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Modernizing **Ontario's Personal** Health Information **Protection Act:**

Recommendations for a Data-Driven Health System

Modernizing Ontario's *Personal Health Information Protection Act*: Recommendations for a Data-Driven Health System

ISBN: 978-1-926850-96-2

How to cite this document:

Cartagena R, Lewandoski A, Paterson M, Schull M, Smeed T, Smith M, Vermeulen M. Modernizing Ontario's *Personal Health Information Protection Act*: Recommendations for a Data-Driven Health System. Toronto, ON: ICES; 2023.

Acknowledgements:

ICES would like to thank the Office of the Information and Privacy Commissioner of Ontario for its continued guidance; the Ontario Ministry of Health for its ongoing support and allowing participation in its modernization consultations; and members of ICES' Public Advisory Council for sharing their time and viewpoints during the preparation of this report.

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Funder Acknowledgement:

ICES is funded in part by the Ontario Ministry of Health and the Strategy for Patient-Oriented Research (SPOR) through the Canadian Institutes for Health Research. The conclusions, opinions, and statements expressed in this report are solely those of ICES and do not necessarily reflect those of ICES funders. No endorsement is intended or should be inferred.



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Executive Summary

Ontario's health system has significantly changed over the last 20 years. We've seen this in the increased coordination of health services and the rapid growth of technologies that collect, store, and produce digital health data. There is also a stronger focus on improving health equity and understanding how social factors impact an individual's health (known as 'social determinants of health'). These transformative changes require modern legislation that enables population data to conduct meaningful analytics and provide insights for the health system.

This report explains how world-leading research and analytics can lead to improved health and health care for everyone. Data sharing also must exist within a framework that protects the patient's privacy and confidentiality. Ontario's *Personal Health Information Protection Act*, 2004 ("**PHIPA**")¹ regulates data sharing between different types of health-related entities. In recognizing the health system changes since PHIPA was enacted in 2004, the Ministry of Health launched a series of consultations with health system stakeholders about their experiences working with PHIPA. These consultations aimed to identify how PHIPA can enable a modernized delivery of health care and where barriers to modernization may exist. ICES met with the Ministry of Health in February 2023 to present its vision for modernizing PHIPA and provided a written submission. This document is a condensed version of our written submission to the Ministry of Health. We also provided a copy of our report to Ontario's privacy regulator, the Information and Privacy Commissioner of Ontario. ICES is well-positioned to provide recommendations to the Ministry of Health on modernizing privacy legislation in Ontario:

- + We have a 30-year history of collecting and linking health data to support meaningful research and analytics that drive innovation in the health system.
- + We engage daily with dozens of organizations and other stakeholders and understand the importance of using data to drive transformational change.
- + We liaise regularly with our ICES Public Advisory Council to have a better pulse on the needs of Ontarians.

Our recommendations are centred on expanding the role of prescribed entities. The Ministry of Health included the prescribed entity designation in PHIPA for organizations approved by Ontario's Information and Privacy Commissioner for conducting health system data analytics. By expanding the role of a trusted organization with the data required for transformational health system changes, Ontario can more rapidly address the ongoing and persistent challenges in its health care delivery. Prescribed entities have decades of experience conducting robust analytics within a strong privacy regime overseen by a provincial privacy regulator. Our recommendations expand how prescribed entities can collect, use and disclose health data, but they do so in a way that continues to preserve individual privacy and confidentiality.

This report is an opportunity to continue ICES' engagement in this conversation with all provincial stakeholders and share our recommendations with our partners and communities as we exchange knowledge and innovative solutions in the data privacy sector. By advancing our vision of improved health and health care for everyone through world-leading research and analytics we hope to advance the dialogue on health system transformation. Our aim in this report is to and stimulate discussion about how robust and creative data frameworks and data governance models will benefit the public and lead to improvements in the health system.

- + We are one of four organizations designated as a 'prescribed entity' under PHIPA, which means we have robust oversight from Ontario's Information and Privacy Commissioner.
- + We are an independent, not-forprofit institute and charity that is arms-length from the government and that, over time, has assisted in forging essential partnerships with First Nations, Inuit, and Métis organizations and communities.

About ICES

ICES is an Ontario-based analytics and research institute that uses population data to generate meaningful insights to improve policy, health care, and health outcomes. ICES is a not-for-profit corporation and registered charity formed in 1992 and receives core funding from the Ontario Ministry of Health. ICES is governed by a Board of Directors and guided by a Scientific Advisory Committee and a Public Advisory Council whose members come from diverse regions and communities across Ontario. The Public Advisory Council was formed in 2018. It comprises members of the public from across the province who provide their thoughts, perspectives, and values to inform ICES activities and how ICES uses data to improve Ontario's health system.

ICES' mission is to translate data into trusted evidence that makes policy and health care better and people healthier. To achieve this mission, ICES collaborates with data custodians, government, policymakers, health system stakeholders, the Information and Privacy Commissioner of Ontario, members of the public, and First Nations, Inuit, and Métis organizations and communities to expand the scope and impact of ICES' health services analytics and research. Over the past 30 years, ICES has developed eight health research and analytic programs across a network of seven sites in the province and has established a secure remote virtual access platform.

It is also important to recognize the historical misuse of data related to certain groups and communities. This makes it essential that there is engagement with the public, patients, and equity-deserving communities when using data, undertaking analytics and research, and interpreting findings. For this reason, ICES is developing a framework to guide approaches that ensure data on race and ethnicity are used in beneficial ways that reduce harm and support the communities reflected in the data.



Recommendations for a Data-Driven Health System

Analytics vs Research:

What's the Difference?

ICES engages in both analytics and research. While these terms are often used together, they refer to different activities with different regulations and requirements:

Analytics is a process of examining existing data to find patterns and trends to gain insights and draw conclusions. For prescribed entities like ICES, analytics are used to evaluate, plan for, or manage the health system. Analytics at ICES typically do not require approval by a research ethics board because these projects are not conducting research as defined in PHIPA. There are exceptions where approval from a research ethics board is needed, however, such as when ICES collects data directly from a researcher or when a law other than PHIPA does not include analytics as a permitted purpose for disclosing data that is identifiable information about a person.

Research involves data (e.g., from studies or clinical trials) and using that data to test hypotheses and extend knowledge. When research involves humans, it requires approval from a research ethics board to ensure participants are protected and to minimize the potential for harm.

The Potential of Prescribed Entities

Along with giving Ontarians more control over collecting, using, and disclosing their personal health information (**PHI**), PHIPA also includes the prescribed entity designation. Organizations designated as prescribed entities may collect PHI from health information custodians for analysis with respect to the evaluation, planning, and management of the health care system. Currently, there are four prescribed entities in Ontario: the Canadian Institute for Health Information; the Pediatric Oncology Group of Ontario; Ontario Health; and ICES.

An important aspect of a prescribed entity's ability to conduct accurate population-based analytics is that PHIPA permits prescribed entities to collect, use and disclose PHI without obtaining consent. If prescribed entities were required to obtain each individual's consent or if individuals could opt out of sharing their PHI, prescribed entities would not be able to do the same kind of meaningful analytics in population health for the benefit of the health system. Recognizing the potential privacy concerns that may arise with an absence of consent, PHIPA entrenches obligations on prescribed entities to have in place practices and procedures that protect the privacy of individuals whose PHI it collects and to maintain the confidentiality of this PHI. There is also strong regulatory oversight of prescribed entities by Ontario's Information and Privacy Commissioner. To maintain a procedures reviewed and approved by Ontario's Information and Privacy Commissioner every three years. When PHIPA was enacted, the foresight to include the prescribed entity designation was new and unique. It allowed Ontario to be an international exemplar for sharing, managing and safeguarding health data. This model has worked well in Ontario for the past 20 years, but the needs and expectations for the use of PHI by prescribed entities have grown over time, and the legislative framework has not evolved in response. Updates to PHIPA would enable prescribed entities to take on an expanded role within Ontario's health system while building on their existing strengths:

- There is a proven track record for the successful prescribed entity model since PHIPA was enacted 20 years ago.
- Prescribed entities have established data holdings curated by subjectmatter experts, meaning they are wellsuited to conduct analytics.
- + ICES specifically is an independent, not-for-profit institute that is at armslength from the government and has forged important partnerships with First Nations, Inuit, and Métis communities.

- + Prescribed entities have conducted population-based analytics that continues to inform government decision-making.
- + Prescribed entities are trusted data stewards of PHI and other personal information of Ontarians.

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What is a **Health** Information **Custodian (HIC)?**

Health information custodians are often associated with organizations traditionally with health care delivery, such as health care practitioners, hospitals, pharmacies, psychiatric facilities, and long-term care homes.

Health information custodians also include health-related organizations such as diagnostic clinics and laboratories, boards of health, the Minister of Health and Long-Term Care, and Canadian Blood Services.

Health information custodians are defined in PHIPA as individuals and organizations permitted to collect, use, and disclose PHI.



Recommendations for a Data-Driven Health System

ICES Recommendations

1. Expand the Authorities of Prescribed Entities for Data Sharing

Prescribed entities are unique in Ontario for possessing comprehensive individual- and population-level data. However, limitations in PHIPA on the disclosure of PHI by prescribed entities create barriers to better supporting Ontario's health system.

PHIPA allows prescribed entities to share PHI with only limited types of organizations. As a result, prescribed entities like ICES cannot rely on their prescribed entity designation to disclose PHI onward for purposes that would benefit the health system. This limitation means that prescribed entities often must disclose PHI for a research purpose, even if the actual need for the data is not research related. These disclosures for research are permitted in PHIPA, but they include specific requirements and limitations on how the PHI may be used by its recipient that may not align with current needs.

Why is this a challenge?

When a disclosure of PHI is classified for a research purpose, it must be approved by a research ethics board before it may occur. While research ethics board oversight is crucial for ensuring that research is conducted ethically, using research-focused processes for non-research purposes occupies time and resources prescribed entities could better allocate to other work that benefits the health system.

How will the recommendation address this?

Revising PHIPA to include additional circumstances in which a prescribed entity can disclose PHI would allow prescribed entities to better share PHI for non-research purposes that support the health system, for example, by sharing PHI with health information custodians to improve timely health care delivery or contacting health information custodians or individuals where the linking of data at ICES shows a risk of serious harm to a person. These revisions would also mean that a prescribed entity's resources can continue to be focused on privacy and security governance rather than spent obtaining unsuitable approvals by research ethics boards.

Case Study Example

Health Quality Ontario, a subset of Ontario Health, operates a program called MyPractice, which generates confidential reports for physicians with data about their practices with an eye toward quality improvement. One key feature of these reports is data about a physician's opioid prescribing habits compared with other physicians in the province.

ICES provides de-identified data related to opioid prescriptions for use in MyPractice reports. Current legislative barriers mean that ICES is limited in its disclosure of information. At most, the information in its reports may show that a percentage of a physician's patients are receiving more opioids than the physician prescribes, meaning that unidentified patients are receiving additional opioid prescriptions from other physicians. But without knowing who these patients are, the physician cannot adjust their prescribing patterns and engage the patient in treatment options to improve the provision of health care.

If PHIPA permitted additional types of disclosures of PHI by prescribed entities, ICES could provide identifiable data in MyPractice reports, enabling physicians to better tailor their care to specific patients. And since these disclosures would remain limited to the physician's patients, the PHI remains restricted to purposes directly related to improving health care delivery.

Recommendations for a Data-Driven Health System

ICES Recommendations

2. Facilitate Collection, Use, and Disclosure of Health-Related Personal Information

Under PHIPA, it is very challenging for prescribed entities to collect, use, and disclose personal information about an individual that is not PHI and to link personal data with PHI.

Why is this a challenge?

While it may seem like health-focused prescribed entities would need access to only PHI, health issues and outcomes are strongly affected by circumstances outside health care and clinical settings. Non-health factors, such as an individual's race, ethnicity, or socioeconomic status, may significantly impact access to health care, service delivery, and outcomes. Not being able to collect personal information or link personal information to PHI limits the ability of prescribed entities to advance health equity goals.

How will the recommendation address this?

ICES' second recommendation is to allow prescribed entities to collect personal information from organizations that are not health information custodians if the personal information contains information that is related to the individual- or population-level health or the wider determinants of health, and if the prescribed entity's purpose of the collection is to evaluate, plan, or manage the overall health of the province and the health system. This access would allow prescribed entities to collect, use, and link personal information with PHI to create valuable insights for health planning while improving health equity.

Case Study Example

The Early Development Instrument is a questionnaire created by the Offord Centre for Child Studies at McMaster University. It is completed for kindergarten-aged children in Ontario to measure each child's ability to meet developmental expectations in various areas. The data collected through this questionnaire helps understand children's developmental health throughout the province and enables policymakers and researchers to create programs that are responsive to and better understand. Developmental needs of children can be a direct, prior effect of social determinants of health while also impacting future health profiles and needs.

Currently, the collection and use of this data by prescribed entities are challenging because it consists of information not commonly understood to be PHI. Classifying this type of data as personal information impedes prescribed entities from collecting and using it even though it can be relevant to the evaluation, planning, and management of the health system.

If PHIPA enabled a prescribed entity to collect data like the Early Development Instrument as a subset of PHI for health-related uses, then the prescribed entity could conduct analytics using the data to help identify the needs of children within specific communities and better evaluate and plan for appropriate health-related policies. The data could answer important questions about social determinants of health and their connection with other health-related factors affecting well-being and development.

Recommendations for a Data-Driven Health System

What are Health Equity and Social Determinants of Health?

Health equity means everyone has a fair opportunity to meet their health potential and are not disadvantaged from attaining it based on their social, economic, or demographic status.

Health equity strives for fairness in distribution of resources needed for health, access to the opportunities available, and supports offered to people when they are ill or trying to prevent illness. An equitable health system offers services that are accessible, available, and acceptable to everyone, regardless of race, social status, economic status, or demographics.

Social determinants of health are the non-medical factors that can positively and negatively influence health outcomes for people, such as living or working conditions, social supports, income, employment, or educational opportunities. Social determinants of health impact a person's access to healthcare and therefore the health system has a responsibility to pursue health equity.

Recommendations for a Data-Driven Health System

ICES Recommendations

3. Revise the Requirement for Consent to Contact to Support Early Identification of At-Risk Individuals

Under current PHIPA regulations, PHI collected by prescribed entities cannot be easily used to support research studies requiring patient contact. This is because a researcher is not permitted to contact any individual or care provider involved in an individual's care unless the prescribed entity first obtains the individual's consent to be contacted.

Why is this a challenge?

Consent to contact requirements arose with the understanding that an individual and their healthcare provider typically have an existing relationship of trust. When disclosing PHI for research, PHIPA permits prescribed entities to act as if they were a health information custodian, so the prescribed entity must first obtain patient consent to be contacted by a researcher. But prescribed entities acting as health information custodians do not have an existing relationship with the individuals who would be contacted. This limits the ability of prescribed entities to support research involving patient contact, even while possessing the data that researchers could use to contact individuals at risk of or suffering from illnesses or their care providers with early prevention and treatment options. Moreover, there is no mechanism is place for researchers, who have received information from prescribed entities acting as health information custodians, to contact the care providers who do have existing relationships with individuals at risk without first requiring the person's consent to be contacted.

How will the recommendation address this?

ICES' third recommendation is to revise PHIPA so that prescribed entities can share PHI about a person to a researcher in specific circumstances without requiring the person's consent to be contacted. It should also include a mechanism for disclosing PHI by a researcher to other health information custodians within at-risk individual's circle of care. However, ICES still advocates for research ethics boards to determine ethically acceptable approaches for contact and recruitment by the researcher in their study.

Case Study Example

Many prescribed entities have data that could be used to identify patients who are sick and may not be receiving recommended care.

For example, data currently at ICES can be used to estimate the risk of kidney failure within two years for those with evidence of chronic kidney disease. This data can also show which patients may not be receiving recommended care and whose illnesses put them at a higher risk for prescribing errors. ICES is aware of patients with declining health but faces barriers in providing this information to their healthcare providers. An ability for ICES to use this data to contact patients and their their healthcare providers before the onset of kidney failure could prevent unnecessary hospitalizations and save lives.

ICES is currently piloting a patient contact study for individuals at risk of kidney failure. But all the challenges prescribed entities face in obtaining patient consent have led to project delays of almost two years. Solutions ICES has identified have satisfied the requirements of PHIPA but with the addition of significant complexity. Legislative reforms are needed to facilitate the use of existing data to advance patient health in a privacy protective manner while also being acceptable to the public.

Recommendations for a Data-Driven Health System

ICES Recommendations

4. Authorize Collection of PHI from Other Jurisdictions Outside of Ontario for Analytic Purposes

Under PHIPA, prescribed entities cannot easily collect and use PHI from other jurisdictions for analytic purposes and, instead, collection and use are restricted to research purposes. This restriction is due to prescribed entities being allowed to collect PHI for analytical purposes only if the PHI is collected from health information custodians, excluding collection from other types of organizations, even if these organizations are authorized to share PHI for analytics.

Why is this a challenge?

Similar to ICES' first recommendation, allowing prescribed entities to collect PHI only for research purposes creates a situation where all activities are classified as research-related, even if that is not the most suitable or accurate category. Research ethics board approval leads to unnecessary use of time and resources for the prescribed entity and the research ethics board conducting the review of the non-research project. Furthermore, ethics approval typically involves an end date after which the data can no longer be used, so continued use of the data means updating or renewing the research ethics board application, often annually. While ethics approval is appropriate for research, it is a further unnecessary use of resources for ongoing analytic activities.

How will the recommendation address this?

ICES' fourth recommendation is revising PHIPA to permit prescribed entities to collect PHI for analytic purposes from organizations that are not health information custodians if those organizations are authorized to disclose for analytic purposes under any other legislation in Ontario or Canada. This would provide explicit permission for prescribed entities to receive PHI for analytic purposes from a broader array of bodies and to devote resources more efficiently to analytical work, strengthening Canada-wide analytics.

Case Study Example

The Canadian Longitudinal Study on Aging is a national, long-term study that collects individual-level information about the biological, medical, psychological, social, lifestyle, and economic aspects of people's lives. This data is available by request to organizations like ICES; however, it would be limited to research purposes because it is not being collected by ICES from a health information custodian under PHIPA. Even though the data would benefit analytics work completed by prescribed entities, such collection, and usage are not currently authorized under PHIPA.

Changes to PHIPA to permit the collection and usage of this data for analytics would give greater insights into improving Ontario's health system by examining the longer-term health factors of individuals in this province and throughout the country.

Recommendations for a Data-Driven Health System

ICES Recommendations

5. Allow for the Adoption of New Technologies for Greater Efficiency

Under PHIPA, a prescribed entity may only use PHI for analytics and research. However, certain basic uses of PHI are necessary for a data-holding organization to function at its best, and these uses are overlooked in PHIPA. For example, it is unclear whether prescribed entities are permitted to use PHI for data quality or improvement activities, education, and training of its agents or to modify the data to conceal individuals' identities, which is a necessary part of creating synthetic data.

Why is this a challenge?

Without specific permission to use PHI for some basic additional functions, prescribed entities cannot take full advantage of the data's potential, limiting their ability to train staff in data management and statistical techniques. Prescribed entities are also currently unable to use PHI to validate and improve PHI as part of improving overall data quality and increased analytic accuracy, contributing to better-informed decision-making in the health system.

How will the recommendation address this?

ICES' fifth recommendation expands and clarifies the purposes for which a prescribed entity can use PHI. This expansion helps ensure that high-quality data is available for analytic purposes; that data can be used for education and training purposes; and that there is the possibility to create and then use privacy-protected data such as synthetic data.

Case Study Example

Synthetic data has an expanding potential utility as this area further develops. By updating PHIPA to ensure proper statutory authorization, prescribed entities are well-positioned to support innovation and maximize benefits for Ontario's health system. Synthetic data can provide a realistic but privacy-preserving option for activities such as:

- data, like quasi-identifiers and full health histories.
- be validated on other datasets.
- engaged to perform work for a prescribed entity.
- the relevant approvals for using PHI.

 Advanced analytics using artificial intelligence and machine learning techniques that would otherwise require large amounts of identifiable

• Machine learning model development and testing that may retain data to

 Developing and testing new systems and software that eventually will access PHI, including instances when third-party service providers are

• Training students, trainees, and researchers in data science and analytic skills before working on analytic and research projects using PHI.

Developing and piloting analytic and research projects before obtaining

Recommendations for a Data-Driven Health System

What is **Synthetic Data?**

Synthetic data is data that is created when an artificial intelligence system is given real data and it learns the patterns contained within it. It is then able to create new data that retains the overall properties of the original data but is not real. This provides the ability to create health data that reflects actual trends and relationships but is truly non-identifiable because the data does not relate to any real individual.

Learn more about synthetic date in <u>this episode</u> of the Information and Privacy Commissioner of Ontario's podcast Info Matters.

Conclusion

To generate the healthcare data necessary to support a health system that meets the needs of Ontarians, the Ministry of Health should consider including broader permissions under PHIPA for how prescribed entities can collect, use, and disclose PHI. Over the past 20 years, prescribed entities have earned the trust of health system stakeholders, scientists, community-based organizations, and the wider public. They have also made great strides in safeguarding PHI and personal information by embedding privacy and security practices in their day-to-day operations. Each prescribed entity obtains approval from Ontario's Information and Privacy Commissioner of their policies, procedures, and practices every three years, confirming the prescribed entity meets its privacy responsibilities and shows its accountability to Ontarians.

ICES and other prescribed entities are well-suited to remain critical allies in the government's mandate to improve the health system by operating as trustworthy data stewards.

Acronyms

PHI PHIPA

Personal Health Information Personal Health Information Protection Act, 2004

