



OFFICE OF THE
INFORMATION &
PRIVACY
COMMISSIONER
for British Columbia

Protecting privacy. Promoting transparency.

REPORT OF THE ROUNDTABLE DISCUSSION ON ACCESS TO DATA FOR HEALTH RESEARCH

Office of the Information & Privacy Commissioner for BC

Held on June 25, 2012
Victoria BC

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TABLE OF CONTENTS

Purpose	3
Background.....	3
Participants and structure of the Meeting.....	3
1. Environmental Scan	5
1. Legislative Framework	5
2. National and International Perspectives	7
3. Categories of Data and De-identification.....	8
4. Ministry of Health and Health Authority processes.....	9
5. Government Perspective and Objectives	9
2. Roundtable Discussion	10
1. What are the Opportunities?	10
2. What are the Barriers?	11
3. What are the Possible Solutions?	13
Observations of the Rapporteur.....	15
Conclusions	15
Next Steps	16
Appendix A – List of Participants	17

PURPOSE

The purpose of this paper is to serve as a record of the roundtable discussion on access to data for health research and to identify next steps.

BACKGROUND

The Information and Privacy Commissioner for British Columbia, Elizabeth Denham, hosted a roundtable discussion on access to data for health research at her office in Victoria on June 25, 2012. She invited a small number of thoughtful individuals, with different perspectives on this issue, to participate in the discussion.

The roundtable was initiated by the Commissioner for two reasons.

First, in response to concerns that privacy is a barrier to health research. There had been recent reports and editorials in the media stating that requirements of the *Freedom of Information and Privacy Act* (“FIPPA”) were impeding important medical research. Moreover, at a conference on the issue of health research held in Vancouver on June 5, 2012 (“The Data Effect”), privacy was characterized as “the elephant in the room”.

The Commissioner is generally responsible for monitoring how FIPPA is administered to ensure that its purposes are achieved. As a result, she wished to determine whether there were, in fact, problems with the interpretation or administration of FIPPA that were the root cause of these concerns. She committed to finding out whether the assertions being made about requirements in privacy law and policy impeding the availability of data for important medical research are well-founded, and, if so, identifying constructive steps to address that problem.

Secondly, the meeting of key stakeholders was a chance to discuss the opportunities, barriers and possible solutions to improving access to data for health research.

PARTICIPANTS AND STRUCTURE OF THE MEETING

Participants in the roundtable discussion included representatives of the research community, data stewards from the Ministry of Health and Vancouver Island Health Authority, privacy experts and elected representatives representing the public interest. The Commissioner also invited an international expert on anonymization and de-identification of data. (See Appendix A for the list of participants.)

In an effort to engender open dialogue and to ensure that participants' views would not be misunderstood or taken out of context, the meeting was conducted in accordance with the Chatham House Rule. Notes taken at the meeting were solely on a non-attribution basis.

The meeting was structured in two parts. The first part was a presentation of background information on specific topics related to the issue. This environmental scan was intended to "level the playing field" in terms of the understanding and awareness of participants of different facets of the issue. Selected participants were asked in advance to prepare and make brief presentations on specific topics.

The second part of the meeting was a focused discussion to identify:

- the opportunities to be gained by providing health researchers with access to data;
- existing barriers to access; and
- possible solutions -- how access to data for health research could be improved.

Prior to the meeting, participants were asked to identify two opportunities, two barriers and two possible solutions and forward them to the Commissioner. These were presented at the meeting as a starting point for discussion.

PART 1: ENVIRONMENTAL SCAN

Information was presented on the following topics related to the conduct of health research in BC:

1. Legislative framework;
2. National and international perspectives;
3. Categories of data and de-identification;
4. Ministry of Health and Health Authority approval processes; and
5. Government perspective and objectives.

1. LEGISLATIVE FRAMEWORK

There are essentially three pieces of legislation in British Columbia that govern access to information for research purposes.

a) Freedom of Information and Protection of Privacy Act (“FIPPA”)

Pursuant to section 35 of FIPPA, a public body has discretionary authority to disclose personal information for a research purpose without the consent of the individual the information is about. Both the Ministry of Health and health authorities are public bodies.

This authority to disclose without consent for a research purpose is subject to four conditions:

- that individually identifiable form is required;
- that any data linking is not harmful;
- that the public body has approved certain conditions (relating to security / confidentiality, de-identification and subsequent use / disclosure); and
- there is a signed research agreement in place.

These requirements are similar to those reflected in analogous legislation in other Provinces in Canada.

Since 2008, the Information and Privacy Commissioner is authorized to approve requests from health researchers for contact information that they can use to recruit participants for their research studies. This is an exception to the general prohibition in FIPPA that information that is disclosed cannot be used for the purpose of contacting a person to participate in the research.

b) *E-Health (Personal Health Information Access and Protection of Privacy) Act (“E-Health Act”)*

The *E-Health Act* was passed in 2008. It established the **Data Stewardship Committee** which is an arm’s length body appointed by the Minister of Health. Its members include representatives of the Ministry of Health; health authorities; the College of Physicians and Surgeons, the College of Pharmacists; the College of Registered Nurses; a health researcher and the public.

The role of the Data Stewardship Committee is to consider requests from health researchers for the disclosure of protected information from a health information bank or ministry database.

The same four conditions for disclosure for a research purpose that are set out in s. 35(1) of FIPPA apply to these disclosures.

The *E-Health Act* includes a prohibition against the disclosure of personal information for the purpose of market research.

As under FIPPA, the Information and Privacy Commissioner must approve requests for contact information for a health research purpose.

c) *Pharmaceutical Services Act (Bill 35)*

This Act was passed during the most recent Session of the Legislature and came into force on May 31, 2012.

Among other things, this Act merged the PharmaNet Stewardship Committee with the Data Stewardship Committee. Previously, a separate PharmaNet Stewardship Committee had been responsible for considering requests from researchers for the disclosure of personal information from PharmaNet. PharmaNet is a provincial electronic database of all prescriptions dispensed in BC that is accessed from pharmacies, hospitals and medical practices. It has been described as a “treasure trove” of data for health research because it has been in operation longer than pharmacy networks in other provinces.

The same four conditions for disclosure for a research purpose that are in FIPPA and the *E-Health Act* apply to disclosures for that purpose from PharmaNet.

The long-standing prohibition against disclosure from PharmaNet for the purpose of market research is continued.

Conclusion: FIPPA, the *E-Health Act* and the new *Pharmaceutical Services Act* clearly provide for access to personal information for research purposes, subject to specific and reasonable conditions that help to ensure the protection of privacy and security of the data. The statutory provisions clearly enable public bodies such as the Ministry of Health and health authorities to disclose data to researchers.

2. NATIONAL AND INTERNATIONAL PERSPECTIVES

Participants heard that balancing the need of health researchers to have access to personal information against the need to protect personal privacy involves two kinds of risk.

The obvious risk is that personal information could be disclosed improperly, either intentionally or unintentionally, resulting in a privacy breach. A breach can cause harm not only to the patients, but also to the careers of researchers and data stewards and the reputations of health care organizations, research institutions and the province. The consequences of privacy breaches are recognizable and real and the media often reports on them. For these reasons, data stewards might become overly risk adverse. The result is that they might have a greater tendency to refuse access to data for research purposes, or to develop meticulous and overly deliberative approval processes that place stringent conditions on researchers. This could cause excessive delays in the researchers obtaining access to the data.

It is often overlooked, however, that preventing researchers from obtaining timely access to necessary data poses a risk known as “the failure to discover”. Every research project presents an opportunity to realize important improvements to the quality and cost-effectiveness of patient care. As it is impossible to know which of the many abandoned research projects could have resulted in important breakthroughs, the risk of failure to discover is not measurable. Consequently, it is not surprising that data stewards may be more concerned about the real and immediate risks of privacy breaches than about the vague and theoretical risks of the failure to discover.

From a national perspective, differences across jurisdictions in access and privacy legislation, as well as administrative practices, present challenges to research crossing these boundaries. While there are similarities in terms of health systems using publicly collected information in de-identified form and patient consent requirements, there are differences with respect to policy and accepted practice; administrative requirements (single data sources and multiple data sources); agreements; exclusions (jurisdictional, credential); lack of transparency; and information gaps (data dictionaries, metadata and sources of data).

There is a need to harmonize across jurisdictions a common set of questions for each research project.

From an international perspective, participants heard that attempts to establish an international registry that is hosted in Canada has faced barriers such as one country taking the position that no personal information be permitted to leave the country. There are also complexities where there are differences in the adherence, compliance and culture of health information practices. It may be possible to have mutual recognition agreements of health information such as exist for prescription drugs.

Conclusion: The immediate risk of disclosure is often more of a concern than the risk of failure to discover. Challenges for research across national and international jurisdictions are significant and varied; there is a need to consider ways to harmonize and support the development of standards.

3. CATEGORIES OF DATA AND DE-IDENTIFICATION

Participants heard that one effective means of facilitating a broad range of research, while protecting privacy is to de-identify the data. However, de-identification is a risk management exercise and cannot guarantee zero risk. There is always the risk that someone could use other sources of information that would enable them to identify the individuals that the de-identification was designed to protect. This process is called re-identification. Resources are limited, and any solutions for data sharing problems must fit within real-world constraints. It is important to determine an acceptable level of risk.

Participants were made aware of two categories of data for health research -- information that the health care system generates and information generated from other sources. An example of the former is structured clinical data (e.g. diagnoses, procedures, dates, drugs, lab tests). Examples of the latter include aggregate census data and statistical surveys.

Sources of data for health research include electronic medical records, hospital information systems and disease-specific registries and research databases.

Conclusion: De-identification, if performed properly, can provide strong assurances about the ability to determine the identity associated with a record. It is possible to produce data sets that have a low risk of re-identification and that have high utility for researchers. The risk of re-identification can be measured objectively, making it easier to manage.

4. MINISTRY OF HEALTH AND HEALTH AUTHORITY PROCESSES

There has been a recent decline in the number of data access requests that researchers have made to the Ministry of Health. Last year, there were 15 requests and 30 information sharing agreements.

This year, there have only been 4 data access requests and 12 information sharing agreements. Possible explanations include the lengthy approval process and a risk adverse culture among ministry staff responsible for responding to access requests. There are approximately 15 ministry staff engaged in responding to access requests at various stages.

The ministry is committed to doing better. The Minister of Health, Honourable Mike de Jong, recently made a commitment to a 60 day turnaround time for the Ministry to respond to data access requests from researchers.

The Vancouver Island Health Authority faces an increasing demand for data that it has been unable to meet. Health authorities do not have robust data warehouse strategies nor access to de-identification processes.

The fact that health authorities use different terminologies and different standards also creates challenges. Other issues include transparency of use so that providers and patients know that health data is being disclosed for research purposes. There is also a need to understand data governance models so that it is clear who is responsible for the data – clinicians, health authorities or the Ministry of Health.

Conclusion: The Ministry of Health has committed to improving its turnaround time to respond to access requests. Health authorities struggle with how best to respond to the demand for data, both from a capacity and privacy perspective. There would be benefit in having a clearer data governance model for data access within the health authority.

5. GOVERNMENT PERSPECTIVE AND OBJECTIVES

The use of data for clinical purposes or for research purposes sometimes merges in real time. There are several objectives in making data available for research: saving lives and decreasing morbidity; saving money in the health care system; and creating an economic development opportunity by attracting research dollars. How do we meet the demands? How do we get it right for BC?

In future, the internet and new technologies will allow patient centricity and this will affect health care. Government can facilitate research through data governance and data architecture that can easily produce data sets that are useful for researchers.

Examples include data related to payments for health services or non-health data that can be linked together to get a more complete view of the individual patient. This initiative to produce data sets is in line with government's commitment to Open Government, which includes its Open Data initiative.

Government is proud of recent amendments to FIPPA with respect to data sharing within common or integrated programs or activities and in the area of data-linking. The legislation provides access to data and data linking, with appropriate controls. The legal framework is not the problem.

Information was also provided to the group about *Healthideas*. This is a data warehouse at the Ministry of Health that is currently under development. The data warehouse contains only Ministry of Health data but also has the capacity to incorporate external data sets. The ministry has two uses in mind: use of the data for the Ministry of Health's program evaluation and research and also external research. Participants queried *Healthideas* purposes and use in the context of Population Data BC and expressed concerns about multiple data warehouses and data silos.

Conclusion: During the subsequent exchange of views on these topics, it became clear that it was accepted without question by all participants that health researchers seeking to access health data in BC face problems. The problems are real and they are systemic. BC has a good reputation nationally and internationally for the quality of its data but a poor reputation for making that data available to researchers. As a result, there has been a loss of funding for research involving the use of health data in BC and researchers are choosing to do research in other jurisdictions. BC is not included in national studies since research institutions build relationships with organizations who will give the data. As a consequence, important medical research is not being conducted in BC.

PART 2: ROUNDTABLE DISCUSSION

Participants were asked to identify, both in advance and at the meeting, of the opportunities, barriers and possible solutions to making data available for health research.

The following is a list of the ideas that were expressed. They were not vetted, nor are they recommendations that were agreed upon by the participants.

1. What are the Opportunities?

Improving the Health of British Columbians

- the results of health research can save lives and decrease morbidity; and
- the use of data can eliminate disease.

Improving the BC Health Care System

- research has a role in health planning;
- efficiencies in health care can be created as a result of research;
- research could have a positive impact on cost effectiveness; and
- would result in enhanced public confidence in the health system.

Economic Development

- use data as an economic tool to attract funding for research; and
- generate revenue.

Supporting Health Research

- Increase awareness of Population Data BC and how it facilitates access to health data for research purposes.
- Make more data available through Health*ideas* (a data warehouse of the Ministry of Health).
- Develop “access by design”:
 - go beyond meeting legislative requirements; and
 - structure data in anticipation of access.
- Inclusion of multiple domains of health data as being available for research.
- Contribute to national quality improvement.
- BC could become a centre for academic research.
- BC could lead in developing a harmonized approach for access among other provinces and territories.
- BC could model privacy and security best practices.
- Increase opportunities to link data and thus improve the quality of the data.
- Expand data holdings e.g. clinical data sets.
- Gain public support for using data for research.

2. What are the Barriers?

Government lacks a vision for health research and lacks the political will to make it a priority.

- Government hasn’t enunciated the importance of doing this work.
- There has been a failure to articulate a vision, direction or strategy.
- There is no demonstrated political will to improve access.

- Need to address BC's poor reputation for making data available for health research.

Data stewards lack an efficient, clear and transparent process to approve data access requests.

- Approval timelines are too long.
- There is a lack of clarity about the approval process.
- There is duplication in the required paperwork / documentation.
- There are inconsistent interpretations of legislative and policy requirements.
- Data is dispersed among multiple silos with multiple data stewards, not all part of the Ministry of Health.
- There are no standard requirements.
- Timeliness of the approval process for research presentations, posters and abstracts.
- The membership and practice of data stewardship committees could be improved.
- The approval processes of Research Ethics Boards, Population Data BC, data stewards and the Information and Privacy Commissioner are sequential.
- There are no processes for access to data by non-academics such as other government ministries.
- There are barriers based on functional roles such as when a health care provider is acting as a researcher or as a clinician.
- There is no mechanism for longitudinal research.

The capacity of data stewards is inadequate

- Responding to research requests is labour intensive and requires significant staff resources.
- The qualifications of those responsible for analyzing data are inadequate.

Uncertainty about data sets

- There is a lack of clarity, transparency and accountability for the sources of data and the data holdings.
- An inventory of data is absent, including definitions and the types of data.
- There are data silos.

Capacity of research projects

- Researchers may lack capacity to generate required documentation.
- Researchers don't always make appropriate requests.
- There is a lack of clarity in data access requests in terms of the types of data and the volume being requested.

3. What are the Possible Solutions?

Government must articulate a vision for health research in BC that has political support.

Researchers should make greater use of de-identified data

- Research Ethics Boards should examine de-identification and the standard of the Canadian Institute for Health Information.

Data stewards should streamline their approval processes in relation to data access requests.

- Simplify the paperwork required of researchers seeking approval.
- Create a centralized mechanism within government that has the authority to rule across silos.
- Establish an expedited review process for:
 - minimal risk studies; and
 - requests from trusted researchers who know the rules and accountabilities.
- Harmonize and clarify the standards and process for approval
 - develop consistent protocols and policies; and
 - use accepted language and protocols for linkages and getting consent.
- Establish a consistent process by designating more databases as health information banks under the *E-Health Act*.
- Develop a process for researchers to apply for approval in advance of their funding applications.

Data stewards should have more capacity

- Increase staff resources in the offices of the data stewards.

Data stewards should improve the transparency and accountability of their approval processes in relation to data access requests.

- Data stewards should publicly report on how long it takes to respond to requests so that the public can hold those organizations accountable.
- Increase the frequency of back-end audits and reviews of how researchers have protected the data after they have received it.

Researchers and research institutions should be educated about the data that is available and the approval processes of data stewards.

- Establish a standard checklist of good practices for researchers.
- Use dummy data sets to teach researchers to make the right requests.

There should be an ability to certify researchers and research institutions as trusted.

- Create a trusted user model for research access.
- Develop a credentials program for researchers.
- It should be noted that this raises questions as to who would assume responsibility for credentialing.

Data stewards should create more avenues to access data

- Finish implementing researcher access to Health*ideas* (the data warehouse of the Ministry of Health).
- Support use of and build on the vetted and operational infrastructure of Population Data BC.

An external arbiter should be established

- Designate an external arbiter for research requests to explain what is permissible under the legislation.
- The external arbiter would be accountable to a third party.
 - engagement and discussion among data stewards would be needed;
 - data stewards are legally responsible for the data and the benefit of; and
 - this approach to them must be carefully thought through.
- Appoint a data access facilitator or data broker.
- A central stewardship model could be an alternative to the arbiter model.

OBSERVATIONS OF THE RAPPORTEUR

There is no desire to change existing privacy laws. The laws provide access to data with reasonable controls. But the laws need to be interpreted and applied correctly and made to work.

There is an approval process established under the *E-Health Act* but only one database has been designated as a health information bank. Approval processes within the Ministry of Health would be more consistent if more databases were designated and the Data Stewardship Committee had greater responsibilities.

Transparency about the approval process is crucial. There are problems with a sequential application process. Is it possible to obtain approval in advance of funding decisions? Is it possible to have the different organizations responsible for approving requests considering them simultaneously?

There is a need for government to consult with the public and to articulate a policy position on research and the value of research.

CONCLUSIONS

This was the first time key stakeholders with diverse perspectives had come together to have a conversation about access to data for health research. Participants appreciated the opportunity to attend the roundtable and felt the dialogue was important and worthwhile.

The roundtable discussion met its objectives. There was consensus that health research in BC is suffering because researchers cannot get timely access to health data. Evidence was presented about the root causes of the problem of access to data for health research in BC and numerous possible solutions to that problem were identified. Media reports that privacy law is a barrier to medical research appeared to be unfounded. It was not the law in and of itself, but rather the interpretation of it that was identified as a barrier.

Many of the barriers that were identified, and the solutions to address them, concerned the administrative operations of data stewards. Participants wanted to know what they could do to help. There was agreement that the process for addressing this issue involves consultation with the stakeholders represented in the room.

NEXT STEPS

The Commissioner committed to compile and publish a summary of the roundtable discussion.

The Ministry of Health and the Commissioner will discuss holding a follow-up meeting to continue the conversation and focus on solutions.

Appendix A

List of Participants

Facilitator

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Research Community

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