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Getting to the Data Portal: Mapping the Route Through a Legal Lens

Karen Weisbaum

Queen's University & Biotika Inc.

and

Margaret Ann Wilkinson

The University of Western Ontario

Karen Weisbaum

- Queen's affiliation (REB, teaching, research)
- HSREB member since 2004; requirements under the TCPS a member with understanding of "relevant law"; requirement under PHIPA for a member with understanding of privacy issues
- Consultant with Biotika; research and consulting in health policy, ethics and law; in recent years, Privacy Impact Assessments ("PIAs") on flows between government and other agencies/organizations for research

Margaret Ann Wilkinson

- Western affiliation (original joint appt Law/FIMS, now Law (but with FIMS for PhD supervision and new Masters of Health Information and at the Ivey School of Business for its Health Sector MBA)
- Past Research Ethics Board (REB) member, Western
- Doctoral dissertation on Personal Data Protections (PDP); past empirical and doctrinal work on professional ethics; intellectual property and information law
- Recent study co-authored with colleague Mark Perry "The Creation of University Intellectual Property: Confidential Information, Data Protection, and Research Ethics," (2010) 26 Canadian Intellectual Property Review 93-122.

Acronym Alphabet

CIHR – Canadian Institutes of Health Research

NSERC – National Science and Engineering Research Council

SSHRC – Social Sciences and Humanities Research Council

Tri-Council – CIHR, NSERC, SSHRC

TCPS – Tri_Council Policy Statement [Ethical Conduct for Research Involving Humans (1st 1998; now 2nd 2010)]

MOU – Memorandum of Understanding (not a contract)

NDA – Non-Disclosure Agreement or Contract for Confidentiality (contracts)

REB – Research Ethics Board

HSREB – Health Sciences Research Ethics Board

MOH – Ministry of Health (in any jurisdiction)

OECD – Organization for Economic Co-operation and Development (international)

PIA – Privacy Impact Assessment

- **FIPPA (1987)** – Freedom of Information and Protection of Privacy Act (Ontario) – governing access and protection of personal data in the public sector (including universities) except, generally, at the municipal level where MFIPPA applies
- **MFIPPA (1989)** – Municipal Freedom of Information and Protection of Privacy Act (Ontario)
- **PIPEDA (2000,** coming into force entirely by **2004**)– Personal Information Protection and Electronic Documents Act (federal – governing personal data protection with respect to private sector entities engaged in commercial activities and all private sector entities governed by the federal government – except where the federal government has recognized provincial statutes as equivalent)
- **PHIPA** – Personal Health Information Protection Act (Ontario) – declared equivalent to PIPEDA and therefore, to that extent, replacing PIPEDA and, where applicable, also replacing previous Ontario public sector legislation FIPPA and MFIPPA for health

Secrecy and Power

"The secret is the social mechanism through which the interests and intentions of particular social actors, making decisions in their daily lives, became translated into inequalities in knowledge … the secret is significant precisely because it the means through which the social distribution of knowledge is shaped by the translation of individual, intentional actions into larger social patterns."

From Kim Scheppele,

Legal Secrets: Equality and Efficiency in the Common Law (1988), p.23

On “Sharing” Data

- Of CIHR, NSERC and SSHRC, only SSHRC has an explicit policy on data sharing – the “SSHRC Research Data Archiving Policy”
- On the other hand, all 3 federal funding agencies have agreed on the “Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans”
- Constitutionally, the role of the federal government in health is constitutionally limited: most law involving delivery of health services must emanate from the provinces …

On the other hand, the health sector is changing and new areas of law, some federal, are increasingly engaged:

In the "older" intersections between medicine and the law, the competence of the health care practitioner was critical

A minimum standard of care was a defence against liability or culpability

Expert testimony of the standard of care was determinative of outcomes

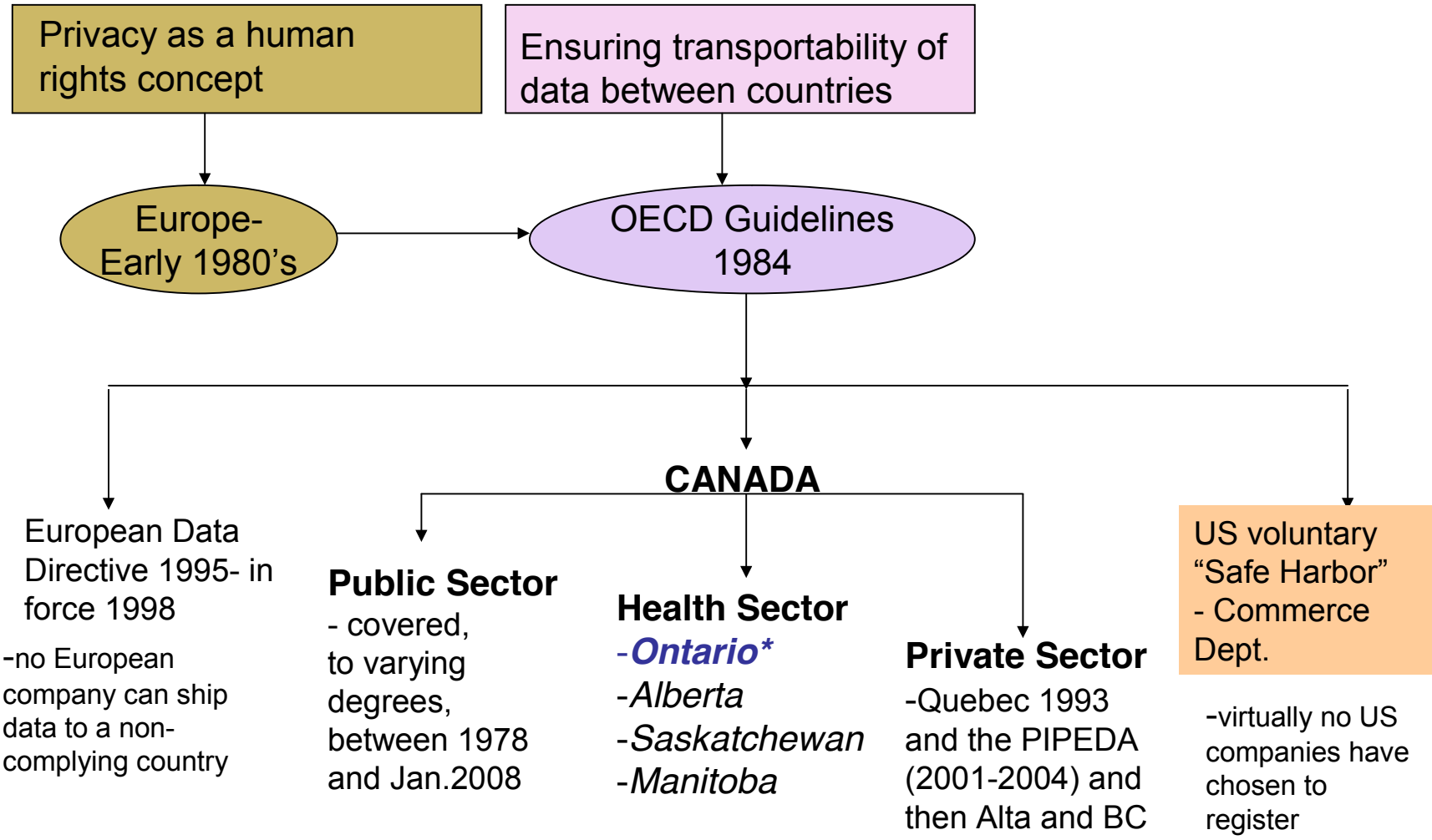
The knowledge of the professional was the most prized commodity – both in health care and in the law – professional competence is still important BUT…

The "new" reality is one of global commodification of drugs, reinforced by law, and empowerment of patients, reinforced by law,

The law determines outcomes – irrespective of the judgment of the medical professionals --

The privileged knowledge is the commoditized knowledge of the scientific community (excluding those who treat the patients – whose knowledge cannot be patented) and the control of information about patients by patients (no matter the source of that knowledge of the patient)

Evolution of Personal Data Protection



On the Purpose of Personal Data Protection Legislation:

- Personal data protection legislation is not just about providing patients with *access* to information about themselves held by the various institutions involved in their health care but also quintessentially about giving those patients legal *control* over information about themselves held by those organizations
- Research exemption in personal data protection laws may apply, e.g., disclosures for research by government (e.g., *Privacy Act (*federal); FIPPA (Ontario gov.)) or other regulated entity (e.g., PHIPA for hospitals, MOH, other health information custodians) (PIA requirements may apply via policy)

“Front End” Issues/Questions for a Health Data Summit

- What do we mean by “data?”
- What is the “data” being collected?
- What do we mean by “health data?”
- Related to the question of “What do we mean by ‘data’?” is the question “What are we doing with the ‘data’?
  - Quality assessment
  - Surveillance
  - Research
  - Other?

Stakeholders in Health Information

- The legal reality around commercially valuable information, if held in confidence by a private sector organization, and the increasing recognition of this information under Canada's international trade treaties, suggests that commercial stakeholders in the health business environment (as well as health care professionals and patients) should be considered, also as *primary* stakeholders in health information
- Another argument for identifying commercial stakeholders as primary stakeholders in health information in the context of health research might be the social value of the innovation (for example, in drug trials designed to support a patent application or access to Canadian markets for a recently patented drug).

Personal Data Protection Vs Confidentiality

- **personal data protection** laws apply only to records which contain information about identifiable individuals, whereas
- the law revolving around **protection of confidential information** applies to information held by an organization in any form and about any subject whatsoever which has been confided to it as a secret
- thus the subject matter of the law of confidential information can cover the same information which is the subject of personal data protection *but* can also embrace a much wider range of information.

What Do We Mean By "Data?"

- Identifiable information
  - Personal/personal health information
  - Professional information
  - Corporate information
- "De-identified" (record-level information)
- Coded/traceable
- Anonymized (vs.) / Anonymous
- Aggregate (with/without small cells?)
- Etc.

PUBLIC SECTOR	PRIVATE SECTOR
A commercial or professional confidence cannot be kept as a matter of law– access is legislated	**Commercial and professional confidences are legally protected through contract and the common action for breach of confidence** • These protections are in line with Canada's international trade obligations • These protections are not the result of government action and therefore cannot be tested against the principles, including access, under *Canadian Charter* • **If information gets into the hands of government, confidentiality cannot be continued – the information becomes subject to the access legislation (where there are limited exceptions for corporate information)**
Personal data protection is legislated • The Supreme Court says a corporation can successfully block release of information about an individual from a government organization to a requestor without the individual's knowledge or participation	**Personal data protection is legislated – but not for the press –** and at a different level for medical information in some provinces
Privacy is not legislated	**Privacy is legislated in some provinces, not Ontario, but nowhere with respect to access by the press, except in Quebec**

Research Purposes

- Is the purpose of collecting the data “research?” (From the beginning of the flow? At some later point?)
- Does the research involve humans? (As participants? Subjects of information? Both?)
- Is ethics review required?
- What is the relationship between statutory requirements that apply to the research activity and ethics review under the “TCPS2?”

University Research and Personal Data Protection Legislation:

- In 6 Canadian jurisdictions, university research ethics policies should refer to personal data protection law because that law governs protection of individuals' identifiable data in university research: Saskatchewan, Nova Scotia, Quebec (for non-scientific research), Manitoba (for health research), Northwest Territories and Nunavut;
- In fact, in the Perry & Wilkinson study of 54 universities, a few Quebec universities did refer to personal data protection statutes, the University of Winnipeg did in Manitoba, but no university in Saskatchewan or Nova Scotia did.
- On the other hand, in an abundance of caution, one supposes, two Ontario universities also referred to personal data protection statutes, as did Alberta and Memorial -- in jurisdictions where the legislation does not apply to university research.

University Research and Protection of Information as a Business Confidence

- In 9 jurisdictions personal data protection legislation does not apply to university research, either because it does not apply to universities at all (Prince Edward Island, New Brunswick, and the Yukon) or because it specifically does not apply to research in universities (Newfoundland & Labrador, Ontario, Manitoba (for non-health research), Alberta, British Columbia, and Quebec (for scientific research).
- In these jurisdictions, confidentiality agreements between the university and companies would be fully legally enforceable (because there is no personal data protection legislation that overrides them).
- In the Perry & Wilkinson study of 54 universities:
  - 2 Quebec universities referred to Non-Disclosure Agreements without indicating that these would not be enforceable in the case of non-scientific research
  - On the other hand, only in 2 universities in British Columbia, 2 in Ontario and 1 in New Brunswick did the research ethics policies acknowledge the existence of Non-Disclosure Agreements -- when 31 universities were studied in the 6 jurisdictions where these Agreements, if entered into, would be binding.

Ethics and Legal Protections

- The ethics review process in universities is required under Memoranda of Understanding between the Tri-council and recipient institutions for all research involving humans
- There is no national statutory scheme for this, but there are intersections and the gaps are (importantly) partly filled by the ethics review process (and separate institutional initiatives), which provide oversight of the conditions under which a researcher can gather information from individuals
- But how does this regime intersect with (1) personal data protection legislation; (2) the law protecting confidential information?

Ethical Norms (e.g., TCPS “1” 1998)

“Although these norms are not law and do not have the force of law, they may, over time and continued usage, begin to establish the standard of care against which courts will eventually measure the conduct of health researchers.”

(P. Kosseim, editor, April 2000 CIHR “A Compendium of Canadian Legislation Respecting the protection of Personal Information in Health Research”)

The Need for Many Perspectives

Taking a “360 degree perspective” on the processes of information flow (throughout the entire range of public and private processes involved in health and before focusing on any one current facet of health law) will help us to develop products, services and policies that are consistent both within Canada and within our international legal environment.

Bridging the Gaps

- Gaps that need to be addressed exist between (a) decisions implemented in law and (b) the actions, situations, persons and information that those legal provisions are supposed to influence.
- The legal framework is one problem—the practices meant to reflect it in the context of the health environment are another…the two *should* be brought together…or should they?