

Tissue Expert Committee Meeting

June 30th, 2009

Sheraton Gateway Hotel, Toronto



The Tissue Expert Committee

Members:

- ❖ Dr. Locksley McGann (Chair)
- ❖ Mr. Mike Bentley
- ❖ Dr. Brian Berry
- ❖ Mr. Scott Brubaker
- ❖ Ms. Mary Gatien
- ❖ Dr. Michael Gross
- ❖ Dr. Frank Hohn
- ❖ Dr. David Howarth
- ❖ Mr. Dermot Kelly
- ❖ Dr. Sarvesh Logsetty
- ❖ Mr. Sean Margueratt
- ❖ Dr. Hassan Moghadam
- ❖ Dr. Jutta Preiksaitis
- ❖ Mr. Christopher Snow

CBS Observers:

- ❖ Dr. Graham Sher (SC Chair)
- ❖ Ms. Sophie de Villers
- ❖ Ms. Kimberly Young
- ❖ Ms. Sylvia Torrance
- ❖ Ms. Lorna Tessier
- ❖ Mr. Jim Mohr

Meeting Objectives

- Understand the process and decide how we will accomplish our goals
- Develop a compelling case demonstrating the priority of OTDT system change
- Identify the key topics for which the committee must advance recommendations and/or consensus
- The OTDT overview documents will **not** be reviewed; however, we welcome any feedback or corrections to make the description of the current state as accurate as possible

Tissue Expert Committee Agenda

Agenda Item	Time
Welcome and Administrative Items	9:30 – 10:00
Current State Briefing	10:00 – 10:45
----- <i>Break</i> -----	
Introduction to Canadian Blood Services	11:00 – 11:15
Review of Methodology to Design National System	11:15 – 11:30
Review of 2008 National Consultation Results	11:30 – 11:45
----- <i>Lunch</i> -----	
Introduction to the Draft Case for Change	12:15 – 12:30
Discuss the Draft Case for Change	12:30 – 2:45
----- <i>Break</i> -----	
Discuss the Solution Design Topics	3:00 – 4:00
Wrap Up and Next Steps	4:00 – 4:30

Administrative Items

- Approve the minutes from the Committee's last meeting on May 21st
- Develop ground rules for working as a committee
- Approve the Terms of Reference



CBS Commitment to Committee Support

CBS will support the committees through the process in part by making the following commitments to the Tissue Expert Committee:

- Schedule key milestone meetings at least three months in advance
- Schedule additional meetings a minimum of one month in advance
- Distribute meeting material two weeks prior to the meeting date
- Distribute meeting minutes no longer than three weeks after the meeting
- Maintain an open channel of communication to receive feedback from any member of the committee

Tissue Expert Committee Principles and Ground Rules

In order to enable the Committee to work as effectively together as possible, principles and ground rules will be established to guide our interactions.

Topics to consider in developing ground rules include:

- Attendance
- Communication
- Confidentiality
- Meeting Conclusion



Administrative Items

- ✓ Approve the minutes from the Committee's last meeting on May 21st
- ✓ Develop ground rules for working as a committee
- Approve the Terms of Reference



Current State Briefing

The Need for Organ and Tissue Donation and Transplantation

- For patients suffering from various ailments including limb-threatening bone tumors, severe burns, periodontal disease and others, tissue transplantation offers hope for sustaining and improving quality of life
- For patients suffering from end-stage organ failure, organ transplantation is generally the best long-term treatment option
- Thousands of Canadians benefitted from transplanted tissue every year
- Approximately 2,000 organ transplants were performed in Canada in 2008¹
- Each year thousands of Canadians choose to give the gift of life to others in need

¹ CORR Year End Tables, 2008

The Tissue Donation and Transplantation community is comprised of a broad variety of stakeholders

- Coroners
- Dental Offices
- Donors
 - Donors
 - Donor's Families
- Hospitals
 - Intensive Care Units
 - Operating Rooms
 - Transplant Surgeons
- Organ Procurement Organizations
 - Coordinators
- Patients
- Tissue Banks
 - Labs
 - Purchasing Functions
- Tissue Processing Facilities
- ...and more

Provincial, Federal and Non-government organizations all play a role in OTDT in Canada

Provincial / Territorial Government - Ministries of Health

Tissue Banks

Transplant Programs

Organ Procurement
Organizations (OPOs)

Federal or Inter-Provincial Government

Health Products and Food
Branch

Public Health Agency of
Canada (PHAC)

Canadian Institute for Health
Information (CIHI) –
Canadian Organ Replacement
Register (CORR)

Canadian
Blood
Services

Non-government

Canadian
Standards
Association

Accreditation
Canada

OTDT is funded and operated within the provincial healthcare context

Provincial / Territorial Government - Ministries of Health

Tissue Banks

Transplant Programs

Organ Procurement
Organizations (OPOs)

- Approximately 32 tissue banks operating in Canada; 90% are part of a hospital
 - Four comprehensive tissue banks
 - Thirteen surgical bone banks
 - Six ocular tissue banks
 - One cardiac tissue bank
 - Eight banks supporting other combinations of tissues
 - Two islet programs
- Transplant programs are typically tissue- or organ-specific; capabilities vary by province and region
- Most provinces have one OPO; some have two OPOs; some are regionally-based

Federal agencies play primarily regulatory and data management roles

- The Canadian federal government plays several regulatory roles in Canada
- The Health Products and Food Branch of Health Canada is responsible for safety regulations focused on transmissible disease
 - Cells, Tissues and Organs regulations were issued in 2007
 - More-than-minimally-processed tissues regulated as medical devices
- PHAC is piloting Cells, Tissues and Organs Surveillance System for identification and assessment of CTO-related issues
- CIHI / CORR perform collection and reporting of organ donation and transplantation data but no data on tissue donation and transplantation

Federal or Inter-Provincial Government

Health Products and Food Branch

Public Health Agency of Canada (PHAC)

Canadian Institute for Health Information (CIHI) –
Canadian Organ Replacement Register (CORR)

Non-government

Canadian Standards Association

Accreditation Canada

Non-governmental organizations also

- The Canadian Standards Association develops Cell, Tissue and Organs regulations for Health Canada
- Accreditation Canada - independent, not-for-profit
 - Responsible for accrediting hospitals
 - Currently expanding scope to include donation and transplantation services

Federal or Inter-Provincial
Government

Health Products and Food
Branch

Public Health Agency of
Canada (PHAC)

Canadian Institute for Health
Information (CIHI) –
Canadian Organ Replacement
Register (CORR)

Canadian
Blood
Services

Non-government

Canadian
Standards
Association

Accreditation
Canada

OTDT Organizations in Canada

- CBS assumed mandate of Canadian Council for Donation and Transplantation in 2008
- Continuing advisory and collaborative work begun by CCDT on organ- and tissue-related topics
- Funding is both provincial and federal
- Conducts many blood operation functions similar to those conducted by tissue banks (e.g. testing, traceability)

Canadian
Blood
Services

Federal or Inter-Provincial Government

Health Products and Food
Branch

Public Health Agency of
Canada (PHAC)

Canadian Institute for Health
Information (CIHI) –
Canadian Organ Replacement
Register (CORR)

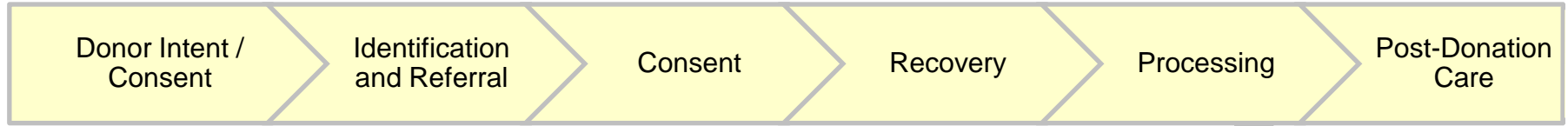
Non-government

Canadian
Standards
Association

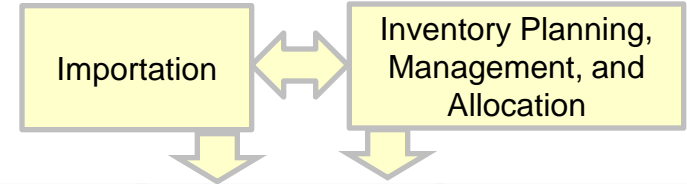
Accreditation
Canada

The Tissue Donation and Transplantation Process

Donation Process



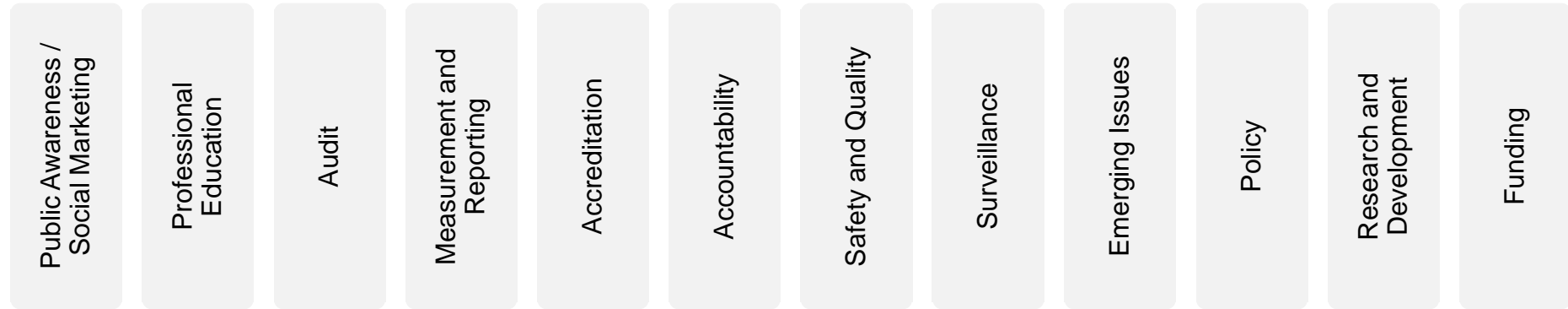
Supply Planning



Transplant Process

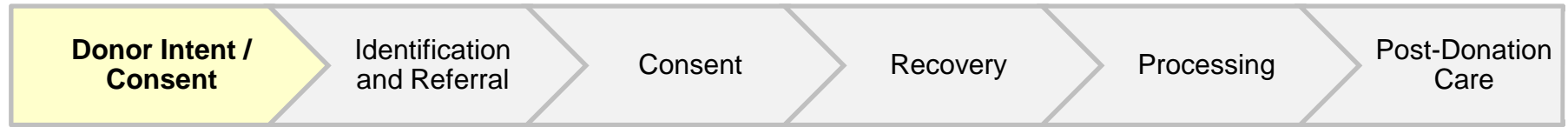


Governance



The Tissue Donation and Transplantation Process

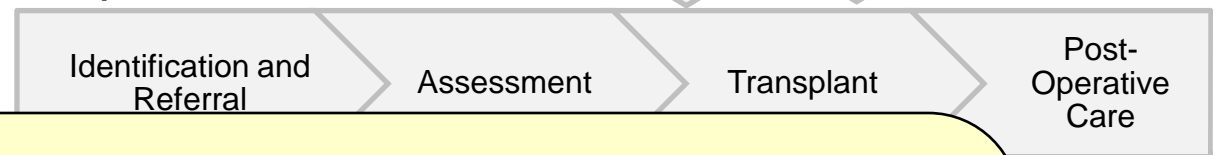
Donation Process



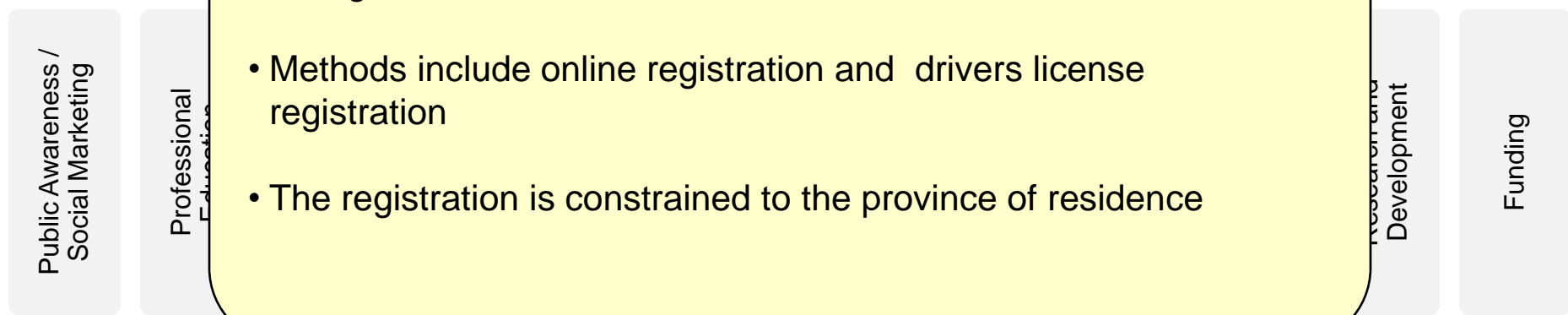
Supply Planning



Transplant Process



Governance



- There are multiple provincial approaches to registration of willingness to donate
- Methods include online registration and drivers license registration
- The registration is constrained to the province of residence

The Tissue Donation and Transplantation Process

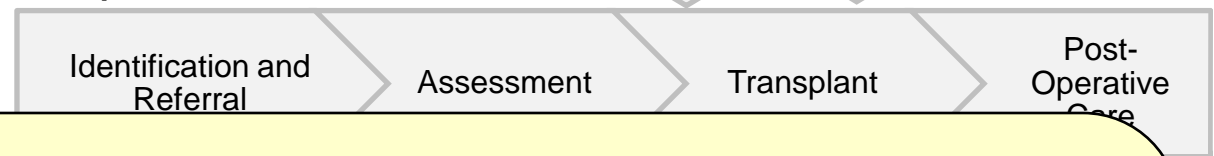
Donation Process



Supply Planning



Transplant Process



- Tissue donors may come from critical care context; however most potential donors are outside the critical care context (e.g., coroner and wards)
- The criteria for donation is much broader than it is for organs; tissue donation potential is thus significantly higher
- Referral is made to tissue bank(s) or OPOs
- Though registered willingness to donate is legally binding, all jurisdictions seek family consent before proceeding with tissue donation

Public Awareness /

Funding

The Tissue Donation and Transplantation Process

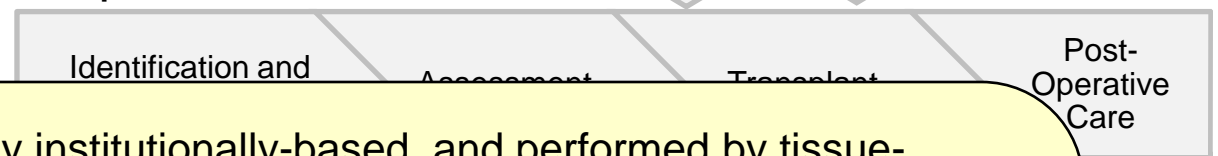
Donation Process



Supply Planning



Transplant Process



- Recovery is typically institutionally-based, and performed by tissue-specific specialists affiliated with tissue banks
- Tissues undergo transmissible disease testing and processes to minimize contamination
- Tissues may be processed by the recovering tissue bank or sent to a domestic or foreign processing facility
- Recovered tissue is subject to mechanical and/or biological processing; all demineralized bone is processed outside of Canada

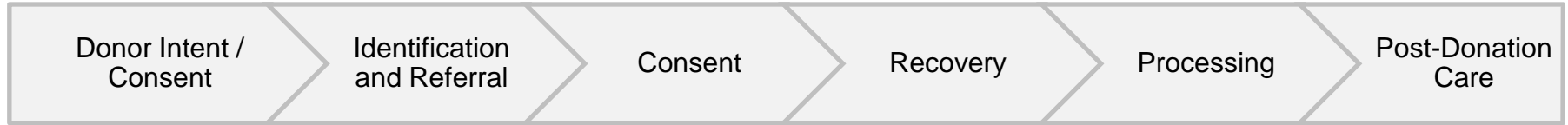
Governance

Public Awareness / Social Marketing

Funding

The Tissue Donation and Transplantation Process

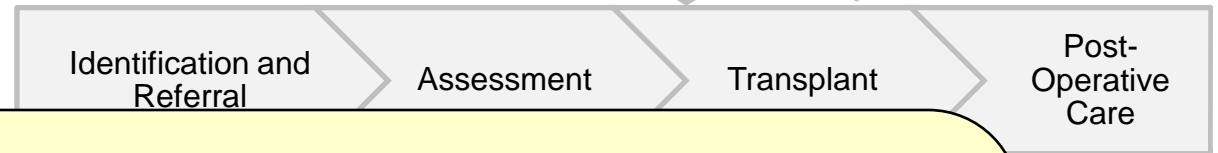
Donation Process



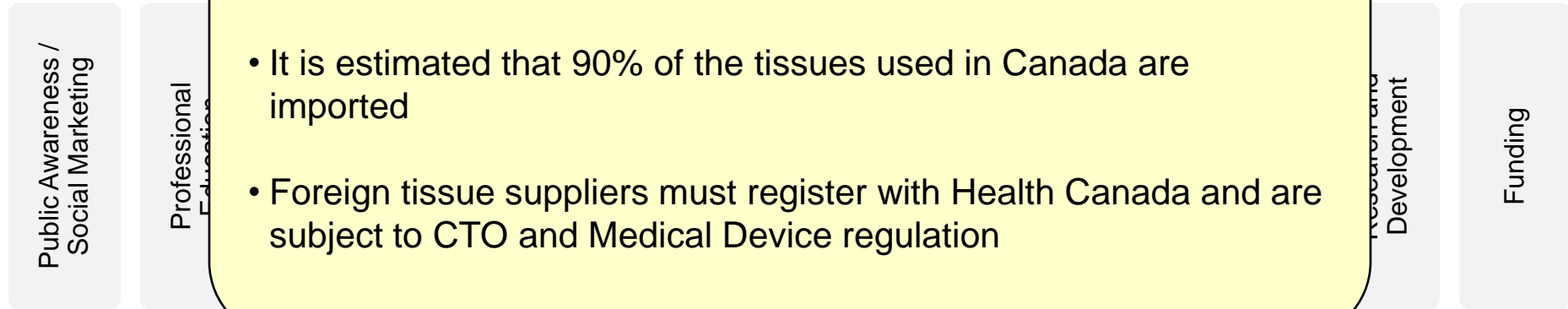
Supply Planning



Transplant Process



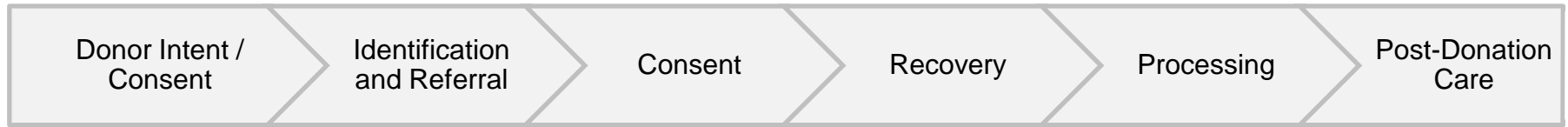
Governance



- Tissues can be purchased directly by end-user (doctor, dentist or hospital) from tissue processors
- It is estimated that 90% of the tissues used in Canada are imported
- Foreign tissue suppliers must register with Health Canada and are subject to CTO and Medical Device regulation

The Tissue Donation and Transplantation Process

Donation Process



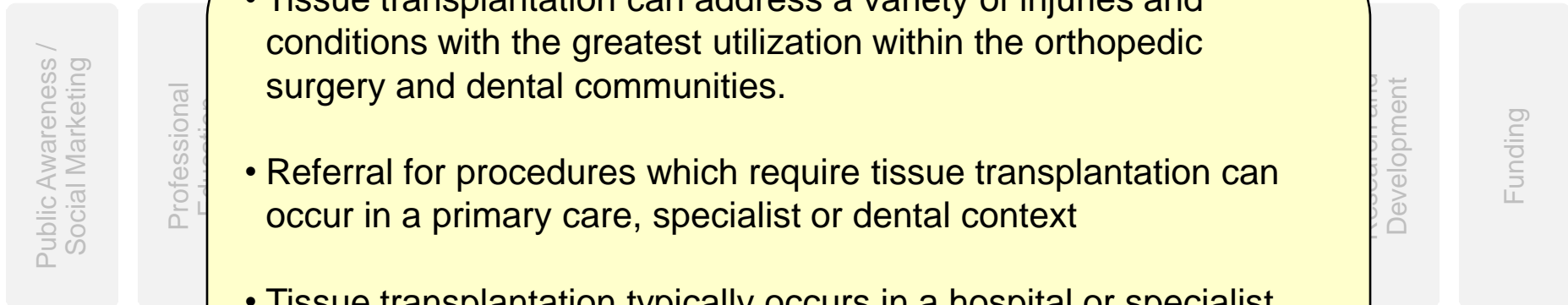
Supply Planning



Transplant Process



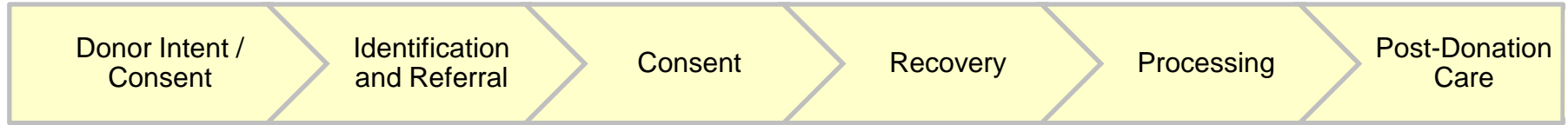
Governance



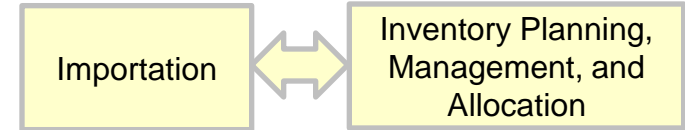
- Tissue transplantation can address a variety of injuries and conditions with the greatest utilization within the orthopedic surgery and dental communities.
- Referral for procedures which require tissue transplantation can occur in a primary care, specialist or dental context
- Tissue transplantation typically occurs in a hospital or specialist office (~50%) or a dental office (~50%)

Current State Briefing – Q&A

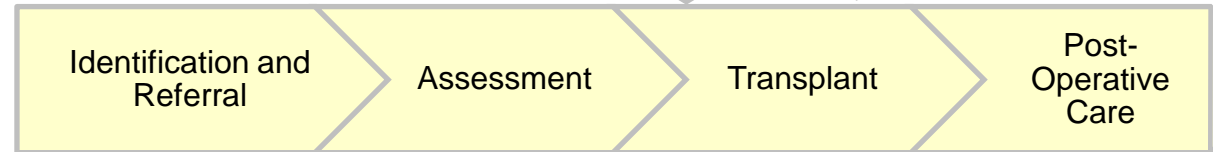
Donation Process



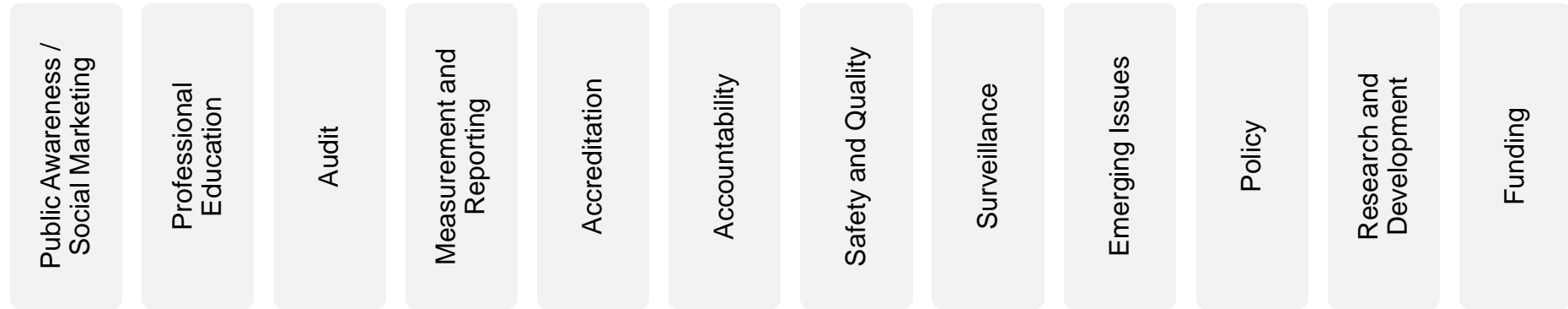
Supply Planning



Transplant Process



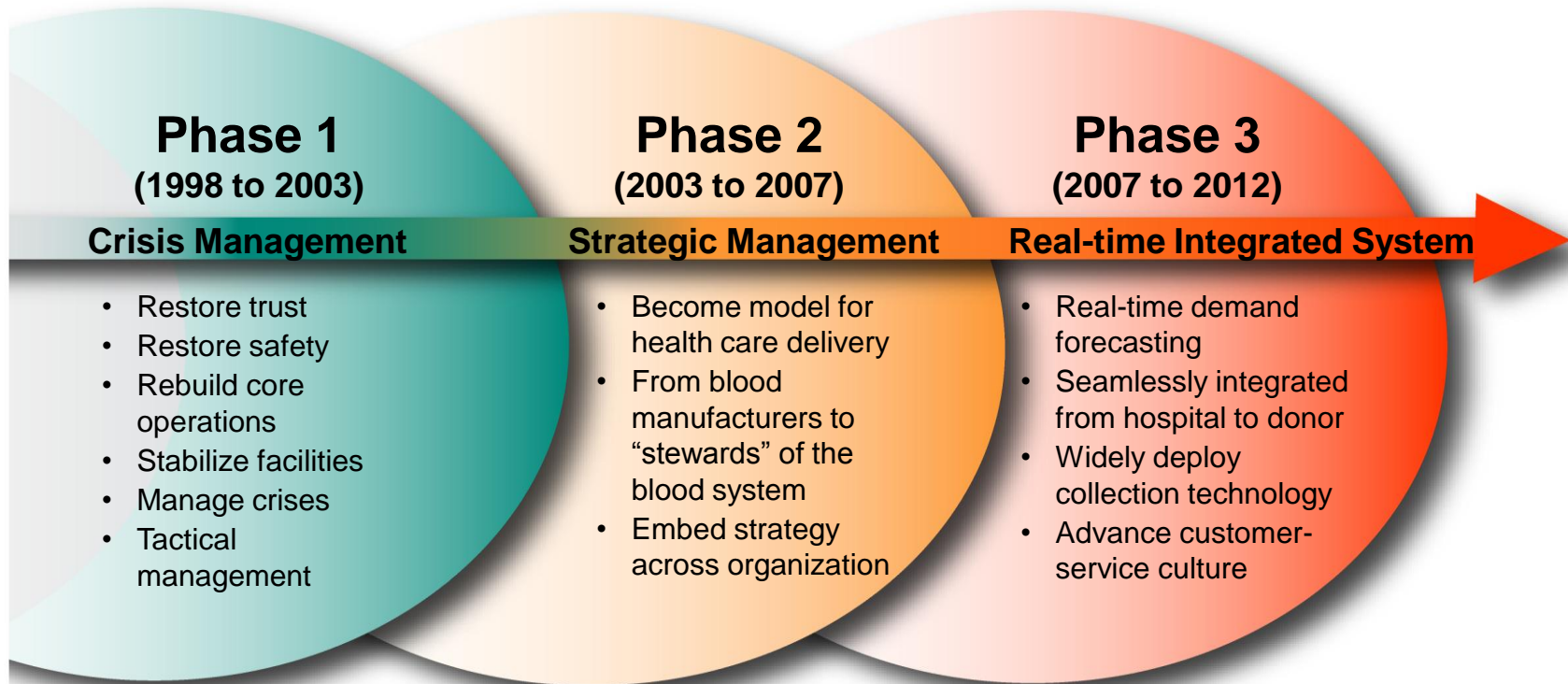
Governance



Introduction to Canadian Blood Services

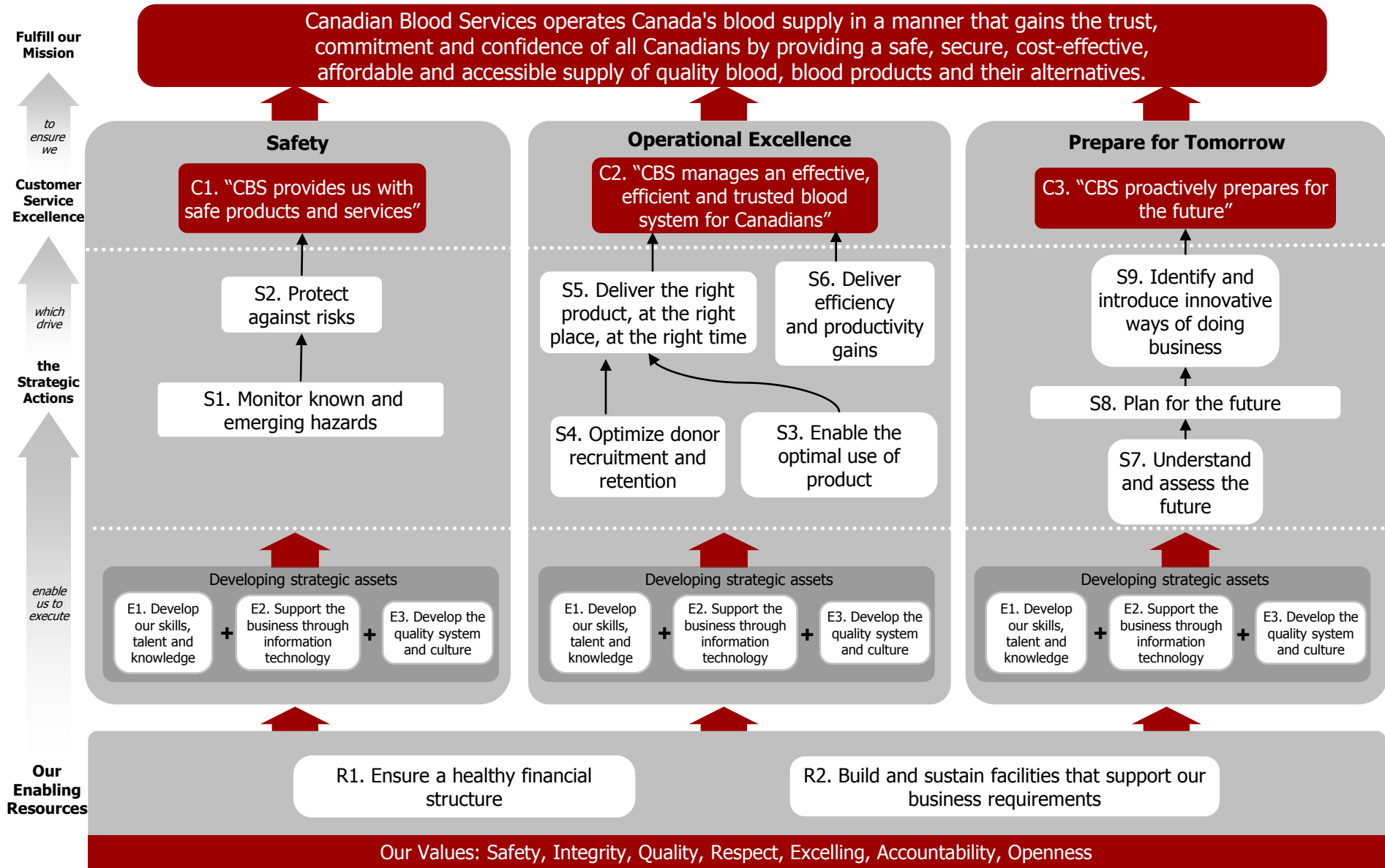


History of Canadian Blood Services



- Canadian Blood Services founded in 1998 as the successor organization to the Canadian Red Cross, as a result of the tainted blood scandal
- Canadian Blood Services has transformed the legacy operations of the Canadian Red Cross into a national integrated service-delivery organization focused on quality and service excellence

The First CBS Corporate Strategy Map



Restoring Public Trust



“I trust Canadian Blood Services to act in the best interests of the public.”

Stakeholders: 97%

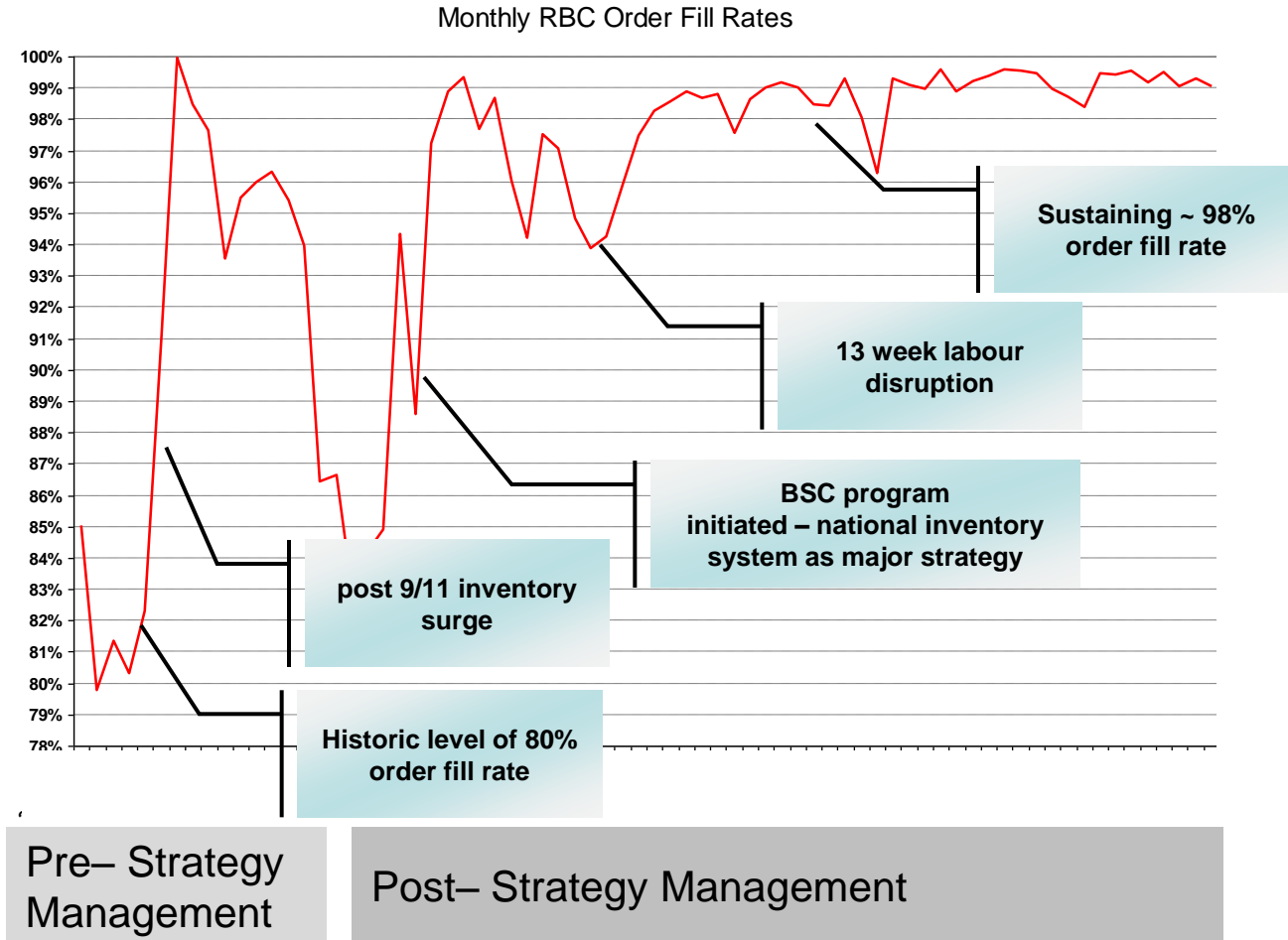
Donors: 92%

Public: 75%

IPSOS-Reid public opinion survey, Winter 2008

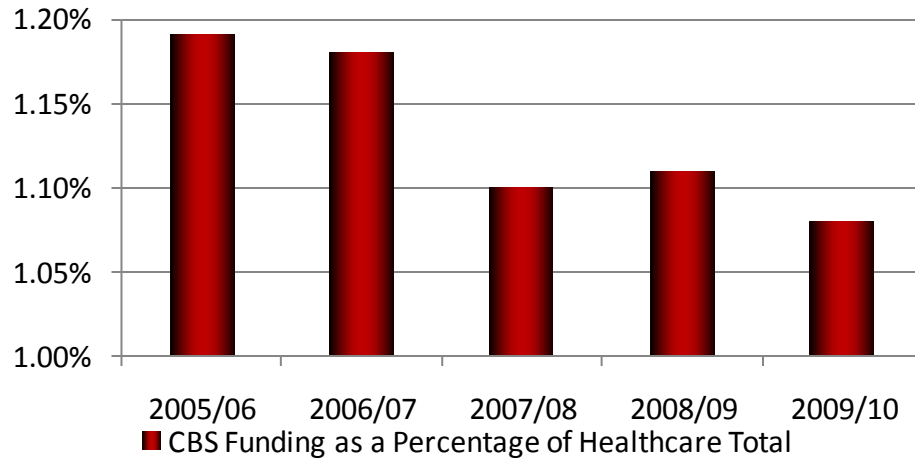
Public trust in the scandal ridden blood system measured < 50%

Monthly hospital order fill rates



Results Amid Change: The New Model in Action

CBS Funding as a Percent of Provincial Healthcare (excl PQ) Total Spending



- Year-over-year increases in core funding have declined for CBS below the general Health Care rate yet CBS has delivered increased value to Canadians
- CBS has increased operational effectiveness. Collections have grown more than 30% since 1998
 - Whole Blood (27%)
 - Plasmapheresis (40%)
 - Plateletpheresis (180%)

Today, More Than Blood Collection ...

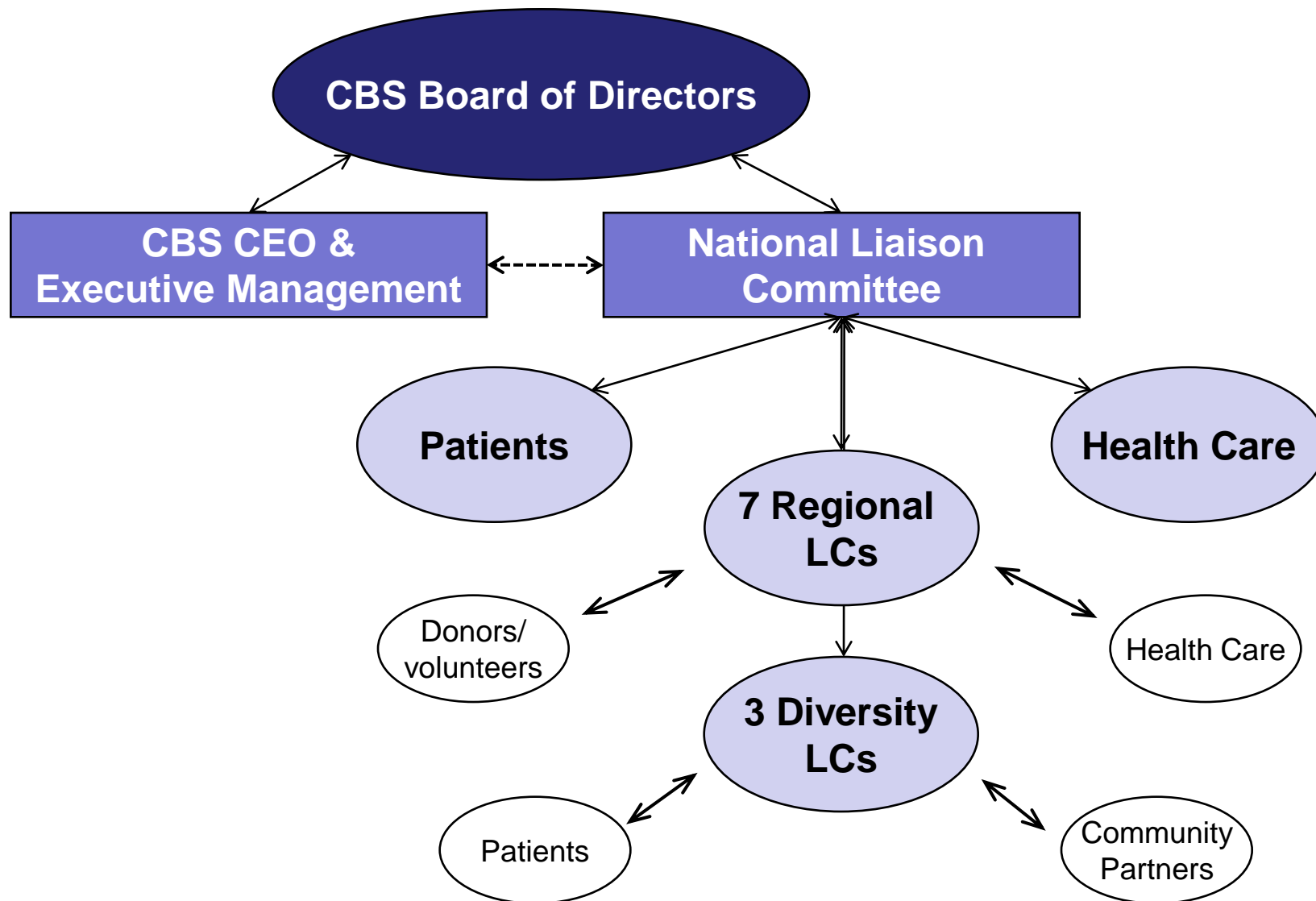
WHAT WE DO:

- **Blood Operations:** Recruit donors, collect, process, test, distribute blood components
- **Plasma Program:** Collect plasma, custom fractionation, purchase and distribute plasma protein products
- **Related Programs:** Education, R&D, clinical consultation
- **OneMatch Marrow and Stem Cell Network:** Linked to 51 other registries worldwide, emerging umbilical cord blood bank
- **Diagnostic Laboratories**
- **Insurance Captive:** Wholly owned subsidiary
- **CBS Fundraising:** To support and extend the mission of CBS

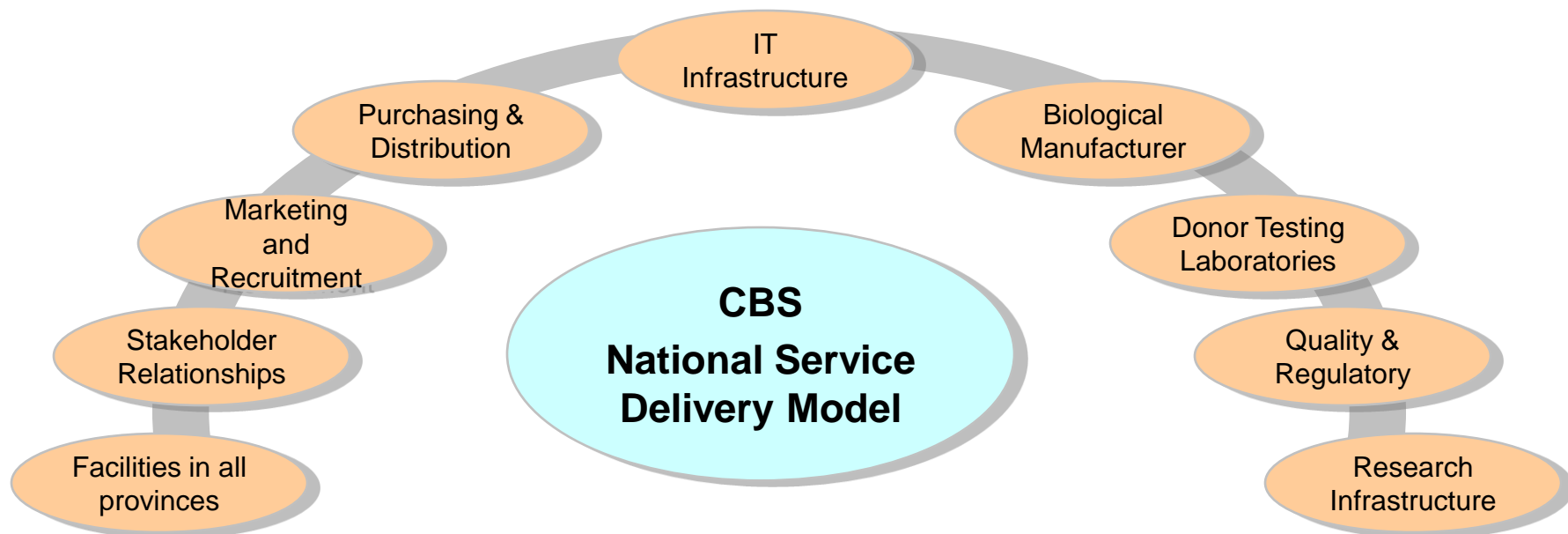
HOW WE DO IT:

- **915,858 Whole Blood Units**
- **52,244 Apheresis Plasma Units**
- **40,847 Apheresis Platelet Units**
- **481,993 Active Donors**
- **220,500 OneMatch Registrants**
- **732 Health Care Facilities Served**
- **4,500 Employees**
- **19,600 Volunteers**
- **\$890 Million Annual Budget**

Liaison Committee Structure



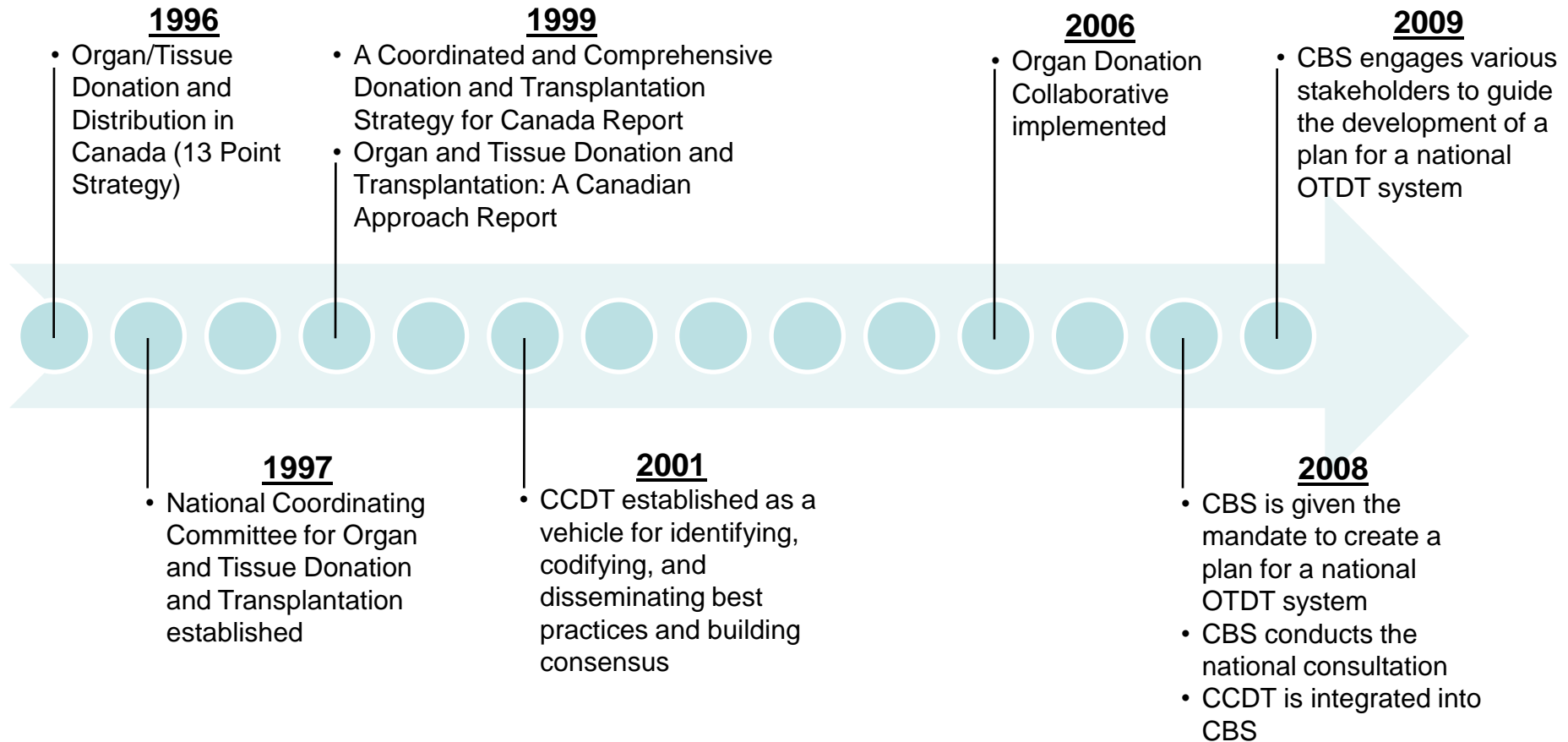
CBS has a unique and distinctive national operating model.



- national, not-for-profit corporation with independent Board of Directors
 - accountable, transparent, with public participation
 - subject to Federal regulations (under Food and Drugs Act)
- P/T Ministers of Health are Members (shareholders) of the corporation
- two wholly owned insurance subsidiaries provide \$1 billion coverage
 - extensive risk management programs embedded

Review of Methodology to Design National System

How did we get here?



The CBS Mandate

Aug 2008 – Canadian Blood Services given a mandate by FPT Deputy Ministers of Health (except Québec) for organ and tissue donation and transplantation:

- Continue work developing policies and knowledge translation for: leading practices, guideline developments, performance measurement, accreditation, public engagement and awareness
- Develop national registries for living donor paired exchanges, urgent status patients and highly sensitized patients
- Design a system for OTDT in Canada in collaboration with the OTDT community

What has CBS done in regards to the mandate to develop an OTDT plan?

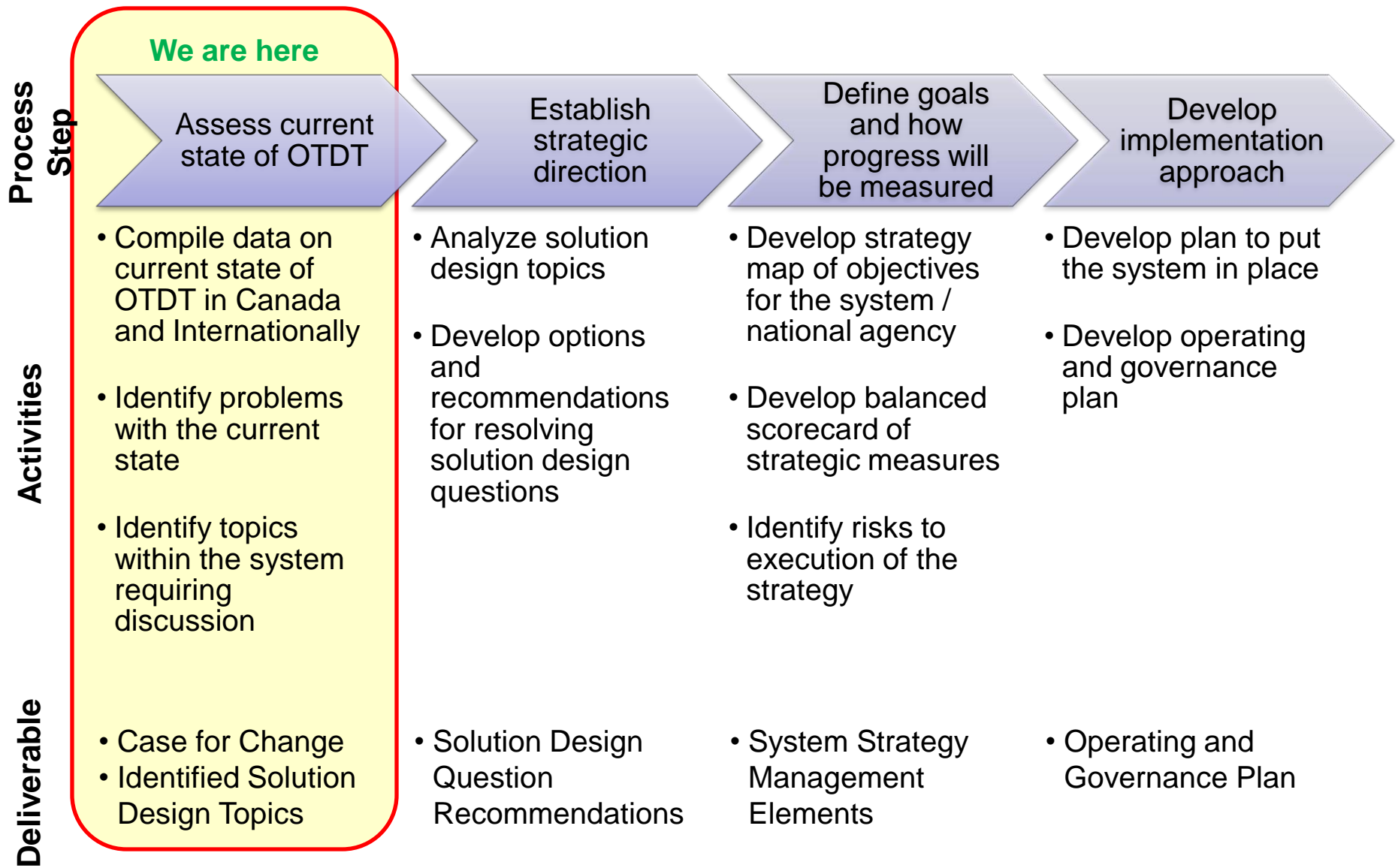
- The National Consultation
- Detailed international consultation with:
 - UK Blood and Transplant
 - Australian experts (ARCBS, Jeremy Chapman)
 - United Network for Organ Sharing (UNOS)
- Discussions with the Health Resources and Services Administration (United States)
- Review of documents and research on the current state of the Canadian system
- Meetings with the Assistant Deputy Ministers Transition Team

The process should be designed to...

- Be consultative, engaging as many stakeholders as possible to generate buy-in
- Be transparent, all activities and outputs demonstrable
- Acknowledge successful elements of the current system, and previous work done
- Be deliberate, logical and drive towards evidence-based conclusions
- Be respectful of the time we request from contributors
- Be completed within a reasonable time



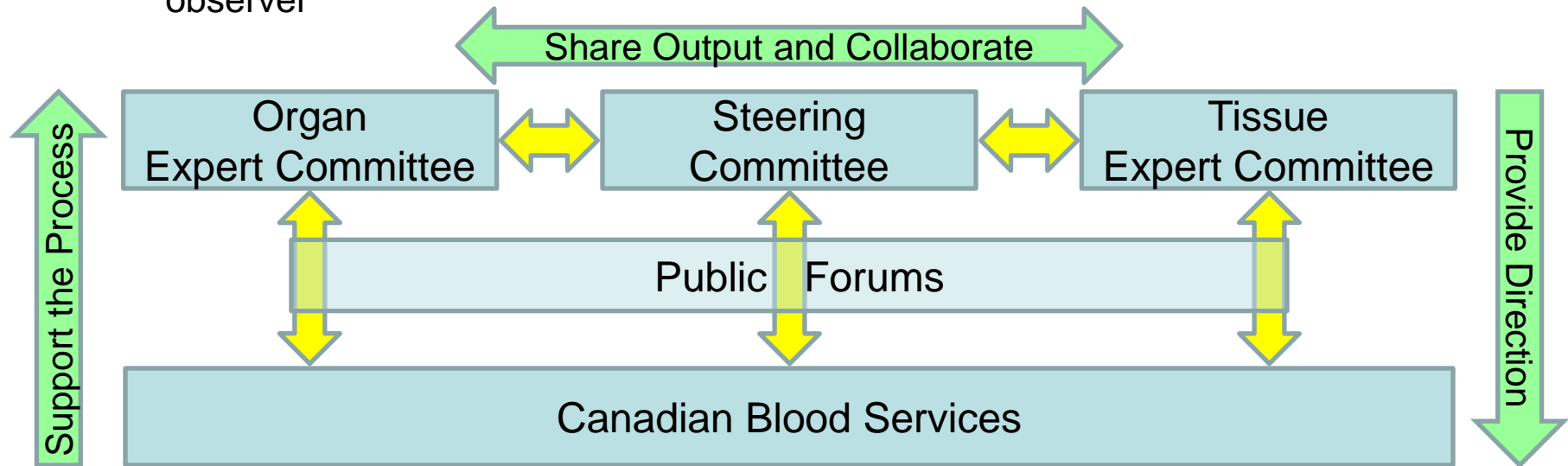
Process Overview



Roles and Responsibilities

The Committees:

- The primary role is providing expert guidance on the content of the plan
- Each committee has a focus that is different from the others
- Committees have equal standing and share output openly
 - The Expert Committee Chairs will attend the Steering Committee meetings as observers
 - The Steering Committee Chair will attend the Expert Committee meetings as an observer



Canadian Blood Services:

- The primary roles are to guide the plan development process and draft related and supporting content

The Public Forums

What:

- 4 – 6 geographically-distributed sessions open to the public to provide thoughts and opinions on OTDT topics
- An electronic forum to make a communication channel available for engaged Canadians who cannot attend a forum in person

Why:

- The public represents a key process stakeholder
- The public has interacted with the system and has opinions to share that are relevant input to the solution design process
- Gaining the support of the ministers is more likely if the public is insistent on OTDT being a priority

When:

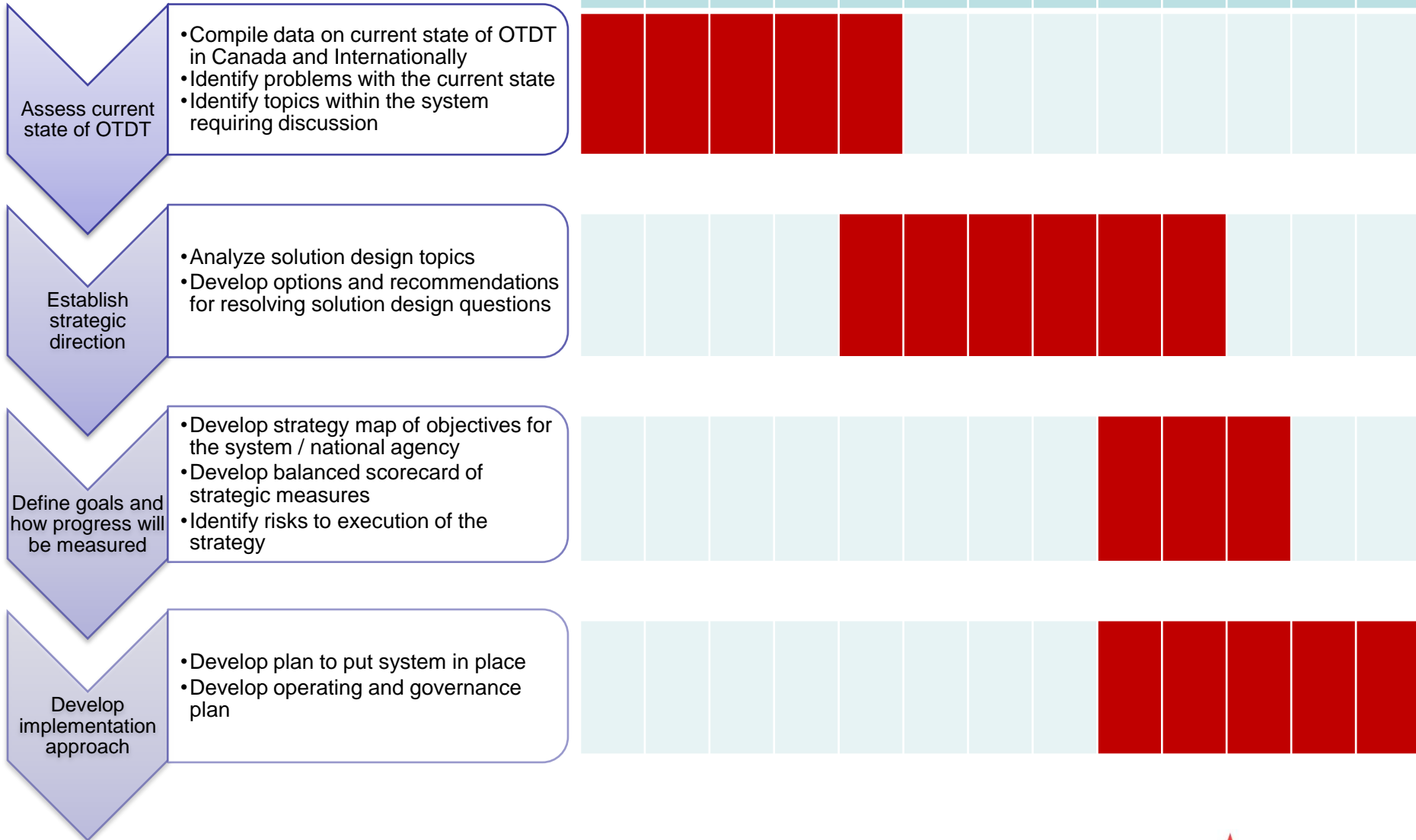
- The public will be engaged during the “Establish Strategic Direction” phase

Process Timeline

Step

Activities

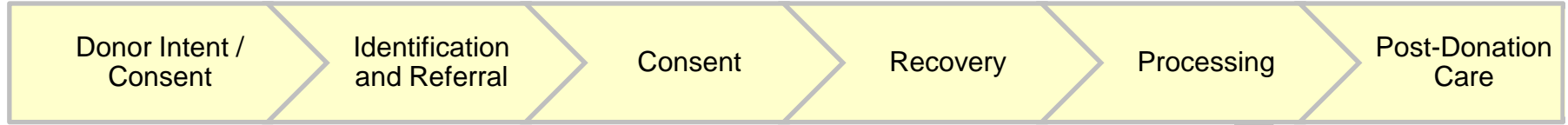
Timeframe



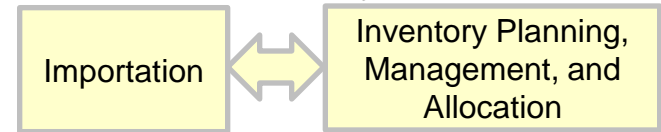
Review of 2008 National Consultation Results

The Tissues Donation and Transplantation Process

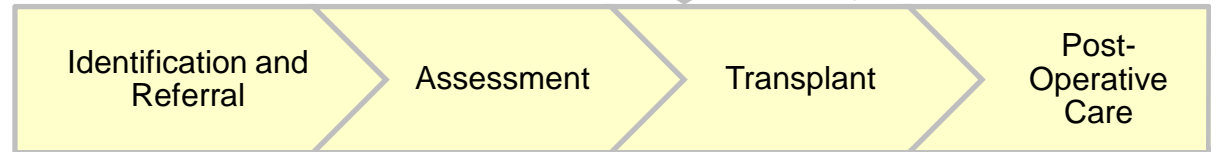
Donation Process



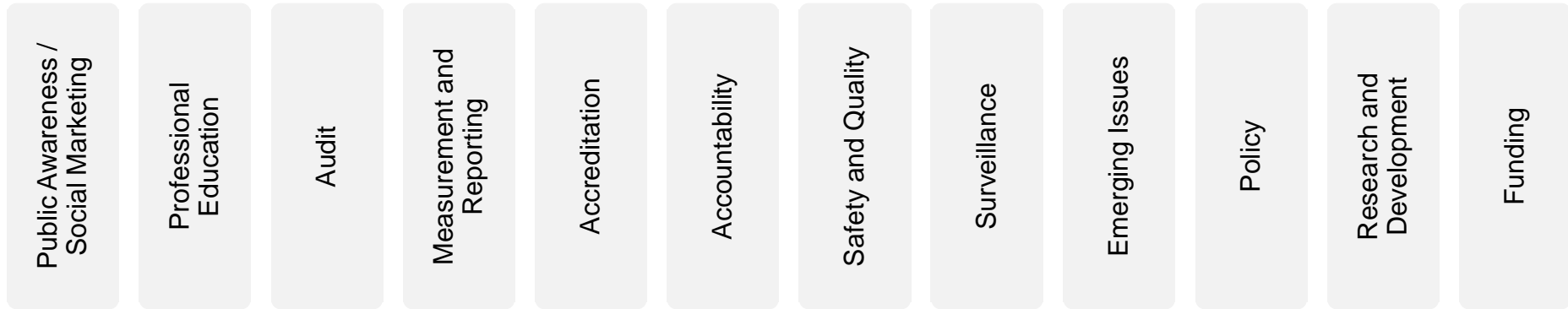
Supply Planning



Transplant Process



Governance



Why a National Consultation was Convened

After receiving a mandate in August of 2008 from FPT Deputy Ministers of Health, CBS organized a national consultation to be convened in September that would engage and solicit the expertise of OTDT stakeholders for several reasons:

- To **listen** to expert opinions, ideas, aspirations, and frustrations regarding the system
- To explore and start to **define** problems, challenges, and risks regarding organ and tissue donation and transplantation in Canada
- To find areas of common understanding and **shared perspective** among participants of a **national vision** and system model
- To identify areas of **informed disagreement** among participants
- To inform the **development of the process** used to create a plan for a national OTDT system

How the National Consultation Worked

“Given the need for national, integrated services in organ and tissue donation and transplantation, how do we establish the system that best meets the needs of Canadian patients?”

Define Opening Question

Select Participants

125 participants across the OTDT community

Synte-gration Event

Participants Agree on Topics

12 topics specific to TDT

Participants Assigned to Topic Teams

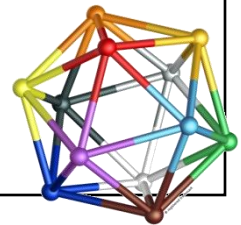
10 or more participants per topic

Topic Teams Meet

Teams discussed each topic

Notes, Recommendations, Action Lists

Recommendations and supporting conversation were documented



Topics Determined and Addressed by Participants

Topics

Tissue Recovery

Tissue Supply

Distribution & End User Integration

Governance

Infrastructure

Funding

Quality

Safety

Research & Development

IT

Public Engagement

Human Resource Strategy

Topics Determined and Addressed by Participants

Tissue Topics

Tissue Recovery

Tissue Supply

Distribution & End User Integration

Governance

Infrastructure

Funding

Quality

Safety

Research & Development

IT

Public Engagement

Human Resource Strategy

Scope

- Donor family support
- Recovery model
- Referral practices

- Current state supply gaps
- Information sharing
- Inventory integration
- Supply targets
- Traceability

- Accountability and audit
- Allocation
- Importation
- Informed consent
- Inventory management
- Traceability

Topics Determined and Addressed by Participants

Tissue Topics

Tissue Recovery

Tissue Supply

Distribution & End User Integration

Governance

Infrastructure

Funding

Quality

Safety

Research & Development

IT

Public Engagement

Human Resource Strategy

Scope

- Current state gaps
- Funding allocation
- Governance by system function
- System implementation oversight

- Current state inventory gaps
- Efficiency and integration
- Infrastructure model
- Measurement

- Accountability
- Current state funding gaps
- FPT variation
- Funding principles
- Governance
- Outcome determined funding

Topics Determined and Addressed by Participants

Tissue Topics

Tissue Recovery

Tissue Supply

Distribution & End User Integration

Governance

Infrastructure

Funding

Quality

Safety

Research & Development

IT

Public Engagement

Human Resource Strategy

Scope

- FPT variation
- Governance
- Measurement
- National goals
- Quality programs and framework
- Roles and responsibilities

- Principles
- Regulation implementation
- Risk management
- Surveillance

- Coordination
- Current state R&D gaps
- Funding
- R&D models

Topics Determined and Addressed by Participants

Tissue Topics

Tissue Recovery

Tissue Supply

Distribution & End User Integration

Governance

Infrastructure

Funding

Quality

Safety

Research & Development

IT

Public Engagement

Human Resource Strategy

Scope

- Current state IT gaps/business case
- Governance
- Information integration

- Consent / intent registry
- Professional marketing
- Public marketing

- Best practice sharing
- Current state HR gaps
- Personnel accreditation
- Professional development
- Retention strategies

Moving Forward...

What we learned from the National Consultation:

- Proposed directions for some of the most pressing tissue donation and transplantation challenges
- Common ground in the tissue community on a wide variety of topics
- Gaps in the community's knowledge and understanding of the current state
- Divergent perspectives in the community about the best way to design a national system

How the results have and will be used:

- Results were an input to the draft Case for Change
- Recommendations have been used to shape the proposal for Solution Design Topics
- Development of materials for the fall meetings will use overall Consultation results as a starting place for the development of solution options

Discuss the Draft Case for Change

What is the purpose of a “Case for Change”

- To achieve a shared understanding of the elements of TDT most in need of improvement
- To identify the elements of TDT that must be emphasized in the final business plan
- To develop common ground we can turn to when developing recommendations to address system challenges
- To create a basis for measuring the success of the national system

Structure of the Case for Change

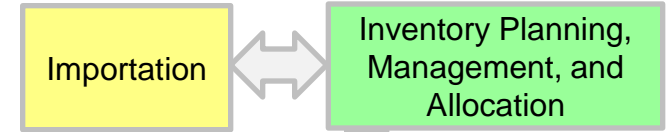
- The Case for Change document has been structured to facilitate a discussion of what most needs to be addressed by the OTDT strategic plan
- Identified weaknesses were grouped into major “problem headlines”; each problem headline is supported by more detailed problem statements, a brief discussion and references to supporting data
- The draft problem statements cover much of the TDT system
 - Safety and Quality
 - Security of Supply
 - Inventory
 - Measurement and Accountability

The Tissue Donation and Transplantation Process

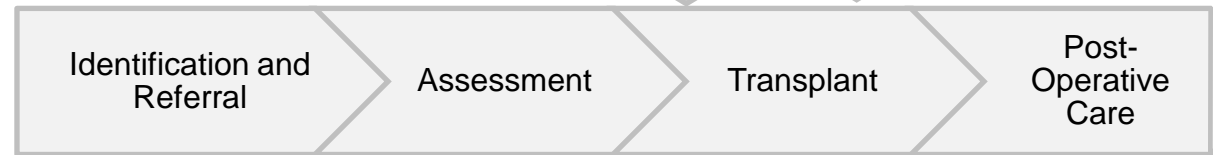
Donation Process



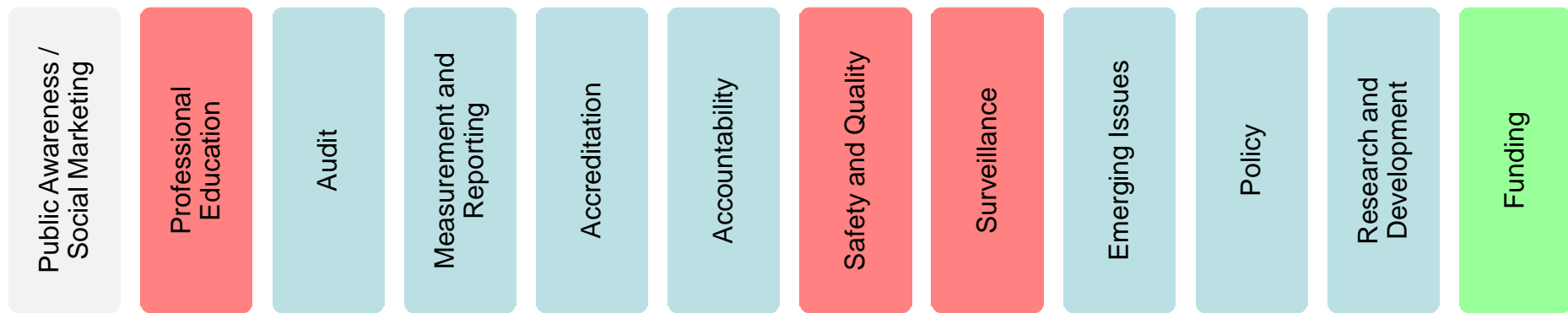
Supply Planning



Transplant Process



Governance



Problem 1:
Safety and Quality

Problem 2:
Security of Supply

Problem 3:
Inventory

Problem 4:
Measurement and Accountability

Problem 1: The current TDT system in Canada lacks a coordinated approach to systematically assessing and ensuring safety and quality

- There is inconsistent application of standards and regulations
- Surveillance for tissue-related adverse events is not yet effective and the traceability of transplanted tissue is incomplete
- There is poor quality and safety control throughout much of the tissue system
- There is little-to-no coordination of risk management activities in the TDT system

Problem 2: Current tissue supply planning practices do not ensure security of supply

- Ninety percent of tissue products transplanted in Canada are imported from foreign sources; advanced tissues are primarily sourced and completely processed outside of Canada
- There exists sufficient donor potential in Canada to ensure security of supply
- Registered intent of potential donors is not regarded as binding despite its binding nature
- Existing donation strategies focus on organ donation and critical care, missing significant tissue donation opportunity outside the critical care context
- There is insufficient capacity to recover and process Canada's tissue donation potential; recovery capability is not geographically aligned to donor potential

Problem 3: The TDT model of independent, uncoordinated tissue banks results in inefficient inventory processing and management

- The independent, fragmented model of tissue banking duplicates government-funded infrastructure and allows for decentralized and uncoordinated inventory
- The lack of standardized supply and demand planning results in misalignment between end user needs and tissue bank inventories
- Uncoordinated interaction with U.S. suppliers and processors results in lower volume agreements at higher cost
- The manufacturing business model of tissue banking is not optimized by its location within the patient service delivery model of hospitals

Problem 4: The current TDT system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvement

- Inconsistent data capture and quality and the lack of centralized reporting and analysis diminishes the system's ability to make evidence-based improvements in practice or policy
- There is no capacity for coordinated, system-wide policy determination in response to both gradual and rapid changes in the operating environment
- Unclear and uncoordinated audit and accountability diminishes both incentives and mechanisms for effecting improvement
- A lack of support for research and development efforts inhibits innovation in process and medical practice

Breakout Sessions

- Over the next hour we will conduct a breakout exercise to discuss the draft case for change in greater detail
- For the first 30 minutes choose a problem to discuss:
 - Problem 1 (Safety and Quality) – main meeting room
 - Problem 2 (Security of Supply) – breakout room
- For the second 30 minutes choose a problem to discuss:
 - Problem 3 (Inventory) – main meeting room
 - Problem 4 (Measurement and Accountability) – breakout room
- Each of the four breakout sections will seek to answer the following questions in regards to the problem statement and description
 - To what extent does the problem statement and supporting bullets capture the nature and scope of the system's short-comings?
 - Among the short-comings identified, which one do you feel is most critical to solve?
 - What data, evidence, or information is required to substantiate or prove the scope or extent of the problem?
- After one hour we will reconvene in the main meeting room

TDT - All Problem Headlines

- Problem 1: The current TDT system in Canada lacks a coordinated approach to systematically assessing and ensuring safety and quality
- Problem 2: Current tissue supply planning practices do not ensure security of supply
- Problem 3: The TDT model of independent, uncoordinated tissue banks results in inefficient inventory processing and management
- Problem 4: The current TDT system lacks the measurement and accountability mechanisms to drive consistent, system-wide performance improvement

Discuss Solution Design Topics

Process Timeline

Step

Activities

Timeframe

Assess current state of OTDT

- Compile data on current state of OTDT in Canada and Internationally
- Identify problems with the current state
- Identify elements of the system requiring new direction

Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Active	Active	Active	Active	Active	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed

Establish strategic direction

- Analyze solution design topics
- Develop options and recommendations for resolving solution design questions

Completed	Completed	Completed	Completed	Completed	Active	Active	Active	Active	Active	Active	Completed	Completed
-----------	-----------	-----------	-----------	-----------	--------	--------	--------	--------	--------	--------	-----------	-----------

Define goals and how progress will be measured

- Develop strategy map of objectives for the system / national agency
- Develop balanced scorecard of strategic measures
- Identify risks to execution of the strategy

Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Active	Active	Active	Completed
-----------	-----------	-----------	-----------	-----------	-----------	-----------	-----------	-----------	--------	--------	--------	-----------

Develop implementation approach

- Develop plan to put system in place
- Develop operating and governance plan

Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Completed	Active	Active	Active	Active
-----------	-----------	-----------	-----------	-----------	-----------	-----------	-----------	-----------	--------	--------	--------	--------

The Committees' Roles During the Next Phase

- Develop solution options and recommendations to be integrated into the OTDT strategic plan, based on inputs such as:
 - Analysis of data, research and other empirical evidence
 - The accumulated experience of provincial efforts
 - The examples of other international TDT systems

The Organ and Tissue Expert Committees:

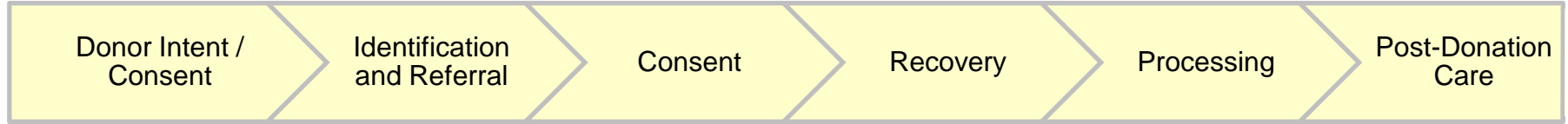
- The Organ and Tissue Expert Committees will provide advice that guides the design of the organs and tissues systems respectively

The Steering Committee:

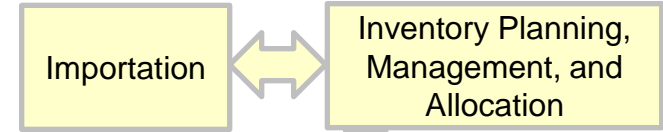
- The Steering Committee will provide guidance on how the OTDT system needs to be structured to function effectively in the context of Canada's overall healthcare system

Recommendations are based on fixing problems and leveraging strengths.

Donation Process



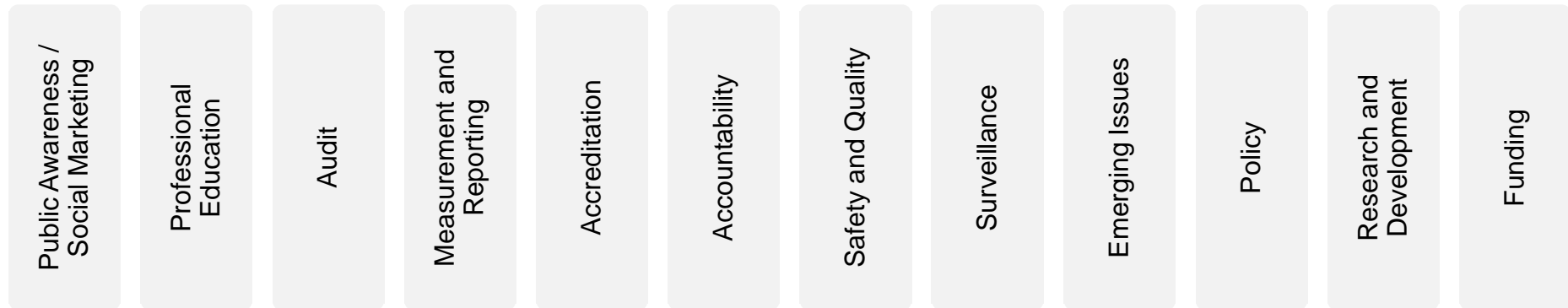
Supply Planning



Transplant Process



Governance



Objective for Today

- In order to properly plan and prepare for the fall meetings and begin work on the right elements of solution design, we must determine
 - Topics for which the committees will provide analysis, options and recommendations
 - An approach to analyzing and providing recommendations for each topic
- The selection of topics should be driven by the need to:
 - Address open questions that are critical to resolve for our OTDT strategy to be clear
 - Advance the consensus of the OTDT community beyond the current level
- The committee may consider several potential approaches for each topic area
 - Approach 1: A **small group** from the committee will discuss the topic and will **present the options and recommendations** to the committee for **review**
 - Approach 2: The **committee** will review information and options as a group and will together **decide on recommendations**
 - Approach 3: The **committee will engage additional experts** from the community to assist in the discussion of the topic and the **determination of recommendations**

Today's Exercise

- Four draft topic areas have been proposed for possible assignment to this committee
- For each topic an approach and example sub-topics have been proposed
- For each topic, the group will answer the following:
 - Does the topic need to be addressed by the committee?
 - Does the proposed resolution approach represent the best way to address each topic?
 - Are the proposed sub-topics “directionally correct?”
- **After today's meeting,**
 - CBS will coordinate and support the analysis and resolution process for each topic regardless of the approach
 - CBS will work with a point person for each topic to clarify the intent of the group and to ensure an effective work process for each topic

Draft Solution Design Topics

Topic	Resolution	Sub-topics
Donation	Tissue Expert Committee	<ul style="list-style-type: none"> • Access to tissue donation outside the critical care context • Translating support for donation into action • Accessibility of donation services
Transplantation	Tissue Expert Committee	<ul style="list-style-type: none"> • Informed consent of patients receiving tissue • Traceability and surveillance • Verifying the long-term efficacy of tissue transplantation
Processing and Supply Planning	Engage additional experts	<ul style="list-style-type: none"> • Ensuring effective and efficient inventory planning and management • Effective and efficient structuring and funding of tissue banking and distribution • Security of supply • Safety and quality assurance
Governance	Tissue Expert Committee	<ul style="list-style-type: none"> • Overall system risk management • Overall measurement and reporting framework for TDT • Overall audit framework for TDT • Scope, level, and structure of policy development • Accountability principles necessary to determine roles and responsibilities

Wrap Up and Next Steps



Next Steps

- Minutes from this meeting will be distributed no later than July 21st
- CBS will be reaching out to relevant committee members for further solution design topic clarification
- The next Tissue Expert Committee meeting is scheduled for October 29th
- Future committee dates are being scheduled

