Workshop #3

Data Governance & Data exchange

Session 1

Workshop #3 Session 1

Some information for a smooth running of the session.

The audio of the session is recorded. **Please only speak in the microphone.**

Please introduce yourself every time before speaking. Do not hesitate to participate and ask questions.

Avoid using your smartphones and laptops if possible.

Please make sure to respect the time allocated for your speech & keep your interventions under 1mn.
Please be on time to the next session.

Workshop #3 Session 1

Facilitators

Michel COLEMAN - London School of Hygiene & Tropical Medicine

Chuck WIGGINS - New Mexico Tumor Registry

Subthemes

- Who "owns" the data?
- Who is responsible for oversight/decisions regarding data sharing?
- What permissions are needed in order to share?
- What specific legal steps need to be accomplished to enable data access?

Discussants

Suzi BIRZ
USA
University of Chicago
Pediatric Cancer Data Commons,
Regulatory and
Data Governance Consultant

Joanne AITKEN
Australia
Cancer Council Queensland
School of Public Health
The University of Queensland
Director of Research,
Honorary Professor

Workshop #3

Data governance and data exchange

Session 1: November 7, 2023, 2:30 pm

Discussant: Suzi Birz

THE UNIVERSITY OF CHICAGO

DATA FOR THE COMMON GOOD

OBJECTIVES

- What permissions are required for data sharing, and why?
- What are the legal requirements that enable and govern data access?
- What obstacles arise in sharing data for international research?
- Is the legal or institutional basis for data sharing too strict?
- Challenges and possible solutions

Permissions and the PCDC

PCDC relies on the data contributor to obtain the permissions.

- We do not validate this by receiving or viewing any of their documentation
- By signing the agreement, they are indicating that they have permission to transmit the data
- The data contributor agreement is our legal mechanism

Partner shall be solely responsible for obtaining all necessary consents and otherwise complying with all Applicable Laws and other restrictions: (i) to transmit any Contributed Data to the University; (ii) to permit the University to store such Contributed Data as part of the Platform; (iii) to provide Authorized Users access to such Contributed Data; and (iv) to permit the University to perform its obligations pursuant to this Agreement

Legal requirements and the PCDC

PCDC relies on the data contributor to obtain provide any laws applicable to their data.

PCDC complies with:

- HIPAA privacy and security
- University of Chicago research policies and procedures
- Federal, state, and local applicable laws
- And any other laws required by the data contributors

Prior to providing any Contributed Data to the University, Partner will provide written notice to University of any Applicable Laws applicable to such Contributed Data. Partner will provide the University of prompt written notice of any new Applicable Laws, or any change in any existing Applicable Laws, that apply to any Contributed Data

Obstacles that arise in data sharing with the PCDC

PCDC's differentiators are also our rate-limiting factors

Differentiator	PCDC's Approach
1. Each data contributor has different and specific privacy regulations.	We have a template Data Contributor Agreement which we negotiate separately with each data contributor
2. Each data contributor retains agency over their data, including what data are added to the disease commons and what projects are approved through the consortium executive (or designated) committee	Each consortium has a consortium executive (or designated) committee vested with this decision making, ensuring disease experts from the data contributors make these decisions
3. All data elements are standardized within the disease and then across the data commons.	Create and adopt a data dictionary of variables and allowable values specific to that disease and later harmonized across the other diseases in the PCDC

Closing thoughts: Too strict? Solutions?

- Data for the Common Good (D4CG) is dedicated to building communities, platforms, and ecosystems that maximize the potential of data to drive discovery and **improve human health.**
  - Our commitment to our mission and our respect for persons include the respect for the regulations around the world that have been enacted to provide protections for human subjects of research and patients.
- **Solutions?**
  - **Motivation**: Recognition that patients and families want their data to be used in any way that adds value and they want to know how their data are used.
  - **Approach**: Listen and work through solutions. Accept that this takes time.
  - **Flexibility**: Be nimble on the operational and technical approaches, including methods for accepting anonymized and pseudonymized data (GDPR).

NIH NATIONAL CANCER INSTITUTE

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#3 Data governance and data exchange

Session 1: November 7, 2023

Discussant: Professor Joanne Aitken

WHO OWNS THE DATA and HOW IS IT SHARED – it depends on …

1. Type of data

- Basic demographic, incidence, mortality data
  (held in population cancer registries)
- Clinical data - stage, treatment, genetics,….
  (often held in public and private hospitals and treatment centres)

2. Data owner

- Public (the state)
- Private institutions
- Other

3. Identifiability

- **Identified** data
  - written consent.
- **Identifiable** (unit record)
  - possible to share without consent under certain conditions as outlined in law.
- **Aggregated**
  - fewer restrictions

CHALLENGES TO BROADENING RESPONSIBLE DATA SHARING

- Public benefit versus risks of sharing health data?

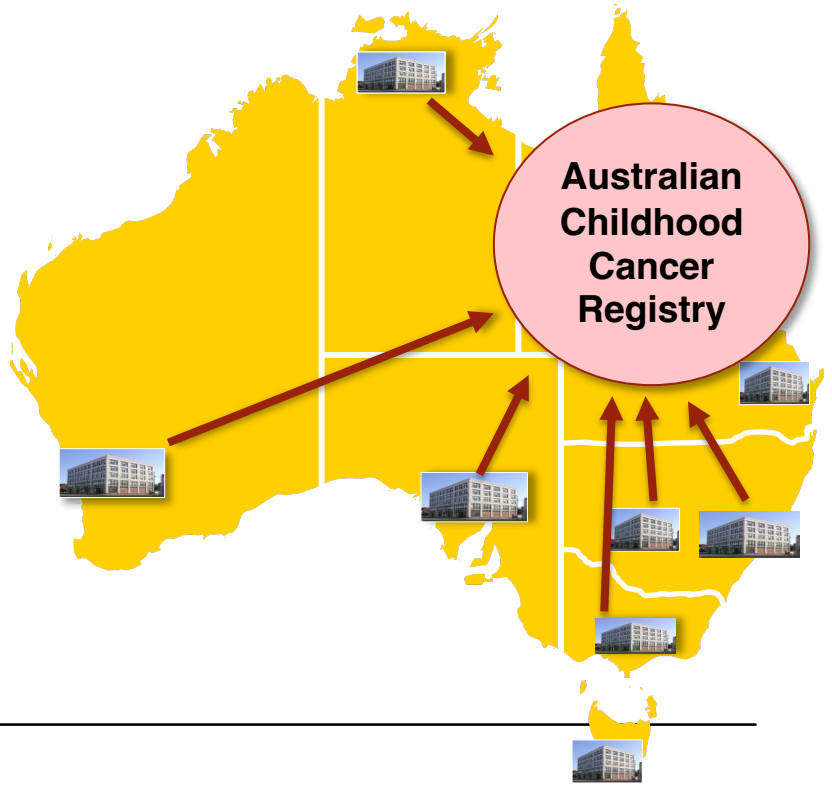
- Data owners/custodians concerned abut risks of :
  - Data security
  - Legal liability
  - Political risks
  - Community attitudes

- Australian surveys have found that the majority of people want their data to contribute to research that will improve health.

- Risk is seen as higher for sharing data internationally rather than domestically.

Success story 1: Australian Childhood Cancer Registry

- Registry and hospital data from all 8 Australian states and territories shared to a central repository
- Ethical and legal approvals required in every state/territory and by every hospital.



Success story 2: International Benchmarking of Childhood cancer Survival by Stage
The BENCHISTA Project

Wide variation of childhood cancer survival across regions

International Collaboration

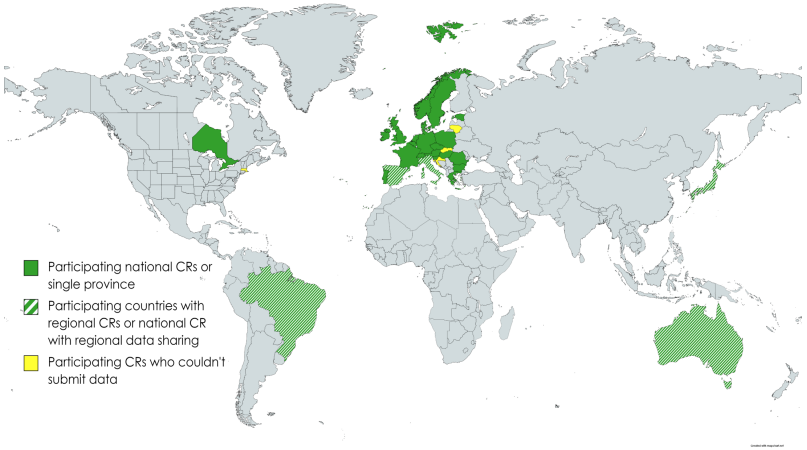
67 PBCRs

28 countries

41 Data Transfer Agreements

10,940 cases

Depersonalised patient-level data.



Item	Overall completeness
Toronto Stage	T1 → 95% T2 → 87%
Surgery	79%
Chemotherapy	81%
Radiotherapy	77%
Non-stage prognosticators	44%
Relapse	73%
Cause of death	71%

PLOS ONE Journal: The BENCHISTA Protocol publication

Frontiers in Oncology: Data Quality and Harmonization in EUROPE & BENCHISTA

Sponsors:
University College London, UK
Fondazione IRCCS Istituto Nazionale dei Tumori, Italy.

Funders:
Children with Cancer UK
Associazione Italiana per la Ricerca sul Cancro (AIRC) Italy

BENCHISTA governance

PI:
Prof Kathy Pritchard-Jones

Co-PI:
Dr Gemma Gatta

Project Management Team:

- ✓ Principal Investigator (PI).
- ✓ Co-Investigator (Co-PI).
- ✓ 4 representatives from participating CRs (Norway, Denmark, Spain and Hungary).
- ✓ 2 members at INT and 1 at UCL.

Independent Advisory Board:

- ✓ A cancer registry director not directly involved in the day-to-day project.
- ✓ Parent and survivor representatives.
- ✓ Clinical executive level members of a national paediatric oncology society.
- ✓ A clinical trial study group.
- ✓ A medical director-level clinician involved in organisation of childhood cancer services.

Project Working Group:

- ✓ One or two representatives from each contributing cancer registry.
- ✓ 6 tumour-specific oncology experts.
- ✓ Representatives from parent/survivor groups.
- ✓ Communication and dissemination partners.

Patient/public involvement and engagement (PPIE) structures