The Digital Society Working Group Report to the Ontario Health Data Council

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Digital Society Working Group
Membership

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- The Digital Society Working Group consists of:
    - **Members**
        - **Kwame McKenzie, (Co-facilitator),** CEO, Wellesley Institute, Director of Health Equity, CAMH, *kwame@wellesleyinstitute.com*
        - **Lyndon Dubeau**, Vice President of Digital and Technology, Ontario Health, *lyndon.dubeau@ontariohealth.ca*
        - **Sylvie Gaskin,** Chief Privacy Officer, Ontario Health, *sylvie.gaskin@ontariohealth.ca*
        - **Debra Grant**, Director of Health Policy, Office of the Information and Privacy Commissioner of Ontario Representative, *debra.grant@ipc.on.ca*
        - **Carmen Jones,** Director of Research and Data Management, Chiefs of Ontario, *carmen.jones@coo.org*
        - **Brent Knowles,** Director, Analytics and Research, College of Nurses of Ontario, *bknowles@cnomail.org*
        - **Kirk Nylen**, Vice President, Integrated Discovery and Informatics, Ontario Brain Institute, *knylen@braininstitute.ca*
        - **P. Alison Paprica,** Assistant Professor, Institute for Health Policy, Management, and Evaluation (UofT); Executive Advisor and Affiliate Scientist at ICES, *alison.paprica@ices.on.ca*
        - **Natalie Raffoul,** Managing Partner, Brion Raffoul IP Group, *nraffoul@bripgroup.com*
        - **Teresa Scassa,** Professor, Faculty of Law, School of Information Studies (U of Ottawa), *teresa.scassa@uottawa.ca*
        - **Jay Shaw,** Research Director, Artificial Intelligence, Ethics and Health, Joint Centre for Bioethics (UofT), *jay.shaw@wchospital.ca*
        - **Don Willison,** Associate Professor, Dalla Lana School of Public Health (UofT), *don.willison@utoronto.ca*

Digital Society Working Group Report

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Executive Summary:

This report summarizes the recommendations of the Digital Society Working Group, sponsored by the Ontario Health Data Council, with the task of devising a list of ethical principles for the use of health information in Ontario and identifying supplemental recommendations that flow from these principles. The proper use of health data is critical for achieving a wide range of advantages for individuals, the healthcare system, and society. This usage, however, has significant ethical weight. Individuals and groups continue to be affected by how their data is used, and negligent use risks invading privacy and causing harm. At the same time, a blanket refusal to use health data is also unethical, as it also causes harm and fails to realize the tremendous benefits of data utilization. The group recommends the adoption of the following five principles:

1. Data for Good
2. Respect for Persons, Communities, and Groups
3. Protect Against Harms
4. Equity
5. Transparency and Accountability

To help ensure these principles are put into practice, the Digital Society Working Group has come up with seven additional recommendations:

1. Use Information for the Benefit of Ontarians
2. Empower Patient Access to their Personal Health Information
3. Involve Members of the Public and Communities in Governance
4. Collect Sociodemographic Information and Make it Available
5. Increase Transparency
6. Respect First Nations, Inuit, and Métis Data Sovereignty
7. Establish a Working Group to Investigate AI, Machine Learning, and Advanced Analytic Techniques

Introduction:

Health information is increasingly collected digitally, and in greater quantities than ever before. This creates new and exciting opportunities to use health information for the benefit of Ontarians. Health information can be used to empower individuals to achieve their health goals, inform population health and wellness initiatives, address health inequities, lead to better care and new tools, and lead to research that will improve the quality of health care.[1] As Ontario moves forward into an information-rich and digitally-driven future, these goals must be pursued with careful thought about how the health information ecosystem in Ontario is changing, and how to protect individual privacy and avoid harming groups and communities. We need to build a trustworthy information governance regime that is responsive to these changes, and that will ensure that health information is being collected and used safely, with Ontarians' interests foremost in mind. Our working group's goal was to set out foundational principles aligned with the values of Ontarians, so that the burden is not put onto individuals to safeguard their data solely via consent to complicated terms and conditions that they may not understand.

To that end, the Digital Society Working Group has identified five principles that are designed to serve as the foundation for decision making in this new digital ecosystem. We propose that policy makers, system administrators, and data stewards at all levels of the health care system consider the five principles when planning, evaluating, and designing policies, processes, procedures, and legislation for this new digital ecosystem. For every proposed policy or recommendation for the collection, use, disclosure, and governance of health information, those tasked with decision making should consider each of the five principles and integrate them into their policies and planning.

In accordance with documents guiding Canada's reconciliation with Indigenous peoples, such as the Articles declared in UNDRIP, Canada's "Principles Respecting the Government of Canada's Relationship with Indigenous Peoples," and the Truth and Reconciliation Commission (TRC) of Canada, the Digital Society Working Group would like to note that all recommendations and principles in this document should be read with the awareness that First Nations, Inuit, and Métis peoples have inherent rights to self-determination and self-governance. This applies to the governance of First Nations, Inuit, and Métis-identifying health information, as well as to conclusions drawn about First Nations, Inuit, and Métis peoples on the basis of that information.

Ontario's current information governance focuses primarily on the protection of individuals' privacy. Ontario has robust health privacy legislation (*PHIPA, 2004*), which sets out the rules for the collection, use, and disclosure of personal health information, along with the rights that patients have to access and control their personal health information. Ontario's independent regulator, the Information and Privacy Commissioner (IPC) enforces these rules. Personal health information, which identifies or could be used to identify an individual, can include information such as names, addresses, and contact information. It can also include indirect identifiers that, when taken together or cross-referenced with other information, allow an individual to be identified.[2] Personal health information is highly sensitive and deserves special protection in legislation. If revealed, personal health information can be used to harm individuals; it may be used to target individuals for identity theft, to blackmail,[3] or to embarrass.[4] It can also cause significant stigma to individuals and also to communities or groups, or even lead to physical harm.[5] Ontario's privacy protection laws are designed to protect individuals from unwarranted disclosures of this kind.

While a focus on protecting individual privacy is central and important, we need to think more broadly about how to protect and serve Ontarians as we move into the new information-rich and digitally integrated ecosystem. New technologies, "big data", and increased access to health information pose new opportunities and challenges; Ontario's health information governance must adapt to these changing circumstances. For example, Ontario's privacy legislation focuses on two fundamental privacy pillars: knowledgeable consent and deidentification. These pillars are important, but they face threats in an information-rich ecosystem. One challenge stems from the complexity of information uses, which makes it increasingly difficult for individuals to be fully informed about what they are consenting to, and the corresponding complexity of health information legislation, which makes it difficult for individuals to know their rights with regard to their information.

Another challenge stems from the increase in information and technological capacity that "big data" (typically understood as an increase in the velocity, volume, variety, and variability of data) poses. In an information-rich and digitally connected ecosystem, de-identification of personal health information[6] is now harder to achieve. The increase in technological capacity, information, and digital connectedness makes it more likely that someone could be re-identified on the basis of some of their information, or from access to non-sensitive and generally available information.[7] The more information there is available, the more it becomes possible to reidentify individuals by linking together disparate datasets to uniquely identify individuals. As more and more information is created and shared, this risk becomes ever more pronounced. The Digital Society Working Group's principles ask us to think about the underlying ethical and value-based rationales for protecting individual privacy and promoting public benefits from data. This is intended to lead those tasked with designing information governance in Ontario to think creatively about how to protect the dignity, integrity, and autonomy of Ontarians, in ways that go beyond current mechanisms.

Ontario's privacy legislation focuses on protecting individual privacy, but does not include specific provisions to protect the aggregate information of communities and groups; this gap has led communities who have suffered historical misuse of their community information to propose their own principles to protect community level information.[8] Health information is increasingly used to make inferences about groups of people, allowing researchers and analysts to generalize across groups in ways that may inadvertently stigmatize or harm.[9] Our traditional privacy mechanisms, of de-identification and individual knowledgeable consent, do not provide adequate protection, since de-identified information might still be used to identify groups or communities, and individual consents cannot speak for the community as a whole.[10] While a focus on individual privacy and its underlying ethical rationale—**respect for persons**—is central and important,[11] the Digital Society Working Group's principles also intentionally include **respect for groups and communities** as a fundamental concern in the governance of health information.

The use of health information can exacerbate, or help to address, existing health inequities. Health inequities are health disparities between groups of people that are unfair or unjust and modifiable.[12] Numerous examples of health inequities have been reported in Ontario, but we still lack complete and accurate information on these health inequities. Health information can be used to identify and address these inequities, and so the **equity** principle states that we must actively mobilize health information to eliminate these health inequities. Part of this work involves creating space and resources for community-led initiatives that work to address health inequities and respect communities, such as the First Nations Information Governance Centre (FNIGC) or the Black Health Equity Working Group, who have produced their own frameworks to govern community level information in OCAP and EGAP respectively.[13] At the same time, new uses for information can run the risk of introducing new health inequities, if such systems make use of biased information or rely on information that fails to sufficiently reflect the diversity of the population, and so we must be vigilant that our collections and uses of health information do not create new inequities.

Two other principles that the Digital Society Working Group has identified focus on using **data for good** and **avoiding causing harm** from the use of health information. Patients, providers, communities, planners, and innovators currently experience a complex, interrelated set of barriers that hinder their ability to use and benefit from health information in Ontario. Many of the barriers are structural, having to do with a lack of resources or systems in place to deal adequately with health information. Barriers include difficulty accessing cost-effective high quality health information, confusion around risks, rules, and responsibilities for health information, burdensome and redundant processes, lack of engagement, empowerment, and partnership, inconsistent levels of technical and legal capacity (at individual and institutional levels), and uncertainty over health information use (i.e. who can access health information, the purposes, and the benefits to individuals and communities). This complex set of factors reduces trust in our health care system and in the information management practices that anchor that system. These factors also hinder the health care system's ability to serve Ontarians in the most effective ways. To realize the full value of the health information collected in Ontario, we need to build trustworthy rules and approaches to the governance of health information, that allow us to use this information for the benefit of all, while ensuring that we avoid harming anyone from its use.[14]

In contrast to an approach that holds that individuals own their own information, the Digital Society Working Group's principles aim to articulate the interests that individuals have in their health information, for example, by explaining that personal health information implicates the dignity and autonomy of individuals. This approach is consistent with Ontario's current information protection laws, which do not say that people own their health information, but that do set out the interests that individuals have in their information, as well as the obligations of those who use the information.[15] For example, those who collect and use health information in Ontario are currently subject to certain kinds of fiduciary obligations and duties; such as a duty to protect the security of patients' personal health information and keep it confidential. On the other side, those who the information is about also have claims over the information, such as laws which stipulate (for example) that you have a right of access to your own personal health information (as *PHIPA, 2004* does). Rights like these protect individuals' interests in their personal health information; they are claim-rights as opposed to property rights. While you may have a right of access to information about you, this does not mean that you have a right to possess it physically.[16] These important rights are designed to secure individual control over information, but they are not the same as ownership rights.

The Digital Society Working Group's principles are based on the ideas that individuals, groups and communities retain an interest in health information, that it can be used to harm or benefit them, and that it can be used in equitable or inequitable ways, whether that information is in the form of personal health information, de-identified personal health information, or statistical or aggregate information. The final principle that the Digital Society Working Group recommends, the principle of **transparency and accountability,** is further key to building a trustworthy health information ecosystem that respects Ontarians' rights. A trustworthy system must have independent oversight and strong rules to ensure accountability for the safety of health information and its appropriate use. A key component to achieving accountability is transparency. Transparency allows public oversight and scrutiny of information governance practices, including what health information is collected, how it is held, to whom it is disclosed, how it is used, and what insights are derived from it.[17] In addition to this, transparency asks that individuals be actively informed about their rights regarding their personal health information (including rights of access, correction, and consent directives). This information should be communicated to Ontarians in easily understandable, accessible, relevant, timely, and accurate ways.[18]

The Digital Society Working Group's principles ask us to broaden our conception of Ontarians' interests in this space. By taking these foundational principles as a starting point, we can build a trustworthy and inclusive information governance system that will unlock the potential of health information in Ontario to be used for good, while protecting individuals, groups, and communities.[19]

Ontario's Guiding Principles for Health Data

Data for Good

The collection, use and disclosure of health information should benefit persons, groups, and society at large.

Health information should be collected, used, and disclosed in ways that create a positive impact on life and well-being. In addition to this, health information should be collected, used, and disclosed in ways that promote social values and goals. Opportunities to use health information for providing care, improving care, or systemic health care benefit should be actively identified and pursued.

The health benefits to people who live in Ontario, and the benefits to the health care system, that can accrue from the collection, use, and disclosure of health information should be actively identified and pursued.

Health information should be used to promote and improve the quantity and quality of life of persons living in Ontario. This includes identifying and considering the ways that health information can be used to impact a person's physical, mental and spiritual health, as well as the factors that determine a person's health. Health determinants can include income and social status; social support networks; education; employment/working conditions; social environments; physical environments; personal health practices and coping skills; healthy child development; gender; and culture.

Improving the quantity and quality of life for Ontarians and for specific groups in Ontario should be actively pursued. Analyzing Ontarians' health information within the healthcare system can lead to new and improved medications, new treatments, and more efficient allocations of resources. We also recognise that there can be risks from disclosing information. Those seeking access to health information should identify how the use of the information will improve the health of residents of Ontario or improve the healthcare system.

Respect for Persons, Communities, and Groups

The use of health information should respect persons, communities, and groups

a) The collection, use, and disclosure of health information should respect the dignity and integrity of persons, communities, and groups.
b) The collection, use, and disclosure of health information should promote the autonomy of persons, communities, and groups.

One of the ways that we can respect persons is by ensuring that a person's personal health information is treated with respect and care. Health information about a person represents the person, and the same is true of group or community-level information. The collection, use, and disclosure of health information should respect the dignity and integrity of the individual. The collection, use, and disclosure of health information about groups or communities should respect the dignity and integrity of those groups or communities.

We show respect for persons in a digitized health care environment by respecting privacy. Any collection, use, or disclosure of personal health information should respect the dignity and integrity of the person, and treat personal health information as a dignity-implicating representation of the person.

Communities and groups likewise deserve respect. Respect for communities requires consideration of communities and groups that may be affected by a particular use or disclosure of health information, and attention to the potential impact of this use on these communities or groups. This includes looking at any potential harm or stigmatization that may occur from the use of a group's health information.

Part of the principle of respect for persons, communities, and groups is the value of autonomy in the collection, use or disclosure of health information. The collection, use, and disclosure of health information should support and should not interfere with a person's ability for self-determination—the ability to live one's life in accordance with one's own values. This includes seeking consent for uses of health information where possible, and only proceeding without consent where justified and appropriate.

The importance of autonomy applies equally to groups and communities. A community's ability to self-determine reflects its autonomy. Respecting this autonomy can involve outreach and consultation with effected groups for projects that would have a significant impact on them.

Protect Against Harms

The collection, use, and disclosure of personal health information should avoid causing harm to any person, any group, or to society at large.

The collection, use, and disclosure of personal health information should be undertaken in such a way as to avoid adverse effects on a person's wellbeing. The collection, use, and disclosure of health information should also avoid adversely affecting the welfare or prospects of groups of people, communities, or society at large. Any risks of harm from the collection, use or disclosure of health information should be actively identified and mitigated.

The principle of protect against harms means that we should actively think about how to mitigate or avoid causing harm with respect to all collections, uses, and disclosures of health information in Ontario.

The expanded use of health information has the potential to provide a significant increase in benefits to persons, groups, and society. Conversely, there is the possibility of significant harms from the misuse or disclosure of sensitive health information. People may incur financial loss or psychological harm, and/or be exposed to discrimination and stigma. The governance of health information should seek to minimize risks, while retaining as many of the benefits of data use as possible.

Not all potential harms flow only to the people whose information is being used. Increasingly the harms of information use are societal and collective, rather than being contained to persons. We must also consider the impacts that the use of health information may have on groups or communities – for example where it leads to decisions being made based on information that is not properly representative. Like person-level harms, these harms should be actively identified and mitigated in any collections, uses, and disclosures of health information.

Equity

The collection, use, and disclosure of health information should promote health equity in Ontario.

Health information should be collected, used, and disclosed in ways that reduce or eliminate existing inequitable health disparities whenever possible. The collection, use, and disclosure of health information should not result in new health inequities.

Health inequities are unjust and avoidable health disparities between groups of people. The governance, collection, use, and disclosure of health information should seek to promote health equity, and should avoid exacerbating pre-existing health inequities or creating new health inequities. In service of the promotion of health equity, there should always be an attempt to raise the welfare of the least-well-off group. If used appropriately, health information may allow us to address health inequities through research, service development, population health measures, and new health and social policy.

Transparency and Accountability

People and communities should be informed about the collection, use, and disclosure of health information. Equally, there needs to be accountability by those who collect, use, and disclose health information.

Persons, individually and collectively, should be informed on how their personal health information in Ontario is collected, used, and disclosed.

Those who collect, use, and disclose the health information of Ontarians should be accountable for the collection, use, and disclosure of health information.

The principle of transparency and accountability tells us that Ontarians must be informed about the uses of health information in Ontario, and that those who hold health information must be accountable for their actions.

People should know the ways that their health information is being used. Transparent information governance allows people to participate in governance decisions, and informs people about the collection, use, and disclosure of health information and any insights that are derived from that information. Transparent practices also enhance accountability. Transparency allows public oversight and scrutiny of information governance practices, including what health information is collected, how it is held, to whom it is disclosed, how it is used, and what rights people have to access and control their own information.

Accountability goes hand in hand with transparency. Ontario's health information governance should be responsive to the needs and preferences of the people it serves, and use this feedback to shape and improve its policies and programs. Together, transparency and accountability stimulate public engagement, improve organizational responsiveness, and ensure the continued safe and effective use of health information.

Transparency and accountability enable one another. Transparency without accountability is toothless; accountability without transparency is unworkable. All collections, uses, and disclosure of health information in Ontario, as well as all information governance policies, should be transparent to the people of Ontario and have clear and enforceable accountability mechanisms and processes in place.

Recommendations from the Principles

1) Use Information for the Benefit of Ontarians

Background:

Patient information is information about people, even when it is anonymized and in aggregate form. There are significant benefits to be gained from the use of patient information, but we must ensure that when Ontarians' information is used, benefits return to the people of Ontario.

Proposal:

Clear pathways should be established to support research and innovation activities where there is benefit to Ontarians. These could include analytics that can improve the health system both locally and overall, research that enables improved administrative processes, affordable access to new treatments or medications, or other benefits determined by the province.

While there is agreement that benefits to Ontarians should be pursued, less clear is what, precisely, those benefits are. Ontario is in need of a framework for understanding how the use of health information will benefit Ontarians, and what those benefits are. The Digital Society Working Group suggests that this framework for understanding how health information can benefit Ontarians should be created with input from an interdisciplinary group of experts, guided by input from consultations with Ontarians.

Decisions about the use of data for the benefit of Ontarians should be done with clear processes in place to ensure transparency and accountability, and that respect the rights, autonomy, and dignity of persons, communities, and groups in Ontario. For example, decisions about what uses of data benefit Ontarians should be undertaken only in consultation with people living in Ontario. These decisions should also be made with clear and enforceable rules in place to ensure accountability, as well as actively communicated to Ontarians to ensure transparency (in line with recommendation 5 in this report). The use of data for the benefit of Ontarians should be planned and undertaken in accordance with community oversight, for example with oversight from community governance tables, as suggested in recommendation 3, and while respecting the rights of First Nations, Inuit, and Métis peoples to self-governance and self determination (recommendation 6). In accordance with the equity principle, the use of data for the benefit of Ontarians should not reinforce pre-existing health inequities or create new health inequities amongst Ontarians.

Principles:

This recommendation is supported by the **data for good principle**, because it aims at ensuring that Ontarians receive a fair benefit for the use of their information. To be supported by the **respect for persons, communities, and groups** principle, the use of data for the benefit of Ontarians should respect the fact that people retain a claim to their information even if it is anonymized or combined with other information, and individuals, communities, and groups should be consulted on their preferences and needs to determine which uses of data will benefit them. To respect the **protect against harms** principle, we must ensure that Ontarians' health information is used in privacy-protective and secure ways, and to respect the **equity** principle, we must ensure that no one group of people is systematically disadvantaged by any uses of Ontarians' health information. This recommendation should also be consistent with **transparency and accountability**; the uses of information should be transparently communicated to the public, and those uses should be subject to oversight and clear and enforceable rules for its use.

2) Empower Patient Access to their Personal Health Information

Background:

Patients should have easy access to their own personal health information, in order to exercise their right to control their personal health information, to encourage persons to be active partners in their care, and to encourage deeper engagement and learning about the value of their data. While patient access to their own personal health information is officially protected by *PHIPA, 2004*, this is currently challenging because it entails requesting documents from different health care providers, and because providers do not always provide this information in seamless, accessible ways. For example, providers use different, independently designed systems that are not currently interoperable. There has also been an emphasis on the provision of information for care providers. While information sharing for providers is crucial in the delivery of care, it does not serve to make the patient an active participant in the use of their information. Chronic disease management, in particular, would benefit from easy access to real-time information.[20]

Proposal:

For purposes of care, we must also make patient access a priority. While access is permitted by *PHIPA, 2004* and endorsed by the *Patient, Family, and Caregiver Declaration of Values* adopted by Ontario's Ministry of Health,[21] we need to encourage a cultural shift where such information is easily and routinely available to patients. The Ministry of Health's *Dialogue on Data* project has proposed the establishment of a Patient Chart. The concept of the Patient Chart emphasizes the patient's interest in and control over their information.

This requires action on two fronts: On the one hand there needs to be developed capacity on the part of the patients, and on the other hand there needs to be tools and support for providers and those holding the information.

Developing patient capacity would require patients to have access to the digital tools and knowledge required to access and use their Patient Chart. This may require Ontario to invest in infrastructure and training for individual Ontarians. If Ontarians have access to their information, this will also help to ensure that their information is correct. However, we must not forget that there are many people who do not have access to the tools and knowledge needed to use a Patient Chart, and intermediate steps will be required to ensure that this does not create new health inequities and that everyone has access to their personal health information.[22]

How to share information, and how to mitigate risks, will be equally important considerations. Providers, including their colleges, will need to work closely with the hospitals, Ontario Health, labs, pharmacies, and other health information custodians to ensure consistent messaging and uniformity in practice and processes. The Information and Privacy Commissioner of Ontario has an important role in ensuring regulation and education amongst health information custodians. Sharing information will include providing digital records but will also include provision in different languages and formats.

We should explore how existing systems might be adapted to offer patients seamless access to their own personal health information. Any new systems adopted should be built with patient access in mind.

Principles:

The principle of **respect for persons**, specifically the importance of individual autonomy, requires patients to have access to their own health information. Respect for autonomy necessitates that individuals have some degree of control over information about them, and access to this information is a critical component of this. Furthermore, the notion of **data for good** supports this recommendation. When patients have meaningful access to their personal health information, they are better able to control their own healthcare and be active participants in their care, and they have the opportunity to enhance their understanding of how health data is collected and used.

The principle of **transparency and accountability** is essential in the development of effective patient access. For example, those who use and disclose personal health information should be accountable for the accuracy and the privacy of what they input into the chart; as well, patients should be aware of their rights with regard to the information in their chart, and how the chart is used within the healthcare system.

In order for effective patient access to be supported by the **equity** principle, individuals must be able to easily access their information without barriers. This means that for this proposal to be equitable and to not create new health inequities, attention and resources need to be put towards enabling all residents of Ontario to access their health information, by providing everyone with accessible digital access and digital literacy.

3) Involve Members of the Public and Communities in Governance

Background:

Health information is highly sensitive, and while it can be used for many good purposes, it also has the potential to harm and stigmatize. These harms may manifest at the individual level, or at the group or community level in virtue of group or community membership.[23]

Public engagement and oversight is an enabler of public trust. Asking Ontarians to play a role in decision making allows them insight into decision making processes and can help to identify and address risks of harm in the secondary use of health information (health information includes personal health information, de-identified information, and statistical/aggregate information), for example, in the risks of health information used in research. Importantly, the potential for harm does not dissipate when an individual's personal health information is de-identified; the potential for research (for example) to draw stigmatizing, inaccurate, or otherwise harmful conclusions about a group of people (for example, a racialized group) remains if the information used is de-identified, and thus not personally identifiable.[24] This is also true of health information used for other purposes within the health care system, for example, in resourcing decisions.

These issues are especially pressing in the case of equity-deserving groups and communities, who stand to be significantly impacted by the use of health information.

Proposal:

In line with calls from groups such as the Black Health Equity Working Group,[25] we recommend that the Ministry of Health form Community Governance Tables to consider and evaluate proposals for the secondary use of health information in Ontario, whether that information is in the form of personal health information, de-identified information, or statistical insights about communities or groups, in Ontario.

Community Governance Tables should be composed of Ontarians to advise on governance, analysis, management, and the use and disclosure of health information (personal health information, de-identified health information, statistical or aggregate health information) in Ontario. Members should be screened for potential conflicts of interest before being invited to sit on Community Governance Tables. How many Community Governance Tables, and for which groups of people, should be decided in consultation with affected stakeholders in Ontario. However, we suggest that two separate kinds of governance tables be formed.

The first will ensure that all Ontarians have a voice in the governance of Ontario's health information, so that the collection and use of Ontarians' health information is in line with Ontarians' interests.[26] This table should be composed of members of the public. How this table should be formed, and who sits on it (for example, whether it should be composed of limitedterm members, or have more of a “citizen jury” structure[27]), should be decided in consultations with members of the public.

The second kind of Community Governance Table (or tables) could be composed of members of equity-deserving communities in Ontario. Who these communities are should be decided in consultation with members of the public, and with to the intent of empowering equity-deserving communities and groups to identify and play a role in mitigating harms from the use of health information that may arise. This recommendation is inspired by the Black health Equity Working Group’s EGAP framework and its recommendation for community data governance.[28]

In addition, since no table can include representation from every relevant group, where there is a reasonable expectation that specific subpopulations or groups would have a particular interest in, or would be affected by, a use of health information, there must be direct engagement tailored for that subpopulation/group.[29]

Principles:

Community governance is supported by many of the Digital Society Working Group’s ethical principles. Ensuring **equity** calls for community governance because the best way to identify both existing and potential future inequities and guard against them is to give a voice to the members of the affected group. For this same reason, the **protect against harms** principle supports this recommendation. **Data for good** also supports community governance, since this allows for the community to make their priorities known, and to ensure the uses of health information remain within the social license. Community governance is a key component of **transparency and accountability** because it provides individuals with the ability to directly influence and hold organizations accountable for their uses of health information.

4) Collect Sociodemographic Information and Make it Available

Background:

Ontarians experience unfair and avoidable health disparities (health inequities).[30] However, without knowing exactly who is affected and where, it is difficult to understand and act on the effects of structural and historical health inequities. The COVID-19 pandemic has made this need even more pressing; for example, racialized communities have been disproportionately negatively affected by the pandemic in Ontario.[31] Consistent with calls from experts and community members across Ontario, we need to collect socioeconomic health information in Ontario, and use it to identify and mitigate health inequities.[32]

Proposal:

Sociodemographic information should be collected and used by researchers and analysts for the purpose of addressing unfair and avoidable health disparities in Ontario. This information could be used to hold the government and others accountable for inequitable health disparities amongst Ontarians.

Sociodemographic information should be collected with clear and consistent standards in place that are informed by experts and responsive to and in alignment with best practices in this space, such as the standards for the collection of race-based information suggested by the Canadian Institute for Health Information.[33]

To ensure that sociodemographic information is not used inappropriately, there must be clear and enforceable rules for its collection, use and disclosure. For example, it should be collected only under conditions of explicit consent, in culturally safe and inclusive ways, and it should only be used with clear anti-discrimination standards in place. Community Governance Tables should provide guidance and oversight for how sociodemographic information i should be collected and used in Ontario.

In addition, sociodemographic information should only be used for purposes that are supported by consultations with the public; for example, preliminary consultations suggest that sociodemographic information should not automatically appear to primary care providers who are looking at a patient's electronic health record.[34] However, this issue needs to be further explored in consultations with the public. Further consultations with Ontarians, and especially with affected groups and communities, should focus on what uses of sociodemographic information are supported by Ontarians, and which uses should be avoided.

Principles:

The collection of sociodemographic information is supported by the **equity** principle since sociodemographic information is key to identifying and addressing health inequities in Ontario.

Without knowing where health inequities exist, we cannot address them, and sociodemographic information will help us to better understand where health inequities exist in Ontario. For this same reason, this recommendation is supported by the **protect against harms** principle; since collecting sociodemographic information for the purpose of addressing health inequalities in Ontario would help address inequitable health disparities amongst Ontarians and improve Ontarians' overall health and wellbeing. If sociodemographic information is collected only with explicit consent, this could be done in a privacy-protective way that respects personal autonomy and choice, consistent with the **respect for persons, groups and communities** principle. Collecting sociodemographic information should also be done in a transparent way, with numerous opportunities for government and community oversight, and with clear and enforceable rules for its collection and use, consistent with the principle of **transparency and accountability**.

5) Increase Transparency

Background:

Health information is increasingly being used for a wide variety of purposes, including for the provision of care, for analytics and resource allocation, and for research. However, most people have a poor understanding of the purposes for and conditions under which their information may be accessed.[35] This points to the need for greater transparency in the use of health information in Ontario. People have a right to know how their information is being used, and the protections and safeguards in place. Transparency is also an important way of building public trust in the management and use of their information.[36]

Proposal:

A series of transparency resources regarding the collection and use of health data should be made available to the public through diverse media. For example, an online Transparency Centre would provide the public with one-stop information services, including culturally appropriate materials developed through community consultation. Through the Transparency Centre, Ontarians could learn about ongoing research supported by their health information and opportunities for public engagement. They could also ask questions and learn how their information is used to improve health outcomes while protecting the privacy and security of health information in Ontario.

In addition, resources should be provided for those who lack access to digital technologies, through making offline versions of these materials available. Furthermore, materials should be made available in plain language and in a variety of languages.[37] Community Governance Tables should be involved to provide insight into how transparency can best be achieved for different communities.

Principles:

This recommendation is supported by the **transparency and accountability** principles, helping to ensure that Ontarians are informed about how their information is being used and the safeguards in place to protect it. This will also allow people to be more involved in the governance of health information.

In order to be consistent with the principle of **equity**, this information needs to be provided in ways that are meaningful, timely, relevant, and accessible to the people of Ontario, for example, by providing information to Ontarians in different formats and languages, and by empowering those who do not currently have access to or know how to use digital technologies to do so.

6) Respect First Nations, Inuit, and Métis Data Sovereignty

Background:

In accordance with documents guiding Canada's reconciliation with Indigenous peoples, such as the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), and in accordance with the Digital Society Working Group's ethical principles for the use of health data, the Digital Society Working Group recommends that the Minister of Health of Ontario recognize Indigenous peoples' right to health data sovereignty in Ontario.

First Nations, Métis, and Inuit peoples have inherent rights to self-determination and self-governance.[38] This applies, similarly, to the governance of Indigenous-identifying health data (or information) and conclusions drawn about First Nations, Inuit, or Métis peoples on the basis of that information. This should apply to the development of policy, legislation or legislative changes, and governance structures for health information that affect First Nations, Inuit, and Métis peoples in Ontario. This recognition is in line with recommendations for reconciliation, such as the Articles declared in UNDRIP,[39] Canada's "Principles Respecting the Government of Canada's Relationship with Indigenous Peoples,"[40] and the Truth and Reconciliation Commission (TRC) of Canada.[41]

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) is a document that identifies "the minimum standards for the survival, dignity and well-being of the indigenous peoples of the world.[42]" UNDRIP was adopted by the United Nations General Assembly in 2007[43] and endorsed by Canada in 2016[44]. On June 16, 2021, Canada's senate passed Bill C-15, *The United Nations Declaration on the Rights of Indigenous Peoples Act,* making it Federal law.[45]

UNDRIP includes a number of Articles that are relevant for the discussion of First Nations, Inuit, and Métis health information governance.

Article 19 of UNDRIP states that:

> "States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior, and informed consent before adopting and implementing legislative or administrative measures that may affect them."[46]

Article 23 of UNDRIP states that:

> "Indigenous peoples have the right to determine and develop priorities and strategies for exercising their right to development. In particular, indigenous peoples have the right to be actively involved in developing and determining health, housing and other economic and social programmes affecting them and, as far as possible, to administer such programmes through their own institutions."[47]

Article 19 of UNDRIP tells us that the government must engage Indigenous peoples, including First Nations, Inuit, and Métis peoples, in determining how their information will be governed. Article 23 says that First Nations, Inuit, and Métis peoples have the right to develop their own governance models and strategies for how their health information will be treated in Ontario, in accordance with their own priorities, and their own digital and data strategies.

Proposal:

We recommend that the Government of Ontario take a distinctions-based approach to the governance of Indigenous health information in Ontario. A distinctions-based approach recognizes that First Nations, Inuit, and Métis peoples are communities and peoples distinct from one another, with distinct cultural heritages and rights to self-determination and self-governance.[48] Further distinctions within First Nations, Inuit, and Métis peoples may be required, if so recommended by First Nations, Inuit, and Métis peoples. As plans for the governance of Ontarians' health information are developed, we recommend the following:

For First Nations health information, we recommend that all uses of First Nations health information, or insights derived about First Nations peoples on the basis of their health information, are done only with the express permission and agreement of First Nations peoples in Ontario. We recommend that Ministry of Health commit to respect the First Nations principles of Ownership, Control, Access, and Possession (OCAP®) and to commit to an "alliance" model with First Nations for the governance of First Nations identifying information, recognizing First Nations' rights to information governance, as a nation-to-province relationship. How to interpret and apply OCAP® should be done in discussion with the First Nations communities affected, but it applies to the governance of First Nations-identifying information or insights derived about First Nations peoples, irrespective of where that information is held. An "alliance" model refers to involving First Nations communities in forming the governance structures for any First Nations information used in Ontario, recognizing their right to health information sovereignty and self-determination. We recommend engaging with First Nations rights holders before developing any information and data governance models and consult with them before making any legislative changes that will affect their health information. The government of Ontario should engage with First Nations peoples living in Ontario on their data and digital strategy, their needs, and how their health information should be governed in Ontario.

For Inuit health information, we recommend that all uses of Inuit/Inuk-identifying information or insights derived about Inuit peoples on the basis of their health information, are done only with the express permission and agreement of Inuit peoples in Ontario, in accordance with any principles that they recommend.[49] We recommend that the government of Ontario engage with Inuit rights holders before developing any information governance models and consult with them before making any legislative changes that will affect their health information, in recognition of their right to self-governance and self-determination. The government should engage with Inuit peoples living in Ontario on their data and digital strategy, their needs, and how their health information should be governed in Ontario.

For Métis information, we recommend that all uses of Métis-identifying information or insights derived about Métis peoples on the basis of their information, are done only with the express permission and agreement of Métis peoples residing in Ontario, for instance via organizations such as the Métis Nation of Ontario, and in accordance with any principles that they recommend.[50] We recommend that the government engage with Métis rights holders before developing any information governance models and consult with them before making any legislative changes that will affect their health information, in recognition of their right to self-governance and self-determination. The government of Ontario should engage with Métis peoples living in Ontario on their data and digital strategy, their needs, and how their health information should be governed in Ontario.

Principles:

Indigenous data sovereignty is also supported by the ethical principles put forward by the Digital Society Working Group. The principle of **respect for persons, groups, and communities** states that we should allow communities to control what happens to community-level information, in recognition of the fact that communities are best positioned to determine what uses of information may be harmful to them. This means asking the communities what their concerns, needs, and priorities are, and to ensure that these concerns, needs, and priorities are respected in the governance of this information. This recommendation is also supported by the principle of **equity**. Indigenous peoples, including First Nations, Inuit, and Métis peoples, have been harmed by irresponsible uses of their information, and they suffer from ongoing health inequities. Ensuring Indigenous data sovereignty is respected is the best way to provide the tools to address pre-existing health inequities and to avoid creating new ones.

7) Establish a Working Group to Investigate AI, Machine Learning, and Advanced Analytic Techniques

Background:

Advanced analytic techniques, such Artificial Intelligence (AI), machine learning, and unsupervised learning, have revolutionized processes in a variety of industries, and they hold out the prospect of similar advances in the healthcare field. For example, there are already machine learning systems capable of categorizing suspicious moles as “benign” or “cancerous” as accurately as a panel of 21 dermatologists.[51] AI has also been used for process optimization to determine staffing, and so on for hospitals.[52] And machine learning has recently been able to solve the “protein folding problem”, which has the potential for huge advances in drug development and health research.[53]

However, the use of such advanced analytic techniques in healthcare also brings with them unique ethical challenges. For example, many machine learning algorithms are “black boxes”—while we can assess the outputs of the algorithm for accuracy, we don’t understand how or why the algorithm comes up with those outputs, which raises worries about regulating such systems.[54] Another ethical worry raised by the use of AI is the potential bias of AI systems. AI systems rely on their training data to produce a model. This can lead to bias, either through training data that itself reflects existing biases, or where the data fails to represent some groups to which the algorithm will be applied.[55] In healthcare settings, this kind of poor performance on specific minority groups can amplify existing health inequities and serve to further marginalize equity-deserving groups. A further challenge is that some machine learning research projects start without specific hypotheses or research questions, instead looking to see what patterns the machine learning system itself discovers in the data. Such projects challenge traditional data minimization practices, since it is impossible to tell what data is relevant and what is irrelevant beforehand, and makes it difficult for research ethics boards to assess these projects. These are just a few examples of the many ethical challenges that AI raises in healthcare, and they will all need to be addressed as this technology becomes ever more powerful and ubiquitous.

Proposal:

These and other emerging ethical issues require investigation by people with experience and expertise in ethics, in the health system, and in advanced analytical techniques. In order to identify, understand, and address the unique ethical challenges of AI, the Digital Society Working Group recommends the formation of a future working group specifically devoted to the issue of the ethics of advanced analytical techniques in the healthcare system. This working group should include people with specific expertise with AI and machine learning systems, as well as those who already work on the ethics of such systems. The group should build off of the excellent work being done already in the ethics of AI and machine learning, investigating both the existing sets of principles for their use and the work being done on how to ethically apply AI and machine learning to health care. The mandate of this group would be to recommend policies and procedures that could be adopted for the use of these techniques in healthcare that would allow the benefits of these technologies to be fully realized while protecting against the dangers.

Principles:

This proposal aligns with the **data for good** principle, since it aims to help us unlock the potential of new technologies to benefit the healthcare system as a whole. It also follows from the principles of **protect against harms** and **equity**, since one of the goals of the group will be to ensure rules and procedures that prevent harm and address health inequities.

Glossary of Terms

Personal Health Information refers to identifying information about an individual that relates to a person's physical or mental health or to the provision of health care to that person, and for which it is reasonably foreseeable in the circumstances that the individual could be identified using that information.

Identifying Information refers to information that may be used to identify an individual. Information may identify an individual directly or indirectly. In context, indirect identifiers may be used (usually in combination) to identify an individual.

De-identified Information refers to identifying information on which appropriate de-identification standards have been applied (for example: all direct identifiers have been removed, risk of re-identification via indirect identifiers has been assessed, some indirect identifiers have been removed to mitigate this risk). The aim of de-identification is to eliminate, as far as reasonably possible, the risk that an individual can be identified on the basis of this information. De-identified information is not the same thing as 'anonymized information', which refers to information where there is no risk of identifying an individual. Information may be more or less de-identified; the risk of re-identification may vary depending on context and risk should be mitigated accordingly.

Big Data refers to large amounts of structured and unstructured data understood to have "volume (large amounts of data), velocity (high speed of access and analysis), and variety (substantial data heterogeneity across individuals and data types)".[56]

Statistical Information refers to non-identifying aggregate information that has been subject to analysis to translate them into a value that describes a relationship between two variables.

Health Information in this context refers generically to health and health-related information, including personal health information, de-identified information, and statistical or aggregate health information.

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[1] Public Health Agency of Canada (2021).

[2] Sometimes indirect identifiers are called “quasi” identifiers. See Information and Privacy Commissioner of Ontario (IPC) (2016).

[3] Blackmailing individuals with their sensitive personal information, as happened after the hack of the Vastaamo mental health clinics, is also possible. Ralston (2021).

[4] For example, Anthem Inc. suffered a catastrophic data breach in which hackers were able to access a database that contained as many as 79 million records of current and former customers, including names, social security numbers, birthdays, addresses, and email. Identity theft can affect people for the rest of their lives (Wilde Mathews (2015)). Notably, Anthem was held accountable for the breach by the U.S. federal government and was fined $16 million dollars because it had failed to implement appropriate security measures to prevent such a breach. In 2017, Anthem was also held accountable in a class-action lawsuit, which cost the company $115 million, plus $15 million for customers’ out of pocket costs related to the breach (Teichert 2018).

[5] Brouwers (2020), Van Brakel (2006).

[6] PHIPA defines de-identification as “to remove any information that identifies the individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify the individual.” (*PHIPA, 2004).*

[7] See Ohm (2010).

[8] A specific example of this is the Ownership, Control, Access and Possession (OCAP) principles for First Nations data (First Nations Information Governance Centre (2020)). See also the Jane Finch Community Research Partnership (2020) principles, and the EGAP principles (Black Health Equity Working Group (2021)).

[9] In addition, with the use of machine learning and AI technologies, it is increasingly possible to use large datasets to produce algorithms that make predictions on the basis of group membership. AI and machine learning systems can end up being biased against minority groups (Obermeyer et al. (2019)).

[10] These problems stand to be exacerbated by the use of machine learning algorithms in health care settings. If the training set for an algorithm contains few or no examples of people from a minority group, then the algorithm may fail to generalize to members of that group. For example, pulse oximeters used to measure blood oxygen

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levels are less reliable on dark-skinned individuals, overestimating the oxygen levels for these patients. This is clearly a potential danger to dark skinned individuals (Feiner, Severinghaus, and Bickler (2007)).

The explanation for this shortcoming is presumably that the pulse oximeters were calibrated on people with lighter skin, and not sufficiently tested on darker-skinned people. Buolamwini and Gebru (2018).

[11] Collecting, using, and disclosing personal health information is working with "human subjects" (Metcalf and Crawford 2016).

[12] Government of Canada (2020).

[13] First Nations Information Governance Centre (2020); Black Health Equity Working Group (2021).

[14] O'Neill (2018).

[15] See McInerney v. MacDonald (1992).

[16] See Scassa (2018) on this point.

[17] See Gaventa and McGee (2013), and Open Government Engagement Team (2015).

[18] See (WMA 2019). See also Paprica et al. (2019a) on open government; (2019b) and (2019c) on making information available in easy to understand formats, and Paprica et al. (2020) for guidance on how to implement transparency in data trusts.

[19] The Digital Society Working Group's principles have been informed by conversations with many experts and by many pre-existing ethical frameworks, including Beauchamp and Childress' *Principles of Biomedical Ethics* (1979), EGAP (2021), the Caldicott Report (1997), Canada's Digital Charter (2020), Eurocities Digital Principles (2019), OCAP (2020), the Frankfurt Big Data Lab, the Jane Finch Community Research Partnership Principles (2020), the MPFAC principles (2021), the Montreal Declaration (2018), the Nuffield Council of Bioethics (2015), the OECD Privacy Principles (2013), the Belmont Report (1979), the CARE principles (2019), the Declaration of Taipei (2002), and the Declaration of Helsinki (1964).

[20] Nenova and Shang (2021), and Bhardwaj et al. (2018).

[21] The purpose of this Patient, Family and Caregiver Declaration of Values, drafted by the Minister's Patient and Family Advisory Council in consultation with Ontarians, is to articulate patient, family and caregiver expectations of Ontario's health care system. MPFAC (July 2021).

[22] These points have recently been emphasized in the Pan-Canadian Health Data Strategy: Building Canada's Health Data Foundation, Expert Advisory Group—Report 2.

[23] Consider the Jane-Finch community Research Partnership's *Principles* document, which explains that research on racialized communities has been harmful and "dehumanizing": "communities, especially from the Global South, have been and continue to be exotified and subject to examination, oversurveillance, experimentation and dehumanizing exploitation. This has specifically been impacting equity seeking groups such as black, Indigenous, racialized and working poor communities…research has been reproducing and perpetuating the impacts of colonialism on marginalized and oppressed people, and the ongoing practice of claiming ownership of participants' knowledge, experience, stories, and time" (Jane Finch Community Research Partnership 2020).

[24] See Jane Finch Community Research Partnership (2020).

[25] Black Health Equity Working Group (2021).

[26] In line with recommendations from Aitken et al. (2020).

[27] For example, the citizen juries utilized by Understanding Patient Data (2021).

[28] Black Health Equity Working Group (2021).

[29] Adapted from Paprica et al. (2020).

[30] Government of Canada (2020).

[31] See Robertson et al. (2020), and Mojtehedzadeh (2020).

[32] McKenzie et al. (2020), and Pinto and Hapsari (2020).

[33] Canadian Institute for Health Information (2020a) and (2018).

[34] *Dialogue on Data* PFAC consultations. See Patient Consultations report (2022).

[35] See Paprica, Melo, and Schull (2019)

[36] See Van Staa et al. (2016)

[37] See Paprica et al. (2019c).

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[38] As recognized in the Government of Canada's "Principles Respecting the Government of Canada's Relationship with Indigenous Peoples". See in particular principle 1 (2021).

[39] United Nations (2007).

[40] Government of Canada (2021).

[41] Truth and Reconciliation Commission of Canada (2015).

[42] UNDRIP, Article 43 (United Nations (2007)).

[43] United Nations (2007).

[44] Coppes (2016).

[45] *UNDRIP Act, 2021* (Canada).

[46] UNDRIP, Article 19 (2007).

[47] UNDRIP, Article 23 (2007).

[48] Supported by the Government of Canada (2021), as well as All Chiefs in Assembly (AOCC Resolution 09/15).

[49] Such as the Inuit principles of Qaujimajatuqangit. See Nunvaut Impact Review Board (n.d.) and CIHI (2020b).

[50] For example, such as OCAS principles (Ownership, Control, Access and Stewardship) (CIHI 2020b).

[51] Esteva et al. (2017).

[52] Fenech, Matthew, Nika Strukelj, Olly Buston (for Wellcome Trust) (2018).

[53] Metz, Cade (2020).

[54] Ribeiro, Singh, and Guestrin (2016)

[55] See for example Buolamwini and Gebru (2018), and Feiner, Severinghaus, and Bickler (2007)

[56] Nicholson Price and Cohen (2019, 37).