario (also known as the Tissue Plan), Ontario has the potential to meet the tissue demand in the province. However, Ontario does not actually

recover sufficient tissue for its own needs. In fact, the Network's 2006 Tissue Plan (the most recent information available) indicated that less than 8% of Ontario's demand for tissue was met by Ontario's tissue donors. Further, at the time of our audit, no skin had been recovered in Ontario since August 2008—because, we were informed, the skin bank lacked the staff to recover it. As well, the Expert Panel's 2009 report noted that, owing to shortages of eyes, a person could expect to wait about 1.5 years for a cornea transplant in Ontario.

Therefore, Ontario hospitals increasingly purchase tissue from other jurisdictions, often from Quebec or the United States. (Eyes may be shared among Canadian jurisdictions at no cost, but Canadian jurisdictions generally do not have a surplus.) Although there is no recent information on how much tissue is purchased, in 2003 it was estimated that hospitals paid \$19 million to acquire tissue from other jurisdictions. Further, the Ministry indicated that there were some concerns with tissue from the United States because of a 2002 Health Canada alert on incidents of infected U.S. tissue and because of U.S. recalls of tissue in 2005 and 2007.

To increase the supply of Ontario tissue, the Network's 2006 Tissue Plan indicated that all hospitals with mechanical ventilators should be required to refer tissue donors. Based on this, there are at least 58 additional hospitals that could be required to report potential tissue donors to the Network. We were informed that one reason the Network has not asked these hospitals to report is limited staff resources, with current resources being focused on organ donation cases rather than tissue.

The 2006 Tissue Plan also recommended that a comprehensive tissue-processing centre should be established and that distribution of tissue should be managed centrally. In addition, the Expert Panel's 2009 report recommended that the Ministry support the development of a co-ordinated, not-for-profit system to process and access tissue to meet the needs of Ontarians. The Expert Panel noted that an integrated approach to managing tissue in Ontario would help ensure that Ontarians have

equitable access to safe, high-quality tissue rather than depending on tissue imported from other jurisdictions.

The Ministry informed us that Canadian Blood Services, in conjunction with the provinces, is drafting a plan for a national tissue strategy. Among other things, the strategy is expected to help ensure equitable access to a safe supply of quality tissue, through the use of standardized centralized processes for tissue recovery, processing, and distribution, as well as its importation when necessary. The Ministry indicated that it will review the proposed national plan, expected in fall 2010, as part of determining any changes that might need to be made to the way tissue is managed in Ontario.

A 2010 study commissioned by Canadian Blood Services noted that the Canadian demand for bone can be expected to undergo strong growth in coming years because an increasing number of procedures using bone (such as hip replacements) are being performed, mostly as a result of the aging population. At the time of our audit, with the exception of eyes, neither the Network nor the Ministry had current information on the demand for tissue in Ontario, the costs paid by hospitals for tissue, the quantity of tissue currently processed and stored in Ontario, or the current capacity for processing and storing tissue in Ontario.

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.

NETWORK RESPONSE

The Network identified in its 2009/10 fiscal year Business Plan the need to work with more hospitals to increase the referrals of potential tissue donors to the Network, and it has begun this work. The Network believes it is important to ensure compliance with the current referral system of reporting deaths before setting criteria whereby health-care practitioners could screen for donation potential. The Network will revisit the suggestion to implement screening criteria when the province has begun to demonstrate a higher degree of referral performance.

The Network reviews consent rates for tissue donation for both the Network and hospital staff and will continue to share performance metrics and best practices for tissue donation with hospitals, with a view to increasing consent rates.

The Network has met with the tissue banks in Ontario to review and streamline the screen-

ing process used to rule out those donors that the tissue banks do not feel would be suitable. This screening tool continues to be assessed and reviewed for improvements as standards change or at the request of the tissue banks.

The Network agrees that the province would be better served with a central tissue-processing capability, and advises that the choice of which organization provides that capability should be done through a competitive process.

MINISTRY RESPONSE

The Ministry agrees with the need to ensure an adequate supply of quality tissue and is working with the Network to support improvements in this area. Further, the Transplant Action Team efforts will, through enhanced communication and education provided to all hospitals and promotion of standardized approaches, assist in increasing the number of identified potential tissue donors.

The Ministry will review the costs and benefits of a centralized tissue-processing model with the Network and consider the recommendations (expected in spring 2011) of Canadian Blood Services, which were requested by the provinces and territories, related to the design of a national organ and tissue donation and transplantation system.

The Ministry will also review the current hospital reimbursement model for organ and tissue donation with the Network and will consult with the Ontario Medical Association regarding physician compensation as part of payment discussions related to the Ministry's 2011 investment funding under the 2008 Physician Services Agreement.

PERFORMANCE MONITORING

Oversight

The 2009 report of the Organ and Tissue Transplantation Wait Times Expert Panel (Expert Panel) stated that “the final requirement to achieve accountability for performance and, ultimately, create an integrated system to support the transplant patient’s journey is oversight for the system.” It further suggested that system oversight is the most critical requirement for an effective and well-functioning provincial donation and transplant system.

In the United States, two oversight organizations receive data from transplant centres and review the centres’ transplant activity, including patient survival rates and the volume of transplants conducted. One of these organizations is the Organ Procurement and Transplantation Network (OPTN), a not-for-profit organization that manages the U.S. organ allocation system and sets out standards for patient survival rates and transplant activity. The other organization is the Centers for Medicare and Medicaid Services (CMS), which regulates transplant programs that receive reimbursement under the U.S. Medicare program. Both organizations monitor compliance with their requirements through on-site reviews of transplant programs.

One factor that contributes to better transplant outcomes is the experience of the surgeons and other staff performing the surgery. Various studies have shown that surgeons need to perform a minimum number of procedures annually to maintain their competency. According to the U.S. OPTN’s standards, a transplant centre is considered “functionally inactive” if no transplants are performed in a three-month period in the case of kidney, liver, or heart transplants, or in a six-month period in the case of pancreas or lung transplants. This designation may lead to the discontinuation of the related transplant program at that centre. Similarly, the U.S. CMS requires hospitals to perform a minimum number of heart, liver, and kidney transplants—generally 10 per year.

However, in Ontario, no minimum number of transplants is required. Further, the Expert Panel’s 2009 report noted that “some transplant centres perform low volumes of transplants, which calls into question whether they should be providing this highly specialised and expensive service.” We noted that two transplant hospitals had very low volumes of certain transplant procedures. In fact, one hospital performed a total of only 20 transplants over the three years ending March 31, 2010, with only six done in the 2009/10 fiscal year. Furthermore, we noted that one-third of the physicians who billed the Ontario Health Insurance Plan (OHIP) for transplant procedures in 2008/09 performed five or fewer transplants that year. (These physicians may have performed other surgical procedures that enabled them to maintain competency in transplants, but this is not independently assessed.)

There is no organization in Ontario responsible for overseeing organ and tissue transplantation activities—for example, by monitoring the number of transplant surgeries performed by hospitals or physicians. In this regard, the Expert Panel recommended that the Ministry determine the best structure for providing effective oversight. Further, the Expert Panel recommended that a system be established to monitor the use of best-practice standards and guidelines for organ transplantation and the outcomes of these procedures. The Ministry indicated that it is in consultation with Canadian Blood Services regarding the design of a national oversight function.

Reporting

The Expert Panel recommended that performance indicators be identified and targets set for donation and transplantation that are linked to outcomes. It also recommended that estimated transplant wait times should be publicly reported on the provincial wait times website.

Although standard outcome measures for organ transplants have generally not been developed

in Ontario, the ultimate measure of a transplant program's success is the extent to which transplant recipients' lives are improved and extended. All of Ontario's transplant hospitals follow organ recipients after surgery and voluntarily forward related transplant data, such as details on organs transplanted and recipient survival information, to the Canadian Organ Replacement Register maintained by the Canadian Institute for Health Information (CIHI). Annually, CIHI sends each hospital its patient survival data, along with comparative information for either Ontario as a whole or all of Canada. However, information on transplant recipient survival is not received or reviewed by the Ministry or the Network.

The U.S. Scientific Registry of Transplant Recipients, a national database of statistics related to organ transplantation, is affiliated with the U.S. OPTN. The registry covers the full range of transplant activity, from organ donation and the wait-list to transplant recipients and survival statistics. This information is available to all the transplant centres. As well, certain information on any hospital that performs transplants—including wait times for organ transplants, the number of transplants performed, and survival statistics for transplant recipients—is also publicly available.

In Ontario, the Network produces an annual report that includes information on certain aspects of the organ donation and transplantation process province-wide, such as the number of individuals on each organ wait-list, the number of organ donors, and the number of each type of organ transplanted. However, the Network's 2008/09 annual report was not publicly released by the Minister until summer 2010. Further, the Network does not have information on patient survival, nor does it publicly release information on wait times for organ transplants or the number of transplants done at each of the eight transplant hospitals.

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.

NETWORK RESPONSE

The Network agrees with the Auditor General that organ and tissue transplantation (as opposed to donation) in Ontario needs more effective provincial oversight. At present, the Network's mandate covers both organ and tissue donation but does not extend to transplantation.

RESPONSE FROM HOSPITALS

One of the transplant hospitals indicated that it believed Canadian Blood Services should take a more active national role in the priority listing of patients for transplant and the standards for monitoring overall performance.

MINISTRY RESPONSE

The Ministry supports the Auditor's position that there needs to be assurance that organ and tissue transplantation and donation in Ontario is meeting the needs of patients safely and efficiently, and, as acknowledged by the Auditor, the Ministry's Organ and Tissue Transplantation

Wait Times Expert Panel made a similar recommendation. Following receipt of the Expert Panel's report, the Ministry immediately began to explore structural options, and the Transplant Action Team is now finalizing a proposal to provide oversight and performance monitoring for organ and tissue transplantation in Ontario. Further, the Ministry has commenced discussions with the Network around an enhanced role to strengthen system oversight. As well, the Ministry supports the use of performance indicators and will work with the Network to identify the appropriate indicators, with consideration of public reporting.