Improving biobank standards

who are they for, what should they address,

and how can we implement them?

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Health Research: key ingredients

Ideas (Researchers)

- Resources (biobanks)
- Tools (technologies)
- Partners (patients)

Progress (detection, treatment, cure)
Definition: • Biobank is a collection of biospecimens and data created in the course of a research project, study, or trial through an activity called biobanking

Activity: • Biobanking comprises enrollment, accrual, processing, annotation, storage and release of biospecimens and health information

Classification: Mono-user

Single user & purpose

Oligo-user

Several, semi-defined users & purposes

Poly-user

Multiple, users & semi-defined purposes
Specifications that lay out the characteristics for a product or process to be recognized for a type of quality

A characteristic of something that denotes the degree to which it approaches excellence or addresses the intended purpose

The intended purpose is constantly evolving
Who are standards for?

- Donor
  - Biospecimen & data
- Internal process
- Product
  - Biospecimen & data
- Research user

Biobank Quality
Who are standards for?

Biobank Quality

Donor

Biospecimen & data

Predictive medicine

Internal process

Biomarkers

Targeted therapies

Product

Biospecimen & data

Research user

Genomics

Proteomics

Metabolomics
What should standards address?

- Standards
  - Biobank Quality
    - Internal process
      - Product
        - Set Quality
          - Donor
            - Biospecimen & data
          - Research user
            - Biospecimen & data
What should standards address?

Biobanking Quality

Donor: Enrollment plan, Consent design, Collection scheme

Internal process: Processing protocol, Storage policy

Product: Annotation strategy, Access system

Research user: Release model

Known Quality
Biobanking issues

- Access
- Scale and efficiency
- Biospecimen and data quality
- Scientific reproducibility
- Public confidence
**Biospecimens and cancer research: Increasing demand**

Average biospecimen cohort size doubles every decade

Human biospecimens underpin ~40% of health research

References
Castillo-Peyallo T, et al Biopreservation and Biobanking 2015
Cole A et al Biopreservation and Biobanking, 2010
Biospecimens and cancer research: Increasing demand

References
Biospecimens: changing appetite

Background data:

- 3 investigators, 1992-2012
- 313/474 papers with biospecimens
Biospecimens and cancer research: Changing needs

- **Biospecimens** with specific composition
- **Cases** in specific categories with outcomes data
- **Cohorts** with specific and multiple selectable features
Needs vary by phase and nature of the research question

- Quality priorities change in terms of types of materials and data
- Choices are influenced by study design
- Decisions are multifactorial
Biospecimen quality: evolving needs

Facets of biospecimen quality

‘Simple’ features
Aspects of quality that are intrinsic to the biospecimen

Consent (narrow, broad)
Subject (age, sex, lifestyle etc) and Clinical (diagnosis, treatment, outcomes)
Collection process (processing, annotation, storage, fractions, products)
Biospecimen (type, condition, preservation, composition)
Facets of biospecimen quality

‘Complex’ features
Aspects of quality that are extrinsic to the biospecimen

‘Simple’ features
Aspects of quality that are intrinsic to the biospecimen

Representation
Linkage
Selectability
Consent
Data
Biobank

Representation (accrual strategies to minimize bias)
Linkage (biospecimens linked to other formats, locations, events over time)
Selectability (Processing and analysis features that enhance classification)
Consent (limitations, re-contact narrow, broad)
Subject (age, sex, lifestyle etc) and Clinical (diagnosis, treatment, outcomes)
Collection process (processing, annotation, storage, fractions, products)
Biospecimen (type, condition, preservation, composition)
How to draw biobanks into a biobanking system and address issues and new challenges?

- Biobanks are a diverse research platform
- Research needs are evolving

- Focus on the main issues in biobanking
  - Connect biobanks in a framework
  - Support biobanks to evolve
Develop national standards
Establish a process for dissemination
Improve access and raise the quality of biobanking
Key principles for the program

Design
• Targeting governance, quality, and access
• Applicable to all sizes & types of biobank
• Standardized but scalable requirements

Delivery
• Delivered through online format
• International scope

Model
• Education focused
• Self assurance based
The key functional elements

- Standards
- Education
- Classification
- Resources
- Locator

National biobanking standards

A Required Organizational Practice (ROP):
Is an essential practice that biobanks must have in place to conduct operations and must agree to adopt to become certified


x13 ROPs
The key functional elements

- Standards
- Education
- Classification
- Resources
- Locator

- Developed through a national grass roots process
- Subjected to national & international expert review
- Accessible online and endorsed by ISBER, ISQA, WHO-IARC

www.biobanking.org
The key functional elements

- Standards
- Education
- Classification
- Resources
- Locator

Scaled requirements for
- Documentation
- Education
The key functional elements

- Standards
- Education
- Classification
- Resources
- Locator

www.biobanking.org
The key functional elements

- Standards
- Education
- Classification
- Resources
- Locator
$1.3 million investment

5% Planning & input
Landscape review, Surveys, Workshops

ISBER

15% Standards
Biobank experts, Working group

MAWG

15% Enrollment Scheme
PM, Coordinators, IT specialists, classification tools, and decision tools

CTRNet

45% Education Course
Project manager, Coordinators, working groups, graphics, instructional designer, copy editors

SOPs

2010

2011

Decision tools

2012

Website

2013

Certification

Docs, templates, tools

45% Overview

25% Specialized modules

5% ROPs

15% SOP updates

$1.3 million investment

2010

2011

2012

2013
CTRNet Certification Program

- Leader: 15 mins - 3 hrs
  - low effort, automated process
  - populates the locator
  - disseminates standards

- Leader + Team: 1 hr - 3 days
  - higher effort, semi-automated process
  - assurance of key documentation and knowledge
  - encourages adoption of common standards
• Growing national & international uptake
  - >350 biobanks, biobank networks, & clinical trial sites have enrolled in the program since 2012
  - ~1000 biobank staff from >25 countries have accessed the education
  - Multiple partnerships implemented or under development for Australia, Germany, Norway, and Ukraine

• Growing requirement for research funding in Canada
  - National cancer research funders moving to require CTRNet registration as a condition of funding
  - Regions and Institutions are moving to implement as a condition of release of funds for new projects
People
Patients
Donors

Biospecimens & Data

Better Care

More Knowledge

Health Research

Biobanks operating independently
Biobanks operating within and linked to an integrated framework
Biobanking sites

www.ctrnet.ca

www.biobanking.org

www.bbrsbiobanking.ca

Current Funders & Partners