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Is Privacy Legislation really a Barrier to Research?

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Overview

- My position
- History
- Process
- Challenges
- Longer-term planning

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Position:

- For the most part, privacy laws themselves are not a barrier
  - Consistent with good research practice
  - Common foundation: OECD Fair information practices
    - Inter-jurisdictional differences interpreting at the margin
  - Challenges exist, but they can be addressed
    - Re-use and sharing of personal data
    - Screening records and first contact of potential research participants
    - Data retention / destruction
- Researchers, ethics boards, and data custodians need to develop innovative practices c/w laws.

ORIGINS OF CONTEMPORARY PRIVACY LAWS

1. Records, Computers and the Rights of Citizens

- 1973, US Dept of Health, Education & Welfare report
  - Response to automated personal data systems proliferation
  - 5 fundamental principles:
    1. There must be no personal-data record-keeping systems whose very existence is secret.
    2. There must be a way for an individual to find out what information about him is in a record and how it is used.
    3. There must be a way for an individual to prevent information about him obtained for one purpose from being used or made available for other purposes without his consent.
    4. There must be a way for an individual to correct or amend a record of identifiable information about him.
    5. Any organization creating, maintaining, using, or disseminating records of identifiable personal data must assure the reliability of the data for their intended use and must take reasonable precautions to prevent misuse of the data.

2. OECD Guidelines on the protection of privacy and trans-border flows of personal data (1980)

- 8 Fair information practices (principles)
- Purpose:
  - To create a common set of standards that would assure the public their information was being used responsibly
    - facilitate the flow of personal information between countries
    - promote international commerce
- Some member countries then adapted

10 Fair Information Practices

(adapted from: CSA Model code for the protection of personal information, 1996)

An organization (or individual):

1. Is accountable for personal information in its custody.
2. Identifies, in advance, the purposes for which information is collected.
3. Obtains consent to collect, use or disclose the information.
4. Limits collection of personal information to that necessary to accomplish the purpose
5. Limits use, disclosure & retention to the purposes for which the information was collected.
6. Ensures information is accurate, complete and current for its intended purposes
7. Employs adequate safeguards – from unauthorized use, disclosure or from corruption
8. Is open about its information use policies and practices
9. Allows people individual access to information about them, and to challenge its accuracy and completeness, and amend as required.
10. Allows individuals to challenge compliance with these principles

Laws apply only to personal/identifiable information

- Identifiable vs. non-identifiable
  - artificial dichotomy

- Continuum
  - individual identifiable
  - individual pseudonymous linkable
  - individual non-identifiable (irreversible)
  - aggregate

Exceptions to consent requirements for collecting P.I. for health research (check against specific legislation)

- Conditions
  - cannot conduct research with aggregated / de-identified data
  - Weighing public interests in: research vs. privacy
  - Not practicable to obtain consent
  - Safeguards in place
  - Limits on further use, disclosure, retention
  - Will not attempt to contact the individual directly w/o prior consent to be contacted
  - Notify original data custodian if breach

Emerging Process:

Satisfy REB / REC / IRB

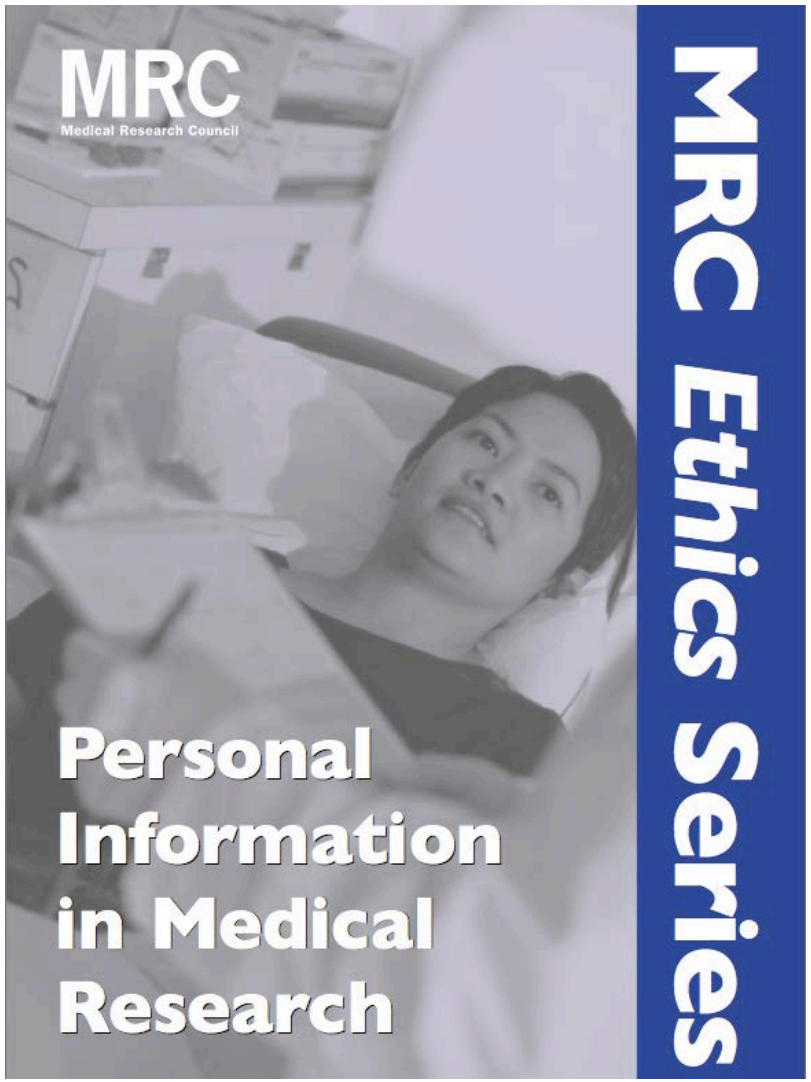
Satisfy data custodian

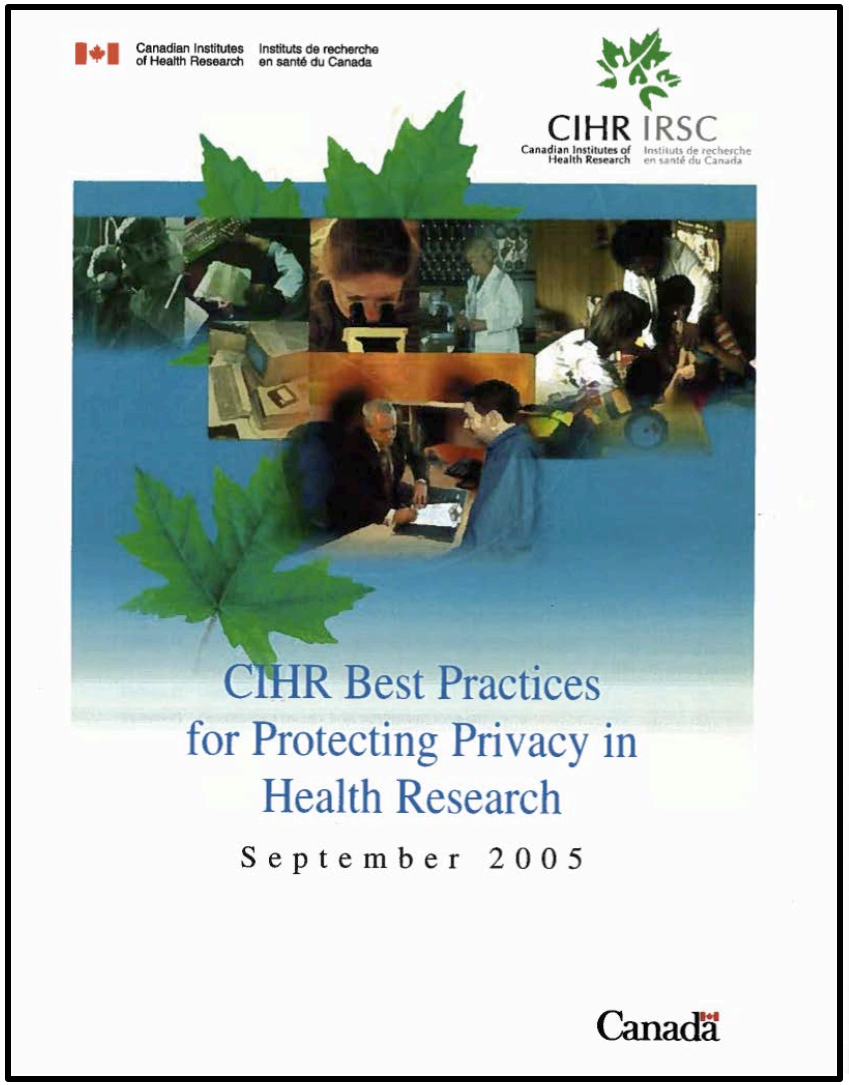
Challenges:

- Inter-jurisdictional differences
- Research studies vs. research platforms
- Data re-use
  - routinely collected data from the health care system
  - data from one study being used for another
  - data sharing with colleagues, students, etc.
- Contacting potential research participants
  - screening
  - first contact
- Data retention / destruction

Inter-jurisdictional differences

- Differences in focus of legislation
  - Generic privacy legislation
  - Specific to health information
- Differences in operationalization
- Need for research-specific guidance…


MRC
Medical Research Council
Personal Information in Medical Research
MRC Ethics Series


Canadian Institutes of Health Research
Instituts de recherche en santé du Canada
CIHR IRSC
CIHR Best Practices for Protecting Privacy in Health Research
September 2005
Canada

Data Re-Use

- Data collected for one research study cannot be used to answer another unrelated research question w/o consent of data subject
- Data collected by one researcher cannot be passed on to another researcher or institution w/o consent of data subject.
- Approaches
  - Seek exemption from REB / REC / IRB
  - Build into initial consent
    - Participation in primary research should not be conditional on consenting to secondary uses
  - May still get additional restrictions from data custodian

Contacting individuals

1. Who may screen records?
   - Reasonable expectation of access to the information of potential participants.
     - Staff of data custodian – Health Records
   - Research assistant?
     - Setting and circumstance-specific
       - Hospitals: may not have access beyond your own patients
       - Family practice: if “deemed employee”

Contacting Individuals

2. First contact
   - Reasonable expectation of access to contact info
   - Method of contact
     - If by telephone, call from onsite
     - If by mail, is this (a) a notice that someone will call or (b) an invitation to reply if interested?
3. Inviting & consenting
   - Concern over undue influence

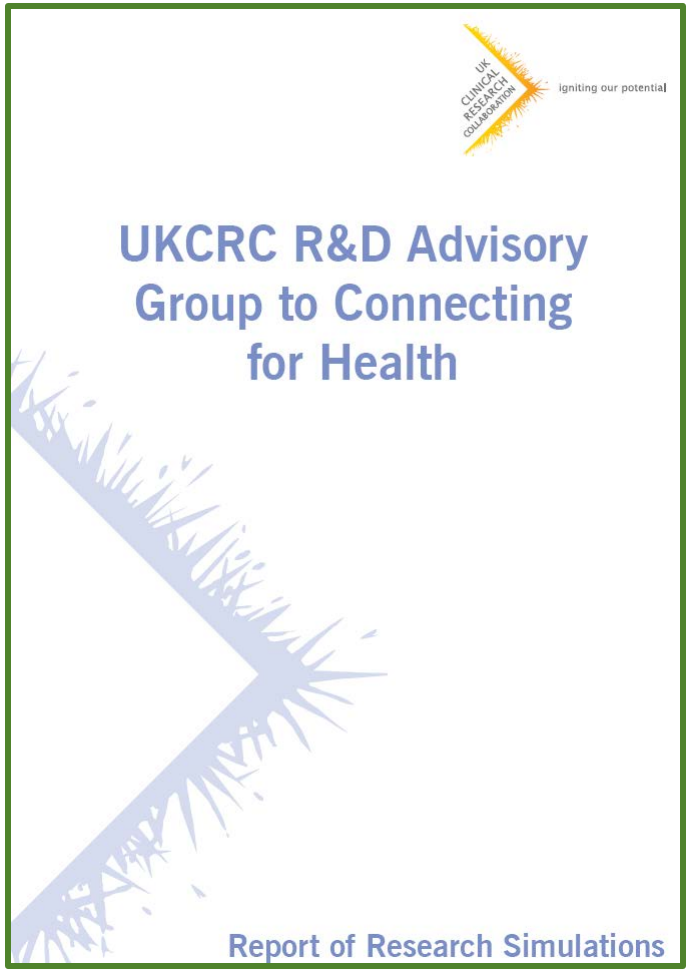
Data retention/destruction

- Data destruction provisions
  - Destruction vs. anonymization of research dataset.
    - Keep for:
      - disputes over findings
      - secondary questions, on approval of REB
    - Specify reasonable retention period
    - ➢ *Consider archiving with a trusted third-party*
  - Potential loss of source data for epidemiologic and public health research
    - e.g. workplace records of employees

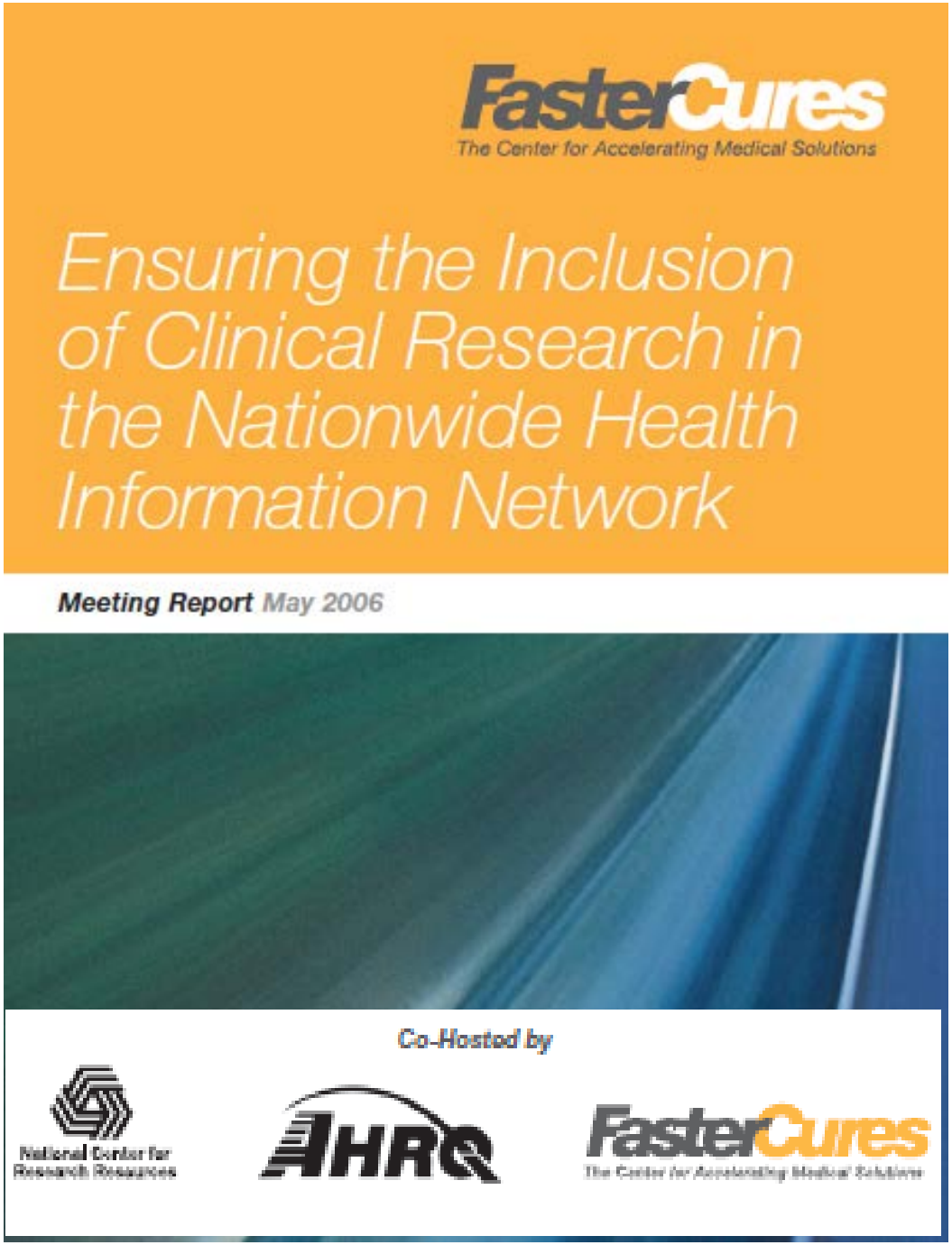
LONGER-TERM PLANNING

UK Clinical Research Collaboration

- Facilitate recruitment of patients into RCTs
  - feasibility assessment
  - ID & recruit patients
  - remote electronic data capture
- Enhance public health research on a national scale.
  - Surveillance (e.g. ADR)
  - Cohort / case-control studies



Source: http://www.ukcrc.org/



- Harnessing of EHR for:
  - post-marketing surveillance
  - population health surveillance
  - Improving subject recruitment for clinical trials
  - http://www.fastercures.org/pdf/FC_AHRQ-NCRR_report.pdf

COMMENTARIES

Pragmatic trials and practice-based research

JAMA 2007;297(4):403-407

Practice-Based Research—"Blue Highways" on the NIH Roadmap

John M. Westfall, MD, MPH
James Mold, MD, MPH
Lyle Fagnan, MD

On the old highway maps of America, the main routes were red and the back roads blue. Now even the colors are changing. But in those brevities just before dawn and a little after dusk—times neither day nor night—the old roads return to the sky some of its color. Then, in truth, they carry a mysterious cast of blue, and it's that time when the pull of the blue highway is strongest, when the open road is a beckoning, a strangeness, a place where a man can lose himself.

William Least Heat-Moon, *Blue Highways*[1]

ratories to the physicians and patients in primary care offices across the United States.

Inventing a new medicine or treatment is only the starting point for improving the health of an individual patient. The magnitude and nature of the work required to translate findings from human medical research into valid and effective clinical practice, as depicted in the current NIH research pipeline diagrams,[3] have been underestimated. Frequently, years or even decades are required for laboratory discoveries to reach clinical practice. It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice.[4] McGlynn et al[5] reported that Americans only receive 50% of the recom-

- Phase 3 & 4 clinical trials
- Observational research
- ID new clinical questions and gaps in care

Conclusions

- Laws, themselves, are not the problems
  - Devil is in the details of interpretation
  - Research community needs to work with data custodians and those governing research to:
    - develop systems that meets the intent of the law, while accommodating the newer research methods
    - look for opportunities to build research in the public interest into long-term vision for health information collected in the course of clinical care.