

## **Position Statements**

Listing and Allocation of Organs for Transplantation to Non-Canadian Residents & Out-of-Country Transplant Funding

November 7, 2016



# LISTING AND ALLOCATION OF ORGANS FOR TRANSPLANTATION TO NON-CANADIAN RESIDENTS

#### POSITION STATEMENT

The Ontario wait list for deceased organ transplantation is intended to serve Canadian residents with provincial or national insurance coverage only. However, in exceptional cases, qualified non-Canadian residents may be listed for organ transplantation. The decision to list will be determined on an individual basis by the transplant programs and ONLY for patients with immediate life threatening emergencies without medically indicated alternative treatments.

Trillium Gift of Life Network (TGLN) recognizes that the Ontario transplant system is a publically funded service dedicated to serving insured residents of Canada. Furthermore, TGLN acknowledges that deceased donor organs are an absolute scarce resource that fails to meet current demands. As such, it is TGLN's position that only Canadian residents who meet the minimum listing criteria are placed on the transplantation wait list.

TGLN understands that on rare occasions, there may be exceptional cases where non-Canadian residents are in urgent need of an organ transplant. In such exceptional cases, individual transplant programs will determine whether transplantation is a viable treatment. The designated transplant programs have the authority to list non-Canadian residents on the Ontario organ transplantation wait list, but must do so with extreme caution, given the scarcity of organs. The decision to list will be determined on a case by case basis and must abide by the ethical principles of justice and utility.

As with all other patients on the wait list, a non-Canadian resident must meet the minimum listing criteria to be eligible for listing.

The decision to list a non-Canadian resident will be determined on a case by case basis and must abide by the ethical principle of utility. All patients must demonstrate their ability to care for the organ post-transplant, including the ability to access lifelong immunosuppressive drugs and therapy. The listing transplant program must have reasonable confidence that the non-Canadian resident has the same ability to care for the donated organ as the Canadian resident who would have received that organ otherwise.

TGLN will allocate organs to all patients listed on the transplantation wait list according to the organ specific allocation algorithms.

TGLN will respect a physician and transplant program's decision to list or not list a non-Canadian resident and allocate deceased organs irrespective of resident status. The decision to list a non-Canadian resident is predicated on the assumption that the patient is facing an immediate life threatening emergency

without medically indicated alternative treatments and that transplant physicians and programs have performed due diligence in determining the patient's eligibility for transplant.

TGLN and Transplant Hospitals will monitor the number of listed and transplanted non-Canadian residents.

There is currently no evidence that listing and allocating deceased donor organs to non-Canadian residents is a significant burden on the Ontario transplantation system. However, TGLN recognizes that organs are a scarce resource for Ontarians, and thus will monitor the number of non-Canadian residents that are listed and transplanted in Ontario transplant programs.

#### Transplant and listing practices for refugees

Given the Government of Canada's commitment to resettle refugees in Canada, TGLN wishes to clarify transplant listing practices for refugees.

Refugees should be listed for all organ transplants, provided they meet the following requirements:

- 1) Meet the provincial listing criteria (including demonstrating the ability to care for the organ post- transplant and access to lifelong immunosuppressive drugs and therapy); and
- 2) Approved for coverage under the Interim Federal Health Program (IFHP) or the Ontario Health Insurance Program (OHIP).

For more information regarding the IFHP, including how to verify if a patient is eligible for IFHP coverage with Medavie Blue Cross, transplant programs are encouraged to consult the Immigration, Refugees and Citizenship Canada (IRCC) website: <a href="http://www.cic.gc.ca/english/refugees/outside/arriving-healthcare/practitioners.asp">http://www.cic.gc.ca/english/refugees/outside/arriving-healthcare/practitioners.asp</a>

For more information regarding OHIP eligibility, including the exemption from the usual 3-month waiting period for coverage for convention refugees and protected persons, transplant programs are encouraged to consult the following website: http://www.health.gov.on.ca/en/public/publications/ohip/ohip eligibility.aspx

#### **BACKGROUND**

Ontario does not have a policy on transplantation for uninsured patients and non-residents. Transplant centers receive requests individually on an ad hoc basis. As the steward of donated organs in Ontario, Trillium Gift of Life Network (TGLN) has carefully considered the risks and ethical issues of allocating this scarce resource amongst patients.

The final position statement was developed upon serious consideration of the principles of justice and utility. An extensive jurisdictional scan and literature review was completed on the listing and allocation practices of organs to non-residents and uninsured patients. A brief summary of how the principles of justice, comprised of equity and fairness, and utility were used to develop the resulting position statement is outlined below:

**Equity** refers to equal access to transplantation without discrimination based on race, religion, sex, age, or mental or physical disability. Equitable access to organs is a main principle for fairness and accessibility. Complete equality would allow non-Canadian residents to be listed and allocated deceased donor organs for transplantation. Ideally, everyone would be treated equally. Unfortunately, organs are scarce resources that fail to meet the current demands and transplants are resource intensive services. The supply of organs is not enough to satisfy the demand, and thus decisions must be made on who should be able to receive limited deceased organs. As such, equality must interact with the other principles of justice to identify which groups should be prioritized.

Fairness would recommend that allocation and transplantation be limited to insured Ontarians and Canadian residents due to TLGN and the Ontario transplant system being a publically funded service. The exclusion of non-residents is a citizenship based claim as it uses residency status as a determining factor of which groups are entitled to benefit from Canadian resources. However, the absolute exclusion of non- residents from public services poses several challenges. First, not all the Canadians who are benefitting from the public system are obliged to contribute to it equally. Canadians are not obliged to be registered donors to be listed and allocated an organ. There is also no financial assessment to determine whether a Canadian patient has been contributing via taxes. Secondly, TGLN experience shows that non-residents contribute to the donor pool; Ontario imports organs from the United States as well as utilizes organs from foreign nationals who have died in Ontario. Non-insured and non-Canadian residents have also contributed to the tax pool via foreign investments, sales tax, and tourism costs without benefitting from the vast majority of public services.

**Utility** maximizes the greatest possible good for the greatest possible number of individuals. The organization is responsible for maximizing benefits from limited resources. The risk of graft loss for patients who will not have access to post-transplant therapy and drugs is substantially high. In Ontario, residents who are covered by the Ontario Health Insurance Plan (OHIP) and who spend a large portion of their income paying out-of-pocket for prescription medications are eligible for coverage under the Trillium Drug Program. The Trillium Drug Program is an income-based program that helps individuals and families who do not have private drug insurance or whose private insurance does not cover all of their drug costs. According to the principle of utility, the exclusion of transplantation for non-Canadian residents who do not have access to post-transplant care is ethically justifiable. Medical professionals are responsible for calculating the risks using available knowledge, which includes acknowledging the reality of sub-optimal conditions that some foreign patients may be returning to.

Members of TGLN's Transplant Ethics Working Group had lengthy debates on how justice and utility can be applied to the transplantation of non-Canadian residents. After several meetings, and upon

counsel of the Transplant Steering Committee, this position statement regarding the listing and allocation of deceased donor organs to non-Canadian residents was developed.

The Transplant Ethics group formally met on the following dates to discuss transplantation for non-Canadian residents:

- November 8, 2013
- February 11, 2014

Discussion highlights were provided for the Transplant Steering Committee on the following dates:

- November 26, 2013
- February 18, 2014

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### OUT-OF-COUNTRY TRANSPLANT FUNDING

#### POSITION STATEMENT

Ontario should not fund out-of-country transplants under any circumstances. Trillium Gift of Life Network (TGLN) unequivocally condemns organ trafficking and believes any ambiguity regarding out-of-country transplantation may undermine this position as well as the Ontario transplant system.

In accordance with the internationally endorsed Declaration of Istanbul on Organ Trafficking and Transplant Tourism, Ontario takes measures to protect vulnerable groups from exploitation due to transplant tourism and the sale of tissues and organs. To diminish organ trafficking opportunities, Ontario strives to provide organs to meet the transplant needs of its residents from donors within its own population and through regional cooperation. The Ontario deceased organ donation and transplantation system ensures that limited Ontario organs are allocated to patients on the wait list based on the principles of justice and equity. Funding residents for out of country transplants results in inequitable access to organs for patients on the wait list and undermines the self-sufficiency principle that the Ontario system is built upon.

TGLN will reconsider this position should a non-experimental, accepted standard of care become available in another country that is not available in Ontario.

Currently, Ontario provides its residents with access to all types of non-experimental organ transplantation. TGLN will reconsider its position on funding out of country transplants should Ontario not be able to provide its residents with a non-experimental and clinically acceptable transplant procedure.

#### **BACKGROUND**

On October 3, 2014 the Out-of-Country Prior Approval Program Health Services Branch, Ministry of Health and Long-Term Care (MOHLTC) requested guidance from TGLN's Transplant Steering Committee (TSC) on funding out-of-country (OOC) transplant procedures. Despite the availability of all types of organ transplantation in Ontario, some patients seek transplant opportunities abroad in an effort to circumvent long wait times.

Since 2000, 87 applications have been received by the MOHLTC for Ontario Health Insurance Program (OHIP) funding to have an organ transplant outside of Canada. The majority of these were for transplants to be performed in the United States; however, there were some for other countries including Pakistan, China, India and the Philippines. Since the beginning of fiscal year 2009/10, all applications for funding of out-of-country organ transplants have been denied by the Ministry. Where applications have requested access to a larger donor pool, applications have generally been denied on the grounds that it is not "generally accepted by the medical profession in Ontario as appropriate" to

place a patient who is on an Ontario organ transplant list on a transplant wait list in another country in order to provide more rapid access. Where applications have requested access to a specific foreign donor, applications have generally been denied on the grounds that the identical or equivalent service is performed in Ontario and information has been provided about initiatives intended to assist foreign donors in travelling to Ontario.

The final position statement was developed following a jurisdictional scan, literature review, and indepth discussions of the ethical issues of equity, utility, financial accountability, safety, solidarity, reciprocity, and organ trafficking. A brief summary of the ethical considerations used to develop the resulting position statement is outlined below:

**Equity:** The Ontario deceased organ allocation system was developed to ensure that patients are considered for transplantation based on medical need and wait time, regardless of race, sex, geographical residence, and socioeconomic basis. Funding out-of-country transplantation fosters inequity since it restricts patients who may not be able to travel due to their medical condition or who lack the time and/or financial resources required for travel.

**Utility:** A patient who receives an OOC transplant may maximize the utility of Ontario donor organs by not using an Ontario organ and making it available for other patients on the wait list. However, where transplantations are carried out in substandard health systems, the same patient may return with more acute symptoms and require a re-transplant.

**Financial Accountability:** Transplant costs may vary significantly in other countries. If a general endorsement of foreign transplants was given, more patients would likely search for shorter wait lists elsewhere. Since it is difficult to predict how many patients would choose to have an OOC transplant, the financial impact of funding OOC transplants on the Ontario health care system is unknown and may be a potential burden to the system.

**Safety:** In Canada, transplants are regulated federally under the Safety of Human Cells, Tissues and Organs for Transplantation Regulations, SOR/2007-118 made under the Food and Drugs Act (the "CTO Regulations"). The CTO Regulations are aimed at improving the protection of the health and safety of Canadian transplant recipients. The recipients of transplants in jurisdictions outside of Canada may or may not have the protection of similar regulatory standards and safety requirements.

**Self-Sufficiency:** As per the Declaration of Istanbul, regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country or through regional cooperation. Outsourcing transplantation undermines efforts within the province to develop a self-sufficient system that ensures equitable access to organ transplantation for all Ontarians.

**Reciprocity:** Only in exceptional cases does Ontario allow non-residents to be placed on the Ontario wait list. Funding OOC transplants would undermine the credibility of the non-resident transplantation

position statement and could potentially lead to challenges based upon reciprocal obligation.

**Organ Trafficking:** Organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity because transplant commercialism targets impoverished and otherwise vulnerable donors. If Ontario were to fund OOC transplants, it could inadvertently become complicit in transplant tourism and organ trafficking.

Members of TGLN's Transplant Ethics Working Group agreed by majority vote on the position to not provide funding for out of country transplants under any circumstances. After several meetings, and upon counsel of the Transplant Steering Committee, this position statement was developed.

The Transplant Ethics group formally met on the following date to discuss funding out-of-country transplants:

• February 3, 2015

Discussion highlights were provided for the Transplant Steering Committee on the following date:

• February 9, 2015

The position takes into consideration that all types of organ transplantation are available in Ontario. It will be reviewed if a non-experimental, accepted standard of care becomes available in another country that is not available in Ontario.

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