HDRN Canada

Public Trust, Literacy and Health Data Foundations in Canada

A Foundational Paper

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We acknowledge that the activities of Health Data Research Network Canada take place on the traditional, ancestral, ceded and unceded territories of First Nations, Inuit, and Métis Peoples across Canada. Our commitment to advancing Indigenous rights and interests informs development of this paper and all work of our Network.

Please note: Words in **bold** are defined in a glossary that accompanies this paper.

List of Acronyms

AI: Artificial intelligence

CARE: Collective benefit, Authority to Control, Responsibility, Ethics

CHIMA: Canadian Health Information Management Association

CIHI: Canadian Institute for Health Information

EGAP: Engagement, Governance, Access, and Protection

FAIR: Findable, Accessible, Interoperable, Reusable

FNIGC: First Nations Information Governance Centre

FPT: Federal/provincial/territorial

FPTI: Federal/provincial/territorial/Indigenous

GPDPR: The General Practice Data for Planning & Research initiative

HDRN Canada: Health Data Research Network Canada

IAP2: International Association for Public Participation

IQ: Inuit Qaujimajatuqangit

MCHP: Manitoba Centre for Health Policy

MMF: Manitoba Métis Federation

NHS: National Health Service

NIST: US National Institute for Standards and Technology

OCAP®: Ownership, Control, Access and Possession

OCAS: Ownership, Control, Access, and Stewardship

OECD: Organisation for Economic Cooperation and Development

UNDRIP: United Nations Declaration on the Rights of Indigenous People

Key Messages

Trust is complex, and public trust in health data collection, sharing and use can fluctuate depending on many factors, including the broader political and social context in which health systems operate.

Data literacy should be viewed as one of several foundational elements that create the possibility of trust, alongside other important elements, such as transparency and public benefit.

Trust comes from trustworthy practice. Organizations and institutions that collect, use and share health data need to demonstrate trustworthy practices that are guided by well-developed principles, including those identified in the *Pan-Canadian Health Data Charter*.

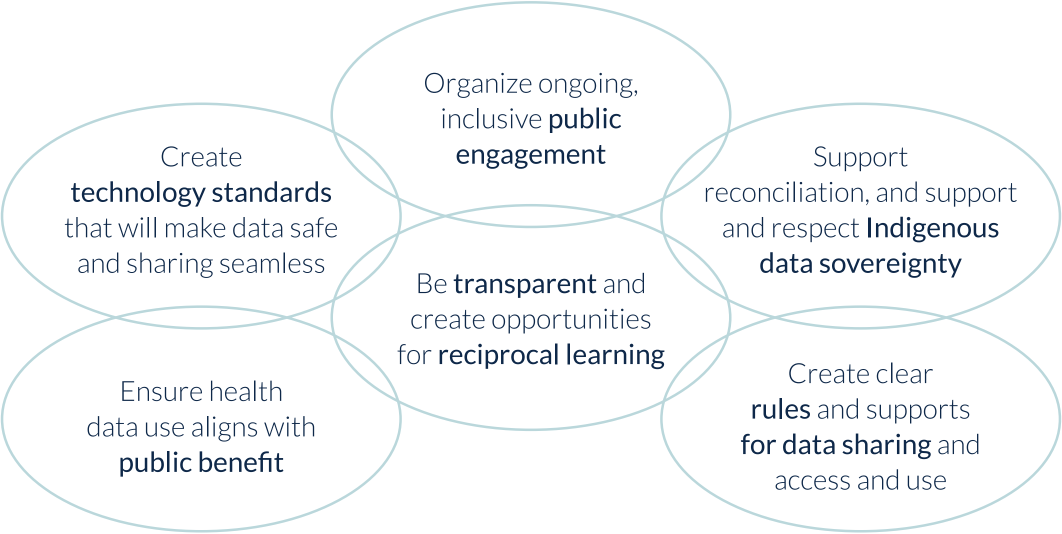
We identify six recommendations for trustworthy practices that include: ongoing, inclusive public engagement; reconciliation that includes respect and support for Indigenous data sovereignty; the alignment of health data use with public benefit; clear rules and supports for data sharing, access and use; technology standards for safe and seamless data sharing; and transparency, communications and reciprocal learning.

Health data collection, sharing and use can result in significant benefits as well as risks. Trustworthy practices should focus on maximizing benefits while minimizing risks through proper protections and guardrails.

True person-centred health data, as outlined in the *Pan-Canadian Health Data Charter*, implies that a broad range of interests should have influence over health data design, access, sharing and use.

Transparency about trustworthy practices and accountability for those practices are essential to earning and maintaining public trust.

Recommendations for trustworthy data practices



Introduction

Public trust in governments, organizations and institutions that collect, protect, share and use health data is critical. **Health data** refers to information that describes a person's health, their health care or anything about their health status or condition. It can be about individuals (**personal health data or information**) or about populations (**population health data**).[1] Access to timely and reliable health data, by health care providers, systems and patients, is the foundation of providing high quality health care services to individuals and public health services to populations. This includes providing care across different parts of the **health system** and across regions and locations. Access to health data is also critical for health system planning, management, public health, evaluation, research and innovation. These uses often involve combining or linking data sets (**data linkage**), and in the case of research and innovation, includes interests from the public, non-profit and private sectors.

As part of the *Working Together to Improve Health Care for Canadians* plan, and in recognition of Canada's fragmented health data ecosystem described by the Expert Advisory Group on a pan-Canadian health data strategy,[2] Budget 2023 confirmed new funding for provinces and territories. Some of these funds are intended to modernize health systems with standardized **health data** and digital tools. Bi-lateral agreements were aligned with the *Pan-Canadian Health Data Charter* ("Charter"), which outlines a shared vision for health data in Canada. The 10 principles of the Charter put people and populations at the centre of health data management (see box below). It starts with principles of person-centred data design, inclusive **data governance**, and **distinctions-based approaches** to data sovereignty as defined by First Nations, Inuit and Métis Peoples, their governments, representatives and expert/technical organizations.

Building on the Charter, this foundational paper on health data expands on these principles. It highlights important considerations for **public trust** and identifies the risks and benefits of **data sharing** as well as the protections interest holders identify to maximize benefits and minimize risks (noting that data sharing does not necessarily imply moving data, and that we use the term interest holders as an alternative to stakeholders[3]). It includes considerations around the uses of health data in clinical care and patients' access to their own health data (often referred to as "**primary uses**"), as well **secondary uses** that include but are not limited to planning, assessment, evaluation, improvement, research and innovation.

This work is meant to help different levels of government and health system organizations work together to earn public trust in and understanding of health data. It can also be useful to other organizations that hold and use health data, for example private insurance providers, community-based physicians, and providers of health services that are not publicly funded. Finally, it will help the public better understand how health data are currently used in Canada, and ways in which they can shape the future of health data.

Contents of this paper

This paper starts by describing foundational elements of trust, trustworthiness and data literacy (Section 1). It then introduces key dimensions of trustworthy practice, drawing on established principles and frameworks including Charter principles (Section 2). These principles serve as a foundation for policy and practice, and help to identify, at a conceptual level, considerations that matter and need attention. Section 2 ends by providing six recommendations for trustworthy data practices based on these guiding principles.

Principles alone do not tell us how something will need to be done. It is important to underline that the associated practices are what give life to those principles in a particular context—such as a country, province or health authority. Section 3 describes the risks and benefits of health data use, and the types of protections (associated practices) that meet public expectations ("**social licence**") and that minimize risks while maximizing benefits. National and international case studies focused on both primary and secondary uses of data are included to help animate promising practices and approaches to the ideas presented in the paper. A glossary of health data related terms, drawing where possible from existing definitions, is included to enhance clarity and accessibility. We use **bold** type to identify terms found in the glossary. The glossary was developed for this paper, but is also a standalone resource for common language to support data collaborations and discussions around public trust in the context of health data collection, sharing and use.

The importance of respect and support for **Indigenous data sovereignty** and Indigenous-led **health data governance** are paramount and inform all aspects of this paper. However, we do not make recommendations for building trust and data literacy that are specific to Indigenous Nations, partners, organizations and communities, as this requires an Indigenous-led collaborative approach. In addition, we do not offer detailed organizational guidelines or provide immediate solutions for data misuse.

Approach

We reviewed relevant grey (e.g., policy reports, working papers, guidelines) and peer-reviewed literature, held focus groups and interviewed key informants. Focus groups and interviews add perspectives from individuals who have expertise related to public trust, public engagement and health data protections, and those who have experience as users of healthcare and public health services. Opportunities for review and comment on key paper materials were included at several different points in the process, including two rounds of public consultations on the health data glossary. For detailed methods, please see Appendix A.

PAN-CANADIAN HEALTH DATA CHARTER

1. Person-centric health information design to ensure that health data follows the individual across points of care to support individual, clinical, and analytical access and use while respecting individual privacy with regard to the handling of their information under existing privacy legislation.
2. Inclusion of diverse members of the public, patients, communities and other partners in culturally integrated health information system development and oversight.
3. Commitment to support First Nations, Inuit and Métis data sovereignty and Indigenous-led governance frameworks.
4. Common standards for terminology, health data design, stewardship, interoperability, access, and portability.
5. The quality, security and privacy of health data to maximize benefits, build trust, and reduce harm to individuals and populations.
6. Timely availability and accessibility of meaningful and comprehensive health data to individuals, decision makers, the health workforce, and researchers to support an individual's health needs, quality health programs and services, population and public health, and research.
7. The ethical use of health data to support decision making, policies, programs, services, statistics, and research for better health outcomes, while respecting the importance of open science and being open-by-design.
8. Data-driven social and technological innovation through partnership, invention, discovery, value creation and international best practice.
9. Literacy regarding health data, health data analysis and digital methods for the public, decision-makers, the health workforce, and researchers.
10. Harmonization of health data governance, oversight, and policy in areas jointly agreed to by federal, provincial and territorial governments for pan-Canadian coordination.

Pan-Canadian Health Data Charter
(Government of Canada, 2023)

Section 1: Building the Foundation: Understanding Trust and Data Literacy

Understanding trust

There is no single, broadly accepted definition of trust, but it is understood to be important in areas or relationships where there is risk, uncertainty and interdependence.[4,5] Trust can be thought of as "one of the interpersonal attitudes required when a person is dependent on another to achieve some goal under conditions of uncertainty."[6] It is important to understand the differences between trust and other related concepts such as reliance, confidence, dependence or obligation.[7] This conceptual distinction is critical if we are to understand and respond to challenges of trust. For example, there is a difference between "reliance" ("I rely on my doctor for prescription refills") or credibility ("I think that person knows what they are talking about") and "trust" ("I trust my partner in our relationship").[7–9]

The importance of this difference becomes very clear when we think about what happens when reliance versus trust fails. A failure in reliance might lead to feelings of disappointment, while a failure in trust would more likely lead to feelings of betrayal.[10] In other words, trust is embedded in relationships and shared values, whereas reliance is more transactional. The challenge for the relationship between governments or institutions and the public is that the public may have a choice about whether to trust, but it often has no choice about its reliance. In other words, there is a power imbalance between people and governments (and between people and other institutions) that is ever-present in discussions about trust.[11]

If or when trust is truly relational, it will also be reciprocal; people will trust institutions, but in equal measure institutions will demonstrate that they trust people.[12,13] As one government minister in Taiwan put it during the COVID-19 pandemic, "to give trust is to get trust."[14] If trust is relational, then clearly it is not equivalent to, nor does it imply, simply doing what you are told. This relational, or reciprocal, aspect of trust is particularly important in the context of health data, not least because power is unequal and because people and communities have been harmed by data misuse. In other words, we consider whether people or organizations *should* be trusted, in light of current or past experiences.[15] This is the normative aspect of trust, which flips the conversation to whether a person or organization is trustworthy. **Trustworthiness** is a set of actions, for example related to accountability and governance mechanisms, that are the basis on which trust is given, withheld, or withdrawn.

Trust cannot be demanded or expected. It is earned through trustworthy behaviour and cannot be rushed.[16] Trust is difficult to achieve and easy to lose and is well-characterized by the phrase “comes on the back of a tortoise and leaves on the back of a horse”. Building trust in how health data are collected, used and shared is not just about improving the health system itself; it is also influenced by the broader political and social context in which health systems exist. Trust is grounded in principles of good governance, law, and ethics, which are essential to the functioning of health systems.[17] While there are calls for increased regulation of institutions responsible for health data to help build public trust, it is equally (or arguably more) important to focus on the relationships and shared values that form the foundation of trust.

In addition, trust does not always carry over from one part of the health system to another. For example, trust in a doctor does not translate to trust in the healthcare system as a whole, and trust in university-based researchers to use health data does not translate to trust in private sector companies using the same data. Trust can also depend on the type of data being used—people may feel differently about **routinely-collected data** (or **administrative data**) compared to sensitive information like **genomic data**. Trust may also fluctuate based on the current public health climate or context, such as after a data breach, or the introduction of a new policy. It can also be affected both positively and negatively by personal experiences (e.g. a lack of responsiveness versus feeling listened to by a health care provider).

In other words, there is no simple ranking of which organizations are trusted the most. Research shows that people in poorer health may have less trust in health systems and how their data are used, but it is not clear whether the lack of trust is a cause or a result.[18] There may be a link between how much control people want over their data and how much they trust an organization: people who have less trust in an organization often want more control, and vice versa.[19] Further, with regard to Indigenous Peoples, it is essential to acknowledge the legacies of abuse, colonialism, and paternalism that have resulted in well-founded mistrust for health and health data systems and the people within those systems.

Ultimately, trust is complex, and is earned. It is the outcome of trustworthy behaviour rather than the thing that is worked on directly. Both reliance and relational aspects of trust are important for health and health data as a way for institutions and organizations to demonstrate they are trustworthy. This would imply moving our focus to questions around what institutions and organizations need to do to be good partners, and how they align their priorities and actions with public and community needs and expectations.

Measuring trust

Given the complexity of trust and the degree to which it varies across different aspects of health and health data, it is clear that more work is needed to monitor and measure trust as the outcome of a set of policies and practices. There is minimal guidance on the measurement of trust, likely due to contested definitions of trust and trustworthiness and the lack of distinction often made between trust and similar concepts, as described above. In addition, there are methodological challenges that arise because trust and trustworthiness are not directly observable; people form their own perceptions of trustworthiness and make decisions about their willingness to trust.[10]

Despite the importance of trust as an outcome, until recently its measurement has been relatively limited. The Organisation for Economic Cooperation and Development (OECD) recently implemented what it intends as a recurring survey on drivers of trust in public institutions.[20] There are other efforts to develop measures of trust in government, including reasons for that trust or distrust, as well as measures of trust in health systems more specifically.[21,22] Ideally, measures of trust will give consideration to the "who" (i.e., the person or organization that needs to earn public trust, or better put, that needs to be trustworthy), the "what" (i.e., the purpose of the data collection, sharing or use) and the "why" (i.e., why people trust or do not trust).

The relationship between trust and health data literacy

Health literacy is the ability to understand, communicate and use health information to make informed decisions about health. **Health data literacy** means having the skills to:

- Understand information presented in various forms;
- Evaluate data to spot when it is used in misleading and wrong ways;
- Collect and handle data that are relevant to specific situations;
- Use data to make decisions about personal and public health; and
- Extract useful information from health data.

Digital health literacy is similar, but adds the ability to find and use health data that are in an electronic format. In other words, health data literacy and digital health literacy help individuals and communities use data to make informed decisions about their own health and understand the benefits and risks of collecting and sharing health data.

An important question is whether there is a direct relationship between literacy and trust, particularly in the context of trust in health data use. The public and those who are part of health care systems need a shared understanding of the "public good at stake",[23] and this shared understanding would depend upon elements of both literacy and trust. However, the conclusions from the literature on trust and literacy are nuanced rather than straightforward.

The United States (US) National Academies of Science, Engineering, and Medicine's Roundtable on Health Literacy highlighted important considerations in the association between trust and literacy. This includes the role of organizational health literacy which entails the "extent to which organizations equitably enable individuals to find, understand and use information… to inform health-related decisions…" as a way to promote trust.[24]

Associations between health literacy and trust have been observed in some studies. For example, one study demonstrated a positive association between health literacy and greater trust in medical care, but the study's design does not allow for making conclusions about the direction of effect.[25] Other studies challenge this assumption, including one that showed a u-shaped curve association between trust and literacy, such that both low and high levels of health literacy were associated with lower trust in public hospitals.[25] A systematic review of the relationship between health literacy and a variety of health outcomes related to diabetes did not find an association between health literacy and trust. Out of 34 articles included in that review only two mentioned trust, with one finding an association and the other not.[26] Another small cross-sectional survey study found a relationship between trust in health care providers and the outcome of glycemic control in diabetes, but no relationship between health literacy and the same outcome, and no association between trust and health literacy.[27] Further complicating this relationship is the current proliferation of misinformation and disinformation, particularly in public health, where individuals experience information overload and require significant critical-thinking skills for informed decision-making.[28]

Taken together, the evidence suggests that health data literacy is essential for helping individuals and organizations make informed decisions about their health, health care and health data, but that greater health data literacy may not inherently increase trust. Rather, health data literacy should be viewed as one of several foundational elements that create the possibility for trust, alongside other key factors such as **transparency** and **public benefit**.

Trust, literacy and health equity

Trust is not equal across all population segments, groups or communities. The misinterpretation of data, the overgeneralization of research results, and/or the inaccurate communication of research findings can impede trust. This is particularly true for marginalized groups or any community that has experienced systemic biases. Inequitable practices erode trust, and the use of health data typically focuses on things that are going badly, often putting blame on communities. Institutional mistrust and systemic **racism** are the most prevalent factors influencing vaccine uptake in marginalized communities.[29] Similarly, stereotyping, discrimination and profiling have been shown to result in mistrust and avoidance of the health care system by Indigenous Peoples.[30] At the same time, recognition of historical inequities should not overshadow ongoing challenges and the fact that "everyday racism… often begins at the front door of … health institutions".[24] That is, systemic racism continues to erode trust in some communities.

Building or repairing trust with under-represented or marginalized communities requires a specific and targeted effort. When equity is prioritized, trust is cultivated as people see their needs and rights acknowledged. This highlights the need for institutional change that prioritizes inclusivity and respect along with transparency. These practices can start to bridge the trust gap between institutions and the public.

All of this would imply a movement away from deficit-based approaches (i.e., a focus on problems with outcomes) to a focus on the "strengths of both individuals and communities" which will ultimately "enhanc[e] the quality and level of data used for advocacy."[31] Furthermore, while improving **health literacy** and **health data literacy** are essential to achieving **health equity**, the need for health literacy is not exclusive to patients, particularly underserved ones. It is also critical to focus on improving health literacy for health system partners including providers, policymakers, researchers, and journalists, ideally including but not limited to cultural competency and cultural humility.[24]

THE GREAT PATIENT DATA GRAB

A case study highlighting principles of trust in health data collection

The General Practice Data for Planning and Research (GPDPR) initiative, introduced by the National Health Service Digital (NHS Digital) in 2021, aimed to centralize patient data from general practice records to enhance health care planning and research. The initiative was met with significant public, patient and professional concerns over consent, privacy and inadequate communication. Critics cited a lack of **transparency** in how data were to be collected, used and shared, and with whom, with many patients unaware of the program's existence and their right to **opt-out**. Others noted that the plan might erode patient trust with their providers and with the NHS.

These concerns underscore the necessity for clear communication, robust data governance, and meaningful **public involvement** in health data initiatives to maintain public trust and ensure public benefit from health data use.

In 2024, NHS Digital committed to restarting the GPDPR data collection only when and if the following criteria were met:

1. Key partners, including the National Data Guardian, are satisfied with the proposed initiative;
2. A **trusted research environment** (i.e., a secure computing environment) has been developed to allow approved researchers to access data;
3. Any previous data collected through the program can be deleted at any time; and
4. People are more aware of the new data collection process as a result of wider engagement and communication.

Read more:

- *About the GPDPR programme* (NHS Digital)
- *The Government's failed data grab*
- *New GP data extraction 'far exceeds' care.data plans, warn privacy campaigners*
- *The National Data Guardian for health and social care*

Section 2: Trust Comes From Trustworthy Practice

Trust is the goal, and it cannot be assumed, demanded or taken for granted. It is the outcome of an ongoing process or relationship. In other words, trust is the result of an individual judging that someone or something is trustworthy. This means that earning and maintaining trust depends on institutions or organizations not just saying the right things but showing on a daily basis that they are trustworthy. They need to have trustworthy practices. Principles are the best guide to practices, because principles identify our purpose and the essential values or priorities that are tied to that purpose. The *Canada Health Act*[32] is a good example of naming a set of principles that resonate with people in Canada. That Act's principles of universality, accessibility, comprehensiveness, portability, and public administration are referred to regularly as the ideal for our health systems. This does not imply that we think we have achieved all of these principles perfectly, but they are important in creating a common vision or touchstone for a common goal.

The *Pan-Canadian Health Data Charter* was inspired by the *Canada Health Act* and provides high-level principles for health data design and use. Provinces and Territories in Canada have agreed to these principles; in the case of Quebec, there is general alignment without formal endorsement. There are 10 principles in the Charter, which in summary call for: person-centred data design; inclusion of the public in health data oversight; commitment to Indigenous data sovereignty; protection of data; common standards, for example for data portability, accessibility and stewardship; timely and accessible data; ethical data use for a broad range of purposes; social and technological innovation; health data literacy for everyone; and harmonization of health data governance, oversight and policy. In other words, data are from the people and for the people; health data must therefore be used in ways and for purposes that maximize benefits and minimize harm.

The Charter principles and a deeper understanding of trust are good starting points because they help both with what we are trying to do with how we should go about doing it. In addition to Charter principles, there are other well-developed principles and related frameworks that will be helpful guides to what trustworthy practices actually look like. Using the Charter as a starting point, we outline six dimensions of trustworthy practice.

Putting people at the centre

The first principle of the Charter calls for "person-centric health information design." **Public engagement**, another form of person-centredness, is central to the second principle, which is "inclusion of diverse members of the public, patients, communities and other partners in culturally integrated health information system development and oversight." This requires that public engagement be ongoing rather than a one-time activity (here, we are using "public" to encompass public, patients, families, communities and other partners). Terminology differs across countries, such as **public and patient involvement** in the UK and **consumer involvement** in Australia, all of which have the same underlying ideas.

The International Association for Public Participation (IAP2) defines a **Spectrum of Public Participation**, ranging from informing (e.g. putting information on a website) to empowerment (e.g. enabling the public to make binding policy). The purpose of this framework is not to identify one particular form of engagement as the "best" in all circumstances, but to suggest careful choice of the right level of engagement given the circumstances and objectives of any particular case.

The lowest level, informing, is arguably always necessary to achieve the transparency expected by the public. Informing is aligned with the requirements to ensure **social licence**,[33] such as the need to communicate with the public about the uses of health data in plain language. Involving the public in "oversight", as suggested by the Charter, necessitates greater collaboration with the public for decision-making. This would be a significant change from current practice, and would require development of processes (ideally with significant input from the public) about, for instance, the most appropriate structure for oversight, the oversight bodies and their activities (e.g. whether an oversight body should sit outside of government). This is a way to create "democratic accountability", which can be described as public health leaders' willingness to discuss their choices openly and to explain their decisions and actions to the public.[34]

While the main purpose of public engagement is not necessarily to increase public trust, if done well it can certainly strengthen the trustworthiness of organizations. The OECD 2024 Trust Survey demonstrated that Canadians are three times more likely to trust the government if they feel they have a say in what the government does.[20] On the other hand, if done poorly, public engagement also has the potential to decrease trust. The same OECD survey indicated that only 40 percent of Canadians believe that the government acts on information from their consultations with the public.

Commitment to Indigenous data sovereignty

The United Nations acknowledges that there are more than 370 million Indigenous People who live in more than 90 countries.[35] Respecting the inherent, Constitutional, and Treaty rights of Indigenous Peoples is essential. Canada demonstrated support for this foundational commitment through signing the *United Nations Declaration on the Rights of Indigenous People* (UNDRIP),[36] passing the *United Nations Declaration on the Rights of Indigenous Peoples Act*,[37] and committing to that Act's associated action plan[38]; British Columbia (BC) and the Northwest Territories also have legislation that frames their commitments to reconciliation.[39] UNDRIP outlines Indigenous Peoples' inherent rights to self-determination and sovereignty, which implies a commitment to building nation-to-nation relationships between Indigenous Nations and federal, provincial and territorial governments. Indigenous data sovereignty is one important piece of this larger set of rights.

Reconciliation in Canada includes taking a **distinctions-based approach** to relationships with First Nations, Inuit and Métis Peoples, recognizing distinct historical and cultural experiences. A distinctions-based approach applies to health data as well, which is the focus of the third principle of the Charter. Data will be collected when Indigenous people receive services through health systems. Any collection of "Indigenous data", for example self-identified Indigenous status, should be determined by Indigenous authorities. Any use of those data should be subject to additional data governance requirements, and ultimately must be guided by principles and practices of data sovereignty as defined by Indigenous Peoples. Sovereignty and self-determination require that Indigenous Peoples have full governance over Indigenous data, and that those data be available for governance and decision-making by Indigenous Peoples.[40]

Indigenous Peoples in Canada have expressed different approaches to data sovereignty. These continue to evolve, both in guiding principles and frameworks and in how they are enacted by individual Nations or Peoples.

The First Nations Information Governance Centre (FNIGC) envisions that every First Nation will achieve data sovereignty in line with its distinct worldview. FNIGC worked with communities in the 1990s to develop the First Nations principles of OCAP®, which stands for ownership, control, access and possession. The development of OCAP® is described as "... self-determination applied to collective data, information and knowledge."[41] Ownership states that a community or group owns information collectively (i.e. have **collective rights**) in the same way that an individual owns his or her personal information. The principle of control extends to the full data lifecycle, from collection through to destruction. Access means both that First Nations have the ability to use data, and also that they control decisions about how or whether others use them. Possession is the means by which First Nations can exercise both ownership and control.[42] Finally, FNIGC is working with First Nations across the country to implement the national *First Nations Data Governance Strategy*.

Métis Nations also developed a set of principles for data, OCAS, that are similar but not identical to OCAP®. OCAS are principles of data governance that describe how Métis citizens' data and information should be collected, protected, used, and shared, and stands for ownership, control, access and stewardship. Ownership in this case includes consideration of possession, or the actual holding of data. Control is about the power to make decisions about data use, and access is the ability to use data. Stewardship includes the ability to manage data and to ensure that they are used for the benefit of and in the interests of Métis Citizens.[43] Inuit also put emphasis on ownership, control and access,[44] along with a set of principles based on honouring Inuit Qaujimajatuqangit (IQ), which means traditional knowledge:

- ᐃᓅᖃᑎᒌᑦᓯᐊᕐᓂᖅ —Inuuqatigiitsiarniq: Respecting others, relationships and caring for people;
- ᑐᙵᓇᕐᓂᖅ —Tunnganarniq: Fostering good spirit by being open, welcoming and inclusive; ᐱᔨᑦᓯᕐᓂᖅ —Pijitsirniq, Serving and providing for family and/or community;
- ᐋᔩᖃᑎᒌᓐᓂᖅ —Aajiiqatigiinniq: Decision making through discussion and consensus;
- ᐱᓕᒻᒪᒃᓴᕐᓂᖅ —Pilimmaksarniq: Development of skills through observation, mentoring, practice, and effort;
- ᐃᑲᔪᖅᑎᒌᓐᓂᖅ —Ikajuqtigiinniqi: Working together for a common cause; and
- ᖃᓄᖅᑑᕐᓂᖅ —Qanuqtuurniq: Being innovative and resourceful.[45]

The Global Indigenous Data Alliance developed a set of principles that were inspired by OCAP® and were intended both to support Indigenous data sovereignty as well as to align with the **FAIR principles** for responsible scientific management.[46] The resulting **CARE principles** focus on collective benefit, authority to control, responsibility and ethics. CARE principles are meant to "...empower Indigenous Peoples by shifting the focus from regulated consultation to value-based relationships that position data approaches within Indigenous cultures and knowledge systems to the benefit of Indigenous Peoples."[35]

A focus on relationships underlies all of these principles and reflects a general collectivist and relational worldview that is common among Indigenous Nations. In pursuit of sovereignty and self-determination as well as Nation (re)building, some scholars suggest that a goal is cultural persistence.[47] This is a shift to acknowledging separateness or autonomy of Indigenous Peoples as opposed to focusing on differences between Indigenous Peoples and settlers. Focusing on "difference", and the desire to eradicate that, was of course the whole purpose of the worst forms of colonial government control over Indigenous Peoples. Protecting against any repeat of that history requires use of data to be controlled by Indigenous Nations, for purposes that are determined by Indigenous Nations. Non-Indigenous people and western methodologies can be part of this data use if and when those are seen as beneficial by Indigenous Peoples and the other values and principles are followed.

There are important ongoing conversations about what is counted as "Indigenous data." It is clear that any kind of flag or marker of Indigenous identity would be included, but it is less clear how data such as six-digit postal codes (which can identify Indigenous communities) should be handled. There are also data sets that over-represent Indigenous Peoples as a result of past and ongoing harms of colonization, for example data from child welfare systems, or data on childhood diabetes. While these conversations will evolve, non-Indigenous led institutions and organizations must ensure that their practices are, and remain, aligned with the decisions of Indigenous Nations.

Organizing data sharing, access and use

The importance of data sharing, and by extension data access and use, is evident in three principles of the Charter. Principle number 6 refers to timely availability and accessibility of health data, number 7 is about ethical use of data while being as open as possible, and number 8 promotes data-driven technological and social innovation. Data collection, sharing and use are often talked about as a "lifecycle" and shown as a loop. Data lifecycles vary, but typically include planning, collection, storage, management, access (or use, disclosure, or sharing), and archiving and/or destruction. Each part of a data lifecycle is associated with principles that are intended to convey trustworthiness. Our focus here is on data access, sharing, and use.

The *Interoperability Saves Lives*[48] report included a data-related harm framework outlining the potential harms that can come from health data use, misuse, or non-use. The added emphasis on misuse (e.g. creating false information) or non-use (e.g. data not being available) are important and often overlooked considerations. Non-use of data might happen in the provision of care because of lack of sharing among providers. Non-use of data can occur in the secondary use space if data are not available or are not shared, or if research findings are not shared; the latter is a well-documented issue in clinical trials and was a reason for rules about registration of all trials. The challenge is that harms from non-use are often indirect and difficult to pin down,[49] and so are often not considered, or they are outweighed by concerns about protection of individual privacy.

The data-related harm framework describes potential harms of use, mis-use or non-use to individuals, to populations, and to the health system, and by extension to the health workforce. Individual harm might come from a data breach, while population harm could come from mis-use of data through stereotyping or discrimination, and systems can be harmed if health data are not used to identify areas for improvement and/or support innovation.[48] Interoperability of data is seen as an antidote to these harms. While there are not commonly accepted principles of interoperability, the guiding view is that health data should be available to the right people at the right time and in the right form.

There is increasing international consensus around the **Five Safes Framework** as a guide for setting policies and providing transparency for data access, sharing and use.[50] As a framework, the intent is not to provide specific rules, because those need to reflect local context, values and priorities. Instead, it outlines five areas for which policies and practices need to be determined. As a whole, addressing the five areas constitutes a comprehensive and balanced approach to an institution's definition of safe data sharing and use. The five areas are:

1. Projects: What is the question or purpose of data use?
2. Data: What data are needed and how detailed or sensitive are they?
3. People: Can the person or organization be trusted to use or share the data appropriately?
4. Settings: Where will the data be used, e.g. in a secured physical or virtual setting controlled by the data provider or a trusted data institution?
5. Outputs: What tables or other information will be made public?

The Five Safes Framework is most associated with the **secondary use** of data. It is important to distinguish between the use of health data to provide care to an individual and the use of health data for public health, planning, quality improvement, research, evaluation, or innovation such as new drug development. The data shared in clinical care contain far more specific details than the data typically shared for secondary use like public health. In a clinical situation, your name and other personal information will be included, while in most other (e.g., non-clinical) cases data will be **de-identified**.

The Five Safes are complemented by international principles for open science, which is defined as "the practice of sharing data, information, tools, and research results, and eliminating barriers to collaboration."[51] The advantages of open science include transparency, accountability, reproducibility, collaboration, and sustainability. Open science includes the **FAIR principles**. Being FAIR means making sure that your data are findable, accessible, interoperable (meaning they can be used with other data sets on the same topic), and reusable.[46] There are also principles emerging from community groups, such as **EGAP (Engagement, Governance, Access, Protection)** developed by the Black Health Equity Working Group and black communities in Toronto during the height of the COVID-19 pandemic.[52]

Data stewardship at an organizational or governmental level requires the connection of these and other principles into a cohesive overarching system. Common standards and approaches to stewardship are called for in Charter principle 4. The Canadian Institute for Health Information

(CIHI) is leading work on developing those common standards, informed by a draft framework developed by a federal, provincial and territorial (FPT) working group under the *Working Together to Improve Health Care for Canadians* plan. It is important to acknowledge that standards for data stewardship are not all, or even mainly, technical in nature. Much of what is called for is a shift in culture, moving from **data custodianship** that puts the highest priority on keeping data safe, to a culture and the related skills and knowledge that will protect data while also enabling uses that have public benefit.

Health data and public benefit

Another general principle, implied but not directly named in the Charter, is that all health data use should be aligned with **public benefit** (or **public good**). This principle is implied in the sense that the Charter places "...people and populations at the core of all decisions about the disclosure, access and use of health information". It is also implied in other Charter principles that refer to data use and to maximizing benefit and minimizing harm. The challenge is the lack of a clear and consistent way to define public benefit. There is not yet a consensus on the best approach to evaluate public benefit, how to account for it in applications, and what (or who) we should draw on to define it in the health data context.[53] This creates a challenge for transparency, and for any assurance that there would be consistency in decision making about health data use. It should be taken as given, however, that the public themselves have a clear and ongoing role in establishing the approach used for evaluating and determining public benefit.

Principles of **bioethics** are a starting point for defining public benefit. Bioethics began to develop in the 1970s in response to some egregious examples of lack of clinical ethics, for example deliberately withholding effective treatment for syphilis in order to study the natural progression of the disease[54,55], and in Canada, nutrition "experiments" on Indigenous children in residential schools.[56] In response, the US federal government set up a commission to create guiding principles for biomedical and behavioural research involving human subjects. The resulting *Belmont Report* was published in 1978 and identified principles of respect for persons (autonomy), beneficence (do no harm; maximize benefits and minimize risks) and justice (treat equals equally).[57]

These principles have clinical roots, but they can be useful more broadly in the health data space as well.[58] Clinical origins, however, can lead to over-emphasizing individual autonomy. Individual choice is, of course, important for decisions about using health care services and consenting to participate in clinical research. **Secondary use** of health data combines data from many people, often full populations. People in those data have commonalities; some may see the same doctor, live in the same community, be related to each other, and so on. Those data are used to study treatments, find patterns and make predictions. The implication is that individual-level data can also embody social relations and collective interests.

Social relationships in data have always been important but are now more obvious and easily understood. Your **genomics data** identify you and can also identify your relatives and possibly other community members. The use of **disaggregated data**, for example by race or disability, can be important for understanding and responding to inequity across populations, but it has also led to stereotyping and discrimination. **Artificial intelligence** (AI) uses data to make predictions; this means that individuals can be affected by health data use, positively or negatively, whether or not their data was used to train the AI model that makes the predictions. All of this suggests the importance of putting the principles of beneficence and justice on equal footing with autonomy.

To summarize, making sure that health data use has public benefit is complex. In all cases, benefits are balanced against risks. Benefits can be easier to see and assess in **primary use**, for example in sharing data among all of an individual's care providers, or making health histories and current medication use available in emergency departments. The balance becomes more complex for **secondary use**, in part because the risks and benefits may not be the same for everyone. The challenge becomes greater still when data use involves the private sector, where commercial gain has to be assessed in relation to public benefit.

A report from the UK proposes three principles for assessing public benefit: purpose, proportionality and responsibility.[53] The purpose should be stated clearly, creating both transparency and a justification for data use. Other research indicates that the public has a fairly broad view of health data use that can have public benefit, from sharing for individual care, to use of data that improves service delivery and helps planning, to research and other uses that have longer-term and more indirect potential benefits.[59] A report from BC on disaggregated data, often referred to as the Grandmother Perspective report, cautions that there is limited benefit in pointing out inequities without an intent to use that information for action that will address them.[60] Proportionality means that people have access only to the data they need, that access to data is given for specific purposes, and that there are structures in place to reduce risks.[53] Responsibility means that the data are suitable for the proposed purpose, and that data can be used safely. There is clear overlap between these principles and the **Five Safes Framework**.

Technology standards that will make data safe and sharing seamless

Principle 5 of the Charter identifies the importance of ensuring the quality, security and privacy of health data, and also makes reference to maximizing benefits and reducing harms of data use. Health data ultimately have to be protected where they are stored, when they are moved, and when they are used. Protection of data when they are moved and used is also part of Charter principle 4, which includes a call for common standards for interoperability and access.

Information security and cybersecurity are key areas for protection of health data in digital form. The foundational principles of information security are: confidentiality—that access is limited to people who need to have it; integrity—that there are no unauthorized changes to data; and availability—that data are there when they are needed.[61] The US National Institute for Standards and Technology (NIST) recently updated their cybersecurity framework. That framework, like the Five Safes, identifies the areas that governments and other organizations should consider when developing their technology systems, but not specific decisions for each of those. This reflects both that technologies change over time, and that security practices need to be fit for purpose.

The NIST framework includes seven dimensions, with governance at the centre and six others in a circle around that centre.[62] Governance refers to organizations having things in place for overall monitoring and management of information security. The six other interrelated dimensions are: *identify* all cybersecurity risks; *protect* against those risks; *detect* attacks or breaches that occur despite those protections; *respond* to attacks and minimize their impact; and *recover* to normal operations, including communications about events. In other words, set up data protection systems that provide all the protection necessary, and still plan for the worst possible outcome.

Protecting data when they are moved and used nicely underlines the relationship between the ideas of **data custodianship** (keeping data safe) and **data stewardship** (ensuring they are used for public benefit). It is not surprising, then, that some of the principles identified as relevant to data access, sharing and use also apply to making data safe and sharing seamless. The distinction is that here the emphasis is on principles for technology and technological standards.

For example, one of the Five Safes is “safe settings,” which identifies where data will be used. The technological implementation of safe settings in the **secondary use** space is increasingly through **trusted analytic environments**.[63,64] Virtual rather than physical environments can reduce the needed number of trusted entities coordinating and supporting data access and use, and both physical and virtual environments eliminate sending data out to users. Virtual access can help address some aspects of equity, for example geographic equity and accessibility in general. Trusted environments also support **data sovereignty**, as they allow ongoing visibility of data use and the ability to turn off access if any issues arise.

Transparency, communications, and learning

Aligning with the Charter provides a common goal for health data-related activity. Principles 1 and 2 of the Charter imply that there should be full transparency on how each of these principles is being met. Transparency is consistently raised by the public as an expectation. Transparency and communications are fundamental as they underpin all other dimensions of trustworthy practice. Trust is not built through action alone—it requires intentional communication and a commitment to health data practices that are both visible and participatory. Transparency is a key ingredient for accountability.[65] As one author put it, "Opening up flows of information changes who can do what. That is why there are few more important struggles in the world today than the battle over who gets to know what."[66]

Transparency about principles (i.e. *what* we are trying to achieve) is important, but so is transparency about how, specifically, these principles are enacted (i.e. *how* we are achieving these goals through policies and practices). Policies or practices that ensure health data are used for public benefit, or that create clear rules for access, sharing and use (as examples) are critical, but their impact is limited if the public is unaware of them. Transparency is often associated with public acceptability (or **social licence**) in health data use. Transparency and **data literacy** are also linked, as fostering an understanding of health data uses requires clear and accessible communication about data use as well as the provision of educational materials to increase data literacy tailored to meet the needs of specific populations.[33]

Transparency does not mean sharing everything. It would likely be more helpful to the public to have transparency on what information is shared through better interoperability standards than transparency on the technical specifications of those standards. Too much information, especially when it is not organized in a meaningful way, can be confusing and then have no real positive effect.[67]

Recommendations for trustworthy practice

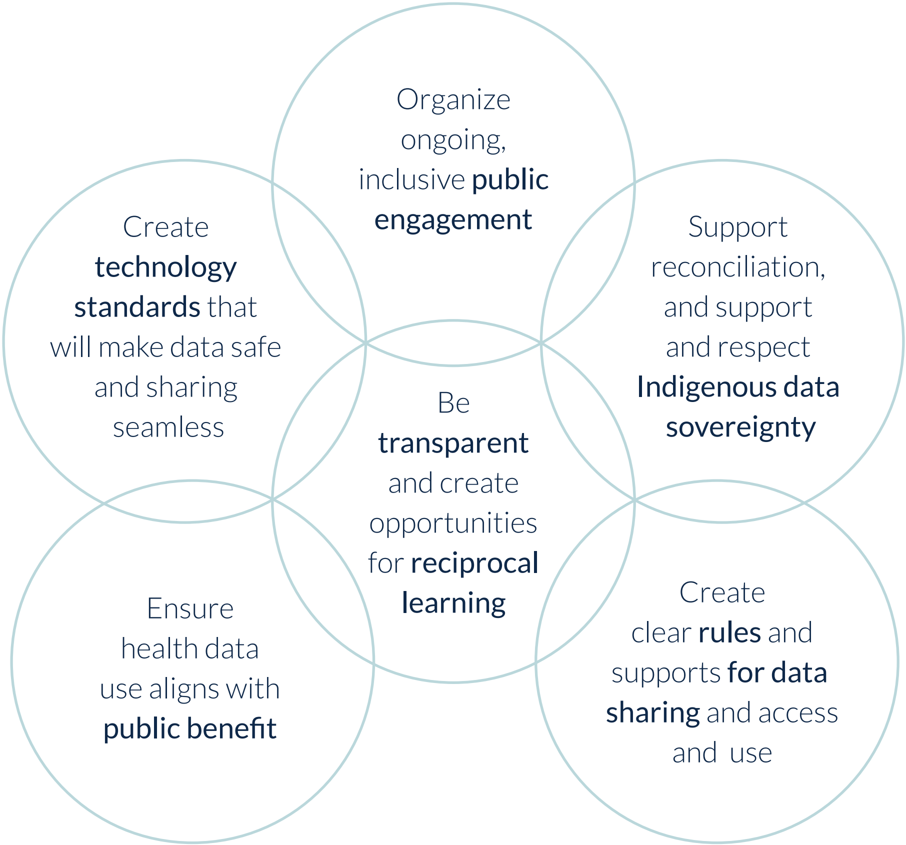
We offer six recommendations for trustworthy practice. These recommendations are intended in the first instance for provincial, territorial and federal governments. They are equally relevant to other institutions and organizations that hold, manage, make available and use health data. Each of the recommendations includes frameworks and/or principles to guide action. This section

(Section 2) provides the recommendations, which will then be used in the next section (Section 3) to show how they can be used in practice.

1. Organize ongoing, inclusive public engagement;
2. Support reconciliation, and support and respect Indigenous data sovereignty;
3. Create clear rules and supports for data sharing and access and use;
4. Ensure health data use aligns with public benefit;
5. Create technology standards that will make data safe and sharing seamless; and
6. Be transparent and create opportunities for reciprocal learning.

See Appendix B for recommendations for trustworthy practices, their alignment with principles and frameworks (including Charter principles) and examples of real-world practices which will be the focus of the next section (Section 3).

Recommendations for trustworthy data practices



Section 3: Benefits, Risks and Protections of Health Data

This section starts with a general overview of the benefits and risks of data sharing. It then uses the six recommendations from the previous section to frame data practices (i.e., protections) in Canada and internationally that exemplify those principles in practice. Finally, we offer recommendations on who should be involved in enacting these practices.

Benefits of health data sharing and use

The use and sharing of health data offers many benefits across both primary and secondary uses and for different groups, including providers, patients, governments, health system planners and innovators. In a health care setting, data sharing enhances quality of care, improves patient safety and reduces the burden on individuals to manage their own health information. This would eliminate the need for "binder medicine", when individuals become overly responsible for managing their own health data and sharing them with health care providers. Digital health innovations, such as remote patient monitoring, can improve quality of care and reduce health systems costs by enabling proactive and timely care.[68,69] They may also help reduce health inequities, for example by increasing access to health services via virtual care for individuals in remote or underserved areas. However, equitable implementation of digital health tools is critical to ensure disparities are not unintentionally widened by worsening the digital divide.[70]

On a broader scale, secondary use of health data supports vibrant research and system innovation, including within governments, universities, nonprofits and charities, and the private sector. It enables a more comprehensive understanding of health trends, leading to higher-quality evidence that can inform effective policy making and improve health care systems. Health data also play a significant role in public health, strengthening preparedness for responses to emergencies, such as pandemics.[71,72]

Risks of health data sharing and use

While sharing health data offers significant benefits in improving patient care and advancing research, it also raises important concerns about privacy, security and potential misuse. Risks from health data sharing and use also look different depending on the particular risk "group". Health data have been (and continue to be) used to stigmatize and harm people, particularly those from underserved or marginalized communities. This can happen in both the primary and secondary use space. For example, the summary report *In Plain Sight: Addressing Indigenous-specific Racism and Dissemination in BC Health Care* was published in 2020 following an investigation into Anti-Indigenous racism in BC's health care system.[30] The report included stories of health care providers guessing the blood alcohol level of Indigenous patients without medical justification, reinforcing deeply-rooted biases and harmful stereotypes. This ultimately led to negative impacts on the quality of care Indigenous patients received, further undermining trust in the health system.

Security breaches are another concern and are particularly challenging in the digital era, because once a breach occurs and sensitive information is exposed, it cannot be undone. A loss of privacy can also occur if data or information about individuals without consent and/or are revealed as the consequence of a breach. In these cases, the risk and consequence for individuals is that their sensitive information is available to non-trusted people, while for governments and health systems the risk and consequence may be more about reputation and hence a loss of public trust.

Conversely, there are also inherent risks to *not* sharing health data appropriately or in a timely manner, both in the primary and secondary data space. The failure to share health data appropriately in health care poses significant risks to patient safety, care quality and efficiency (see Greg's Wings case study below). A lack of **interoperability** (i.e., the inability for patient data to flow seamlessly between different providers and patients) can lead to fragmented care, which then increases the possibility of misdiagnosis, missed diagnoses and unnecessary testing. Inadequate health data sharing between providers can exacerbate delays in treatment, hinder coordination between multidisciplinary teams and consequently negatively impact patient outcomes. In the secondary use context, the Expert Advisory Group for the *Pan-Canadian Health Data Strategy* highlighted significant gaps in Canada's health data ecosystem that were exposed during the COVID-19 pandemic, leading to a delayed public health response, such as the inability to track accurately the virus's spread or monitor vaccine distribution and coverage.[71]

Health data practices must both minimize risk (such as privacy breaches and misuse) and leverage data to maximize public benefit.

It is also important to acknowledge that both benefits and risks evolve. The development of AI and potential for health data use in AI models is an important example of change. Since trust is in constant negotiation and the nature of health data and associated risks and benefits evolves, we can expect that trustworthy practices will have to evolve as well.

GREG'S WINGS

A case study in the risks of fragmented health data sharing

Greg Price's experience highlights critical failures in health information and data sharing that contributed to delays in the diagnosis and care of testicular cancer, a treatable health condition. He is the only Canadian whose death has been attributed by an independent body to the poor management of his health information, although his lived experience is certainly not unique. Fragmented communication between health care providers led to missed opportunities for timely intervention, and essential health information (like test results and referrals) were not effectively acted upon. The lack of a coordinated system meant that Greg's health information was siloed across different institutions. These gaps in information sharing resulted in delays that led to the mismanagement of his condition and ultimately his death in 2012.

Following his death, Greg Price's family has advocated for significant healthcare reforms, including a fully interoperable health system. Since 2012, there have been strides towards improving interoperability in Canada's healthcare system. Initiatives like the *Interoperability Saves Lives* report[48] and the *Shared Pan-Canadian Interoperability Roadmap*[73] highlight the urgent need for seamless health data sharing to enhance patient outcomes. Additionally, former Bill C-72, the *Connected Care for Canadians Act*,[74] was introduced in June 2024. This Bill aimed to enable interoperability by requiring vendors to meet established standards and prohibiting data blocking. Under former Bill C-72, vendors would have been prevented from obstructing or interfering with the access, use, or exchange of electronic health information stored within their platforms. These efforts reflect a growing recognition of the need for a more connected and patient-centred healthcare system in Canada.

Read more:

- *Greg's Wings*
- *Continuity of Patient Care Study* (Health Quality Council of Alberta, 2013)
- *The Connected Care for Canadians Act* (Government of Canada, 2024)
- *Pan-Canadian Interoperability Roadmap* (Canada Health Infoway, 2023)
- Alberta Virtual Care Coordinating Body:
    - *Interoperability Saves Lives* (2023)
    - *Data Disarray* (2024)
    - *Disconnected Care* (2025)

Trustworthy practices

Organize ongoing, inclusive public engagement

Prioritizing inclusive, ongoing public engagement requires aligning engagement approaches with objectives, as outlined in the IAP2 framework, which emphasizes engagement at most, if not all, levels. When the public plays a role in oversight (as highlighted in the Charter), engagement should lean toward the more collaborative end of the spectrum, complemented by other practices that foster transparency and trust.

Representative deliberative processes are gaining greater legitimacy for engagement at the higher end of the spectrum, with mechanisms such as citizens' juries or public assemblies playing a key role. A notable example is a deliberative public engagement process held in Vancouver, BC, where residents were brought together over four days to provide recommendations on acceptable data use within an evolving landscape of digital data from public and private sources, and our ability to link those data together at an individual level.[75] Permanent deliberative bodies can also be established as a way to identify priorities that require additional input from the public.[76] These processes can also be designed to ensure that voices from marginalized communities are heard, as was shown through the OneLondon deliberations on health data.[77]

Deliberative processes should be contextualized within a broader spectrum of public participation models when this comprehensive type of engagement may not be feasible, or even necessary. For instance, routine trust surveys (such as the OECD Survey on Drivers of Trust in Public Institutions)[20] can monitor public perceptions and experiences over time, while focus groups can facilitate discussions on less complex topics or specific issues. Sequencing and/or diversifying engagement methods can also help leverage the strengths of various public participation methods and meet the accessibility needs of diverse communities. For example, the University of Wollongong (Australia) conducted a national survey that explored public attitudes in Australia toward sharing health data with private companies for research and development,[78] which was followed by two Citizens' Juries to identify gaps in public perspectives not addressed in the survey.[79]

The *Public Engagement on Health Data Toolkit* (Simon Fraser University) offers a comprehensive overview and planning template for engagements, incorporating a broad range of public participation models, including public consultations, dialogues, open houses, and online surveys.

Support reconciliation, and respect and support Indigenous data sovereignty

We are a long way from seeing full realization of true Indigenous data sovereignty. While there is still a journey ahead, there are many promising developments, and we highlight a few here, indicating activities of Indigenous Peoples, collaborations between Indigenous and settler organizations, and changes in practices of non-Indigenous led institutions.

The FNIGC led the development of a First Nations Data Governance Strategy, which "...envisions a First Nations-led, national network of regional information governance centres across the country equipped with the knowledge, skills, and infrastructure needed to serve the information needs of First Nations people and communities."[80,81] The plan is to implement this strategy in three phases, starting with foundational elements, then moving to the development of the required human and technical capacities, and finally to an ongoing sustainable and "evergreen" system. It is understood that an evergreen set of regional data centres will continue to evolve, and that the whole process of implementation is likely to take a decade or more.[82] Implementation is in the first phase, following the delivery of the strategy in 2020 and funding committed in Federal Budget 2021. Other commitments include the Canadian federal government's royal assent of legislation enshrining commitments to UNDRIP in 2021 and announcement of an associated action plan in 2023. Allocation of funding by the federal government to the next phases will be an important signal of an ongoing commitment to reconciliation.

The development of a profile of Métis health status offers an example of collaboration between Indigenous and non-Indigenous organizations, in this case the Manitoba Métis Federation (MMF) and the Manitoba Centre for Health Policy (MCHP—which is part of the University of Manitoba).[83] The working relationship for this comprehensive profile began with the MMF recognizing the need for Métis-specific health information for their own planning and service development. The groups worked together to define the Métis population in Manitoba, to develop a Métis Population Database, and to agree on the ongoing rules for use of that database. The rules agreed to were based on the OCAS framework, and require "...approvals from MMF, MCHP, Manitoba Health's Health Information Privacy Committee (which protects all Manitoba citizens' right to privacy), and the University of Manitoba's Health Research Ethics Board (the group which evaluates academic ethics),[83] and other government ministries and agencies as necessary.

This work was extended in 2013 with the development of research protocols by the University of Manitoba for working with Indigenous Peoples.[84] Development of these protocols was led by a First Nations, Métis, and Inuit Research Engagement Steering Committee that included Indigenous and non-Indigenous members from inside and outside the University. The research protocols provide guidance on how research with Indigenous Nations should be conducted, and include reference to OCAP®, OCAS and IQ (traditional knowledge). There are other examples of co-development of research practices, such as a Code of Research Ethics used to guide a Kahnawà:ke Schools Diabetes Prevention Program.[85] In this case, a Community Advisory Board was established to make decisions on all requests for use of collected data, to assess "...cultural relevance and to assess benefit to the community."[85]

The benefits of building trustworthy practices and true relationships over time can be seen in other research undertaken in Manitoba. The Manitoba Inuit Association approached the MCHP in 2016 with an interest in developing population-based strategies for health and well-being of Inuit in Manitoba. This is an ongoing partnership that is driven by community interests and includes community members in all aspects of the research, including authorship on papers.[86,87] It has also produced unanticipated benefits, including greater visibility of Inuit and their needs and contributions, and greater connection across communities.[88]

There are similar long-standing relationships in Ontario between ICES, a research institute that also holds, uses, and shares a number of different linkable data sets, and First Nations governing bodies including the Chiefs of Ontario, Grand Council Treaty #3, and Kenora Chiefs Advisory. Clear and legally binding data governance agreements with these bodies establish mechanisms for approval of the use of data which could identify First Nations communities or individuals in ICES data. As a result, any use of such data requires approval by research committees led by First Nations partner organizations, and may also require engagement with communities. There is a similar data governance agreement with the Métis Nation of Ontario regarding Métis identifying data. In addition, ICES provides training on Indigenous history, social context and worldviews for staff and researchers, and there is a commitment to building expertise in data analysis and epidemiology in Indigenous communities.[89] In other words, specific policies and procedures of ICES, a non-Indigenous institution, were established to support Indigenous data sovereignty.

Create clear rules and supports for data sharing, access and use

Principles and frameworks such as FAIR, OCAP®, OCAS, IQ, EGAP and the Five Safes are only a guide to practice. Policies and processes are what give life to principles in any institution. Clearly written policies then make it possible to be transparent about practices.

Consent is a key practice that shows commitment to the bioethics principle of respect for persons (autonomy). Data flows for **primary use** generally require some form of consent, and it is a required component in clinical research that is testing a new drug or device. The **secondary use** area is slightly different. **Routinely-collected data**, for example, are often collected based on authority in relation to providing a service, and can be used for purposes that are consistent with that collection.[90] Even though individual consent is not required for all uses of data, individuals represented in those data still have interests in data use, and institutions have obligations in relation to those interests. This is one reason for increasing focus on community governance, such as expressed by the Black Health Equity Working Group through their EGAP principles.[52] (See more related to this in the sub-section below, on public benefit.)

The Five Safes have been used to frame policies in many governments and organizations, particularly in the United Kingdom (UK), Australia and Canada. The details of implementation vary, but there are some commonalities in requirements. We provide here a brief summary of the kinds of requirements that are often included for each of the dimensions of the **Five Safes Framework**.

1. Projects: Scientific peer review; ethics review; and demonstration of public benefit.
2. Data: De-identification; limiting access to data sets required for the project.
3. People: Identified users who are part of an accountable institution (e.g. university); privacy training; signed agreements.
4. Settings: Use of trusted secure environments (which increasingly are virtual); two factor authentication for access; controlled movement of any outputs of analysis.
5. Outputs: Vetting of anything to move out of the secure setting; review of written material.

The **FAIR principles** are a way to support use of health data as part of a commitment to open science. FAIR is about making health data findable, accessible, interoperable and reusable. In other areas of science there is a strong focus through FAIR on data deposit, which means putting research data in a place that can be found and is accessible[73] to other researchers. In the health data space, this kind of deposit is not always possible, because the data are sensitive, and because the data are governed by governments and other institutions (decisions about data sharing are not made by data users).

Making data “accessible” also means documenting what is in the data, how they can be used, any potential biases, data quality considerations, and other considerations for use. There is increasing recognition that this documentation, which is called **metadata**, is critical for any kind of data use or re-use, for example because metadata can help assess whether data are fit for the purpose intended. Even more importantly, there are ways to share information that support health data use that can evolve as people build tools or concepts or analytic approaches. As a simple example, many people are interested in using health data to understand costs of different approaches to care. Not all data come with cost information, so that has to be added, and there are many different, often complex, ways to do this. Sharing these methods in a way that can be reused easily is consistent with FAIR principles. Good examples of this practice are the long-standing and well-used Concept Dictionary created and curated by MCHP,[91] and a newer phenotype library developed in the UK.[92]

All of these practices are part of data stewardship. Agreement across federal, provincial and territorial organizations on common approaches will be important for meeting the objectives outlined in the Charter. CIHI is leading work on defining and harmonizing data stewardship practices.

Ensure health data use aligns with public benefit

One way to ensure that uses of health data have public benefit is to involve members of the public in setting guidelines and guardrails. Community governance was identified in BC's Grandmother Perspective report. Following the publication of that report in 2020, BC introduced and passed the *Anti-Racism Data Act*, which became law in 2022.[93] That Act mandated the creation of an Anti-Racism Data Committee which includes community members from across BC with a variety of backgrounds and experiences.[94] The terms of reference says: "The purpose of the committee is to support government's work to implement the Act and support meaningful community involvement in the development of government's collection, use and disclosure of information for the purposes of identifying and eliminating systemic racism and advancing racial equity."[95]

The Caldicott Principles (see box below) were developed through a literature review and public engagement in the UK, motivated by the increase of health data in digital form. These principles guide the practice of Caldicott Guardians in the UK. Caldicott Guardians serve an advisory role within organizations that provide publicly funded services, and are found in institutions that support secondary use as well. They provide advice within organizations to help guide data sharing decisions. The advice must of course fit within what is legally allowed, but often has an ethical dimension and areas of uncertainty (for example, whether a health care provider can share suicide risk information with a patient's psychiatrist). Caldicott Guardians can also respond to national programs that seek advice. This advice is supported by a panel of experts, and there is a learning program in place for all Caldicott Guardians.

In the **secondary use** space, there is increasing attention to involvement of diverse voices and perspectives in research projects, for example through the Canadian Institutes for Health Research Strategy for Patient Oriented Research.[96] The intent is that through patient and public engagement, research questions will better reflect community priorities and needs, and the analysis and interpretation of data will benefit from the knowledge and expertise of engaged communities. It is expected that this will increase the likelihood and speed of use of the resulting evidence, whether by communities themselves or by decision and policy makers in public health and health care systems.

Organizations that facilitate access to health data for **secondary uses** also play an important role in advancing public benefit through their collaborations with researchers and knowledge users, including those in the private sector. The National Data Guardian in England and Understanding

PRINCIPLES IN PRACTICE

The Caldicott Principles and Caldicott Guardians

The Caldicott Principles were originally developed in 1997 in the UK through a commissioned review led by Dame Fiona Caldicott. The review was motivated by increasing public concern about use of health data in the NHS, driven by the increasing use of computers and the creation of digital data. We highlight these principles because they have shaped many health data discussions and, with some revisions, are still actively in use in the UK.

Caldicott Principles are intended to guide both organizations and patients and apply to all data collected for the provision of health and social care services where patients can be identified and where they would expect this to be kept private. Caldicott Guardians play senior roles in organizations that use and/or share health and social care information. They oversee the upholding of Caldicott Principles and provide advice in complex or unique cases. The eight principles can be summarized as follows: the use and purpose of information should be legal and well justified; confidential information should be kept to the minimum necessary and shared only with people who need it; all who use information should be aware of their responsibilities; the duty to share information is as important as the duty to protect confidentiality; and people should be informed about use of their data.

Read more about the eight *Caldicott Principles*.

Patient Data (an organization that provides objective information on how data are used in the NHS) commissioned a public deliberation on how the members of the public would define and assess public benefit. Participants emphasized the importance of trust and transparency, supported commercial (private sector) use of health data as long as there is also clear public benefit, and recognized that there can only be public benefit if data are used.[97] The views and recommendations from this deliberation were used by the National Data Guardian to produce guidance intended to instill practices that would build trust in data use. The guidance suggests assessing the "public" part of any potential data use and the "benefit" part, and provides examples of the types of benefits that are acceptable. These range from understanding community needs to finding new treatments to exploratory research.[98] Ongoing public input, in particular for "edge cases" was also seen as important.

Create technology standards that will make data safe and sharing seamless

There is a clear need for common interoperability standards, as these define the safe technological processes for sharing data across institutions and across provincial and territorial boundaries. The *Interoperability Saves Lives* report[48] and the health data-related harm framework make the case for interoperability. There is work underway on this, defined by the *Pan-Canadian Interoperability Roadmap*, which outlines shared responsibility for the vision of "a modernized health system built on connected care."[73] Canada Health Infoway and CIHI are leading the way on this work.

In June 2024, federal Health Minister Mark Holland announced a new bill, the *Connected Care Act* (Bill C-72).[74] This Act was designed to ensure that patients can have access to their own data, that technology providers (vendors) adopt common standards for data that support interoperability, and to ensure that health data can and will flow as needed across institutions and geographic boundaries. To be clear, technology must be designed to respond to and enable the policy decisions that are made elsewhere. Technologies (and vendors) do not dictate what is shared, but make it possible to do so when proper approvals are in place.

The announcement of the *Connected Care Act* can be seen *here*, and included comments from Greg Price's sister, Teri Price, who is Co-Founder and Executive Director of Greg's Wings. The Act did not receive royal assent before the prorogation of Parliament in early January 2025. This means that in order to move forward, the Act will have to be reintroduced in the next Parliament.

Be transparent and create opportunities for reciprocal learning

The Ipsos Mori *One-Way Mirror Report* from the UK[99] identifies four "key tests" for public acceptability and transparency:

1. Why: Are data being used for public benefit or profit?
2. Who: Is the organization using health data considered trustworthy?
3. What: Are the data sensitive and can they identify me?
4. How: Are there safeguards in place to keep the data private and secure?

These transparency considerations align well with the **Five Safes Framework**, and underscore the importance of institutions enacting open and visible policies and processes related to health data collection, sharing and use. As mentioned in Section 2, transparency in decision-making processes (as opposed to the technical aspects of health data), is especially important because it ensures that institutions are accountable for the values and priorities that guide their specific actions. Communications about health data should also be accessible in writing, language and format, and produced using accessibility standards.

Data saves lives: Reshaping health and social care with data,[100] the UK government's strategy to ensure the safe and effective use of health data, demonstrates effective strategies for communicating health data benefits, risks, and protections to the public. In addition to conducting large-scale public consultations and the establishment of advisory panels focused on communications, the strategy also included the development of a "*data pact*" which aims to "provide clarity and certainty about what does—and does not—happen to health and care data." Toolkits for the public and other key health data partners have also been created to facilitate community dialogue about health data; these toolkits provide information on the *basics of health data*, *artificial intelligence*, and how to *establish community-led patient registries*.

Following Greg Price's death in 2012, through the not-for-profit *Greg's Wings*, his family has advocated strongly for health information management reform (see box above). This includes a focus on transparent communication with the public and support of data literacy and training initiatives. *Falling Through the Cracks*, the short film which highlights Greg's experience navigating the healthcare system, has been viewed and discussed with many patient and community groups, as well as with the general public. Greg's Wings has also partnered with the Canadian Health Information Management Association (CHIMA) to enhance health information education across a variety of academic programs.

There are additional transparency requirements in Canada, for example with respect to communication in both official languages, and in alignment with commitments to reconciliation with Indigenous Peoples. Perhaps most importantly, a commitment to transparency should include an ongoing commitment to accountability for trustworthy practices. It is important for governments, institutions and organizations to define and share their practices, as informed by engagement with the public, Indigenous Peoples and other interest holders. It is equally important for there to be regular and transparent reporting on whether and how those commitments are enacted, and where practices have fallen short, including but not limited to any data breaches. This should be paired with regular measurement and reporting of trust, how that is interpreted, and how any trust deficits are being addressed.

In other words, the existing power dynamics will need to shift. The idea of reciprocal learning is tied to reciprocal trust. Institutions act on input from the public, share with the public, and enable the public to respond. This creates a learning cycle that aligns with Charter principle 1 on involving the public in design and oversight of health data. It is consistent with community inputs to governance of health data, and with extending notions of privacy protection to populations and communities as well as individuals. Knowledge and insights can and should move in both directions and have influence on the future of health data.

Final Thoughts, Including Who Should Be Involved

Trust is an important goal for health data and for the health systems that rely on those data. Health data literacy is a necessary foundation, and a laudable goal in and of itself, but its relationship with trust is complex and not well understood. Trust ultimately depends on trustworthy practices, and those practices must evolve as health data and the opportunities to use them evolve.

In this paper, we offer a pathway to trustworthy practice for governments, organizations and institutions that collect, use and share health data through six principles-based recommendations:

1. Organize ongoing, inclusive public engagement;
2. Support reconciliation, and respect and support Indigenous data sovereignty;
3. Create clear rules and supports for data sharing, access and use;
4. Ensure health data use aligns with public benefit;
5. Create technology standards that will make data safe and sharing seamless; and
6. Be transparent and create opportunities for reciprocal learning.

These recommendations for trustworthy practice help identify what needs to be done, but how decisions are made and who is involved are also important. Here we offer final reflections on both who needs to be involved in informing the specifics around trustworthy practices and what is ultimately at stake.

It is clear that federal, provincial and territorial (FPT) governments have a clear role, as do organizations such as CIHI and Canada Health Infoway. There should also be continued movement towards including Indigenous Peoples, which would reflect true federal/provincial/territorial/Indigenous (FPTI) working relationships, in recognition of nation-to-nation commitments embedded in being a signatory to UNDRIP and in law such as the federal *UNDRIP Act*.[36,37]

Governments have significant responsibilities for decisions about data collection, protection, sharing and use. They are not, however, the only relevant groups. If the aim is person-centred health data design, the health data that are part of that design should come from ministries of health, but also electronic medical records (which are not always under government authority), and private-pay providers and organizations such as physiotherapy, home care, and long-term care. Non-profit organizations, health charities and others also have interests in health information as an input to their services and activities. The public, patients, and family members also clearly have interests in health data. This framing expands the way we should think about who is involved.

The multitude of interests involved in both **primary** and **secondary uses** of health data make clear that there is no simple one-size-fits-all solution for trustworthy practices. The processes used to govern data collection, protection, sharing and use must align with their intended purpose. They will need to evolve over time, as data, technology, analytic approaches, and public expectations also evolve. Public trust must be earned and can easily be lost. Trust is based on relationships that are mutual and require ongoing attention.

Trustworthy practices should be transparent, and part of that transparency is showing accountability for both successes and failures in meeting the intended practices. Trust itself should be measured and monitored over time, as part of an ongoing dialogue between the public and the governments, institutions and organizations that have responsibility for health data.

Earning and keeping public trust is both a laudable and achievable goal. It will require changes in practice, including adopting new models of data stewardship and creating more interoperability in technologies, policies, standards, and relationships across organizations and geography. The principles of the Health Data Charter provide a common goal, and trustworthy practices can help earn the public trust that will be essential for getting there.

Appendix A: Methods

This paper was developed through a review of relevant peer-reviewed and grey literature, as well as relevant existing frameworks. The latter were identified based on the authors' existing knowledge, input from colleagues at the Public Health Agency of Canada and Health Canada, and through colleagues, reviewers, focus groups and interviews, and reading. Focus groups and key informant interviews were conducted to add perspectives and feedback to the work. The steps undertaken throughout the process included:

Phase 1: Development of health data glossary

- Review of existing health data glossaries;
- Proposal for grouping terms using plain language definitions to align with contents of this paper;
- Two rounds of public consultation to confirm terms and definitions.

Phase 2: Building the Foundation (Section 1) and Trust Comes from Trustworthy Practice (Section 2)

- Literature review focused on principles of public trust and relationship with health data literacy;
- Focus group #1 (eight participants);
- Key informant interviews held with experts in trust and public engagement;
- Feedback synthesized and draft of Sections 1 and 2 developed.

Phase 3: Benefits, Risks and Protections of Health Data (Section 3)

- Literature review focused on benefits, risks and protections of health data in the Canadian context;
- Focus group #2 (eight participants);
- Key informant interview held with expert in data protections;
- Feedback synthesized and draft of Section 3 developed.

Phase 4: Engagement with Health Data Research Network Canada's Public Advisory Council (PAC) and Public Engagement Working Group (PE WG)

- Focus group #3 held with members of HDRN Canada's PAC and PE WG (11 participants) focused on building the foundation (Section 1), trust comes from trustworthy practice (Section 2) and the benefits, risks and protections of health data (Section 3)

Phase 5: Case study development

- Development of real-world case studies based on literature review, focus groups and key informant interviews.

Phase 6: Final paper development

- Drafting of the final paper and review by relevant health data partners, including members of the public.

Engagement methods

Potential participants for focus groups and key informant interviews were identified based on previous engagements and ongoing working relationships with the project team. Recruitment was conducted through direct contact via email. Focus groups and key informant interviews included individuals with lived experience as well as people with expertise in public engagement, data privacy/ethics, public trust, inclusion, diversity, equity and accessibility, and Indigenous data sovereignty.

Focus groups: Three online 90-minute focus groups were facilitated by members of the project team. A live whiteboard was used to facilitate discussion. Background material and discussion questions were provided one week in advance of each session. An honorarium of $50 was provided to participants who identified as patient/public partners.

Key informant interviews: Four 60-minute semi-structured interviews were facilitated by two members of the project team. Sample questions used to guide the discussion were shared one week in advance of the interviews.

Appendix B: Trustworthy Practices and Alignment with Charter Principles

Charter principles	Dimensions of trustworthy practice	Recommendations	Related principles or frameworks	Noteworthy practices
Person-centred data design (1); Inclusion of the public in health data oversight (2)	Putting people at the centre	Prioritize ongoing, inclusive public engagement	IAP2 framework	Trust Surveys; Australian Citizen Juries; BC Data Deliberation; Public Engagement on Health Data Toolkit (Simon Fraser University)
Commitment to Indigenous data sovereignty (3)	Commitment to Indigenous data sovereignty	Support reconciliation and respect Indigenous data sovereignty	OCAP®; OCAS; IQ; CARE	BC DRIPA and related report; FNIGC data strategy
Ethical data use for a broad range of purposes (7); Social and technological innovation (8)	Health data and public benefit	Ensure health data use aligns with public benefit/good	Caldicott Principles; Principles of bioethics; Data governance and stewardship framework being led by CIHI; EGAP	BC Anti-Racism Data Act and Anti-Racism Data Committee; ICES private sector work
Timely and accessible data (6); Harmonization of health data governance, oversight, and policy (10)	Organizing data sharing, access and use	Create clear rules for data sharing, access and use	Five Safes Framework; FAIR Principles; Harm Framework (from Interoperability Saves Lives); Data governance and stewardship framework being led by CIHI	Concept Dictionary (Manitoba Centre for Health Policy); Phenotype library (UK)
Common standards for example for data portability, accessibility and stewardship (4); protection of data (5)	Technology standards that will make data safe and sharing seamless	Create technology standards that will make data safe and sharing seamless	Five Safes Framework (specifically, "safe settings"); The US National Institute for Standards and Technology (NIST) cybersecurity framework	Pan-Canadian interoperability roadmap; Digital Governance Standards Institute
Inclusion of the public in health data oversight (2); Health data literacy for everyone (9)	Transparency, communications, and learning	Be transparent and create opportunities for bi-directional learning	Transparency; Literacy	Data Saves Lives; Greg's Wings

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