

Ministry of Health Administrative Data & Research

Health Data Forum
Regina, Saskatchewan - November 17, 2010

Jacque Messer-Lepage, Risk & Relationship Management Branch
Winanne Downey, Population Health Branch
Ministry of Health



Saskatchewan
Ministry of
Health

OBJECTIVES

- To provide an overview of legal and policy issues relating to the use of personal health information for research.
- To highlight the major databases and issues to consider when using them for research.
- To describe the process for using the data for research.



The Health Information Protection Act
and secondary use of data...



Saskatchewan
Ministry of
Health

The Health Information Protection Act (HIPA)

- Proclaimed in September 2003
- Created for the health sector in Saskatchewan
- The Act applies to:
 - trustees,
 - with personal health information,
 - There are some exceptions.



A trustee includes... *(Section 2(t))*

- government institutions
- regional health authorities and affiliates
- special care home
- personal care homes
- mental health facilities
- laboratories
- pharmacies
- community clinics
- Saskatchewan Cancer Agency
- ambulance operators
- regulated health professions
- health profession regulatory bodies
- others can be added through regulations



Personal Health Information

(Section 2(m))

- The Act applies to “personal health information”:
 - about the health of an individual;
 - with respect to a health service provided to an individual;
 - collected incidental to providing health service.
 - registration information (e.g., name, address, Health Services Number)



Exceptions

- The Act does not apply to: *(Section 3)*
 - statistical or de-identified information.
 - administrative information or other records of a trustee.
- HIPA prevails over all other statutes – with limited exceptions, for example: *(Section 4(4))*
 - *The Public Health Act, The Mental Health Services Act, Workers Compensation Act.*



Use and Disclosure for Research

(section 29)

- HIPA does not define research but provides guidelines on what is **not** considered to be research;
- De-identified information is not protected;
- HIPA establishes rules for use or disclosure of PHI for research



Use and Disclosure for Research – *Continued* (section 29)

- **Use and disclosure with express consent** requires that certain conditions are met:
 - The trustee *must believe* that the research is not contrary to public interest;
 - Research ethics committee approval; and,
 - The researcher must enter into an agreement with the trustee that details conditions of ‘data use and/or disclosure’.



Use and Disclosure for Research – *Continued* (*section 29*)

- **Use and disclosure without consent** can occur if all of the conditions of the previous slide are met, ***and***,
 - the research cannot be done with de-identified information;
 - it is not reasonably practical to obtain consent, and,
 - The research ethics committee believes the benefits outweigh the risk to privacy.



Valid Express Consent

- In order for express consent to be valid, it must:
 - Relate to the purpose or proposed use for which the PHI was initially collected;
 - Be informed;
 - Be voluntary and not obtained through misrepresentation, fraud or coercion.



*Disclosure can occur
without consent in specific
situations....*



Linkage and Consent

Sometimes linkage can create privacy
issues...



Freedom of Information and Protection of Privacy Act (FOIPPA)

We are also accountable to the FOIPPA
legislation...



Freedom of Information and Protection of Privacy Act (FOIP)

- It's been the law in Saskatchewan since 1992
- Applies to executive government institutions, including :
 - Departments, agencies, boards, commissions, and Crown corporations;
- The Act:
 - As mentioned, it provides the public with rights to access government records; and
 - Set out privacy protection rules for personal information in government.



Things to Consider as a Researcher...

REB approval...



Saskatchewan
Ministry of
Health

Things to Consider *Continued...*

- Are there any legislative or organizational requirements?
- Will personal health information be disclosed or linked for research purposes?



Criteria & Process for Evaluation & Approval of Research Ethics Boards (REB)/ Committees (REC)

- REB/REC Criteria

- Members must have knowledge in methods of research, ethics, law, and privacy;
- The REB must operate under sponsorship of research institution, university, RHA or public body;
- The REB must adhere to national standards...
 - *Tri-Council Policy Statement, ICH Good Clinical Practice: Consolidated Guidelines, Food & Drug Regulations-Amendment (Clinical Trial Framework)*



Criteria & Process for Evaluation & Approval of Research Ethics Boards – *Continued*

- Process

- REB provides written application to Health
- Health evaluates application against criteria
- Health will make recommendation to Minister to approve REB for purposes of section 29 of HIPA
- Minister gives approval through written directive



It is important to note that REB approval *does not* equate to Ministry of Health approval...



EHR and EMR Data

A rich data source but how accessible is it going to be?



Data Sources

- Population registry
- Outpatient prescription drug data
- Hospital separation data
- Physician services
- Cancer services (SK Cancer Agency)
- Vital statistics
- Other (e.g., long term care, home care)



Strengths

- Individual identifier (HSN).
- Population-based.
- Updated registry - valid denominator data.
- Electronically linkable.
- Cross-sectional and longitudinal studies.
- Cohort and case-control methodologies.
- Standard international coding system used.



Weaknesses

- Administrative databases. (Exception: cancer registry)
- Pop'n relatively small for rare conditions.
- Condition cannot be identified if it doesn't result in a service.
- Outpatient diagnostic information less complete and less specific.
- Information on some confounders and risk factors not available.



Administrative Data

- Extensions of billing or record keeping systems.
- Not designed specifically for research, evaluation, surveillance, health status reporting, etc.



Interpretation Issues

- Influence of program features.
- Program changes.
- Change in data elements collected.
- Change in definition of data elements.
- Changes in coding.



Validity & Reliability

- Validity and reliability issues not unique to administrative databases.
- Researchers must be aware of limitations of design and data interpretation.



Current Data Structure

- Databases not linked or integrated.
- Documentation of changes over time may exist in various locations.
- Linkage and refinements required for individual projects.



Guidelines for Use of Data

- Legislative conditions.
- Approval from the Ministry's Data Access Review Committee and REC (if required).
- Consent required to link administrative data with data collected from subjects.
- Confidentiality of patient and health-care provider protected.



Balancing Privacy/Access

- Confidentiality maintained through access and data-release mechanisms.
 - Source (“raw”) data accessed only by authorized Ministry of Health personnel.
 - Data edited or summarized to include variables required for analyses (“need-to-know” principle).
 - If person-level datasets released, all identifiers pseudo-identified and minimum cell-size requirements applied where necessary.
 - Identifiable data released only with patient consent.



Project Stages

Grant application

- Assess feasibility.
- Protocol.
- Assess resource requirements.
- Prepare budget.

Funding confirmed

- Add project to workplan.
- Obtain approvals (e.g., DARC, REC).
- Formal agreement.
- Tailor computer code to study's requirements.
- Extract data & prepare study output.
- Quality assurance & data documentation.
- Review reports / publications



What's Worked Well

- Research project suited to data available.
- Research question well articulated ... technical details specified (e.g., case definitions) ... objectives support data requested.
- Close communication with Ministry ... consent forms, timely notification of grant awards, realistic time expectations.
- Professor/supervisor is primary contact for student project.



Contacts

- Privacy / HIPA questions:
 - Risk & Relationship Management Branch
- Single database research:
 - Information Services, Health Information Solutions Centre
- Data linkage research:
 - Epidemiology & Research Unit, Population Health Branch



QUESTIONS

- ??

