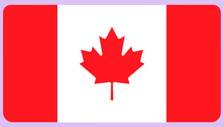
Health Data Governance

Legislative and Regulatory Landscape Review



CANADA

COUNTRY REPORT

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This health data governance country landscape report was developed by Transform Health, with contributions from Research ICT Solutions and Baker Botts. This work was funded by the Patrick J. McGovern Foundation and Fondation Botnar.

Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

Transform Health

1. Introduction

This report analyses the legislative and regulatory landscape of Canada to understand how and to what extent the governance of health data is addressed. The Health Data Governance Principles (HDG Principles[1]) served as a framework for this analysis to explore and document how the principles manifest in the existing legal and regulatory environment. This review entailed a content analysis of relevant legal texts against the eight HDG Principles.

This report identifies best practices for Canada's health data governance, including recommendations on how to strengthen the health data governance landscape. It discusses the multifaceted approach to safeguarding personal health information, emphasising privacy, security, and equitable access. The report highlights challenges such as managing consent, addressing technological advancements, and ensuring interoperability. Recommendations focus on enhancing data protection, governance, and fostering innovation while maintaining ethical standards. This discussion underscores the need for continuous updates to governance frameworks to align with evolving healthcare landscapes and technological advancements.

Health Data Governance Principles

Protect People

- Protect individuals & communities
- Build trust in data systems
- Ensure data security

Promote health value

- Enhance health systems & services
- Promote data sharing & interoperability
- Enhance health systems & services

Prioritise equity

- Establish data rights & ownership
- Promote equitable benefit from health data

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[1] View the Health Data Governance Principles: https://healthdataprinciples.org

2. National Legislative and Regulatory Overview

The following sources were used for purposes of analysing the legislative and regulatory system of Canada:

- Constitution Act, 1867, 30 & 31 Vict., c. 3 (U.K.), reprinted in R.S.C., No. 5 (Appendix 1985) (Can.)
- Canadian Bill of Rights, S.C. 1960, c. 44 (Can.)
- Constitution Act, 1982, being Schedule B to the Canada Act, 1982, c. 11 (U.K.)
- Privacy Act, R.S.C., 1985, c. P-21 (Can.)
- Access to Information Act, R.S.C., 1985, c. A-1 (Can.)
- Canada Health Act, R.S.C., 1985, c. C-6 (Can.)
- Telecommunications Act, S.C. 1993, c. 38 (Can.)
- Health Information Act, R.S.A. 2000, c. H-5 (Can.)
- Department of Health Act, S.C. 1996, c. 8 (Can.)
- Personal Information Protection and Electronic Documents Act, S.C. 2000, c. 5 (Can.)
- Information and Privacy Commissioner of Ontario, *A Guide to the Personal Health Information Protection Act* (rev. Apr. 2016)
- Government of Canada, *Canada's Universal Health-Care System: Achieving Its Potential* (2020)
- Canada Health Infoway, *Privacy as an Enabler: Sharing Personal Health Information for Interoperability Primer* (2021)
- Canadian Institute for Health Information (CIHI), *Health Data and Information Governance and Capability Framework* (2021)
- Canadian Institute for Health Information (CIHI), Health Data and Information Governance and Capability Framework Toolkit (2022)
- Canadian Institute for Health Information (CIHI), *Health Data and Information Governance and Capability Framework Supplementary Toolkit* (2022)
- Expert Advisory Group, *Pan-Canadian Health Data Strategy: Toward a World-Class Health Data System – Final Report* (May 2022)
- Canadian Institute for Health Information (CIHI), *Standards 101: Creating Data Standards and Governance to Support Collection, Analysis, and Reporting* (2023)
- Canadian Medical Association *(CMA), CMA Code of Ethics and Professionalism* (rev. 2018). Canadian Medical Association (CMA), *CMA Code of Ethics and Professionalism: Brochure* (rev. 2018). DLA Piper, *Data Protection Laws of the World: Canada* (2023)
- Immigration, Refugees and Citizenship Canada, *2023-26 IRCC Data Strategy Directions for the Strategic Management and Increased Impact of Data* (2023)

3. Analysis of the National Legislative and Regulatory Environment

The currently enacted or most recently published legislative and regulatory instruments in Canada relating to the eight HDG Principles are discussed under the sub-heading of each respective principle below.

3.1. Protecting Individuals and Communities

Canada's regulatory framework prioritises the protection of individuals and communities through comprehensive legal and ethical standards. The Constitution Act, 1982, while not explicitly addressing health or personal data protection, ensures fundamental rights, with Section 7 protecting the right to life, liberty, and security of the person and Section 8 safeguarding against unreasonable search or seizure, indirectly protecting privacy. The Privacy Act outlines clear principles for the federal government's handling of personal information, including health data, establishing obligations for transparency and security.

The Canada Health Act emphasises equitable access to health services and protects personal data indirectly by mandating accountability and accessibility in healthcare administration. Similarly, the Canadian Bill of Rights reinforces fundamental freedoms that indirectly protect health and personal data rights. At the provincial level, the Health Information Act (Alberta) directly governs the management of health information, with specific rules for custodians handling health records.

Frameworks like the CIHI Health Data and Information Governance Framework outline policies for responsible health data governance, and the CMA Code of Ethics provides ethical guidelines for healthcare professionals to safeguard patient confidentiality.

The proposed Pan-Canadian Health Data Charter outlines principles for improving data collection, ensuring quality, security, and privacy of health data while promoting accessibility and equity.

Collectively, these instruments ensure a multi-layered approach to protecting personal health data, safeguarding privacy, and promoting equity in healthcare delivery.

3.2. Building Trust in Data Systems

Trust in Canada's data systems is built on transparency, accountability, and stakeholder engagement. The Privacy Act and Personal Information Protection and Electronic Documents Act (PIPEDA) establish robust mechanisms for the fair collection, use, and disclosure of personal data, requiring organisations to obtain informed consent and implement safeguards. The Access to Information Act complements these frameworks by enabling individuals to access government-held records, enhancing transparency.

At the federal level, the CIHI Governance Framework promotes accountability and best practices in health data stewardship. Oversight mechanisms, such as privacy commissioners and review boards, enforce compliance and investigate breaches, building trust in the system. The Health Information Act (Alberta) mandates custodians to protect health information while ensuring individuals can access and correct their records.

Stakeholder engagement is emphasised in governance policies and through professional codes like the CMA Code of Ethics, which stress ethical conduct, competence, and transparency in healthcare. Legislative initiatives such as Bill C-27 aim to modernise privacy laws, clarify consent requirements, and enhance enforcement, ensuring individuals' confidence in the security and fairness of data systems.

3.3. Ensuring Data Security

Data security is a critical focus of Canada's health data governance framework. The Privacy Act and PIPEDA impose obligations on organisations to implement security measures to protect personal information against unauthorised access, loss, or disclosure. Division 1.1 of PIPEDA, in particular, establishes breach reporting and notification requirements for organisations.

The Access to Information Act and the Telecommunications Act also address data security in their respective domains. At the national level, frameworks like CIHI's Privacy and Security Standards and the 2023–2026 Data Strategy provide comprehensive guidelines for securing health data across the healthcare system. The Health Information Act (Alberta) outlines specific security duties for custodians managing health records, such as implementing physical, administrative, and technical safeguards.

Professional standards, as articulated in the CMA Code of Ethics, underscore the duty of confidentiality and appropriate use of patient data. These combined measures ensure that Canada's regulatory framework prioritises robust security protections for health data, mitigating risks and maintaining public trust.

3.4. Enhancing Health Services and Systems

Canada's regulatory framework leverages health data governance to enhance healthcare services and systems. The Canada Health Act underpins this effort by ensuring equitable access to healthcare services, laying the foundation for inclusive and efficient healthcare delivery. Provincial statutes like the Health Information Act (Alberta) enable the secure exchange of health data, facilitating better decision-making and resource allocation.

The CIHI Governance Framework promotes interoperability and data integration to support evidence-based healthcare planning and delivery. Documents like the Digital Health Strategy emphasise the importance of informatisation, data analytics, and system-wide connectivity to optimise patient care. These measures collectively aim to modernise Canada's healthcare infrastructure while addressing challenges like health inequities and access disparities, ensuring the healthcare system is efficient, equitable, and responsive.

3.5. Promoting Data Sharing and Interoperability

Data sharing and interoperability are key priorities in Canada's health data governance framework. The Privacy Act and PIPEDA set conditions for data sharing under specific circumstances, ensuring that privacy is not compromised. Frameworks like the CIHI Health Data and Information Governance Framework promote the adoption of interoperability standards and best practices for data sharing in the healthcare sector. These initiatives aim to establish secure, standardised, and efficient mechanisms for sharing health data while safeguarding privacy and security.

The Telecommunications Act supports interoperability in communications networks, indirectly contributing to better integration of health systems. Similarly, the Health Information Act (Alberta) facilitates electronic health record sharing among healthcare providers, enabling coordinated care and reducing duplication.

3.6. Facilitating Innovation Using Health Data

Canada's regulatory framework supports innovation using health data while maintaining strict privacy protections. The Health Information Act (Alberta) allows health data to be used for research and innovation, subject to ethical approvals and privacy safeguards. Similarly, the CIHI Governance Toolkit promotes analytics and data-driven decision-making to advance healthcare innovation.

Privacy laws such as PIPEDA and frameworks like the Digital Health Strategy enable the secure use of health data for research, telehealth, and new technology development. Professional guidelines in the CMA Code of Ethics encourage contributions to medical advancements, further fostering an environment of innovation. These measures collectively ensure that health data can be responsibly utilised to improve healthcare delivery and outcomes.

3.7. Promoting Equitable Benefits from Health Data

The equitable use of health data is a guiding principle in Canada's health data governance framework. The Canada Health Act ensures equitable access to healthcare services, which indirectly supports the fair distribution of health data benefits. The Health Information Act (Alberta) provides patients with access to their health records, promoting transparency and equity.

Frameworks like the CIHI Standards stratify health data to identify and address disparities, while professional ethics, such as the CMA Code of Ethics, stress commitments to justice and reducing health inequities. Broader policy discussions emphasise the importance of reconciliation with Indigenous populations and addressing social determinants of health. While specific legal provisions on equitable benefits from health data are limited, these measures collectively promote fairness in the use and distribution of health data.

3.8. Establishing Data Rights and Ownership

Canada's legal frameworks establish clear data rights and ownership principles. PIPEDA grants individuals ownership over their personal information, including rights to access, correct, and delete their data. The Privacy Act governs the use and disclosure of personal information by federal institutions, ensuring accountability and transparency.

The Health Information Act (Alberta) establishes custodial responsibilities for health data, balancing individual rights with organisational needs for data processing. Frameworks like the CIHI Governance Toolkit focus on data stewardship, ensuring ethical management of health data. Professional codes, such as the CMA Code of Ethics, reinforce these principles by mandating confidentiality and patient-centred data practices. Together, these instruments safeguard data rights and ensure responsible governance of health information.

4. Best practices

Canada's health data legislative and regulatory framework incorporates established best practices to ensure the responsible and effective management of health data. These emphasise privacy, security, governance, collaboration, and adaptability to evolving technological and societal needs.

- **Comprehensive Governance and Privacy Frameworks:** Canada employs robust governance structures that integrate principles such as purpose limitation, necessity, and proportionality into data handling processes. Laws like the Privacy Act and PIPEDA, complemented by provincial legislation like Alberta's Health Information Act, ensure that data collection, retention, protection, and access respect individual rights, including the ability to access and correct personal health information.
- **Health Data Protection and Security:** Strong security measures, including anonymisation, encryption, and breach notification protocols, are implemented to protect personal health information. These measures align with federal and provincial legal requirements, safeguarding data against unauthorised access and misuse while reinforcing public trust in the system.
- **Stakeholder Engagement and Ethical Governance:** Active engagement with diverse stakeholders - including patients, healthcare providers, policymakers, and Indigenous communities - ensures transparency and inclusivity in data governance. Ethical principles such as confidentiality, integrity, and fairness guide the management and use of health data, fostering trust and legitimacy.
- **Interoperability and Data Standards:** Canada prioritises interoperability through the development of common data standards and system architecture, enabling secure and effective data sharing across jurisdictions. Frameworks like the Pan-Canadian Health Data Strategy support harmonised practices, ensuring consistency and collaboration among healthcare providers and systems.
- **Continuous Improvement and Capacity Building:** Ongoing evaluation, education, and capacity-building initiatives are integral to Canada's approach. By adapting governance frameworks to technological advancements and public expectations, Canada strengthens its health data systems. Partnerships between public and private sectors enhance the quality, accessibility, and equity of healthcare services.

These best practices collectively ensure that health data is managed securely and equitably, balancing privacy protections with the facilitation of healthcare innovation and improvement.

5. Gaps

Despite the comprehensive health data governance framework in Canada, gaps remain that hinder the full potential of health data utilisation:

- **Inconsistent Scope and Coverage:** The regulatory framework is fragmented, with provincial laws like the Health Information Act (Alberta) applying only within specific jurisdictions, leaving gaps in governance across provinces or for non-custodians like private companies.
- **Challenges with Consent and Patient Participation:** There are difficulties in managing consent, particularly for implied consent scenarios, and limited mechanisms to actively engage patients in decisions about their health data usage.
- **Insufficient Data Security and Privacy Standards for Emerging Technology:** Existing regulations lack specific guidance on modern challenges, such as cybersecurity risks, data breaches, and the use of artificial intelligence and machine learning in healthcare.
- **Interoperability Barriers:** A lack of uniform data standards and clear protocols for data sharing across systems and jurisdictions impedes the efficient exchange and use of health data.
- **Limited Monitoring and Enforcement Mechanisms:** There is insufficient emphasis on compliance monitoring and enforcement to ensure adherence to privacy and data security regulations, particularly at the federal level.
- **Lack of Clarity on Emerging Uses of Health Data:** The framework does not fully address the governance of novel applications, such as predictive analytics, digital health platforms, and commercial exploitation of health data.

These best practices collectively ensure that health data is managed securely and equitably, balancing privacy protections with the facilitation of healthcare innovation and improvement.

6. Recommendations

To address the identified gaps and improve health data governance in Canada, the following recommendations are proposed:

- **Develop a Pan-Canadian Governance Framework:** Establish a unified national framework for health data governance, building on the Pan-Canadian Health Data Strategy, to harmonise standards and guidelines across provinces and sectors. This should include mechanisms for cross-jurisdictional data sharing and collaboration.
- **Enhance Privacy and Security Measures:** Introduce detailed and enforceable standards for data privacy and cybersecurity, ensuring that modern threats like AI misuse and ransomware attacks are addressed. This includes implementing breach notification requirements and adopting secure infrastructure for health data storage and transfer.
- **Expand Patient Participation and Consent Mechanisms:** Simplify and clarify consent processes, providing patients with greater control over their data. Develop digital tools for managing consent, improving transparency, and enabling patients to make informed decisions about how their data is used.
- **Strengthen Interoperability and Data Standards:** Adopt common data architecture and standards to promote interoperability between healthcare systems. Establish certification processes and guidelines to ensure privacy and security in interoperable systems.

- **Modernise Legal Frameworks for Emerging Technologies:** Update existing legislation, such as PIPEDA and the Privacy Act, to address emerging uses of health data, including AI, predictive analytics, and telehealth. Incorporate ethical guidelines for the responsible use of advanced technologies in healthcare.
- **Establish Robust Monitoring and Enforcement Mechanisms:** Develop stronger compliance monitoring tools and enforcement mechanisms, including independent oversight bodies, to ensure adherence to privacy and security laws. Provide clear penalties for non-compliance and violations.
- **Promote Equity and Inclusiveness in Health Data Use:** Ensure health data governance frameworks address systemic inequities, including by supporting Indigenous data sovereignty, addressing social determinants of health, and tailoring policies to underserved communities.
- **Encourage Innovation While Protecting Privacy:** Leverage health data for research and innovation by creating safe environments for data sharing, such as privacy-preserving analytics and secure research platforms. Balance privacy with the need for innovation to improve healthcare outcomes.

These recommendations aim to modernise Canada's health data governance framework, ensuring it remains adaptable, equitable, and capable of addressing emerging healthcare challenges while safeguarding individuals' rights.

7. Discussion of research results

The findings highlight Canada's comprehensive efforts to establish a robust health data governance framework, while identifying gaps and challenges that impede progress. The framework balances privacy protection, transparency, and ethical considerations with the need for innovation and interoperability. Best practices like governance frameworks, stakeholder engagement, and interoperability initiatives provide a solid foundation, however, issues such as fragmented regulations, insufficient consent mechanisms, and a lack of alignment with emerging technologies require attention. The recommendations offer a roadmap for addressing these gaps, with an emphasis on harmonising governance, enhancing privacy and security, and promoting equitable benefits from health data.

8. Conclusion

The analysis of Canada's health data governance framework underscores the importance of balancing privacy, security, and equity with the facilitation of innovation and interoperability. While the framework reflects strong foundations in protecting personal health information, challenges like inconsistent regulatory coverage, technological advancements, and equity concerns necessitate updates and improvements. The recommendations provided—such as creating a Pan-Canadian governance framework, addressing emerging technologies, and promoting equity—aim to ensure Canada remains a leader in health data governance. By addressing these gaps, Canada can fully harness the potential of health data to transform healthcare delivery, improve patient outcomes, and foster public trust in its healthcare system.