Canadian Blood Services
Société canadienne du sang

Canadian Blood Services

Data, Analytics and Reporting System Workshop

Tuesday, June 27, 2013

Toronto, Ontario

2013-09-30

Contents

Appendices:

Planning Committee

Kimberly Young:	Executive Director, Organ Donation and Transplantation, Canadian Blood Services (Chair)
Brent Diverty:	Vice-President, Programs, Canadian Institute for Health Information (CIHI)
S. Joseph Kim:	President, Canadian Organ Replacement Register (CORR)
Peter Nickerson:	Medical Director, Organ Donation and Transplantation, Canadian Blood Services
Sam Shemie:	Medical Director, Organ Donation and Transplantation, Canadian Blood Services
Kathryn Tinckam:	Co-Director, HLA Laboratory, Renal Transplant Physician, University Health Network (Toronto)
Greg Webster:	Director, Acute and Ambulatory Care Information Services, CIHI

Support:

Sylvia Torrance, Director, Organ Donation and Transplantation, Canadian Blood Services

Sean Delaney, Director, Organ Donation and Transplantation, Canadian Blood Services

JoAnne Lussier-True, Sr Project Manager, Organ Donation and Transplantation, Canadian Blood Services

Strachan-Tomlinson (Process consulting/facilitation/report)

Acronyms

BMT	Bone Marrow Transplant
CBS	Canadian Blood Services
CIHI	Canadian Institute for Health Information
CNTRP	Canadian National Transplant Research Program
CORR	Canadian Organ Replacement Register
CTA	Call to Action
CTR	Canadian Transplant Registry
DAD	Discharge Abstract Database
HRSA	Health Resources and Services Administration
HSP	Highly Sensitized Patient Registry
ICES	Institute for Clinical Evaluation Sciences
LDPE	Living Donor Paired Exchange
LVAD	Left Ventricle Assisted Device
MELD	Model for End Stage Liver Disease
NKRAC	National Kidney Registry Advisory Committee
NOW	National Organ Waitlist
ODO	Organ Donation Organization
OECD	Organization for Economic Cooperation and Development
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
SAF	Standard Analysis Files
SEER	Surveillance, Epidemiology and End Results (cancer)
SNOD	Specialist Nurse for Organ Donation (NHSBT)
SOP	Standard Operating Procedure
SRTR	Scientific Registry of Transplant Recipients
UNOS	United Network for Organ Sharing
USRDS	United States Renal Data System

Executive Summary

Data analysis and reporting play a pivotal role in improving donation and transplant practices and patient care, informing health care policy and supporting planning and research. To build on previous collaborative efforts with the Canadian organ donation and transplantation (ODT) community to develop a pan-Canadian system for data, analytics and reporting, Canadian Blood Services organized a one-day workshop to explore ways to move this work forward.

Workshop objectives were to:

- Review the vision for a national ODT integrated data management and analytics system,
- Develop consensus on system guidelines,
- Review the current state of data management in Canada and internationally,
- Identify the operational, reporting, and research information needs of stakeholders,
- Review and update a draft model for an integrated data, analytics and reporting system,
- Identify and describe opportunities, challenges, and benefits, and
- Outline next steps for moving forward.

This report provides an overview of the workshop discussions, focusing primarily on participants' reflections, suggestions and questions in relation to the draft proposed vision, data model and system guidelines.

Three perspectives provided the basis for discussions throughout the meeting: participants' points of view were summarized in a pre-workshop survey; presentations and discussions of lessons learned in the UK and US systems brought international perspectives; and representatives of CORR and CIHI presented a draft model and commented on progress to date in the Canadian system.

The draft future data model, outlining the basic elements of the data system was presented. This model, which was the culmination of discussions between Canadian Blood Services, CIHI, CORR and other key stakeholders over the past few years, was discussed by participants. After discussion, the model was revised (the new draft was presented at the end of the workshop).

Workshop participants then created a new vision statement:

> "A world-leading data system that provides timely access to high quality ODT information for patient care, system management, and accountability."

The system guidelines were reviewed: governance, data scope, data compliance, data standardization, data quality, data stewardship, data accessibility, and system efficiency. While participants in general agreed with the guidelines, there were suggestions for revision of the descriptions. They also identified the challenges, supports and actions that would be associated with implementation of the guidelines. A framework was developed, showing the priority and order of implementation.

Because this process was a consultation rather than a decision-making meeting, participants recognized that additional broader consultations would also contribute to the development of the final vision statement, guidelines and data model. Next steps in the process were identified and included developing essential data sets, working with ministries of health, and providing additional opportunities for stakeholder input into the process.

Introduction

Data analysis and reporting play a pivotal role in enabling process improvements and efficiencies that will enhance transplant practices, improve patient care, inform health care policy, support planning for the delivery of services, and increase scientific knowledge. The purpose of this workshop was to build on previous collaborative efforts with the Canadian organ donation and transplantation community to develop a pan-Canadian system for data collection, governance, and associated services.

There are currently three national organ donation and transplantation registries operated by Canadian Blood Services: Living Donor Paired Exchange (LDPE, started in 2008), National Organ Waitlist (NOW, started in 2012), and Highly Sensitized Patient (HSP, started in 2013). The national registry system includes a data warehouse with business intelligence tools that provide accurate, timely and comprehensive data to support research, national and provincial performance measurement, and the modeling and analytical needs of the Canadian organ donation and transplantation community.

Workshop objectives were to consult with system partners to:

a. Review the vision for a national organ donation and transplantation integrated data management and analytics system,
b. Develop consensus on system guidelines,
c. Review the current state of data management in Canada and internationally with respect to data collection, analysis and reporting,
d. Identify the operational, reporting, and research information needs of stakeholders,
e. Review and update a draft future data model for an integrated data, analytics and reporting system,
f. Identify and describe opportunities, challenges, and benefits, and
g. Outline next steps for moving forward.

This report provides an overview of the workshop results, focusing primarily on participants' reflections, suggestions and questions in relation to the draft proposed vision, future data model and system guidelines.

Participants' original words and phrases are used throughout the report to represent the results of discussions. Conflicting statements represent differences of opinion among participants. In addition, in some cases participants may represent as factual, items that may not be entirely correct. In these cases, participants' understandings are included as they were initially provided. Discussion points have been synthesized, and are presented in the order in which they emerged.

Because this meeting was one of a number of consultations, this report will provide initial input as a basis for further consultations with the organ donation and transplantation community and the Canadian public.

The Workshop Process

The introductory remarks for this workshop provided an historical and contextual framework for the day (Appendix C1).

Kimberly Young (Executive Director, Organ Donation and Transplantation, Canadian Blood Services) welcomed participants (list provided in Appendix A), thanking them for contributing their time. After outlining the history of ODT data, analytics and reporting in Canada and the significant progress made to date, Kimberly described the nature and input of stakeholders, the initial "Call to Action Data Model", and the ongoing data system development process of which this meeting is a part.

Dr. Peter Nickerson (Medical Director, Organ Donation and Transplantation, Canadian Blood Services) provided context for the meeting's purpose and objectives. He described the drivers of change within Canada, and outlined a proposed vision for a national data system. He concluded by providing an overview of the eight proposed data system guidelines to be reviewed at this meeting.

The meeting facilitator Dorothy Strachan then outlined the purpose, objectives and agenda (Appendix B) for the day. Presentations and discussions followed, after which participants reviewed a proposed system vision, draft model, and guidelines.

Assumptions

Core Assumptions are the agreed-upon "givens" that provide a common starting point for reflection, discussion and decision-making. The assumptions for this workshop were:

- An effective national system is required to improve data capture and management, patient care and service delivery, and to support research and the evolution of health care policy.
- Discussions at this workshop will be informed by available information based on national and international experience and current practice.

Key Considerations

The following important circumstances, facts, data and concerns were taken into account during the workshop:

- This effort is a continuation of previous work to develop and evolve a comprehensive data management and analytics system for ODT in Canada. This is one step in a broad consultative process providing opportunities for future input.
- Collaboration across stakeholder groups is essential to shape a solution that will work for all parties.
- An incremental approach is essential to the development of a national ODT data, analytics, and reporting system(s).
- Existing models provide an opportunity to optimize service delivery, improve efficiencies, and be responsive to emerging situations.

Scope

The following areas were in scope for this workshop:

- National and international scans
- Gaps, barriers, opportunities and potential benefits of the current Canadian system
- Vision and system guidelines for a potential new system
- Operational, reporting and research needs of stakeholders
- Identification of next steps.

Four areas were out of scope:

- Clinical trials
- Defining roles and responsibilities
- Review of funding/financial models
- Tissue donation and transplantation.

Outcomes

Immediate outcomes (within 6 months) were to:

- Identify the initial steps needed to achieve the future state of the data management, analytics and reporting system
- Consult with key stakeholders
- Move forward with deliverables identified at the workshop.

Intermediate and long-term outcomes were to establish the key elements and processes identified in the data management, analytics, and reporting model.

Presentations and Discussions

Three perspectives provided the basis for discussions throughout this meeting: participants' points of view were summarized in a pre-workshop survey; presentations and discussions of lessons learned in the UK and US systems brought international perspectives; and representatives of CORR presented a draft data model and CIHI commented on progress to date in the Canadian system and considerations for developing and a national ODT data and reporting system.

Participant Perspectives

Dr. Kathryn Tinckam, Co-Director, HLA Laboratory, Renal Transplant Physician with the University Health Network in Toronto summarized the results of a survey (69% response rate) conducted and analyzed by Strachan-Tomlinson (Appendix C2) in preparation for this meeting. In summarizing the survey results, Dr. Tinckam made the point that participants viewed access to data as very important to a successful system and that data must be available to all qualified persons in Canada, as a national transplant resource.

Discussion

The survey showed a high level of support for mandatory data reporting, and while the support for public reporting was lower, this is not reflective of the very strong desire for public reporting elsewhere, e.g., in the US there is transparent reporting down to the centre and clinician levels in some cases.

- There is a variety of data sets being used, for both reporting and for accessing information. Duplicate data entry into multiple data sets was seen as a burden and something to be avoided in a future system.
- National data for all aspects of the system should be included: donation, transplantation referral, listing, transplantation and follow-up/outcomes.
- Important features of a data system include: quality improvement, governance and accountability, access to data, "one-stop shopping", accuracy, mandatory, single entry, system wide.

International Perspectives

Two speakers described the UK and USA systems, highlighting the strengths and challenges in each country's approach.

Dr. Kathryn Tinckam's presentation on "A UK Perspective: Data Driving System Improvements" (Appendix C3) was an environmental scan of the NHSBT ODT United Kingdom Transplant Registry http://www.odt.nhs.uk/.

Those interviewed regarding the UK system emphasized: a) the importance of well documented data ownership and accessibility principles, b) data stewards are invaluable for system efficiency and functionality, and c) human resource solutions for data compliance and standardization are essential to an efficient and effective system. Concluding remarks in her presentation emphasized that the UK system is in evolution with a focus on improving standardization and formalizing governance and stewardship guidelines.

In his presentation on "A US System Perspective: Data Management and Analytics," Dr. Bertram L. Kasiske, Project Director at the Scientific Registry of Transplant Recipients in the US, and formerly Deputy Director of the US Renal Data System (USRDS) shared what he learned through his leadership roles over the past several years (Appendix C4). Dr. Kasiske's presentation focused on three areas: organization structure, SRTR data sources and SRTR reporting. His overview and insights on the role of the US government in transplantation stimulated discussions comparing the US and Canadian approaches in this area.

Discussion

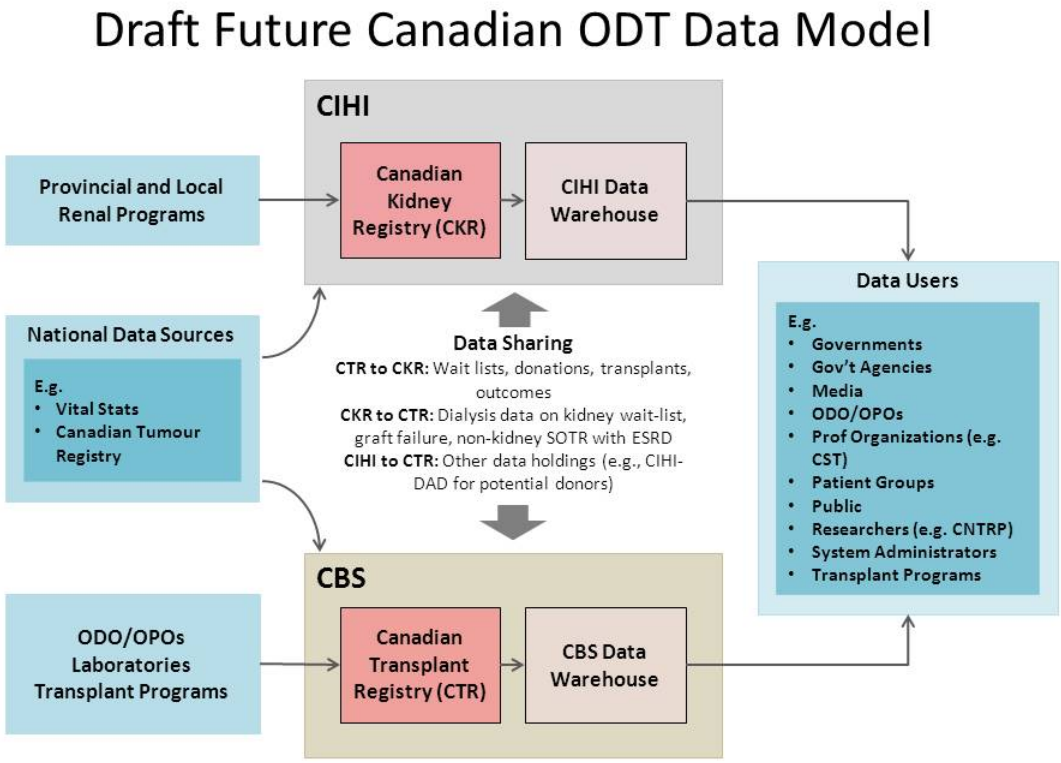
- The older the person, the more accurate the data in the death master file.
- Organ allocation data is mandatory and is audited by OPTN teams. There are other data types that are voluntary and not audited, but they are considered to be less accurate.
- People want to see good data on outcomes, and they will voluntarily contribute that data if it is in turn made accessible to them. Much of the data collected by UNOS is voluntary and most centres collect it because it is so important nationally, regionally and at the centre level.
- Every US transplant patient has to be registered. Those registration fees (approximately $500 per registration) make up a large part of the SRTR budget. Health Resources and Services Administration (HRSA) is responsible for oversight on mandatory registration.
- Size and the growing ability to link to other types of data are two distinguishing features of the SRTR.
- SRTR lessons learned: data elements could have been selected in a more evidence-based way (e.g., not by the recommendations of committees of clinicians). Definitions need to be airtight and tested: the current elements have led to 'on the ground' challenges with gathering data, e.g., coordinator consistency in collecting data.
- The SRTR doesn't have good metrics for deceased donation, despite numerous attempts.

Canadian Perspectives

Two Canadian leaders with current experience in ODT data, analytics and reporting reflected on the strengths, weaknesses and potential of the Canadian system while engaging participants in thoughtful discussions about how to move forward.

In his presentation on "A Draft Canadian Model", Dr. S. Joseph Kim (President, CORR) introduced a draft future data model which was the culmination of discussions between Canadian Blood Services, CORR and other key stakeholders over the past few years (Appendix C5). He emphasized that one workshop goal was to focus on how guidelines for a national data system could inform its development moving forward. It is important to note that this is a preliminary draft model based on several assumptions. For example, data sharing and privacy requirement details are still to be confirmed. There is an assumption that the Canadian Organ Replacement Register (CORR), operated by CIHI, will transition to a renal focus (e.g., CKR) once the CTR covers the current CORR transplantation data collection—to avoid duplication. System-level reporting roles are also to be confirmed at a later time.

The draft model provided at the meeting was revised during workshop discussions related to the eight proposed system guidelines outlined in this report.



Notes:

1. Data sharing and privacy requirement details to be confirmed.
2. Assumption that Canadian Organ Replacement Register (CORR) transitions to a renal focus (e.g., CKR) once CTR covers current CORR transplantation data collection.
3. CTR and CKR will each have their own data governance structure and analytic capacity.
4. System-level reporting roles to be clarified.

Discussion

- System governance needs to be determined, and data sharing among current databases requires further discussion. There is a lot of rich data untapped in CIHI/CORR.
    - Data analytics could follow several models. Should there be a separate analytics arm (like the US) or should it rest with the CKR and CTR (like the UK)? A separate data analytic arm may add scientific rigor.
    - CIHI would continue to do system level reporting on CORR (CKR) and possibly aspects of CTR data. CIHI, Canadian Blood Services and others could coordinate efforts for joint reports.
    - There is no registry that looks at the entire process from referral of patients to transplant programs.
- Data will be used for more than just research – it is also for system analysis and to drive outcome improvements for patients.
- Data gaps include: deceased donor potential, access to the system for patients with end organ failure (e.g., for those not on the waitlist or those in remote areas), post-transplant data, consent refusal rates, time of referral to wait-listing at the transplant programs, wait-list activity (including holds and deactivations), donor data related to recipient outcomes.
- We need a system to aspire to – one that will be viewed as contributing to improving ODT systems in each jurisdiction – not something that will be seen as punitive. Transparency is essential to this approach.
- Given their mandates to collect front-line data, ODOs may be the best players to discuss changes with provincial governments.
- If we have a partnership with Statistics Canada, we may be able to look at all deaths (both before and after transplantation as well as among potential deceased donors) using vital statistics data.
- What are some innovative ways to fund this system?
    - CNTRP has resources for analysis. Leveraging with CTR could provide additional analysis capacity.
- When the community speaks with a single voice, the results are impressive.
- Money will be an issue so there will be a need to prioritize activities.

Mr. Brent Diverty, Vice-President, Programs, Canadian Institute for Health Information (CIHI) spoke on "System-Level Reporting and Data Sharing Strategies in Canada" from a CIHI perspective (Appendix C6). His candid comments on the current system stimulated participants to think about the vision for a Canadian model. In summarizing the key points in this presentation, Mr. Diverty emphasized the importance of "starting at the end" by specifying the data elements to be captured from the perspective of each key stakeholder group. He also made the points that patient care in program management is paramount; that technology is an enabler, not an end solution; and that data supply is enhanced when data providers see value through feedback.

Discussion

- CIHI was formed out of legacy organizations with existing databases (e.g., CORR). CIHI is trying to capture all the activity in the Canadian health system, e.g., health expenditure, workforce, and service data in one place.
- The acute care discharge abstract database (DAD) is one of CIHI's flagship data holdings. For some non-acute data holdings, CIHI uses standardized clinical assessments for patients/residents as a means to collect data from the point of care. Care planning triggers are returned to clinicians, as well as outcome scales and quality indicators with benchmarks.
- Getting information back to people makes them want to continue to submit data. The process is largely about people valuing the information and seeing its importance.
- CIHI tries to avoid collecting non-standardized data. There is not always good adherence to pan-Canadian standards in certain jurisdictions, and CIHI works to make the data comparable.
- Modifying existing systems is generally cheaper than building new ones.

Vision for a National Data System

Based on the perspectives of participants in the pre-workshop survey and the views of international and Canadian speakers, workshop participants discussed and provided feedback on a proposed system vision and eight guidelines provided to them prior to the workshop.[1]

Proposed Vision

The proposed draft vision was:

- A national ODT data system, which is trusted, timely, transparent, comprehensive and standardized, and that enables the ODT system to evolve policy, system design and patient care
- A system that is appropriately resourced with skilled personnel, including front line data collection services, IT (hardware, software, infrastructure), and data management, project management, and analytics
- A system that can be leveraged by relevant stakeholders in Canada.

This group condensed and shortened this proposed vision, suggesting the following:

> "A world-leading data system that provides timely access to high quality ODT information for patient care, system management and accountability."

Participants recognized that each of the three items at the end of the vision would need concise definitions to support this strategic statement.

In addition, because this process was a consultation rather than a decision-making meeting, this suggested revision was offered with the recognition that additional broader consultations would also contribute to the development of a final vision statement.

Discussion

- Words and phrase such as "mandatory", "research", "leverage", and "policy design" can be controversial. The language for the final three areas should be crafted carefully to stay within the scope of the data system.

[1] See Appendix E for the original vision and system guidelines distributed prior to the workshop.

System Guidelines

Based on experience in other countries, planning committee members recognized the importance of having clear system guidelines to support a draft Canadian Data Model. The eight system guidelines reviewed during this consultation workshop are intended (when finalized) to remain constant as goals in the development of a data management, analytics and reporting system. Each is supported by several criteria to enable benchmarking for successful implementation.

Workshop participants were divided into six groups and discussed system guidelines in both small groups and plenary. In the first session three groups focused on Governance and three on Stewardship given their fundamental nature in the system. In the next session, each group discussed one of the six remaining guidelines. Summaries of group discussions follow.

A. Governance

The following was the guideline as originally presented to participants:

The organizations, agencies and governments that collectively operate the organ donation and transplantation system in Canada will work together to create and maintain a data system that responds to the needs of its users.

a. The overarching framework for data governance will be reviewed and authorized by provincial and territorial governments.

b. The data governance framework will define accountabilities for cross-functional, data-related decisions and processes, and include a national governance body to provide direction.

Meeting Discussion:

When reviewing this guideline description, participants emphasized the importance of clearly defining governance in terms of leadership, accountabilities, responsibilities; who provides oversight and support; and what is needed to improve patient services. There should be a single framework for data governance that is applicable to everyone.

Challenges related to implementing this system guideline:

- Sustainable funding
- Data standardization and harmonization
- Building consensus on a model and then getting commitments to sign on and stay on, e.g., from programs and provincial/territorial governments
- Loss of stakeholder autonomy and fundamental differences in approach between the current and proposed models.

Supports that will enable implementation of this system guideline:

- Sustainable federal and provincial/territorial government funding and agreements
- A demonstration of the value of participating e.g., reports tailored to stakeholder needs
- Building on governance models from other jurisdictions (other registry experiences)

- Using the momentum for national initiatives, i.e., the emerging acceptance of national programs and the work already done in Call to Action.

Suggested Actions

a. Identify all stakeholders impacted by current and potential national ODT governance structures.
b. Identify the stakeholders who have seats at the national governance body and recruit them to provide leadership.
c. Review the draft model with jurisdictional stakeholders (e.g., provincial governments).
d. Obtain buy-in from all ODOs.
e. Analyze system benefits at multiple levels including patient care and economics.
f. Recruit groups that represent patient interests.
g. Create a draft governance framework, clearly define responsibility and accountability, and use the framework to determine where barriers exist.
h. Convince provincial governments of the need for stable funding and support.

Other Comments

- Should governance and stewardship be combined?
- Governance should not include overseeing day-to-day operations of each of the components. It must incorporate regional/jurisdictional information flow requirements and the fit with ODOs, laboratories, and transplant programs.
- Should point a. (“The overarching framework…”) be removed from this section?
- Numerous stakeholders are not reflected in the model and may be impacted by the governance structure (e.g., smaller centres, pre-and post-transplant follow-up programs).
- Who will govern implementation? How do you establish an authority?

B. Data Scope

The following was the guideline as originally presented to participants:

To ensure comprehensive data, collection and reporting will encompass system-wide information generated throughout the entire donation and transplantation process.

a. A system-wide collection of data is required to inform the national system regarding:

- All donors, all recipients
- All transactions (e.g., organ allocation, offers and accepts/declines)
- All transplants (e.g., related and unrelated living, NDD, DCD)
- All outcomes
- All provinces and territories.

b. Donation data begins from the time a potential donor is identified, to the time of donation (or beyond for living donors).

c. Transplantation data begins from the point of referral of a patient to an organ replacement program, and is followed until the death of the patient.

Meeting Discussion:

When reviewing this guideline description, participants suggested more specificity to define "all outcomes;" an expansion of "c" to "all potential donors and recipients" to address the issue of patient access; and inclusion of processes of care information, (e.g., drugs, patient compliance with treatment, donor and recipient management) in particular for post-transplant situations.

Challenges related to implementing this system guideline:

- Coming to agreement on specific data elements and prioritization
- Defining the denominator for end-stage organ failure
- Lack of human resources and/or technology to do data collection.

Supports that will enable implementation of this system guideline:

- CIHI, i.e., an existing national structure to collect data
- Resources (including technology) for ODOs and HLA labs to provide data
- Hospital databases that can support implementation.

Suggested actions

a. Define the information needs and outputs, the actual data elements that need to be captured, and define 'all outcomes'.

b. Scan existing sources (e.g., CIHI, DAD) to identify data elements.

c. Work with CIHI to modify the DAD. Include specific donation and transplantation fields and how they should be prioritized.

Other Comments

- Scope will be dictated by what is feasible. Focus on existing accessible data sources.
- Item (b) under guideline “G. Data Accessibility” (“The data structures will be designed to enable linkages between data sources so that the entire life cycle of the patient/donor can be evaluated) should be included in this “Scope” Guideline rather than under “G. Data Accessibility”.
- Standardization is a prerequisite for efficiency, and without efficiency there will be no compliance.
- There is a need to define the denominator for end organ failure.

C. Data Compliance

The following was the guideline as originally presented to participants:

Mandatory comprehensive data collection and timely reporting are required to enable performance benchmarking within Canada.

a. ODT programs and organizations will be required to submit a minimum set of data in a timely manner.
b. The minimum data set will be established by the governance body and will contain a set of variables sufficient for a broad spectrum of analysis related to ODT.

Meeting Discussion:

When reviewing this guideline description, participants suggested including both mandatory and voluntary aspects of data collection; broadening "performance benchmarking" to "achieve the vision of the data system"; defining 'broad spectrum analysis'; and ensuring that accuracy and quality are essential components of compliance.

Challenges related to implementing this system guideline:

- Lack of the laws required to make data collection and reporting mandatory
- Provinces not currently collecting the required data
- Lack of resources for data entry and verification.

Supports that will enable implementation of this system guideline:

- Adequate funding for data entry and staff training
- A feedback loop from users to the governance body to add mandatory data elements
- Minimizing data entry and improving compliance by making the data elements part of the everyday operational workflow
- Accreditation, e.g., Health Canada audits, Accreditation Canada.

Suggested Actions

a. Identify the key data elements.
b. Explore funding options for data entry.
c. Explore the mechanisms required to make participation mandatory.
d. Vet the minimum data set with the governance body, the community, and a wide variety of stakeholders.

Other Comments

- How do we ensure compliance? Should funding be tied to collection of data elements?
  - Data related to the business of transplantation is already collected, and there is no need for that to be made mandatory.
  - The UK has a 'voluntary plus' system that works best without the threats that 'mandatory' implies.
  - 'Mandatory' is important – we need universal participation.

    - We need to get data without the punitive side of things. The US had an unpleasant and contentious experience with mandatory requirements.

- Don’t limit data collection to a mandatory data set – allow for voluntary data collection.
- Develop a clearer description of ‘broad spectrum analysis’.

D. Data Standardization

The following was the guideline as originally presented to participants:

In order for the various provincial, territorial and central data systems to communicate with one another, it is critical to have common definitions of data fields. Required components include:

a. Documented standard data definitions, standard operating procedures and valid analytic design,
b. A required set of baseline variables sufficient for a broad spectrum of analysis related to ODT,
c. Private and Public Standard Analysis Files available to both private and public data users to ensure standard analysis of common variables.

Meeting Discussion:

When reviewing this guideline description participants suggested standardized, measurable, objective baseline data elements for each patient and donor, and ensuring that there is a balance between little/too much information.

Challenges related to the implementation of this system guideline:

- Data gaps: both organ-specific and those common to all areas
- Efficient electronic data linkages and exchanges
- Data consistency.

Supports that will enable implementation of this system guideline:

- An environmental scan of what data is collected in other countries
- A Canadian health record standard
- The engagement of organ-specific groups in the process
- Finding the balance between ideal and essential data will help get others on board
- Standardized definitions
- Minimizing the use of subjective data.

Suggested Actions

a. Complete an environmental scan including ODOs, transplant centres, and international registries.
b. Review and share data dictionaries.

Other Comments

- Standardization is a prerequisite for data quality.
- Work has begun on the creation of a minimal data set, starting with liver transplantation. We need to be as comprehensive as possible, but the practical issues around priority data collection are key. Kidney is also in progress via the National Kidney Registry Advisory Committee.

- Collect the basic data on every transplant patient. Learn from the UNOS experience but avoid too severe a cut to minimal data sets.
- Require consent to facilitate research on donation and transplantation.
- Data linkages are essential. How can CIHI assist in national linkages?

E. Data Quality

The following was the guideline as originally presented to participants:

High data quality (accurate, reliable, complete, and timely) is paramount to achieving a trusted system for informed decision making.

a. Data should be validated at multiple levels to ensure quality (e.g., audits, cross-validation through existing data-sets, checks when entering data).

Meeting Discussion:

When reviewing this guideline description participants suggested including "essential data quality recognized at data entry";

Challenges related to implementation of this system guideline:

- Point of care training and support for data collection.

Supports that will enable implementation of this system guideline:

- Sharing of accurate information back to front line users
- Regular audits
- The funding of data capture and training, including ongoing support
- The elimination of dual data entry
- A small, high-quality data set rather than a large poor-quality data set.

Suggested Actions

a. Provide the funding required for data quality capture as well as training.
b. Keep the focus on quality with an opportunity to test early, i.e., a beta-test.
c. Review existing models on an ongoing basis. Find out what others have done with their systems to achieve the best quality.
d. Create clear definitions, documentation and tools, from user guides to SOPs.

Other Comments

- Data collectors are the most important quality filter for information going into the system.
- Accuracy and quality are fundamental to system development.
- We cannot have any paper-based data collection.
- Spend the money on building the database. We can get the money for analysis later on.
- UK correspondents felt that their data accuracy was 'almost flawless' because they had such clear rules.
- We don't have to build towards quality – we can do it right from the start.
- It is difficult for untrained individuals lacking medical knowledge to make point of care assessments.
- When less data is required, it is likely to be of higher quality.

F. Data Stewardship

The following was the guideline as originally presented to participants:

The organizations, agencies and governments that collect, share and report on ODT data are all stewards of the data they hold. They must ensure that they protect the data that is entrusted to them by patients and donors.

a. Data management activities must comply with provincial and territorial regulations for data privacy, access and security, and with data sharing agreements.
b. Respect for individual privacy will be maintained by releasing the minimal amount of personal information required (e.g., de-identified data as a standard).
c. Over-arching policies for release of data will be approved by the governance body. These may include requirements for internal reviews prior to data release/publication.

Meeting Discussion:

When reviewing this guideline description, there was considerable agreement that this guideline be integrated with the "Governance" guideline. Others suggested that this guideline could be re-named "Privacy". In addition, participants suggested using a stronger word than 'respect' for individual privacy; adding more specificity to point 'c'; removing the example in point 'b' as it is potentially exclusionary.

Challenges related to implementation of this system guideline:

- Engagement of data collectors
- Funding and resource allocation
- Cross-jurisdictional sharing, e.g., different requirements in different jurisdictions
- The physical location for data storage
- The potential reluctance of struggling programs to share their data
- User group accessibility and level of accessibility will need to be defined for various groups, e.g., how do we balance researcher requirements with patients? Patients have to know that some data needs to be shared for transplantation purposes.
- The designation of mandatory and voluntary data collection.

Supports that will enable implementation of this system guideline:

- Privacy laws and regulations, including privacy officers within organizations to ensure privacy
- Inter-provincial and national data sharing agreements
- Stakeholder and public access to reported data
- Research ethics boards
- Transparent policies
- Policies regarding the appropriate public release of data
- Independent audits of data quality.

Suggested Actions

a. Develop a list of required policies.
b. Develop a data governance body endorsed by key players.
c. Develop policies for the release of data (e.g., de-identification).
d. Complete the required data sharing agreements, e.g., among provincial/territorial jurisdictions and between providers of data and those receiving it (Canadian Blood Services).
e. Designate one organization to hold information.
f. Generate buy-in for the approach to data stewardship.
g. Create mechanisms to analyze and deal with issues.

Other Comments

- Define data release policies needed depending on users, e.g. researchers, the public.
  - Primary data contributors should be able to use the data internally to drive quality improvement and to inform their business locally.
  - Two levels of consent are necessary for data access: a dataset subject to privacy laws, and a dataset where consent is more flexible.
  - Respect privacy but have flexibility in the system to keep stakeholders engaged.
  - There must be sharing among organizations at every point throughout the model.
- A single statement can't adequately cover the need for privacy – stewardship is the foundation for a high performance model.
  - Database linkages bring a new level of complexity, as does the need for consent.
- Will researchers have their work reviewed before publishing?
- All provinces must submit and receive the same data. Uniform standards are key.
- There mustn't be barriers for those looking for data. Data must not be suppressed.
- Use and link data from as many sources as possible.
- Quality assurance needs to be at arm's length from the organization of the system. Research and analytics may also need to be separate.
- De-identified data is a misnomer: data can be linked.

G. Data Accessibility

The following was the guideline as originally presented to participants:

Data should be available to all legitimate stakeholders who wish to improve decision-making for the benefit of the ODT system.

a. The data structures will be designed to allow different access to different levels of users, e.g., from occasional users, to power users who may access data with advanced software support tools.
b. The data structures will be designed to enable linkages between data sources so that the entire life cycle of the patient/donor can be evaluated.

Meeting Discussion:

When reviewing this guideline description participants suggested replacing the word 'legitimate' with 'appropriate' or 'approved'. They also noted that (a) is an output, e.g., reporting, and (b) is an input, e.g., data entry.

Challenges related to implementation of this system guideline:

- Cost and scope
- Priorities, e.g., which projects are taken on first? What reports are generated, e.g., to ODOs, transplant centres, the public, and government?
- Balancing privacy with information needs.

Supports that will enable implementation of this system guideline:

- Examples from other systems on how to do successful reporting
- A responsive system whereby system outputs are accessible to primary data suppliers
- Clear requirements
- Careful management of expectations, e.g., regarding deliverables, priority of reports, privacy considerations.

Suggested Actions

a. Find good examples of reporting systems (these could be from outside health care).
b. Funding – what is feasible from a cost perspective?
c. Clarify responsibilities for data dissemination and reporting.
d. Data linkages –IT support (resources) may be difficult for smaller jurisdictions.
e. Create an advisory committee to determine who has data access.
f. Define and include registry outputs and data access in the proposed model.

Other Comments

- Rather than the word 'legitimate' in the first sentence of the guideline, use 'appropriate', or 'approved'.
- Instead of 'for the benefit of the ODT system' make the vision statement about patient care.

- Who is going to do the analysis and the reporting? Who are the stakeholders and funders?
- Access must be for a purpose consistent with collection, e.g., no market research.
- Where does historic data fit in? The legacy data at CORR is quite comprehensive. Don't disregard old data: we could complete prior legacy data sets.
- This should be a segmented set of products and services, e.g., real time reports for point of care data suppliers with a different process for third party data requests.
- Where does government fit?
- Data must be held in responsible hands. Those who are given access must have Research Ethics Board approval, and privacy concerns must be addressed.

H. System Efficiency

The following was the guideline as originally presented to participants:

As part of the public health care system, data services must make responsible use of public resources.

a. To reduce redundancy, the system will strive to capture front-line data only one time, i.e., not from multiple points.
b. Alignment with existing infrastructure wherever appropriate, will enhance one another's roles.
c. Existing structures will be reorganized, where needed and appropriate, to minimize duplication of roles and activities.
d. The central data system will strive to the highest level of performance (as achieved in the standardization of HLA laboratory protocols and definitions) to ensure all provincial/territorial systems perform to the most efficient, effective level.

Meeting Discussion:

When reviewing this guideline description participants suggested clarifying the perspective of 'c' by saying "utilize existing data sources efficiently/linkages to existing data;" considering whether 'd' would be more in line with the data scope guideline; and clarifying the purpose of the regular review of data elements collected, e.g., is this about efficiency or about paring down/essential elements?

Challenges related to implementation of this system guideline:

- Variance in standardization by jurisdiction
- Differing practices and process of care which could infer differences in feasibility/resources required to collect data
- Potential inefficiency of current data collection (that we are building on)
- Lack of resources.

Supports that will enable implementation of this system guideline:

- Momentum/motivation, e.g., regarding work already completed and existing interfaces
- Accountability and justification for funding
- Responsiveness to demands of the public re: efficiency.

Suggested Actions

a. Define a minimum (essential or core) dataset and organ-specific definitions.
b. Determine by region what data is currently collected and definitions used.
c. Create an iterative improvement process. Identify barriers and develop strategies that work across multiple centres.
d. Identify common areas of efficiency e.g., common platforms. Work from the data capture needed for national initiatives.

e. Use a modular approach to data collection: a core module collected all the time; another collected some of the time; and a third collected under certain circumstances.

Other Comments

- The highest level of system performance could come from collecting data elements that lead to a more efficient health care system. Collectors will have the most insight.
- Identify what is already collected as well as any additional resources required to bring people up to a minimum standard.
- What are the broader considerations for funding?
  - Create a business plan for how the data collection system might fund itself.
  - How will post marketing and safety happen?
  - How does an organ donation management system work in the context of a national system?
  - We have to be fiscally responsible to those holding the purse strings.
- Sharing of linked data is high in terms of privacy issues. CIHI does national level linkages on a case-by-case basis, and rarely releases linked data.
- Those providing data must be able to get data returned to them.

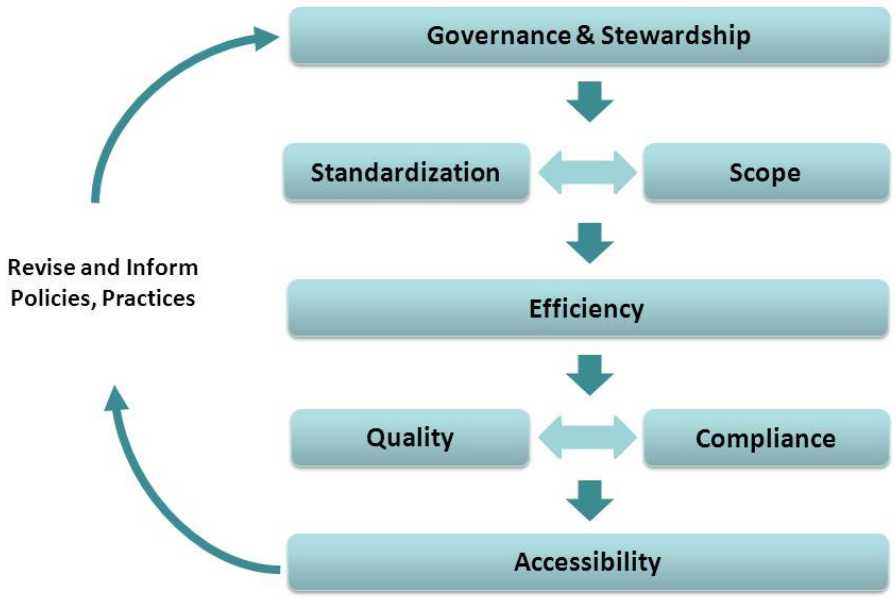
Implementation and Change Framework

A hierarchy for the guidelines was suggested, that outlines the priorities and order that should be followed in establishing the data system:

- The highest priority is to create an agreed-upon governance structure to define roles, responsibilities and accountabilities.
- Once this is established, the scope of the data can be defined along with the data standards and definitions.
- The system design and operating procedures can then be applied to maximize system efficiencies.
- An efficient, well-governed system will drive quality data collection and compliance, as users recognize the value of providing input to the system.
- Having the previous elements in place will promote data accessibility, through transparent data analysis and reporting.

The framework has a feedback mechanism, as reporting and data will inform the development and revision of policies and practices and, in turn, modify governance as the system evolves.

Implementation and Change Framework



Conclusion

Kimberly Young (Executive Director, Organ Donation and Transplantation, Canadian Blood Services) thanked participants for their participation and their commitment, expressing her hope that the work of the day had inspired participants to work collaboratively to move the proposed model forward. She highlighted some of the upcoming steps in the process: developing the essential data sets, working with ministries of health, and additional opportunities for stakeholder input into the process.