USE OF DATA FROM THE EHR FOR HEALTH RESEARCH – GOVERNANCE CHALLENGES IN CANADA AND POTENTIAL SOLUTIONS

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Disclaimer

- The views and opinions contained in this presentation are those of the author and do not necessarily reflect the views and opinions of the Office of the Privacy Commissioner of Canada, or of the Government of Canada.

Assumption

- Information in the health record is very rich in indirectly identifying data
  - Linkable data from interoperable EHR will be even richer
  - Very difficult to sufficiently de-identify the data to the point where we could declare truly anonymous
    - Fully anonymous datasets are of little use for contemporary research purposes

General Challenges in conducting comparative analyses across Canada

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The vision:

Better care through timely access to secure health information when and where it's needed.

See how we're making it happen.

About *Infoway*

Infoway is a not-for-profit organization that collaborates with the provinces and territories, health care providers and technology solution providers to accelerate the use of electronic health records (EHRs) in Canada.

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Learn more about

- Our Vision
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Quick downloads

Annual Report PDF E-BOOK
2008-2009: Building a Health Lega

Business Plan PDF E-BOOK
2009-2010: Making health informa
better for Canadians

The common interoperable Electronic Health Record

- A potential source of rich clinical data for researchers?

Federated government system

- Provincial jurisdiction over health (mostly)
- Provincial jurisdiction over privacy (mostly)
  - Some jurisdictions have specific legislation for *health* information

Electronic Health Record Systems

- Pan-Canadian specifications through Infoway
  - … but provincial implementation
- Research uses are not explicitly the purview of Infoway

Governance Challenges

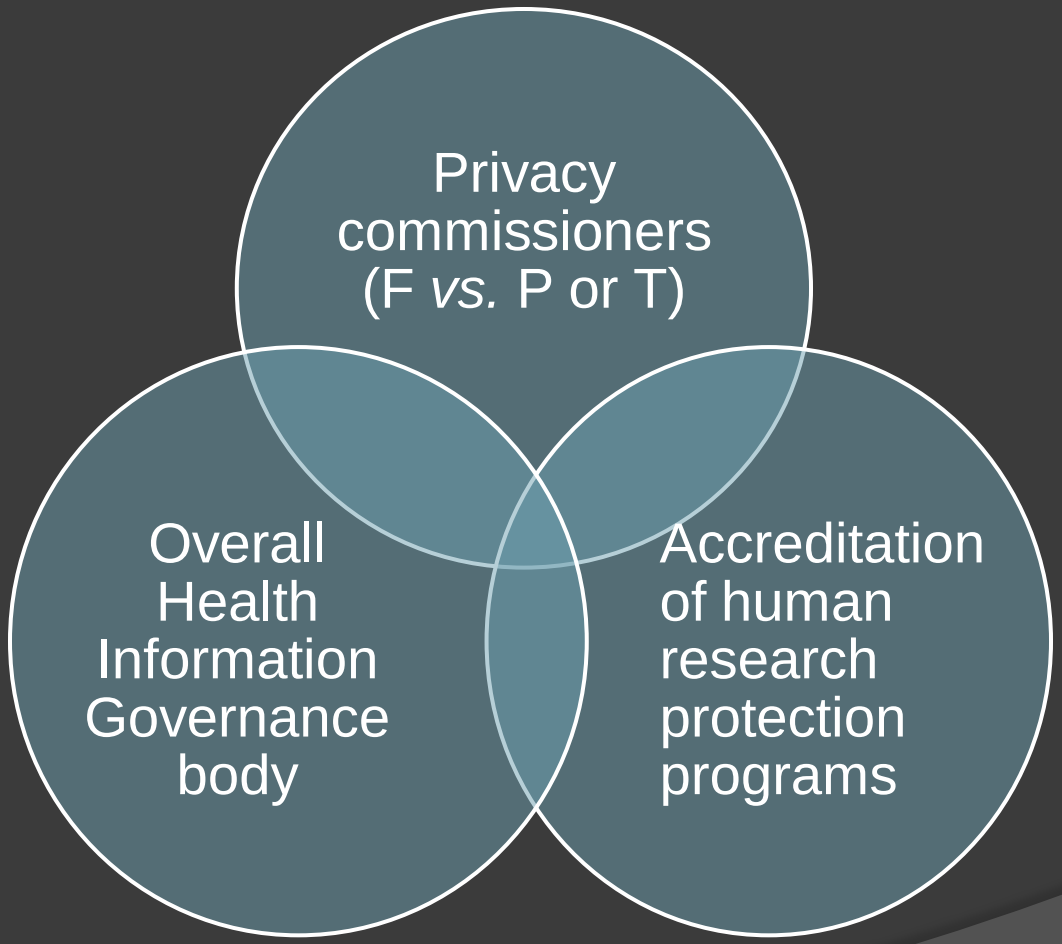
Many parties involved in governance over research uses of PHI

- Law makers (provincial & federal)
- Policy makers (including ethics policy)
- Those overseeing use
  - Privacy commissioners
  - Ethics Boards
  - Data custodians

- Inconsistency or confusion in interpretation of law
  - e.g. When is it impracticable to obtain consent?

- Interpretation errs on the side of restricting access
- Privacy as a smoke screen

Overlapping jurisdictions

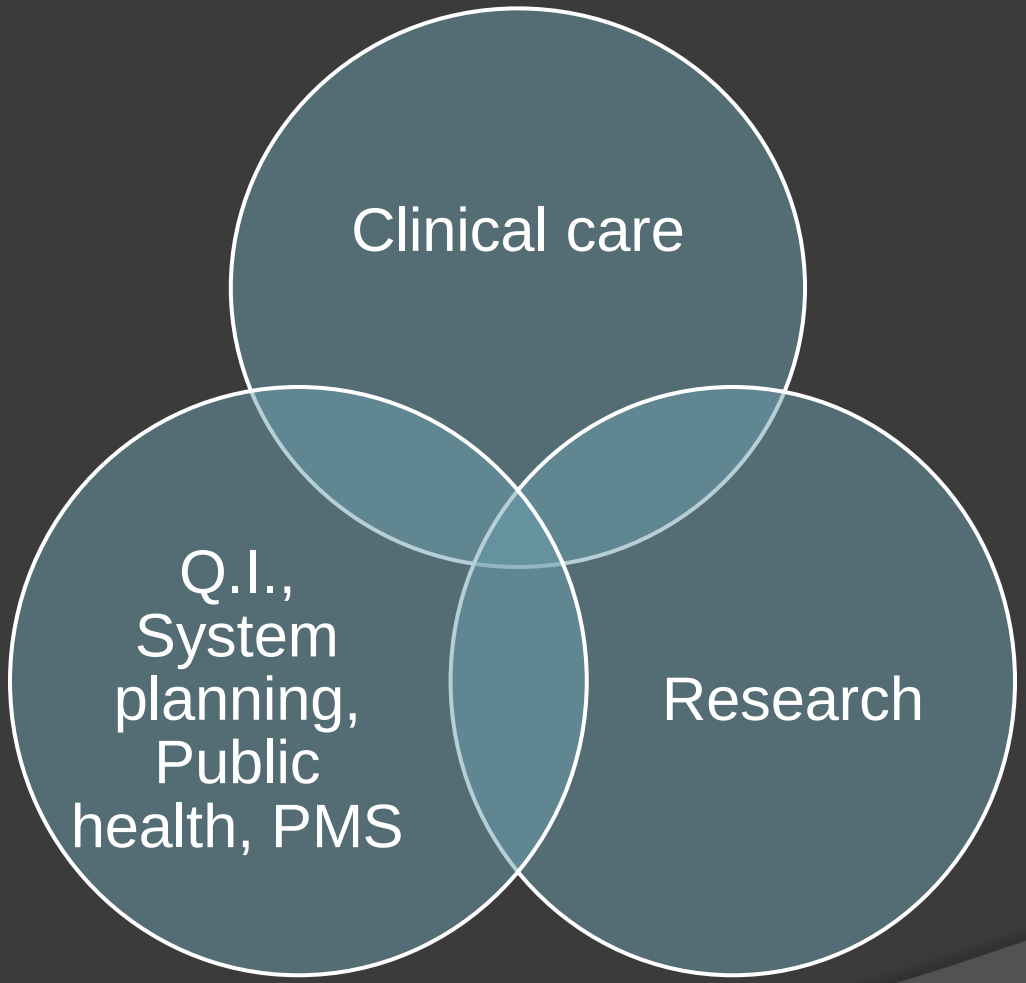


Additional Governance Challenges

- Indistinct boundaries between different types of (secondary) uses
  - … but differing oversight
    research ←→ QI, program evaluation, planning.
- Shift in way observational research is conducted
  - Discrete projects → research platforms
    - Challenges current norms
      - Limiting collection principle
      - Limiting retention
      - Existing consent practices
- Potential proliferation of data access points and databases

- Upcoming challenges:
  - Use of EHR for recruiting for clinical trials
  - Whole genome mapping & translational bioinformatics

Indistinct Boundaries



Changing nature of observational research

Past Practice

- Existing data
  - Administrative records
  - Clinical records (paper)
  - Limited capacity for record linkage
    - limited number of centres
- Prospective
  - One-off surveys
  - Finite studies

Emerging Practice

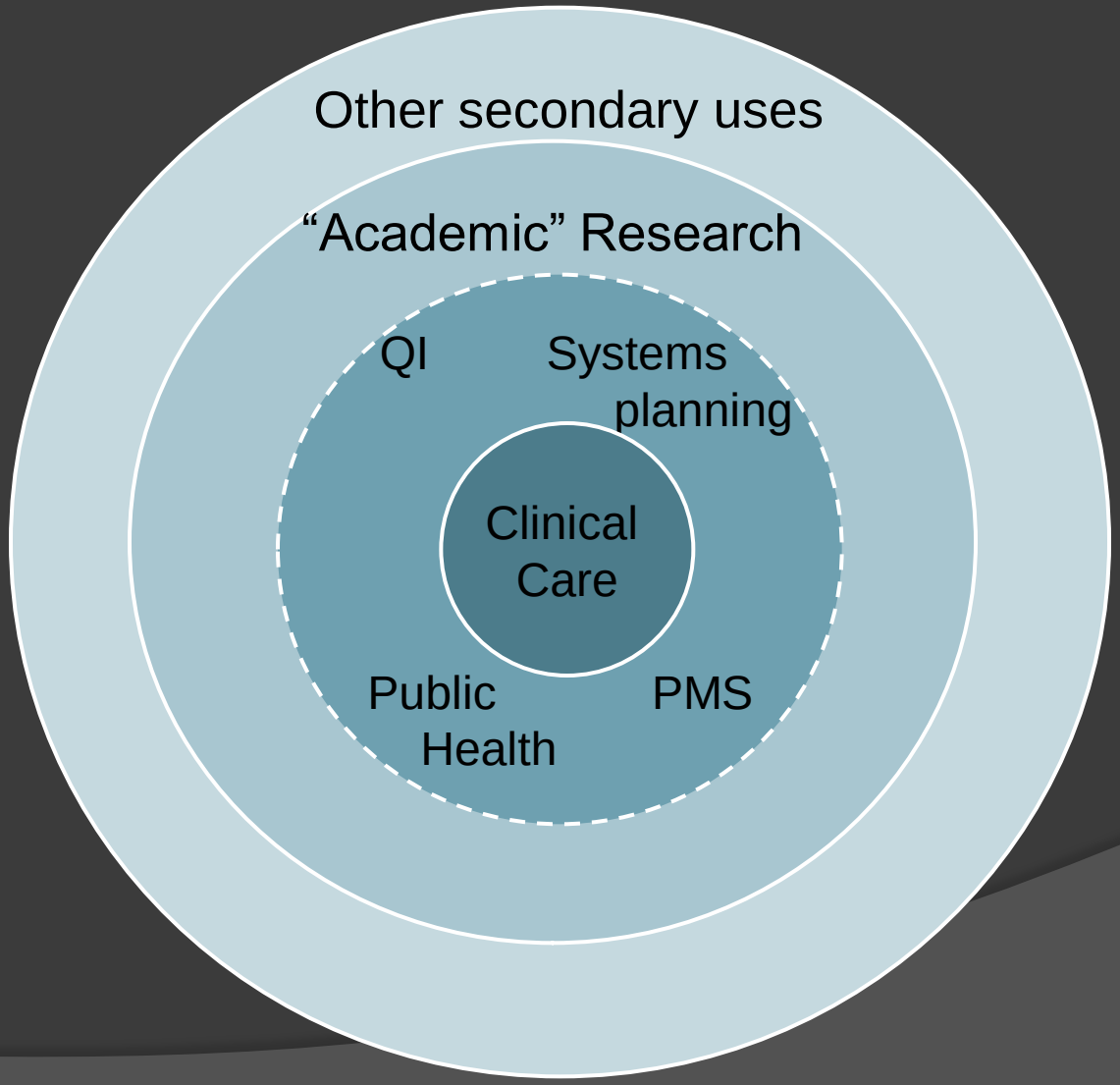
- Existing data
  - Electronic health records
  - Non-health information
    - Income, education, housing, social benefits
  - Record linkage common
- Prospectively collected:
  - Registries
    - Disease-specific
    - Cross-national
  - Bio-banks
    - Linked with clinical data
  - Longitudinal surveys
  - “Practical trials” & post-marketing surveillance

Governance over repositories

- As the research enterprise scales up from individual research projects to huge research platforms, how does that affect:
  - the respective roles of the REB, data custodian, and privacy commissioner?
    - Development of data repository
      vs.
    - Review of projects
      vs.
    - Governance over information use practices across projects over time.
  - the need for specialty review bodies at the regional, provincial, or national level?

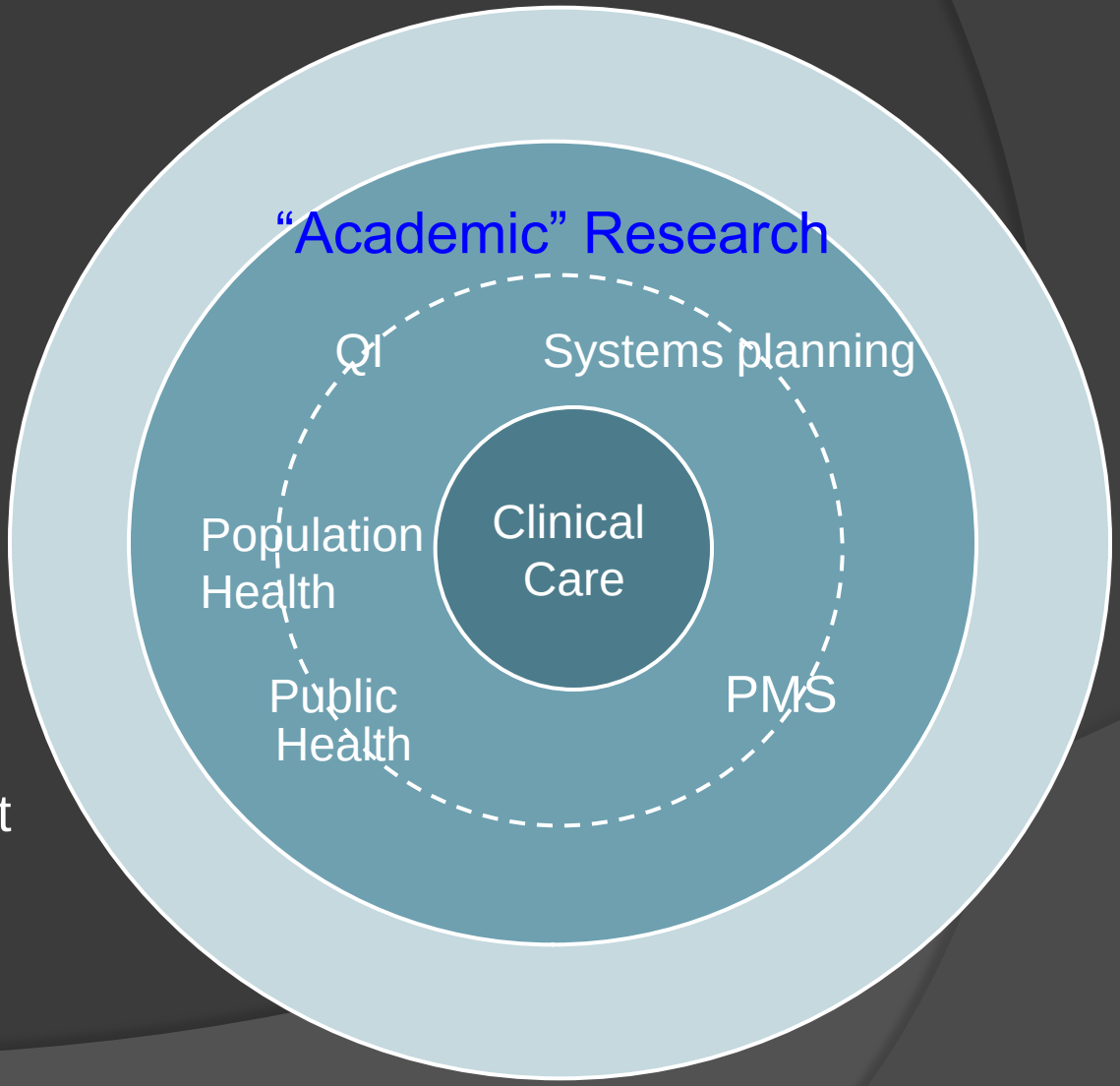
Possible ways forward

Current Conceptualization – primary & secondary uses of data



Re-conceptualizing use of health information

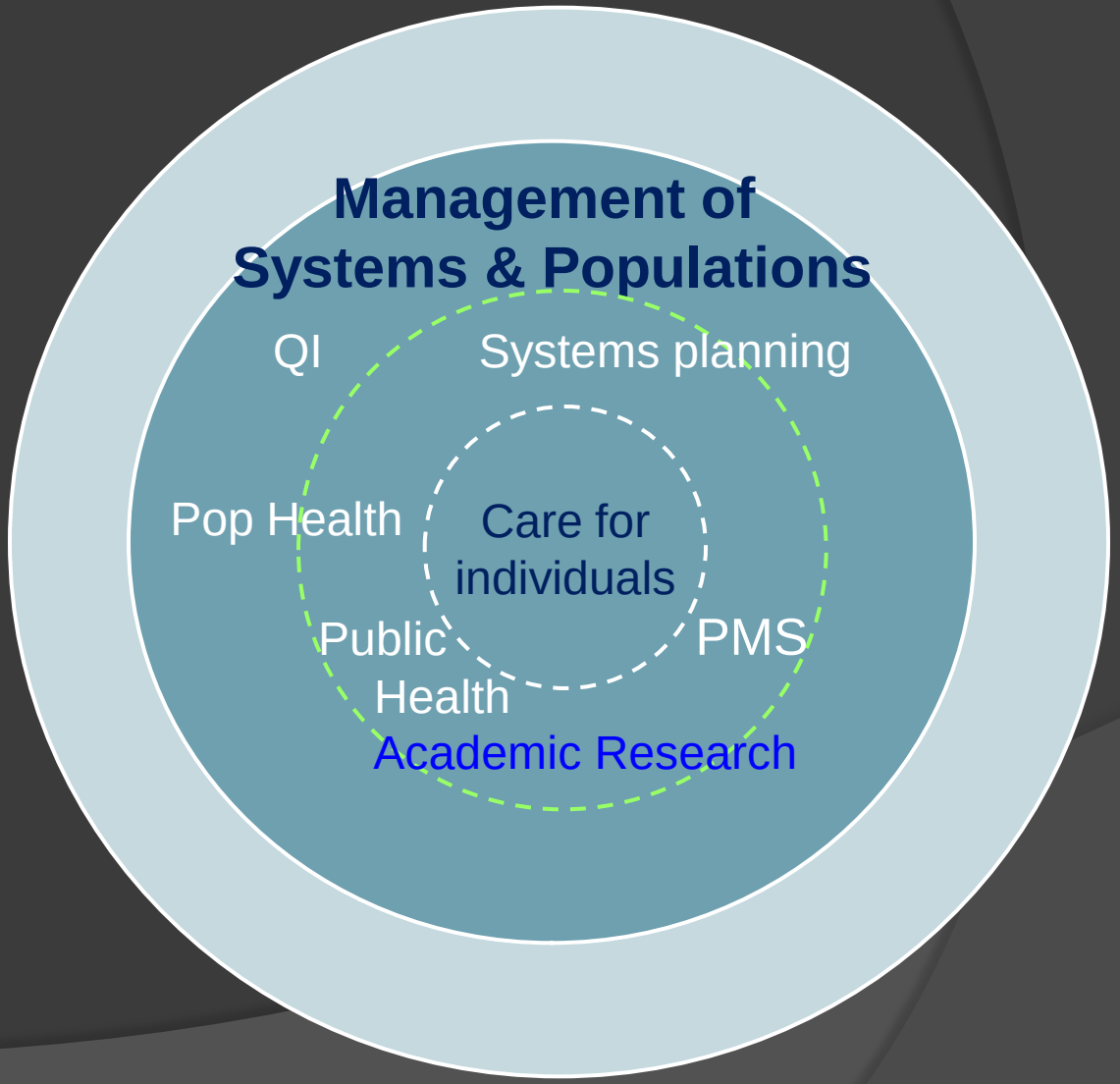
- Dissolve artificial boundary between research and Q.I., planning, PMS, etc.
- Ethics review proportionate to risk
- Consider under what circumstances consent would be required for research uses
- Consider default consent options for particular uses.



Re-conceptualizing uses of health information

Possible next step:

- 3 types of permitted uses. Mgt of:
  - health of individuals
  - health of populations
  - health care system
- Information use supporting these activities
  - Ethical scrutiny proportionate to risk



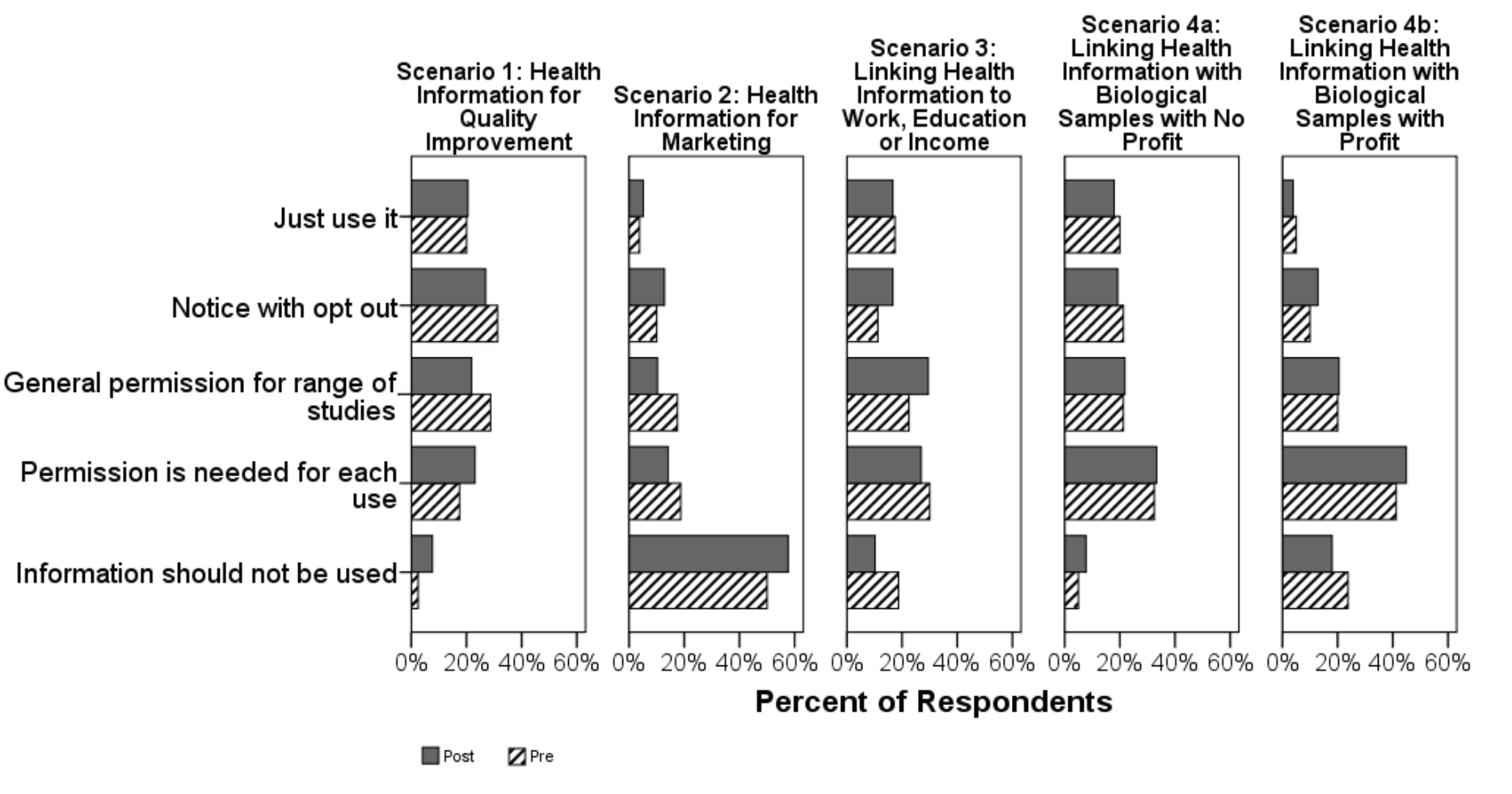
Notes:

- Does not mean that researchers have free-access to any data that they want.
  - Still require:
    - REB-approved protocols for specific projects
    - Justification of which variables are needed for analysis
    - Data protections
    - Restrictions on use and disclosure
- Does not mean there is no consent process for research uses of information.

Role of the individual patient in this systems approach to consent

- Dynamic consent model for different uses of PHI
  - For some purposes, opt-in / for others, opt-out, for others still, legally mandated
    - Default settings for different types of uses +/- ability to modify consent option
- Multiple approaches of administering – e.g.
  - when encountering the health care system
  - when getting health card renewed
- Need an individual to broker the authorization process. For example:
  - specialty nurse who is not a care provider & not working for researchers
- Role of patient portals in interoperable EHR system
  - document & communicate consent choices
  - inform what uses have been made of their PHI

Consent choices for research use of PHI across scenarios



Willison et al. BMC Medical Ethics 2008

Proposed approach to a dynamic model of consent for different uses of PHI

Example of Research Use	Proposed Default	Proposed Patient Options
Public health surveillance, with no individual contact	Mandatory participation*	None
Post-marketing surveillance of selected new drugs and for devices, with no individual contact	Mandatory participation*	None
Quality Improvement / systems planning, with no individual contact	Notification with option to opt-out**	1) opt-out – project specific 2) opt-out – any research
Population health, with no individual contact	Notification with option to opt-out**	1) opt-out – project specific 2) opt-out – any research
Research involving linkage of health information with biological samples, whether or not profit involved	Opt-in – broad consent	1) Opt-in, project-specific. 2) Do not contact for this type of research
Developing a registry of people willing to participate in prospective research	Opt-in – health care provider must make first contact	1) Researcher may contact patient directly. 2) Do not contact for this type of research

* For transparency, there should also be public notification of the uses made of this information
** Where practicable (e.g. using patient portals to one's EHR), the notification should be individualized.

Role of the public

- At the level of individual projects
  - e.g. consult with a representative group of affected persons.
- At the broader governance level
  - directing how the proceeds of IPP may be distributed e.g. Winnickoff
- Challenge: getting a representative group

Research Data Repositories

- Provincial-level repositories
  - EHR data
    - Accessible to researchers who apply
      - with REB-approved protocols
      - meeting data steward's criteria
  - To be determined:
    - Who would manage these repositories?
      - Health information custodian or trusted third-party with data management expertise
    - Access vs. disclosure of data
      - Disclosure only to institutions with the capacity to adequately safeguard data
        - Includes not allowing researcher to copy to own files

- Institutional level holdings:
  - Most disclosures of data from provincial-level repositories
  - Most researcher-generated holdings
- Researcher
  - Strictly limit to those with sufficient resources to manage secure uses

AUDIT

Who may set up and operate a registry / biobank?

- The researcher(s)?
- The host institution?
- Government?
- A trusted third-party?

Issues:

- ownership vs. stewardship
- capacity to manage data / samples over 20+ years
- governance over management & uses