

Steering Committee Meeting

October 14th, 2009

Sheraton Gateway Hotel, Toronto



Meeting Objectives

- Review preparations for the upcoming OEC and TEC meetings
- Identify System Principles for OTDT in Canada
- Review and discuss OTDT Public Affairs plan
- Discuss what can make this strategic plan most successful



Steering Committee Agenda

Discussion Item	Time
Welcome and Administrative Items	8:30 – 8:45
Review of TEC and OEC Meeting Preparations	8:45 – 10:15
----- <i>Break</i> -----	
System Principles	10:30 – 12:00
----- <i>Lunch</i> -----	
System Principles (continued)	12:30 – 2:00
----- <i>Break</i> -----	
Public Affairs Plan	2:15 – 3:15
----- <i>Break</i> -----	
What Will Make This Strategic Plan a Success	3:30 – 4:45
Wrap Up and Next Steps	4:45 – 5:00

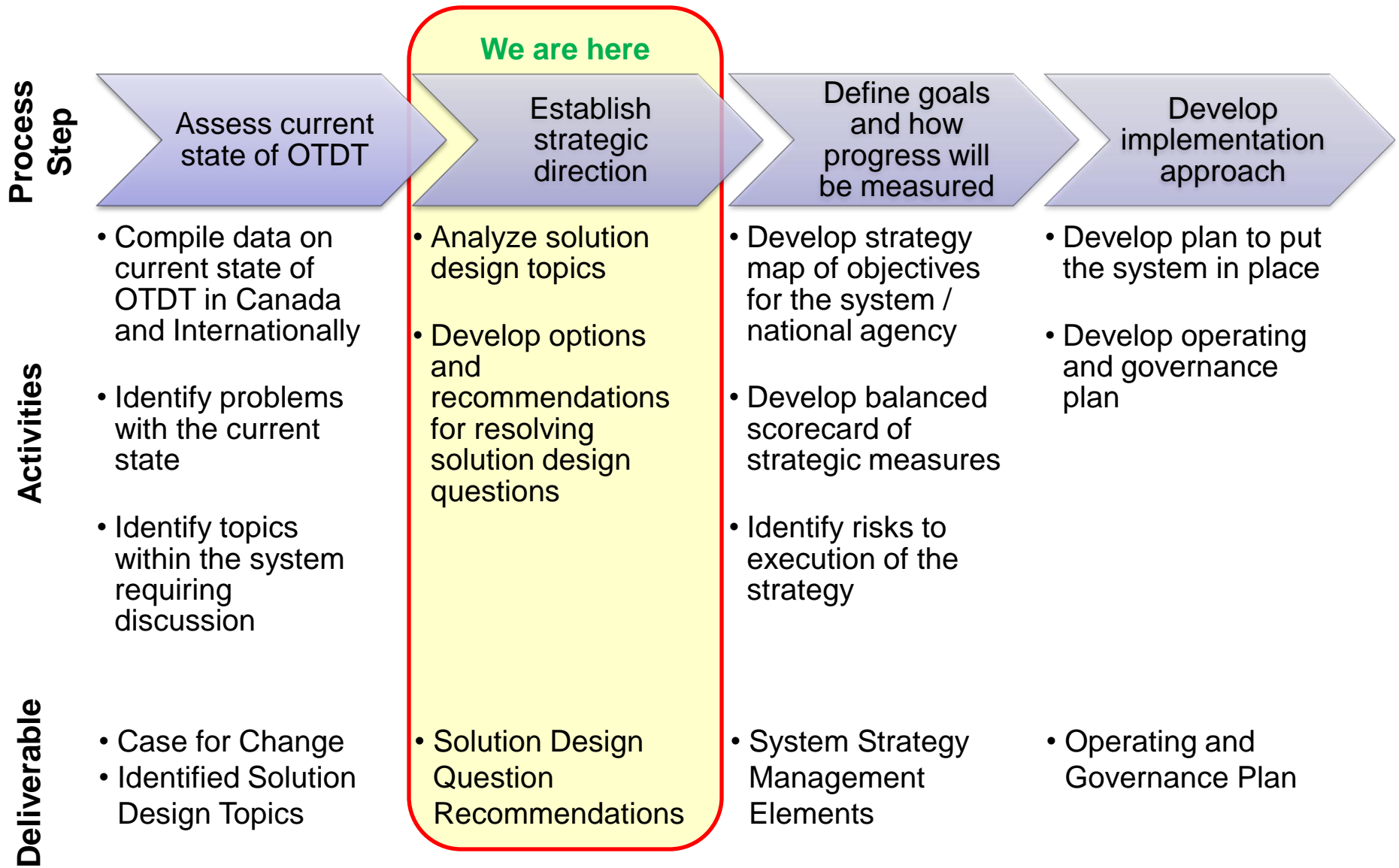
Administrative Items

- Approve the minutes from the Committee's last meeting on June 29, 2009
- Review action items from last meeting



Reviewing Preparations for the TEC and OEC Meetings

Process Overview: A Refresher



In general, we propose to focus first on procedural recommendations, then principles of governance and last roles and responsibilities



- **Ethics**
- **Responsibilities**
- **Methods**

The system should comply with the Charter of Rights and with provincial privacy legislation

- **Safety, Supply, Efficiency**
- **Donation, Transplantation, Allocation**

Identification and Referral should be made routine through the following mechanisms...

- **Policy, Measurement, Accountability**

All donation and transplantation data should be collected nationally and made available to the community

- **Roles, Responsibilities, Relationships**

Consensus policy should be developed nationally and implemented locally

Examples only

Tissues Case for Change

Draft Case for Change	Revised Case for Change
1. The current TDT system in Canada lacks a coordinated approach to systematically assessing and ensuring safety and quality.	1. The safety and quality of tissue product in Canada cannot be assured.
2. Current tissue supply planning practices do not ensure security of supply.	2. Current Canadian tissue supply practices do not ensure security of supply.
3. The TDT model of independent, uncoordinated tissue banks results in inefficient inventory processing and management.	3. The Canadian tissue system of independent and uncoordinated tissue banks results in inefficient tissue collection, processing and distribution.
4. The current TDT system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvement.	4. The current tissue system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvements.

Tissues Solution Design Topics

Revised Case for Change	Solution Design Questions
The safety and quality of tissue product in Canada cannot be assured.	<ol style="list-style-type: none">1. How can the Canadian tissues system best ensure consistent safety and quality?2. What is the best strategy to achieve the regulatory requirements for traceability?
Current Canadian tissue supply practices do not ensure security of supply.	<ol style="list-style-type: none">1. For recovery and processing, what is the best balance between domestic and imported tissue?
The Canadian tissue system of independent and uncoordinated tissue banks results in inefficient tissue collection, processing and distribution.	<ol style="list-style-type: none">1. How can the system best ensure that supply is aligned with demand?
The current tissue system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvements.	<ol style="list-style-type: none">1. What TDT data should be captured or used and how should it be captured and used?2. How should policies be developed, approved and maintained to support the objectives defined in the solution recommendations?3. How should measurement, accountability and funding be organized to deliver the most successful TDT system?

Organs Case for Change

Draft Case for Change	Revised Case for Change
1. Canada is failing to realize its potential for organ donation.	1. Canada is failing to realize its potential for organ donation.
2. Patients with end-stage organ failure are an under-serviced population.	2. The Canadian organ donation and transplantation system is not equitable or transparent.
3. The quality and efficiency of allocation, utilization, and transplantation of donated organs are constrained by resource and technology limitations.	3. There are system inefficiencies associated with patient assessment and organ allocation that can impact patient wait times and health.
4. The current ODT system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvement .	4. The current organ system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvements.

Organs Solution Design Topics

Case for Change	Solution Design Questions
Canada is failing to realize its potential for organ donation.	<ol style="list-style-type: none">1. How can the system best enable the public to turn support for organ donation into action?2. How can the system improve and increase identification and referral of potential donors?3. What resourcing model(s) best accommodate organ donation services?
The Canadian organ donation and transplantation system is not equitable or transparent.	<ol style="list-style-type: none">1. To what extent should practices in patient referral and waitlist management be consistent? What are the best mechanisms for achieving this?2. What principles should guide an improved approach to organ allocation?
There are system inefficiencies associated with patient assessment and organ allocation that can impact patient wait times and health.	<ol style="list-style-type: none">1. What operating and resource models best accommodate organ transplantation?
The current organ system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvements.	<ol style="list-style-type: none">1. What ODT data should be captured and used and how should it be captured and used?2. How should policies be developed, approved and maintained to support the objectives defined in the solution recommendations?3. How should measurement, accountability and funding be organized to deliver the most successful ODT system?

Solution Design after the October committee meetings

- The Expert Committees, in their upcoming meetings, will evaluate the solution options and agree on their next steps to finalize design recommendations
- The results of each committees' deliberations will be synthesized and shared with the steering committee
- Canadian Blood Services will continue consultations with stakeholder and expert communities
- The Expert Committees will be encouraged to share the discussions with others in the community



OTDT in Canada: System Principles

What are “System Principles” and why do we need them?

- System Principles are the declared, fundamental purposes, beliefs and assumptions that underlie system design and implementation
 - World Health Organization: “to provide an orderly, ethical framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes”
 - The Board of Assisted Human Reproduction Canada “has adopted a set of principles to guide its activities and operations”
 - The document, “Building a National Diabetes Strategy” [for Canada] identifies “potential principles for collaboration” and “principles for action”
- 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 (e.g., Canada Health Act)

What kinds of principles do healthcare systems use?

Motivation	Scope	Style
<p>Moral philosophy and individual rights</p> <ul style="list-style-type: none"> • “<i>Integrity</i>” <p>The responsibilities and expectations of public organizations</p> <ul style="list-style-type: none"> • “<i>Accountability</i>” <p>How organizations and systems ought to be structured, operated and funded</p> <ul style="list-style-type: none"> • “<i>Collaborative</i>” 	<p>“Universal”</p> <ul style="list-style-type: none"> • Valid even outside the system • Often enshrined in law • “<i>Fairness</i>”, “<i>Transparency</i>” <p>“Context-specific”</p> <ul style="list-style-type: none"> • Valid specifically in the system or location • “<i>Portability</i>” (Canada Health Act) <p>“Situational”</p> <ul style="list-style-type: none"> • Critical to express for the moment • “<i>Safety is paramount...</i>” (CBS) 	<p>“Headlines” vs. Long form “Proclamations”</p> <p>Mandates vs. Encouragements</p>

Given the need for System Principles, what are we trying to achieve today?

- Framing Statement:

“The Steering Committee has determined that the following principles will guide the design, implementation and governance of OTDT in Canada...”

The Process

- We will separate into two discussion groups
 - Universal principles
 - OTDT-specific principles
- The groups will ruminate and reflect for 30 minutes, then return to the group for discussion
- A template and background materials will be provided

The Discussion

- As required, seek clarity on material provided
- Identify principles not provided in background materials and suggest new or alternate ones
- Surface areas where the Steering Committee should focus most intensely

System Principles: What happens when we get back together as a group?

- Each group will have 5 minutes to describe to the full Steering Committee their initial impressions of which principles should govern OTDT.
- As an example, you may want to think about how your small group would respond to the following statements:
 - *“For us to provide the best advice, we must spend most of our time discussing...”*
 - *“We need additional clarity and work around...(the following issues)*
 - *“We think we’ve missed the mark on some key principles that need to be added or redefined.”*

The group discussion will occur in two parts

- Part 1
 - A focused discussion on principle specifics – what's in, what's out, what requires further discussion
- Key questions to consider:
 - Is anything listed here surprising to you? Are you struggling with anything?
 - Which principles are easiest to define and you agree are essential?
 - Which ones do you think require deeper reflection from the group?
- Part 2
 - A discussion to review the draft principles as a portfolio
- Key questions to consider:
 - Are there conflicts/inconsistencies between principles?
 - Where are the principles mutually reinforcing?
 - What must we do to ensure the successful implementation of these principles?

Suggested Principles for Discussion - Possible Universal Principles (1 of 2)

Possible Principle	Why is it important for OTDT?	Possible definitions	Discussion
Safety of products and procedures	Organ and tissue testing and traceability	The importance of protection of life and quality of life and of the avoidance of adverse events	Balance with cost and risk
Autonomy of individuals	Deceased and living donation; rights of recipients and rights of donors	The individual right to permit or prohibit medical procedures	Opt-in vs. Presumed Consent for deceased donation? Any principles relating to living donation?
Access to OTDT services	Access a function only of medical need	The individual right to receive medically necessary care regardless of financial means	Does this overlap with equity? Is it sufficiently important on its own? Are there implications of using it in the context of a scarce resource?
Equity / Fairness / Justice of allocation	Access to a transplant regardless of...	The goal of equal treatment of individuals	Tension with “utility”

Suggested Principles for Discussion - Possible Universal Principles (2 of 2)

Possible Principle	Why is it important for OTDT?	Possible definitions	Discussion
Utility of allocation	Allocation to maximize total benefit to the population	The goal of “optimizing use of the resources so the greatest total benefit is obtained”	Tension with “equity”; Is it appropriate to emphasize the “needs of the population?”
Privacy of information	Current privacy laws	The protection of individual information	Tension with transparency
Responsible, Accountable, Transparent	Publicly open standards and performance; responsibilities of any coordinating agency	Performance is measured and reported and organization is responsive	If there is/are responsibilities that should be enshrined as principles, which is/are most important?

Suggested Principles for Discussion - Possible OTDT-specific Principles

Possible Principle	Why is it important for OTDT?	Possible definitions	Discussion
Collaboration	Ensure broad input on policy, continue the project principle of “consultative”	System aims pursued in inclusive manner inviting broad participation and input	Collaboration focus: partners and/or public?
Independence	Roles, responsibilities and buy-in in an inter-provincial system	System recognizes the autonomy and accountability of partners in the system (e.g. provinces, RHAs)	Is it necessary to communicate explicitly? Can it be effectively balanced?
Security of Supply / Self-Sufficiency	Tissue Case for Change	A goal of supplying a certain percentage of national demand with domestic supply and/or processing	Should a certain level of security of supply be a system goal? If so, should it be a <i>principle</i> ?
Evidence-based decision-making	Continue the project principle of “evidence-based”; used by other OTDT systems	System policies based on sound processes and information	“Evidence” in general or “evidence of benefit”? Is this necessary to emphasize objectivity of allocation?

Suggested Principles for Discussion - Possible OTDT-specific Principles

Possible Principle	Why is it important for OTDT?	Possible definitions	Discussion
Traceability	Tissue Case for Change	The capability of locating and linking donation through storage, distribution and transplantation, in both directions, as well as linking donor and recipient information.	Does the tissue safety and quality concern suggest or justify
Financial Efficiency	Plan being “fundable” an important goal	System aims pursued with responsible financial stewardship	Is this a necessary principle in these times?

OTDT Public Affairs Plan



Canadian Blood Services
given green light to do for
organs and tissues what it
did for blood

A new beginning for
Organs and Tissues

Public Affairs Plan Outline

- Guiding Principles
- Strategic Approach
- Stakeholder Analysis
- 3 Pillars
 - Stakeholder relations
 - Government relations
 - Media relations
- Quebec Strategy
- Expert Strategy
- Summary
- Discussion

Guiding Principles

- Ensure broad outreach that takes into account Canada's diversity
- Generate balanced involvement
- Operate in an open, transparent and trusted manner
- Create opportunities to engage & collaborate with F/P/T partners, stakeholders and the public



Strategic Approach

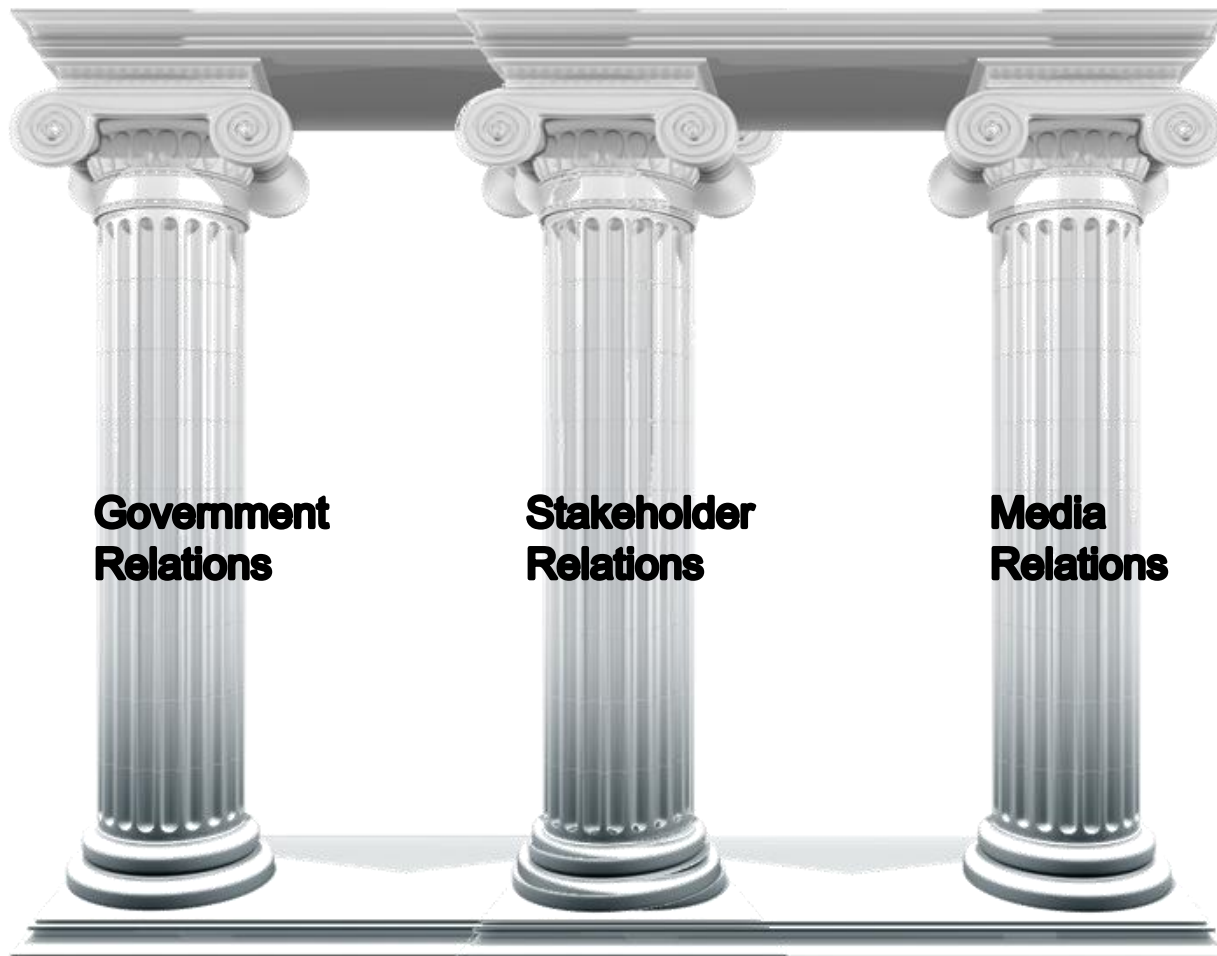
- Inspire & motivate stakeholders
- Build towards a crescendo in June 2010
- Lay the groundwork for implementation
- Use events as foundation
- Establish sustainable partnerships
- Tap into existing meetings
- Leverage network to raise awareness with the decision-makers
- Meet unique needs of organ and tissue communities

Stakeholder Analysis

- Stakeholder mapping to understand the players
- Social Network Analysis to determine connections
- Focus on groups and individuals that have an interest in OTDT
- Connect with groups that advocate on behalf of patients
- Specific outreach to experts
- Need to clarify Quebec's role



3 Pillars



Stakeholder Relations

- Divided into two categories:
 - Professionals
 - Organs
 - i.e. Professional Societies, Regional Health Authorities, EMS, Transplant Programs, OPOs, etc.
 - Tissues
 - i.e. Tissue Banks, Medical Examiners, Plastic Surgeons, Oral Surgeons, Tissue Programs and Centres, etc.
 - Attentive Publics
 - Members of the public & groups who are predisposed
 - i.e. Transplant recipients, living donors and their families, deceased donor families, Kidney Foundation, etc.

Stakeholder Relations

- Professionals
 - meet with groups, dovetail on meetings, etc.
- Attentive Publics
 - Public Dialogues will give the public a chance to speak up in their communities
 - Pre & post event GR briefings of FPTs
 - Pre-event media blitz
 - Site visits with local healthcare partners
 - CBS staff presentations
- London (Oct. 24), Vancouver (Nov. 14), Edmonton (Jan. 16), Halifax (Feb. 6), Winnipeg (Feb. 13), Montreal (Mar. 13)

Government Relations

- Mandate agreed upon
- Plan must be fundable, actionable and seen as a priority
- Respect federal and provincial jurisdictions
- Respect variations in provincial investment; need to demonstrate how national coordination will improve performance, not hinder best performing provinces
- Look at governments from a broader perspective; make outreach to multiple levels



Government Relations

- Three approaches:
 - Direct Influence
 - Through champions
 - Direct/Indirect Influence
 - Through stakeholder partners
 - Indirect Influence
 - Through media and the public



Media Relations

- Comprehensive media strategy to support all activities
- Ensure all activities are highly visible
- Organ story is an easy one to tell, tissue requires additional effort
- Tap into health reporters
- Use of advocates to tell their stories



Media Relations

- Organs
 - Create buzz around the public consultations
 - Target professional association newsletters and websites
 - Identify advocates and champions for the cause
 - Capitalize on events like National OTDT Week
- Tissues
 - Leverage public interest in organs issues to introduce tissues story
 - Focus story on the concepts of safety and source
 - Target professionals in the field to tell the story; they will be the drivers for change
 - Target trade publications of interest to the tissue banking community

Quebec Strategy

- Clarify nature and level of Quebec's participation in a national system
- Organs
 - Secure participation and funding for the registries
 - Design a strategy that benefits Quebec patients
- Tissues
 - Share expertise and encourage collaboration



Expert Strategy

- Many experts have invested significantly in improving patient outcomes
- Experts are best positioned to help design the ideal system
- Experts identified by their area of expertise and geography, not as part of a supply chain
- We agree a new system will benefit patients, but we expect a diversity of opinions on how to accomplish that
- We need the diverse and broad perspectives to build a credible plan
 - Using various methodologies and approaches

Summary

- 145 points of outreach/engagements are planned:
 - 28 to organ specific groups
 - 23 to tissue specific groups
 - 94 that touch both
- Partnerships established with:
 - 8 Organ specific groups (Kidney Foundation, Diabetes, CTA, CST, Canadian Healthcare Conference, Liver Foundation, CIHI/CORR, Cystic Fibrosis Foundation)
 - 9 Tissue specific groups (Canadian Assoc. of Eye and Tissue Banks, CNIB, AATB, Assoc. of Medical Examiners, Assoc. of Oral and Maxillofacial Surgeons, Eye Bank of America, CDA, Canadian Orthopaedic Surgeon Society, Periodontal Surgeons)
 - 9 groups that touch both (Lions Club, Elks Club, Critical Care Society, Critical Care Nurses Association, Emergency Physicians Association, Aboriginal Health Coalition, CMA, Aboriginal Nurses Association, Patient Safety Institute)

Discussion

- Is there anything missing?
- If we could do only one thing, what is the most important?
- What will be our greatest challenge?

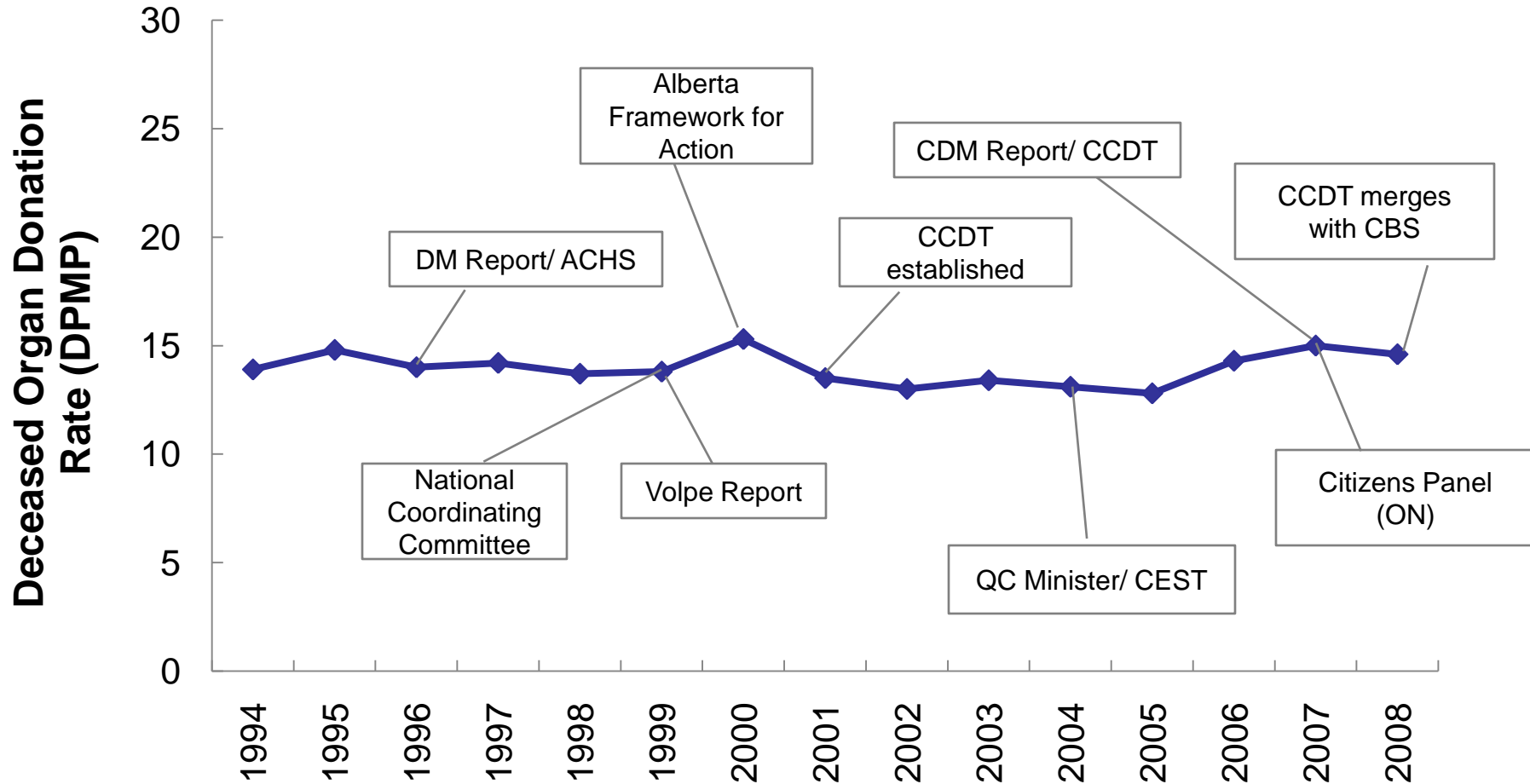


Making the OTDT Strategic Plan a Success

Objective of this session

- To discuss how to make the OTDT strategic plan more successful,
- By establishing the historical context of OTDT in Canada, and
- By proposing a point of view on what that history means to our planning process

We will not be the first to make recommendations to improve OTDT in Canada



Source: CORR 2007 Annual Report and E-Statistics

Recent reports and recommendations

Volpe Report (1999)	<ul style="list-style-type: none">• Federal Standing Committee recommended establishment of Canadian Transplant Network
National Coordinating Committee (1999)	<ul style="list-style-type: none">• Recommended establishment of Canadian Council for Donation and Transplantation (CCDT)
Alberta Framework for Action (2000)	<ul style="list-style-type: none">• 99 recommendations for provincial OTDT system
Report to the Premier's Advisory Board (ON - 2000)	<ul style="list-style-type: none">• Recommended costing and analysis of organ and tissue activities
Feasibility of a Pre-hospital Tissue Procurement Program (BC - 2006)	<ul style="list-style-type: none">• Develop program models and pilot study for tissue procurement
Strategic Plan to Improve Tissue Donation (ON - 2006)	<ul style="list-style-type: none">• Consolidate and standardize tissue activities for provincial system
CCDT Five-year Strategic Plan (2007)	<ul style="list-style-type: none">• Recommendations for extension of mandate
Citizens Panel on Increasing Organ Donations (ON - 2007)	<ul style="list-style-type: none">• Recommendations focused on mechanisms to increase donation rates

Since the CBS Mandate for OTDT, we have sought advice on how we can succeed



Canadian OTDT Community

- National Consultation
- Direct consultation with experts and stakeholders

International OTDT Community

- Australia
- UK
- US

- Australia
 - Taskforce recommended national coordinating authority for blood, tissue and transplant
 - In-hospital coordinators
 - National registries and public awareness
 - Plan approved (2008)
- UK
 - Taskforce recommended national donation and transplant authority
 - Hospital staffing and funding
 - National public awareness
 - Plan approved (2008)
- US
 - OPTN (donation / transplantation) and SRTR (data) established 1984
 - UNOS contracted to operate OPTN

Discussion: What will make *this* strategic plan for OTDT a successful one?

- Convey a **sense of urgency** about the state of OTDT → *The Case for Change*
- Actively **engage the public** for its input and support → *Public Dialogues*

- **Respect the differences** between Organs and Tissues → *Separate OEC and TEC*
- Have the **support of experts** in the community → *OEC, TEC, PA Plan*

- Base solutions on **evidence, expertise and a process** → *Solution Design Process*

- Be **focused** on what is most important - the “critical few” → *Strategy Map of Objectives*
- Commit to **self-evaluation and improvement** → *Balanced Scorecard of Measures*

- Be **practical and implementable** →
- Be clear about who will be **accountable** for what →
- Be **affordable** →
- Be **easy to understand** →
- Demonstrate **progress quickly** →
- **Stand out** compared to other priorities →

Upcoming Activities and Next Steps

Upcoming Activities and Next Steps

- Upcoming Activities
 - International Conference Call series
 - Tissue End User Forum
 - Public Dialogues
- Next Steps for Steering Committee
 - Principles
 - The substance of our discussion today will be shared with the OEC and TEC as they begin to discuss solution design
 - We propose to convene a bioethics “round table” to review and advise us on the preliminary principles
 - Minutes from this meeting will be distributed
 - The results of the OEC and TEC meetings will be sent to you
 - The next Steering Committee meeting is scheduled for January 20