

# Tissue Expert Committee Meeting

*October 29<sup>th</sup>, 2009*

Sheraton Gateway Hotel, Toronto



## Meeting Objectives

- Establish strategic direction by discussing solution options to four strategic questions in light of system principles
- By the time we leave today, we will have...
  - Revised the options
  - Identified areas of consensus where preliminary recommendations are readily apparent
  - Identified options that need further input and consideration prior to determining a recommendation
  - Identify data sources to support recommendations



# Agenda

Discussion Item	Time
Welcome and approval of agenda	8:30 - 8:45
Review of preliminary OTDT system principles	8:45 - 9:15
Overview of CBS programs	9:15 - 10:15
----- Break -----	
Review tissue survey - preliminary data	10:30 - 11:30
Introduction to design discussions	11:30 - 12:00
----- Lunch -----	
Design discussions	12:30 - 4:00
Review of design discussions	4:00 - 4:45
Wrap-up and next steps	4:45 - 5:00

## Administrative Items

- Approve the minutes from the Committee's June meeting



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

## Overview of CBS Programs



## Purpose

- Review Canadian Blood Services programs
- Compare Canadian Blood Services programs and tissue systems, to understand areas of commonality



## Structure of Blood System in Canada

- There are two blood systems in Canada – Canadian Blood Services and Héma-Québec.
- Both were created in 1998 in the wake of the Krever Inquiry, to restore safety and integrity to Canada's blood system.
- Canadian Blood Services statistics:
  - Whole Blood Collections: 915,858 units
  - Plasmapheresis Collections: 55,244
  - Plateletpheresis Collections: 40,847 units
  - Plasma Protein Products: 1.2 million vials of product (26 different types, 40 different brands, 77 different SKUs)

# Canadian Blood Services



- **National presence (except QC)**

- 41 permanent collection sites
- 20,000 collection clinics annually
- 8 OneMatch Stem Cell and Marrow Network sites
- 3 testing laboratories
- 12 manufacturing sites
- 4,700 employees; 17,000 volunteers
- 450,000 active donors

- Serve **732** hospitals / health authorities across Canada
- Budget > **\$950** million
- Multiple business lines:
  - Transfusable products
  - Plasma protein products
  - Stem cells
  - Diagnostic services

# Canadian Blood Services - Business Lines and Governance

## Blood Operations

- Recruit donors, collect blood, manufacture components, test, distribute to hospitals

## Plasma Protein Products

- Collect plasma, custom fractionation, acquire plasma derivatives, recombinant proteins and synthetic equivalents

## OneMatch Marrow and Stem Cell Network

- Linked to 51 other registries worldwide
- Emerging umbilical cord blood bank

## Diagnostic Laboratories

- ABO, Rh and antibody testing of expectant and post-partum mothers
- Pre-transfusion and crossmatch testing of blood for patients requiring transfusions

## Organ & Tissue Donation & Transplantation

- Organ Registries
- National mandate evolving

## CBS Foundation

- To support and extend the mission of Canadian Blood Services

### Corporate Members

Provincial (except Quebec) and Territorial Ministers of Health (12)

### Board of Directors

1 Chair, 4 Directors from regions, 2 Directors from the general public, 6 Directors providing technical expertise

### Canadian Blood Services

#### Executive Management Team

##### Chief Executive Officer

Chief Operating Officer  
VP Corporate Services and Chief Financial Officer  
VP General Counsel & Corporate Secretary  
VP Quality & Regulatory Affairs  
VP Medical, Scientific & Research Affairs  
VP Strategy Management  
VP Talent Management  
VP Public Affairs

Business Performance Councils

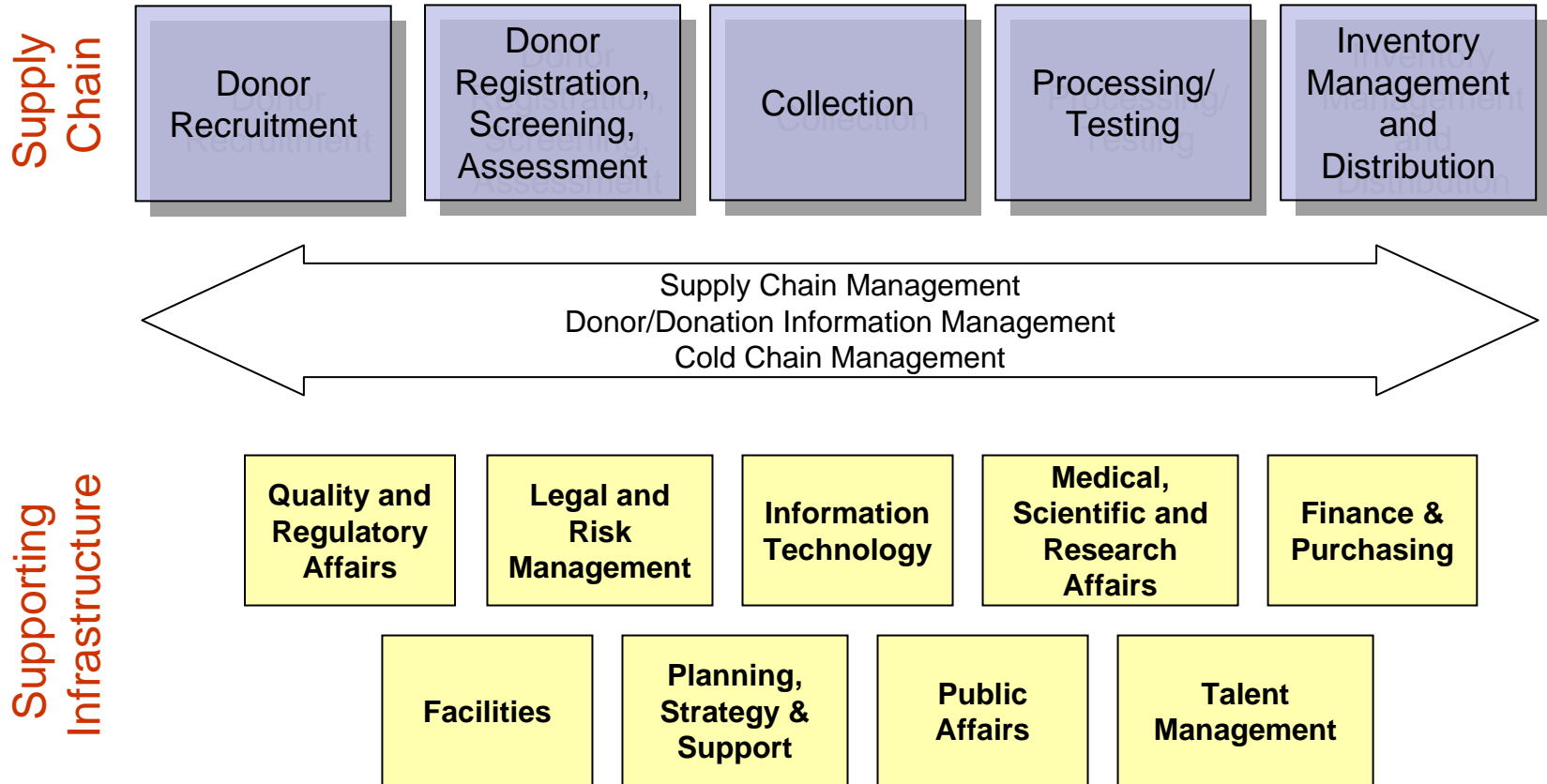
Divisional, Business Line, Regional,  
Local Management Teams

Canadian Blood Services Staff

Volunteers



# System Structure



# Donor Recruitment



## Canadian Blood Services Operations

Blood and Plasma	<ul style="list-style-type: none"><li>•Recruit donors for immediate donation<ul style="list-style-type: none"><li>–National Marketing Campaigns / National Brand to boost public awareness</li><li>–National Call Center to book appointments</li><li>National Donor/Donation Database (MAK Progesa)</li><li>–Customer Relationship Management tools</li><li>–National Donor Registry for HLA typed donors</li></ul></li></ul>
Stem Cell	<ul style="list-style-type: none"><li>•Recruit donors for future potential donation<ul style="list-style-type: none"><li>–OneMatch Donor Registry</li></ul></li></ul>
Organs	<ul style="list-style-type: none"><li>•Living Donor Paired Exchange database and matching algorithm for potential living donors and recipients</li><li>•Limited donor recruitment through website and pamphlets</li></ul>

## Tissue system

- Recruit donors for future potential deceased donation
  - Local public awareness campaigns
  - Some provincial registries
  - Health professional education strategies
- Recruit donors for living donation
  - Hospital living donation programs
  - Health professional education strategies

# Donor Registration, Screening, Assessment



## Canadian Blood Services Operations

Blood,  
Plasma and  
Stem Cell

- Register donors into national donor/donation database
- Health assessment obtained from donor
  - Medical and social history questionnaire
  - Blood pressure and temperature (blood and plasma only)
- Deferral, if required

## Tissue system

- Health assessment obtained from donor family
  - Medical and social history questionnaire
- Medical record review
- Medical history from family physician if available
- Potentially, autopsy results
- Donor declined if any issues

# Collection



## Canadian Blood Services Operations

### Blood and Plasma

- Collect at mobile or permanent clinic
- Collected by nurse / phlebotomist
- Standardized labelling (ISBT 128)
- Donation data captured in national donor/donation database
- Products forwarded to lab for processing

### Stem Cells

- Collect at hospital
- Specialized recovery team
- Standardized labelling (ISBT 128)
- Donation data captured in national OneMatch database
- Products forwarded to lab for processing

## Tissue system

- Donor physical examination
- Collect at hospital, tissue bank or other location (sterile rooms required)
- Specialized recovery team
- Labelled according to local practices

# Processing / Testing



## Canadian Blood Services Operations

### Blood and Plasma

- Whole blood processed into components
- Additional processing for specialized products
  - Freezing
  - Irradiation
- All donors tested for ABO Rh, TD markers, HLA as required
  - Consolidated Testing Laboratories (Calgary, Toronto, Halifax)
  - National Reference Laboratory (Ottawa)
  - ASHI accredited HLA labs (Ottawa, Winnipeg)

## Tissue system

- Tissue processed into allografts
  - Base Tissues
  - Demineralization
  - Machined grafts
- Bioburden reduction
  - Disinfection
  - Sterilization; chemical or irradiation
- Storage Processes
  - Freezing
  - Lyophilization
- All donors tested for TD markers
- All tissue cultured for bacteria

# Inventory Management and Distribution



## Canadian Blood Services Operations

Blood,  
Plasma and  
Stem Cell

- Release to Inventory
  - Automated through MAK Progesa system
  - ..
- Storage
  - At 12 manufacturing sites
  - Interim storage of Plasma Protein Products at central national warehouse
- Distribute to hospitals
  - From 13 depots
  - To 730+ hospitals and health care clinics

- Real-time inventory management system (MAK Progesa)
- SAP Financial system for tracking costs and inventory management of Plasma Protein Products

## Tissue system

- Release to Inventory
- Storage
  - 29 tissue banks
- Distribute to hospitals, health care clinics and dental clinics

# Inventory Management and Distribution (cont'd)



## Canadian Blood Services Operations

### Exported/ Imported Product

- Send plasma for further manufacturing of IVIG and Albumin outside of Canada
- Additional Plasma Protein and Recombinant products purchased and distributed from central warehouse to depots
- Distribute to hospitals

- Supplier qualification and auditing
- Supplier / processing contracts and volume price agreements
- SAP inventory management system for tracking and billing

## Tissue system

- Send tissue for processing outside of Canada
- Import finished product
  - Purchased by individual tissue bank, hospital, health care clinic or dental clinic

# Canadian Blood Services Supporting Infrastructure (1 of 3)

## Quality and Regulatory Affairs

- Regulatory:
  - Food and Drug Act and Regulations
  - Medical Devices
  - Safety of Human Cells, Tissues and Organs for Transplantation (CTO)
  - Nuclear Safety and Control Acts and Regulations
  - HC Guidance Documents and Directives
  - Provincial regulations
  - US FDA Part 607 (for imported product)
- Surveillance: Internal reports from hospital
- Internal audits
- Quality framework
- Standard processes for lookbacks, tracebacks, recalls, deviation
- Support for licensing, audit management and accreditation

## Legal and Risk Management

- Health law, product liability, insurance law, risk management
- Privacy, records and information management, Board administration
- Code of Conduct, lobbyist registration, corporate filings, support for governance projects
- Policy Development and Policy Review
- Plans for: Disaster Recovery; IT recovery; Business Continuity; Pandemic Planning
- Captive Insurance

## Medical, Scientific and Research Affairs

- Supports research related to improvements in the blood supply. There are areas which overlap between blood and tissues which could leverage this infrastructure.
- Medical / technical expertise that contributes to policy development
- MSRA med micro on staff – monitoring of Emerging issues (Policy Development)

## Canadian Blood Services Supporting Infrastructure (2 of 3)

Finance & Purchasing	<ul style="list-style-type: none"><li>• Financial and Operational reporting</li><li>• Procurement infrastructure, volume purchasing and contract agreements</li><li>• Integrated end-to-end supply chain</li></ul>
Facilities	<ul style="list-style-type: none"><li>• Processing, testing, storage, distribution and office facilities across the country (total of 66 sites)</li><li>• Transport vehicles and contracts</li><li>• Expertise in building and managing labs</li><li>• Cold chain</li></ul>
Public Affairs	<ul style="list-style-type: none"><li>• Government Relations</li><li>• Stakeholder Management</li><li>• Media Relations</li></ul>
Strategy, Planning & Support	<ul style="list-style-type: none"><li>• Strategic and Business Planning</li><li>• Market Knowledge and Donor Insight (including demand forecasting and analysis)</li><li>• Benchmarking studies</li><li>• Balanced scorecard performance tracking</li><li>• Project Management</li></ul>
Talent Management	<ul style="list-style-type: none"><li>• Attract, train and retain employees with technical and medical background</li></ul>
Information Technology	<ul style="list-style-type: none"><li>• Donor/Donation Information Systems</li><li>• General Business Applications and Support</li><li>• Data Warehouse</li><li>• National Service Desk</li><li>• Voice and Data Communications</li><li>• Server and Storage Management</li><li>• Records Management</li></ul>

## CBS Tissue Survey - Preliminary Results



## Background

- At the September 2008 National OTDT Stakeholder Consultation, tissue participants identified the lack of national data in describing the tissue system in Canada
- Through surveys, site visits and conference calls, Canadian Blood Services has collected data related to:
  - Canadian tissue supply
  - Canadian tissue demand
  - International tissue supply and demand
- A summary of the preliminary data is presented today



# This is not the first attempt to capture data on the Canadian tissue system

## Currently available tissue information

- Allograft supply and demand data are not current
- Survey response rates from tissue end-user groups were low
  - Extrapolations required to estimate national demand
- Reports provide different estimated ranges for musculoskeletal allograft demand
- DBM report (2006) provides quality data on allograft usage in dental settings



## Scope of new tissue survey

- **Environmental scan of national tissue programs** to understand current supply of tissues and existing infrastructure
- **Obtain current data on the demand for allograft tissues** within Canadian hospitals including the number imported from the United States
- **Environmental scan of international programs** to understand options for a national framework



## Supply Information – Initial Findings

- Survey Response Rate: 87% (20/23 programs)
- Direct consultations: Discussions with 21/23 programs
- 6 surgical bone banks have closed or have discontinued recovery since 2003
- Based on a comparison of 2008 and 2002 data:
  - number of recovered tissues increased by 24.9%
  - number of processed tissues decreased by 12.1%
- 75% of all musculoskeletal tissue recovered is recovered by the 4 Comprehensive Tissue Banks
- Collaborations with US processors are developing
- Funding within a hospital environment remains a challenge
- Most tissue banks only distribute within their region
- Most tissue banks are not involved with research and development activities

## Supply Information - Summary

- **Specific tissue programs have improved and expanded services** in the past six years
- Individual program **improvements are not observed system-wide** at the national level
- A final report summarizing the survey and the consultation work will be available for next meeting

## Demand Information

The assessment of Canadian allograft demand had two areas of focus:

- **Ocular Allografts** in Canada: Ocular tissue programs were requested to complete a survey to assess ocular demand
- **Musculoskeletal, Cardiovascular and Skin Allografts** in Canadian Hospitals: Operating Room managers were requested to complete a survey to assess demand



## Ocular Demand - Initial Findings

- Survey Response Rate: 8/10 eye banks (survey not sent to 2 Quebec banks)
- Wait times for corneas vary between 3 months and 36 months
- Minimal transfer of corneas between provinces
- No importation of corneas from the United States reported. (Quebec is pursuing importation to address their corneal wait lists).
- Clear preference for Canadian suppliers



## Musculoskeletal, Cardiovascular & Skin Allograft Demand

- Surveys were initially sent to 3 pilot sites
- The responses from pilot sites indicated that data on allograft usage and cost is not readily available or accessible in the hospital OR environment:
  - Management of allografts in Canadian hospitals is often not centralized
  - Allografts are managed by numerous individuals with various support systems
- Rolling out the survey to all Canadian hospitals would likely result in a poor response rate and incomplete data
- As a result, the strategy for obtaining Canadian demand data is being reviewed



## International Data

- Approach
  - Assess models and programs by reviewing websites and relevant literature
  - Interview program representatives
  - Countries assessed included United States, Australia, United Kingdom and Spain
- Initial Findings
  - There is a limited amount of published data on national tissue frameworks or models
  - National tissue system development has been initiated in certain jurisdictions, but no fully implemented integrated system was identified
- Work continues to obtain international data

## Next Steps

- Complete supply report by end of 2009
- Continue to obtain data required for strategic plan, including engaging end-users to gather insights into purchasing practices and product use

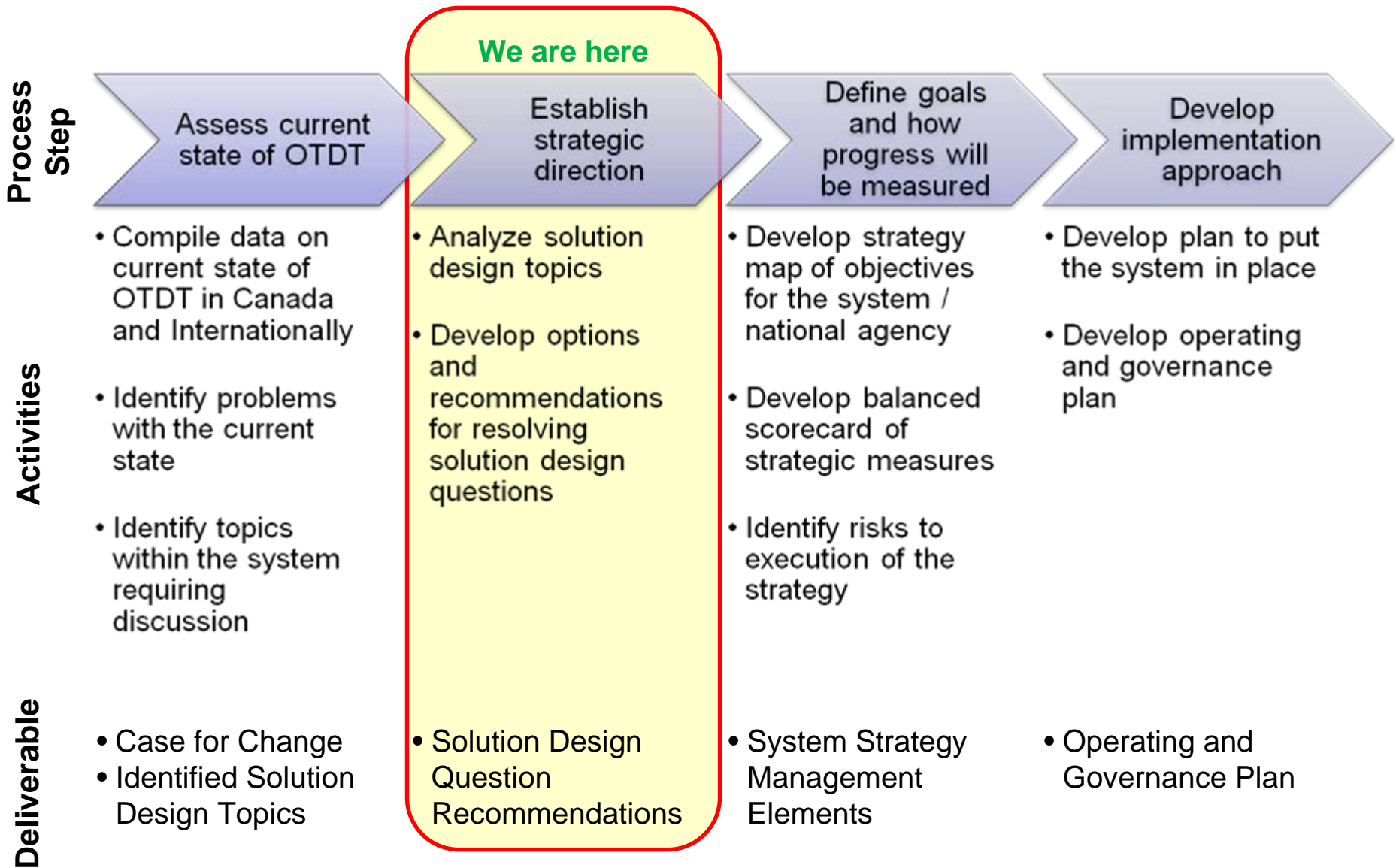
## Introduction to Design Discussions



## The context for solution design

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.

# 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**

# Tissue Solution Design Topics

Revised Case for Change	Solution Design Questions
<p>The safety and quality of tissue product in Canada cannot be assured.</p>	<ol style="list-style-type: none"><li>1. How can the Canadian tissues system best ensure consistent safety and quality?</li><li>2. What is the best strategy to achieve the regulatory requirements for traceability?</li></ol>
<p>Current Canadian tissue supply practices do not ensure security of supply.</p>	<ol style="list-style-type: none"><li>3. For recovery and processing, what is the best balance between domestic and imported tissue?</li></ol>
<p>The Canadian tissue system of independent and uncoordinated tissue banks results in inefficient tissue collection, processing and distribution.</p>	<ol style="list-style-type: none"><li>4. How can the system best ensure that supply is aligned with demand?</li></ol>
<p>The current tissue system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvements.</p>	<ol style="list-style-type: none"><li>5. What TDT data should be captured or used and how should it be captured and used?</li><li>6. How should policies be developed, approved and maintained to support the objectives defined in the solution recommendations?</li><li>7. How should measurement, accountability and funding be organized to deliver the most successful TDT system?</li></ol>

## Today's Discussions (1 of 2)

Question	Options
1. How can the Canadian tissues system best ensure consistent safety and quality?	<ul style="list-style-type: none"><li>▪ Solutions for source establishments<ul style="list-style-type: none"><li>▪ National standardized quality program</li><li>▪ Centrally supported, independently operated quality programs</li></ul></li><li>▪ Solutions for transplant establishments<ul style="list-style-type: none"><li>▪ Update Accreditation Canada standards</li></ul></li></ul>
2. What is the best strategy to achieve the regulatory requirements for traceability?	<ul style="list-style-type: none"><li>▪ Solutions for source and transplant establishments<ul style="list-style-type: none"><li>▪ Common coding and labeling system</li><li>▪ Information standards and sharing</li><li>▪ Single, integrated information platform</li><li>▪ Informed consent</li><li>▪ Audit and accountability</li></ul></li></ul>

## Today's Discussions (2 of 2)

Question	Options
3. For recovery and processing, what is the best balance between domestic and imported tissue?	<ul style="list-style-type: none"><li>▪ 100% domestic self-sufficiency of donation and processing</li><li>▪ 100% importation of product and processing</li><li>▪ 100% domestic self-sufficiency of donation; processing in Canada and US</li></ul>
4. How can the system best ensure that supply is aligned with demand?	<ul style="list-style-type: none"><li>▪ National or Provincial approaches to:<ul style="list-style-type: none"><li>▪ End User Relationship Management</li><li>▪ Demand Forecasting</li><li>▪ Production Flexibility</li><li>▪ Inventory Management</li></ul></li></ul>

## Design Discussions

## Background:

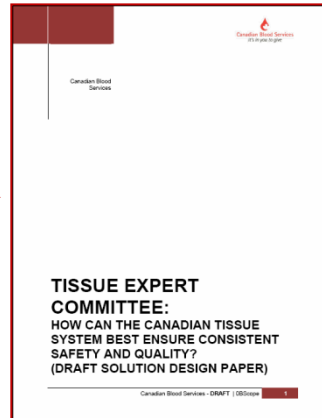
Today's discussion is the result of an organized process to arrive at more concrete system options.

Case for Change

*What are we trying to fix?*

Design Questions

*What are the key system issues around which we must seek clarity?*

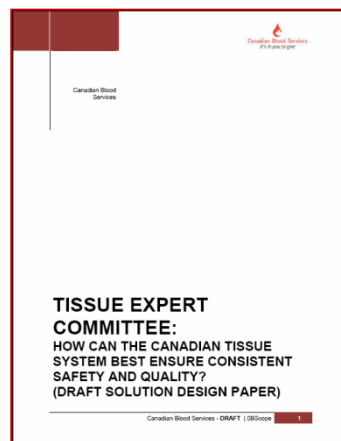


*What are the various ways we could proceed?*

TODAY'S DISCUSSION

## Background:

The objective is to leverage your expertise to arrive at the best possible option for each Design Question.



*What are the various ways we could proceed?*

What options are not feasible? Why?

What options have we missed?

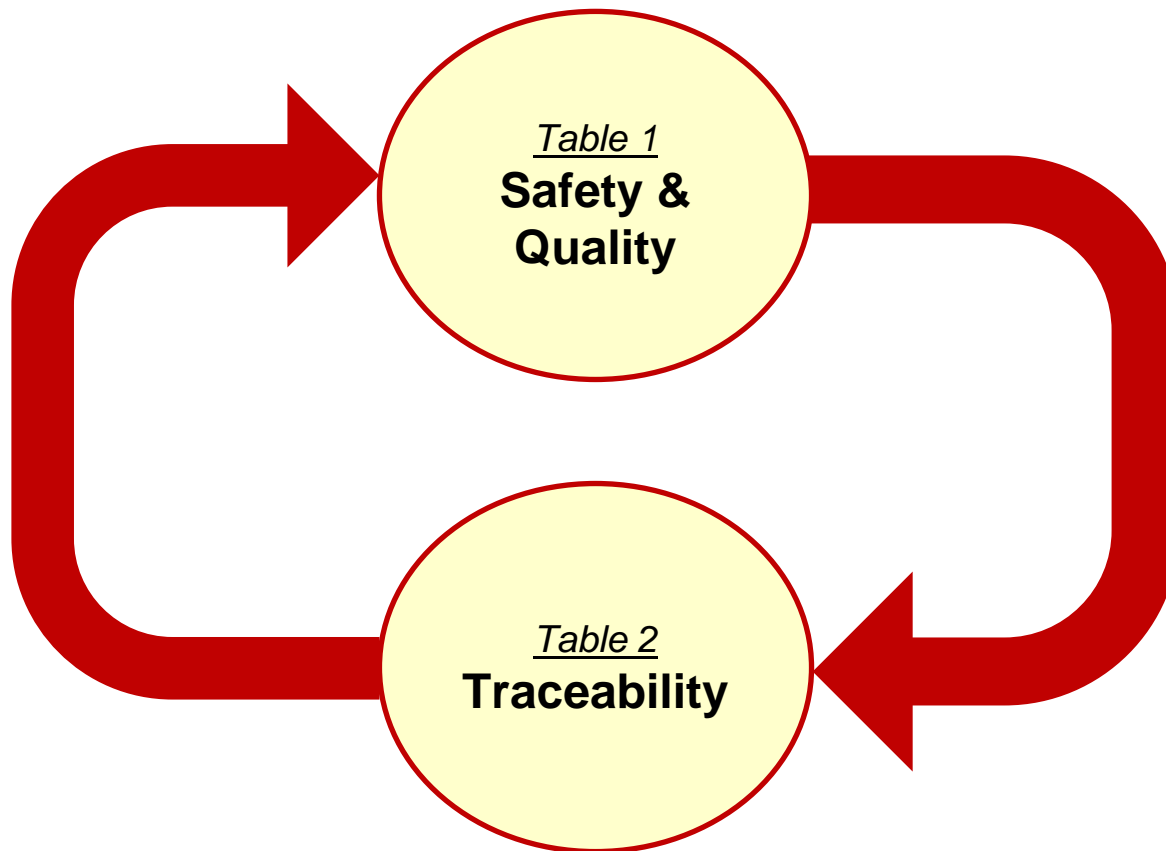
What are the best options? Why?

## Discussion Approach:

To maximize discussion, you will focus your discussion around two “topic tables”

*Round 1: 30 minutes*

*Round 2 and 3: 15 minutes*



## Discussion Approach:

Our goal is to provide all with the opportunity to discuss each Design Question, capture all perspectives and share the results.

1. Table discussions will not be 'facilitated'
  2. Timekeeper will keep the conversations moving forward
  3. Two participants per table are asked to volunteer for roles; **host** and **scribe**
  4. Closing plenary session will provide opportunity for further comments/ideas/synthesis.
- Table Host: Remain at the same table for the entire round of conversations to facilitate the linking and connecting of ideas.
  - Participants: Address the questions at the table by drafting ideas and/or reacting to the ideas of others
  - Scribe: Keep a written record of the table's conversation

## Discussion Approach:

**Our goal is to provide all with the opportunity to discuss each Design Question, capture all perspectives and share the results.**

1. Discussion begins at your home table.
  - Scribe summarizes and capture outputs
  - After 30 minutes, as a group, rotate to the next table (all except the Table Host)
2. At New table:
  - Host summarizes previous discussion
  - React to the prior group's ideas/add ideas to table top
  - Scribe continues to capture thoughts/outputs
3. After 15 minutes, return to your home table:
  - Host summarizes discussion
  - Read reactions and additions of other groups to the original work
  - Seek clarification of comments when necessary
  - Synthesize the overall output for the table
  - Scribe – captures the overall output for the table (template)
  - Determine presenter for plenary



## Challenge questions for each group to answer

- For each design question:
  - What options are not feasible? Why?
  - What options have we missed?
  - What are the best options? Why?
  - What evidence is critical to making a recommendation?

## Keep In Mind...

- The options in the papers are a starting point for discussion - you are encouraged to bring in great solution ideas that were missed, or recombine the draft options into better solutions
- All options are on the table; don't let implementation barriers get in the way of identifying the best solutions
- Seek common ground when discussions do not seem to yield easy agreement, sorting through areas of disagreement is important but takes time
- We have provided some structure to make sure all voices are heard and that we address every topic, but ultimately, this is your dialogue

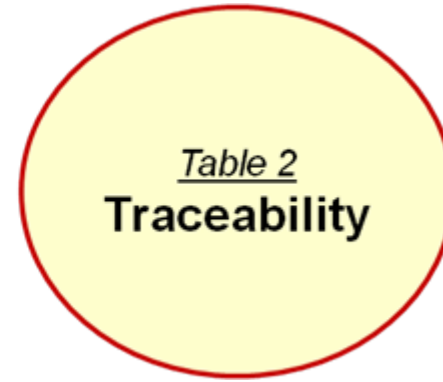


# Design Table Assignments - Round 1



## **Group 1**

Mike B  
Mary  
Scott  
Brian  
David H  
Sean  
Jim  
Christian



## **Group 2**

Locksley  
Chris  
Mike G  
Janet  
Dermott  
Kim  
Sophie

# Design Table Assignments - Round 2



## **Group 1**

Locksley  
Mike B  
Mary  
David  
Chris  
Jim  
Sophie



## **Group 2**

Mike G  
Scott  
Dermott  
Brian  
Janet  
Sean  
Kim  
Christian

## Synthesis and Review

**The goal of solution design is to establish direction that will address the most critical problems with the system**

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

Current Canadian tissue supply practices do not ensure security of supply.

The Canadian tissue system of independent and uncoordinated tissue banks results in inefficient tissue collection, processing and distribution.

## A Synthesis of Today's Discussions

<b>Safety and Quality</b>	<b>Traceability</b>
<b>Security of Supply</b>	<b>Supply-Demand Alignment</b>

## How do we bring closure to these solution design questions?

- Some areas needing further analysis and/or consultation remain
- There is an opportunity to use the time before the January meeting to resolve some of the areas where a recommendation has not yet been determined
- What is the best method for solidifying complete recommendations for the solution design questions?

## Wrap-Up and Next Steps



## Upcoming Activities and Next Steps

- Upcoming Activities
  - International Conference Call series
  - Public Dialogues
  - End-Users Dialogues
- Next Steps for TEC
  - Minutes from this meeting will be distributed no later than November 19<sup>th</sup>
  - The next in-person Tissue Expert Committee meeting is scheduled for January 13<sup>th</sup>
  - Future conference call(s) will be scheduled