RESEARCH

The Evolution of Eye Banking and Regulatory Standards in Canada

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The Canadian National Institute for the Blind (CNIB) and the University of Toronto established the Eye Bank of Canada (Ontario Division) in 1955 as a response to the soldiers suffering from corneal blindness due to chemical warfare during WW II. The first corneal transplant was performed in November of 1955. The eyes were processed at the Eye Bank by the administrator Mrs. Anne Wolf, who was the pioneer of eye banking in Canada. As a result of her dedication in educating both the medical profession and the public there was an increase in not only eye donations, but organ donations as well. As a result of this work she received the Order of Canada in 2005. [i]

Changes Since the 1950's

Eye Banking progressed slowly over the next four decades, and most eye banks in Canada were mainly supported through either the CNIB, or the Lions Clubs. In the late 1990's, donation rates were low, resulting in long waiting times. The average wait time in Canada at that point was between three and five years.

Since there were no Medical Standards of Practice eye banks looked to the Eye Bank Association of America (EBAA) for the Medical Standards of Practice. It was not

mandatory to follow EBAA Medical Standards, and accreditation was voluntary.

The eye banking community, as well as the organ and tissue banking community, was concerned about the lack of national standards of practice in light of The Royal Commission of Inquiry on the Blood System in Canada, more commonly referred to as the Krever Commission or Krever Inquiry. The Krever Inquiry was a Royal Commission headed by Mr. Justice Horace Krever at the request of the Canadian Government in October 1993. The purpose of the Inquiry was to investigate allegations that the system (government, non-government and private organizations) responsible for the supply of blood and blood products to the health care system was inadequate and had allowed contaminated blood into the blood supply. [ii]

In 1998, at the Canadian Association of Transplantation conference held in Mont Tremblant, Quebec, a group of eye and tissue bank staff met informally and agreed on starting an information group, where information could be shared on a national level and have input into the process of establishing National Standards. This group was named Canadian Tissue Bank Interest Group (CTBIG) and consisted of 15 members across Canada. The purpose of this group was to

have a united Canadian voice for eye and tissue banks. During the next five years, as Standards were being developed, the CTBIG realized the need for a stronger organization and in 2006 became a not-for-profit corporation, registered with the federal government as the Canadian Association of Eye and Tissue Banks.

The Development of National Standards and Regulations

In 1996 Health Canada began to address the need for regulations and the concerns of stakeholders by striking a working group of experts to start and develop national safety standards for cells, tissues and organs for transplantation. In 2000 Health Canada signed a contract with the Canadian Standards Association (CSA) to facilitate the development of national standards related to the safety of human cells, tissues, and organs (CTOs) used for transplantation. Technical subcommittees were formed that included (1)experts from various fields of practice related to the donation and transplantation of cells, tissues and organs;(2) stakeholders from the public organizations, including recipients; as well as (3)representatives from Health Canada, and (4)Provincial

and Territorial governments.[iii]

In June 2003, the CSA published six documents:

- National Standards for Cells, Tissues, and Organs for Transplantation and

    - Assisted Reproduction: General Requirements, Z900.1-03 [iv]

- National Standards, Tissues for Assisted Reproduction, Z900.2.1-03[v]

- National Standards for Tissues for Transplantation, Z900.2.2-03[vi]

- National Standards for Perfusable Organs for Transplantation Z900.2.3-

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- National Standards for Ocular Tissues for Transplantation, Z900.2.4-03[viii]

- National Standards, Lymphohematopoietic Cells for Transplantation, Z900.2.5-03[ix]

In January 2003 Health Canada, as an interim measure, until the new safety regulations came into force, issued a Directive entitled "Technical Requirements to address the Safety of Human, Cells, Tissues, and Organs for Transplantation".[x] A Guidance Document was also published at the same time, called the "Basic Safety Requirements for Human Cells, Tissues, and Organs for Transplantation.[xi]

In March 2003, Health Canada initiated a national review of all establishments handling and/or processing CTO for transplantation, in order to assess their adherence to basic

safety requirements, as specified in the Directive and Guidance Document. This review was a two- step process. The first phase required establishments to submit documentation from programs involved in the handling and/or processing of CTO. The second phase involved an on-site inspection of each establishment by the Health Canada Inspectorate. [xii] The review provided insight for both Health Canada and the CTO establishments with respect to the level of adherence in the CTO community to the safety requirements outlined in the Health Canada Guidance document.

In the years between 2003 and 2005, representatives from Health Canada met with key stakeholders across Canada on several occasions to obtain their feedback on the development of the regulatory framework for the safety of CTOs. Eye Banks were asked to provide feedback with respect to topics such as importation, establishment registration, quality assurance, and reporting requirements. The information provided helped to guide the creation of a draft Guidance Document that was published for comment by Health Canada in 2005.

The final version of the Guidance Document was released in June 2009. [Xiii] On December 7, 2007 Health Canada published the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations), pursuant to Canada's Food and Drugs Act. Canada was the first country to implement a comprehensive set of regulations for the safety of cells, tissues and organs in one document. The scope of the Regulations applies to human organs, and minimally manipulated cells and tissues intended for homologous

use in transplantation in another individual. [xiv] The Regulations set out the basic safety requirements with respect to donor screening, donor testing, collection/retrieval, processing, preservation, packaging, labeling, storage, quarantine, record keeping, distribution, importation, error, accident and adverse reaction reporting and investigation.

Under the CTOs Regulations, no establishment shall transplant a cell, tissue or organ unless it is processed by an establishment that is registered with Health Canada.[xv] Registered establishments are subject to site inspections by the Health Canada Inspectorate.

The National Standards that were published by the CSA form the basis for the safety requirements that have been incorporated in the CTO regulatory framework. The CTO Regulations directly reference sections of the Standards thus making them mandatory. It is important to note that the CSA Standards speak to various aspects of the donation and transplantation process. However, as the Federal Government's authority is limited to the safety of CTOs, every section that is referenced in the Regulations is related to the safety of CTO. Sections in the Standards that relate to the practice of medicine are not referenced in the CTO Regulations as this falls under provincial jurisdiction.

Donation Rates and the Future of a Canadian Eye Banking System

"Two reports highlighting concerns about a persistent and growing gap between the supply of and demand for organs and tissues for transplantation in Canada were issued

in 1999, one by the House of Commons Standing Committee on Health and the other by the National Coordinating Committee for Organ and Tissue Donation, Distribution and Transplantation".[xvi]

"In its September 1999 response to the House of Commons Health Committee's report, the government stated that it accepted the recommendations "as the framework for discussions with the provinces and territories towards the establishment of a sustainable solution for transplantation in Canada" and acknowledged that proper implementation would be dependent on support from all levels of government." [Xvii] The Federal Government in 2001 established the Canadian Council for the Donation and Transplantation (CCDT) as an advisory body to the Conference of Deputy Ministers of Health.[xviii] "The mandate of the CCDT was to provide action on:

- A coordinated pan-Canadian strategy and high-quality provincial/territorial strategies;
- Standards and clinical practice guidelines based on leading/best practices;
- Social marketing strategies and their implementation;
- Pan Canadian information management systems ;
- Educational resources for interdisciplinary professionals involved in donation and transplantation processes ;
- A system to monitor the performance of the Canadian experience against the experience in other jurisdictions and progress towards implementation targets; and

- An ongoing process to identify emerging issues and link to the strategic process"[xix].

In 2008 the Federal Government invited Canadian Blood Services(CBS) to participate in looking at a national system for organs and tissues. CBS was established following the Krever Inquiry and re-developed the blood system for Canadians. As a result of their success in rebuilding and sustaining a safe supply of blood and blood products, the Federal Government asked CBS to undertake a project that would investigate what a national system for Cells, Tissues and Organs would look like. In September 2008, key stakeholders representing all organs programs, eye banks and tissue banks in Canada met in Gatineau Quebec for four days to answer the question:

"Given the need for national, integrated services in tissue donation and transplantation, how do we establish the system that best meets the need of Canadian patients?"[xx]

At this time the CCDT was established as an unincorporated association funded by Health Canada. As part of this new initiative the CCDT was disbanded and was reorganized as a separate department within CBS. This new department was given the mandate to act on the recommendations of the organ and tissue community as a result of the Gatineau Meetings.

Three committees were struck, The Organ and Tissue Donation and

Transplantation Steering Committee, the Expert Organ Committee and the Tissue Expert Community.[xx]

The purpose of these committees was to help lead the CBS in the development of a national strategic plan for organ and tissue donation and transplantation in Canada. Between 2008 and 2011, the Committees developed a *CALL TO ACTION* report which was submitted to the Conference of Deputy Ministers of Health in June 2011. This report was accepted by the Conference and released to the public on June 20, 2012.

The report recommends that independent eye and tissue banks become part of a single system, governed and funded by CBS that involves all aspects of donation and transplantation. [xxii] The complete CALL TO ACTION report, including the 25 recommendations, can be viewed at the Canadian Blood Services website. www@blood.ca

In 2008 The Public Health Agency of Canada, Department of Transfusion and Transplantation Adverse Events Section, had been given federal funding to develop a surveillance system for Adverse Events for Cells, Tissues, and Organs (CTOSS). Key stakeholders within the tissue community were asked to be part of the development of this new Surveillance System. Currently PHAC, and the working groups have developed the tools used to report Adverse Reactions to the Public Health Agency of Canada. Currently Nova Scotia, New Brunswick, Quebec, Ontario and Alberta are part of a Pilot Project to develop educational tools for front line medical health care workers; to identify

adverse reactions, and how to report these events to the appropriate authorities.

Canada in the past decade has undergone major advances in the development of National Standards and Regulations but also in looking towards the future that will enable a steady, safe supply of tissues for Canadians.

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