

Tissue Expert Committee

April 19, 2010



Objectives for Today's Meeting

- Review progress to date and understand the next steps in the process
- Review and discuss the TDT system strategy and system design

Agenda

Welcome and follow-up on action items	8:30 - 8:45
Guest speaker: Kelvin Brockbank	8:45 - 9:45
Activity to date	9:45 - 10:15
Strategic Destination	10:15 - 10:30
Break	10:30 - 10:45
Strategy Map	10:45 - 11:45
Introduction to system design	11:45 - 12:00
Lunch	12:00 - 12:30
System design requirements and open questions	12:30 - 4:15
Wrap-up and next steps	4:15 - 4:30

Follow-up on Action Items

- Approval of previous meeting minutes
- Public Case for Change
- Disclosures



Guest Speaker:

Kelvin Brockbank

President and Chief Science Officer, Cell & Tissue Systems



Activity to Date and Next Steps



In June of 2009 we agreed on the Case for Change.

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

Current Canadian tissue practices do not ensure security of supply

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

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

In October of 2009 we agreed on preferred solutions for several solution design questions.

- **How can the Canadian tissues system best ensure consistent safety and quality?**
 - Single, standard quality program with national scope with regional/local customization
 - Quality standards for transplant establishments
- **What is the best strategy to achieve the regulatory requirements for traceability?**
 - Ensured end to end traceability of allograft tissue
 - Standardized packaging and labeling (including coding and ISBT 128)
 - Standard guidelines for informed consent
 - Compliance mechanisms for quality standards and regulations (e.g. accreditation, audit)
- **For recovery and processing, what is the best balance between domestic and imported tissue?**
 - Tissue is a national resource; donation is not a right
 - Supply would be a combination of Canadian and American donor source and processing
 - Security of supply management will have to be responsive to external stimuli
 - A call centre would support tissue donation, improving access to potential tissue donors
- **How can the system best ensure that supply is aligned with demand?**
 - End user relationship management is important to align supply with demand
 - Strong relationship with the users both from demand and supply point of view
 - Appropriate medical utilization management needs to be part of the strategy

In January of 2010, we discussed and articulated preferred solutions for a second set of solution design questions.

- **How can the system best increase identification and referral?**
 - Referral should happen in both acute and non-acute environments, in-hospital and out-of hospital and should be mandatory (through legislation)
 - Professional education is needed, including MEs and coroners
 - Referrals should be made to a central call centre
 - There should be nationally standardized identification and referral practices
- **How can the system optimize consent and recovery?**
 - Professional requestors obtain family consent and provide bereavement services
 - Requestors should be available 24/7
 - Consent can be sought by phone
 - Synergies between organ donation requestors and tissue donation should be sought
 - First-person consent should be available to requestors
 - Recovery should be performed by multi-tissue teams with geographic focus
 - A standard Canadian training program should be developed for tissue recovery
- **To what degree should Canada be in the business of recovering and processing tissue?**
 - *Recommendations were tissue-specific; theme across tissue types include:*
 - Centralization of processing
 - Increase in the recovery and processing of basic tissue types

Strategic Planning Engagement

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

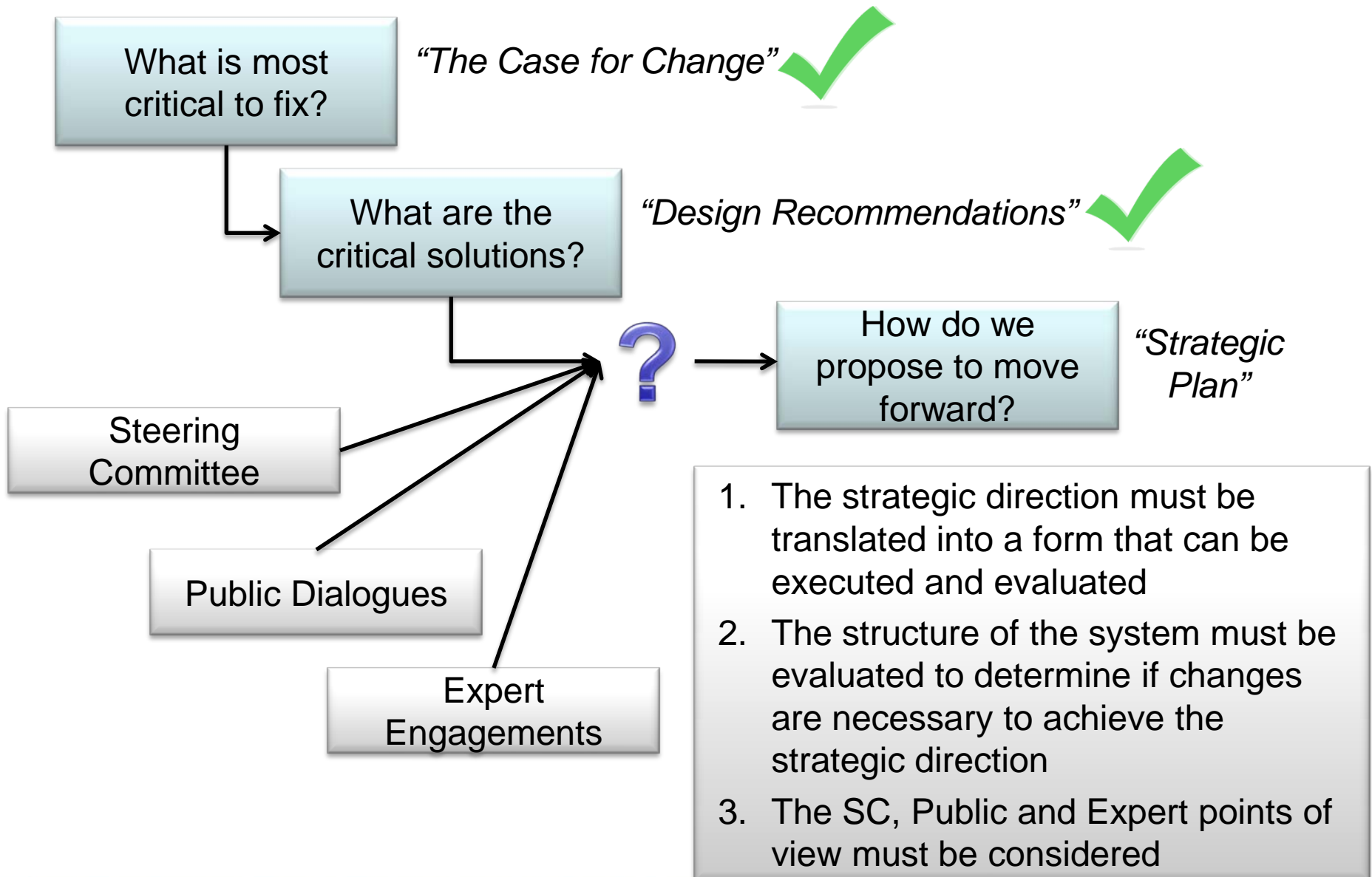
Partnership Building

- Partnership Roundtable

Government Engagement

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

How do we transition into 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

A critical foundation for both the system strategy and system design are the system principles

- The Steering Committee, with feedback from both Expert Committees and various stakeholder groups has drafted a set of principles for the ODT and TDT systems
- These principles build on those implied by the Canada Health Act and align with those prescribed by the World Health Organization

Collaboration and Integration

Safety

Fairness

Accountability

Self-Sufficiency (Organs)

Cost-Effectiveness

Security of Supply (Tissues)

Privacy

Population-Based System

Ethical Practices

TDT System Strategy



Purpose of this Discussion

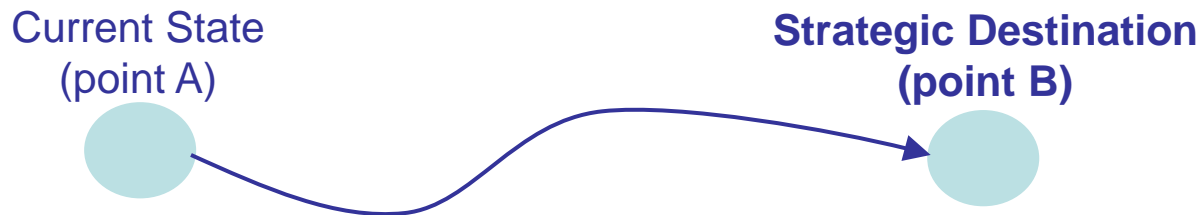
- To introduce the strategy management tools we will use to translate and communicate the TDT system strategy
- To review and discuss the draft strategic destination and draft strategy map



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

- Although there are different frameworks for articulating 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 statement
 - Strategy map
 - Objective descriptions
 - Measures
 - Initiatives
- Ultimately the Balanced Scorecard is designed to articulate the strategy in such a way that it can be successful 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

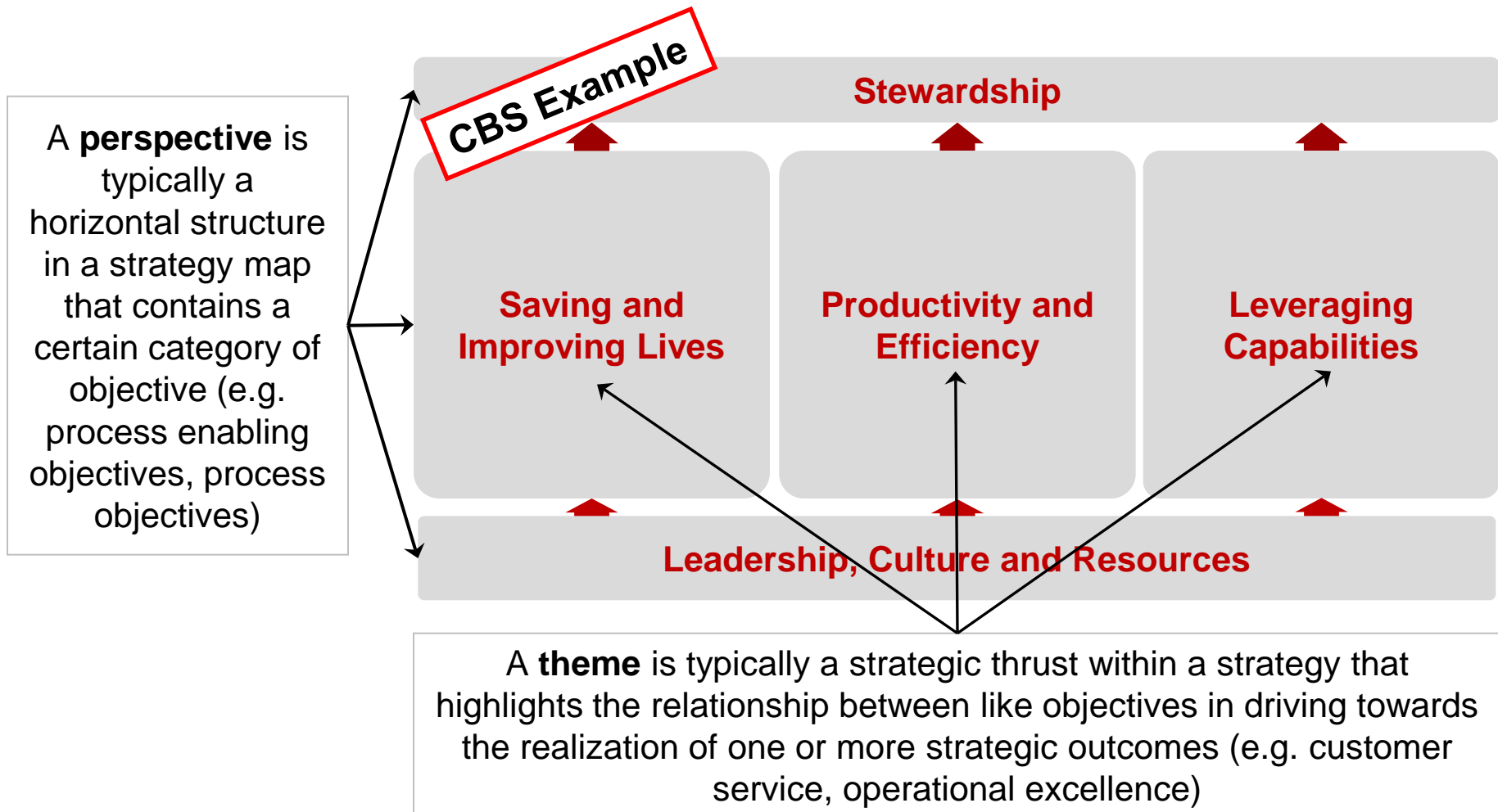
“For patients with XYZ condition...”

3. Identify the timeline for execution

“In the next three years”

While the strategic destination describes the ultimate goal, the strategy map describes how the goal will be achieved.

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



There are many functions of a clear and thoughtful strategy map.

- A strategy map...
 - Communicates the ultimate outcomes the system should achieve and the path to achieving them in an easily-consumed format
 - Articulates the strategic hypotheses such that they can be tested and adapted over time
 - Supports system governance by creating a context for measurement and accountability



To identify the ultimate indicator of success, we considered the needs of three categories of ultimate customer.

Public

Canadians trust that the system is safe and responsible in its treatment of donors and patients, in its approach to allocation, in the stewardship of public funding

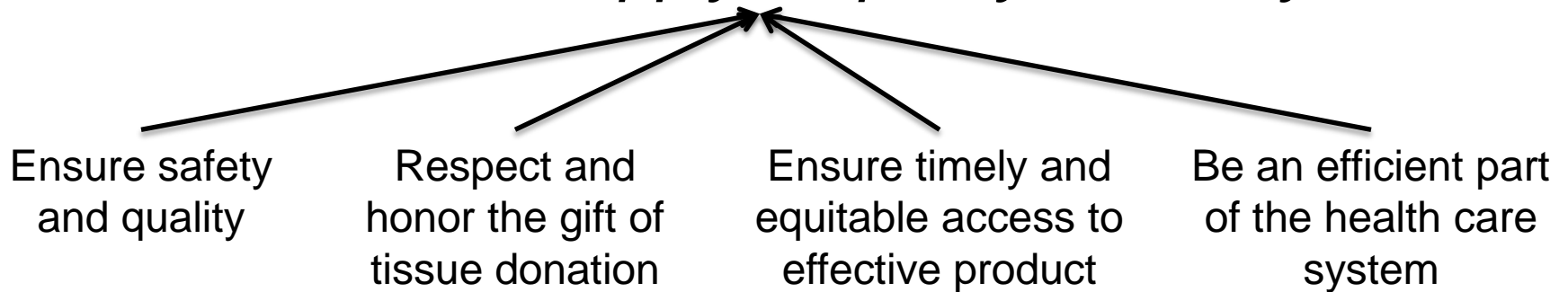
Donors

Potential donors' wishes are honored and donor families are respected during and after the donation process

Patients

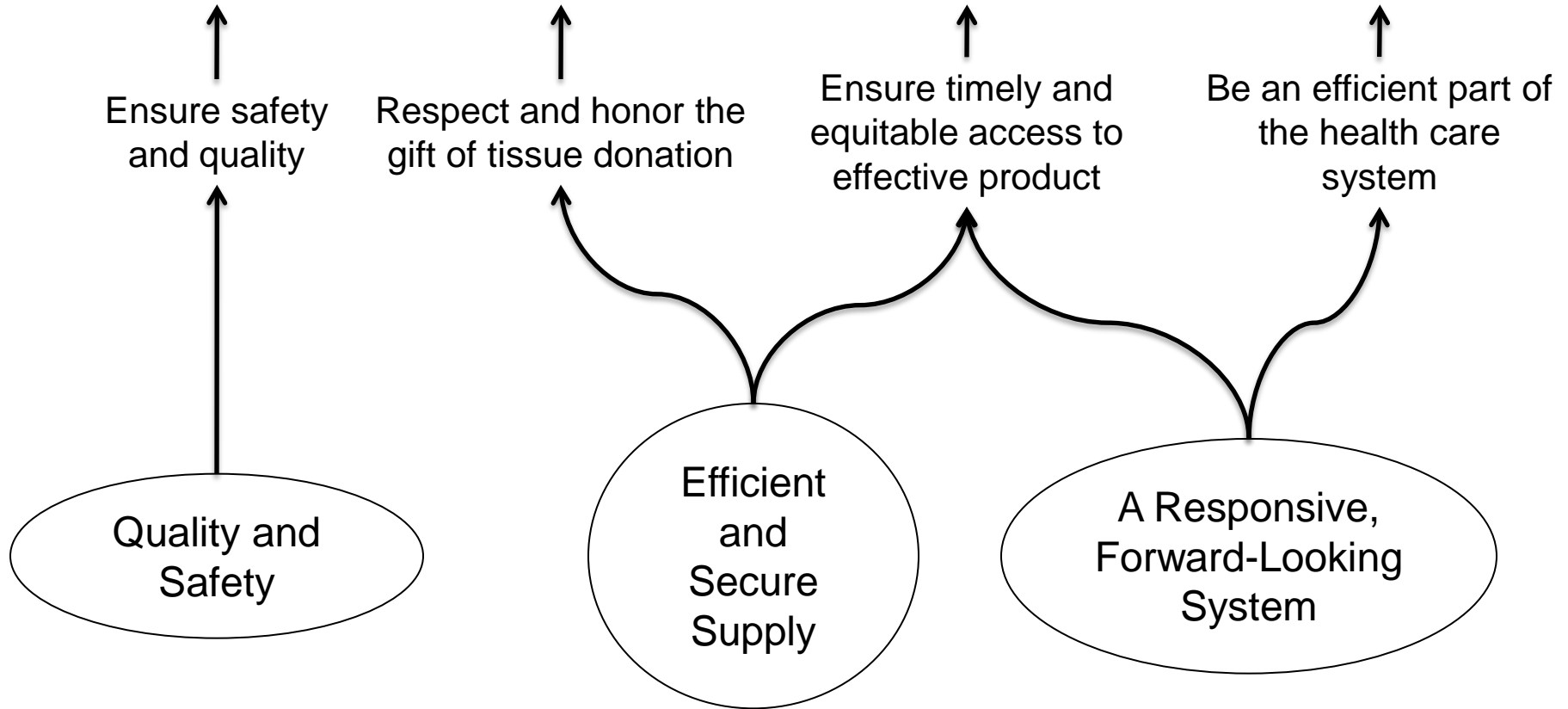
Patients believe there is a system in place that ensures them a secure supply of safe, effective tissue

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



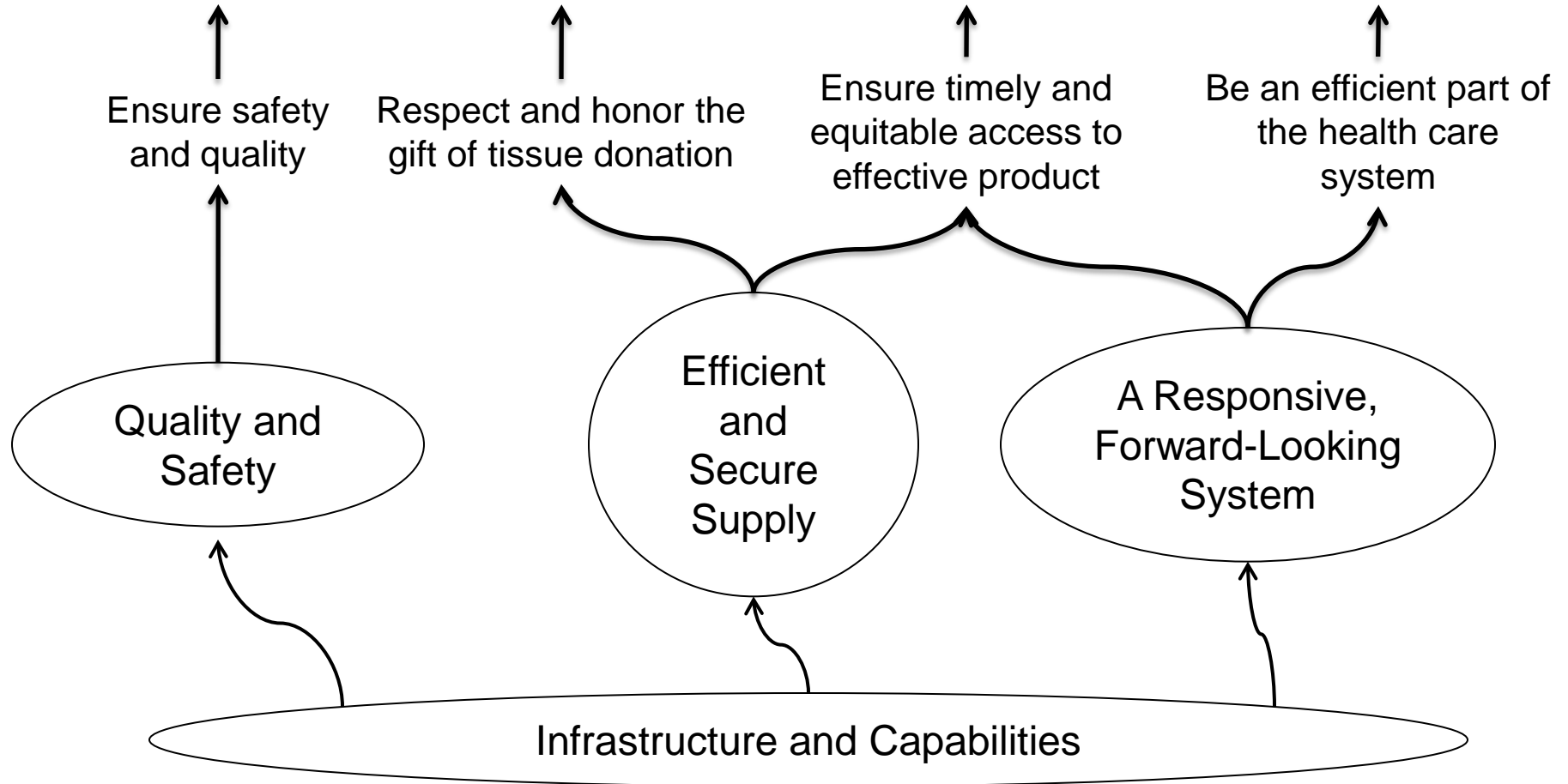
What are the key system improvements that will achieve this destination?

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

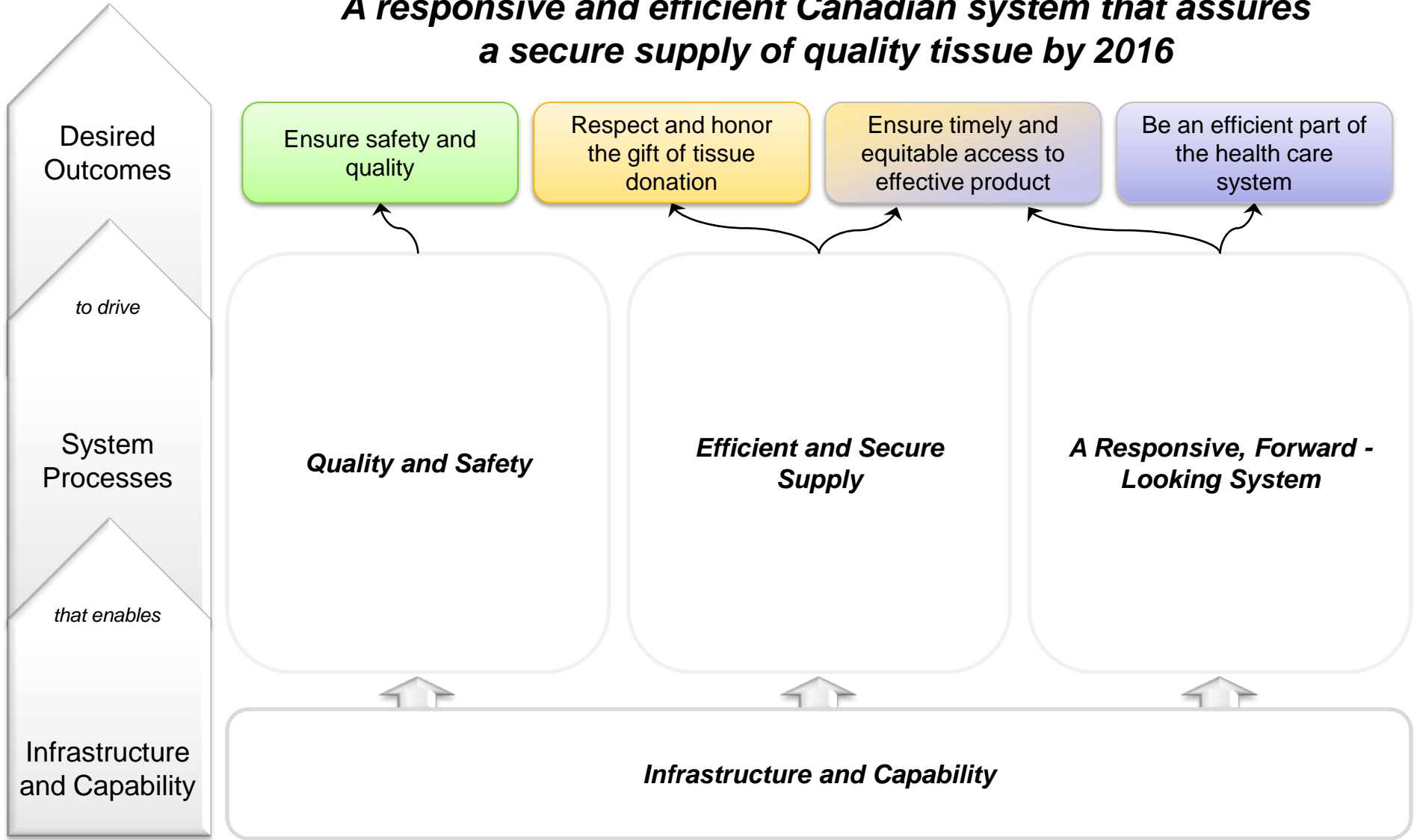


Where do these improvements occur and who makes them happen?

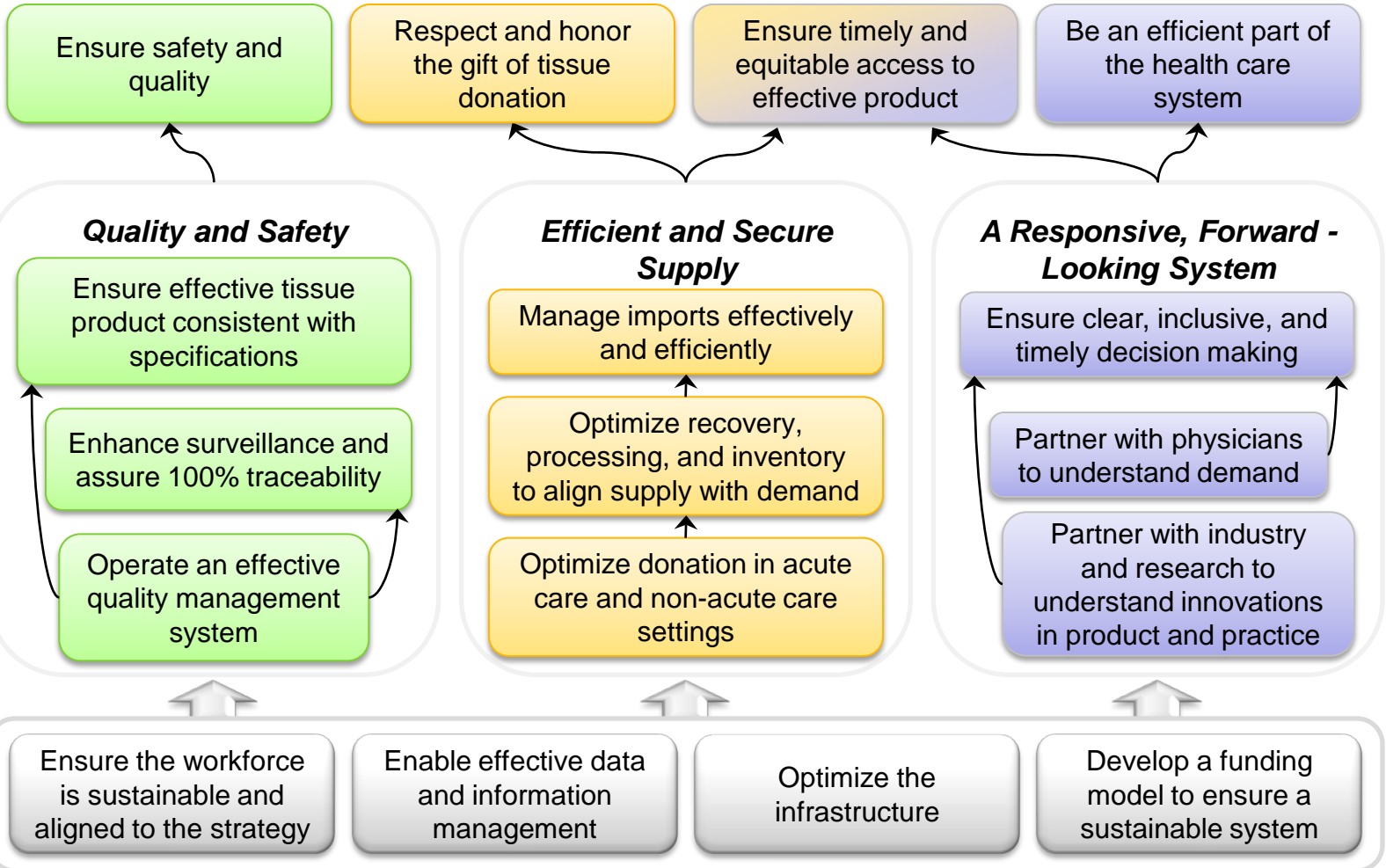
“A responsive and efficient Canadian system that assures a secure supply of quality tissue by 2016”



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



The Strategy Map is a portion of the Kaplan-Norton Balanced Scorecard performance management system.

Desired Outcomes

Ensure timely and equitable access to effective product

System Processes

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

Infrastructure & Capabilities

Workforce

Data

Infrastructure

Funding

ILLUSTRATIVE

How we will evaluate progress and drive the desired behaviors

Measures

- % of demand supplied domestically (current performance: X% skin, Y% cornea)

The desired level of performance

Targets

- 2016 targets:
 - X+A% (skin)
 - Y-B% (cornea)

Key projects required to achieve the objective

Initiatives

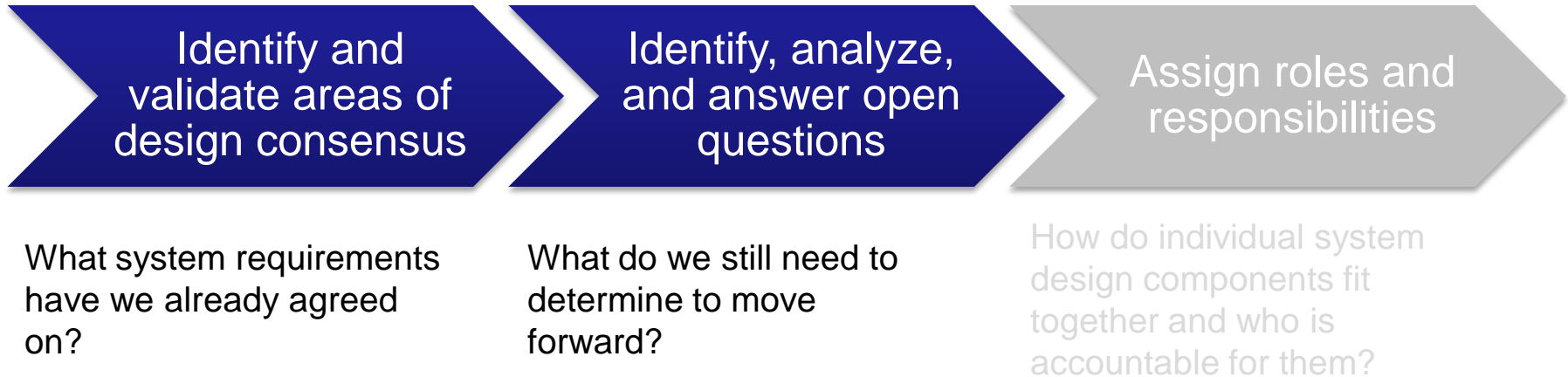
- Negotiate a portfolio of contracts with US processors

TDT System Design



Process for and Purpose of this Discussion

Process:



Purpose of Today's Discussion:

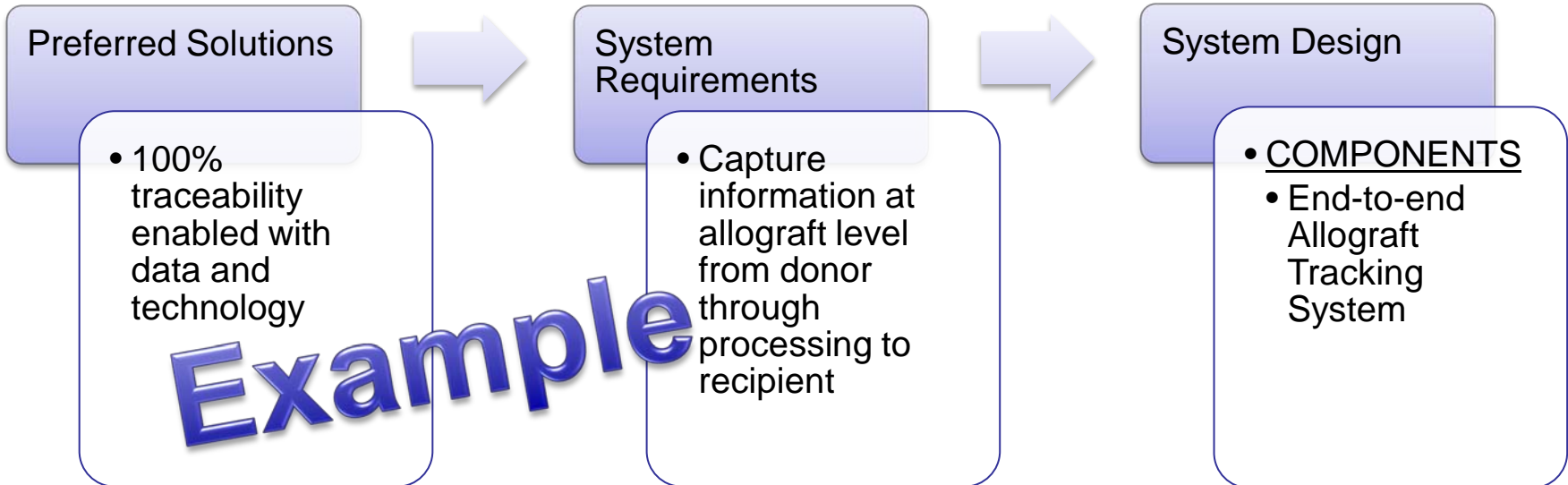
- To understand the process for proposing TDT system design
- To validate the draft system design requirements and begin to answer the most critical open questions that remain

System Design begins with TEC recommendations

“What did we recommend?”

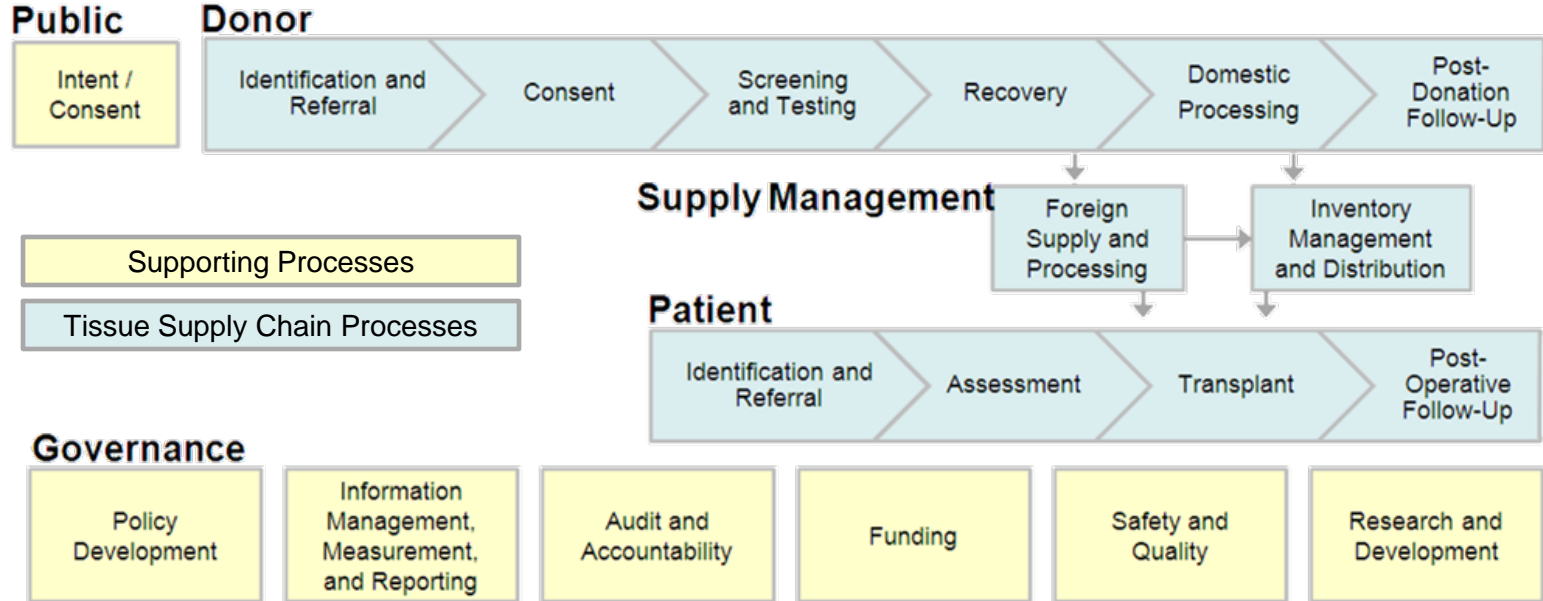
“How must the system function?”

“What structures must the system have?”



In this meeting, we will validate the requirements and discuss critical questions that remain open

This afternoon we seek to validate system design and answer open questions for several key process areas.



- 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 processors?
- 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?

TEC Preferred Solutions

- A nationally standardized quality program, which could have some customization at the regional / local level
- Existing banks meet the required standards and regulations
- Traceability is an essential aspect of the system
- Standardized packaging and labeling including coding, ISBT128, unique donor numbers, and a real-time integrated information system

Public Feedback

- Create a national program for traceability
- Develop national quality system which supports standardization, training and accreditation

Expert Feedback

- Increased centralization and standardization will improve safety and quality
- Leverage quality expertise from Canadian Blood Services
- A central organization should help develop standards consistently across the country

Quality

System Requirements



- Operate based on a single, standardized approach to quality
- Make available quality tools
- Comply with uniform quality standards
- Collect all traceability data in a single technology system with national scope
- Ensure compliance with traceability requirements
- Ensure standardized packaging, coding, and labeling for domestic products in the single tissue inventory with national scope

System Design

COMPONENTS:

- Safety Regulations (including traceability)
- Safety and Quality Oversight
- Product Specifications
- End to End Allograft Tracking System
- Single Tissue Inventory

OPEN QUESTION:

What is the scope of a single, standardized quality program?



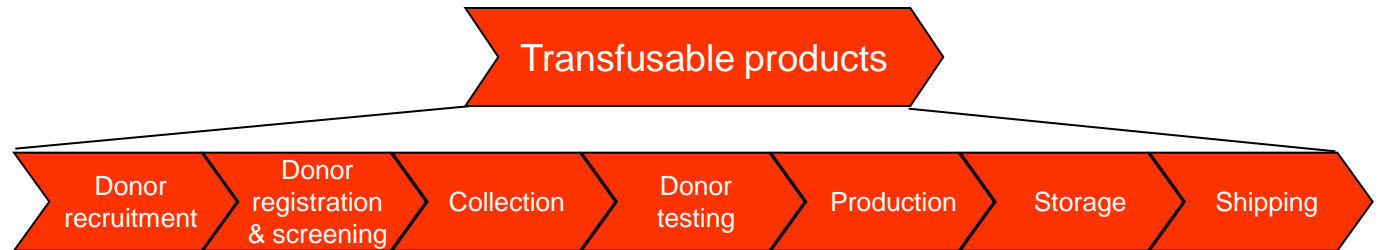
Standardization vs local customization

Product realization



Striving for complete standardization:

- Product specifications
- Core manufacturing processes (work instructions, forms, etc.)



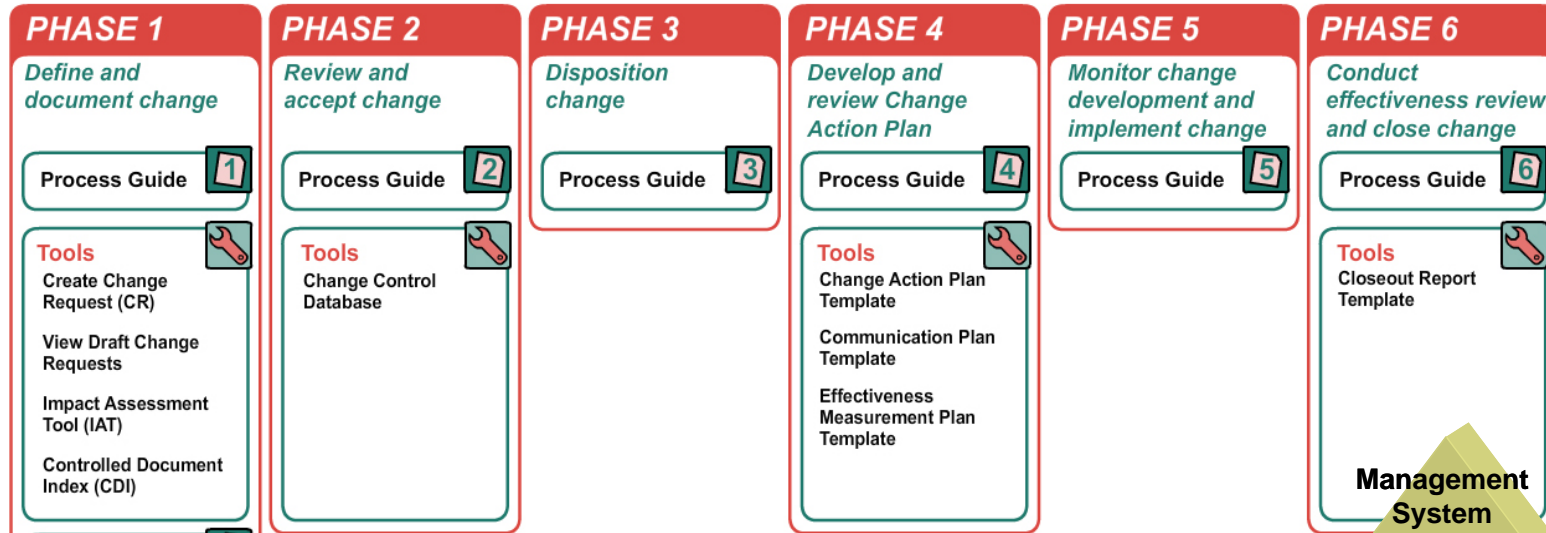
- Product labelling (labels, package insert)

A unit of blood from Vancouver meets clinicians' needs to the same extent as a unit of blood from Halifax

Standardization vs local customization

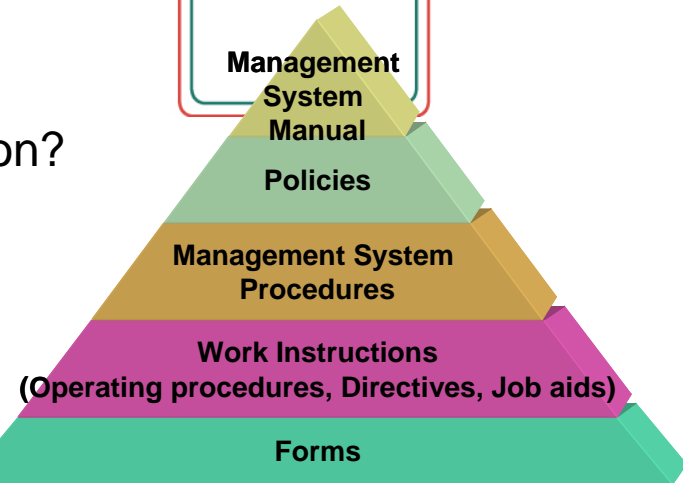
Enabling processes

Change Control Policy  SOP 08 500  Process Guide 



What is the right level of standardization/customization?

- General directions/expectations ⇨ Policy level
- What needs to be done ⇨ Management system procedure
- How it needs to be done ⇨ Work instructions
- How it is documented ⇨ Forms



Quality:

What is the scope of a single, standardized quality program?

Options:

The single, standardized quality program ensures a single set of quality standards, product specifications, processes, and tools will be developed and consistently implemented by all processors and recovery organizations in Canada

The single, standardized quality program will make available a single set of quality standards, product specifications, processes, and tools to all processors to utilize as they wish; audits will ensure compliance with regulations and mandatory standards

Alignment with strategy and principles

- Maintains the same level of quality in each source establishment
- Cheaper in the long term to have a single shared quality management program and set of tools
- Ensures a consistent response to emerging quality situations

- Individual source establishments may implement innovative quality processes faster than the system

Conflict with strategy and/or principles

- Coordinating a response to emerging quality issues may not be as rapid as the current capabilities of some programs

- Allows for variation in product quality
- Allows for variation in product specifications
- Inconsistent response to emerging safety and quality issues (e.g. transmissible diseases), likely leading to higher safety risk in some programs

Supply Chain:

Part 1 – Supply Planning and Processing

TEC Preferred Solutions

- Security of supply management will have to be responsive to external stimuli like changes in demand
- Management of end-user relationships and technology is important for understanding demand and aligning supply
- Centralized processing is needed, if cost-efficiency is to be achieved
- Processing is best supported outside of the hospital environment
- Processing facility locations should be based in-part on tissue shelf-life
- Reduce or eliminate processing of cardiac tissue
- Expand capacity for processing of tissue when the capacity makes the supply more efficient and secure

Public Feedback

- Centralize, enhance and streamline the capabilities of tissue processing and distribution in Canada
- Assess costs of local versus imported tissue sources

Expert Feedback

- Canada needs to increase its processing of tissue allografts
- Centralizing of processing should be considered for efficiency gains
- Reliance on U.S. processors is likely on-going for some tissues
- Need to find the balance between domestic and imported tissue

Supply Chain:

Part 1 – Supply Planning and Processing

System Requirements

- Ensure strong relationships between the demand planning activity and end users
- Produce a single supply and demand plan that balances domestically and imported product and aligns supply with Canadian end-user demand
- Revise and manage against the supply and demand plan to ensure security of supply despite risks
- Centralize tissue processing to improve efficiency and quality
- Determine production capacity for each tissue type and based on an ongoing understanding of demand, utilization, and processing capability
- Evaluate the feasibility of processing advanced tissues in Canadian facilities
- Import product for which domestic production is not sufficient



System Design

COMPONENTS:

- Supply and Demand Plan
- Domestic Processors
- Channels for Imported Tissue
- Canadian Tissue Demand Data
- Canadian Tissue Supply Data
- Processing Capability Evaluation

OPEN QUESTIONS:

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 processors?

Supply Chain: Should there be centralized accountability and authority for ensuring a secure supply of tissue in Canada?

Options:	Yes, a central agency will have the authority to manage domestic processing against the supply plan and will be held accountable	No, a consortium of all Canadian processors and other organizations will adjust the supply plan and processing targets
<p>Alignment with strategy and principles</p>	<ul style="list-style-type: none"> • Strong accountability for security of supply • Rapid ability to adjust processing (and by extension recovery) to meet updated supply requirements • A single organization is accountable for Canadian supply and demand data 	<ul style="list-style-type: none"> • Competition between processors for a greater share of processing may result in greater innovation and efficiency
<p>Conflict with strategy and/or principles</p>		<ul style="list-style-type: none"> • Lower degree of accountability for security of supply • Processors will need to make compromises amongst each other to set supply targets for each processors • Adjusting supply targets to changing market conditions will be less responsive

Supply Chain: If there is a single, central supply planning agency, what is the relationship between supply planning and processors?

Options:	Canadian processors are contracted by the supply planning agency	Canadian processors are integrated into the supply planning agency
<p>Alignment with strategy and principles</p>	<ul style="list-style-type: none"> • Competition between processors for contracts may lead to more rapid innovation and greater efficiencies 	<ul style="list-style-type: none"> • Allows seamless integration between the supply planning process and the production process • Ensures processing capacity will be maintained and made available for production of tissue • Consolidated demand for recovered tissue • Single accountability for product quality • Single accountability for processing data
<p>Conflict with strategy and/or principles</p>	<ul style="list-style-type: none"> • Does not ensure security of supply (as processors could opt to not participate) • Adjustment to the supply plan would require revisions to contracts or contracts that are established with provisions for increased and decreased supply needs 	<ul style="list-style-type: none"> • May be less responsive to innovation

Supply Chain:

Part 2 – Recovery and Inventory

TEC Preferred Solutions

- Tissue recovery should be performed by trained, multi-tissue recovery teams, focused geographically
- Recovery training should be provided by a standard program
- Recovery activity must be linked to demand and must be efficient
- Recovery must be increased to support demand by processors
- Skin should be kept in inventory as emergency stock, in case of a natural disaster or other catastrophe
- Change the funding model to support sharing of inventory across provincial borders
- Centralized distribution would allow cost savings through bulk purchasing
- National distribution system

Public Feedback

- Recovery should maximize the donor's gift
- To make inventory management more efficient, consolidate processing and distribution

Expert Feedback

- Canada needs to increase its recovery of tissue allografts

Supply Chain: Part 2 – Recovery and Inventory

System Requirements



- Consistently train multi-tissue recovery teams
- Recover all tissue types needed at each recovery (except ocular-only recoveries)
- Align recovery activity with the volume required by the supply and demand plan
- Keep sufficient inventory on hand at all times to have a secure supply and ability to respond to emergencies
- Make finished tissue product available through a single tissue inventory with national scope
- Employ a funding model that incentivizes purchase of tissue from the single tissue inventory

System Design

COMPONENTS:

- Recovery Training
- Multi-Tissue Recovery Teams
- Ocular Recovery Teams
- Supply Plan
- Single Tissue Inventory
- Distribution System

OPEN QUESTIONS:

What is the relationship between processors and recovery organizations?

What product is available from the single tissue inventory?



Supply Chain: What is the relationship between processors and recovery organizations? (If processors are contracted)

Options:	Processing facilities contract recovery organizations	Single agency with national scope that operates a recovery organization
<p>Alignment with strategy and principles</p>	<ul style="list-style-type: none"> • Perhaps stronger focus on the maintenance of relationships with sources of tissue donors by some recovery organizations 	<ul style="list-style-type: none"> • Consistent training of recovery teams • Recoveries are coordinated centrally to optimize efficiency of each recovery and the process as a whole • Single source for recovery data • Single point of accountability for recovering adequate volume of tissue
<p>Conflict with strategy and/or principles</p>	<ul style="list-style-type: none"> • Recovery organizations contracted by processors will likely only recover the tissue types for which they are contracted, which may be less efficient • Multiple sources for recovery data • Relying on recovery contracts for necessary supply compromises security of supply 	<ul style="list-style-type: none"> • May require carrying the cost of surplus recovery teams in periods when production is slow

Supply Chain: What is the relationship between processors and recovery organizations? (If processors are integrated)

Options:	Processors contract recovery organizations	Single agency with national scope that operates a recovery organization
<p>Alignment with strategy and principles</p>	<ul style="list-style-type: none"> • Perhaps stronger focus on the maintenance of relationships with sources of tissue donors by some recovery organizations 	<ul style="list-style-type: none"> • Consistent training of recovery teams • Recoveries are coordinated centrally to optimize efficiency of each recovery and the process as a whole • Tight relationship with the single supply and demand plan • Single source for recovery data • Single point of accountability for recovering adequate volume of tissue
<p>Conflict with strategy and/or principles</p>	<ul style="list-style-type: none"> • Multiple sources for recovery data • Relying on recoveries contracts for necessary supply compromises security of supply 	<ul style="list-style-type: none"> • May require carrying the cost of surplus recovery teams in periods when production is slow

Supply Chain:

What product is available from the single tissue inventory?

Options:	Domestically-produced product only	Frequently used product	All product 'selected' for use in Canada
Alignment with strategy and principles	<ul style="list-style-type: none">• A single tissue inventory with national scope would only incur cost of storing domestically-produced product	<ul style="list-style-type: none">• Bulk purchasing of frequently used imported product would save the system money• Cheaper imported product cost could drive greater access to effective product	<ul style="list-style-type: none">• Selected tissues ensure evidence-based quality or tissue• Bulk purchase of all selected tissue product• Cheaper imported product cost could drive greater access to effective product• All selected tissue product would be available through a single ordering interface• Accurate tissue demand data for all of Canada• Greatest opportunity for security of supply
Conflict with strategy and/or principles	<ul style="list-style-type: none">• End users will have to have relationships with multiple suppliers• Would not ensure security of supply	<ul style="list-style-type: none">• End users using specialty tissue products will still need to maintain supply channels with US banks• Would not ensure security of supply	<ul style="list-style-type: none">• New products coming to market in other countries will take time to go through the selection process• End-users will effectively have limited choice of product

Identification, Referral, Consent, and Screening

TEC Preferred Solutions

- Donors should be identified and referred from both hospitals and medical examiner / coroner offices
- Support will be needed to integrate MEs and coroners into the referral pipeline
- Front line hospital staff can play a role in identifying potential donors
- Referrals should be made to a central call centre
- Legislated donor referral
- Professional, trained requestors should be used to obtain consent and should be available 24/7
- Consent can be gained by phone
- The synergy between obtaining consent for organ donation and for tissue donation should be optimized

Public Feedback

- Train all health professionals to recognize donation opportunities
- Change system to ensure donors' wishes are respected

Expert Feedback

- Greatest donation potential is outside the ICU
- Need to make donor identification part of end-of-life care
- Should implement a call centre for tissue referrals
- Need to work with hospitals to increase potential tissue donors

Identification, Referral, Consent, and Screening

System Requirements



System Design

- Refer every potential donor from both hospitals and from ME and coroner offices
- Utilize front-line hospital staff for the identification and referral of potential tissue donors
- Use professional, trained requestors to seek consent
- Make available professional, trained, requestors 24/7 through a referral centre
- Leverage OPOs to seek tissue donation consent from potential organ donors

COMPONENTS:

- Referral Centre
- ICUs
- Non-Acute Hospital Setting
- Medical Examiners
- Coroners
- Requestor Training
- Professional Requestors

OPEN QUESTION:

How should the referral centre(s) be organized?



Identification, Referral, Consent, and Screening: How should the referral centre(s) be organized?

Options:	Single agency with national scope and a single set of standards	Multiple independent agencies and a variety of standards	Single agency with national scope and existing referral centres; a single set of standards
<p>Alignment with strategy and principles</p>	<ul style="list-style-type: none"> • Smallest investment for a referral centre to be available 24/7 • One single source for referral centre data 		<ul style="list-style-type: none"> • Provides a cost-effective option without forcing the closure of provincial centres
<p>Conflict with strategy and/or principles</p>		<ul style="list-style-type: none"> • Duplicates infrastructure across the country • Multiple sources for referral centre data 	<ul style="list-style-type: none"> • Duplicates infrastructure in a few provinces • Multiple sources for referral centre data

TEC Preferred Solutions

- Donor registries should be considered as a mechanism for improving consent rates
- Expressed first person intent/consent should be available to the professional requestor

Public Feedback

- National school curriculum on donation

Expert Feedback

- Need the ability to tailor social marketing for certain demographics and geographies
- There should be an donor registry (linked to an integrated data mgmt system)

Public Awareness

System Requirements

- Provide a registry for the public to express intent/consent
- Ensure the registry system accessible by requestors



System Design

COMPONENTS:

- Donor Registry System



Public Awareness

- Conversations with experts and the public suggest that there should be a single approach to public awareness and social marketing for the country
- The OEC has already recommended a national strategy for public awareness and social marketing that tissue donation awareness efforts could cost effectively leverage for its public awareness and social marketing needs
- The OEC preliminary direction around the necessity of a donor registry is consistent with the preliminary recommendations of this committee
- Based on these facts, we suggest that the tissue community join with the organ community in supporting a national strategy and approach to public awareness and social marketing in which the need for both tissue and organ donation is explicit

OEC DISCUSSION SLIDE –

Public & Professional Awareness, Donor Intent / Consent

OEC Preferred Solutions

- Develop a national approach to increase public and professional awareness, supported by research, taking advantage of technology, measuring outcomes
- Use donor registries to better inform and measure public awareness efforts, improve access to ICU, and to provide info for family consent conversations

Public Feedback

- Raise awareness through public and professional education
- Single Canadian registry for donation
- Make it easier to express first person consent and harder for families to overrule expressed consent

Expert Feedback

- Public awareness and professional education are needed to increase donation
- CBS' experience says national approach must be supplemented by locally-driven specialization

OEC DISCUSSION SLIDE –

Public & Professional Awareness, Donor Intent / Consent

System Requirements



- Design, implement and manage national social marketing efforts
- Design, implement and manage local social marketing efforts
- Coordinate national and local efforts to ensure consistency of messaging and take advantage of economies of scale where possible
- Develop, implement and maintain donor registries

System Design

COMPONENTS:

- National ODT Public/Professional Awareness
- Donor Registry(ies)

OPEN QUESTIONS:

What approach to donor registries should we recommend?

Wrap-Up and Next Steps

Next Steps in System Design

- We will update the strategy map
- We will draft measures for your review in June
- We will integrate all system design requirements and components into a holistic view for your review in June
- The Committee will meet again on Friday, June 18

