

Tissue Expert Committee Meeting

January 13th, 2010

Sheraton Gateway Hotel, Toronto



Meeting Objectives

- Review feedback on the committee's proposed options
- Continue to establish strategic direction for Tissue Donation and Transplantation in Canada
 - Quality systems
 - Increasing tissue donation
 - Canadian production of tissue allografts
- Understand the TDT costing activities underway and the gaps in system data

Agenda

Discussion Item	Time
Welcome and follow-up on action items	8:30 – 8:45
Review of activity to date	8:45 – 9:15
Quality systems	9:15 – 10:15
--Break--	
Increasing tissue donation	10:30 – 12:15
--Lunch--	
Canadian production of tissue allografts	12:45 – 2:45
--Break--	
Costing and data gaps	3:00 – 4:15
Wrap-up and next steps	4:15 – 4:30

Follow-up on Action Items

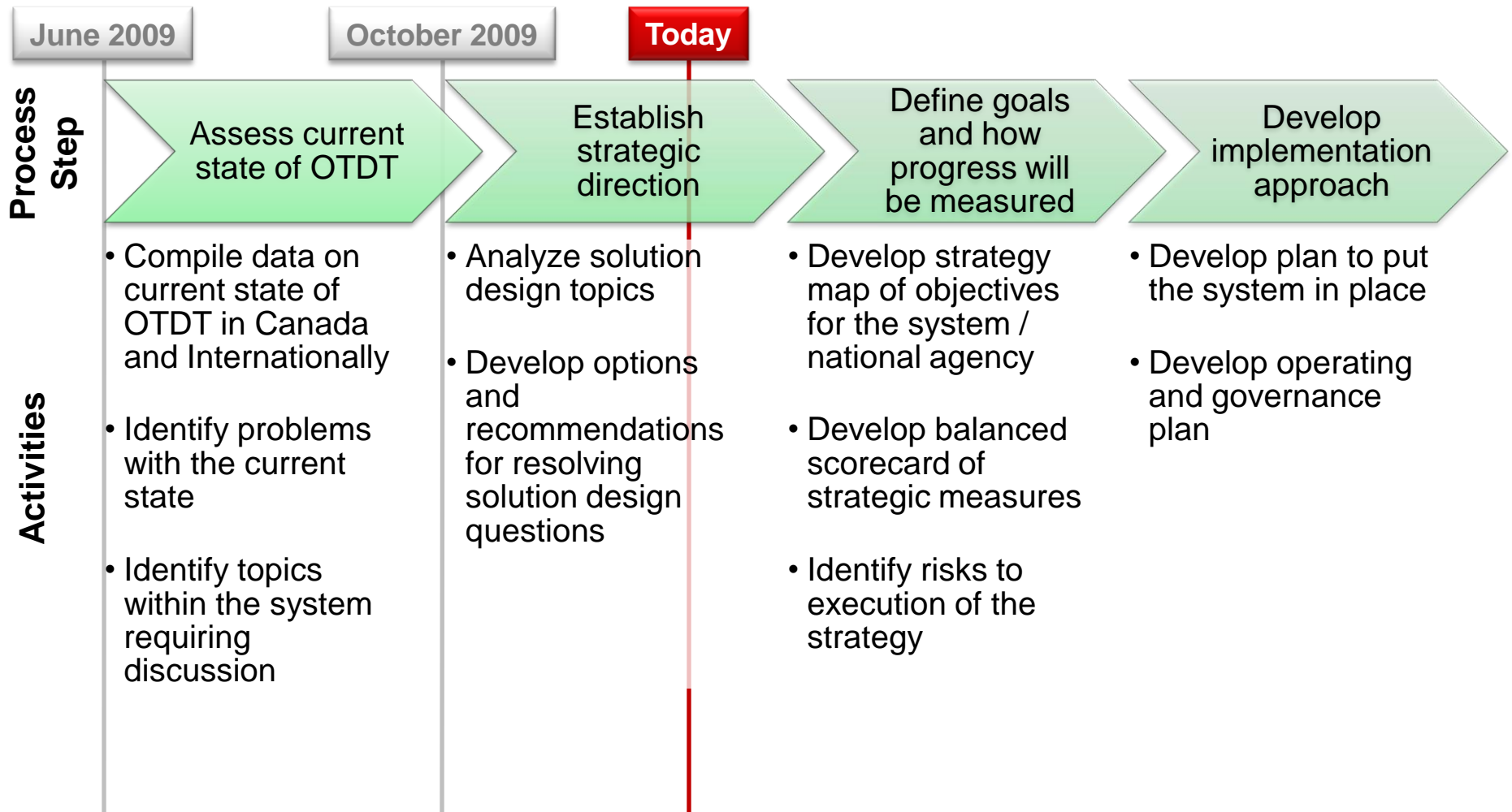
- The ocular supply survey
- The Canadian supply survey
- Draft public case for change available for review



Review of Activity to Date



The Strategic Planning Process



The preliminary recommendations addressed design questions to resolve system challenges

System Challenge

Design Question

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?

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

Public Engagement To-Date

- Two dialogues complete (London, Vancouver)
- Future dialogues scheduled in Edmonton, Halifax, Moncton, Regina, St. John's (NFLD), Toronto, and Winnipeg
- At the public dialogues we have presented the case for change and have used a facilitation approach that allows the participants to raise the topics and issues that they wish to discuss
- The format of the public dialogs is being updated based on the learnings from the first two dialogues
- Feedback from the dialogues has been positive based on both the participation in discussions and the evaluation completed by participants at the end of the day

Expert Engagement To-Date

- **Initial visit** to Saskatchewan
 - Meeting with medical directors of transplant program and ICU, tissue bank staff and TEC member
 - Meeting with St. Paul's Hospital CEO
 - Noon rounds at St. Paul's with Regina participants linked by videoconference
 - Multi-disciplinary rounds at St. Paul's
- **Upcoming expert engagements** events have been confirmed for January and February in New Brunswick, Newfoundland and Labrador, Nova Scotia, Alberta, and British Columbia
- Saskatchewan discussions were driven by **three questions**
 1. Are we missing any critical elements in the Case for Change?
 2. What is the most important element that needs to be fixed?
 3. Are there other options we should consider as part of system design?
- The **Case for Change received strong support** and no major gaps were identified
- The initial preferred **options presented to the participants were well-supported** with no major conflicts or new suggestions

October TEC Meeting Output (1/4)

Question: How can the Canadian tissues system best ensure consistent safety and quality?

Preferred Options:

- ❖ A nationally standardized quality program at source although “quality program” needs to be defined
 - ❖ Acknowledgement that a standardized quality program could have some customization at the regional/local level.
- ❖ There is support for national quality standards for transplant establishments

Public Feedback:

- Set and enforce national standards; strict guidelines and evidence requirements to ensure safety of all tissue donations
- Enforce greater compliance with existing regulations
- Banks need to assume full responsibility for the quality of end products

October TEC Meeting Output (2/4)

Question: What is the best strategy to achieve the regulatory requirements for traceability?

Preferred Options:

- ❖ Traceability is an essential aspect of the system and that status quo is not an option
- ❖ There is a need to have accountability and audit for traceability which should also cover imported tissues
- ❖ Standardized packaging and labelling including coding, ISBT 128, unique donor numbers, real time integrated information system
- ❖ An information platform is needed that would hold different data including donors, recipients and all types of tissue products
- ❖ Need standard guidelines for the information a recipient receives (informed consent) but flexibility in how the information is given
- ❖ Accreditation and audit should be a requirement

Public Feedback:

- Create a program for national traceability

October TEC Meeting Output (3/4)

Question: For recovery and processing, what is the best balance between domestic and imported tissue?

Preferred Options:

- ❖ Tissue is a national resource for all Canadians
- ❖ Donation is not a right but there is a need to look at principles of access
- ❖ 100% importation is not a valid option
- ❖ Security of supply of donation can be approached separately from security of supply of processing
- ❖ Recommend a combination of Canadian and American donor source and processing
- ❖ Security of supply management will have to be responsive to external stimuli, including economic changes and changes in demand and supply
- ❖ A call centre that would support tissue donation would improve access to potential tissue donors

Public Feedback:

- Increase donation capability for tissues
- Assess costs of importing versus local procurement for tissues
- Ensure reliable procurement by getting tissues locally

October TEC Meeting Output (4/4)

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

Preferred Options:

- ❖ There should be the capacity/motivation for a Canadian supply side to take advantage of innovation and new technologies that would grow out of the demand in Canada.
- ❖ Although supply and demand are different, a nationally organized program with regional or provincial hubs is recommended
 - ❖ Supply could be regionally based to take advantage of efficiencies
- ❖ End user relationship management is important to align supply with demand
 - ❖ There has to be an intimate relationship with the users both from demand and supply point of view; this could be at a national/regional level or the individual user level
- ❖ Appropriate medical utilization management needs to be part of the strategy
- ❖ Demand forecasting should be driven by the end-user relationship strategy and technology

Public Feedback:

- Streamline processing and distribution
- Create a national inventory system to maximize available Canadian product
- Reduce the number of tissue banks

Quality Systems

Purpose of this Discussion

- In our October meeting, the committee supported, in principle, national standards for quality systems to ensure safety and quality in the Tissues system
- The committee asked for additional discussion of what a national quality system for tissues might entail
- This presentation will explore what would be involved in implementing and sustaining a quality system for tissues



Increasing Tissue Donation

Purpose of this Discussion

- In October, the committee agreed that Canadian demand would best be met by a balance of domestic and imported tissue, but that any successful system design would include increased Canadian donation of tissue
- Canadian Blood Services has developed a paper to support the discussion of the appropriate strategic direction to increase tissue donation in Canada
- The objective for this conversation is to develop preliminary recommendations on
 - how tissue donors are identified and referred,
 - how consent is obtained, and
 - how tissues are recovered

Tissue Donation

Tissue Donation Process



- The scope of our conversation on tissue donation is limited to identification and referral, consent, and recovery

Donor Potential

- The number of potential tissue donors in the acute care setting could meet the gap between basic allograft supply and demand, even after considering consent rates**
- There is also an opportunity to identify donors outside the acute care setting e.g. A review of medical examiner/coroner databases indicated that 43% of accidental deaths and 44% of natural deaths met eligibility criteria for tissue donation*.

* Tissue Donation Potential Beyond Acute Care, Prepared by CIHI for CCDT, 2004

** Estimating Potential Tissue Donors in Canada from 1995-2000: An Exploratory Analysis Based on Acute Care Hospital Admission Data, Prepared by CIHI for CCDT, January 2004

Identification and Referral

- Multiple professional groups can be involved in the identification and referral of tissue donors:
 - Paramedics
 - Emergency department staff
 - Coroners / medical examiners
 - Funeral home directors
- Legislation requiring the referral of tissue donors currently exists in some provinces
- In regions where tissue recovery capacity does not exist, potential tissue donors are not referred
- Past experience demonstrates that legislation and 'Routine Notification and Request' practice implementation alone are not enough to sustain increased donation performance

Options for Discussion:

- Identification and referral in hospital by front-line health care providers
- Identification and referral in hospital by functions or departments with responsibility for recording deaths
- Identification and referral in medical examiner and coroner offices

Consent

- Currently consent is typically sought by the organization to which the potential donor was referred (either an OPO or a tissue bank)
- In some jurisdictions, OPOs are involved with obtaining consent for both the donation of organs and tissues from a potential donor
- Practice is to obtain consent for donation from next of kin irrespective of province legislation and possibly in conflict with expressed first person consent

Options for Discussion:

Who:

- Front-line health care providers that have established contact with the potential donor's next of kin seek consent
- Dedicated or trained coordinators or requestors seek consent from the potential donor's next of kin

How:

- Obtain consent through a telephone conversation
- Ready access to donor registries to inform consent conversations with next of kin

Canadian mechanisms for expressing intent/consent

	DPMP (2008)		Registry	Mechanism to Indicate Intent / Consent	Performance
	Organ	Tissue			
BC	12.3	116	Opt-in and Opt-out	On-line or mail in registration form	734,000 registered (17% of pop.)
AB	11.4	92	No	Sign health care card - either yes or no	Unknown
SK	12.0	30	No	Apply a sticker to health card to indicate intent (not consent)	Unknown
MB	11.7	151	No	Sign donor card (available on-line or at all licensing agents)	Unknown
ON	13.6	123	Opt-in	When renewing health care card or by mailing in a form from Trillium Gift of Life or MOHLTC	~ 27% of people with photo health care card
QC	19.4	n/a	No	Sign and affix a sticker to health card. Independent registry kept by notaries	Unknown
NB	16.5 (Atlantic combined)	234	No	Sign health care card - either yes or no	262,100 yes – (36% of pop.) 224,923 – no (31% of pop.)
NS		152	Opt-in	Register via health care card renewal	~500,000 (50% of pop.)
PE		0	No	Affix a red sticker on health card or have a red heart engraved on driver's license	Unknown
NL		14	No	Sign organ donor card or check the box on the driver's license renewal form	Unknown

Usefulness of Registries

- Reported usefulness of consent to donate registries identified by Canadian and international sources and internationally:

Utility	Jurisdiction
<p>Supports public awareness:</p> <ul style="list-style-type: none"> – Powerful call to action – Supports targeting and assessment of the effectiveness of public awareness / marketing activities – Allows monitoring of registrations by demographic profile and geography to better target education activities 	<p>ON, BC, USA, Australia</p>
<p>Supports donation consent process:</p> <ul style="list-style-type: none"> – Tool to inform donor families of loved one's wishes – If recognized as legally binding, assures registrants that their choice is honored – Provides health professionals and/or OPO with an accessible source of information about consent – Provides an entry point to a conversation about donation with family 	<p>ON, BC, USA</p>
<p>Increases effectiveness and efficiency:</p> <ul style="list-style-type: none"> – On line access viewed as more secure and timely than manual processes – Contributes to more timely donor identification and management, which may translate to improved OTPD and graft survival rates and save the additional costs associated with obtaining family to consent 	<p>BC, USA, UK, Australia</p>

Recovery

- Most provinces do not have programs to allow for donation outside of larger population centers
- Larger tissue programs tend to use tissue recovery teams to recover multiple tissues from a single donor
- Ocular tissue recovery currently exhibits a different general model in that physicians **often** do the recoveries and there **is** a larger recovery network in comparison to other tissue types

Options for Discussion:

- Physician recoveries
- Tissue specialist teams
- Multi-tissue recoveries
- Ocular recovery network

Public and Expert Feedback on Tissue Donation

Public:

- Increase donation capability
- Educate health professionals to educate the public on tissue versus organ donation
- Educate the public on the importance of donating tissue as well as organs
- Legislate the recovery of tissue without requiring the permission of the deceased's family

Expert:

- Emergency departments and medical wards are areas of opportunity where potential tissue donors are lost
- Professional and public education and awareness are critical to increasing tissue donation.

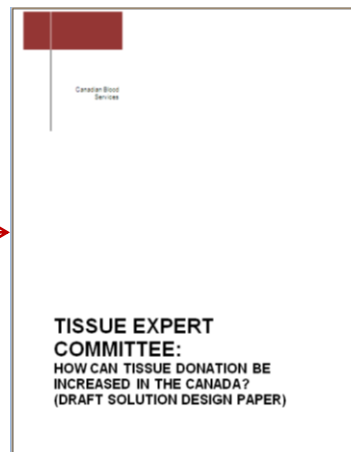
Today's Discussion:

Case for Change

What are we trying to fix?

Design Questions

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



What are the various ways we could proceed?

TODAY'S DISCUSSION

Leverage your expertise to arrive at the best possible option.

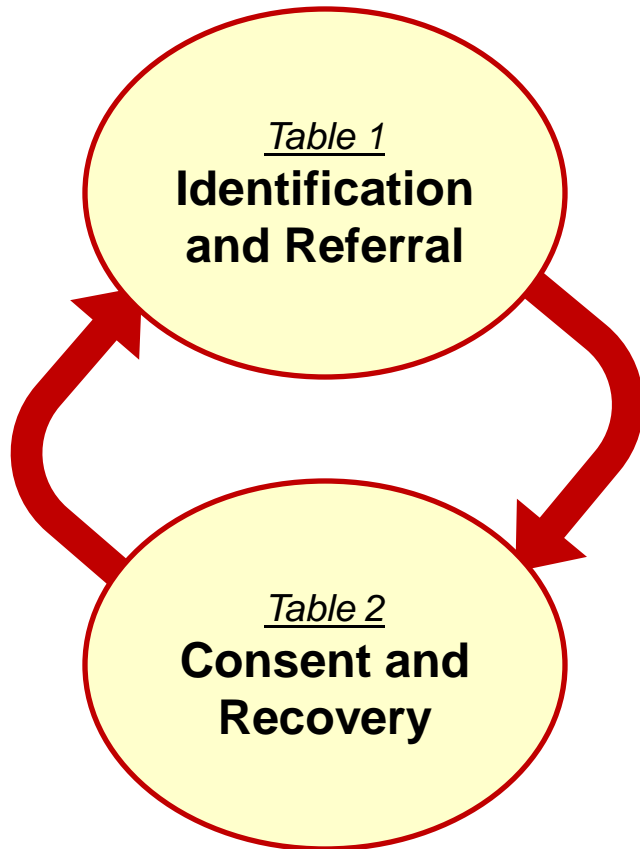
Discussion Approach:

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

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

Discussion Approach:

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



1. Discussion begins at your home table (30 minutes)
 - Choose a host and scribe
 - After 30 minutes rotate to the next table (all except the Table Host)
2. At new table (15 minutes)
 - Host summarizes previous discussion
 - React to the prior group’s ideas/add ideas to table top
 - Scribe continues to capture thoughts/outputs
3. Return to your home table (15 minutes)
 - Host summarizes reactions and additions of other group to the original work
 - Prepare final conclusions for plenary presentation
 - Scribe – captures the overall output for the table
 - Determine presenter for plenary
4. Plenary discussion (10 minutes each topic)
 - Each table presents conclusions to each question discussed at their table

Challenge questions for each group to answer

Table 1: Identification and Referral

1. What donor pool(s) will best yield the desired supply?
2. How can the target donor pool(s) best be identified and referred?
3. What mechanism(s) need to be implemented to improve identification and referral?

Table 2: Consent and Recovery

1. What is the best way to obtain consent for donation?
2. What is the most efficient and effective route for recovering sufficient tissue to achieve supply targets?
3. What mechanism(s) need to be implemented to improve consent and recovery practices and results?

Keep In Mind...

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

Table Groups

Table 1
**Identification
and Referral**

Mike B
Mary
Scott
Brian
David H
Sean
Jim

Table 2
**Consent and
Recovery**

Locksley
Chris
Mike G
Janet
Dermott
Kim

Canadian Production of Tissue Allografts

Purpose of this Discussion

- In October, the committee agreed that Canadian demand would best be met by a balance of domestic and imported tissue, but that this balance would be tissue specific with some tissues being completely imported and some possibly being completely domestic
- Canadian Blood Services has developed two papers to support the discussion of the appropriate strategic direction for each tissue in regards to production:
 - “*What role should surgical bone have in the Canadian tissue system?*” and
 - “*What is the role of Canadian allograft processing in the future?*”
- We would ideally conclude our discussion on this topic today by having preliminary recommendations on
 - how much of each tissue type Canada should process,
 - how much of each tissue type Canada should recover (and export for processing), and
 - how much of each tissue type Canada should import

Surgical Bone – Model Comparison

Canada:

- 15 Canadian tissue banks (7 “stand alone surgical bone banks”) recovered over 1700 Femoral Heads (FHs) in 2008
- Average number of FHs recovered by programs is 125 (min 4, max 458)
- The number of surgical bone banks has been decreasing
- 5 of 15 banks irradiated FH grafts in 2008

Australia:

- Majority of musculoskeletal tissue is from living donors
- Due to increasing demand there is a trend towards using cadaveric donors

United States:

- Few surgical bone programs
- FHs and other cancellous bone grafts are readily available from deceased donors

United Kingdom:

- NHSBT Tissue Service coordinates with 91 orthopedic departments and recovers FHs from 5000 patients per year
 - FHs are provided as fresh frozen or gamma irradiated

Surgical Bone – Options and Considerations

Options for Discussion:

- **Status quo** – Keep existing surgical bone programs and processes in their current state
- **Centralized and coordinated** – Standardized national program with trained staff onsite, recovered tissue evaluated and stored centrally (UK model)
- **Transition away from surgical bone banking** – Use FHs from cadaveric donors and pre-processed cancellous bone in procedures where FHs are morselized

Considerations:

- Understanding how FH grafts are currently used within Canada will assist with defining a role for surgical bone banking

Tissue Production Models (excluding surgical bone)

Canada:

- Allograft production by Canadian banks has remained stable since 2002 on average
- Yield per donor is 21 allografts per donor on average
- Comprehensive tissue banks have demonstrated greater efficiency as demonstrated in their production per million population performance

United States:

- Competitive, private-sector market servicing domestic and international demand
- 32 facilities processing 49,000 donors or about 2,141,152 allografts and tissue devices with a yield of 49 allografts per donor
- 86 ocular recovery programs supporting distribution of about 50,122 corneas

United Kingdom:

- Competitive market with the largest market player associated with NHSBT
- NHSBT Tissue Service manages 400 cadaveric recoveries annually (supplying about 100% of skin market, 70% of base bone product market, 50% of surgical bone market, and 10% of heart valve market)

Canadian Production and Utilization – Ocular

Allograft Product	Surgical Utilization	Canadian Supply	Imported Supply
Corneas (PK, DALK, DSAEK)	1,976 (2008)	2,404 (2008)	0%
Sclera	988 (2008)	1,019 (2008)	0%
Amniotic membrane	Unknown	200	Unknown

General Notes:

- 65 ophthalmologists transplanting corneas
- 75% of surgery cancellations are due to tissue unavailability; there is a cornea waiting list of 2,348 patients as of 2008
- There is wide variability in cornea availability by province
- Ocular tissue processing has increased 14% between 2002 and 2008

Market Direction:

- Shift to greater utilization of partial thickness corneal transplant procedures (now 36.1% of all transplants)
- Partial thickness processing has been implemented by two Canadian eye banks
- DMEK procedures, increasingly used in the US, has a tissue discard rate of 30%

Canadian Production and Utilization – Skin

Allograft Product	Surgical Utilization	Canadian Supply	Imported Supply
Skin	1,513 (Est. 2002)	768 (2008)	50% (Est.)

General Notes:

- 4 Canadian tissue banks identify as skin banks and provide to 14 burn treatment centers
 - 2 banks in Alberta supplied 71% of Canadian supply
 - Remaining banks supplied 27% and 2% of Canadian supply
- No Canadian skin supply is directed at the dental market
- Skin allograft production by Canadian banks has decreased 65% between 2002 and 2008

Market Direction:

- Autologous skin transplantation is utilized when possible to avoid rejection
- The use of laboratory cultured autografts is growing
- Human, cultured human, and xenograft tissue sources are all in use for surgical and wound care applications
- Surgeons are trending towards ordering skin from commercial US suppliers

Canadian Production and Utilization – Cardiac

Allograft Product	Surgical Utilization	Canadian Supply	Imported Supply
Cardiac	801 (Est. 2002)	105 (2008)	87% (Est.)

General Notes:

- 3 banks process cardiac valves
- 1 tissue bank supplies unprocessed cardiac tissue to US processors and is not counted in the Canadian supply figure
- Canadian banks currently do not produce vascular tissue (veins)
- Cardiac tissue processing decreased 58% and recovery decreased 56% between 2002 and 2008

Market Direction:

- Human tissue valves are in short supply (especially smaller sizes)
- Limitations of mechanical valves is risk of thrombosis
- Human allograft valves are utilized in approximately 4% of valve replacement cases with remaining market share captured by mechanical and xenograft valves.

Canadian Production and Utilization – Tendons and Soft Tissue

Allograft Product	Surgical Utilization	Canadian Supply	Imported Supply
Tendons	1,232 (Est. 2002)	945 (2008)	23% (Est.)
Fascia lata	Unknown	46 (2008)	Unknown
Meniscus	Unknown	30 (2008)	Unknown
Pericardium	Unknown	29 (2008)	Unknown

General Notes:

- 5 banks produce tendons, 2 produce fascia and meniscus, 1 produces pericardium
- Attributes of the tissue produced vary between programs
- Tendon processing in Canada increased 103% while soft tissue processing decreased 75% between 2002 and 2008

Market Direction:

- There are 1,181 orthopedic surgeons practicing in Canada
- Tendons are in high demand, especially in the sports medicine community
- The dental community utilizes soft tissue, but there is currently no Canadian production of soft tissue directed at dental demand

Canadian Production and Utilization – Musculoskeletal Base Tissues, Machined and Demineralized Grafts

Allograft Product	Surgical Utilization	Canadian Supply	Imported Supply
Surgical bone	820 (2008)	1,271 (2008)	0% (Est.)
Cancellous	3,313 (2002)	1,838 (2008)	45% (Est.)
Small structure	2,762 (2002)	139 (2008)	95% (Est.)
Large structure	2,418 (2002)	869 (2008)	64% (Est.)
Machined grafts	Unknown	0 (2008)	100%
DBM	64,004cc (2005)	0 (2008)	100%

General Notes:

- 6 tissue banks process cadaver bone with two more intending to enter the market
- Product characteristics vary between programs
- Processing of cancellous bone increased 100% while processing of small and large structural grafts decreased by 67% and 41% respectively between 2002 and 2008

Market Direction:

- Cancellous and small structure grafts are high demand products where often there is not the supply to meet end user requests
- Newer products featuring innovative developments (e.g. stem cells) are garnering awareness that is driving adoption

Canadian Production of Tissue Allografts - Discussion

- In our last meeting, the committee decided that in general, a balance of domestic and imported tissue was the best supply approach
- The committee also recognized that determining the right balance needs to be tissue-specific
- Because of the number of tissue types we want to cover, this discussion will be different from the Donation conversation:
 - Table facilitators
 - Shorter discussions without rotations
 - Feedback and synthesis for every tissue type will occur in plenary

Discussion Timing

TIME	TABLE 1	TABLE 2
Choose tables for discussions		
10 minutes	• Surgical bone questions	• Surgical bone questions
10 minutes	• Ocular questions	• Skin questions
Plenary		
20 minutes	• Report surgical bone question 1	
		• Report surgical bone question 2
10 minutes	• Report ocular	
		• Report skin
Choose tables for next discussions		
10 minutes	• Cardiac / MS questions	• Tendons / soft tissue questions
Plenary		
20 minutes	• Report cardiac / MS	
		• Report tendons / soft tissue

Production and Utilization Questions

Surgical bone:

1. What is the future of surgical bone usage in Canada?
2. If surgical bone continues to be used, what is the best approach for producing it?

Other tissue types:

1. To what degree should Canada be in the business of processing this tissue type?
2. To what degree should Canada be in the business of recovering this tissue type?

Costing and Data Gaps

Purpose of this Discussion

- Part of developing a plan for an OTDT system is understanding the financial costs of the changes proposed to the system
- In order to understand these costs and assess the overall cost of the plan, we have launched the costing workstream of the planning process
- Today the costing process being used and the preliminary results of the first phase of costing work will be presented followed by a discussion of costing gaps and limitations

Study Purpose, Method & Scope

- Study Purpose:
 - To identify the costs associated with each element of Tissue Donation and Transplantation system
 - Along supply chain
 - Objective: To establish an “order of magnitude” costing estimate
- Method:
 - Review of existing reports and data sources
 - Documentation of gaps/limitations
- Scope:
 - Canada minus Quebec
 - No new data collection
 - Dental + non-dental (importation)
- Framework for Analysis:
 - Domestic tissue banking
 - Tissue Importation
 - Transplantation (corneas only)

Overview of Tissue Banking in Canada, 2008/09

- 23 banks in Canada – 2008 (excluding Quebec)
 - 3 Comprehensive Tissue Banks
 - 1 Recovery Bank with Processing Partnerships
 - 7 Surgical Bone Banks
 - 7 Tissue Specific Banks - 5 Musculoskeletal (MSK), 1 Cardiac, 1 Skin
 - 5 stand-alone Eye Banks
- A comparison of tissue bank activity between 2002 and 2008:
 - no major changes in overall production activity
 - some changes in the number of specific tissue types produced
- Yield: average of 21 allografts/donor
 - Higher allograft yields at comprehensive tissue banks
- Cost efficiencies correlated with:
 - Higher donor volumes
 - Centres processing multiple types of tissues

Source: CBS (2009), "Tissue Expert Committee: What is the Role of Canadian Allograft Processing in the Future? (Draft Solution Design Paper)".

Human Tissue Banking (Canada)

General Approach for Determining Total Cost of Human Tissue Banking

1. Determine Canadian supply

- Canadian Blood Services (2009), “National Survey for Supply of Human Allograft Tissue in Canada “. Snapshot survey asks about 2008 volumes
 - Assumptions:
 - no double-counting of recoveries , especially in cases where recovery and processing are undertaken in different places.
 - Tissues/Donor ratios have remained constant over time

2. Calculate cost per donor for each tissue type

- Goss Gilroy Inc. (2003), “Human Tissue Banking in Canada, Costing and Economic Analysis,” prepared for CCDT. Presents costs by process flow function.
- Limitations:
 - Data is dated (2002) – pre-CTO/CSA, although strong QA focus
 - Data anonymized and averaged
 - Small study sample size
 - Due consideration not given to cost subsidies (e.g. by hospital)
 - Not a true case costing exercise

3. Calculate total cost by process flow

Summary: Calculated Canadian Tissue Banking Costs, 2009

Costs per Tissue Donor	Calculated Average 2009 Costs				
	Ocular	Cadaveric MSK	Living MSK	Skin	Cardio-vascular
Screening & Recovery	\$483	\$4,992	\$107	\$1,156	\$1,333
Testing	\$107	\$793	\$73	\$175	\$135
Processing	\$256	\$1,226	\$12	\$2,192	\$1,248
Storage and Distribution	\$145	\$719	\$66	\$755	\$335
Quality Assurance	\$165	\$401	\$123	\$641	\$462
Total Variable Costs	\$1,156	\$8,132	\$381	\$4,918	\$3,514
Capital	\$326	\$723	\$106	\$1,267	\$480
Salaries & Wages	\$252	\$868	\$181	\$210	\$130
QA	\$0	\$44	\$26	\$15	\$44
Other Fixed Expenses	\$73	\$498	\$42	\$2,103	\$137
Total Fixed Costs	\$651	\$2,134	\$354	\$3,595	\$791
Total Costs	\$1,807	\$10,266	\$735	\$8,513	\$4,305
Variable Cost Proportion	64%	79%	52%	58%	82%
Fixed Cost Proportion	36%	21%	48%	42%	18%



Key Assumptions/Limitations

- **Ocular Tissue** (sample: 1 Cdn eye bank, 1 Cdn tissue bank represented ~8% of Cdn volumes)
 - Difference in CDN eye bank and tissue bank costs attributed to fact that the eye bank's donor volume exceeded that for the tissue bank by a factor of nearly five, hence labour costs per donor were much lower.
 - Gap: no investigation into cost subsidies that could be artificially lowering costs.
 - US data (n=1): both variable and fixed costs higher (total variable costs of \$1500 CAD; total fixed costs of \$920 CAD); exchange rate of \$1.5625 CDN/US)
- **Surgical Bone Banking** (sample: 4 Cdn tissue banks represented ~1/3 of total volumes)
 - Several factors for lower SBB costs—integration with surgery, cost subsidies by hospital, lesser focus on QA
 - Gap: no investigation into cost subsidies that could be artificially lowering costs.

Key Assumptions/Limitations

- **Cadaveric MSK Banking** (sample: 2 Cdn tissue banks represented ~1/2 of Cdn volumes)
 - Large difference between Min and Max values attributed to differing processes
 - Min – used technicians to recover/process multiple tissue types; Max – medical interns for single tissue recovery
 - Assumption: Average costs are representative of 2009 environment.
- **Skin** (sample: 2 Cdn tissue banks represented ~63% of total Cdn volumes)
 - Assume 20 skin grafts/donor
 - Costing data available from one US bank (total variable costs of \$3572 CAD; total fixed costs of \$1906 CAD) – US values between min and max Cdn values
 - Report suggests fixed costs for US bank were probably lower due to higher volumes – suggesting economies of scale; not known how capital costs would affect fixed costs (e.g. costs of owning a dermatome)
 - Assume yield/donor consistent over time
- **Cardiac Tissue** (sample: 2 Cdn tissue banks represented ~56% of total volumes)
 - Assume yield: 2/donor
 - To retain anonymity, report only presented average costs (no min or max). However, total costs per donor deemed to be comparable (15% difference).
 - Assume yield/donor consistent over time

Estimated Cost of Human Tissue Banking in Canada, 2009

Estimated 2009 Tissue Banking Costs - Canada	Donor Volumes	Total Variable Costs	Total Costs (V+F)
Corneas only	2,336	\$ 2,700,606	\$ 4,220,415
Ocular (with other tissues processing)	334	\$ 386,131	\$ 603,433
Surgical Bone Banking	1,748	\$ 666,444	\$ 1,285,592
Cadaveric Musculoskeletal Tissue Banking	278	\$ 2,119,462	\$ 2,675,613
Skin Tissue Banking	156	\$ 767,249	\$ 1,328,057
Cardiac Tissue Banking	125	\$ 410,055	\$ 502,343
TOTAL		\$ 7,049,948	\$ 10,615,453

- Note: total tissue bank budgets across Canada estimated to be around \$10 million, excluding revenues, recoveries, subsidies. (Source: 2009 CBS Supply Survey). Same order of magnitude.

Tissue Importation Costs

Estimated Importation Volumes: Bone Products

	BONE					
	Surgical Bone only	Pre-packaged Cancellous (50cc)	Demineralized Bone Products (cc)	Mineralized Freeze Dried Bone Products	LARGE Structural Bone Grafts	SMALL Structural Bone Grafts
Annual Historical Demand	1,883	3,361	48,003	15,237	2,418	2,795
Growth Rate (CAGR of 2008-13)	N/A	5.0%	10.0%	10%	10.0%	5.0%
2008/09 Utilization	820	4,505	70,281	26,994	3,241	3,746
2008/09 Domestic Supply	1,271	1,838	-	-	869	139
Est. Importation Volumes	-	2,667	70,281	26,994	2,372	3,607

CIHI (2003), "Demand for Allograft Tissue in Canada" and "...Integrating Dental Demand"

CCDT (2006), "Evaluation of Surgical Bone Banking and Utilization in Canada"

BCC Research (2008), "Market Research Report: Organ and Tissue Transplantation and Alternatives, HLC102D"

Note: Growth in demand for Remineralized products assumed to be the same as for demineralized bone products.

CBS (2009), "Supply of Human Allograft Tissue in Canada, Preliminary Data Analysis"

CBS (2009), "Tissue Expert Committee: What is the Role of Canadian Allograft Processing in the Future?"

For DBM, historical demand (2005) was 64,004 cc, including Quebec. This was reduced by 25% to exclude Quebec volumes.

Assumption: Estimated Importation Volumes assume no wastage (all products imported were transplanted).

Estimated Importation Volumes: Tendons, Skin, Soft Tissue

	Tendons	Skin Products (sq cm)	Soft Tissue (e.g. fascia lata)
Annual Historical Demand	1,232	151,300	608
Growth Rate (CAGR of 2008-13)		7.0%	5.0%
Annual Growth Rate	12.2%		
2008/09 Utilization	2,465	227,061	815
2008/09 Domestic Supply	945	74,900	76
Est. Importation Volumes	1,520	152,161	739

Convert # grafts into cc's of skin tissue required. Assume 100 cm² of skin required per graft. Convert packages of skin (domestic supply) to surface area assuming average of 100 cm² per package.

GAP: Exclusion of dental volumes - uncertainty about reported data.

CIHI (2003), "Demand for Allograft Tissue in Canada"

Note: forecasted 1-2 year increase in demand for tendon tissue was 26%. Based on 2-year increase, CAGR=12.2%.

BCC Research (2008), "Market Research Report: Organ and Tissue Transplantation and Alternatives, HLC102D"

Assume: growth in demand for soft tissues is same as growth in demand for base allografts (BCC).

CBS (2009), "Supply of Human Allograft Tissue in Canada, Preliminary Data Analysis"

Assumption: Estimated Importation Volumes assume no wastage (all products imported were transplanted).

Estimated Importation Volumes: Ocular & Cardiac Tissues

	CARDIAC				OCULAR		
	Aortic Valves	Pulmonary	Conduits	Pericardium	Corneas	Sclera	Amniotic Membrane
		Valves		Pieces			
Annual Historical Demand	285	215	301	16	2,345	158	51
Growth Rate (CAGR of 2008-13)	5.2%	5.2%	5.2%	5.2%	N/A	N/A	N/A
Annual Growth Rate							
2008/09 Utilization	387	292	409	22	1,976	988	206
2008/09 Domestic Supply	47	35	18	29	2,404	1,019	212
Est. Importation Volumes	340	257	391	-	-	-	-

CIHI (2003), "Demand for Allograft Tissue in Canada"

BCC Research (2008), "Market Research Report: Organ and Tissue Transplantation and Alternatives, HLC102D"

CBS (2009), "Supply of Human Allograft Tissue in Canada, Preliminary Data Analysis"

Assume that ratio of utilization/production for amniotic membrane is similar to that of sclera.

Assumption: Estimated Importation Volumes assume no wastage (all products imported were transplanted).

Estimated Importation Costs: Bone Products

	BONE						Subtotal (Bone)
	Surgical Bone only	Pre-packaged Cancellous (50cc)	Demineralized Bone Products (cc)	Mineralized Freeze Dried Bone Products	LARGE Structural Bone Grafts	SMALL Structural Bone Grafts	
Est. Importation Volumes	-	2,667	70,281	26,994	2,372	3,607	105,921
<u>Determination of Unit Costs</u>							
Per Unit Costs	N/A	\$ 763.90	\$ 202	\$ 202	\$ 1,189.61	\$ 1,303.22	
Adjusted to 2009 values (\$CDN)		\$ 834.74	\$ 234.30	\$ 234.30	\$ 1,299.92	\$ 1,424.07	
Total Importation Costs	N/A	\$ 2,226,241	\$ 16,466,661	\$ 6,324,609	\$ 3,083,411	\$ 5,136,603	\$ 33,237,524
Allocation to Dental (cost)		negligible	~10%	100%		negligible	
Dental Import Costs			\$ 1,646,666	\$ 6,324,609			\$ 7,971,275
Non-Dental Import Costs		\$ 2,226,241	\$ 14,819,995	\$ -	\$ 3,083,411	\$ 5,136,603	\$ 25,266,249

Source: CCDT (2006), Deloitte Inc. "Human Tissue Importation Practices in Canada". Calculated per unit pricing in \$CAD

Note: Importation study excludes imports by dentists and oral surgeons.

Peak Research (2006), "Market Evaluation of Demineralized Bone Matrix Products In Canada" (cost of \$12.9 million USD for 64,000 cc's)

Assumption: that per unit costs for mineralized bone products is same as that for demineralized bone products.

Estimated Importation Costs: Tendons, Skin & Soft Tissue

	Tendons	Skin Products (sq cm)	Soft Tissue (e.g. fascia lata)
Est. Importation Volumes	1,520	152,161	739
<u>Determination of Unit Costs</u>			
Per Unit Costs	\$ 1,363.46	\$ 1.25	\$ 707.45
Adjusted to 2009 values (\$CDN)	\$ 1,489.89	\$ 1.33	\$ 752.60
Total Importation Costs	\$2,264,627	\$ 202,342	\$ 556,174
Allocation to Dental (cost)		dental excl	dental excl
Dental Import Costs			
Non-Dental Import Costs	\$2,264,627	\$ 202,342	\$ 556,174

Source: CCDT (2006), Deloitte Inc. "Human Tissue Importation Practices in Canada". Calculated per unit pricing in \$CAD

Note: Importation study excludes imports by dentists and oral surgeons.

Source: Musculoskeletal Transplant Foundation price list (in \$USD) for selected Canadian exports (2009).

Assume all units are fascia lata.

Comprehensive Tissue Centre (Edmonton, 2009), Regional Tissue Bank (Halifax, 2008) price lists (average of \$1.25/cm² of skin)

Assumption: that per unit costs of skin imports is nominally the same as domestic pricing. Detailed study planned for early 2010 by CBS to determine skin importation volumes and pricing.

Estimated Importation Costs: Cardiac Products

	CARDIAC				Subtotal (Cardiac)
	Aortic Valves	Pulmonary Valves	Conduits	Pericardium Pieces	
Est. Importation Volumes	340	257	391	-	988
<u>Determination of Unit Costs</u>					
Per Unit Costs	\$ 5,820.52	\$ 5,820.52	\$ 5,820.52	N/A	
Adjusted to 2009 values (\$CDN)	\$ 6,360.24	\$ 6,360.24	\$ 6,360.24		
Total Importation Costs	\$ 2,162,480	\$1,634,581	\$ 2,486,852	N/A	\$ 6,283,914
Allocation to Dental					
Dental Import Costs					\$ -
Non-Dental Import Costs	\$ 2,162,480	\$1,634,581	\$ 2,486,852		\$ 6,283,914

Source: CCDT (2006), Deloitte Inc. "Human Tissue Importation Practices in Canada". Calculated per unit pricing in \$CAD

Total Estimated Importation Costs, 2008/09

Importation Costs (\$CAD millions)	BONE	TENDONS	SKIN	SOFT TISSUE	CARDIAC	OCULAR	TOTAL
Dental Import Costs	\$ 8.0	\$ -	out of scope	out of scope	\$ -	\$ -	\$ 8.0
Non-Dental Import Costs	\$ 25.3	\$ 2.3	\$ 0.2	\$ 0.6	\$ 6.3	\$ -	\$ 34.6
TOTAL	\$ 33.2	\$ 2.3	\$ 0.2	\$ 0.6	\$ 6.3	\$ -	\$ 42.5

Tissue Transplantation Costs

Scope: Corneal transplants only

Transplantation: Corneal Transplantation Costing

Cost Category	Assumptions	\$ per Corneal Transplant
Hospital Costs	-used Alberta avg inpt cost 2004/05 - adjusted for inflation (3% pa) compounded over 4 years	\$ 3,016.36
Hospital-based Surgeon Fees	- averaged Physician Fees for lamellar and penetrating corneal transplants (assume equal proportions) - assumed that neuro consults were required in BC for 20% of cases - calculated weighted average for BC (10%), AB (10%), ON (40%) volumes	\$ 731.86
Hospital-based Anaesthesiologist Fees	- averaged Alberta anaesthesia fees	\$ 239.40
Pharmacy Costs (outside hospital)	-multiplied Quebec pharmacy costs by ratio of Canada (\$3016):Quebec (\$1942) hospital costs	\$ 523.44
Medical Visits	-multiplied Quebec medical visits costs by ratio of Canada (\$3016):Quebec (\$1942) hospital costs	\$ 428.69
TOTAL COST per CORNEAL TRANSPLANT		\$ 4,940
TOTAL NUMBER of Corneal Transplants	Source: CBS (2009), "Ocular Tissue Banks Survey: Analysis of Survey Data." Assume 2009=2008 volumes.	1,976
TOTAL COST OF CORNEAL TRANSPLANTS		\$ 9,760,947

Note: Corneal tissue recovery and processing has been costed separately.

Estimation of Known System Support / Infrastructure Funding (Organs and Tissue jointly)

Source of Infrastructure Funding	\$ millions
Public Awareness (Source: CCDT (2005), "Documentation of Current Levels of Resources Allocated to Public Awareness and Education Initiatives - Results of the January 2005 Survey") - assumption: level has remained constant	\$ 1.5
CBS (system design, Registry, forums, workshops, knowledge transfer, development of accreditation standards)	\$ 7.2
Research (Basic Science Committee - transplant research funding by CIHR, CDA, BC Transplant, Kidney Foundation, M. Smith Foundation, FRSQ, Heart & Stroke Foundation)	\$ 14.9
Living Donor Paired Exchange Registry (excludes \$250K for capital purchases - hardware and software; includes \$1 million operating costs)	\$ 1.0
Health Canada Regulatory Function	N/A
PHAC Surveillance Costs	N/A
CSA Costs	N/A
Accreditation Canada	N/A
In-kind donations (e.g. Lion's Club)	N/A
OPO's	N/A
TOTAL - in excess of	\$ 24.6

Summary: Estimated Total Tissue Donation and Transplantation Costs for Canada, 2009

2009	Comments	\$ millions
Domestic Tissue Banking	-based on use of Goss Gilroy costs (2002) and CBS Supply Survey (2008)	\$ 10.6
Importation	-dental ~\$8 million; excludes soft tissue and skin tissue imports for dental use	\$ 42.5
Transplantation	- corneal transplants only	\$ 9.8
TOTAL		\$ 62.9

Note: costs above do not include costs for public awareness and infrastructure funding (such as OPOs).

- Note: objective is to establish “order of magnitude”
- Infrastructure costs for organs and tissues combined exceed \$24.8 million.

Summary of Key Gaps/Limitations

- Goss Gilroy costing data has limitations (dated, anonymized and averaged, does not consider variations in processing sophistication or subsidies and recoveries of costs). Need to assume yield/donor and composition of products by tissue type has remained constant 2002-2009.
- Allocation of fixed costs, including capital, assumed to remain constant over time – beyond scope to assess. Understanding of investment in, and depreciated value of, tissue facilities and capital equipment is limited.
- Cost data associated with transplantation is limited to corneal transplants.
 - Represents ‘best guess’ with numerous sources of provincial data being used for costing
 - Rationale: While most tissue grafts are used as a medical supply or product within another procedure (e.g. total hip reconstruction) some procedures such as fresh osteochondral grafts could be considered transplants and costing data is not currently available.
- Demand (utilization volumes) and the proportion which is imported is currently unknown and has been estimated using available data
 - Skin tissue imports: Canadian nominal prices have been applied. (The demand for more advanced, highly processed skin tissues e.g. acellular dermal matrix, is unknown)
 - Dental imports of skin and soft tissue have been excluded from this report because of concerns with integrity of 2003 data
 - Concerted effort currently underway at CBS to quantify utilization, the percentage of the utilization that is imported and the costs associated with importation
- Known support and infrastructure costs for the system have been calculated, where possible, for organ and tissues data combined. Other infrastructure costs unknown.

Wrap-up and Next Steps



In subsequent meetings, we will begin to translate the strategy into objectives, measures and a plan for execution

