A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada

A Report from the National Coordinating Committee for Organ and Tissue Donation, Distribution and Transplantation November 30, 1999

Ms. Anne McFarlane Chair Federal/Provincial/Territorial Advisory Committee on Health Services

Dear Ms. McFarlane:

On behalf of the National Co-ordinating Committee for Organ and Tissue Donation, Distribution and Transplantation, we respectfully submit this document describing our recommendations for a co-ordinated and comprehensive organ and tissue donation, distribution and transplant system for Canada.

We are grateful to the dedicated Canadians who agreed to be members of the Committee. Our work was greatly aided by the contribution of additional individuals, who, because of their expertise, contributed to two workshops organized by our Committee. We are appreciative to all for their knowledge, experience and unwavering commitment to the development of an accountable and sustainable donation and transplantation system in Canada.

Our report outlines a strategy to strengthen Canada's donation and transplant system. It has many components. All are believed necessary for the success of a nation-wide system – a system that will be consumer and family-centred, accountable and sustainable. Core donation and transplant functions are supported by a number of critical support processes that also foster a quality management approach to this area of health care. A Donation and Transplant Council, comprised of representatives from key stakeholder groups, is identified to support and lead the initiative.

Immediate implementation of this comprehensive approach to organ and tissue donation and transplantation will reduce the death rate for those in need of transplants. It will begin to provide an improved quality of life for individuals in need of organ and tissue transplant procedures.

We respectfully request that you give serious consideration to the recommendation contained in Section 6.0, Support Processes. These seven functions are critical if the proposed targets are to be realised and performance in donation and transplant outcomes is to be sustained. In particular we draw your attention to page 13, Administration and Operations:

"The provinces and territories have overall responsibility for the delivery of donation and transplant programs, ensuring compliance with provincial / territorial standards and guidelines, ...[and to] provide adequate funding and resources for designated donation and transplant facilities to undertake all activities related to service delivery and accomplish expected performance outcomes."

Ms. Anne McFarlane Page 2

This strategy will cost money, whether by new funding or through reallocation of existing funds. However, the return on this investment will be profound – both through reduced dialysis costs, and in providing Canadians with life sustaining therapy or treatment to significantly improve their quality of life. Though the cost savings of transplantation visa-vie other therapies for end stage renal failure in Canada have yet to be determined, published reports from other jurisdictions indicate that potential savings are enormous. We have no reason to doubt that these cost savings would also be realised in Canada. Therefore, we urge you and your colleagues in the Advisory Committee for Health Services (ACHS), to ask the provincial and territorial Ministers of Health to take immediate steps to evaluate /coordinate existing budgets that fund donation and transplant practices. This, with additional new funds will ensure successful implementation of this much needed and essential nation-wide initiative.

In conclusion, the recommendations contained in our report provide the federal, provincial and territorial governments with the strategy for creating a coordinated, and comprehensive donation and transplantation system for Canada. It is our goal that the Canadian Council for Donation and Transplantation be in place by April 1, 2000 to lead this process.

Above all, we commend the ACHS for directing the attention of the Ministers of Health to the need to enhance organ and tissue donation and transplantation in Canada. In doing so, we believe you will positively impact the lives of many Canadians.

Accordingly, this document is respectfully submitted for your consideration.

Yours truly,

Philip Belitsky MD, FRCSC Non-Government Co-Chair (Nova Scotia) Prudence Taylor RN MN Government Co-chair (Alberta)

National Coordinating Committee For Organ & Tissue Donation, Distribution & Transplantation

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Government Representative; Quebec Government Representative; Ontario Government Representative; Health Canada Government Representative, New Brunswick Canadian Association of Transplantation Canadian Council on Health Services Accreditation Canadian Organ Replacement Registry Canadian Society of Transplantation The Kidney Foundation of Canada

Government Co-Chair May 1999 - March 2000; Alberta Government Co-Chair 1997- 1999: Nova Scotia

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Acknowledgements

The National Co-ordinating Committee for Organ and Tissue Donation, Distribution and Transplantation acknowledges the thoughtful guidence and support provided by Mr. Malcolm Maxwell, (Yukon) Chair, Federal / Provincial / Territorial Advisory Committee for Health Services, throughout the deliberations of this Committee.

A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada

Report of the National Coordinating Committee for Organ and Tissue Donation and Transplantation

Introduction & Background

Introduction

For over a decade Canada has supported that transplantation of organs and tissues represent successful therapeutic modalities for the treatment of end stage diseases. These therapies generally achieve better survival rates than alternative treatments, while providing for improved quality of life¹. Canada is recognized as a leader in the science of transplantation and in patient outcomes in terms of graft and patient survival. However, Canada's donation rate is low compared to other developed countries. This has resulted in increased demands on the health care system in terms of the provision of alternative treatments such as renal dialysis, and lost opportunities for individuals to have an enhanced quality of life through transplantation.

Furthermore, there is increasing reliance on imported tissue such as bone and heart valves, in order to meet the escalating Canadian needs for obtaining human tissue, necessary for modern medical interventions.

This document describes a strategy to enhance organ and tissue donation, distribution and transplantation in Canada. It defines roles and responsibilities for the three levels of health care delivery in Canada; service provider/ region, provincial/territorial and federal/national and resource requirements necessary to support the proposed framework.

This is the report of the National Coordinating Committee for Organ and Tissue Donation, Distribution and Transplantation, a working group of the Federal/Provincial/Territorial Advisory Committee for Health Services (ACHS). The strategy is based on the knowledge and expertise of individuals who have a stakeholder role or interest in this area of health care.

Background and Chronology

September 1995

The Federal / Provincial / Territorial (FPT) Ministers of Health agree to undertake a nation wide strategy to address problems impacting donation and transplantation in Canada.

1996

The ACHS commissions a national study to identify the issues. The findings of this initiative are described in the report, "Organ

¹ Vital Organ Transplant Centres – Guidelines (1986). National Health and Welfare, Ottawa.

and Tissue donation and Distribution in Canada: A Discussion Document, (1996)". This report:

- Identifies thirteen strategies and 35 initiatives to address Canada's donation and transplantation issues.
- Recommends a multifaceted approach with input from government, professional societies and organ foundations
- Recommends a national / provincial strategy to address the three major themes:
 - Development of national outcome and process standards
 - Enhancement of national and provincial organ and tissue donation and distribution systems
 - Improvement of public and professional awareness and knowledge

1997

The FPT Ministers' of Health approve the proposed strategy and recommend a coordinating committee be convened to develop an implementation plan to address the 13 strategy elements.

The project is given a three year mandate and a budget of \$500,000.00

May 1998

The membership of the National Coordinating Committee for Organ and Tissue Donation, Distribution and Transplantation (NCC) is finalized

November 1998

Non-government co-chair appointed.

Work commences on approach to implement 13 point strategy.

December 1998

The Honorable Alan Rock, Minister of Health announces the Standing Committee on Health (SCH) will undertake a study to look at the donation crisis in Canada.

The NCC cooperates with the SCH by providing information and appearing as invited witnesses before the inquiry.

April 1999

The report of the SCH inquiry, " Organ and Tissue Donation and Transplantation: A Canadian Approach", is released. The report contains 18 recommendations, including support for a

comprehensive donation and transplant system in Canada, and, that Health Canada would work with the NCC to achieve such a system.

March 1999

NCC meets with consultants from Spain regarding the Spanish model of donation.

June 1999

ACHS is directed by the FPT Deputy Ministers of Health to bring forward an Interim Report to the Ministers on Organ and Tissue Donation and Transplantation to include: 1) a framework for action at the local, provincial / territorial, and national levels which would result in a sustained systematic approach to increasing the rates of organ and tissue donation and transplantation in Canada, 2) principles to guide officials in preparing an organizational financial plan for collaborative action to support donation and transplant activities and, 3) a goal expressed in donations per million population annually in Canada in the year 2005.

NCC workshop is held in Aylmer Quebec, to develop recommendations and processes to address the 13 strategy elements. The need for a coordinated and comprehensive strategy identified.

July 1999

ACHS is given direction by the Deputy Ministers of Health to proceed with the preparation of an Interim Report for discussion at the Conference of Ministers of Health in September 1999.

August 1999

NCC releases the proceedings of its invitational workshop, including recommendations to the ACHS for a set of principles to direct a sustained effort to increase the level of organ and tissue donation and transplantation in Canada

September 1999

As an outcome of their meeting in Prince Edward Island, the Ministers of Health ask the NCC to submit an operational business plan to the ACHS for the transplantation strategy.

NCC invitational workshop is held in Montreal, Quebec to define proposed roles, responsibilities and accountabilities of stakeholders within the coordinated, comprehensive. This step is necessary to respond to the requests of the Ministers of Health for an operational business plan. A Vision for Canada's Health System

Canada's Health System

The structure of Canada's Health System influenced the decisions of the NCC in regard to the design of a strategy to enhance donation and transplantation in Canada. The NCC recognized the distinct roles of the federal and provincial/territorial governments in the regulation, funding and delivery of health services.

This strategy calls for a coordinated network of services that are critical to enhancing donation and transplantation. Therefore, it is essential for the governments of Canada to engage in a true working partnership under which this donation and transplant strategy would be administered, adjudicated and financed.

Over-Arching Goals

The NCC considered the goals agreed to by the Ministers of Health, in regard to the future health system for Canadians:

- To preserve, protect and improve the health of Canadians
- To ensure reasonable access to an appropriate range of health benefits anywhere in Canada based on need and not the ability to pay.
- To ensure long-term sustainability of the health system.

Principles

The framework developed for a coordinated and comprehensive donation and transplant system, builds on the guidelines and recommendations of the Conference of Provincial/Territorial Ministers of Health, ("*A Renewed Vision for Canada's Health System.*") These principles were considered by the Working Group on Organ/tissue Donation and Distribution, who undertook the diagnostic phase of this initiative.

Five principles were key in defining the strategic direction for donation and transplantation in Canada:

Accountability

For public trust, there is a need to understand who is responsible to whom for what. By defining roles and responsibilities for stakeholders, the governments will be accountable to Canadians for the donation and transplant service provided.

Quality

Canadians in need must be assured that the processes employed will optimize donation and transplant outcomes in terms of survival and quality of life, and will meet the highest quality and safety standards. Using a quality management approach, process and outcome standards will be measured to monitor and evaluate hospital performance. Designing a Nation-Wide Framework **Evidence Based Decision Making**

Sound information is important for improving the quality of decision-making. Evidence was drawn from the scientific literature and analysis of strategies used in benchmark institutions / countries.

Sustainability

It is essential that the donation and transplant strategy be sustainable for the future. The system design should ensure optimal donation and transplant practices that will lead to desired outcomes in terms of the availability and quality of services.

Client / Family Centered

The concerns and dignity of clients and their families are paramount. The proposed strategy respects the autonomy, dignity and beneficence of those individuals and families involved in the donation process as well as transplant recipients.

The coordinated and comprehensive donation and transplant strategy builds upon resources within the Canadian health system. Critical functions and support processes require coordination and integration at the three levels of service provider/hospital, provincial/territorial and national. This can be achieved through a multidisciplinary, partnership approach encompassing a framework for the delivery of donation and transplant health services.

National Vision

A national vision for donation and transplantation is required to:

- Ensure that efforts to achieve excellence are proactive
- Facilitate informed decision making in regard to the preferred system for meeting consumer needs, providing additional services and designating donation and transplant facilities.

Building Blocks

Six components or building blocks critical to the design of a health system were used as the theoretical framework for the strategy.

Strategic Direction

Defines and describes future direction, measurable goals, key success factors, performance measures and targets.

Processes

Describes the core functions and critical support processes essential to achieving the targets and outcomes for the services

A nation-wide donation and transplant strategy needs to address these six components. provided.

People & Organization

Describes the accountability relationships and the communication flows, defining roles and responsibilities and qualifications needed.

Technology

Describes the technical environment required to support the core functions and critical processes.

Legislation & Policies

Describes the regulatory requirements that must be met and the key policies within which the programs and services operate

Physical Infrastructure

Describes the physical location of facilities where the service providers deliver the health service.

Goal

- To increase the number of organs and tissues available for transplantation, and
- To increase the number of organ and tissue transplants that will provide an improved quality of life to those receiving.

Targets

Within five years of implementing a coordinated and comprehensive strategy for organ and tissue donation, Canada will have:

- 25 organ donors per million population (DPMP). Canada now has 14.2 DPMP. This target would result in an increase of about 2 donors per million population per year for the five-year period.
- 25 DPMP will be the goal of every province / territory.

This will result in a nation wide annual increase of approximately 330 more organ donors at the end of the five year period.

At the end of the five year period, the following increases in the number of organ transplants are anticipated:

- 165 more heart transplants 50% of donors meeting the criteria for heart donation
- 281 more liver transplants

These goals and targets can be achieved providing all building blocks in the development of the

strategy are addressed.

Strategic Direction

National Coordinating Committee on Organ and Tissue Donation and Transplantation

85% of donors meeting the criteria for liver donation

- 66 more lung transplants 20% of donors meeting the criteria for lung donation
- 646 more kidney transplants
 660 more kidneys and 95% of donors meeting the
 criteria for kidney donation
- Two and a half times more tissue donors. Unlike organ donors, the Canadian tissue donation rate is unknown, as there is no national reporting mechanism to capture this data. The clinical experts assume that in order to meet the future demand for tissue, the current donation rate would need to increase by two and a half times the current volume.

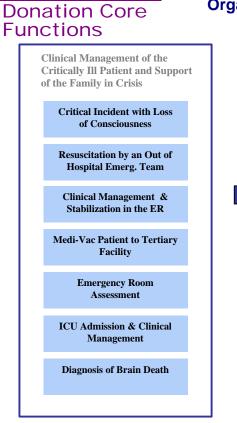
Core Functions

For both donation and transplantation to succeed, the core functions where direct service is provided to the consumer need to be defined. These functions describe a distinct health event (service).

- The provinces / territories are accountable and responsible for the delivery of the core functions
- High quality donation and transplant services require policies, standards and guidelines, that address each event
- The policies, standards and guidelines are developed around the principles for success and need to define:
 - What the service is
 - > Who provides the service
 - Who is accountable and responsible for the service
 - Where will the service be provided
 - How will the service be delivered
 - How will the service be measured in terms of expectations and outcomes, including customer satisfaction
 - What will the service require in terms of materials, technology and funding
 - How much the service costs

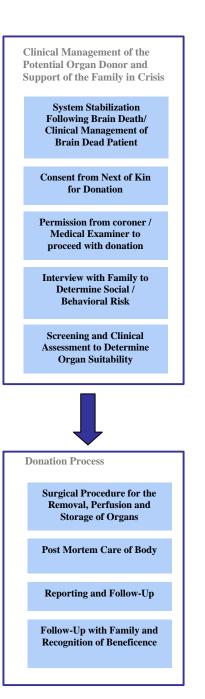
Processes

Organ Donation - Core Functions



The function and discipline of coordinating the care of organ donors falls within the domain of critical care medicine.

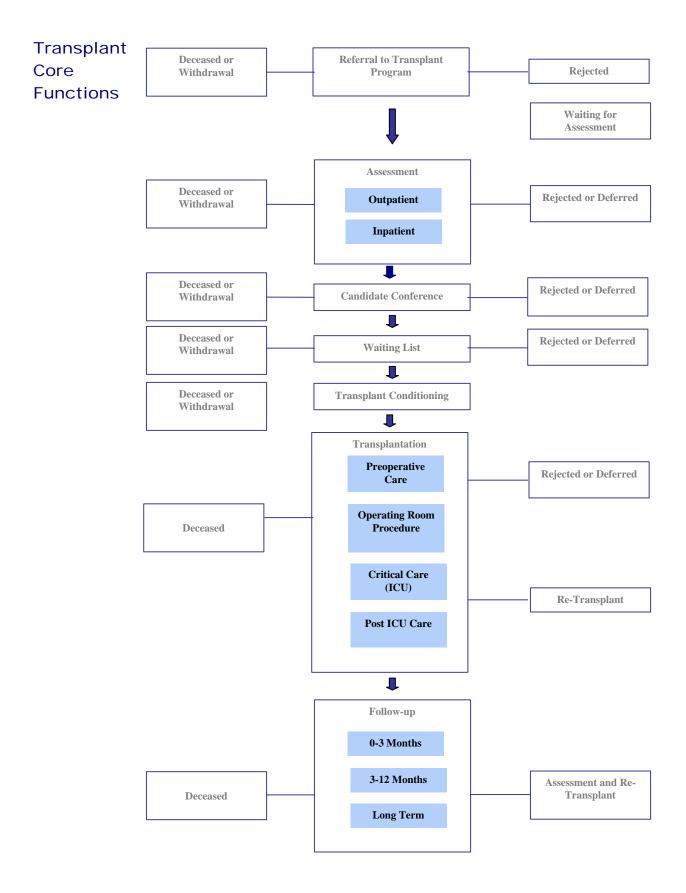
- Organ donation is the outcome of a complex set of events linked to the management of the critically ill patient who dies from a catastrophic cerebral event
- Provinces / territories need to designate intensive care units for the management of the brain dead patient.
- Expert clinical management is essential to optimizing organ function in the brain dead patient
- Bereavement support of family members is an essential component of supportive care of the potential organ donor
- Coordination is key to optimizing best outcomes.



Transplant Core Functions

The function and discipline of coordinating the care of organ transplant patients falls within the domain of transplant/immunology medicine.

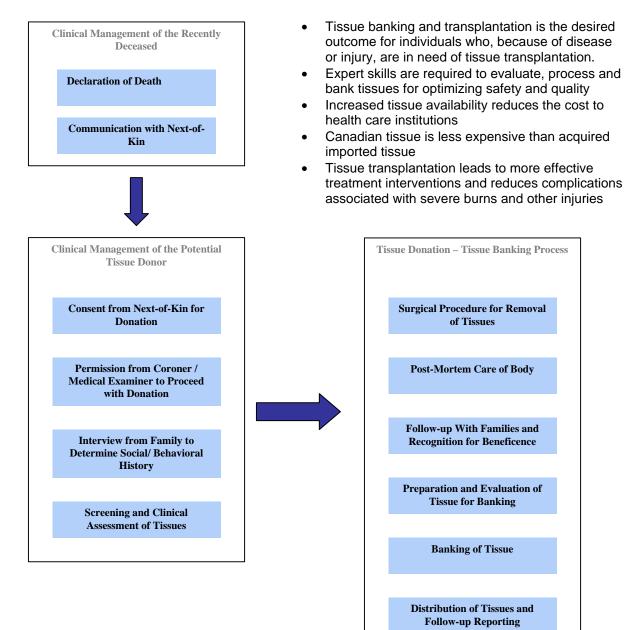
- Transplantation is the desired outcome of patients with end stage organ failure.
- Transplantation improves quality of life and reduces lost opportunities for full participation in society.
- Expert clinical management is essential to optimizing transplant outcomes
- Incremental transplant costs increase with the number of patients who enter the transplant process but do not receive a transplant
- Increased organ availability reduces the incremental costs related to:
 - Deaths while on the waiting list
 - Deferrals because of underlying complications due to disease processes or complications
 - Prolonged waiting times and the costs of providing care.



Tissue Banking Core Functions

Process

The function and discipline of tissue banking falls within the domain of surgical medicine.



Support Processes

- Support processes are a number of functions, which provide essential support to each identified unique event of the core functions for donation and transplantation.
- Support processes provide the quality management framework essential for achieving targets and sustaining performance.

Professional Competency and Education

All service providers need knowledge and skills to perform their roles in order to provide high quality care to donors, their families and transplant recipients.

An educated and skilled workforce enables cost savings to be achieved through quality service delivery and designation of functions to appropriate personnel to improve efficiencies in terms of service delivery and cost.

Coroners / Medical Examiners:

Programs to prepare practitioners to participate in organ and tissue donation.

Nursing:

Programs to prepare nurses for practice in the field of donation and transplantation are required.

- Certificate in donation nursing
- Certificate in transplant nursing
- University programs (Masters level) for degrees in advanced practice nursing in the field of donation and transplantation are desirable.

Physicians:

Programs to prepare physicians for practice in donation and transplantation.

- Those working in emergency rooms and critical care areas will have knowledge in the area of interacting with families in crisis and best practice in how to engage in donation discussions with family members.
- Clinical competencies related to the care of the brain dead patient

Professional competency around donation and transplant practice should be part of professional competency evaluations tied to privileges.

Pastoral Care:

Programs to support patient/family questions and concerns regarding spirituality and transplantation and in the provision of bereavement support.

Social Workers:

Programs to prepare social workers to coordinate benefits for transplant recipients and their families and in the provision of psycho-social support around issues related to death and transplantation.

Tissue Banking:

Programs to prepare tissue-banking technologists with the required knowledge and skills to recover, process, bank and distribute high quality tissue for transplantation.

 To create a Canadian certification program for tissue bank technologists through a Canadian education institute.

Professional Development Programs:

Designated donation and transplant facilities to have professional development programs for all levels of employees. Such programs will be tied to accreditation standards for designated facilities.

Public Education and Social Marketing

Within the framework of holistic health, educational and social marketing campaigns are conducted to strengthen consumer knowledge, enable informed choices and to increase support and participation in donation and transplantation health services.

- Public education is the design and distribution of information that may increase knowledge in the population.
 - > A multidisciplinary approach is required.
 - Collaboration with non-government organizations and key stakeholders to foster a broad understanding of donations and the outcome of transplantation.
- Social marketing is the design, implementation and control of programs seeking to increase the acceptability of a social idea or cause in a target group.
 - Different programs need to be designed to address the needs and beliefs of individual target groups
 - Programs must emphasize health promotion, protection and disease and injury prevention
 - Strategies will be population-based and culture sensitive.

Policies, Standards and Guidelines

Policies, standards and guidelines ensure, quality, safety, acceptability, equity and cost effectiveness of services provided.

Standards define the criteria against which actual results; outcomes and overall performance will be evaluated.

- Standards will be tied to the hospital accreditation process.
- The safety standards for perfusable organs, ocular tissue, tissue (other than ocular), sperm, bone marrow and xeno-transplantation will be referenced in the *Foods* and Drugs Act.

Policies and guidelines define the scope of the service and expectations for how the service will be delivered, monitored and evaluated.

- Policies, standards and guidelines will be developed by the provinces and territories
- Policies, standards and guidelines need to be adopted by all governments
- The provinces / territories will be responsible for the implementation of policies, standards and guidelines approved by the Minister's of Health

Administration and Operations

The provinces and territories have overall responsibility for the delivery of donation and transplant programs, ensuring compliance with provincial / territorial policies, standards and guidelines.

- Will designate where donation and transplant services are delivered
- Provide adequate funding and resources for designated donation and transplant facilities to undertake all activities related to service delivery and accomplish expected standard performance outcomes.
- Ensure provincial / territorial coordination.

Monitoring and Evaluation

Program performance will be monitored and evaluated by the provinces / territories to determine:

- Organ and tissue donation rates compared to the national target
- Transplant outcomes achievements in morbidity and mortality
- *Effectiveness* in terms of implementation and application of practice and safety standards
- Satisfaction in terms of consumers and service providers
- *Cost-effectiveness* in terms of the overall strategy, service delivery and outcomes.

Surveillance

Epidemiological data about donation and transplantation will be sought to understand population trends.

- Prevalence and incidence of conditions leading to brain death/death
- Incidence, prevalence and mortality from diseases requiring transplant intervention
- Incidence, prevalence and mortality from post transplant conditions, (transplant type, disease, sex and age stratified)
- Risk factors associated with pre-transplant conditions
- Risk factors associated with donation
- Risk factors associated with transplantation
- Availability of organs and tissues
- Access to transplantation, equity of organ sharing practices

Trends analysis will be monitored and information used for the design and implementation of new programs.

Quality Assurance

Ongoing investigation and analysis identifies ways to continually improve donation and transplantation practices and identify ways to reduce the need for transplantation through health promotion and disease and injury prevention strategies.

- Identifies alternative and more effective methods of treating diseases
- Identifies mechanisms to engage public commitment and participation in holistic health practices, including support for donation
- Furthers the understanding of transplant surgery, medicine and immunology to provide improved transplant outcomes
- Identifies mechanisms to engage public commitment and participation in donation
- Plan, implement and evaluate appropriate action plans to address substandard outcomes
- Practices associated with organ and tissue donation outcomes
- Practices associated with transplantation
- Practices associated with tissue banking
- Public education and social marketing strategies

People & Organization

The coordinated and comprehensive donation and transplant strategy is supported nationally by a Council, Secretariat and three Advisory Committees.

- A permanent structure to facilitate and support the provinces / territories to create and maintain:
- National practice standards
- National safety standards
- Minimal data sets
- Information systems network
- Social marketing strategy
- Mechanisms for assessing adherence to the standards and monitoring hospital / facility and provincial / territorial performance
- Development of consensus documents / reports
- Supporting the provinces / territories with monitoring, evaluation and reporting functions.

The Canadian Council for Donation and Transplantation

The Canadian Council for Donation and Transplantation will report to the Ministers' of Health through the FPT ACHS. (See appendix A)

- To support provincial / territorial activities through the development, implementation, monitoring and evaluation of strategies that would enhance donation and transplantation.
- To provide nationwide leadership by; advising, coordinating, facilitating and evaluating the development, implementation and evaluation of strategies directed at enhancing the practice of organ and tissue donation and transplantation.
- Membership 12 15 members appointed by ACHS.
- Members selected from stakeholder organizations and would include representatives from government, clinical disciplines concerned with donation and transplantation, epidemiology, ethics, and the public.
- Chair to be appointed by ACHS. (*Dual chair positions, non-government and government should be considered for the transition phase).*
- Quarterly meetings.
- Members on the Council should receive professional service remuneration according to guidelines established by the ACHS.
- Health Canada would provide resources to support the Council activities.

Secretariat

A permanent structure to support activities of the Council and three Advisory Committees. (Appendix B).

To facilitate and coordinate activities as directed by the Council.

Accountable to the Council and report through Health Canada.

In response to directions of the Council, responsibilities will include:

- Policy development
- Surveillance
- Health strategy development
- Legislation review and development
- Ethical review and assessment
- Information systems development
- Professional education programming / resourcing
- Public education
- Social marketing
- Communications
- Facilitating, coordinating and responding to requests from the Council.
- Contracting with consultants

Staffing:

- Senior manager
- Administrative support
- Consultants on a term / contract basis
- Others (Epidemiology, Ethics, Communication, Legal Support)

Advisory Committees

Three Advisory Committees (AC) report to the Council. (Appendix C)

Donation Advisory Committee

Organ Transplant Advisory Committee

Tissue Advisory Committees

To provide expert advice to the Council on issues related to: safety and practice standards, guidelines, outcomes, professional and public education program requirements and social marketing strategies.

Council appoints members to the Advisory Committees

Members on the Advisory Committees would receive professional service remuneration according to guidelines established by the ACHS.

Health Canada would provide resources to support the Advisory Committee activities.

Numerous stakeholders have roles in assuring successful donation and transplant outcomes.

Collaboration and partnerships are essential

Roles and functions clearly defined

Articulated accountability and authority

Roles and Accountability

Accountability	Role	Rationale
The public	Practice healthy behaviors Make informed choices in regard to participation in donation or transplant health services	Each person has a responsibility to participate in holistic health practices that will avoid unnecessary costs to the health system
		By making informed decisions and choices, individuals can plan for health / life outcomes.
Federal Government	Provides a grant to support the Council and associated support structure (secretariat and three expert working groups)	The federal government is the overall protector of the national health system
	Licenses drugs and medical devices	It is a partner in health with the provinces and territories
	Provides a role in the areas health promotion and protection	To ensure public policy. Legislatior health programs and standards are in place to protect and promote the health of the population
	Provides funding to the provinces / territories	
	Responsible for implementing public education and social marketing strategies directed at organ and tissue donation to aboriginal people, the Canadian Forces and RCMP	
	To participate in ongoing dialogue with the provinces and territories around issues impacting the successful realization of this strategy Forces and the RCMP	

Provincial / Territorial Governments

Support the principles of the *Canada Health Act* and provide management and resources to maintain a national health system

Set policy

Establish legislation

Designates donation and transplant facilities

Monitors compliance with standards

Evaluates and endorses policies, standards and guidelines developed by the Council

Undertakes health surveillance functions

Monitors program performance and assesses the effectiveness of donation and transplant programs

Initiates interventions to improve program results

Allocates resources to the hospitals / health regions

Provide direction to the Council

Ensures a provincial co-ordination strategy is in place for donation and transplant activities

The Canadian Council for Donation and Transplantation To advise the FPT ACHS on overall policy direction, standards and guidelines for the delivery, coordination and evaluation of organ and tissue donation and transplantation

To facilitate the development, implementation and evaluation of practice and safety standards, data sets. Information systems networks, provincial / territorial reporting requirements and the design and evaluation of professional and public education and social marketing strategies.

See appendix A: The Canadian Council for Donation and Transplantation Responsible for the overall direction and operation of the provincial / territorial health systems

Responsible for maintaining a national partnership with the federal government:

- to preserve, protect and improve the health of Canadians
- to ensure the long term sustainability of the donation and transplant strategy
- to link health policy with economic and social policy
- for appropriate accountability for the use of public funds and for the results achieved

The mandate of the Council is to take leadership in the areas / issues that concern donation and transplantation where there is a need for national coordination or standards. Health Regions / Hospitals / Coroners /Medical Examiners Facilities Primarily responsible to:

Facilitate donation and transplantation in designated facilities by ensuring the availability of resources for services to be carried out and sustained

Ensuring all designated donation and transplant facilities including tissue banks are accredited by a Canadian accreditation authority

Ensuring the support structure is in place for entering data in a timely manner and accessing data for the coordination and management of donation and transplant processes

Ensuring hospital / regional policies and procedures concerning donation and transplant practices / services are current and articulated to service providers

To ensure professionals engaged in donation and transplant practice have the knowledge and skill requisites necessary to deliver this health service

Participating in provincial / territorial performance evaluation of outcomes

To provide resources for bereavement support personnel to be part of the critical care team

To provide private areas for families to congregate and grieve and participate in religious rituals as approved by hospital / regional authorities Mandated to deliver designated services to the population as a whole and those at risk of specific health problems

Employ qualified practitioners / service providers and operate designated facilities

Knowledgeable about their communities and residents, knowing what strategies are most effective

Accountable to the provincial / territorial governments

Service Provider

Own continuing professional education

Participating in professional / staff development programs

Understand and respect the roles and responsibilities of others in the donation and transplant continuum

Complying with national standards, policies and guidelines in terms of donation and transplantation practice

Coordinating the transplantation process

Coordination of donation and tissue banking practices

Delivery of health care to potential donors, families and transplant recipients

Undertaking tissue banking services

Follow-up with clinical results where indicated

Enter data into data base

Participate in overall-program assessment and evaluation

Through provincial / territorial legislation, are responsible for the provision of health care to individual consumers

Through interaction with consumers on a variety of health issues, provide an opportunity to promote healthy choices and options, including donation

Provides a point of contact within the hospital / region for other health professionals

Legislation & Policies

Policies, Standards and Guidelines

Organ and tissue donation and transplant practice and safety standards are necessary to guide stakeholders in the development, implementation and evaluation of donation and transplant programs.

- Policies, standards and guidelines of national concern will be drafted by the Council on the recommendations from the Advisory Committees and provinces / territories for approval by the Ministers of Health
- Health Canada has taken lead in drafting the General Standard for the Safety of Organs and Tissues for Transplantation and is in the process of approving final drafts of the organ / tissue subsets. These standards will be referenced in the *Food and Drugs Act*

Legislation

Enabling legislation includes:

- Canada Health Act
- Food and Drugs Act
- Provincial Legislation
- Human Tissue Gift Act
- Privacy legislation
- Other

An information system designed to support over-all data needs

In collaboration with the stakeholders the Council will define the necessary information technology support and infrastructure, minimum data set requirements and processes for data collection, management, sharing and reporting

Coordinated national network that connects the service providers, provinces / territories and other stakeholders

The Council will take lead for the development / expansion of a central registry and database accessible to authorized stakeholders for specified and mutually agreed-upon purposes

Policies and regulations for access, use and disclosure of data will be required for:

- Performance monitoring
- Program evaluation
- Population surveillance activities
- Quality Assurance

Technology & Information Systems

Information System Development - Roles & Accountability

Stakeholder Accountability	Roles and Responsibilities
Federal Government	Design, develop and maintain the central database
	Collect data from the provinces / territories
	Analyze data for monitoring overall achievement targets and program evaluation
	Reporting outcomes to the public and provinces
	Custodians of the database
Council	Develop the data set
	Develop policies in regard to authorized stakeholder access for mutually agreed-upon purposes
	Develop standards for performance monitoring, program evaluation, research and surveillance
Provinces / Territories	Establishing a coordinated provincial / territorial network that connects specified donor and transplant centres and tissue banks with the central database
Hospitals / Regions	Submit data to central database
	Access data to plan strategies to enhance public education and social marketing programs and professional education programs
	Assess provincial performance, identifying barriers to services
Service Providers / Tissue Banks	Submit donation and transplant data to central database
	Access data to conduct quality assurance audits
	Access data for research
	Access data for coordination of donation and transplant activities

Physical Infrastructure

The provinces / territories operate health care facilities for donation and transplantation and tissue banks

Provide office accommodation to support administrative functions.

Allocate resources through regions / hospitals

Facilities

The provinces / territories will designate donation, tissue banking and transplant hospitals / facilities

The facilities will have mission statements applicable to their role in donation, tissue banking and transplantation

The facilities will be required to meet accreditation standards applicable to donation, tissue banking and transplantation as defined in the Canadian General Standard for the Safety of Organs and Tissues for Transplantation and the associated clinical sub-sets.

A Collaborative Network

A collaborative network of stakeholders is involved in ensuring successful donation and transplant outcomes.

An accountability structure is required to provide overall governance and management of donation and transplant programs

The accountability structure needs to:

- Preserve, protect and improve the health of Canadians
- Ensure reasonable access to appropriate range of health benefits anywhere in Canada based on needs and not the ability to pay.
- Endure long-term sustainability of the health system.

Donation and transplant programs are coordinated at the level of hospitals / facilities

Collaboration and cooperation is fostered among all stakeholders

Resources are used efficiently and cost-effectively to deliver the services

High quality services are provided

On going monitoring and evaluation of donation and transplant programs are conducted

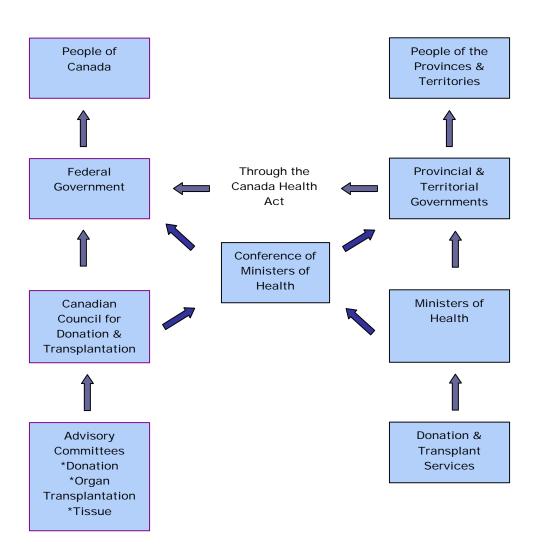
Consistent and current professional education is provided

Donors and families are recognized for their beneficence

Public input and participation occurs

Modification to the framework will occur in accordance with quality assurance methodologies that are evidence based.

Organization and Accountability Relationships



Business Case

Economic Evaluation

Analysis of costs for alternative treatment programs forms the basis for economic evaluation of health care

High-cost services such as transplantation need to substantiate their appropriateness through cost-effectiveness analysis that considers:

- Direct costs for different types of treatment
- Fixed and variable costs looked at separately
- Program costs
- Patient and graft survival
- Quality of life
- Quality Adjusted Life Years
- Opportunity costs (to determine program benefits)
- Standardized methodology

Cost Effectiveness

- Grounds for determining priorities in health care
- Determines health outcomes achievable
- Facilitates program planning / budgeting

Renal Transplantation

Transplantation is the most cost-effective treatment for kidney failure.

Literature provides some perspective of potential savings of renal transplantation.

• Canada (BC)¹

\$Can 51,406 cost savings realized after year one and subsequent years of functioning graft

- France² Beneficial cost savings of \$US148,580 over 4 years
- Italy³
 Each year post transplantation 32% of the cost of dialysis
- Netherlands⁴ Hemodialysis least cost effective treatment

50% higher than transplant costs

Sweden⁵
 \$US625,000 cost savings per average kidney transplanted

Issues

Poor understanding of real costs associated with donation and transplantation in Canada because of the lack of an extensive body of Canadian data

Foreign data:

- Reflect foreign practices and costs
- Differences in methodology and variables used
- Small sample sizes
- Costs poorly defined in terms of what is included
- Outliers not factored in

¹ Keown, P., (1999) Transplant Proceedings, 31

² Cogny-Van Weyddevelt, F., et al, (1996) Transplant Proceedings, 28:5

³ Lensia, L., et al, (1995) Transplant Proceedings, 277:6

⁴ de Wit, D. A., et al., (1998) Health Policy, 44

⁵ Karlberg, I. & Nyberg, G., (1995) International Journal of Technology Assessment in Health Care, 11:3

 Assumes all patients on most expensive dialysis treatment (does not factor in those transplanted pre dialysis and those on the less expensive form peritoneal dialysis)

Current evidence suggests that the cost of savings increases with each year of graft survival and that this trend is likely to continue.

Recommendation

- The provinces/territories undertake a collaborative study to determine the true costs, cost benefit/utility of transplantation in Canada.
- Suggest economic modelling (Markov Chain) be used in determining Canadian cost -effectiveness / cost-utility:
 - Accommodates a number of variables (i.e. costs related to different modes of dialysis or underlying diseases)
 - Accommodates the wide range of acute, transient / chronic events associated with donors and transplant patients.
- Decision trees map out clinical management courses allowing estimation of probability for each discrete pathway

Operational Business Plan

3 year plan

Identifies federal and provincial/territorial responsibilities

Start up and development costs higher (years 1&2, than maintenance, year 3)

Proposed Operational Budget – Annual Incremental Requirements Health Canada

Description	2000/01	2001/02	2002/03
Council	.15M	-	-
15 members per committee x 4 meetings per year: Travel & Accommodation & Professional Service Fees			
Advisory Committees (3)	.6M	-	-
15 members X4 meetings per year: Travel & Accommodation & Professional Service Fees			
Secretariat	.35		
Labour (Senior Strategy Lead, policy analyst, epidemiologist, Administration support)	.5	-	(.3)
Contracts / Consultants Supplies, equipment	.3	(.1)	(.1)
Administration support to council (travel & accommodation), office supplies	.03	-	-
Sub Total	1.18M	(. 1M)	(.4M)
Monitoring, Evaluation & Reporting	.1M	.2M	.2M
Development Standards, and Guidelines	.3M	-	(200,000)
Surveillance	.1M	.05M	.05M
Professional Education			
National forum for service providers	1.0	(1.0)	
Development of Tissue Banking Technology Training Program in one Canadian Facility Nursing: Donation or Transplant Certification Program	1.0	1.0	
Sub Total		.5	(.3)
	2.0M	.5M	(.3M)
Public	1.0	(5)	
Public Education Materials	2.0	(.5)	
Social Marketing Family Recognition (medals)	1.0	.2	.2
Sub Total	4.0M	(. 3 M)	.2M
Information System / Technology	4.0		(1.0)
Business case, design architecture, technology development, privacy impact assessment	4.0 .5	(2.0) (.45)	(1.0)
Data Set, reporting and analytical functions, Ongoing operational management / support	.2		
Sub Total	4.6M	(2.45M)	(1.0M)
	23.4	. ,	. ,
Promotion, Prevention, Protection Diseases, behaviours and situations that leads to organ failure	.2M		
Ouality Assurance	4.0M		
Public willingness, strategies for hard to reach population, PPP initiatives, donor & transplant related	4.0111		
Totals	\$17.68M	\$(2.1M)	\$(1.45M)

Provinces / Territories: Estimated Annual Incremental Requirements

Description	2000/01	2001/02	2002/03
Provincial Tissue Banking Centres Provinces should designate tissue banking centres and provide resources to accommodate the increased supply based on provincial / territorial targets (labour, supplies, equipment)	2M		
 Provincial Donor Co-ordination Designated organ and tissue donor facilities should have resources, (including ICU beds and operating room time) to provide the necessary donor services and #s of personnel to provide 24 hour a day 7 day a week co-ordination of cases. Bereavement support teams associated with designated ICUs 	10M	2M	1M
Transplant Cases To accommodate the increased number of transplant procedures in terms of professional support for evaluation, teaching, counselling and follow-up and access to facilities for transplant procedures (beds, operating room time, drugs, diagnostic interventions	5M	14M	3M
Monitoring, Evaluation & Reporting Designated organ and tissue donor facilities and tissue banks should have resources to monitor performance and outcomes based on nationally agreed practice and safety standards, utilising the national data set. Aggregate provincial / territorial data should be submitted to the national data base Provincial / territorial public reports on performance outcomes	1.2M	.3M	.3M
Implementation of Standards & Guidelines Organ, tissue, ocular tissue, bone marrow	5M	(3M)	(1M)
 Professional Education Measures to ensure that stakeholders have the requisite knowledge and skill to practice in the area of donation and transplantation. Resources for ongoing professional education and hospital development 	3M	2M	(3 M)
Provincial Public Education / Social Marketing Resources to deliver and evaluate public education and social marketing strategies	4 M		
Surveillance Surveillance practices to identify population trends in causes of death and diseases requiring transplant intervention and transplant outcomes	1M		.2M
Promotion, Prevention & Protection Strategies to pre-empt the need for transplantation and prolong graft survival and development / management of other chronic medical problems	2M		
Information System / Technology Hardware, software and resources to access and submit data to the national data base and to support clinical donation and transplant activities (i.e. accessing the recipient waiting list to match donors and recipients)	10M	30M	(20M)
Totals	\$43.2M	\$30M	(19.5 M)

Evaluation

The Canadian Council for Donation and Transplantation will provide an annual public report and evaluation of national outcomes and overall performance to ACHS for the next five years. Also, on year five, the Council will undergo an independent organizational evaluation and review. This would look at but not be limited to the following:

- Overall impact of the strategy on donation and transplant rates in Canada
- Assessment of Council effectiveness
- Assessment of Council structure
- Provincial / territorial satisfaction with Council support
- Stakeholder satisfaction with Council support

An independent consultant would undertake this evaluation.

Appendix A

Principles for a Coordinated and Comprehensive Canadian Strategy for Organ and Tissue Donation and Transplantation¹

In June 1999, the National Co-ordinating Committee released the proceedings of an invitational conference including recommendations to the Advisory Committee on Health Services for a set of principles to direct a sustained effort to increase the level of organ and tissue donation and transplantation in Canada.			
These principles represent the advice of experts in the related specialized areas of medicine and nursing on the most desirable assignment of responsibilities to provide Canadians with a co ordinated, comprehensive and integrated strategy to increase donation and transplantation.			
These principles were approved by the Conference of Ministers of Health, Prince Edward Island, September 1999.			
 A National Goal expressed in donors per million population (DPMP) annually should be established. (The current Canadian rate is 14 DPMP. The benchmark nation is Spain at 31 DPMP). A co-ordinated, comprehensive and integrated donation and transplantation strategy is required. The strategy should be directed by a Council, appointed by the Federal, Provincial and Territorial Governments, which would maintain a regular reporting link to the Ministers of Health through the Advisory Committee on Health Services. The Council should include representatives from government, clinical disciplines concerned with donation and transplantation, epidemiologists, ethicists, and the public. The Council should: Provide oversight and monitoring of the implementation of the strategy; Provide expertise for the development of standards and recommendations for future consideration; Approve and oversee the implementation of social marketing strategies; Monitor and report on the outcomes of the strategy through 			

¹ Supported by the Conference of Ministers of Health (P. E. I. September 1999) Appendix A

- The Council should have an ongoing Secretariat to support Health Ministries and service providers to create and maintain components of a strategy including:
 - National practice standards;
 - National safety standards;
 - Social marketing strategy;
 - Mechanisms for assessing adherence to the standards of the Canadian Council on Health Services Accreditation (CCHSA);
 - Development of consensus reports;
 - Supporting Provincial and Territorial activities related to donation and transplantation.
- The Secretariat should be funded by Health Canada.
- 4. Provinces and Territories should designate critical care units whose mandate will include the responsibility for donation. Staff within these units will be provided with the necessary education and training to identify potential donors, diagnose brain death, maintain clinical support of the donor until organ recovery is possible, and provide bereavement support to the family.
- 5. Provinces and Territories should ensure that organ donation and co-ordination activities will be encompassed within critical care services at the community level. In addition, tissue donation should be formally linked to organ donation activities at the community level.
- 6. Provinces and Territories should participate in developing, and be responsible for reporting against, common standards for the listing of transplant candidates, organ allocation, sharing practices, and organ and tissue transplant outcomes.
- Reporting requirements for all hospital services with respect to organ and tissue donation and transplant activities should be incorporated within the standards for accreditation established by the Canadian Council on Health Services Accreditation.
- 8. Provinces and Territories should ensure that inter-provincial billing agreements will cover costs for organ donation, tissue banking, and organ allocation and transplantation.
- 9. Federal, Provincial and Territorial Governments should ensure the safety, quality and consistency of all organs and tissues for transplantation, through comprehensive national safety standards implemented with support from F/PIT governments and service providers for compliance and enforcement.
- 10.Provincial and Territorial governments should fund those elements of the strategy which fall within Provincial and Territorial health systems.

- 11. Federal, Provincial and Territorial Governments should recognize the critical role of social attitudes in increased organ donation and-agree to participate and share the costs of a collaborative ongoing social marketing strategy that crosses all societal groups to assist individuals in making personal decisions about organ and tissue donation.
- 12. The Council on Organ and Tissue Donation and Transplantation should be responsible for the development and implementation of an evaluation plan for strategy and the submission of a final evaluation report to Ministers at the end of the fifth year of its work.

Appendix B

The Canadian Council for Donation and Transplantation (CCDT)

Council Vision & Purpose	To improve the results of organ and tissue donation and transplantation in Canada.
Mandate	The mandate of the Council will be to:
	 To provide nationwide leadership by advising, coordinating, facilitating and evaluating the development, implementation and evaluation of strategies directed at enhancing the practice of organ and tissue donation and transplantation.
	• To support provincial / territorial activities through the development, implementation, monitoring and evaluation of strategies to enhance donation and transplantation.
	 To advise the Federal / Provincial / Territorial Advisory Committee for Health Services on the overall direction, coordination and evaluation of organ and tissue donation and transplantation.
	• To provide national leadership in the development and implementation of practice and safety standards, consensus statements, data sets, information systems networks, practices for reporting and evaluating of provincial / territorial outcomes, education and social marketing.
	 To enhance accountability for activities associated with organ and tissue donation and transplantation.
	The Council is not envisioned to be a regulatory body with direct responsibilities for evaluating activities. The principle role of the Council is to provide leadership to facilitate and coordinate a national strategy for organ and tissue donation in Canada.
Accountability	The Council shall be accountable to the ACHS.
Responsibilities	The Council shall:
	 Provide a national forum to address issues related to organ and tissue donation and transplantation faced by the provinces / territories.
	Make recommendations on matters falling within its mandate.
	• Establish program standards, guidelines and outcome goals for donation, tissue banking and transplant initiatives as recommended by the Advisory Committees and or the provinces / territories.

- Evaluate proposals and recommendations for new types of organ and tissue transplants and tissue banking activities.
- Monitor and evaluate practices around adherence and enforcement of safety standards and report these to the provinces / territories.
- Monitor and evaluate the need for new and revised safety standards and report on these to the provinces / territories.
- Monitor and evaluate practice standards for donation, transplantation and tissue banking and adherence to standards for the delivery of high quality services and report outcomes to the provinces / territories.
- Facilitate the dissemination of information and best practices related to organ and tissue donation and transplantation.
- Submit annual accountability reports to the Ministers' of Health through the Advisory Committee on Health Services.
- Submit other reports as requested by the Advisory Committee on Health Services.
- Provide an annual public report through the Federal / Provincial /Territorial Ministers' of Health
- The Council should not approve, nor regulate, nor set rules. However, the Council may have to set benchmarks where necessary.
- The Council will be guided by the principles for a Coordinated and Comprehensive Canadian Strategy for Organ and Tissue Donation and Transplantation approved by the Ministers of Health at their Meeting in Prince Edward Island in September 1999.

Membership	 12 - 15 members as recommended by the Conference of Deputy Ministers. Members shall be selected from stakeholder organizations and shall include a broad representation from professional associations and societies linked to organ and tissue donation, tissue banking and transplantation, government, standards and accrediting bodies, epidemiology, ethics, and the public. The chairs of the Advisory Committee will be members of Council. The Council Chair shall to be appointed or recommended by the Conference of Deputy Members. Dual chair positions with non government and government representatives should be considered for the transition phase. The leadership qualities of the chair will be critical for advancing the agenda of the Council. Committee members would be expected to participate in meetings of the Council held quarterly.
Secretariat	The Council and Advisory Committees would be supported by a

permanent secretariat.

Appendix C

Secretariat of the Canadian Council for Donation and Transplantation (CCDT)

Mandate

The mandate of the Secretariat of the CCDT is to assist and support the activities of the CCDT and its advisory committees and to perform tasks as required.

Responsibilities

The responsibilities of the Secretariat shall include:

- Supporting the work of the CCDT.
- Assisting the CCDT in establishing the Advisory Committees (AC).
- Providing support to the CCDT and the Advisory Committees, including:
 - Facilitating meetings;
 - Preparing background documents; and
 - > Conducting research and policy analysis.
- Facilitating communication between the CCDT, AC's, the provinces I territories and stakeholders including the public.
- Coordinating working groups for the development of consensus documents.
- Facilitating the development and review of proposed standards.
- Facilitating the implementation of agreed upon standards.
- Coordinating the social marketing strategy.
- Responding to provinces requests for outcome data and reports.
- Responding to provinces I territories requests for outcome data and reports at the direction of the Council.
- Coordinating the preparation of an annual report for dissemination to the public and stakeholders,
- Coordinating the development of the information systems network.
- Contracting consultants and temporary support personnel as necessary.
- Other duties as determined by the CCDT.

Resources

The Secretariat shall be staffed appropriately to support the activities that are required by the CCDT.

A permanent project manager will lead the secretariat. This individual shall be responsible for the recruitment and management of Secretariat staff and for supervising work contracted to external consultants.

Secretariat staffing shall remain flexible, with the majority of the work contracted out. In addition to administrative support staff, dedicated permanent staff are envisioned to support work of the CCDT and its AC's associated with:

- Information Technology and Information Management;
- Statistical Research and Outcomes Analysis (potentially epidemiology)

Appendix D

Advisory Committees to the Canadian Council for Donation and Transplantation

Advisory Committees	There shall be three permanent advisory committees to address the respective areas of: • Donation • Organ Transplantation • Tissue Transplantation and Banking
Mandate of the Advisory Committees	To provide expert advice to the Canadian Council for Donation and Transplantation on standards, guidelines, practice and outcome goals for donation, organ transplantation and tissue transplantation and banking.
Responsibilities	 To provide advice to the Canadian Council for Donation and Transplantation on the establishment of standards, goals and outcomes. To respond to requests from the provinces / territories in regard to donation, organ transplantation and tissue transplantation and banking issues. To respond to requests from CCDT to investigate issues and or make recommendations on matters related to donation, organ transplantation and tissue transplantation and banking. To monitor the effectiveness of national safety and practice standards and assess opportunities for change in policy and service delivery. To advise and coordinate public education I social marketing strategies. To facilitate communication among all stakeholders. To evaluate the national strategy to enhance donation and transplantation in Canada and submit quarterly reports to the Canadian Council for Donation and Transplantation.
Accountability	The Advisory Committees shall be accountable to the CCDT. It is anticipated that the CCDT will refine the mandate, responsibilities and membership of the Advisory Committees at one of its inaugural meetings.

Membership	The CCDT will appoint members to the Advisory Committees. The members shall be drawn from existing (national) organizations involved in organ and tissue activities and will include public representation.
Secretariat	The work of the Advisory Committees will be supported by the secretariat of the CCDT.