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Our understanding of the clinical significance of genomic data is rapidly evolving. The meaning of a patient's test results can therefore change over time. Re-analysis of genomic data over time and patient recontact offer an opportunity to improve patient health. But are physicians legally responsible to do so? Professional associations worldwide are outlining best practices for genetic recontact. To inform Canadian guidelines and courts faced with this issue, we review Canadian case law to determine if there is a likely doctrinal basis for judicial recognition of a duty to recontact in genetics. Foreign guidelines or malpractice case law may not adequately reflect the peculiarities of Canada's diverse legal and public health systems. A threshold consideration is the duration of the physician-patient relationship, seeing as physicians do not generally owe legal duties to former patients. This legal relationship endures according to the need for continued care as well as the subjective perspectives of both physician and patient. Satisfying these criteria in genetics can be difficult because of interpretative uncertainty or the absence of definitive intervention. Moreover, coordination of genetic analysis, communication, and follow-up care between healthcare professionals is complex, leading to problems of incomplete hand-off between laboratories, specialists, and primary care providers. The key challenge for plaintiffs will be to establish fault, that is, breach of a duty. Physicians in Canada traditionally have duties to diagnose, inform, follow-up and of confidentiality. We conclude that a legal duty of genetic recontact is only likely in specific circumstances where physicians acquire updated genetic information of clear health significance. This remains unlikely unless health systems or laboratories commit to systemic and adaptive reanalysis. This may change with the confluence of whole genome testing and advanced health information technologies ("HIT"). Whole genome sequences include millions of individual genetic variants and in turn, millions of opportunities for adaptive reinterpretation. HIT enables data sharing between laboratories, automated re-analysis of genomic test results, and new lines of communication with physicians and patients. Fundamentally, it is only health systems or institutions that can provide the infrastructure needed to adapt patient care in step with an evolving genetic knowledgebase.

Healthcare and health systems are radically different than they were 20 years ago. Among other changes, paper processes have been replaced by computer and digital workflows to the point that all health sector organizations have become data custodians. Between demographics (e.g., the higher health-care needs of an increasing large older adult population), new health-related issues

(e.g., many people living with multiple chronic conditions), and new opportunities (e.g., virtual visits and digital self-management) the health system is going to continue to change. Artificial intelligence ("AI") has the potential to enhance the next generation of technology-based approaches to health care and support data-driven decisions that improve the health and well-being of people around the world.

Conference Report: Health Data Protection Law in the Era of Big Data: Risks and Opportunities for Modernization **Volume 40, No. 1** **5**
Rosario G. Cartagena, P. Alison Paprica & Eric Sutherland

On February 27, 2019 over 100 experts came together to explore ways to modernize privacy and access legislation in Ontario.

Overall, there was resounding support for modernizing the privacy and access framework in Ontario. We live in a time where the push toward healthcare transformation and the pull to better align to technological advancement is driven by data. Data is at the centre of this transformational wave because:

- data can be used for system-wide evaluation, monitoring and planning of healthcare programs;
- data can be used to guide clinical decisionmaking through artificial intelligence algorithms;
- data can be used for machine learning to create advanced technologies to improve efficiencies and delivery.

Therefore, if we have wider access to data, the improvements to healthcare are boundless. The challenge, of course, is that data originates from patients. The case studies we explored and the recommendations that follow, advocate for broader access to data while maintaining strong data protections.

For researchers and policymakers to understand the best way forward in healthcare, they must have access to data that allows them to make accurate and informed decisions. Ontario's privacy legislation is 15 years old and its access legislation is 29 years old — the time to modernize is now. Ontario must be visionary in creating data protection legislation of the future, balancing privacy and access, and lastly, keeping trust and transparency at the helm. It is no small task, but one that can be done with goodwill, creativity and a deep understanding of how all stakeholders interact with patients and data.

The morning speakers included some of the major players in the system: Canadian Institute for Health Information ("CIHI"); Vector Institute; Ministry of Health and Long-Term Care; Ministry of Government and Consumer Services; and the Information and Privacy Commissioner of Ontario ("IPC"). The afternoon speakers presented the case studies and were a mix of patients, healthcare providers, policymakers, government, private entities and lawyers. Lastly, two forward-thinking Ontarians closed the conference: Dean Adalsteinn Brown, the Dalla Lana School of Public Health and Dr. Sacha Bhatia, Director, Women's College Hospital Institute for Health System Solutions and Virtual Care.

The following recommendations arose from the case studies presented and discussed at the conference:

Case Study #1: Recommendation - Using Prescribed Entity and Prescribed Registry Data for Health Care Delivery or Public Health Management

Case Study #2: Recommendation - Partnering with the Private Sector to Provide Patients with Access to Their Own Data

Case Study #3: Recommendation - Hospitals Sharing Real Time Data to Enable AI Studies That Involve More Than One Site

Case Study #4: Recommendation - Involving Regulators, Researchers and Care Providers in Developing and Refining Adaptive Regulation for New Technologies

Case Study #5: Recommendation - Learning from New Brunswick's Success with Legislation that Allows for the Collection and Use of Health AND Non-Health Data.

Current Challenges in Disclosing PHI for Quality and Research Purposes **Volume 40, No. 1** **35**
Mary Jane Dykeman

A common question asked of health privacy lawyers is how personal health information ("PHI") may be used and disclosed under Ontario's *Personal Health Information Protection Act* ("PHIPA"), especially for secondary purposes.

This requires analysis of the applicable legal authority, such as the model for consent (whether implied, express, or no consent), a research ethics board ("REB") waiver of consent, or being designated as a prescribed registry or entity due to a specific mandate within the health system.

Data, Privacy and the Pandemic **Volume 40, No. 4** **98**
Teresa Scassa

The current COVID-19 pandemic has raised numerous privacy issues as governments and the private sector explore the different ways in which personal data might be used to predict, plan and to resolve problems. This article considers a number of developments in Canada and highlights the privacy issues they raise.

Disability Rights Concerns and Clinical Triage Protocol Development During the COVID-19 Pandemic **Volume 40, No. 4** **103**
Trudo Lemmens & Roxanne Mykitiuk

In the context of the COVID-19 pandemic a number of jurisdictions and authorities have drafted triage protocols to guide decision making in the face of severe shortage of ventilators and intensive care resources. Several of these have evoked debate about their compatibility with human rights standards, and in particular the rights of people with disabilities. In Canada, the Canadian Medical Association came out with a general Framework for Ethical Decision Making, while Ontario Health produced a draft Clinical Triage Protocol for Major Surge in COVID Pandemic. In this commentary we critically review both documents to determine how their development process and their substantive provisions align with approaches to substantive equality and the promotion of human rights of persons with disabilities. We offer a number of recommendations to ensure that the human rights of persons with disabilities are promoted in COVID-19 triage policies.

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Good Intentions: An Examination of the Legal and Ethical Harms Caused to Donor-Conceived People and Ova Donors in Canada by its Criminalization of Compensated Gamete Donation, and the Proposed Remedies **Volume 40, No. 3** **82**
S.R. Cohen & S. Winsor

The *Assisted Human Reproduction Act* ("AHRA") passed federally in 2004 made compensating a gamete donor a criminal activity punishable by up to 10 years in jail and/or a fine of up to $500,000. The justification lay in equating gamete compensation with the commodification of human tissues and the exploitation of children, women, and men. With this new law, Canada quickly became almost completely dependent on imported gametes to meet its citizens' needs. We will explain in this paper how criminalizing compensated gamete donation has hindered Parliament's legislative goals set out in s. 2 of the Act and harmed the very people the AHRA intended to protect—in particular, donor-conceived people and ova donors. We will use the doctrine of double effect to demonstrate that reasonable compensation to gamete donors is ethically permissible; and will outline how donors and recipients can benefit from gamete donation policy and practices that are regulated as health and parentage matters, not criminal ones.

Getting Connected: Digital Health and Information Sharing under Bill 74 **Volume 40, No. 1** **27**
Daniel Fabiano & Sophie MacRae

This bulletin provides an overview of the technology, information sharing and privacy aspects of Ontario's new health care legislation, enacted by *Bill 74: The People's Health Care Act, 2019*, and describes the province's vision for an integrated and connected healthcare system.

The first call for self-assessments from health service providers who would like to be designated as an Ontario Health Team, a designation created by the new *Connecting Care Act, 2019*, closed on May 15, 2019. Self-assessments can still be submitted, and the next deadline is expected to be announced by the Ontario Ministry of Health and Long-Term Care ("Ministry"). Certain groups will be selected to submit a full application based on the self assessments. Providers that would

like to become an Ontario Health Team must successfully complete an application and in-person visit, and begin implementation of the Ontario Health Team model (at which time they will be referred to as an "Ontario Health Team Candidate"), before they will be designated as an Ontario Health Team (a stage referred to as "maturity"). Digital health capabilities are expected in applicants, Ontario Health Team Candidates and Ontario Health Teams.

The Ministry has released a guidance document for applicants, *Ontario Health Teams: Guidance for Health Care Providers and Organizations* ("Guidance Document"). Among the Ministry's expectations are compliance with a number of digital and privacy-related standards. The proposed "digital first approach" will require Ontario Health Teams to provide digital choices for patients to access care and health information, and use digital tools to communicate and share information among providers. Applicants will be expected to expand their digital tools during implementation. The Ministry has committed to minimizing barriers for the first Ontario Health Team Candidates.

This bulletin describes the role of technology and information sharing in the Ontario Health Team model, sets out the expectations at each phase of becoming an Ontario Health Team and describes the tools, services and steps that the Ministry has proposed to advance the model. It also includes privacy considerations that each member of a proposed Ontario Health Team must consider when implementing the model.

Re-thinking Risk in Canadian Healthcare to Promote Better Patient Outcomes: A Commentary **Volume 40, No. 1** **31**
R.S. Bhatia & L.T. Kelley

As Ontario moves towards providing integrated patient care services by establishing Ontario Health Teams ("OHTs"), the government has clearly signaled that digital tools and advanced data analytics will be a key enabler of care delivery across heath care siloes. To facilitate integrated care, the perspective on data sharing needs to change from the current institutionally-focused, risk averse, ownership model to one in which data is shared across the continuum of care. In this commentary, we will discuss the need for modern approaches to data sharing that balance patient privacy and the use of data to promote high quality integrated care.

Using Prescribed Entity Data for Healthcare Delivery and Public Health Management **Volume 40, No. 1** **43**
Zohra Bhimani, Amit X. Garg, Michael Bowmile, Jennifer L. Gibson, Rosario G. Cartagena, Craig Lindsay, Navdeep Tangri & Danielle M. Nash

While electronic healthcare administrative data can be leveraged to identify patients who may benefit from interventions to improve the care they receive, such opportunities are often not pursued in the interest of patient privacy. For example, in Ontario, Canada, health privacy legislation authorizes certain prescribed entities to collect personal health information from Health Information Custodians without patient consent for the purposes of managing and monitoring the healthcare system. This information can also be used to identify patients with health conditions or risk profiles who are not receiving the most appropriate care, or whose current care plan may be harmful to them. However, Ontario's legislation restricts the identification of patients through regulations on the storage, use and disclosure of personal health information, including the removal of personal identifiers from data before it is analyzed for approved purposes. Using Ontario health law as a framework, this article explores the possible clinical, ethical, and social implications of implementing a mechanism that would allow patients

to be contacted if gaps in their care were identified within electronic healthcare administrative databases, highlighting examples from the United States and the United Kingdom.