

Organ and Tissue Donation and Transplantation Steering Committee

April 29, 2010



Purpose of this Meeting

- To update the committee on the strategic planning process, including both expert committees and the public engagement plans
- To review and discuss the system strategies and emerging system designs for organs and tissues



Agenda

Welcome and Follow-up on Action Items	8:30 - 8:45
Activities to Date and Next Steps	8:45 - 9:15
Organ System Strategy	9:15 - 10:00
Break	10:00 - 10:15
Organ System Design	10:15 - 11:45
Dr. Gary Levy / Lunch	11:45 - 1:15
Organ System Design (cont'd)	1:15 – 1:45
Tissue System Strategy	1:45 – 2:30
Break	2:30 – 2:45
Tissue System Design	2:45 – 4:15
Next Steps and Wrap-up	4:15 - 4:30

Follow-up on Action Items

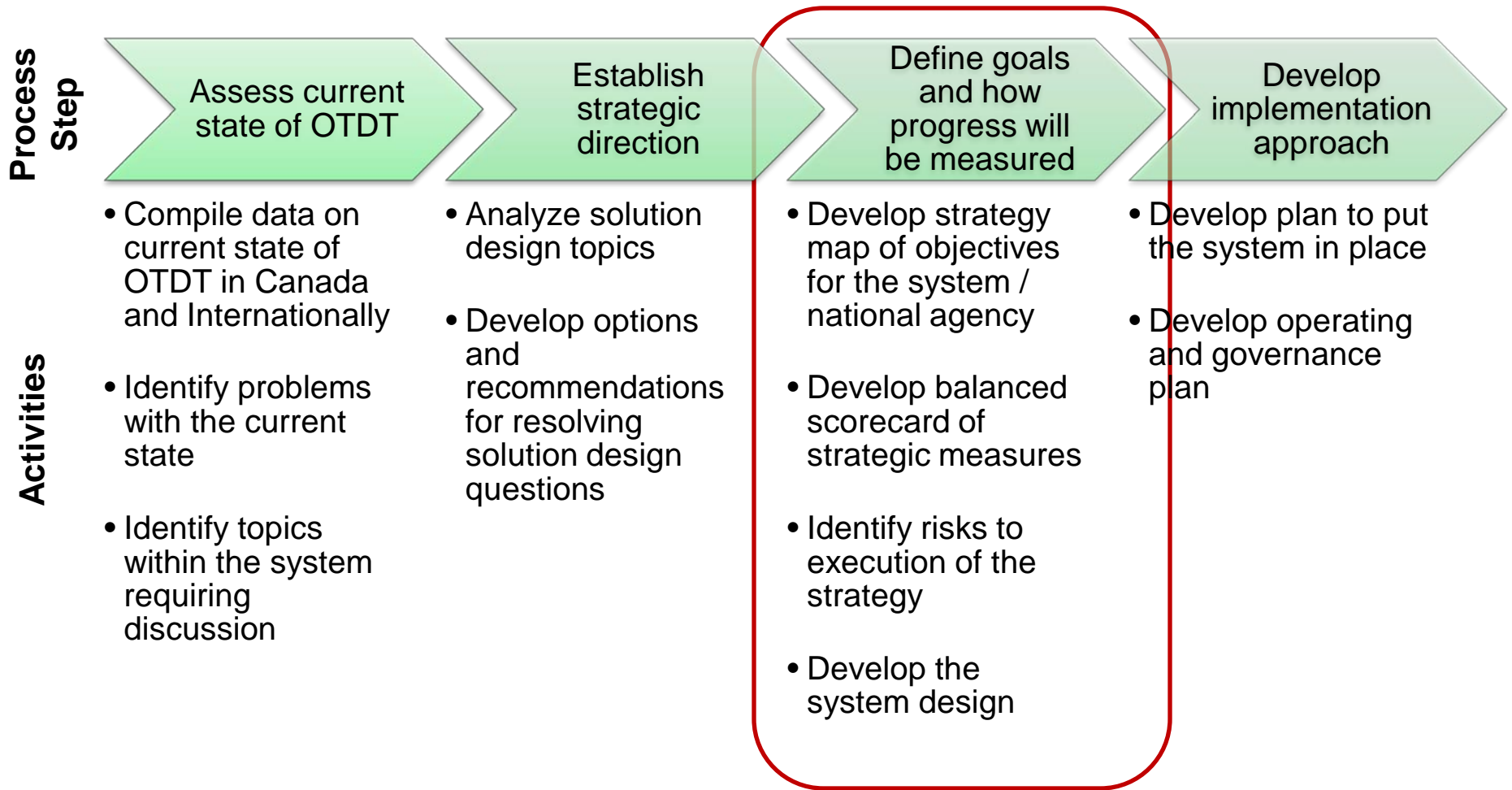
- Approval of previous meeting minutes (October 14, January 20)
- Public Case for Change
- Conflict-of-interest disclosure forms



Activity to Date and Next Steps



The Strategic Planning Process



Organ Expert Committee – June, October, and January Meeting Discussions

Canada is failing to realize its potential for organ donation

- How can the system best enable the public to turn support for organ donation into action?
- How can the system improve and increase identification and referral of potential donors?
- What resourcing model(s) best accommodate organ donation services?
- Should intent/consent registries be utilized in Canada? For what purpose?

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

- To what extent should practices in patient referral and waitlist management be consistent? What are the best mechanisms for achieving this?
- 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

- What operating and resource models best accommodate organ transplantation?

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

- *To be determined as part of system design and governance planning*

Organ Expert Committee – This Week's Meeting

OEC Agenda Topics

Welcome and follow-up on action items

Update on CBS registry work: Ed Cole,
Peter Nickerson

Activity to date

Strategic Destination

Strategy Map

Introduction to system design

System design requirements and open
questions

Wrap-up and next steps

Open questions discussed:

- What approach to intent/consent to donate registries should we recommend?
- How similar should allocation rules be across provinces and programs?
- *Given...* to what extent should allocation processes occur within a single system...?
- What additional accountability mechanisms will ensure that ODT service delivery organizations will comply with agreed-to standards, policies and performance?

Organ Key Messages from Expert Engagements and Public Dialogues

Public and Professional Awareness

- Educate the public on the importance of donation and consent, through diverse channels
- Support for donor registries
- Make it easier for public to express consent
- Presumed consent should be considered
- Professional education to increase recognition of potential donors and to make donation a routine part of end-of-life care

Donation

- Streamline system for identification and referral
- Increase donation through DCD and ECD
- Support donation in outlying hospitals

Allocation

- Promote fair, transparent and equitable allocation standards
- Consistent national application of allocation principles with accountability for practices
- Consider a real-time donor database and a national allocation and offer management centre
- Need a “payback” system, so net exporters of organs are not disadvantaged

Transplantation

- Advocate for a national wait list
- Standardized criteria for transplantation eligibility
- Need a support group for transplant patients

Safety and Quality

- National safety / quality standards are required
- Need a central organization to help develop standards consistently across the country

Policy development

- Need national policy leadership
- Need to describe the governance structure and ensure broad representation

Information mgmt, measurement and reporting

- Create transparent, real-time data management system (linked to national registries)
- Need resources to support data entry
- Need tracking and traceability

Audit and accountability

- National oversight of OPOs
- Need open, transparent, accountable system which discloses all information and ensures compliance with standards and metrics

Funding

- Funding for living donor assessment and reimbursement
- Financial help for patients incurring personal costs
- Adequate funding for hospitals, ORs and ICUs
- Need to understand the true cost of ODT and develop a strong business case
- Need funding to follow the patient

Tissue Expert Committee – June, October, and January Meeting Discussions

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

- How can the Canadian tissues system best ensure consistent safety and quality?
- What is the best strategy to achieve the regulatory requirements for traceability?

Current Canadian tissue practices do not ensure security of supply

- For recovery and processing, what is the best balance between domestic and imported tissue?
- How can the system best increase identification and referral?
- How can the system optimize consent and recovery?
- To what degree should Canada be in the business of recovering and processing tissue?

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

- How can the system best ensure that supply is aligned with demand?

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

- *Strategic direction will be developed as part of the governance plan*

Tissue Expert Committee – Last Week's Meeting

TEC Agenda Topics

Welcome and follow-up on action items

Guest speaker: Kelvin Brockbank

Activity to date

Strategic Destination

Strategy Map

Introduction to system design

System design requirements and open questions

Wrap-up and next steps

Open questions discussed:

- What is the scope of a single, standardized quality program?
- Should there be centralized accountability and authority for ensuring a secure supply of tissue in Canada?
- If there is a single, central supply planning agency, what is the relationship between supply planning and Canadian processing?
- What is the relationship between processors and recovery organizations?
- What product is available from the single tissue inventory?
- How should the referral centre(s) be organized?

Tissue Key Messages from Expert Engagements and Public Dialogues

Public and Professional Awareness

- Need increased public and professional awareness including an understanding of consent and donation's benefits
- Need to educate different demographic and cultural groups
- Intent to donate registries should be used

Donation and Consent

- Need to increase donation
- Need to recognize the biggest potential in emergency departments and outside the hospital
- Mandatory referral of tissue donors
- Should implement a call centre for referrals
- Trained professionals should obtain consent
- Need to ensure that recipients give informed consent before transplantation occurs

Processing, Distribution, and Allocation

- Centralize and enhance the capabilities of domestic tissue processing and distribution
- Canada needs to increase its recovery and processing of tissue allografts
- Need to determine the right balance of domestic and imported tissue
- Allocation practices (for cornea) should be fair and equitable despite geography
- Consider a national allocation and offer management centre

Safety and quality

- Create a national program for traceability
- Centralization and standardization to support safety and quality
- Need a central organization to help develop standards consistently across the country

Policy development

- Need national policy leadership
- Need to describe the system's governance structure and ensure broad representation

Information mgmt., measurement and reporting

- Need data on allograft utilization
- Create a real-time, integrated tissue data management system, available nationally, to support decision making, performance improvement and accountability

Audit and accountability

- Need accountability mechanisms
- Ensure monitoring and compliance to standards and metrics
- Need open, transparent and accountable system and processes which disclose all information

Funding

- Need to understand the true cost of supporting TDT and fund accordingly
- Adequate funding will be a key success factor to implement national TDT improvements

Strategic Planning Engagement - Approach

Public Dialogues

- Inform the public about OTDT
- Receive feedback and learn what the public values

Expert Engagement

- Inform experts regarding the planning process
- Receive feedback on content drafted to date

Partnership Building

- Enhance and build partnerships with other organizations in support of the OTDT cause

Government Engagement

- Inform government regarding the state of OTDT and the progress of the planning process

Strategic Planning Engagement - Recent Developments

Public Dialogues

- Recently completed Edmonton, Halifax, Winnipeg, Regina, St. John's
- Upcoming events in Moncton and Toronto

Expert Engagement

- Recent activity in BC, AB, MB, ON, NS, NB, NFLD
- Recently speaking with many professional associations and societies

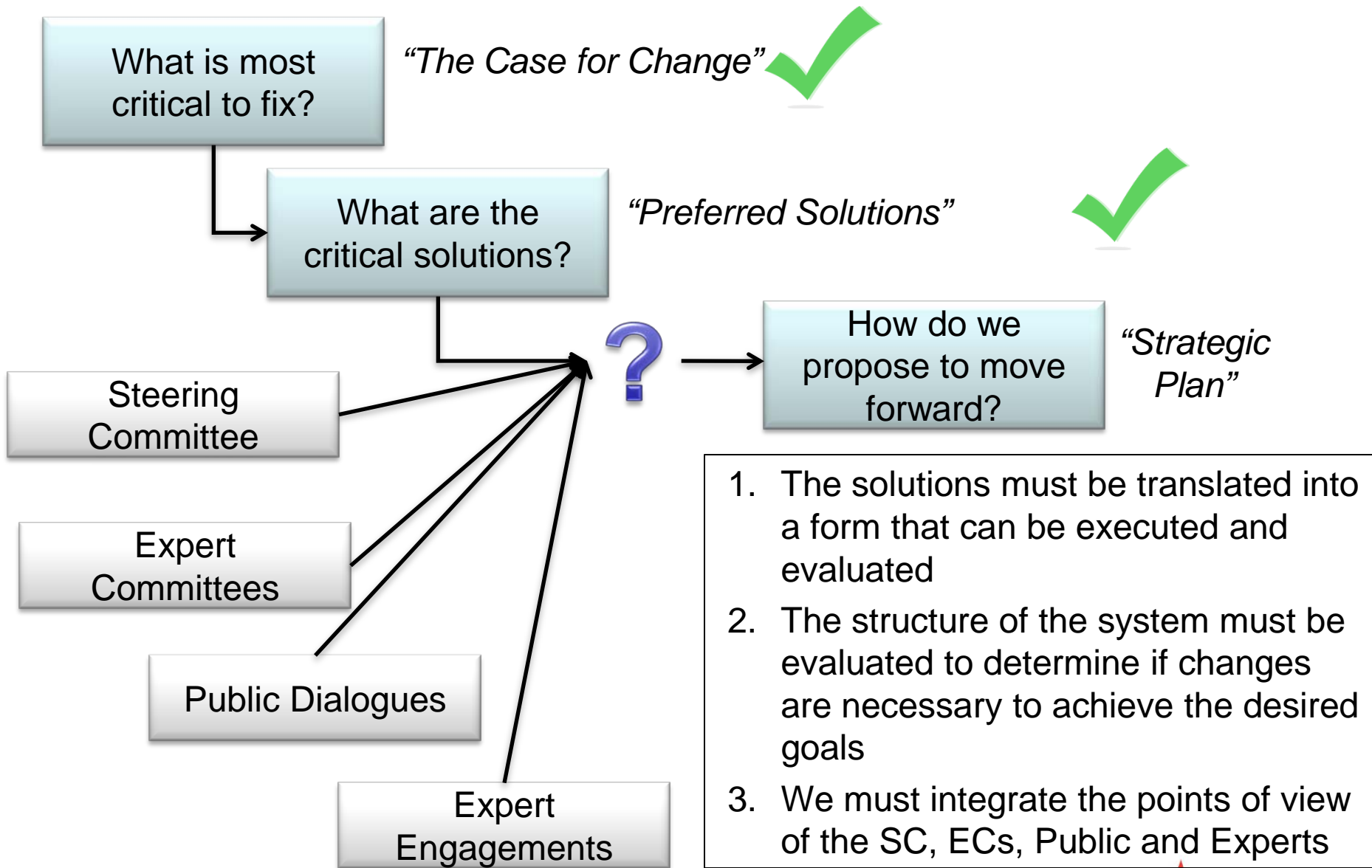
Partnership Building

- Partnership Roundtable

Government Engagement

- Meetings with PT blood contacts for updates on OTDT
- Upcoming June 7th meeting with DMs

What is the next phase of the process?



What are the next steps?

System Strategy

- Translate committee direction into actionable form
- Describe the ultimate goals and the changes needed to achieve them
- Integrate the public and expert feedback

System Design

- Describe the changes in system structure necessary to execute the strategy
- Describe roles and responsibilities
- Describe how major activities are coordinated and how accountability is achieved

System Principles

The draft System Principles have been discussed at each public and expert engagement

Collaboration and Integration

Safety

Fairness

Accountability

Self-Sufficiency (Organs)

Cost-Effectiveness

Security of Supply (Tissues)

Privacy

Population-Based System

Ethical Practices

What are our goals for today?

- Help us ensure that we are in the right direction on the System Strategy and System Design:
 - Are the ultimate goals worthwhile? Are they compelling?
 - Are there gaps in the strategy or system design?
 - How can we resolve the challenges with implementation and governance of the strategy and system design?

Organ System Strategy



Approach for Discussing Organ System Strategy and System Design

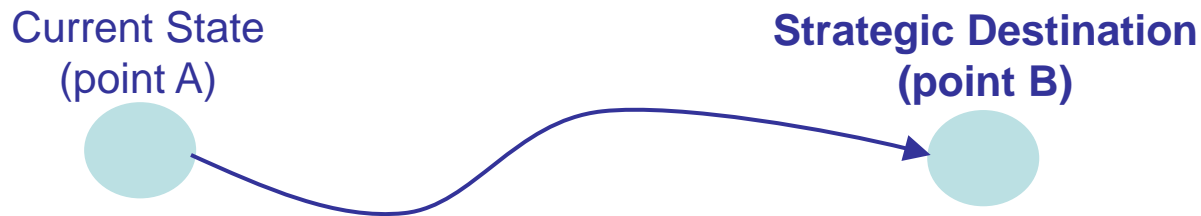
- To recap the Organ Expert Committee's recommendations to date
- To review and discuss the draft Strategic Destination and Strategy Map
- To review and discuss the emerging System Design



The tool we will use to articulate the performance strategy is the Kaplan-Norton Balanced Scorecard.

- Although there are different frameworks for describing and managing a performance strategy, we have chosen the Kaplan-Norton Balanced Scorecard
 - Canadian Blood Services credits this framework for their success in strategic management
- There are several key components to a Kaplan-Norton Balanced Scorecard:
 - Strategic destination
 - Strategy map
 - Objective descriptions
 - Measures
 - Initiatives
- Ultimately the Balanced Scorecard is designed to describe the strategy in such a way that it can be successfully communicated, executed, measured, and managed

Translating recommendations into strategy begins by identifying the ultimate outcomes we want the system to achieve



A **Strategic Destination** uses three components to answer the question: *Where are we going?*

1. Quantify the ultimate indicator of success

“Double patient satisfaction...”

2. Define the scope of where success will be attained

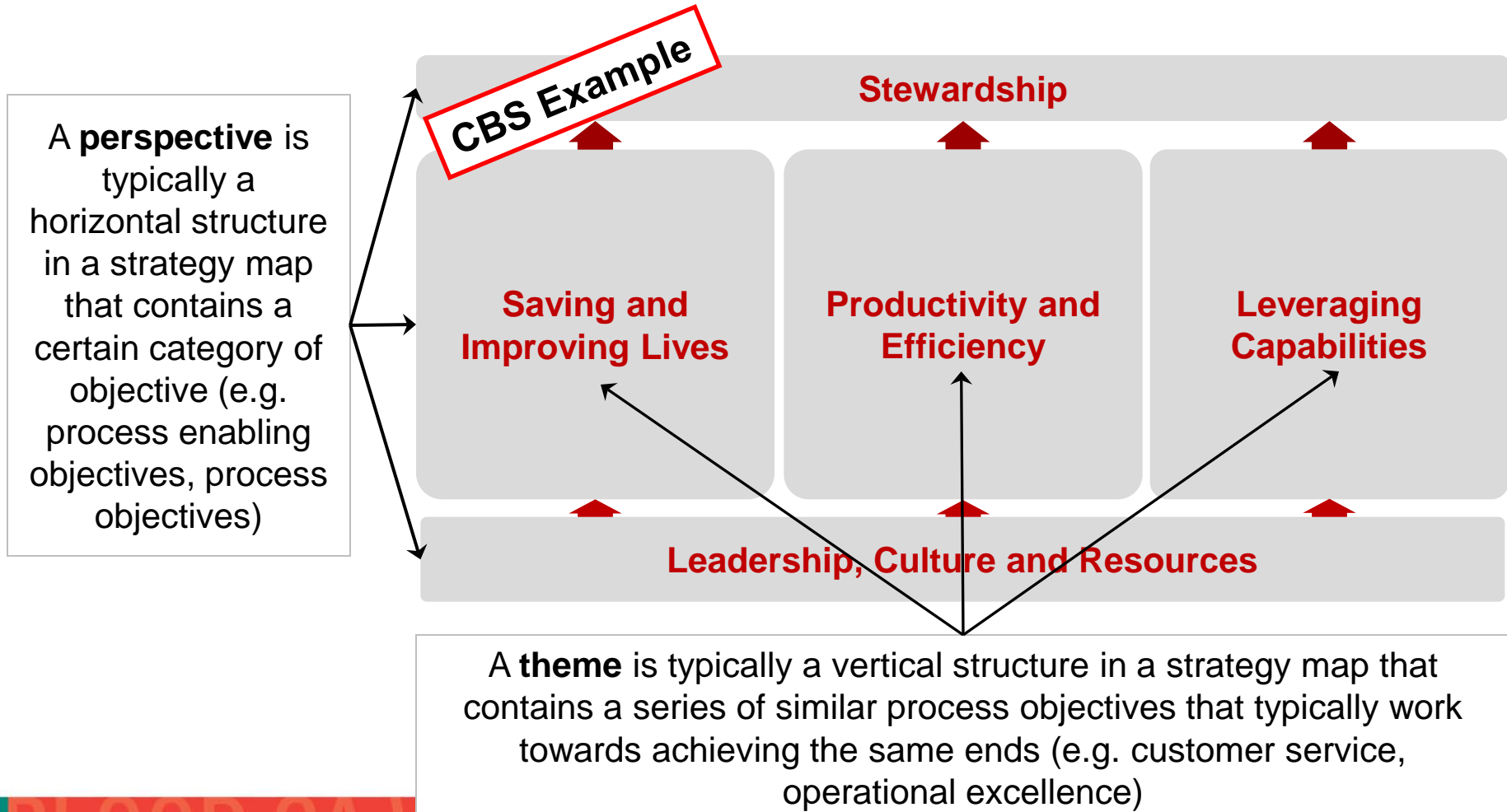
“For patients with XYZ condition...”

3. Identify the timeline for execution

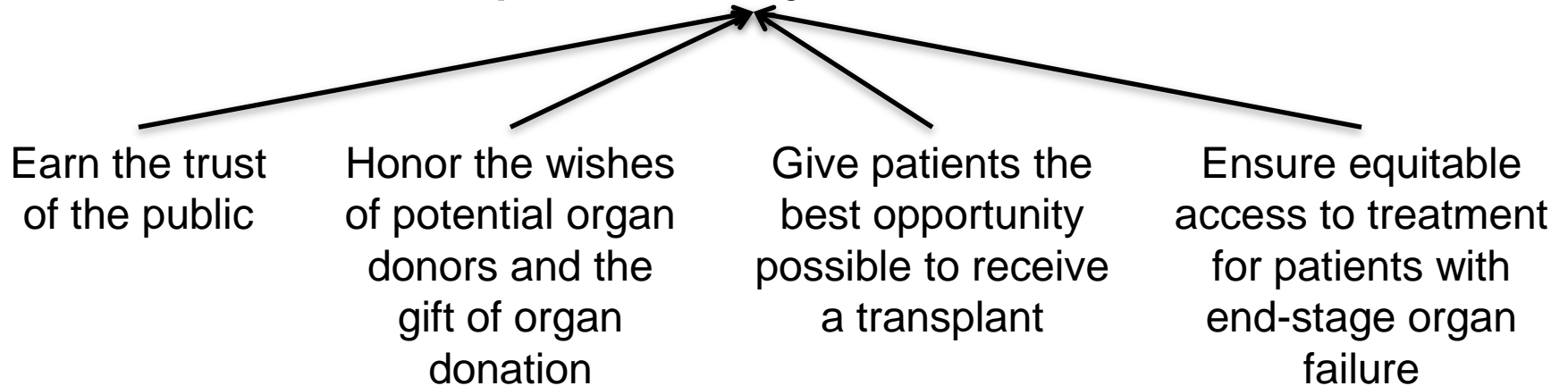
“In the next three years”

After the strategic destination has been articulated, themes and objectives supporting the outcome are derived and arranged visually in a strategy map.

A **strategy map** is a one-page visual representation of an organization's strategy that depicts both desired outcomes and critical drivers across multiple perspectives and themes

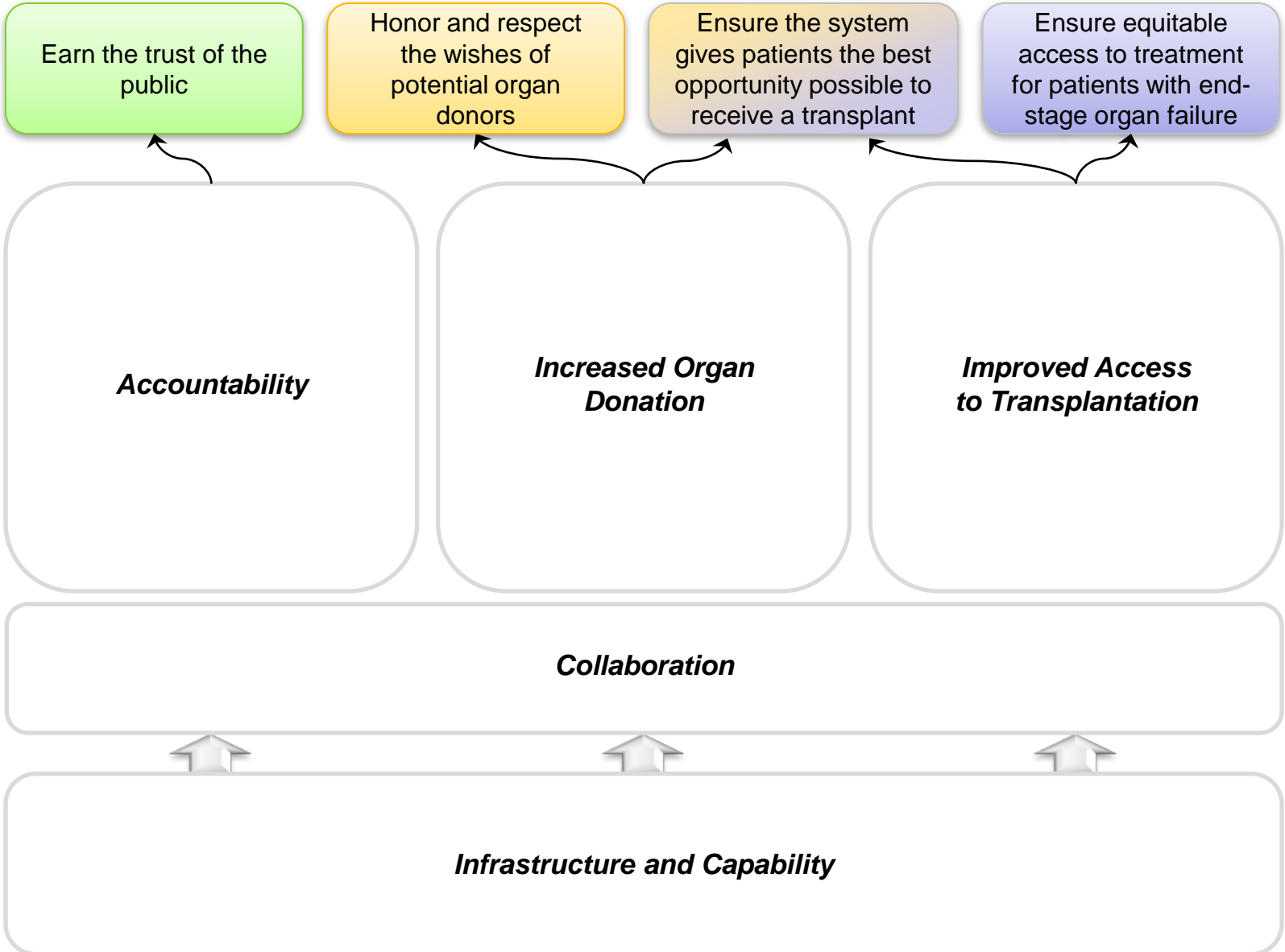


“A trusted and self-sufficient system for Canadian patients by 2016”



DRAFT - Organ Donation and Transplantation Strategy Map

A trusted and self-sufficient system for Canadian patients by 2016



Desired Outcomes

to drive

System Processes

that enables

Infrastructure and Capability

Earn the trust of the public

Honor and respect the wishes of potential organ donors

Ensure the system gives patients the best opportunity possible to receive a transplant

Ensure equitable access to treatment for patients with end-stage organ failure

Accountability

Increased Organ Donation

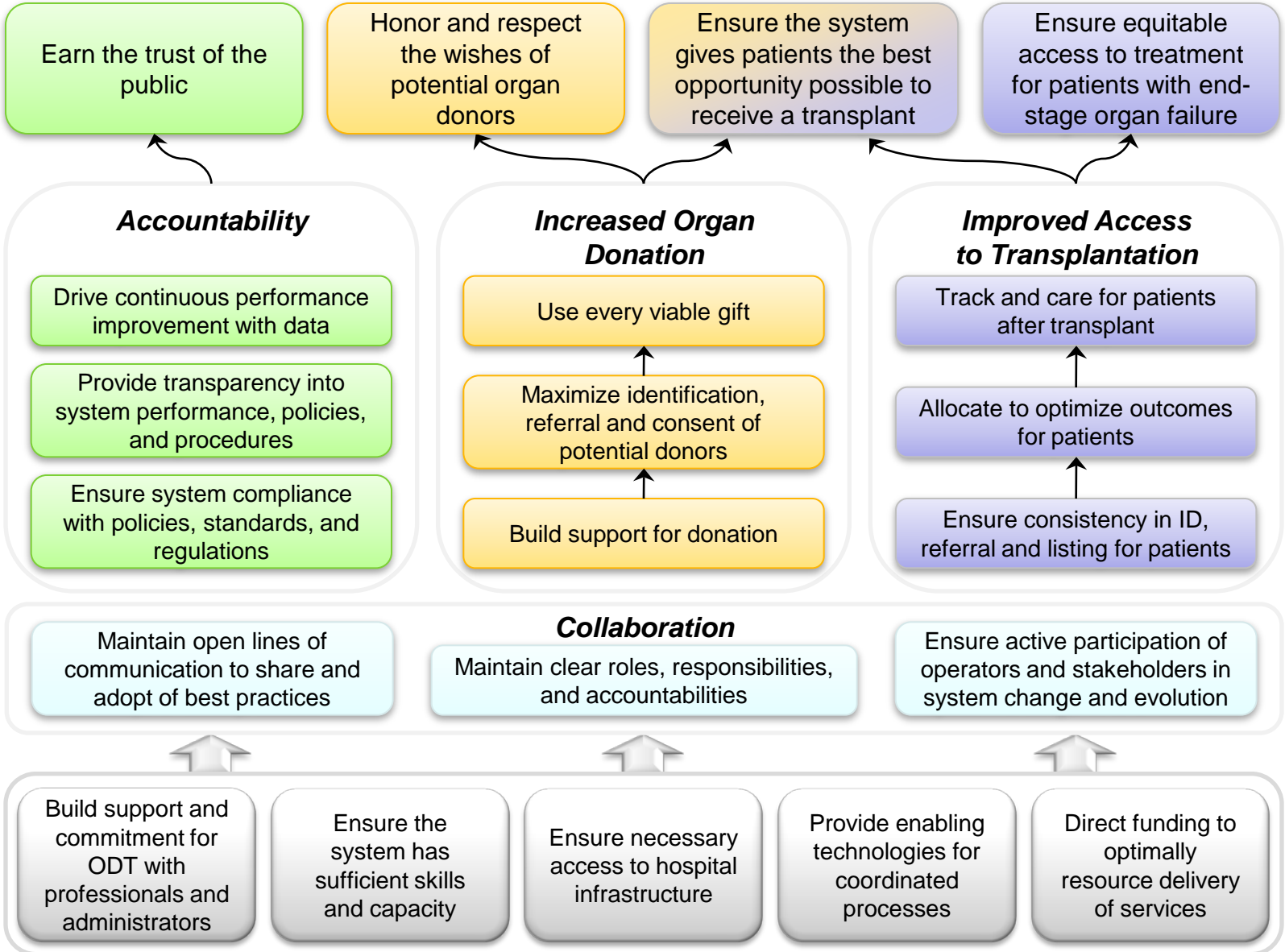
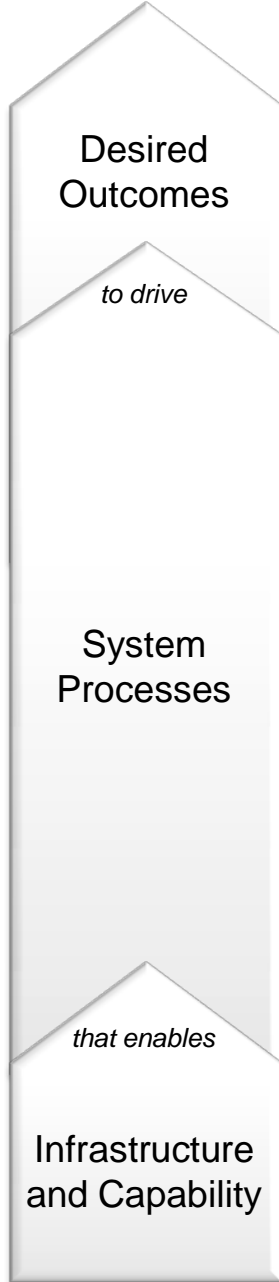
Improved Access to Transplantation

Collaboration

Infrastructure and Capability

DRAFT - Organ Donation and Transplantation Strategy Map

A trusted and self-sufficient system for Canadian patients by 2016



The Balanced Scorecard is more than just objectives.

Desired Outcomes

Ensure the system gives patients the best opportunity possible to receive a transplant

System Processes

Increased Organ Donation

Utilize every viable gift

Maximize identification, referral and consent of potential donors

Build support for donation

Infrastructure & Capabilities

Workforce

Data

Infrastructure

Funding

ILLUSTRATIVE

How we will evaluate progress and drive the desired behaviors

Measures

- Organs per donor
 - X (SCD)
 - Y (ECD)

The desired level of performance

Targets

- 2015 targets:
 - X+A (SCD)
 - Y+B (ECD)

Key projects required to achieve the objective

Initiatives

- Automated matching system

Organ System Design



What are the next steps?

System Strategy

- Translate committee direction into actionable form
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System Design

- Describe the changes in system structure necessary to execute the strategy
- Describe roles and responsibilities
- Describe how major activities are coordinated and how accountability is achieved

System Principles

How we have approached system design with the Expert Committees

April

- Expert Committees validated requirements for system design and answered questions regarding gaps in direction
- Steering Committee discusses key challenges of the emerging system design

May

- Requirements of the system design and implied components of the system are translated into a single, understandable system design

June

- All committees review the system designs
- Expert Committees assign accountabilities for system roles, processes, and systems



The emerging system design addresses the strategy: Accountability Theme

Accountability

Drive continuous performance improvement with data

Provide transparency into system performance, policies, and procedures

Ensure system compliance with policies, standards, and regulations

System Design

- Accountability for compliance with national policies, standards and processes, including reporting requirements:
 - Oversight authority
 - Accreditation
 - TBD
- Accountability for performance:
 - TBD
- National mandatory collection of performance and operational data:
 - Single patient wait list IT system
 - Organ allocation IT system
 - TBD
- Data review and analysis

Open Question:

❖ What mechanisms will ensure that ODT service delivery organizations will be accountable for agreed-to standards, policies and performance?

The emerging system design addresses the strategy: Increase Organ Donation Theme

Increased Organ Donation

Use every viable gift

Maximize identification, referral and consent of potential donors

Build support for donation

System Design

- Professionalization of donation services through:
 - Donation policy, best practices, standardized procedure development (including standard referral triggers)
 - Donation training development and liaison with professional colleges and associations
 - Dedicated, funded donation specialist (physicians and donor coordinators)
- Monitoring compliance to policies, best practices and SOPs
- Legislation for mandatory referral of potential donors
- Expanded DCD and living donor programs
- National social marketing campaigns
- Donor intent / consent registries

Open Question:

❖ What approach to donor registries should we recommend?

The emerging system design addresses the strategy: Improved Access to Transplantation Theme

Improved Access to Transplantation

Track and care for
patients after
transplant

Allocate to optimize
outcomes for
patients

Ensure consistency
in ID, referral and
listing for patients

System Design

- Standard allocation policies and algorithm development
- IT system for organ allocation and data management
- Monitoring compliance to allocation policies
- Data review and analysis
- Standard patient referral and listing rules development
- IT system for central patient wait lists
- Monitoring compliance to referral and wait list rules

Open Questions:

- ❖ Should allocation rules be consistent across provinces and programs?
- ❖ How should a central system support allocation (beyond LDPE, urgent status and HSP)?

The emerging system design addresses the strategy: Collaboration Theme

Collaboration

Maintain open lines of communication to share and adopt of best practices

Maintain clear roles, responsibilities, and accountabilities

Ensure active participation of operators and stakeholders in system change and evolution

System Design

- Donation policy, best practices, standardized procedure development
- Donation training development and liaison with professional colleges and associations
- Roles and responsibilities:
 - TBD at June meeting
- Governance model:
 - TBD at June meeting

The emerging system design addresses the strategy: Infrastructure and Capability Perspective

Infrastructure and Capability

Build support and commitment for ODT with professionals and administrators

Ensure the system has sufficient skills and capacity

Ensure necessary access to hospital infrastructure

Provide enabling technologies for coordinated processes

Direct funding to optimally resource delivery of services

System Design

- Professionalization of donation services
 - Donation policy, best practices, standardized procedure
 - Donation training development and liaison with professional colleges and associations
 - Dedicated, funded donation specialist (physicians and donor coordinators)
- IT systems for patient wait lists and allocation
- Financial support/resources for data entry at hospitals
- Availability of at least one 24/7 donation centre per region
- Dedicated, base funding with reimbursement for increased activity above baseline
- Activity-based funding for ODT services delivered by other hospital department (e.g. donor testing, patient testing, ICU, OR, on-call)
- Coordinated approach to evaluate new drugs and technologies
- Funding to support research and development

Common Features in Emerging System Design

Increased consistency through policies and standards

- Recommendations for national policies and standards in donation, transplantation and allocation
- Support for information systems that support monitoring

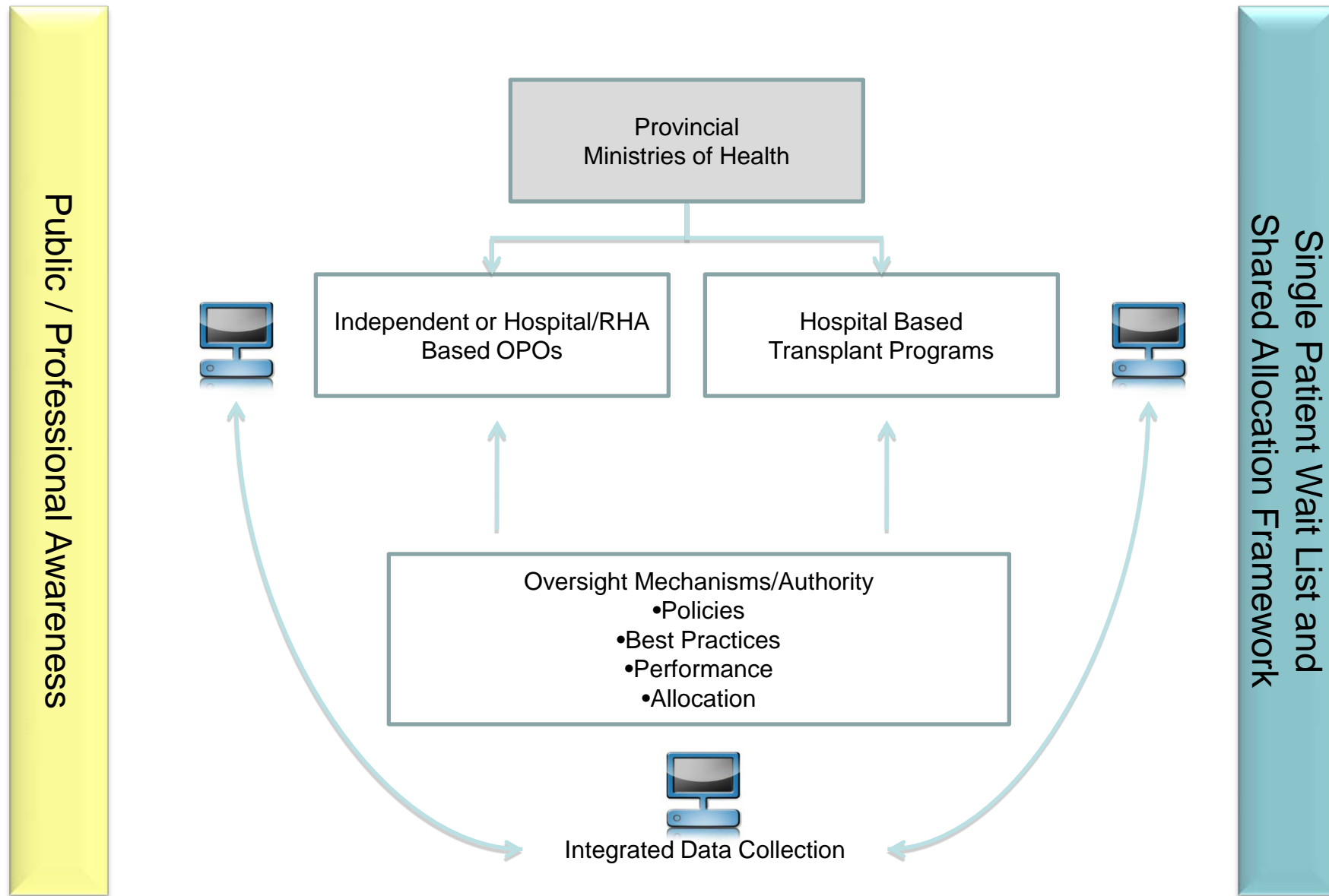
Performance improvement through data and analysis

- Recommendations for single waitlist, donor registries and continued collaboration on measures
- Some public and expert support for central allocation systems

Increased capacity through aligned resources

- Recommendations for dedicated funding linked to donors and patients instead of within global budgets
- Dedicated, funded donation specialist

Overview of Emerging System Design (Service Delivery)



***Guest Speaker:
Dr. Gary Levy***

Organ System Design



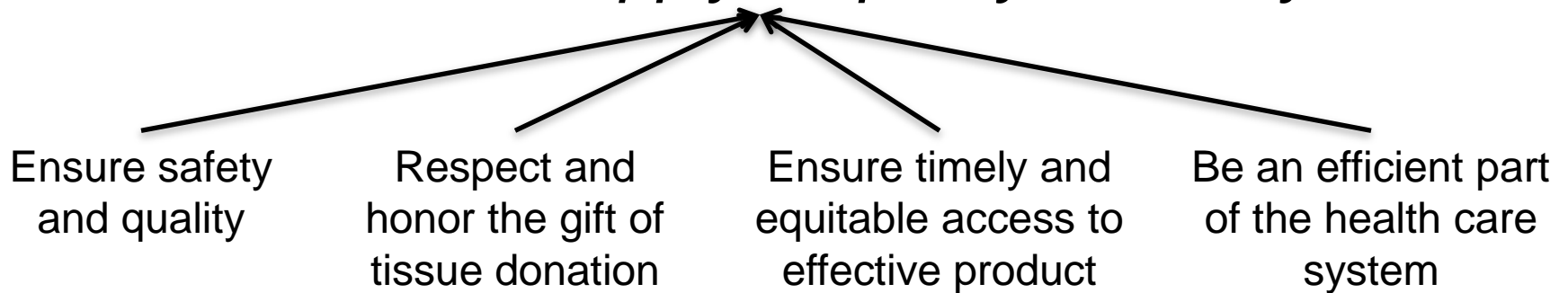
Challenges with ODT

- **How can we approach standardization and central oversight while respecting provincial management and investment?**
- **How can we drive joint commitment to performance improvement across provincial boundaries?**

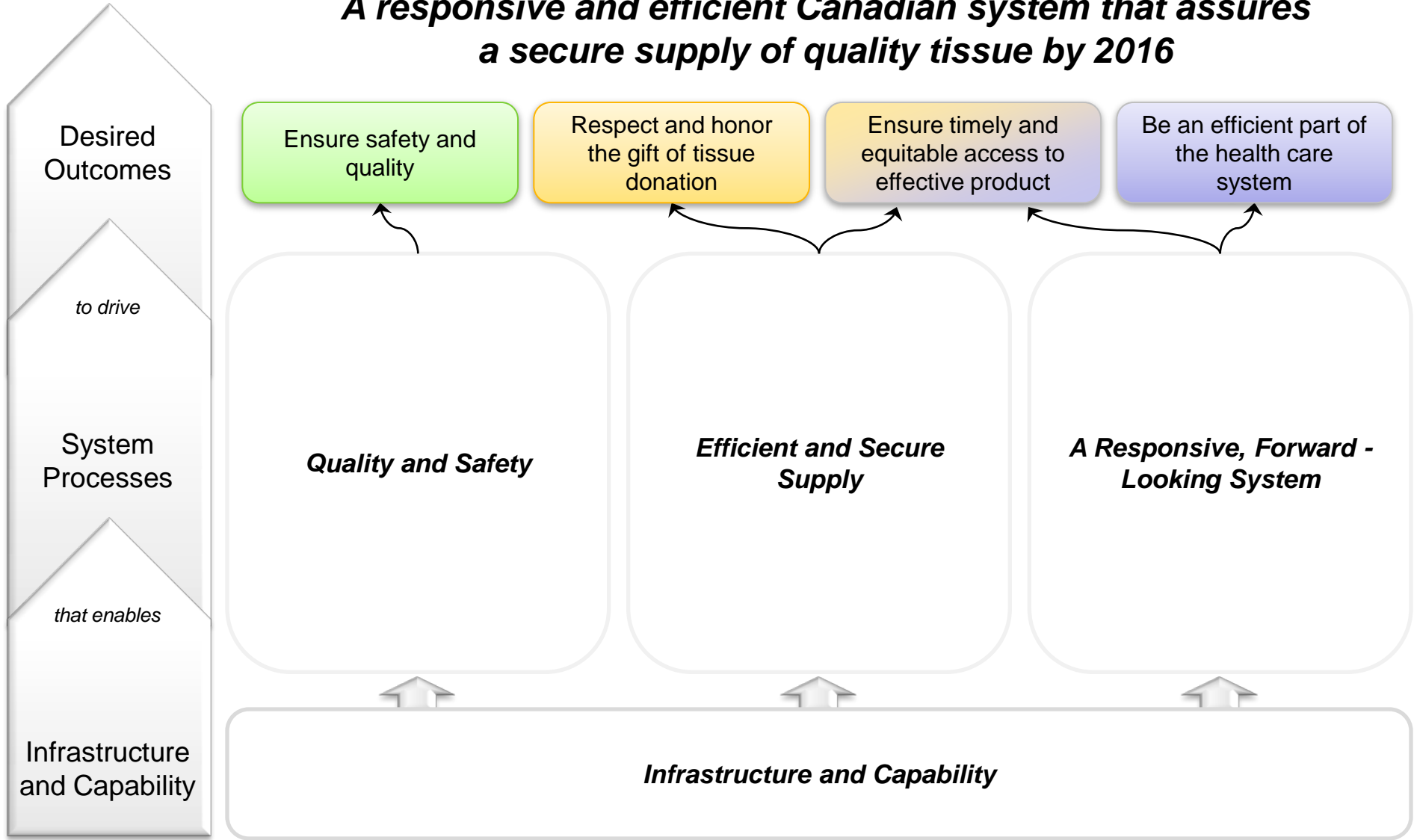


Tissue System Strategy

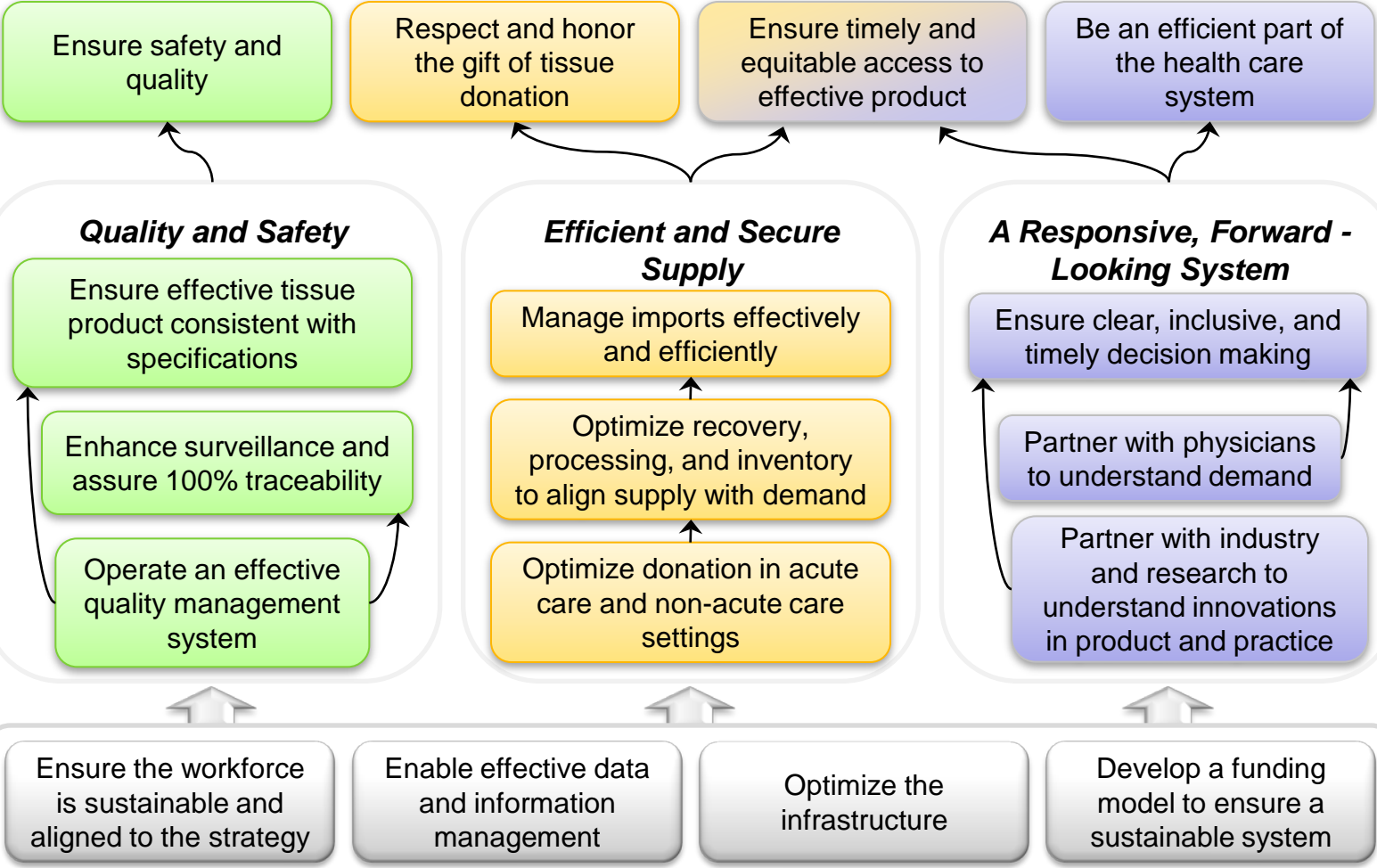
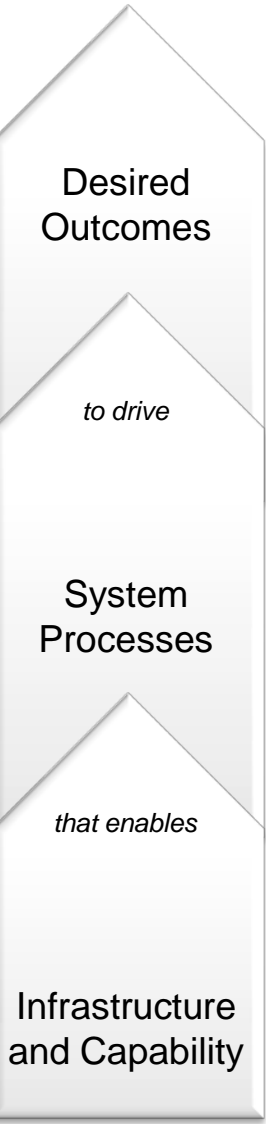
“A responsive and efficient Canadian system that assures a secure supply of quality tissue by 2016”



A responsive and efficient Canadian system that assures a secure supply of quality tissue by 2016



A responsive and efficient Canadian system that assures a secure supply of quality tissue by 2016



Tissue System Design



The emerging system design addresses the strategy: 'Quality and Safety' Theme

Quality and Safety

Ensure effective tissue product consistent with specifications

Enhance surveillance and assure 100% traceability

Operate an effective quality management system

System Design

- Development of a single, standardized quality program that ensures a single set of quality standards, product specifications, processes, and tools, to be consistently implemented by all processors and recovery organizations in Canada
 - Standardized packaging, coding, and labeling (ISBT 128) for domestic products in the single tissue inventory with national scope
 - Single technology system with national scope to collect all traceability data
- Monitoring of compliance with quality standards
- Standard guidelines for informed consent

The emerging system design addresses the strategy: 'Efficient and Secure Supply' Theme

Efficient and Secure Supply

Manage imports effectively and efficiently

Optimize recovery, processing, and inventory to align supply with demand

Optimize donation in acute care and non-acute care settings

System Design

- A central agency to develop a central supply plan and to manage domestic processing and importation against the supply plan, from processing to distribution
 - Scope covers all tissues and tissue devices
- A single agency with national scope for tissue recovery, with the option to contract for some recovery
 - Multi-tissue recovery teams that are consistently trained
- A single referral centre agency (24/7) with national scope
 - Referrals from hospitals, medical examiners and coroner offices
 - Consent obtained by professional, trained requestors
 - Intent/consent registries accessible by requestors
 - Development of standards for referral, consent and screening
 - Bereavement support and family follow-up
- Legal framework for consent/donation

The emerging system design addresses the strategy: 'A Responsive, Forward-Looking System' Theme

A Responsive, Forward-Looking System

Ensure clear,
inclusive, and timely
decision making

Partner with
physicians to
understand
demand

Partner with
industry and
research to
understand
innovations in
product and
practice

System Design

- Demand planning capabilities with strong relationships with end users
 - Evaluate the feasibility of processing advanced tissues in Canadian facilities
- Coordinated approach and funding to support research and development

The emerging system design addresses the strategy: 'Infrastructure and Capability' Perspective

Infrastructure and Capability

Ensure the workforce is sustainable and aligned to the strategy

Enable effective data and information management

Optimize the infrastructure

Develop a funding model to ensure a sustainable system

System Design

- Standardized training programs for tissue recovery and processing
- Information technology to support:
 - Demand forecasting and supply planning
 - Inventory management
 - Traceability
 - Medical outcomes/utilization management
- Consolidation of tissue processing
- A funding model that incentivizes purchase of tissue from the single tissue inventory

Standardization and centralization of processes and infrastructure

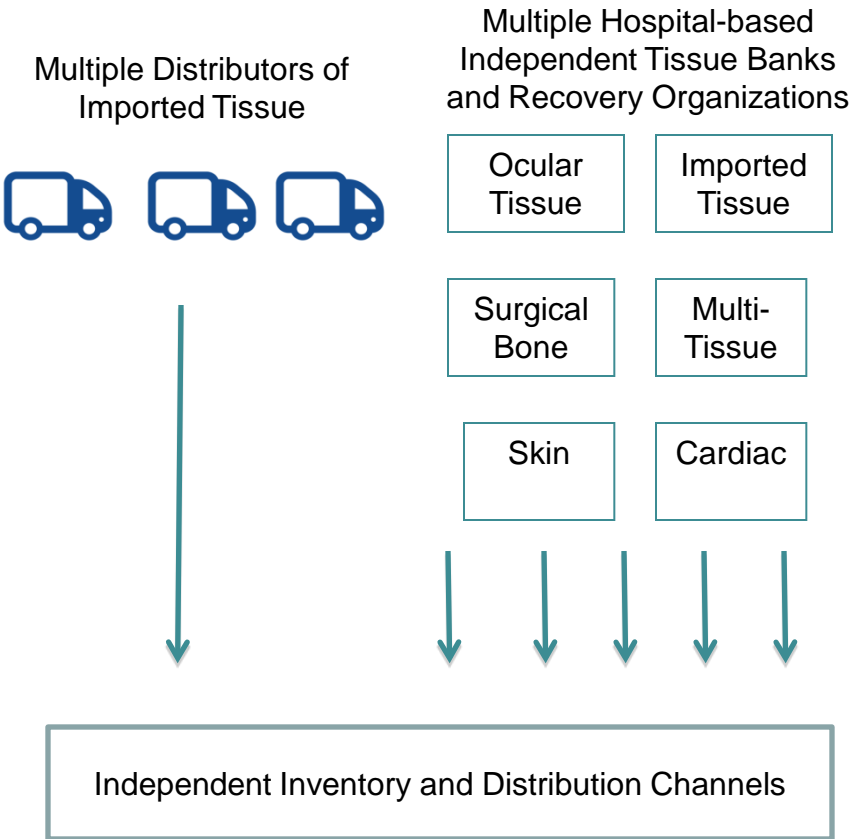
- Specific recommendations for national supply-planning, consolidated tissue processing and central purchasing and inventory
- Specific recommendations for national allograft tracking and product inventory systems

Emphasis on quality

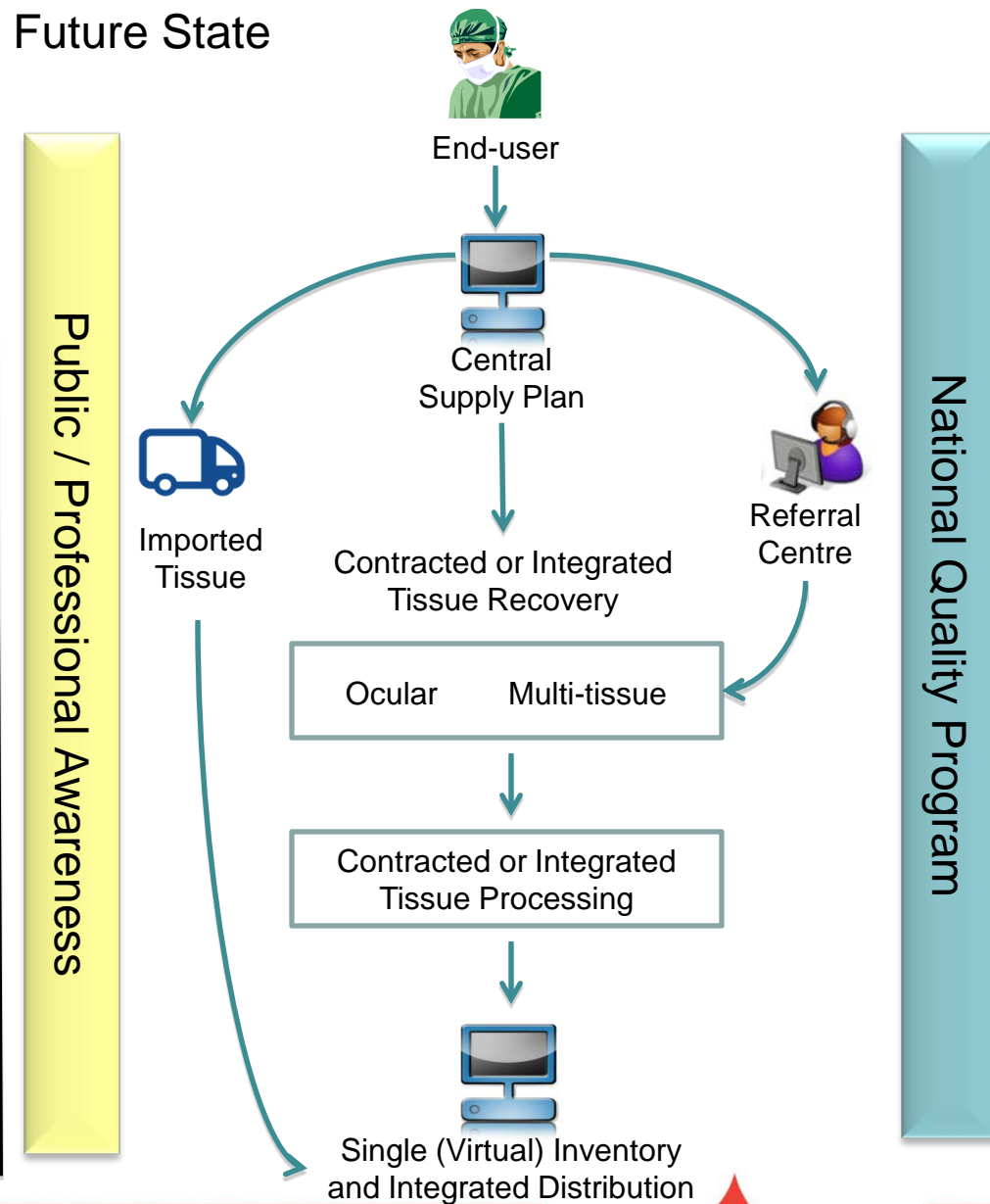
- Specific recommendations for a strong national quality system with standard product packaging and labelling
- Traceability, surveillance and informed consent among the first solutions the TEC agreed on

Overview of Emerging System Design

Current State



Future State



Challenges with TDT

- **How can transition to an integrated system be achieved, in a manner that is fair, feasible and acceptable to governments and tissue banks?**
- **What is the role of a publicly funded system within a private/competitive market?**
- **What funding mechanism will best support the transition and future state?**



Wrap-Up and Next Steps



Next Steps

- Ethics review of principles
- Synthesis of system design
- Drafting strategic measures and targets
- Next meeting on Wednesday, June 16th