

# Steering Committee Meeting

*January 20<sup>th</sup>, 2010*

Sheraton Gateway Hotel, Toronto



## Meeting Objectives

- Review and discuss the activities of the Tissue and Organ Expert committees
- Explore model designs and performance of other world-class systems
- Review and discuss previous recommendations on improving OTDT
- Advance our work on System Principles to further inform System Design and the planning process
- Understand the costing activities underway and the gaps in costing data

# Agenda

Discussion Item	Time
Welcome and follow-up on action items	8:30 - 8:45
Review of activity to date	8:45 - 9:15
--Break--	
International OTDT models and performance	9:30 – 10:30
Analysis of key government OTDT reports	10:30 - 12:00
--Lunch--	
System principles	12:30 - 2:45
--Break--	
Introduction to organ and tissue costing	3:00 - 4:15
Wrap-up and next steps	4:15 - 4:30

## Follow-up on Action Items

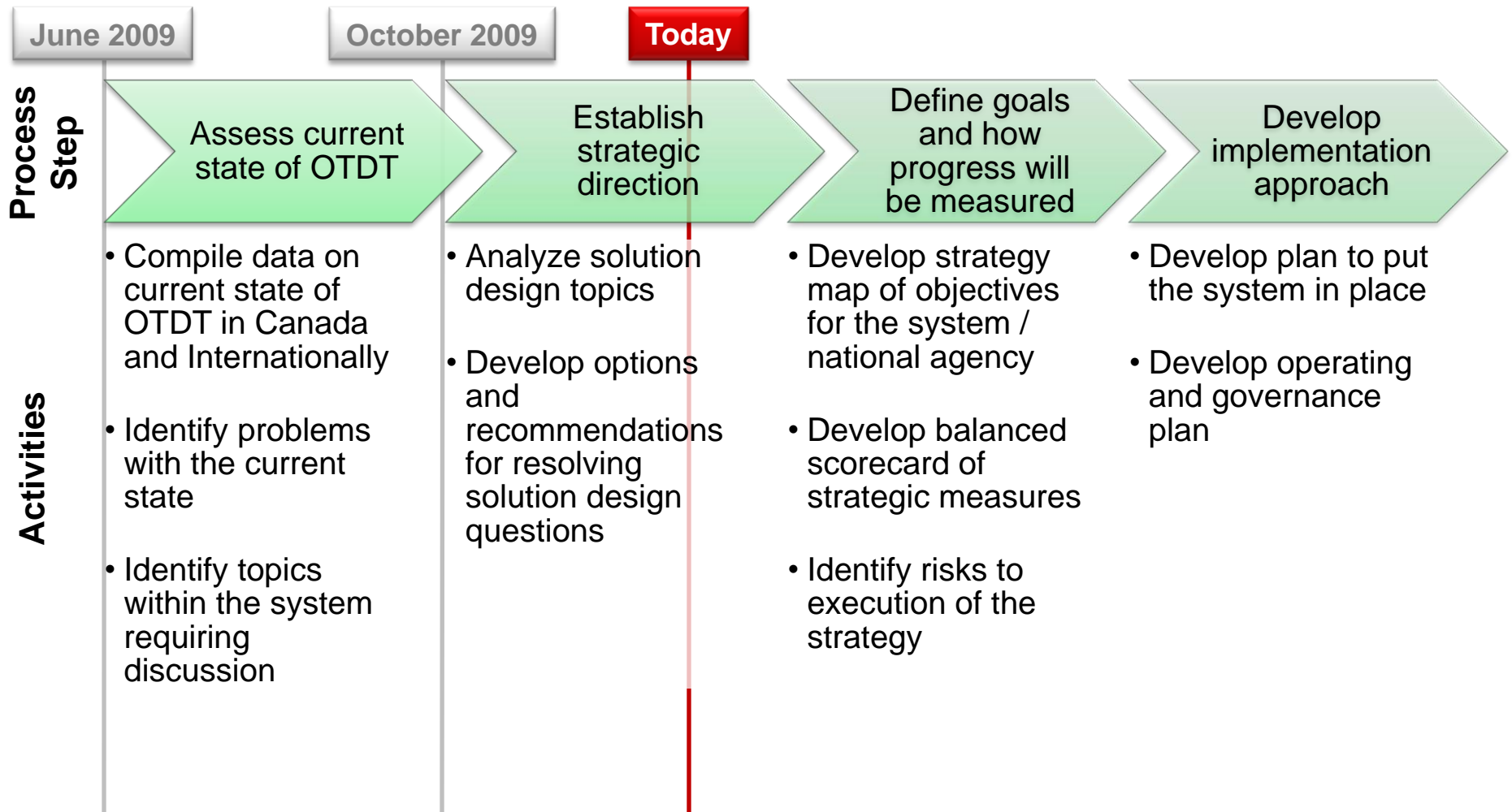
- Approve minutes from the last meeting
- Revised Case for Change (public version)



## ***Review of Activity to Date***



# The Strategic Planning Process



# Tissue Expert Committee - System Challenges and Initial Recommendations

The safety and quality of tissue product in Canada cannot be assured

- A nationally standardized quality program at source and transplant establishments
- 100% traceability and accountability for completeness; strive for ISBT128 compliance

Current Canadian tissue practices do not ensure security of supply

- Supply should continue to be a combination of domestic and imported tissue
- Domestic donation should be increased to better manage supply risk

Independent and uncoordinated Canadian tissue banks results in inefficient tissue collection, processing, and distribution

- *Recommendations from the latest meeting are discussed on the next two slides*

Lack of measurement and accountability to drive consistent, system-wide improvements

## Tissue Expert Committee – Highlights from Recent Meeting

In last week's meeting, there was a consensus on several key elements:

1. Donor identification – tissue donors should be identified and referred both from hospitals and from Medical Examiner/Coroner offices outside the hospitals
2. Donor referral
  - All Provinces should have mandatory donor referral legislation
  - Referral should be made to a central call centre
3. Donor consent
  - Trained staff should obtain the family's consent while front-line healthcare workers should be focused on identification and referral; obtaining consent by telephone is effective and should be expanded
  - Registries are useful to obtain consent and should be supported
4. Tissue recovery – should be done by trained individuals, and multiple tissues should be recovered from donors

## Tissue Expert Committee – Highlights from Recent Meeting (continued)

5. Canadian tissue banks should increase the amount of ocular, skin, soft tissue and bone they process and distribute. Cardiac tissue could be processed in the US in a more cost-effective manner. Surgical bone banks should conform to national standards, but are likely to decline over time. Contract processing in the US to have Canadian tissue made into advanced products should be considered.
6. Processing should be consolidated into a cost-effective model that also ensures security of supply. Processing activity is likely better managed outside of a hospital environment.



# Organ Expert Committee - System Challenges and Initial Recommendations

Canada is failing to realize its potential for organ donation

- National approach to public awareness
- Mandatory identification and referral of potential donors
- Registration of intent / consent to donate
- Dedicated funding of donation medical experts
- Develop and implement professional training

The Canadian organ donation and transplantation system is not equitable and transparent

- National standards for transplant centre referral and for listing
- Common online waitlist system
- Allocation principles (more to follow)

There are system inefficiencies associated with patient assessment and organ allocation that can impact patient wait times and health

- Funding following the patient from assessment through transplantation to follow-up

Lack of measurement and accountability to drive consistent, system-wide improvements

## Organ Expert Committee - Guest Presentations

In last week's Organ Expert Committee meeting, two guest presenters shared perspectives on organ allocation systems:

### Key messages from Dr. Alan Leichtman (University of Michigan; involved with UNOS and Scientific Registry of Transplant Recipients (SRTR))

- Allocation elements should be measurable and clinically meaningful
- Trade-offs may be required, e.g., between maximizing transplant outcomes (waitlist survival, incremental survival) or rewarding other considerations (waiting time, children first)
- Allocation rules should avoid arbitrary cutoffs with no medical rationale
- Allocation priorities should assign similar scores to similar patients
- Payback / balancing systems should be avoided if possible
- Transition to future state must be considered

## Organ Expert Committee - Guest Presentations

In last week's Organ Expert Committee meeting, two guest presenters shared perspectives on organ allocation systems:

### Key messages from Dr. Axel Rahmel (Eurotransplant)

- Countries integrating into Eurotransplant have benefitted from transparency, an increase in trust and better help for special patient groups
- Lack of mandatory data reporting viewed as a major deficient
- An auditing system will be introduced in Eurotransplant to ensure accurate status listings and overall compliance with policy
- Policy set by Eurotransplant is binding on all partners
- Some local variation is permitted within aspects of the Eurotransplant system, but these variations translate into higher overall cost
- The determination of Eurotransplant allocation policy is a bureaucratic process

## Draft Organ Allocation Principles

- ❖ **Equity**: Equal access without discrimination, at the individual level (gender, race, religion, or age) and at the geographical level (access should not differ based on where in Canada a patient lives), for both living and deceased donor transplantation services. i.e. equivalent access for equivalent conditions
- ❖ **Utility**: Maximizing post-transplant outcomes for each available organ
- ❖ **Medical Need**: Patient urgency, objectively measured, to minimize death on wait lists
- ❖ **Balance**: There needs to exist a reasonable balance between equity, utility, and medical need
- ❖ **Evidence-Based Criteria**: Medically and scientifically sound, organ specific
- ❖ **Transparency**: Criteria and processes, developed with input from the public and professionals, are clear and readily available to all
- ❖ **Accountability**: Responsibility to monitor and audit processes, actions and outcomes to enable policy improvement and to ensure compliance with allocation and utilization policies

## Organ Expert Committee - Highlights of Recent Meeting

- Some “draft” allocation principles were clarified by the committee
  - Consensus that organs are a “national resource,” but some members reluctant to endorse this due to uncertainty of the implications of this on provinces and local transplant programs
    - Transition to new system will be needed for buy-in
    - Committee requested CBS to investigate public opinion to ascertain whether or not public support is dependent on local use of locally donated organs
  - Support for “evidence-based” and “transparent” allocation, as well as “monitoring and auditing,” was re-affirmed by the committee
- The committee identified some important policy and infrastructure implications for these principles
  - National, mandatory data reporting
  - Formal structure to review data, policy and determine national standards
  - Audit / compliance system to ensure that policies and standards are being followed
  - Standardization with a national oversight body
- The committee supported, in principle, registration of intent/consent as part of the strategy, with details to be determined at a later date

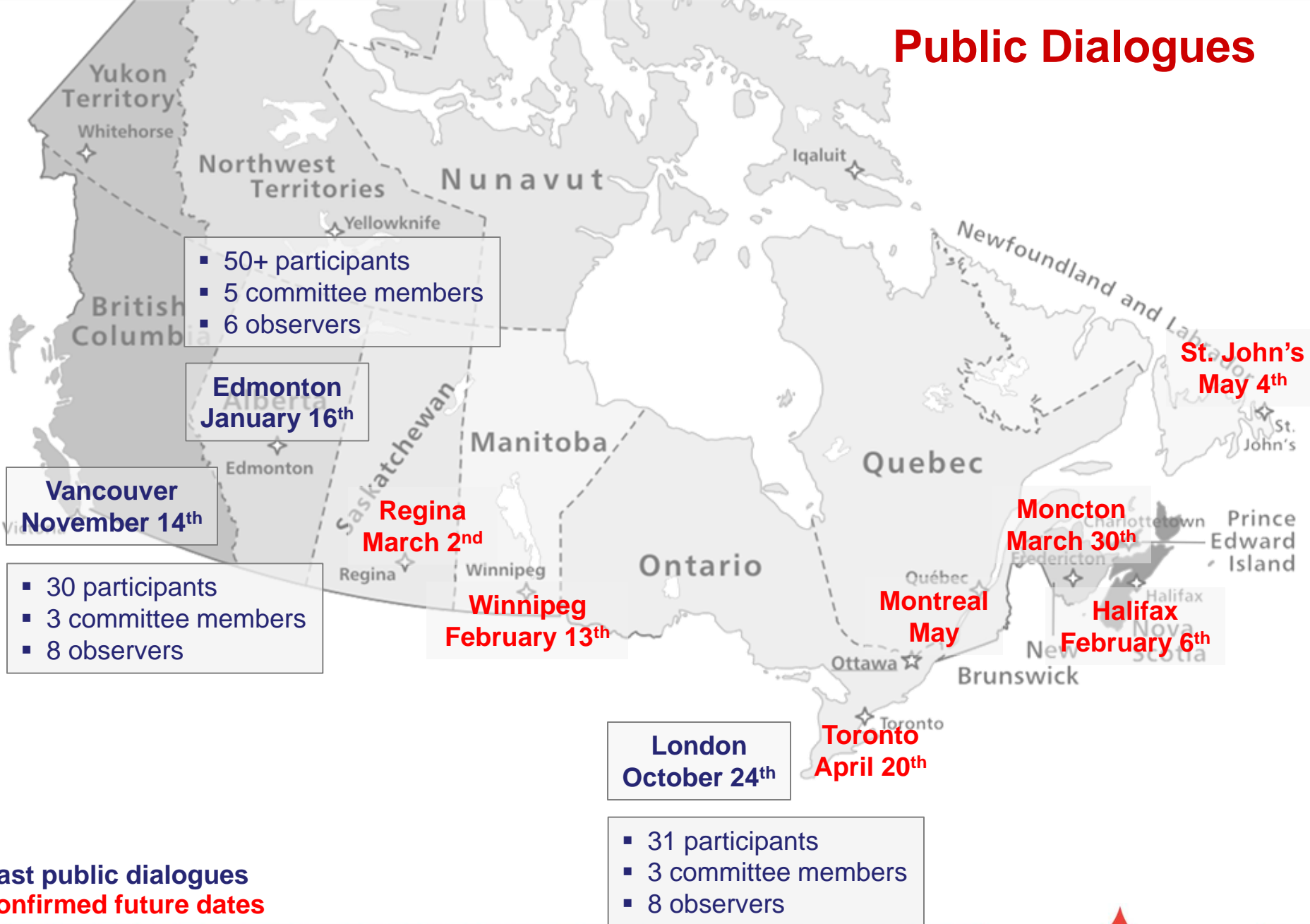
## Public Dialogues

- Create an opportunity for the public to provide input
- Validate the Case for Change and initial design options
- Understand the public perspective on System Principles
- Begin to generate momentum to support change

## Expert Engagement

- Engage those who have been working to improve the system
- Validate the Case for Change and initial design options
- Ensure a diversity of informed viewpoints are considered in system design
- Begin to build buy-in for the new strategic direction

# Public Dialogues



Past public dialogues  
Confirmed future dates

## Public Dialogues – Tissue Feedback

With respect to tissues, the Public Dialogues so far have voiced support for the following ideas:

- **National standards** that are enforced
- Need for a **national traceability** program
- Guidelines to ensure the **safety** of all tissue **donations**
- **Accountability** for end product **quality**
- **Best practice** sharing
- **Enable health professionals** to educate the public
- Increase **public awareness** of the importance of donation and current system challenges
- Increase **donation** capability
- Assess costs of **importation** verses domestic procurement and processing
- Streamline **processing** and **distribution**
- Reduce the **number of tissue banks**
- Create a national **inventory** system



## Public Dialogues – Organ Feedback

With respect to organs, the Public Dialogues so far have voiced support for the following ideas:

- **Single national registry** for intent-to-donate
- **Single national waitlist** with standards for referral and list management
- Investment in **public awareness and education** efforts
- Improved and **accelerated testing and evaluation** for potential donors and potential recipients

## Expert Engagement To-Date

- **Initial visit** to Saskatchewan
  - Meeting with medical directors of transplant program and ICU, tissue bank staff and TEC member
  - Meeting with St. Paul's Hospital CEO
  - Noon rounds at St. Paul's with Regina participants linked by videoconference
  - Multi-disciplinary rounds at St. Paul's
- **Upcoming expert engagements** events have been confirmed for January and February in New Brunswick, Newfoundland and Labrador, Nova Scotia, Alberta and British Columbia
- Saskatchewan discussions were driven by **three questions**
  1. Are we missing any critical elements in the Case for Change?
  2. What is the most important element that needs to be fixed?
  3. Are there other options we should consider as part of system design?
- The **Case for Change received strong support** and no major gaps were identified
- The initial preferred **options presented to the visit were well-supported** with no major conflicts or new suggestions

## Additionally, organizations with a stake in OTDT have begun to provide feedback

- **Canadian Cardiac Transplant Network** sent a letter of support with specific suggestions to the Chair of the OEC
  - Support a single, online, national waitlist
  - Support national oversight of Organ Procurement Organizations with shared policies and transparency across P/Ts
- **Canadian Cystic Fibrosis Foundation** presented to the open session of the Canadian Blood Services Board meeting
  - Seek recommendations to address the financial burden on individuals who require an organ transplant, especially when they must relocate

## ***International OTDT Models and Performance***

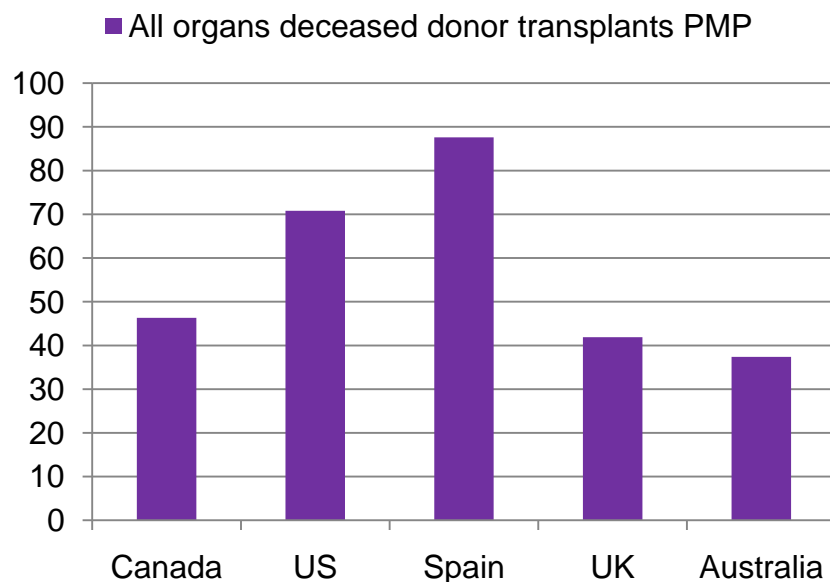
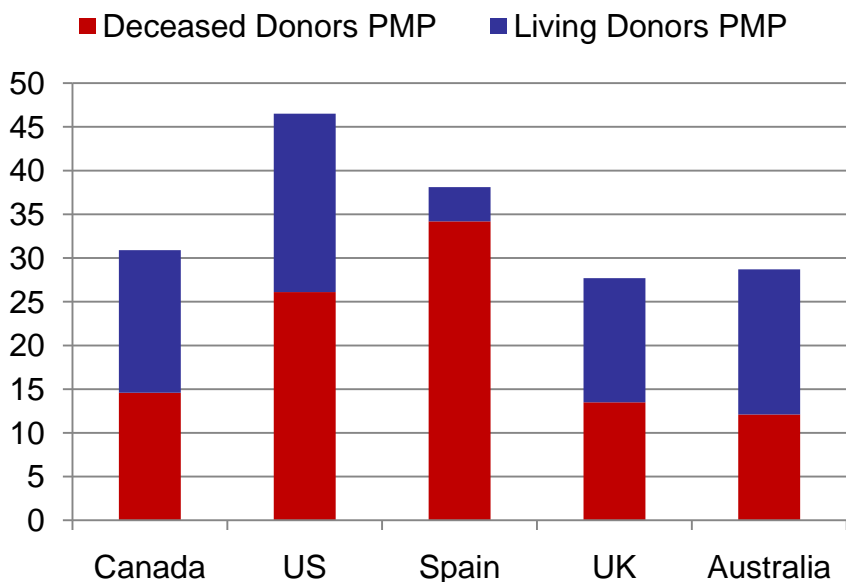
## Purpose

- To understand and compare system models and performance
- To discuss lessons learned from the experiences of other jurisdictions



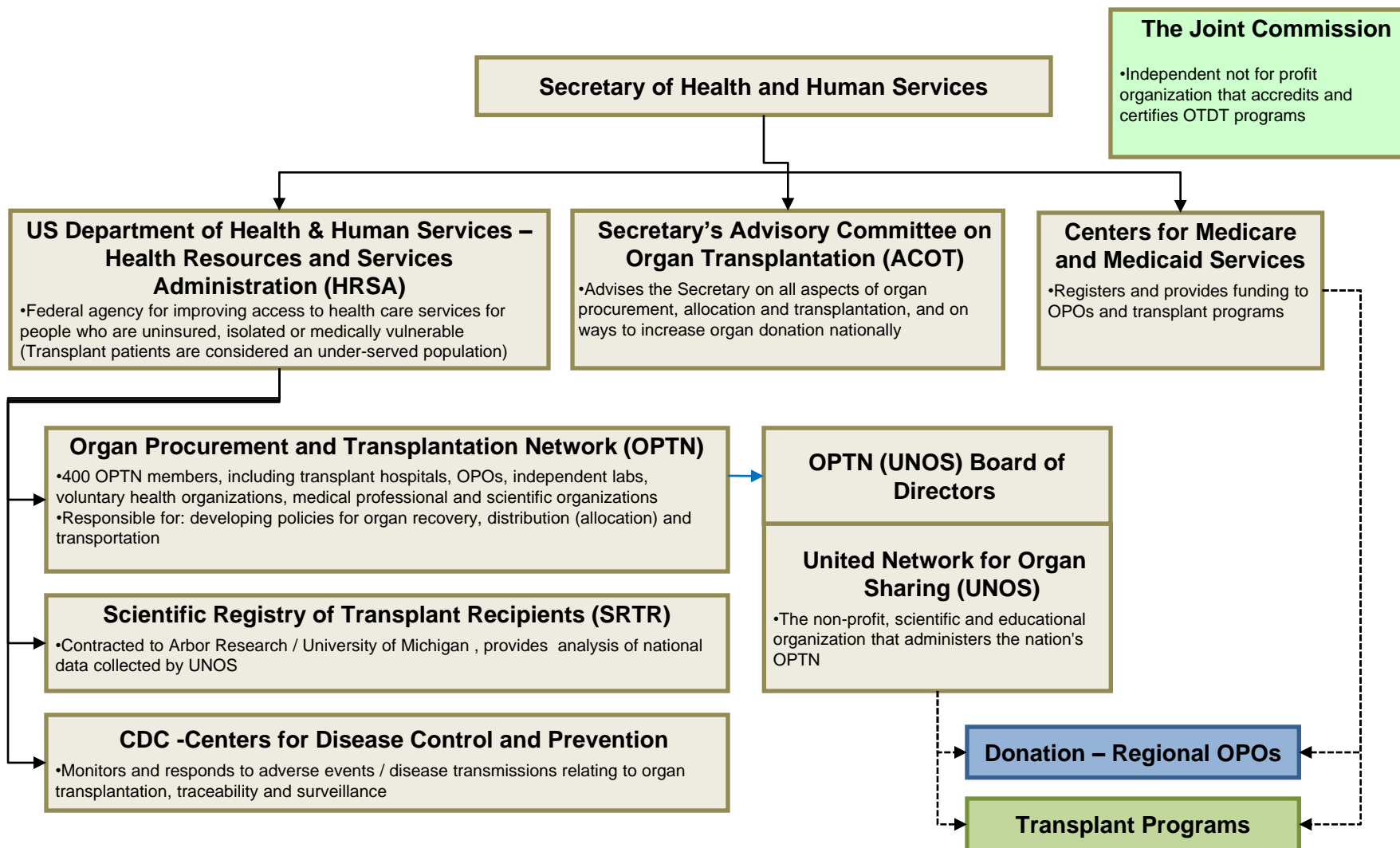
## ***Organs***

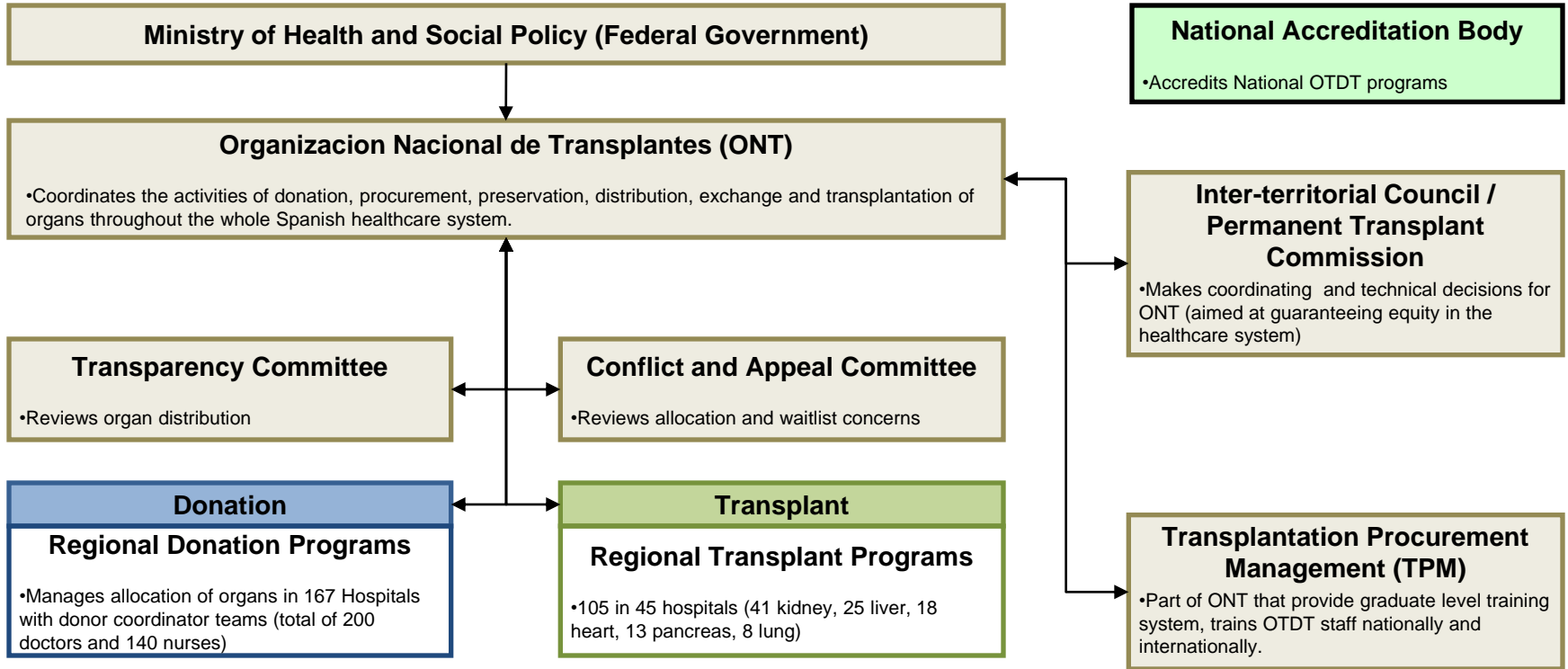
	Canada	US	Spain	UK	Australia
Wait List # of patients, all organs, per million population (PMP)	132	341		127	70
Deceased Donors PMP	14.6	26.1	34.2	13.5	12.1
Living Donors PMP	16.3	20.4	3.9	14.2	16.6
All organs deceased donor transplants PMP	46.3	70.8	87.6	41.9	37.4
Patient 3 year survival Kidney (deceased donor)	92%	88%		90%	91%

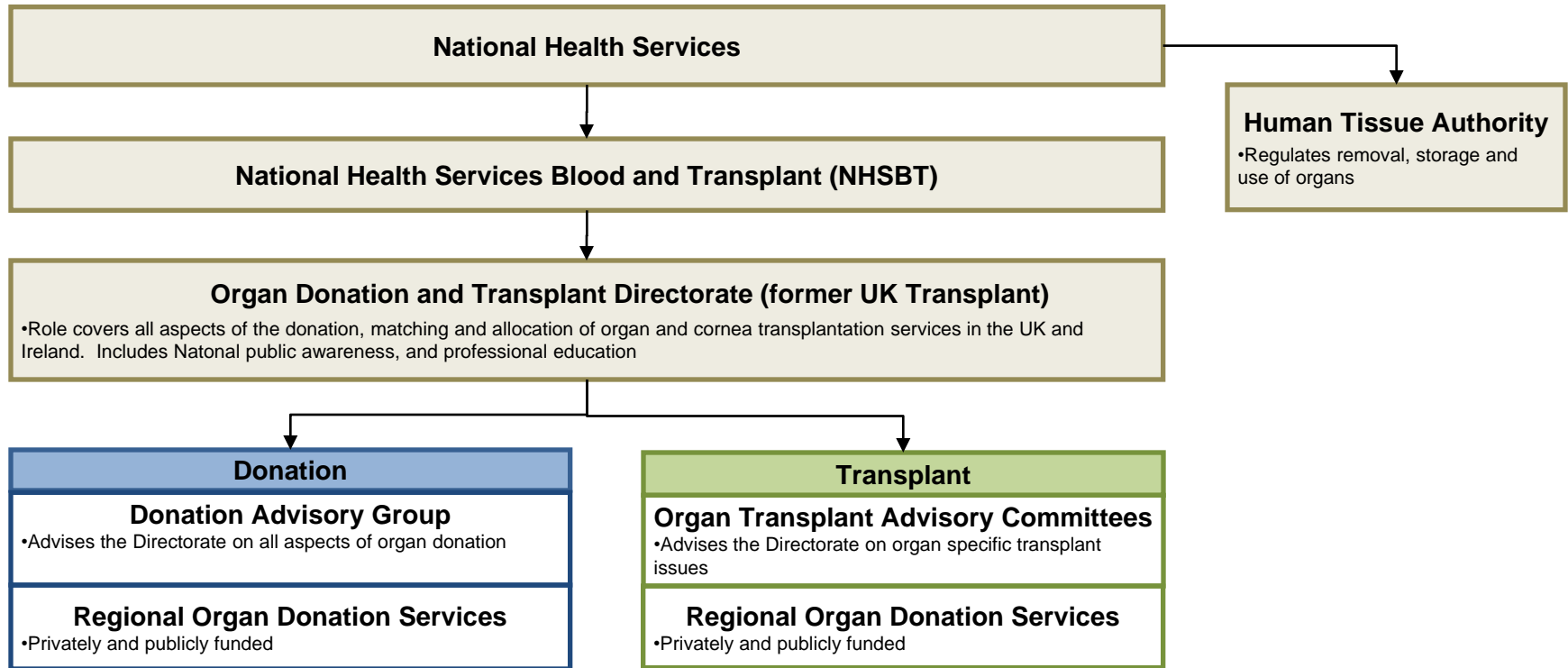


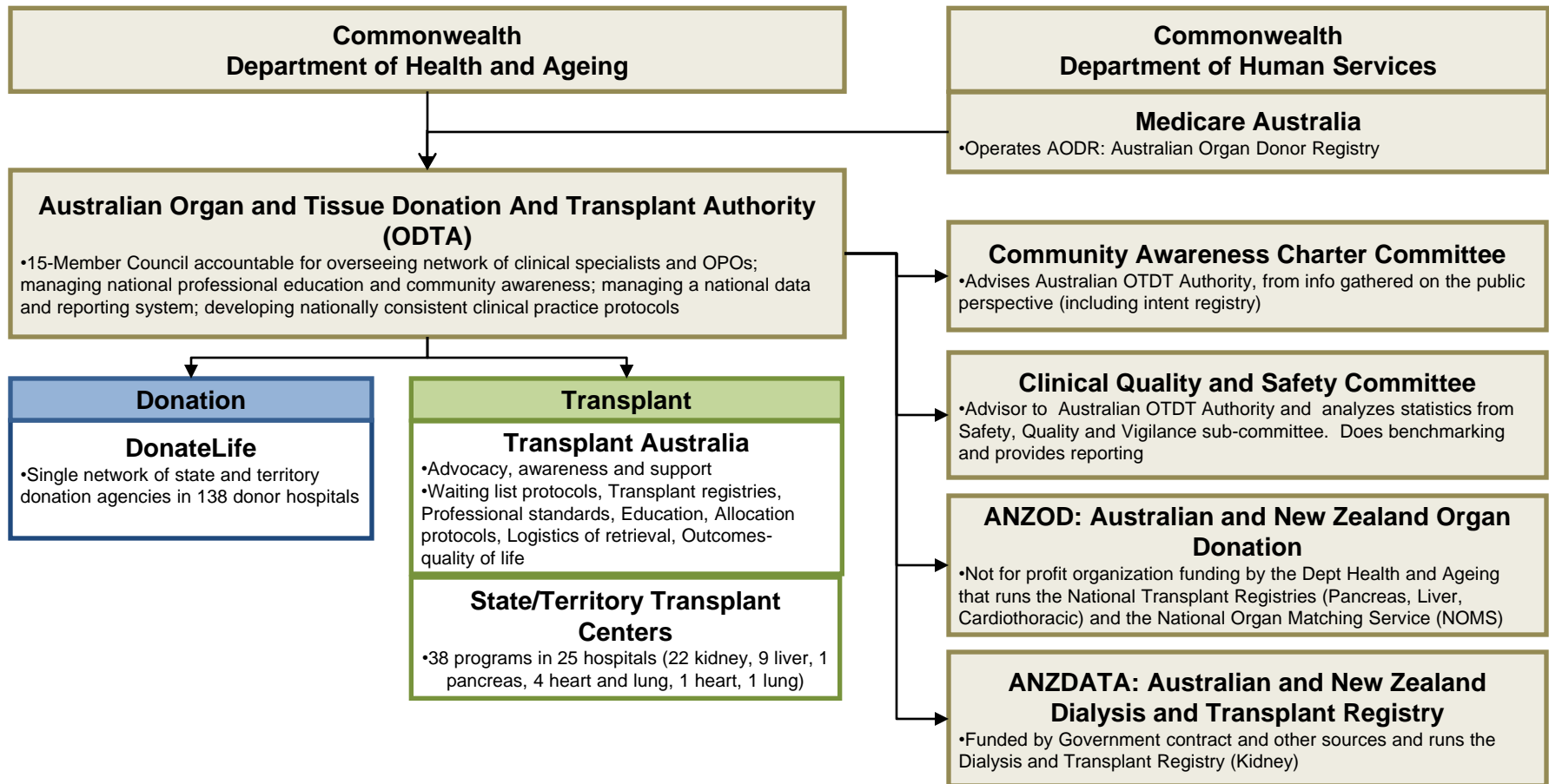
Data sources: Canada – CORR; Other countries – Organ Transplant program websites

- Organ donation and transplantation services are delivered by programs either at the provincial or program level
- Services are provided predominately by transplant programs, organ procurement organizations (OPOs), and hospital acute care departments
  - Transplant programs are affiliated with hospitals
  - OPOs are either hospital-based or government-supported independent organizations
- There is regulatory involvement at the federal level (e.g., Health Canada, PHAC)
- Little coordination exists across provinces (e.g. LDPE)
- Organ sharing beyond provincial boundaries is only based on medical need (i.e. national urgent status), with the exception of kidneys
- Some funding arrangements exist for services provided to residents of other provinces (e.g. transplants for P.E.I. residents)





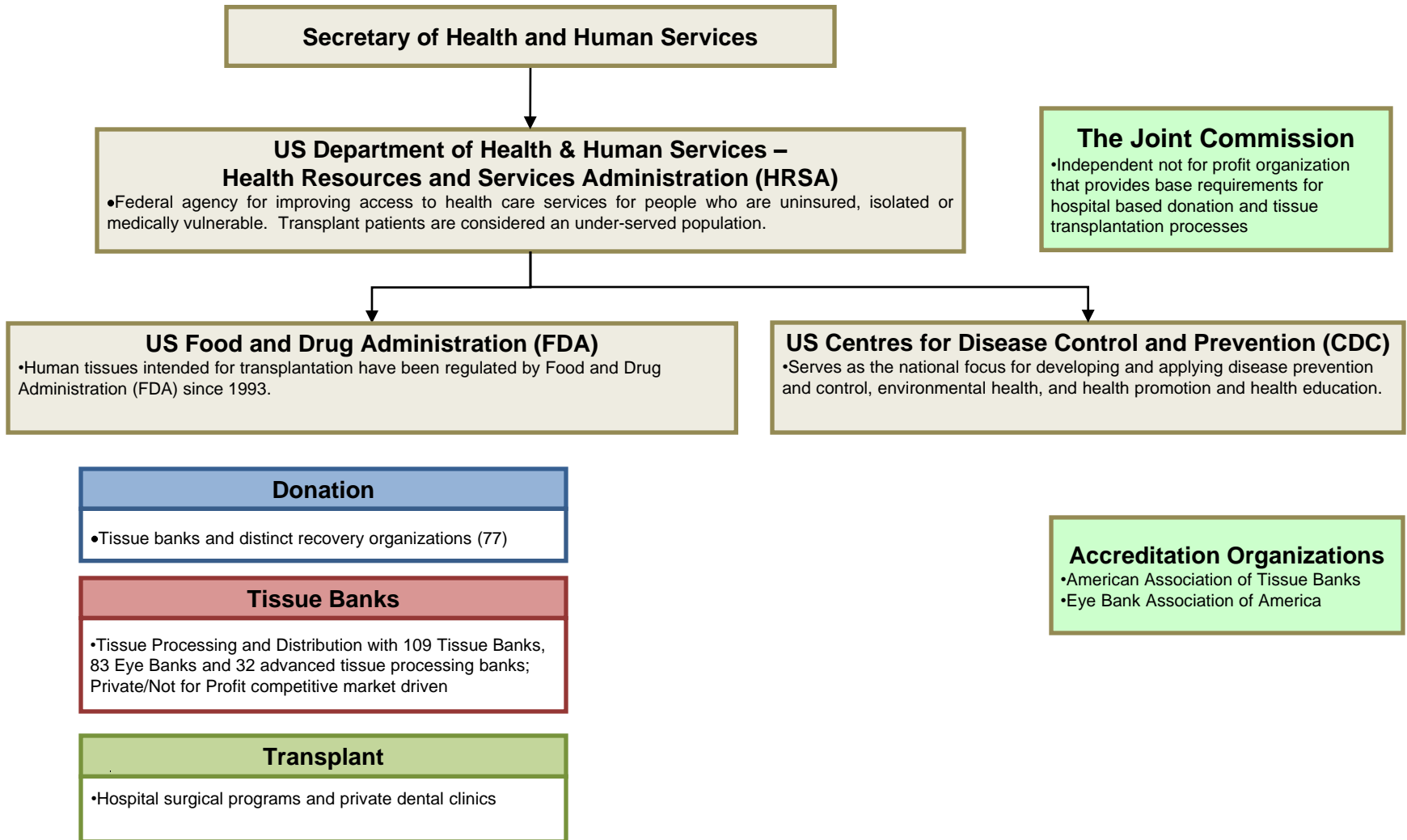


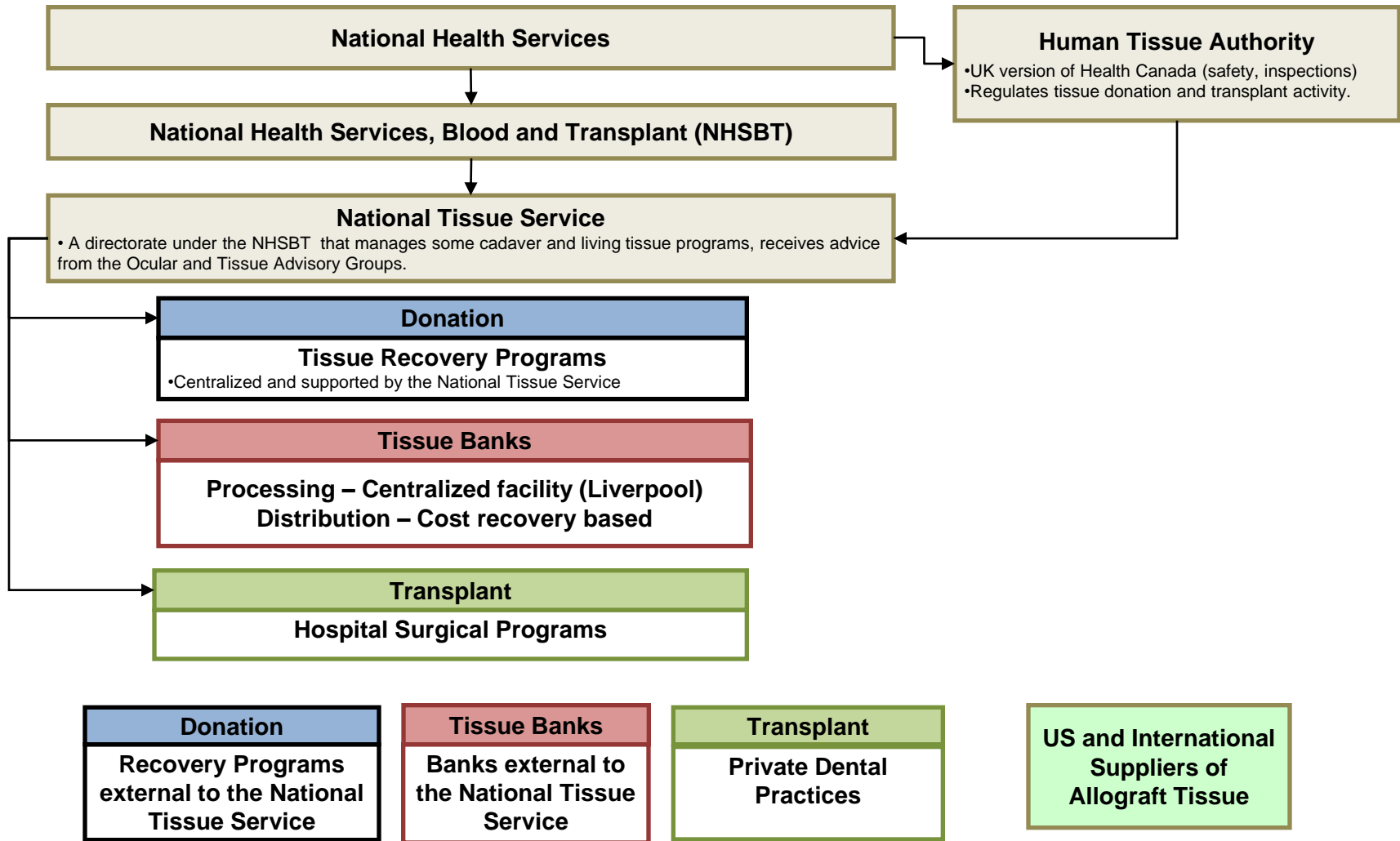


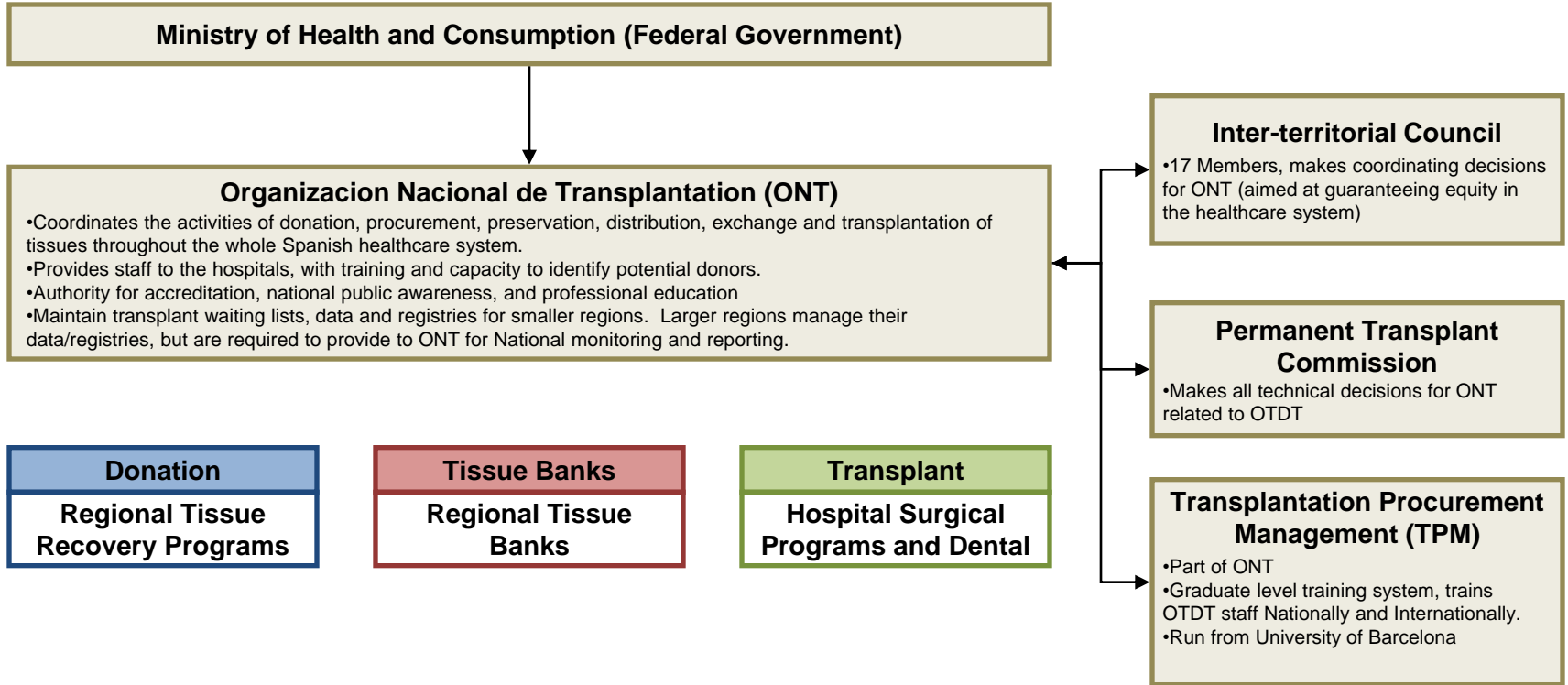
- Natural evolution of donation and transplantation programs is not sufficient to yield optimal results at an aggregate national level
- Some governance body responsible for oversight, policy development, and allocation management is a common national component of a ODT system
- Donation practices are best performed by specialists in donation just as transplantation practices are best performed by transplantation specialists
- Professional education is necessary to equip medical staff (e.g. physicians, nurses) to achieve excellence in organ donation and transplantation practices
- Public awareness is critical to realizing a higher consent rate
- Financial investment is necessary as a catalyst for transformational change

# *Tissue*

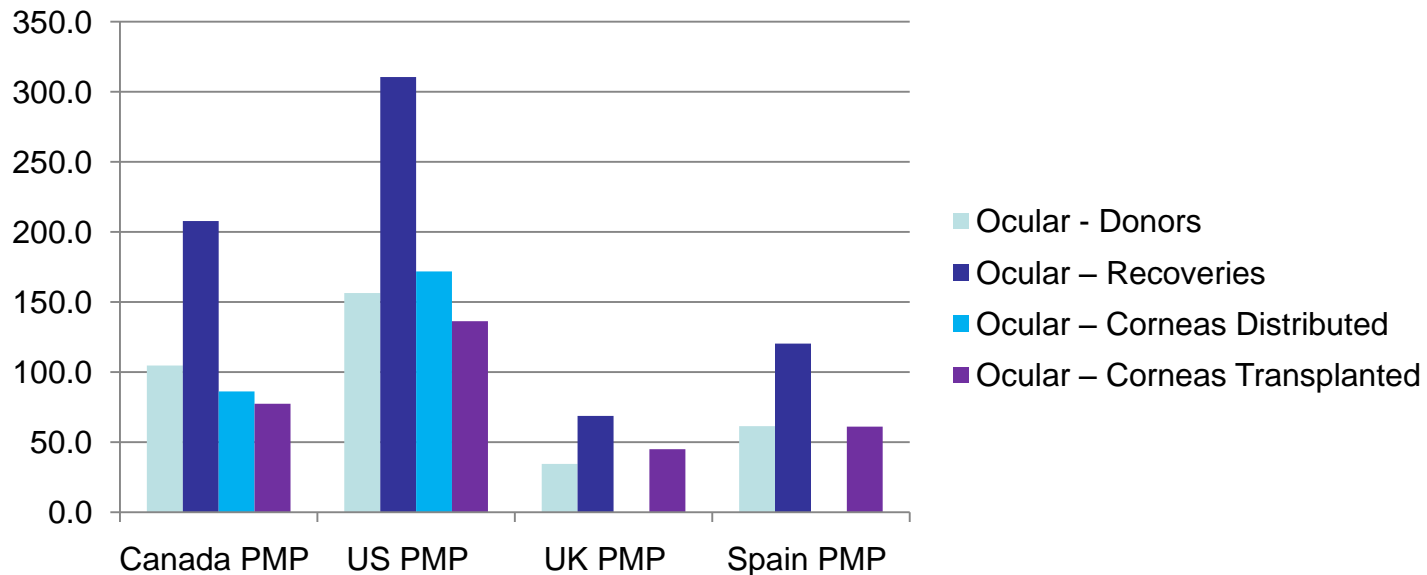
- In the current 'system', tissue recovery programs are almost always affiliated with a tissue bank
- The inventory management portion of the 'system' is comprised of independent banks each processing, and/or distributing different non-exclusive inventories of products
- Tissue banks vary in size from comprehensive banks serving regions of a province to small banks predominantly serving the needs of a single hospital department or surgeon
- The transplant side of the 'system' is made up of surgeons in many different types of programs within hospitals (e.g., cardiac, orthopedic) and dentists
- A large portion of the supply is imported directly from the U.S. by end-users
- The system is predominantly funded through hospital budgets and dental insurance
- There is regulatory involvement at the federal level (e.g., Health Canada, PHAC, CSA)
- There is limited collaboration between entities within the 'system' (the ocular community being a notable exception)







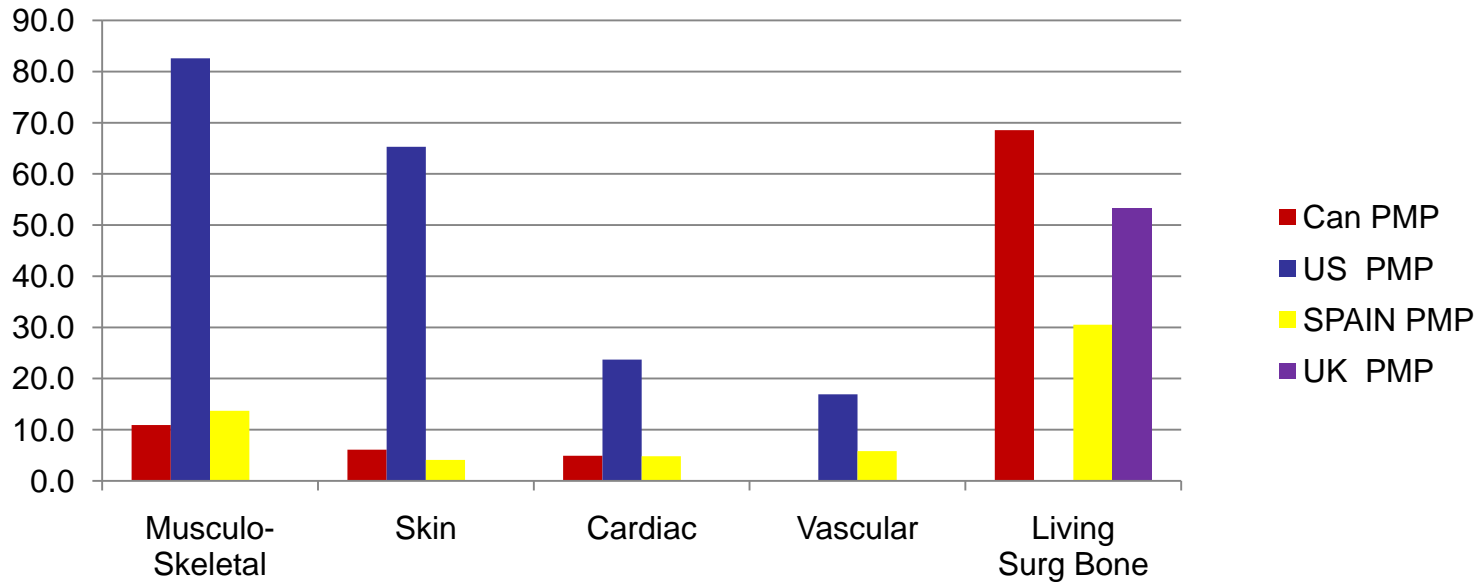
	Canada		US		UK		Spain	
	#	PMP	#	PMP	#	PMP	#	PMP
Ocular - Donors	2670	104.7	47776	156.4	2075	34.5	2843	61.5
Ocular – Recoveries	5300	207.8	94864	310.6	4134	68.8	5564	120.4
Ocular – Corneas Distributed	2200	86.3	52487	171.9				
Ocular – Corneas Transplanted	1976	77.5	41652	136.4	2711	45.0	2822	61.1



Data Sources: US – 2008 Eye Bank Association of America (EBAA) Statistics, UK – Data is for Corneas only, from the 2008 Blood and Transplant Annual Report, Canada – Canadian Blood Services Tissue survey 2009. Data is for all provinces except Quebec, Spain – 2008 ONT Tissue Annual Report

# Comparing Countries – Tissue Donors

		Canada		US		UK		Spain	
		#	PMP	#	PMP	#	PMP	#	PMP
Deceased	Musculoskeletal Donors	278	10.9	25157	82.6			635	13.7
	Skin Donors	156	6.1	19854	65.3			191	4.1
	Cardiac Donors	125	4.9	7216	23.7			222	4.8
	Vascular Donors			5153	16.9			267	5.8
Living	Surgical Bone Donors	1748	68.5	0	0	3200	53.2	1410	30.5



Data sources: Canada – Canadian Blood Services Tissue survey 2009. Data is for all provinces except Quebec. U.S. – From the 2007 American Association of Tissue Banks (AATB) survey, Spain – 2008 ONT Tissue Annual Report.

Distribution from Deceased Donors	Canada		US		UK		Spain	
	#	PMP	#	PMP	#	PMP	#	PMP
Musculoskeletal Grafts	3223	126.4	1166968	3836.2				
Soft Tissue Grafts	1013	39.7	152082	499.9				
Skin Grafts	317	12.4	312189	1026.3			1775	38.4
Cardiac Grafts	198	7.8	5349	17.6			182	3.9
Vascular Grafts	0	0	3592	11.8			262	5.7

Data sources: Canada – Canadian Blood Services Tissue survey 2009. Data is for all provinces except Quebec.  
 U.S. – From the 2007 American Association of Tissue Banks (AATB) survey, Spain – 2008 ONT Tissue Annual Report.

- Data (and data-based conclusions) for tissue donation and transplantation are difficult to obtain
- The US, competitive and largely for-profit market, is the world leader in both donation and utilization of tissue allografts
- "Success" varies by tissue; most countries are at- or near-sufficiency in corneas but importation is critical for advanced tissue types
- In each country, safety regulation is a national role; quality is also pursued nationally (governmental or non-governmental accreditation)
- Each country seeks to achieve access and efficiency
  - US provides both via a market approach
  - UK seeks efficiency via centralized recovery and processing but allows private tissue banking and importation as well
- Based on UK NTS experience, planning for increased capacity must be done carefully to optimize investment.

## ***Analysis of Key Government OTDT Reports***



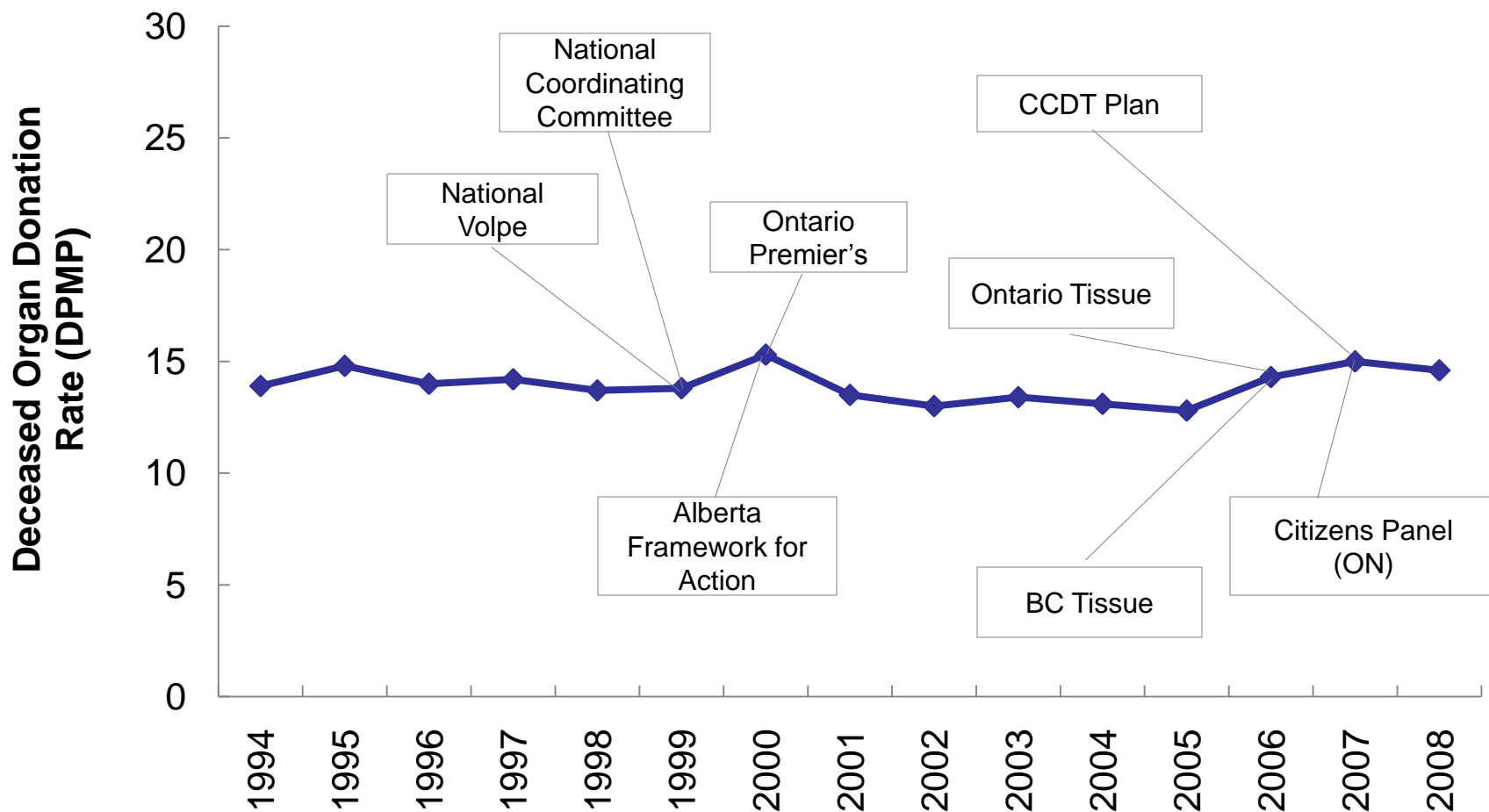
## Introduction

- This study provides an analysis of OTDT recommendations made in key government reports over the last ten years.
- It studies the recommendations which were implemented, partially implemented, or not implemented, across a number of dimensions.
- From this analysis, we attempt to determine what makes recommendations more likely to be implemented, and what factors may prevent implementation.
- This will be used to inform future recommendations in our national system design for OTDT.

## Methodology

- Nine publicly available government reports were analyzed for this study
  - Organ and Tissue Donation – A Canadian approach (Volpe)
  - A Report from the National Coordinating Committee (NCC) for Organ Donation, Distribution and Transplantation
  - A Coordinated and Integrate Organ and Tissue Donation and Transplant System for Alberta
  - Report to the Premier’s Advisory Board on Organ & Tissue Donation (Ontario)
  - Feasibility of a Pre-hospital Tissue Procurement Program in British Columbia
  - Strategic Plan to Improve Tissue Donation Activities in Ontario
  - Moving Forward to 2012 (CCDT)
  - The Citizens Panel on Increasing Organ Donations Report (Ontario)
  - Organ Donation and Transplantation in Canada (Library of Parliament)
- Recommendations from these reports were placed into categories, to aid understanding and analysis.

# Chronology of Reports

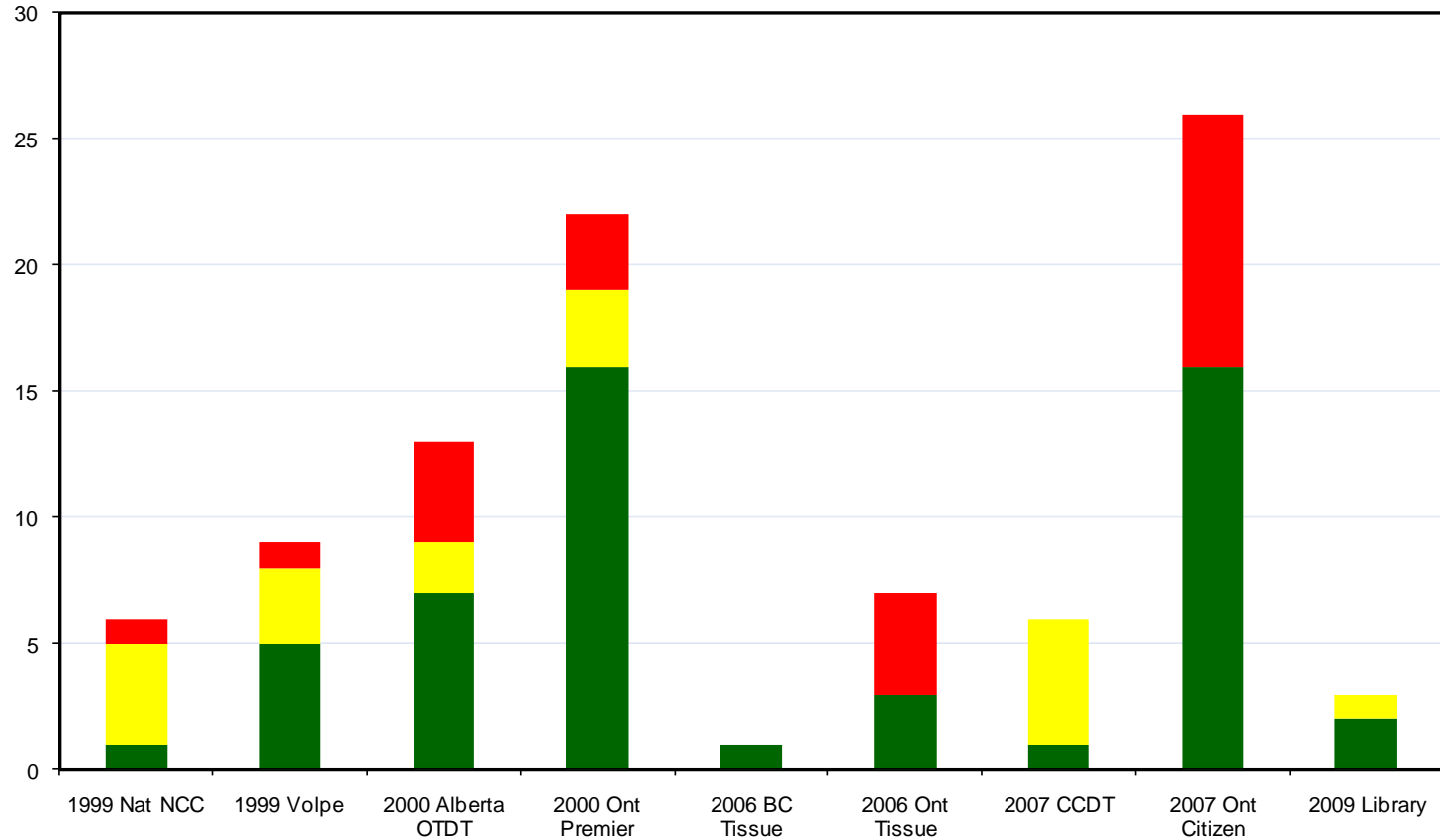


Donor data from CORR

# Analysis by individual report

Implemented  
Yes  
Partial  
No

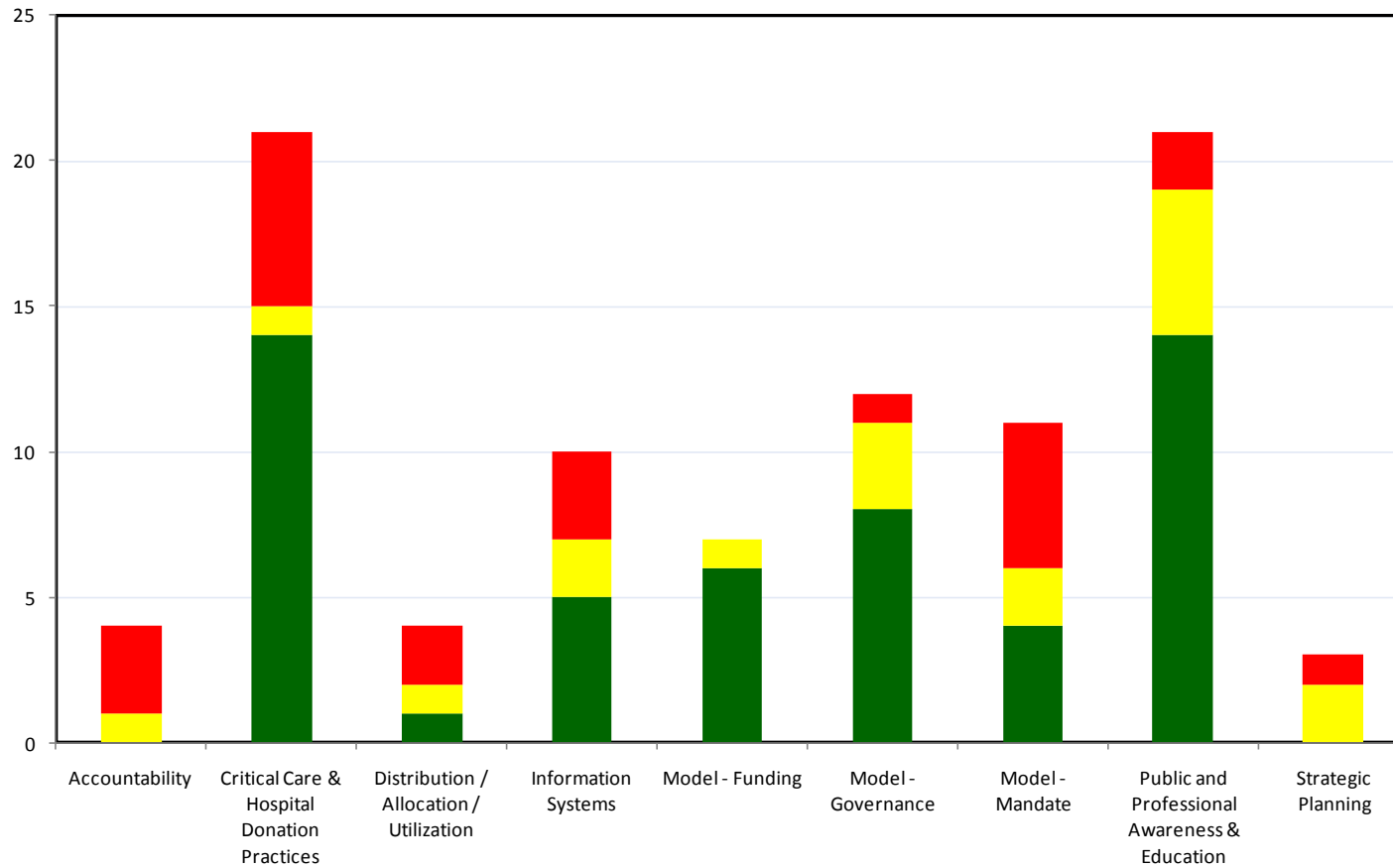
## Implementation Status of Recommendations by Report



# Analysis by categories and scope

Implemented  
Yes  
Partial  
No

## Implementation Status of Recommendations by Category



## Analysis of repeat recommendations

Recommendation	1999 Volpe	1999 National NCC	2000 Alberta OTDT	2000 Ontario Premier	2006 BC Tissue	2006 Ontario Tissue	2007 CCDT	2007 Citizen Report	2009 Library
1. Central body to oversee or to run some aspect of OTDT	Yellow	Yellow	Yellow	Green	White	Red	Yellow	White	Yellow
2. Central info system for OTDT data	White	Red	Red	White	White	Red	Yellow	Green	Yellow
3. Legislation be passed to support some aspect of OTDT	White	Green	Green	Yellow	White	Red	White	Yellow	White
4. Public awareness or education activities for organ/tissue donation	White	White	Red	Green	White	White	Yellow	Yellow	Green
5. Hospital changes to increase donors	White	White	Green	Green	White	Yellow	White	Yellow	White

Implemented:

■ Yes   
 ■ Partial   
 ■ No   
  Recommendation not made

# Recent Report - Ontario Wait Times Panel

## Increasing organ and tissue donation

- Trillium to lead development of marketing and education plans to increase awareness
- Hospital and funding changes to strengthen the donation culture in hospitals
- Improved support and recognition for donors

## Equitable access to organs and tissues

- A review of allocation and distribution process in Ontario

## Transplant-related care

- Best practice development for health care providers
- Development of resources for patients
- Monitoring of outcomes

## Accountability for performance

- Development of standard definitions and target setting
- Determination of oversight roles for OTDT in Ontario

## Conclusions

- Over the past decade, reports at both National and Provincial level have made numerous recommendations to improve the OTDT system in Canada.
- Many of the recommendations made in these reports have been implemented.
  - Implementation has been higher for tactical recommendations in areas such as public awareness and hospital donation practices
  - These were often easier to implement, as they did not require big budgets or system changes
- Recommendations for systemic changes have also been made, but implemented much less often. These include recommendations for:
  - central management and oversight of OTDT activities
  - programs and hospitals being accountable for increasing donor conversion
  - system performance being measured and improvements mandated
  - information systems to hold central data

## Conclusions (continued)

- Even with the changes made, OTDT system performance has not improved over this time period.
- Some recommendations are difficult to implement, and factors may have prevented their implementation.
  - resolving jurisdictional differences
  - agreeing on accountability and roles
  - available funding
- Some recommendations although implemented did not impact performance.
- Need to make sure that future recommendations learn from the knowledge of the past.

## Discussion

- Discuss how future recommendations should be designed to make them easier to implement and to improve OTDT system performance in Canada.
- How can we approach system design and role determination in a way that maximizes the effectiveness of the system while being realistic about the structure of healthcare in Canada?
- Should funding recommendations assume the status quo or be open to creative approaches (e.g., funding for performance)?

## ***System Principles***

## The objective of today's discussion

- To provide the necessary support and guidance for system design by solidifying our point of view on key system principles



## Context and Background for Continuing the Discussion of Principles

- System Principles are the declared, fundamental purposes, beliefs and assumptions that underlie system design and implementation
- For OTDT in Canada, System Principles should:
  - Guide the design and development of the national system; they should not be window dressing or post-decision justification
  - Address the sensitive medical and ethical issues facing OTDT
  - Provide common ground for discussions and disagreements as relatively fixed reference points that all participants can agree on
  - Ensure that the OTDT system is aligned with broader healthcare system principles and with international standards for Organs and Tissues

## Summary of October Discussion on Principles

- **Safety** - While risk can be reduced to as low as reasonably achievable, zero-risk is not possible. **A risk based approach** can be used to balance safety benefit and cost.
- **Privacy** - **Individual privacy should be protected but should not be a barrier** to collaboration and development of Canadian, inter-provincial systems, especially registries.
- **Equity / Fairness / Access / Utility** - Access should encompass both opportunity to donate as well as access to transplantations. The majority of the Steering Committee agreed that the system **should strive for equitable access** for all Canadians.
- **Adequacy** - The Steering Committee recognized that while the **tissue system should be able to meet all needs for Canadian patients, fulfilling 100% of the organ demand was not possible**. The system should however maximize the number of organs based on donor potential.
- **System Efficiency and Effectiveness** - Given the economic situation, the system should optimize resources and outcomes to be **as efficient and effective as possible**.



# Initial public feedback with possible relevance to System Principles

## Tissues

- There should be enforced national standards and national traceability
- There should be accountability for end product quality and guidelines to ensure safety
- There should be best practice sharing
- Streamline processing and distribution and create a national inventory system

## Organs

- Support for efforts at a national level - waitlist, education programs, registry, referral standards
- Consideration of “opt-out” (AKA “presumed consent” system and other mechanisms to increase consent and conversion

## General OTDT Feedback

- The system must be transparent, accountable and open
- The system must be fair and equitable
- The system must be safe and trustworthy
- The system must be national in scope and supported by the Canada Health Act

## Initial expert feedback with possible relevance to System Principles

- National standards and guidelines with accountability for consistent implementation across the country
- Coordinating body for unbiased advice and leadership
- National tissue database needed
- Interest in the Spanish model (nominally “presumed consent” for donation)
- Interest in the Australian experience with respect to Aboriginal issues including diabetes

# System Principles will guide system design from multiple perspectives

## Ethics and Human Rights

- Altruistic donation

## Safety and Quality

- Traceability\*
- Quality Systems\*

## Alignment with int'l standards

- WHO Guiding Principles
- Istanbul declaration on Transplant Commercialism

## System Principles

## Equity and Fairness

- Allocation priorities\*
- Differences in donation performance

## Federal / Provincial balance

- Roles and responsibilities

## The Canadian healthcare system

- Access, flexibility and cost
- Innovation
- Self-sufficiency\*

## Responsibilities to the public

- Accountability
- Transparency
- Integrity

\* - discussed in October

## Discussions - Tissue

Topic	Question	Possible Scenarios
1. Tensions among patient needs, physician choice, access and efficiency	<ul style="list-style-type: none"> <li>Do we want a system that encourages use of the “latest and greatest” and “cutting edge” products, at the possible expense of greater cost and limited access for others?</li> </ul>	<ul style="list-style-type: none"> <li>A system with maximal choice for physicians</li> <li>A system that assures access and maximizes efficiency but may limit physician product purchasing flexibility</li> </ul>
2. Tensions among security of supply, innovation and efficiency	<ul style="list-style-type: none"> <li>For tissues that Canada already produces, is it a valid strategy to improve security of supply by increasing Canadian tissue donation therefore reducing reliance on imports from the US?</li> <li>Is “innovation” a principle to embrace? Do we want to develop domestic sources of new tissue types in Canada and attempt to be internationally competitive ?</li> </ul>	<ul style="list-style-type: none"> <li>Improved security of supply for some tissue by consolidating and increasing overall Canadian production, and continued 100% importation of newest and most complex products</li> <li>Investment in developing new industry to ensure security of supply in more or all tissue types</li> </ul>
3. Equity of access to donation	<ul style="list-style-type: none"> <li>Do we want a tissues system that ensures equity of access to donation, even at possibly great expense?</li> <li>Do we want a tissues system that emphasizes efficient supply even if access donation is not equally available to all Canadians?</li> </ul>	<ul style="list-style-type: none"> <li>A system that recovers tissue from all consenting individuals regardless of location</li> <li>A system that determines recovery locations based on analysis</li> </ul>

## Discussions - Organs

Topic	Question	Possible Scenarios
1. Tensions among status quo, equity, benefit and local concerns	<ul style="list-style-type: none"> <li>• How do we resolve the concern about “subsidizing” and “punishing” based on donation performance?</li> <li>• Who “owns” a donated organ? The program? The province? The nation?</li> </ul>	<ul style="list-style-type: none"> <li>• Continued local “ownership” of donated organs, with limited, ad-hoc sharing and the urgent status waitlist</li> <li>• “National ownership” of donated organs with coordinated sharing (though most organs still stay local due to utility/quality criteria)</li> </ul>
2. Equity of access to donation	<ul style="list-style-type: none"> <li>• Should the system consider organ donation a “service” that must be equally accessible to all Canadians?</li> <li>• Is it acceptable to limit Organ donation services to certain hospitals based on skill limitations and cost-benefit analyses?</li> </ul>	<ul style="list-style-type: none"> <li>• A system that focuses donation resources and skills at designated hospitals, possibly missing some donation opportunities</li> <li>• A system that accommodates every donation at great expense and possibly risk (e.g., if quality is compromised)</li> </ul>
3. Living Donation	<ul style="list-style-type: none"> <li>• Should we do more to encourage living donation (at possible increased cost) or a more risk-averse position?</li> <li>• Does the Canada Health Act require more complete funding in support of living donors?</li> </ul>	<ul style="list-style-type: none"> <li>• Living Donation becomes a major part of public awareness and public education campaigns</li> <li>• Living Donation becomes more fully funded</li> <li>• Status quo of provincial determination of emphasis</li> </ul>

## Discussions - Organs and Tissues

Topic	Question	Possible Scenarios
1. Fundamental ethics of organ and tissue donation	<ul style="list-style-type: none"> <li>• Do we want to align with the WHO Guiding Principles, reaffirming that all donation is altruistic and opposing compensation?</li> <li>• Do we endorse the Istanbul Declaration and make elimination / decrease of transplant tourism and organ trafficking a system principle?</li> <li>• Should we consider any of the controversial innovations being used by other nations to drive donation, such as “presumed consent” or “extra points for registered donors?”</li> </ul>	<ul style="list-style-type: none"> <li>• Status quo on fundamental ethics of donation</li> <li>• A new position that seeks dramatic increases in donation, possibly requiring consideration of more controversial considerations               <ul style="list-style-type: none"> <li>• Points for being on registry</li> <li>• Presumed consent</li> <li>• Expanded compensation options</li> </ul> </li> <li>• An “evolving” approach that affirms the status quo for now but encourages periodic reconsideration</li> </ul>
2. Healthcare in Canada, Federal/Provincial responsibilities	<ul style="list-style-type: none"> <li>• How can we approach role determination in a way that maximizes the effectiveness of the system while being realistic about the structure of healthcare in Canada?</li> <li>• Should funding recommendations assume the status quo or be open to creative approaches (e.g., funding for performance)?</li> </ul>	<ul style="list-style-type: none"> <li>• Provinces pay for the tissue used in their provinces and this funds a global budget (like blood collection). Hospitals do not pay directly for Canadian tissue.</li> <li>• Hospitals are billed directly for each tissue product they purchase from the central tissue processor (cost recovery and direct competition with US commercial vendors).</li> </ul>

# Synthesis and Review

## Ethics and Human Rights

- Altruistic donation

## Safety and Quality

- Traceability\*
- Quality Systems\*

## Alignment with int'l standards

- WHO Guiding Principles
- Istanbul declaration on Transplant Commercialism

## Equity and Fairness

- Allocation priorities\*
- Differences in donation performance

## System Principles

## Federal / Provincial balance

- Roles and responsibilities

## The Canadian healthcare system

- Access, flexibility and cost
- Innovation
- Self-sufficiency\*

## Responsibilities to the public

- Accountability
- Transparency
- Integrity

\* - discussed in October

## World Health Organization Principles for OTDT (summarized)

- **Consent required** for deceased donation
- **Avoidance of conflicts of interest** between donation and transplantation doctors
- **Living donation is acceptable under certain conditions** (legal competence, no coercion, informed consent, care for the donor)
- **Prohibition on living donation by minors** “except under narrow exceptions allowed by national law”
- **Prohibition on sale and purchase** of tissues and organs (expense reimbursement is acceptable)
- **Prohibition on advertising** availability of tissues and organs
- **Prohibition on utilization of improperly obtained tissues and organs** (e.g. coercion, payment)
- **No profiteering** by hospitals or professionals
- **Allocation must be equitable, transparent, based on “clinical criteria and ethical norms”**
- **Quality systems, traceability, vigilance and national reporting required** for safety, quality and efficacy
- **Transparency essential while protecting anonymity and privacy** of donors and recipients

## Canada Health Act Principles (summarized)

**Public Administration** - “The intent...is that the provincial and territorial health care insurance plans are administered and operated on a non-profit basis by a public authority”

**Comprehensiveness** - “requires that the health care insurance plan of a province or territory must cover all insured health services provided by hospitals, physicians or dentists (i.e., surgical-dental services which require a hospital setting)”

**Universality** - “all insured residents of a province or territory must be entitled to the insured health services provided by the provincial or territorial health care insurance plan on uniform terms and conditions”

**Portability** - “...The portability criterion does not entitle a person to seek services in another province, territory or country, but is intended to permit a person to receive necessary services in relation to an urgent or emergent need when absent on a temporary basis, such as on business or vacation”

**Accessibility** - “to ensure...reasonable access to...services...unprecluded or unimpeded...by charges or other means....[requires] reasonable compensation...for...services....payment to hospitals”

## ***Introduction to Organ and Tissue Costing***

## *Wrap-up and Next Steps*

## In subsequent meetings, we will begin to translate the strategy into objectives, measures and a plan for execution

