Public Health Ontario | Santé publique Ontario

Position Statement: A Provincial Immunization Registry for Ontario

September 2024

OIAC — Ontario Immunization Advisory Committee

CCOI — Comité consultatif ontarien de l'immunisation

About Public Health Ontario

Public Health Ontario (PHO) is an agency of the Government of Ontario dedicated to protecting and promoting the health of all Ontarians and reducing inequities in health. PHO links public health practitioners, front-line health workers and researchers to the best scientific intelligence and knowledge from around the world. For more information about PHO, visit publichealthontario.ca.

About the Ontario Immunization Advisory Committee

The Ontario Immunization Advisory Committee (OIAC) is a multidisciplinary scientific advisory body that provides evidence-based advice to PHO on vaccines and immunization matters including vaccine program implementation in Ontario, priority populations and clinical guidance. The focus of the OIAC's work is on publicly-funded vaccines and immunization programs in Ontario, including COVID-19 and those under consideration for new programming. For more information about the OIAC and its members contact secretariat@oahpp.ca.

Acknowledgements

This statement was prepared by the OIAC Secretariat, on behalf of the OIAC. OIAC acknowledges the contribution of PHO staff within Health Protection, Communications Services, and Library Services.

The OIAC acknowledges the contributions of the province of Manitoba (Princy Mathew, Katrina Will and Arielle Goldman Smith) and the Nova Scotia Department of Health and Wellness for their review of the sections on Manitoba's and Nova Scotia's immunization registries.

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Citation

Plain Language Summary

Immunization registries are vital tools to make sure that Ontario's immunization programs provide the most benefit for individuals and communities. Immunization registries are electronic systems that record people's vaccinations over time. Currently, Ontario does not have a reliable, complete or timely system to record vaccinations for all people in the province. Most people in Ontario still have a paper-based "yellow immunization card" to document their past vaccines. Having an immunization registry would benefit individuals, families, health care providers, public health and researchers. It would help reduce the burden of diseases that vaccines can prevent, make it easier for people to get vaccinated, improve the delivery of Ontario's immunization programs, and ensure better use of health resources.

The Ontario Immunization Advisory Committee (OIAC) is an external group of experts that provides advice to Public Health Ontario about new and existing vaccines and Ontario's immunization programs. The OIAC is strongly urging the Ontario Ministry of Health to develop and put into action a provincial immunization registry. This registry should include vaccination records for everyone in Ontario and provide real-time access to individuals and their health care providers. This OIAC position statement outlines seven recommendations on what is needed for Ontario to implement an immunization registry.

> The Ontario Immunization Advisory Committee strongly urges the Ontario Ministry of Health to develop and put into action a provincial immunization registry.

Executive Summary

Immunization registries are essential for maximizing the benefits of Ontario's immunization programs. An immunization registry is an electronic system that records a person's vaccinations. It includes information for all vaccines that a person receives in their lifetime and captures vaccines delivered in all settings (e.g., doctor's offices, clinics, schools, workplaces, pharmacies, long-term care homes).

Ontario does not have a reliable, complete or timely way to record immunization information for all people in Ontario. Its current system for collecting immunization information is outdated and mostly limited to school-aged children. Most people in Ontario still have a paper-based record, known as their "yellow immunization card", which documents their past immunizations. The COVID-19 pandemic showed us that a centralized, electronic vaccination record for everyone in Ontario is not only feasible but also the foundation of a high-performing immunization system in the 21st century.[1,2]

Having a provincial immunization registry would benefit individuals, families, health care providers, public health and researchers. It would help reduce the burden of vaccine-preventable diseases on individuals and the health system, increase access to and improve the efficiency of Ontario's immunization programs, and optimize the use of finite health care resources. It can be used to evaluate new or existing immunization programs. Ongoing investment in a provincial immunization registry will also be critical for responding to future outbreaks and helping Ontario prepare for the next pandemic.

> The Ontario Immunization Advisory Committee strongly urges the Ontario Ministry of Health to develop and implement a comprehensive provincial immunization registry.

OIAC Recommendations

The Ontario Immunization Advisory Committee (OIAC) is an external group of experts that provides advice on publicly-funded vaccines and immunization programs to Public Health Ontario. Over a series of meetings, the OIAC reviewed information on existing immunization information systems in Canada, national standards for immunization registries, and Ontario's current immunization laws and policies. This OIAC position statement features seven recommendations based on three guiding principles that serve as a strong recommendation for a comprehensive provincial immunization registry for Ontario. These recommendations are aligned with Ontario's broader public health and digital health strategies, which seek to integrate and improve access to health information across the health system for the effective and coordinated delivery of health care services to all people in Ontario.[3-6]

Guiding Principles

The OIAC recommendations for an immunization registry are based on the following guiding principles:

- All people in Ontario and their health care providers require equitable and timely access to their complete immunization record to make informed decisions about their health.

- Health care providers and public health require an immunization registry to assess, maintain and document immunizations to deliver vaccines efficiently and appropriately across the health system.

- Public health, policy makers and researchers require real-time, individual-level immunization data to monitor the uptake, safety, effectiveness and impact of new and existing vaccine programs and to ensure that vaccine programs provide the best use of finite health care resources.

Summary of Recommendations

1   The OIAC recommends that Ontario implement a comprehensive electronic immunization registry that captures all immunizations administered across the lifespan by all immunization providers in all settings.

2   Provincial legislation and policy supports are needed and should be developed to enable the real-time collection, use and confidential sharing of immunization data across the health system. Accessible, comprehensive immunization data are necessary for the monitoring of new and existing immunization programs and to optimize immunization program management and delivery.

3   The Ontario Ministry of Health should consult and work in partnership with key immunization interest holders locally, provincially and nationally to ensure that all health care providers, local and provincial public health and members of the public have timely and equitable access to individual-level immunization records.

4   Technological innovations should be leveraged and implemented to ensure that a provincial immunization registry is accessible, adaptable, secure and scalable and reduces the burden on health care providers to enter and access data.

5   The Ontario Ministry of Health should adopt the *Canadian Immunization Registry Functional Standards* as a preliminary framework for developing a provincial immunization registry. Functional standards to support vaccine inventory and supply chain management and vaccine-preventable disease case and outbreak management should be incorporated and remuneration for health care providers related to immunization administration should be integrated.

6   A provincial immunization registry should support interoperability within and between organizational and jurisdictional boundaries to allow for secure access and confidential exchange of immunization data, including standardized data elements and vaccine terminology. Routine integration of an immunization registry with other health data systems is recommended to maximize the individual- and population-level health benefits of vaccines.

7   An interconnected provincial immunization registry should provide real-time, individual-level immunization data to individuals and an expanding network of immunizers, with connections for clinical use, immunization program monitoring and evaluation, and research. This includes monitoring of inequities in vaccine coverage, assessment of vaccine program impact, and real-time vaccine safety surveillance for maintaining public confidence in vaccines.

Benefits of an Immunization Registry for Ontario

Immunization registries offer benefits to users across Ontario's health system

Individuals and Families

Health Care Providers

Local Public Health

Provincial Public Health

Researchers

Immunization registries are a vital tool for Ontario's health system

Protect people in Ontario from vaccine-preventable diseases

- Keep people healthy and reduce time lost from school or work
- Make it easier for individuals and families to access vaccines and their vaccination record for work, school or travel
- Prevent and respond to outbreaks caused by vaccine-preventable diseases

Provide more efficient and accessible health care

- Provide reminders when individuals are due for vaccinations
- Make it easier for health care providers to access and keep track of their patients' vaccinations; avoid lost or misplaced paper immunization records
- Support health care providers to offer vaccines at every health care visit

Improve efficiencies within the health system

- Minimize costs and reduce the burden on the health system due to vaccine-preventable diseases
- Ensure appropriate public spending on vaccines and use of health resources
- Manage vaccine inventory and supply chains to prevent wastage of vaccine doses

Monitor and evaluate vaccine uptake, safety and effectiveness

- Make sure that everyone in Ontario has equitable access to vaccines
- Identify and report rare side effects following immunization to maintain public trust and confidence in vaccines
- Find out how well vaccines protect individuals to maximize their impact

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Overview

Immunization registries are essential for monitoring and evaluating the impact of new and existing immunization programs and for efficient and effective immunization program management and delivery. With expanding pressures on health systems and rising health care costs, there is an increased need to identify interventions to improve access to and uptake of vaccines and to mitigate the burden of vaccine-preventable diseases on the public health and health care systems.

During the COVID-19 pandemic response, the Ontario Immunization Advisory Committee (OIAC) leveraged near real-time data from Ontario's COVID-19 vaccine registry (COVaxON) to provide timely and evidence-based COVID-19 immunization program recommendations. COVaxON includes all COVID-19 vaccines administered by all health care providers in Ontario as a requirement under the *COVID-19 Vaccination Reporting Act*.[7,8] As Ontario moved out of the pandemic response phase, the work of the OIAC has shifted to other topics, including pediatric, adult and high-risk immunization programs, for which there is no comprehensive provincial immunization registry available to inform program planning and evaluation and population-level recommendations. The recent expansion of vaccine program delivery across providers and settings has made a centralized provincial immunization registry necessary to provide all clinicians and individuals with timely and equitable access to immunization records.[9,10]

The OIAC met on May 24 and June 28, 2023, to review evidence on the current state of immunization data available in Ontario. At the June 28th meeting, members reviewed the existing provincial immunization legislation and policies in Ontario, including their constraints. Members also reviewed the *Canadian Immunization Registry Functional Standards* and functional standards from other jurisdictions. On September 13, 2023, the OIAC reconvened to review a jurisdictional scan on immunization registries in other Canadian provinces and territories, including a presentation from Manitoba, which has a long-standing, comprehensive immunization registry. On October 11, 2023, the OIAC met and approved a series of guiding principles and recommendations for a comprehensive immunization registry in Ontario.

Content and Scope

This position statement features seven recommendations based on three guiding principles that serve as a strong recommendation from the OIAC for a comprehensive immunization registry for Ontario. Supporting evidence and case studies are presented to provide the context and rationale for the committee's recommendations. Recommendations on a specific registry platform, implementation details and privacy policy and legislation were considered out of scope for this statement.

Intended Audience

The intended primary audience of this position statement are decision makers at the Ontario Ministry of Health (e.g., Office of the Chief Medical Officer of Health, Public Health I&IT Solutions Branch). Secondary audiences include other key immunization interest holders (i.e., groups using immunization data) in Ontario, including: the Council of Ontario Medical Officers of Health, Association of Local Public Health Agencies, Ontario's public health units, and health care providers and their respective professional associations (e.g., Ontario College of Family Physicians, Ontario Medical Association, Registered Nurses' Association of Ontario, Ontario Pharmacist Association). These recommendations may also interest the general public as they offer health benefits that extend to all people in Ontario.

About Immunization Registries

Immunization registries are confidential, population-based, computerized information systems that collect immunization data about all persons within a defined geographic area.[11] Immunization registries are ideally centralized and comprehensive, recording all doses of vaccines administered by all health care providers to individuals of all ages and maintaining vaccination histories across the lifespan to ensure appropriate and timely immunizations.[2] Depending on the jurisdiction, an immunization registry may be referred to as an immunization information system, immunization repository, vaccine registry or public health information management system.

Immunization registries are essential tools for maximizing the benefits of immunization in the 21st century.[1] Over the last several decades, the number of vaccine products and complexity of immunization schedules have grown exponentially, with a substantial number of new vaccines for older adults, and greater proportion of the adult population living with chronic and immune-compromising conditions resulting in greater susceptibility to infectious diseases.[1] Vaccine-preventable diseases account for substantial morbidity and are resource intensive for the public health and acute care systems. Efforts to prevent disease and improve access to vaccines have led to an expansion in the network of immunizers and settings where patients can receive vaccines (e.g., pharmacies).[9,10]

Despite these advances, Ontario lacks a centralized, comprehensive immunization registry to support provider assessments of up-to-date immunization status, eligibility for vaccines or additional doses, reminder-recall for timely administration of upcoming or overdue vaccines, safe administration of vaccines (i.e., the right person, vaccine product and dose at the right time), and specialist consultations (e.g., vaccine product information to support individual clinical advice for future doses following an adverse event following immunization [AEFI]).

Documentation systems used by health care providers to capture administered vaccines vary by vaccine product, program (e.g., routine, high-risk, school-based, older adult), provider type and setting. In Ontario, the individual and/or their parent or guardian is often the sole record keeper responsible for maintaining their complete immunization record (i.e., paper "yellow card"), compiled from various providers and sources. This is in contrast to other areas of Ontario's health care system where there has been notable movement towards patients having electronic access to their own health and medical information.

Immunization Registries in Canada: Historical Context

In Canada, health care delivery, which includes immunization, is a provincial and territorial responsibility. Provinces and territories vary in the extent to which an immunization registry is in place to capture immunizations, vaccines that are publicly-funded, service delivery models (e.g., providers involved, programs delivered), and polices and legislation related to both immunization and privacy.[12-14] Almost all provinces and territories in Canada have an electronic immunization registry; however, the scope, attributes, functionality and comprehensiveness varies (e.g., providers with access, vaccines recorded, reporting requirements).[12] Canada does not have a national immunization registry; nonetheless, calls to implement provincial and territorial immunization registries have been present for at least three decades.[12-28]

In 1998, Health Canada convened the *Canadian Consensus Conference on a National Immunization Records System* where immunization interest holders defined objectives, components and design elements that are foundational to an immunization registry. This conference emphasized the urgent need for all provinces and territories to establish a comprehensive immunization registry.[12,15] In 2003, federal, provincial and territorial Deputy Ministers of Health approved the *National Immunization Strategy*, which provided a framework for pan-Canadian collaboration to improve the effectiveness and efficiency of vaccine programs in Canada. The report outlined five components, including one detailing a commitment to developing comprehensive registries and strengthening inter-jurisdictional networks to provide relevant, accurate, timely and compatible data for immunization surveillance and transfer of (and access to) individual immunization records.[29] This component also included developing data standards and core data elements. Commitment to the coordination and use of immunization registries to improve immunization coverage was reaffirmed upon review of the *National Immunization Strategy* in 2013 and 2016.[11,30]

Following the 2003 outbreak of Severe Acute Respiratory Syndrome (SARS), an independent report from the National Advisory Committee on SARS and Public Health identified a need for the federal government to invest in a consolidated public health surveillance system to track vaccinations and immunization coverage that could help mitigate the risks associated with infectious diseases by facilitating coordination across provincial/territorial boundaries.[18] In response to this recommendation, the Government of Canada provided funding to Canada Health Infoway to work with Canada's federal, provincial and territorial governments to develop a national, integrated public health surveillance solution known as Panorama, developed by IBM, which has been implemented to varying degrees in most provinces and territories.[12,28]

Nearly a decade later, a 2014 report from the Advisory Committee for Ontario's Immunization System Review, a committee established by the Chief Medical Officer of Health, recommended that a provincial immunization registry be developed in Ontario immediately, noting that it would be foundational to the functioning of the entire immunization system.[20] Similarly in 2014, the Office of the Auditor General of Ontario released its annual report including a value-for-money audit on immunization.[21] In their audit, the Auditor General highlighted the many limitations of the current system, including issues with data accuracy and completeness, noting that the full benefits of Panorama would not be recognized until all providers can electronically record vaccinations at the time of administration. This shortcoming was highlighted again in the Auditor General's 2022 annual report on the COVID-19 vaccination program.[22] In that report, the Auditor General noted that the lack of a comprehensive immunization registry required the Ministry of Health to create a new database specifically for COVID-19 vaccines, which increased costs, while also limiting Ontario's ability to rapidly respond to future disease outbreaks.

In the 2015 report *Immunization 2020 - Modernizing Ontario's Publicly Funded Immunization Programs*, the provincial government outlined a roadmap for achieving a high-performing, integrated immunization system and referenced utilizing Panorama as a priority to advance the vision of a provincial registry to record and track immunizations of all people in Ontario.[24] The report recommended leveraging existing data standards in Panorama to support electronic linkages to other systems to enable reliable vaccine program surveillance (i.e., coverage and safety monitoring), inventory management, and case and outbreak management. In addition, it identified the need to explore opportunities to strengthen health care provider reporting of immunizations and public access to immunization records through a secure online portal.[24]

In 2020, the Pan-Canadian Health Data Strategy Expert Advisory Group was convened to establish a common foundation to improve the way provinces and territories use, share and manage health data. This includes enabling clinicians to provide better care, giving the public access to their own health data, and supporting the use of health data to improve health care, public health and population health.[31,32] A series of three reports from the Expert Advisory Group highlighted the current state of health data and a vision for the Canadian health data ecosystem and offered principles for strengthening our health data systems.[31,32] The first report notes that, despite large-scale investments in Panorama as a comprehensive pan-Canadian solution, Canada instead has a series of decentralized registries, with no ability to integrate or scale.[33] Moreover, the report suggests that the lack of appreciation for the value of long-term consistency, unclear accountability, and a lack of trust among users has contributed to the inability of Panorama to fulfill its intended purpose. It concludes that strong and consistent leadership is required to advocate for decisions aligned with the long-term goals of an immunization registry.[33]

> Cumulatively, these reports highlight the need for a reliable, timely and accessible provincial immunization registry to support both individual and population health.

Current Immunization Landscape in Ontario

Ontario's Digital Health Immunization Repository

Ontario established the Digital Health Immunization Repository (DHIR) between 2013 and 2016, which involved the migration of immunization data from decentralized databases at each public health unit (PHU), collectively known as the Immunization Records Information System (IRIS), to a centralized, electronic provincial repository. Ontario's DHIR is primarily used to collect and maintain immunization records for select vaccines for children under the *Immunization of School Pupils Act (ISPA),* and *Childcare and Early Years Act (CCEYA)*, as well as grade 7 school-based immunization programs delivered by Ontario's 34 PHUs.[34-37] The ISPA requires students in Ontario be vaccinated against nine designated diseases or have a valid exemption, as outlined in the Act and *Ontario Regulation 261/13*.[36] Panorama is the front-end user application used to access information in the DHIR. In Ontario, both the immunization module and inventory module are used within Panorama. The immunization module is a centralized registry of standardized electronic immunization data accessible to all PHUs. The inventory module captures data for the monitoring, ordering and delivery of publicly-funded vaccines through the Ontario Government Pharmaceutical and Medical Supply Services.

The collection and entry of immunization information in the DHIR is largely driven by ISPA for many routine infant and childhood immunizations.[36] PHUs rely on parental and/or provider reporting for immunizations administered in primary care; whereas, PHUs directly enter adolescent immunizations administered in school-based programs into the DHIR.[35,36] Parents may report childhood immunization records to PHUs at the time of school entry and periodically thereafter through paper documentation sent by fax or mail, as well as through web-based (e.g., Immunization Connect Ontario [ICON]) or consumer (e.g., CanImmunize) applications.[35,38] Panorama contains a unique identifier for each client, has the ability to record information about consent, contraindications, medical and non-medical exemptions to immunization and has the functionality to capture limited information on adverse events following immunization (AEFIs). Individual-level immunization data can be extracted from the DHIR for immunization coverage assessments, but the completeness of data varies.

Key Challenges and Limitations with the Current Provincial Immunization Landscape

Panorama offers opportunities for standardized entry of individual-level immunization data due to its centralized, electronic nature; however, there are several challenges within the existing provincial immunization landscape that limit the functionality of Panorama to serve as a provincial immunization registry for all vaccine programs, as is done in some other provinces and territories.

Data in the DHIR are not comprehensive of all publicly-funded vaccine programs. Furthermore, the DHIR does not capture vaccines delivered in all health care settings. Currently, health care providers in Ontario are not required to report administered vaccines to public health. The ISPA drives the entry of immunization records in the DHIR.[36] Thus, any disruption to ISPA immunization record collection, entry, assessment and enforcement activities within a PHU may result in under-reporting of immunizations and an inability to perform accurate and timely assessments of immunization coverage, as observed during the COVID-19 pandemic for routine immunization programs.[39,40] In addition, PHUs have no legislative authority to collect and assess immunizations administered by other health care providers for infant, pre-school, adult and high-risk vaccine programs not covered in the ISPA. Thus, vaccine doses administered to children outside of the PHU are not reliably captured in the DHIR until the time of licenced childcare or school entry.

Access to Ontario's DHIR for the purposes of immunization record viewing, provider documentation and/or retrospective record entry are limited to PHU staff. Only vaccines administered by public health (e.g., school-based vaccines) are directly entered in Panorama; those delivered by primary care or pharmacies are not captured unless submitted to public health. Additionally, since the system relies on parental reporting, there are several challenges associated with data quality and completeness, including reporting inaccuracies (e.g., no requirement for health care provider documentation or validation) and missing, delayed or incomplete immunization records. Many parents are not aware of their responsibility to report immunizations received in primary care to public health, and the complexity of Ontario's immunization schedule and thus the burden to report has increased substantially in recent decades.[41,42]

The current system also has several limitations for performing timely and accurate immunization program surveillance in Ontario. With the exception of ISPA, school-based and COVID-19 vaccine programs, there is currently no system in place to capture vaccines and monitor immunization programs in a timely way for infants and preschool-aged children. In addition, for adults and high-risk populations, there is no comparable immunization registry that can be used to monitor vaccine uptake. Immunization coverage for school-aged children assessed using the DHIR, although fairly comprehensive, introduces significant time lags and is highly dependent on ISPA and CCEYA activities, which vary considerably depending on the cohort(s) assessed, time of year and PHU.[36,37] For non-ISPA vaccine programs (e.g., *Haemophilus influenzae* type b, pneumococcal vaccines), parents/guardians are not required to submit immunization records, so immunization coverage assessments probably underestimate true coverage for these diseases. Since coverage estimates are performed retrospectively, they have limited ability to provide real-time assessments of the population-level impacts. For instance, immunization coverage for meningococcal conjugate C vaccine and pneumococcal conjugate vaccine are not routinely assessed in Ontario until age 7, despite the fact that these vaccines are given in infancy and the greatest burden of disease is in infants and young children.

In the absence of a comprehensive provincial immunization registry that captures data on all publicly-funded immunization programs across the lifespan, substantial efforts have been made to evaluate and link other data sources to monitor and evaluate immunization programs. Administrative data sources such as provider billing data (i.e., Ontario Health Insurance Plan [OHIP] billing codes) and electronic medical records (EMRs) provide some individual-level immunization data and have been used for immunization coverage estimates and assessments of program impact. However, there are several limitations associated with these non-registry data sources including the completeness, representativeness and standardization of the data. These methods have moderate sensitivity and are not comprehensive.[43] Vaccine-specific OHIP provider billing codes are not available for many publicly-funded vaccines; they do not include vaccines delivered in some settings (e.g., pharmacy, public health, workplace clinics), those delivered to non-OHIP clients, and those not billed for by providers due to the limited financial incentives associated with administering vaccines or vaccines which are privately purchased.[43-45]

Non-standardized data elements (e.g., patient details) and vaccine terminology (e.g., different names for the same vaccine) across health care provider EMRs also limits interoperability, namely the exchange and use of immunization data across systems for program monitoring and evaluation. These databases often only capture OHIP-eligible patients or those within a given EMR network and thus may not be representative of the Ontario population. In addition, there are currently no routine linkages between the DHIR and population registries (e.g., OHIP eligibility database [Registered Persons Database] that includes all OHIP eligible individuals), disease surveillance and AEFI reporting systems (i.e., Public Health Case and Contact Management Solution [CCM], Integrated Public Health Information System [iPHIS]) or other health data sets for immunization program monitoring and evaluation.[46-48]

Ontario's COVID-19 Immunization Registry

The COVID-19 pandemic emergency response highlighted many gaps in Ontario's immunization and disease surveillance information technology (IT) infrastructure. During the early phases of the pandemic, the provincial government used the *Emergency Management and Civil Protections Act* to mandate the collection and use of COVID-19 vaccine administration data and fund IT systems to support COVID-19 vaccine program management.[49] In 2021, the *COVID-19 Vaccination Reporting Act* was passed, which required health care providers to record all administered COVID-19 vaccines on behalf of the Ministry of Health in a centralized electronic immunization registry known as COVaxON.[7,8,50] COVaxON was developed as a secure, web-based system to capture individual-level data on all COVID-19 vaccine doses administered by all immunizers in all health care settings in Ontario or to residents of Ontario (i.e., vaccine doses administered out of province).[51] The scale and comprehensiveness of the COVID-19 immunization registry and data elements collected were novel within Ontario's typical immunization IT data infrastructure. All immunizers were provided with direct access to COVaxON for documentation.

The COVaxON platform is scalable, adaptable and utilizes standardized terminology and mandatory data elements to support interoperability of immunization data at a provincial, national and international level. It facilitated access to COVID-19 vaccine certificates at a time when these were needed for travel, work and recreational activities. A secure, web-based platform provides individuals' access to their COVID-19 immunization history and vaccine certificate, complete with a digital QR code and unique client identifier.[52]

COVaxON was essential for producing and leveraging near real-time, comprehensive immunization program surveillance outputs to support evidence-based recommendations for programmatic and clinical decision-making. By capturing individual-level immunization data on all COVID-19 vaccine doses administered in Ontario, this system allowed for routine linkages to COVID-19 case and AEFI data to support case and contact management and AEFI investigations; to case outcome and denominator data in the OHIP eligibility database; and to Ontario's Digital Health Drug Repository (DHDR) for health care provider viewing of a client's COVID-19 immunization status. These linkages enabled near real-time monitoring and evaluation of COVID-19 vaccine coverage, safety, effectiveness and program impact, including the impact of vaccination on disease transmission, severity (e.g., hospitalization, intensive care unit admission and death) and the need for additional doses (e.g., degree and duration of protection).[51,53-62] In addition, data from COVaxON was used to identify cohorts, communities and other equity-deserving populations with low vaccine uptake or those that were at higher risk of exposure or severe disease, which allowed for prioritized immunization program delivery during periods of constrained supply and heightened epidemiologic risk.[63-66]

Similarly, passive vaccine safety surveillance using individual-level immunization data from COVaxON linked to AEFI data was used to rapidly identify product-specific differences in the rates of myocarditis and pericarditis following receipt of a COVID-19 mRNA vaccine.[53] These findings led Ontario, followed by the National Advisory Committee on Immunization (NACI), to issue a preferential product recommendation for adolescents and young adults to lower the risk of adverse events and ensure ongoing confidence in the COVID-19 vaccination program during the pandemic.[67,68] Moreover, real-time, accessible, individual-level immunization records allowed researchers to assess vaccine effectiveness, waning immunity, optimal scheduling of doses and the need for additional COVID-19 vaccine booster doses to inform program recommendations.[54-60] These studies highlight the essential role that an interconnected, comprehensive provincial immunization registry offers in providing real-time immunization data for vaccine program surveillance and maintaining public confidence in vaccine programs for routine immunizations and responsive immunization efforts within the context of outbreaks and pandemics.

> A provincial immunization registry would provide real-time immunization data, allowing Ontario to better monitor the uptake, safety and effectiveness of new and existing immunization programs.

Table 1: Characteristics of the Digital Health Immunization Repository, COVID-19 Immunization Registry and Administrative Data

Characteristic	Digital Health Immunization Repository (DHIR)	COVID-19 Immunization Registry (COVaxON)	Administrative Data (e.g., OHIP provider billing data)
Vaccine Programs Captured	• Routine publicly-funded (child and adolescent) and school-based vaccines • Not comprehensive (relies on parent and/or health care provider reporting to PHU for routine vaccines) • Limited to school-aged children and those in licenced child care	• All COVID-19 vaccines provided by all health care providers in Ontario or to residents of Ontario (i.e., vaccine doses administered out of province) across the lifespan	• Routine publicly-funded vaccines (infant to older adult) administered in primary care • Not comprehensive (e.g., very limited capture of vaccines without OHIP vaccine-specific billing codes, does not capture doses administered by non-fee-for-service providers [e.g., nurse practitioners])
Reminder-Recall	• Send notices to remind individuals about recommended vaccines (school-aged children and those in licenced child care) • Forecaster functionality (used for ISPA and school-based clinics)	• Send notices to remind individuals about recommended vaccines • Forecaster functionality	• N/A
Access to Immunization Records	• Access limited to PHU staff • Online portal (ICON) for parent/guardian reporting of childhood immunizations	• Access for authorized health care providers/immunizers through web-based platform and viewing via Ontario's Digital Health Drug Repository • Public access to individual COVID-19 vaccination record/certificate	• Access to de-identified OHIP-billing data is limited and with significant time lags
Entry of Immunization Records	• Retrospective entry of individual-level immunization data driven-by ISPA activities (routine vaccines)	• Real-time and retrospective entry (e.g., out-of-province doses) of individual-level immunization data	• Retrospective entry of individual-level immunization data via OHIP-billing data

Characteristic	Digital Health Immunization Repository (DHIR)	COVID-19 Immunization Registry (COVaxON)	Administrative Data (e.g., OHIP provider billing data)
Data Elements & Terminology	• Standardized data elements, required data elements	• Standardized data elements, terminology and required data elements	• Generic and vaccine-specific OHIP billing codes
Support for Vaccine Programs	• PHU inventory management • Mass immunization clinic set up • Mobile tool for clinics (m-Imms)	• Inventory management • Mass immunization clinics set up • Linkages with scheduling/ booking system	• N/A
Monitoring and Evaluation	• Individual-level immunization data for retrospective assessments of immunization coverage and program impact	• Individual-level immunization data with routine linkages to other provincial databases to support near real-time immunization program monitoring and evaluation (including immunization coverage)	• Numerator for retrospective assessments of immunization coverage and program impact
Limitations	• Reliance on parent and/or health care provider reporting • Only captures immunization data for some vaccines for school-aged children and those in licenced childcare • Limited/incomplete reporting and capture of immunizations delivered outside PHU setting • Long delays in data entry (retrospective) • Very limited record validation • Not accessible to health care providers outside PHUs	• Limited to COVD-19 vaccines • Administrative burden of data entry on health care provider/ immunizer/ public health	• Comprehensiveness is limited • Data are not available in real-time • No OHIP vaccine-specific billing codes for some publicly-funded vaccines • Doses administered by non-fee-for-service providers and/or unbilled doses are not captured • Access generally limited to researchers

The Case for a Comprehensive Provincial Immunization Registry for Ontario

Ontario's experience with the COVID-19 pandemic response illustrated that the time is now to implement a scalable, centralized provincial immunization registry. The pandemic demonstrated that a comprehensive registry is feasible and foundational for a modern, high-performing immunization system in Ontario. The Ontario Immunization Advisory Committee (OIAC) affirms recommendations made by other provincial and national expert advisory committees and professional associations over the last three decades: **a comprehensive immunization registry is urgently needed in Ontario.**[13-15,18-27]

A comprehensive provincial immunization registry offers an opportunity to improve efficiencies in the delivery of health care services and promote equitable access to vaccines. These benefits are particularly timely given the current climate of limited health care resources, increasing global spread of vaccine-preventable diseases and heightened risk of outbreaks due to travel, and slow recovery of immunization coverage following the pandemic. A provincial registry would reduce the substantive administrative burden placed on individuals, health care providers and public health to track down, access and assess their own or their patient's immunization records; allows for the identification of unimmunized and under-immunized individuals to mitigate the risk of vaccine-preventable diseases; and promotes delivery of immunizations at every health care encounter to maximize the benefits of vaccines. Moreover, immunization registries are integral for successful immunization program delivery and management, population health assessments, identifying inequities in vaccine access and/or coverage and conducting robust vaccine effectiveness and safety surveillance and research.[69]

> The OIAC strongly urges the Ontario Ministry of Health to develop and implement a comprehensive immunization registry in Ontario.

Immunization registries are an integral component of successful immunization program management and delivery.

Immunization registries support all aspects of immunization program management and delivery, including vaccine inventory and supply chain management, identifying unimmunized and under-immunized individuals, and documenting administered immunizations. Immunization registries allow health care providers to access to their patients' complete immunization history to ensure that patients receive the right vaccine product at the right time, prevent under- or over-immunization, and maintain a high standard of patient care.[24,70,71] Given the increasing complexity of primary care, immunization registries would also help minimize workload and administrative demands on already overburdened health care professionals. Vaccines are widely recognized as one of the most cost-effective health interventions.[24] Health system spending on disease prevention efforts, such as immunization, may even be cost-saving, allowing more money to go to other areas of health care delivery. They can prevent and/or reduce the severity of acute infection and associated long-term sequelae, thereby reducing the burden on the health system and wider economy (e.g., fewer days off work or school, fewer medical visits).[69,71,72] Additionally, vaccine program decision-making incorporates reviews of cost-effectiveness analyses and relies on effective immunization program management and delivery to ensure programs meet their intended goals. Thus, even the most cost-effective vaccine programs still require efficient methods to monitor vaccine usage and wastage and manage inventory. Immunization registries are ideally scalable, accessible and adaptable to support these functions and meet the evolving needs of immunization programs.

Immunization registries can mitigate disease risk during outbreaks.

The last two decades have been marked by outbreaks and pandemics of emerging, re-emerging and endemic pathogens, including several public health emergencies of international concern.[73] Travel and social networks have increased the likelihood of imported disease and subsequent transmission. The COVID-19 pandemic led to disruptions in the delivery of routine immunizations and significant declines in immunization coverage were observed in Ontario and globally.[39,40,74,75] This has been accompanied by reduced public confidence in vaccines and localized outbreaks of vaccine-preventable diseases (e.g., measles), particularly in under-immunized populations.[76,77] Ontario needs to better prepare for new and emerging pathogens with pandemic potential.

Immunization registries are a critical component of emergency preparedness for future outbreaks. Immunization registries can identify susceptible individuals and communities during an outbreak and provide forecaster and reminder-recall functions for routine immunizations. An immunization registry forecaster is a decision support tool that validates immunizations and forecasts when an individual is eligible or due for immunizations based on information about the client (e.g., age, immunization history, medical condition(s)) and a set of logic rules using immunization schedules. Immunization forecaster and reminder-recall tools offer the opportunity to proactively identify unimmunized or under-immunized individuals at every health care encounter to improve immunization coverage. This feature was illustrated with COVaxON when eligible high-risk individuals were emailed reminders about their next COVID-19 vaccine dose. In addition, robust immunization data could allow health care providers and public health to quickly identify and offer post-exposure prophylaxis to susceptible contacts of vaccine-preventable diseases (e.g. measles) to reduce their risk of disease and help prevent ongoing spread.

Comprehensive immunization registries enable monitoring of new or existing immunization programs.

Immunization registries provide population-based, comprehensive data sources that are the gold standard for estimating vaccine coverage, safety, effectiveness and program impact. Immunization registries enable monitoring for inequities in vaccine coverage and targeted strategies to improve equitable vaccine uptake. In Ontario, public health units currently have limited ability to monitor new or existing immunization programs for infants, pre-school-aged children, adults and high-risk groups. These vaccine programs are not routinely or comprehensively captured in the Digital Health Immunization Repository. Over the last decade, the number of adult vaccine programs has expanded rapidly, which has the potential to greatly improve health outcomes for older adults. At present, Ontario does not have existing infrastructure to determine optimal vaccination schedules (e.g., timing, boosters) and monitor vaccine uptake and effectiveness for adult vaccine programs, nor does it have a tool to support health care provider vaccine administration (e.g., identifying eligible individuals using immunization forecaster and reminder-recall tools). The absence of a centralized and comprehensive immunization registry in Ontario limits the province's ability to effectively implement and assess the impact of new vaccination programs and evaluate and improve existing vaccine programs.

Immunization registries facilitate robust, high-quality vaccine safety surveillance and maintain public trust and confidence in vaccines.

Individual-level dose administration data contained within an immunization registry provide an accurate denominator for estimating rates of adverse events following immunization (AEFI). These data are essential for population-based assessments of vaccine safety (e.g., detection of rare vaccine safety signals) and are particularly important for new vaccine programs and those offered to special populations (e.g., immunocompromised due to disease or treatment, pregnant individuals, other high-risk populations) who might not have been included in the original clinical trials. Denominator data from population-based immunization registries can be linked to AEFI data to perform post-market passive vaccine safety surveillance to provide a more accurate, comprehensive and transparent reflection of the safety profile over time that reflects the real-world use of vaccines, which is an important component in maintaining public trust and confidence in vaccine programs.

Immunization registries have uses across the health system and thus benefit all health system users.

Immunization registries offer benefits to several interest holders (users of immunization data) across the health system including: individuals, health care providers, local and provincial public health and researchers (Figure 1). At the individual level, access to a single consolidated immunization record offers convenience and supports timely, equitable access to vaccines. Immunization registries support individuals and families in checking their vaccination status and accessing their complete immunization records for health, travel, childcare, school, occupational and/or workplace requirements. At the population level, registries promote continuity of care across the health system by providing all immunizers with real-time access to an individual's complete immunization history, ensuring that clients receive the right vaccine at the right time. Immunization registries are also essential for monitoring immunization coverage and safety, evaluating immunization programs, and conducting research.

Figure 1: Summary of Provincial Immunization Registry Functionality by Interest Holder Type. The left-hand column outlines the key functions of immunization registries by interest holder (user) type and the interactions between various immunizer registry interest holders (users) at the individual and population level.
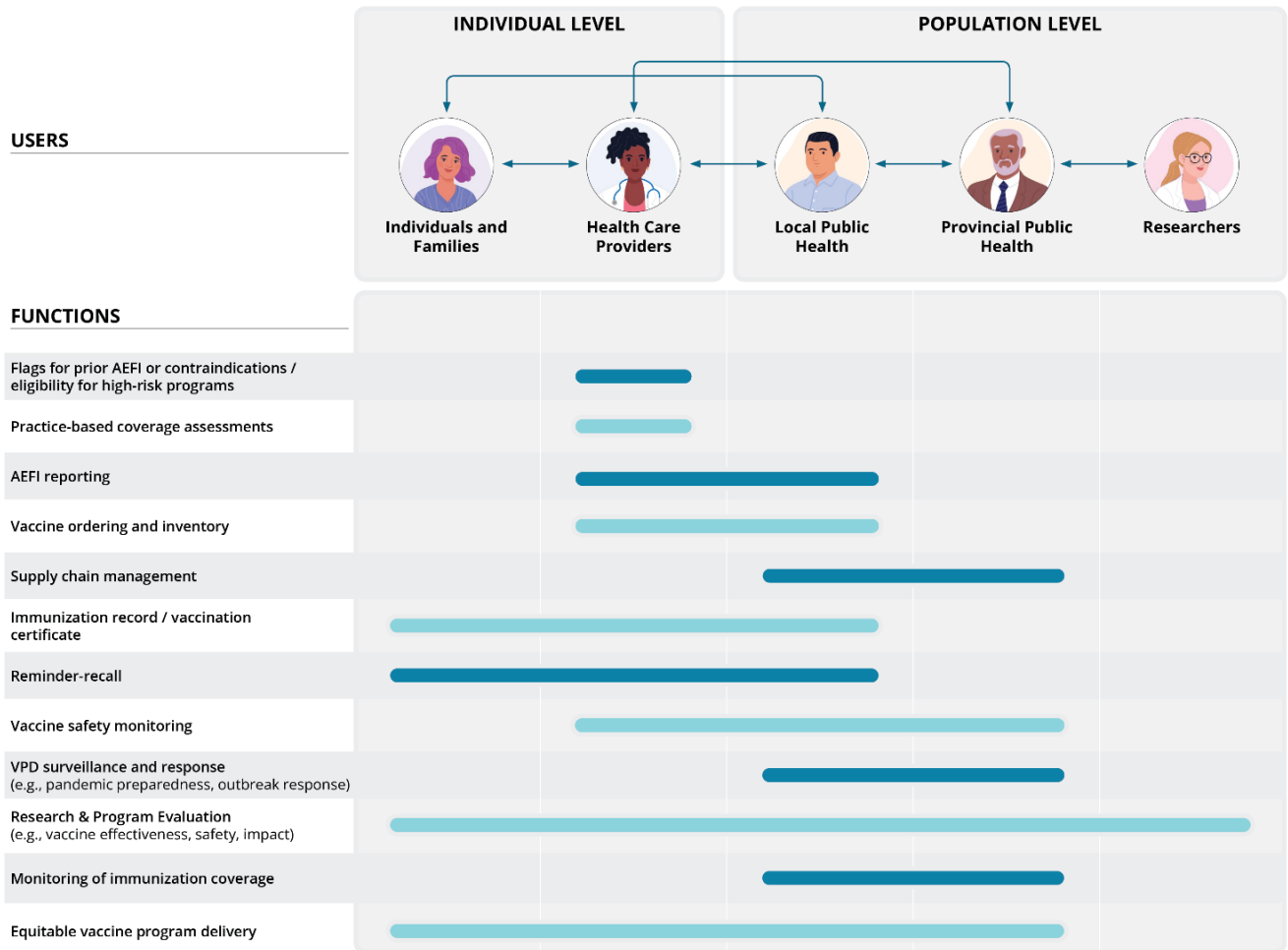
AEFI - Adverse Event Following Immunization, VPD - Vaccine Preventable Diseases

Recommendations and Evidence Synthesis

The Ontario Immunization Advisory Committee (OIAC) has prepared seven recommendations based on three guiding principles for the Ontario Ministry of Health to develop and implement a comprehensive provincial immunization registry. These recommendations and guiding principles are summarized below, along with a synthesis of relevant evidence to support each recommendation.

Guiding Principles for a Provincial Immunization Registry

The OIAC recommendations for a comprehensive provincial immunization registry for Ontario are based on the following guiding principles:

- All people in Ontario and their health care providers require equitable and timely access to their complete immunization record to make informed decisions about their health.

- Health care providers and public health require an immunization registry to assess, maintain and document immunizations to deliver vaccines efficiently and appropriately across the health system.

- Public health, policy makers and researchers require real-time, individual-level immunization data to monitor the uptake, safety, effectiveness and impact of new and existing vaccine programs and to ensure vaccine programs provide the best use of finite health care resources.

Recommendation 1: The OIAC recommends that Ontario implement a comprehensive electronic immunization registry that captures all immunizations administered across the lifespan by all immunization providers in all settings.

A comprehensive immunization registry is urgently needed in Ontario. Immunization registries are the cornerstone of high-performing immunization systems. They maximize the benefits of vaccines for individuals and communities as well as society more broadly by minimizing disruption caused by disease.[20] High immunization coverage is essential for maintaining population-level immunity and reduces the risk of disease transmission and outbreaks. Robust individual-level data from an immunization registry can be used to identify unimmunized or under-immunized individuals and communities using forecaster and reminder-recall functions. These tools allow immunizers to offer appropriate vaccines in a timely and equitable manner to prevent disease outbreaks. An immunization registry is critical for supporting all aspects of immunization program delivery, inventory management, surveillance and evaluation. Additionally, immunization registries provide individuals with timely and equitable access to their complete immunization record for health, school, occupational or travel requirements. Figure 1 and Table 2 summarizes the uses of individual-level immunization registry data for interest holders (users) across the health system.

Table 2: Uses of Provincial Immunization Registry Data across the Ontario Health System

Individuals	Health Care Providers	Local Public Health	Provincial Public Health
• Access own comprehensive immunization record (e.g., education, volunteering, employment, travel, medical indications) • Provide reminder-recall when due for vaccine	• Access patient's comprehensive immunization history, including reason for non-immunization (e.g., exemptions, AEFIs, contraindications) in real-time • Make informed diagnoses and individualized care plans for their patients • Identify unimmunized or under-immunized patients within practice and ensure that recommended immunizations are delivered according to the publicly-funded schedule • Coordinate immunization activities among immunizers (e.g., primary care, pharmacy, PHUs) • Record clinical advice regarding vaccines for patients with past AEFIs or specific contraindications (e.g., special populations, historical AEFI)	• Forecast routine vaccines for reminder-recall, mass immunization or school clinics, school/childcare requirements, etc. • Conduct local coverage assessments to identify unimmunized and under-immunized individuals/populations for targeted outreach and ensure health equity • Use vaccine product data to support individual AEFI investigations and clinical advice, and provincial vaccine safety surveillance • Link case management and investigations systems to identify individuals at risk (e.g., case and contact management, disease outbreaks) • Vaccine inventory and supply chain management • Better overall delivery and management of immunization programs	• Monitor vaccine uptake, coverage and effectiveness using a comprehensive, population-based approach • Conduct vaccine safety surveillance and timely investigation of novel and/or rare vaccine safety signals • Perform local, regional and provincial risk assessments, surveillance and outbreak response • Research and evaluate program impact (i.e., need for additional doses, effectiveness of vaccine schedule, etc.) • Inform evidence-based program and policy decisions • Return on investment for publicly-funded vaccines

A comprehensive provincial immunization registry would provide all people in Ontario with a longitudinal immunization record capturing all immunizations administered across the lifespan. There are several general features of a population-based immunization registry. An immunization registry should be comprehensive, such that it captures all privately purchased and publicly-funded vaccines administered as part of Ontario's routine and/or high-risk programs. Vaccine administration data should be obtained from all immunizers across the health system (i.e., participation of all providers as the default) and ideally at the point-of-care, allowing for near real-time access to vaccination data. The registry should also capture historical immunization records, including vaccine doses received outside of the province (e.g., newcomers, inter-provincial records). Additionally, using standardized data elements and terminology would support interoperability within and between organizational and jurisdictional boundaries and enable access and exchange of immunization data to consolidate immunization records from multiple health care providers and sources into a single, centralized immunization record for individual and clinical use. These attributes are aligned with Ontario's broader public health and digital health strategies, which seek to integrate and improve access to health information across the health system for the effective and coordinated delivery of health care (including public health) services to the people of Ontario.[3-6] They also align with the *Joint Federal, Provincial, and Territorial Action Plan on Health Data and Digital Health*, which aims to promote alignment between provincial and territorial health data policies and increase access to high-quality health data that is easily and securely accessible to Canadians and their healthcare providers.[78]

To successfully implement a comprehensive, electronic provincial immunization registry, the Ontario Ministry of Health will need to clearly define the vision and objectives for a provincial immunization registry. This initiative will require careful planning and a commitment to a long-term, sustainable implementation strategy, including leveraging the strengths of existing information technology (IT) systems and resources, identifying gaps in existing systems and processes, and soliciting interest holder input to understand key requirements and system design features.[1,20,79] The Ministry of Health should actively engage an inter-disciplinary team (e.g., IT specialists, clinical front-end users, local and provincial public health authorities, public users) in the planning and implementation stages; this engagement will be essential for optimizing the functionality, interoperability and end-user experience. Supportive legislation and policies that clearly outline the required data elements, documentation and/or reporting standards, and appropriate collection, use and exchange of immunization data, all while maintaining individual patient confidentiality, will also be needed. The successful implementation of the COVaxON immunization registry in Ontario serves as a proof-of-principle for these requirements.

Case Study: Manitoba Public Health Information Management System

The province of Manitoba has a long-standing, centralized, comprehensive population-based immunization registry. The Public Health Information Management System (PHIMS) is an integrated, electronic information system that supports the collection and dissemination of information for various public health initiatives and direct service delivery, including immunizations, vaccine inventory, communicable disease and outbreak management and surveillance. The PHIMS immunization registry uses Panorama (IBM) and captures all vaccines included in Manitoba's publicly-funded immunization program and is also configured to capture any vaccine product authorized by Health Canada. Vaccines not authorized by Health Canada, but used in other countries, may also be added *ad hoc*. The PHIMS immunization registry is based on Manitoba's Health Client Registry, which captures clients registered for the Manitoba Health Services Insurance Plan (MHSIP), such that all Manitobans with provincial health insurance coverage are automatically added to the immunization registry, with the option to manually add visitors and newcomers.[80,81] Uses and functions of the PHIMS immunization registry include: recording of immunization events, adverse events following immunization (AEFIs) and consent for immunization; a mass immunization event tool; forecaster decision-making support based on the provincial immunization schedule; vaccine inventory management; reminder-recall functionality including reports and outreach letters; and integration with disease investigation modules for determination of immunization status and eligibility for vaccination during case investigations.

PHIMS was implemented in all of Manitoba's health regions between 2015 – 2018, including First Nations communities and those receiving vaccines through the First Nations and Inuit Health Branch (FNIHB) and is considered a tripartite project between Manitoba Health, First Nations Health and Social Secretariat of Manitoba and FNIHB.[81] Support for PHIMS was obtained from the Chiefs in Assembly as part of the *Manitoba First Nations eHealth Long-term Strategy*.[81,82] Manitoba's Immunization Regulation of *The Public Health Act* requires health care providers administering vaccines to record the immunization in the patient's health record, including specific details about the vaccine and event.[83] Immunizers are required to report all publicly-funded vaccines administered in PHIMS as soon as possible. Reporting is tied to electronic uploads from the Drug Program Information Network (DPIN) for vaccines administered in pharmacies and the Claims Processing System for fee-for-service provider billings (using tariff codes for all publicly-funded vaccines) and other salaried health care providers that shadow bill. Records for non-fee-for-service providers (e.g., pharmacists) are also captured in the PHIMS. While only certain providers have direct access to PHIMS, information in the PHIMS immunization registry can be viewed by eligible health care providers using eChart Manitoba.[84]

The success of Manitoba's immunization registry has been attributed to strong leadership and commitment to maintaining and continuously improving a comprehensive registry. Incorporating adult education and change management principles have been integral for end-user engagement and optimal user experience.

Recommendation 2: Provincial legislation and policy supports are needed and should be developed to enable the real-time collection, use and confidential sharing of immunization data across the health system. Accessible, comprehensive immunization data are necessary for the monitoring of new and existing immunization programs and to optimize immunization program management and delivery.

In order to establish and maximize the potential of immunization registries, strong legislative and policy supports for the collection, use and sharing of immunization information are needed. Key components of the legal framework should include data security, consent and privacy procedures to maintain data confidentiality and integrity, as well as guidance on ethical and responsible data access, entry and use.[85,86] Ensuring legislation and policies clearly describe how the information will be used and who will have access would streamline information sharing processes and serve to build public trust by providing clarity on the use of personal health information.[4] Additionally, policies and legislation that outline minimum key data elements for entry into the immunization registry would support interoperability with existing health information systems and facilitate robust vaccine surveillance activities (e.g., safety monitoring).[87]

Aside from the *COVID-19 Vaccination Reporting Act* passed in 2021,[8] Ontario does not have any legislative requirements for the comprehensive capture of all vaccines administered in Ontario in an immunization registry for all age groups. For example, the *Childcare and Early Years Act (CCEYA)* notes that operators should collect early childhood immunizations and exemptions but does not define required data elements.[37] In contrast, the *Immunization of School Pupils Act (ISPA)* explicitly indicates that public health units (PHUs) are required to capture specific immunization details for all students for select designated diseases (e.g., immunizing agent, date, vaccine reactions, exemptions).[36] Despite this, immunization records for children and adolescents in the Digital Health Immunization Repository (DHIR) often remain incomplete as health care providers are not required to report immunizations under either the CCEYA or ISPA. Thus, the onus for reporting their child's immunizations to public health falls to parents or guardians.

Furthermore, Ontario does not currently have legislation or policies to support the capture of individual-level immunization data for vaccines administered as part of Ontario's publicly-funded adult or high-risk vaccine programs (e.g., respiratory syncytial virus, herpes zoster or pneumococcal conjugate vaccines), limiting opportunities to evaluate these programs. Monitoring and evaluating the uptake, safety and effectiveness of high-risk and adult immunization programs is essential for determining the duration and degree of protection offered by vaccines to ensure they are having their intended effect, which is particularly important for older adults who are more susceptible to infection and whose immune response to vaccinations weakens with age through a process called immunosenescence.

In Ontario, the Ministry of Health is not the sole health information custodian of immunization data and governance of immunization records are spread across several authorities and immunizers, including the Ministry of Health (e.g., COVID-19), PHUs (e.g., childhood and school-based immunizations entered in the DHIR) and health care providers (e.g., vaccines captured in electronic medical records).[88-90]

Public Health Ontario is responsible for preparing provincial immunization coverage surveillance reports,[89] but these reports are currently limited to immunization records reported in the DHIR or COVaxON.[39,40] As immunization data for people in Ontario are fragmented with no single repository or system containing complete information, assessing an individual's full vaccination history, such as when they are hospitalized with invasive vaccine-preventable disease or when case and contact management is performed during outbreaks, is often challenging.

Canadian provinces and territories with strong, enabling policies and legislation for immunization tend to have more comprehensive capture of immunization data in their immunization registries. In Ontario, the *COVID-19 Vaccination Reporting Act* mandated the reporting of all COVID-19 vaccines administered in Ontario and outlined information required to be documented in COVaxON.[8] Similarly, the *Alberta Public Health Act* and *Quebec Public Health Act* clearly outline health care provider responsibilities to report immunizations.[91,92] These acts contain detailed legislation to support data collection in their respective provincial immunization registries, including: reporting timelines; required client and immunization event information (e.g., date of birth, vaccine product name, vaccine lot number, injection site); and other relevant clinical documentation (e.g., intent to vaccinate, refusals, contraindications, consent). Similar changes to legislation and policies would be required to support a comprehensive immunization registry in Ontario encompassing all publicly-funded and privately purchased vaccines.

Recommendation 3: The Ontario Ministry of Health should consult and work in partnership with key immunization interest holders locally, provincially and nationally to ensure that all health care providers, local and provincial public health and members of the public have timely and equitable access to individual-level immunization records.

Several distinct user groups, each with unique uses and specific requirements of a registry, would need authorization to enter and access data contained within a provincial immunization registry (Figure 1 and Table 2). These would include key immunization interest holders such as individuals, health care providers, public health authorities and researchers. Ideally, a provincial immunization registry would have a secure public-facing portal to ensure that individuals and families have timely and equitable access to their personal health information. Additionally, health care providers would require access in order to provide a high standard of care for their patients. Providing all people in Ontario and their health care providers with timely and equitable access to their personal immunization record would empower individuals to take charge of their health.[93] Such information access would ensure that all individuals can be appropriately assessed and immunized at every health care encounter, regardless of the provider or setting, thereby improving vaccine convenience, uptake and equity. Public health authorities at the local (e.g., PHUs) and provincial (e.g., Ministry of Health through Public Health Ontario) level require access to monitor immunization coverage, inform evidence-based program and policy decisions, and ensure return on investment for our publicly-funded immunization programs. Subject to data governance and sharing agreements, a provincial immunization registry could potentially facilitate sharing of immunization data at a national level with the Public Health Agency of Canada and other provinces and territories. Researchers also require access to de-identified data in order to carry out vaccine effectiveness, modelling and program impact studies and cost-effectiveness analyses.

To develop an interconnected system with multiple user groups, the Ontario Ministry of Health must carefully consider users' needs and the required technical specifications, desired functionality and outputs. They should engage with key immunization interest holders and collaborate with IT experts and data management specialists early in the development process to establish this foundation. They should also consult with members of the public to ensure that the public-facing portal is usable and the development process is transparent. Furthermore, Indigenous groups (First Nations, Inuit and Métis) should be engaged to ensure that the data governance framework supporting the provincial immunization registry is aligned with OCAP (ownership, control, access and possession), OCAS (ownership, control, access and stewardship), and Guiding Inuit Qaujimajatuqangit (IQ) principles.[94-96] Public Health Ontario may also play a larger role in a future provincial immunization registry as part of its *Strategic Plan 2024-29* to lead provincial public health data transformation.[97] Firmly establishing the IT, data management and functional requirements of an immunization registry will guide the successful development of an efficient, interoperable and user-friendly system that will address the needs of intended end-users and ensure timely and equitable access to immunization information.

Recommendation 4: Technological innovations should be leveraged and implemented to ensure that a provincial immunization registry is accessible, adaptable, secure and scalable and reduces the burden on health care providers to enter and access data.

Ontario's *Digital First for Health Strategy* includes plans to expand data access for patients and improve data integration and interconnectivity for health care providers to access patient records and perform predictive analytics.[6] Currently, health care provider documentation and/or electronic medical record (EMR) systems are not routinely linked to the DHIR to enable the timely flow of vaccine doses delivered in settings outside of PHUs. To align with the vision for Ontario's digital health reform, new and/or existing technological innovations must be leveraged to ensure seamless integration and compatibility between different sources of immunization information. These sources include immunization records in the DHIR and/or EMRs, physician billing claims for vaccines submitted to the Ontario Health Insurance Plan (OHIP), and pharmacy reimbursement claims for publicly-funded pharmacy drugs and services (e.g., vaccines and immunization services) contained within the Digital Health Drug Repository (DHDR).[7,98,99]

As detailed above, Manitoba's Panorama-based immunization registry is integrated with several health and billing system databases to ensure the comprehensive capture of immunization data across the province (see Case Study: Manitoba Public Health Information Management System). In the same way, existing systems and health information repositories in Ontario must be leveraged to allow for the comprehensive capture of immunization data in a provincial registry, while facilitating health care provider access, minimizing new IT infrastructure requirements, and reducing the burden of provider-based data entry (e.g., linkages between DHIR and the OHIP-billing data, OHIP eligibility database, DHDR and EMRs). During the COVID-19 pandemic, the provincial COVID-19 immunization registry (COVaxON) was integrated with the DHDR allowing authorized health care providers to view their patients' COVaxON record in real-time through ConnectingOntario Clinical Viewer or Clinical Connect™ or select primary care OntarioMD-certified EMRs.[7,98,99] This linkage illustrated the utility of integrating existing health information systems with immunization registries to facilitate access to vaccine information.

Several factors must be carefully considered to accomplish seamless connectivity and/or integration of systems to an immunization registry. For instance, in 2017, eHealth Ontario developed a health care provider reporting program, ICON for Health Care Providers (ICON-HCP), to capture childhood immunizations for ISPA-designated diseases administered by physicians and nurses.[100,101] However, this program was not compatible with all provincial EMRs and vaccine product names were not standardized across EMR systems. This example illustrates why consulting with key interest holders (e.g., front-line health care providers, IT specialists) early in the development process to identify technological and system requirements will be critical. Efforts should be made to minimize manual and/or redundant provider documentation to reduce administrative workloads for front-line health care providers and public health. Other important considerations include using standard vaccine terminology (e.g., SNOMED Clinical Terminology [CT]) across health records and developing specific OHIP-billing codes for all vaccines that will feed into the immunization registry.[44,102,103]

Recommendation 5: The Ontario Ministry of Health should adopt the *Canadian Immunization Registry Functional Standards* as a preliminary framework for developing a provincial immunization registry. Functional standards to support vaccine inventory and supply chain management and vaccine-preventable disease case and outbreak management should be incorporated and remuneration for health care providers related to immunization administration should be integrated.

The Canadian Immunization Registry and Coverage (CIRC) Network developed the *Canadian Immunization Registry Functional Standards (IRFS) 2020 – 2024* to support the development of an interconnected network of immunization registries across Canada.[104] The IRFS consists of 15 functional standards, organized into four overarching goals, which describe the minimum functional capabilities of an immunization registry required to support immunization providers, vaccination programs, Canadian consumers and other immunization interest holders (Appendix A). The overarching Canadian IRFS goals for immunization registry functionality include: (1) supporting the delivery and capture of immunization records and services at the point of service delivery, regardless of the care setting; (2) maintaining standards-based, complete, accurate and timely data on all clients and immunization services delivered; (3) providing reliable digital access and exchange of electronic immunization information across all health provider types with other jurisdictions (including federal), consistent with current legislative and interoperability standards requirements; and (4) supporting timely and accurate adverse events following immunization (AEFI) reporting.[104]

While the IRFS provide a comprehensive framework of registry functions, other functionalities should be considered to support the management and surveillance of vaccine programs in Ontario, including:

- **Vaccine inventory and supply chain management.** Real-time and accurate information about Ontario's vaccine inventory would provide a clear line of sight into incoming and outgoing vaccine doses, prevent vaccine wastage, improve demand forecasting and ensure sufficient vaccine supply.[28] In 2015, the British Columbia Ministry of Health evaluated the vaccine inventory module in Panorama and projected an annual savings of approximately $2 million in reduced vaccine wastage, returns and improved productivity.[28] While Ontario also uses the inventory module in Panorama, it does not regularly track individual doses. Ontario has historically had challenges with vaccine inventory management and wastage. The 2014 Annual Report of the Office of the Auditor General of Ontario found that of the 4.6 million influenza vaccine doses purchased during the 2013-14 season the Ontario Ministry of Health wasted 584,000 doses and could not account for almost 961,000 doses.[21]

Similarly, in 2022, the Ontario Auditor General noted that the lack of integration of the vaccine inventory component of COVaxON to all systems in the supply chain led to inaccurate estimates of COVID-19 vaccine inventory and poor forecasting of public demand for vaccines, which contributed to vaccine wastage.[22] These examples underscore the value that an integrated vaccine inventory and supply chain management functionality could bring to the immunization system in Ontario.

- **Assessment of vaccination status for vaccine-preventable disease case and outbreak management.** Rapidly assessing vaccination status and following up with susceptible individuals is an integral part of case and contact management and outbreak responses. An immunization registry would reduce the administrative workload associated with accessing, entering and assessing immunization records for cases and contacts and would preserve local PHU capacity for other public health programs, benefiting individuals, families and communities across Ontario. The United States' *Immunization Information System Functional Standards* facilitate immunization program activities in schools and childcare settings (e.g., identification of children at risk, compliance with legislation) and support public health responses during disease outbreaks (e.g., leveraging existing vaccine inventory, rapid assessment of immunization status).[105] Similarly, the *Australian Immunisation Register Act* also requires functionality to identify regions at risk during outbreaks (e.g., areas with low vaccine uptake).[106] This functionality would greatly facilitate timely and efficient outbreak response and minimize the cost and workload associated with carrying out case and contact management.

  For instance, during a 2015 measles outbreak in Toronto, the absence of a comprehensive provincial registry challenged Toronto Public Health's ability to efficiently manage the outbreak response. Due to the inability to easily assess an individual's immunization status, Toronto Public Health was required to call and send letters to over 1,500 high-risk contacts to ensure appropriate medical follow-up, which led to significant delays in identifying under-immunized individuals for post-exposure prophylaxis and overwhelmed public health capacity of the PHU.[107] In contrast, the New York Citywide Immunization Registry allowed that jurisdiction to efficiently manage the public health response to an outbreak of measles in New York City that occurred between September 2018 and July 2019. Their registry collects data on all vaccine doses administered to children 18 years of age and under within 14 days of administration and was used to determine the immunization status of cases and contacts, provide data on immunization coverage, and assess the impact of vaccination on limiting disease spread.[108]

- **Integration with health care provider remuneration or billing systems.** Integrating the provincial immunization registry with health care provider remuneration or billing systems would facilitate tracking of immunization-related services, provide an incentive for maintaining complete immunization records, and reduce duplicating administrative tasks and workload associated with documenting vaccines in more than one system (i.e., EMR, health care provider billing and immunization registry systems). Both the Australian Immunisation Register and the United Kingdom's Child Health Information System require health care providers to report administered immunizations to receive compensation.[106,109]

  These linkages would provide an additional data stream to assess immunization coverage and program impact. However, in Ontario, not all health care providers use OHIP billing codes for vaccine services (e.g., public health, workplace clinics and other non-fee for service providers) and there are small financial incentives for fee-for-service providers to administer and bill for vaccines. For this reason, OHIP billing data alone would not be sufficient for monitoring and evaluating immunization programs and has only moderate sensitivity.[43]

Recommendation 6: A provincial immunization registry should support interoperability within and between organizational and jurisdictional boundaries to allow for secure access and confidential exchange of immunization data, including standardized data elements and vaccine terminology. Routine integration of an immunization registry with other health data systems is recommended to maximize the individual- and population-level health benefits of vaccines.

While almost all provinces and territories have an electronic immunization registry, they differ with respect to the vaccines and/or vaccine programs captured, providers who can access these data, and linkages to other data systems. Ontario's current DHIR is quickly becoming ineffective and outdated due to the increasing complexity of immunization delivery and need for flow of information between immunizers, health care providers, public health authorities and other health system users. Efficient and secure transfer of information between the immunization registry and linked systems (e.g., OHIP billing, EMR, pharmacy documentation systems) and other data sets (e.g., those held at ICES, a health services research institute with access to record-level, coded and linkable health datasets) would be essential to maximize the benefit of a provincial immunization registry.[110,111] Routine linkages to the OHIP eligibility database, which provides information on all individuals registered under OHIP and those who are eligible for the Ontario Drug Benefit program, would ensure that all people in Ontario are captured in the immunization registry from birth and allow all providers to assess a patient's immunization status.[46]

Interoperability is defined as the ability of computer systems and software products to seamlessly exchange and make use of stored data. Interoperability of immunization data would require the adoption of standards and processes (e.g., best practices for data entry) that would ensure compatibility, privacy and secure data transfer between systems.[87] As identified through the challenges with the implementation of ICON-HCP, adopting standardized vaccine terminology (e.g. SNOMED Clinical Terminology[CT]) and clearly delineating national immunization data elements to be entered is necessary to facilitate the transfer and consistency of data across linked systems.[102-104,112] This interoperability would support federal initiatives that are currently underway to give Canadians access to their digital immunization record and facilitate interprovincial data sharing when individuals move across the country. The exchange of confidential immunization data between organizations and jurisdictions would require data governance and data sharing agreements to be established and strict privacy policies to be put in place. To ensure secure access to health data, trustworthy digital identities must be established for all users. Infrastructure for consent and data access management that can be tailored according to user roles must also be in place to support online access to information.

Case Study: Interoperability of the Nova Scotia Immunization Registry

Nova Scotia implemented Panorama as its provincial immunization registry between 2017 and 2018. The Nova Scotia provincial immunization registry captures all publicly-funded or privately purchased vaccines through linkages and interoperability with the following systems:

Physician EMRs: Automated entry of vaccination information is available for EMRs that have been verified through the Electronic Medical Records and Integrated Solutions program. The Electronic Medical Records and Integration Solutions is a digital health program under the Department of Health and Wellness that works with EMR vendors and advisors to ensure the privacy and security of EMRs, interoperability of EMRs with existing system (e.g., Panorama), and appropriate capture of health data in accordance with provincial standards.[113,114]

CANImmunize: Nova Scotia has partnered with CANImmunize and utilizes the ClinicFlow software to schedule mass immunization clinics, book online vaccine appointments (i.e., COVID-19 vaccines), manage consent and clinical documentation, and organize provider billing for publicly-funded vaccines.[115] Updated digital extracts are transferred nightly from CANImmunize into Panorama.[116]

Drug Information System: The Nova Scotia Drug Information System is a province-wide system that contains a complete medication profile for anyone filling a prescription from a community pharmacy in Nova Scotia.[117] Privately purchased vaccines billed through a drug plan that are captured by pharmacy systems feed into the Drug Information System and are uploaded to Panorama.

Recommendation 7: An interconnected provincial immunization registry should provide real-time, individual-level immunization data to individuals and an expanding network of immunizers, with connections for clinical use, immunization program monitoring and evaluation, and research. This includes monitoring of inequities in vaccine coverage, assessment of vaccine program impact, and real-time vaccine safety surveillance for maintaining public confidence in vaccines.

In Ontario, vaccines may be administered by several health care providers, but most often are given by public health nurses (e.g., school-based programs) or primary care providers (e.g., routine childhood and adult vaccinations). Given the range of authorized immunizers and points of administration across the province, along with an expanding network of immunizers (e.g., pharmacists, midwives), it is essential for an immunization registry to have routine linkages and interconnectivity with various systems (e.g., physician billing systems, EMRs, pharmacy systems) to optimize data flow and access to immunization data. Individual-level immunization information within an interconnected, provincial immunization registry is fundamental for evaluating immunization programs, conducting surveillance, maintaining continuity of care across the health system, and identifying strategies to address vaccine hesitancy and health inequities in vaccine access and coverage.[118]

With vaccine hesitancy becoming a growing concern,[119,120] timely and accurate data on vaccine safety and effectiveness is needed to promptly address emerging safety signals and maintain public confidence in vaccines. This includes identifying individuals and communities with low vaccine uptake for targeted outreach and addressing challenges and barriers to vaccination. An interconnected provincial immunization registry infrastructure is also critical to monitoring and assessing the impact of new immunization programs. During the COVID-19 pandemic, surveillance outputs produced using data from COVaxON were used to quickly identify cohorts, communities and other equity-deserving populations with low vaccine uptake or at higher risk of exposure or severe disease, which allowed for vaccine policies to be adjusted and implementation approaches to be prioritized and targeted during periods of constrained supply and heightened epidemiologic risk.[63-66] Similarly, passive vaccine safety surveillance using individual-level immunization data from COVaxON linked to AEFI data was used to rapidly identify product-specific vaccine safety signals, which led Ontario and the National Advisory Committee on Immunization to issue preferential recommendations for COVID-19 vaccines in near real-time.[53,67,68] In addition, individual-level immunization data allowed researchers to evaluate vaccine effectiveness, optimize scheduling, and inform provincial vaccine program recommendations, including the need for additional doses.[54-60] COVaxON also allowed health care providers to assess immunization status in real-time and offer vaccine to individuals at every health care encounter.

Conclusions

Immunization registries are essential for maximizing the benefits of vaccines in the 21st century.[1] An immunization registry would provide more efficient and accessible health care for people in Ontario and protect them from vaccine-preventable diseases, improve efficiencies within Ontario's health system, and allow for comprehensive program monitoring and evaluation of vaccine uptake, safety and effectiveness. The timely use and sharing of immunization data has the potential to improve health outcomes for individuals and families and increase efficiency in the assessment and delivery of vaccines at every health care encounter. Moreover, implementing a comprehensive immunization registry is aligned with Ontario's broader public health and digital health strategies, which seek to integrate and improve access to health information across the health system for the effective and coordinated delivery of health care services to everyone in Ontario.[3-6]

An immunization registry would ensure that all people in Ontario and their health care providers have equitable and timely access to their comprehensive immunization record, particularly for our high-risk and adult immunization programs which are not currently captured in Ontario's Digital Health Immunization Repository. Early engagement with communities and Indigenous groups will be needed to ensure that data governance frameworks are aligned with OCAP (ownership, control, access and possession), OCAS (ownership, control, access and stewardship), and Guiding Inuit Qaujimajatuqangit (IQ) principles.[94-96] With a growing number of vaccine programs and settings in which vaccines are being offered, Ontario needs strong leadership and commitment for a long-term, consistent and sustainable strategy to capture and access immunization data across the health system.

The last two decades have been marked by outbreaks and pandemics of emerging, re-emerging and endemic pathogens, including several public health emergencies of international concern.[73] Travel and social networks have increased the likelihood of imported disease and transmission; yet, systems to assess immunization status in real-time or identify unimmunized or under-immunized individuals are not timely or readily available. The COVID-19 pandemic response illustrated that a scalable, provincial immunization registry is foundational for health system functioning and has affirmed recommendations made by other provincial and national expert advisory committees and professional associations over the last three decades – that a comprehensive immunization registry is urgently needed in Ontario.

Glossary of Terms

AEFI	Adverse Event Following Immunization
CCEYA	Child Care and Early Years Act
CIRC	Canadian Immunization Registry and Coverage Network
DHDR	Digital Health Drug Repository
DHIR	Digital Health Immunization Repository
EMR	Electronic Medical Record
FNIHB	First Nations Inuit Health Branch
ICON	Immunization Connect Ontario
ICON-HCP	Immunization Connect Ontario for Health Care Providers
IRFS	Immunization Registry Functional Standards
ISPA	Immunization of School Pupils Act
IT	Information Technology
OHIP	Ontario Health Insurance Plan
OIAC	Ontario Immunization Advisory Committee
PHIMS	Public Health Information Management System
PHU	Public Health Unit
SARS	Severe Acute Respiratory Syndrome
SNOMED CT	Systematized Medical Nomenclature for Medicine – Clinical Terminology

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Appendix A: Canadian Immunization Registry Goals and Corresponding Functional Standards 2020-2024

Immunization Registry Goal #1: The immunization registry supports the capture of immunization records and the delivery of immunization services, regardless of care setting.

#	Functional Standards
1.1	The immunization registry provides complete and accurate individual immunization records for people of all ages, accessible to authorized users before and at the point and time where immunization services are being delivered.
1.2	The immunization registry has the ability to capture both historical and current immunization services.
1.3	The immunization registry has an automated function that determines vaccines eligible, due or overdue (vaccine forecast) in a manner consistent with current jurisdictional immunization schedules or national guidelines. Results of the forecaster are displayed to authorized user each time a client's record is viewed and can enable the production of reminder or recall notifications.

Immunization Registry Goal #2: The immunization registry maintains standards-based, complete, accurate and timely data on all clients and immunization services delivered

#	Functional Standards
2.1	The jurisdiction has policies or legislation in place regarding the requirement of all immunization providers, regardless of setting, to submit standards-based, complete, accurate and timely records for all immunization services delivered.
2.2	The immunization registry captures and exchanges consolidated immunization records from all source databases for people of all ages within the jurisdiction.
2.3	The immunization registry has rules in place that will automatically identify, prevent and resolve duplicate client records or vaccination events and flag invalid doses and unsuccessful exchanges of information.
2.4	The immunization registry, at a minimum, can capture and exchange client-specific data for all immunization registry National Immunization Data Elements (see Appendix A), to the extent permitted by provincial or territorial law.
2.5	The immunization registry captures and exchanges immunization and demographic information with the authorized systems and users to facilitate tracking and sharing of vaccination events, regardless of provider. The process by which immunization records are updated or exchange should be timely.
2.6	The immunization registry provides authorized users with an accurate numerator for the estimation of coverage at the population level to support and inform both the control and management of vaccine-preventable disease outbreaks and efforts to improve coverage of immunization rates. Denominator data will ideally be sourced from within the registry, however linkages to jurisdictional record-level population databases are also acceptable.

Immunization Registry Goal #3: The immunization registry proves reliable digital access and exchange of electronic immunization information across all health providers with other jurisdictions (including federal), consistent with current legislative and interoperability requirements.

#	Functional Standards
3.1	The immunization registry has documented authorization (for example, memoranda of understanding, interagency agreements, data sharing agreements) to request and receive immunization information from other immunization registries to the extent permitted by provincial or territorial law. • In jurisdictions where privacy laws prevent data sharing between registries without patient, parental or caregiver consent, but allow registries to share data to a third party with patient, parental or caregiver consent, processes will be developed to seek such consent. In such cases, once consent is granted, the information will be transferred directly from one registry to the other without further patient or parent intervention.
3.2	The immunization registry can query another immunization registry for an immunization history, to the extent permitted by provincial or territorial law.
3.3	The immunization registry can provide client demographic and immunization records to immunization registries in other jurisdictions for clients who reside in those jurisdictions, to the extent permitted by provincial or territorial law.
3.4	When the immunization registry receives queries or submissions from other health information systems, it can generate an automatic response in accordance with jurisdictionally agreed immunization interoperability standards for message content, format and transport.
3.5	The immunization registry can provide access for individuals to their personal records.

Immunization Registry Goal #4: The immunization registry supports timely and accurate AEFI reporting

#	Functional Standards
4.1	The immunization registry provides the necessary reports and functionality to facilitate investigations of AEFIs and vaccine recalls, when necessary, including the identification of recipients by vaccine product, lot, manufacturer, provider, or time frame.

Source: Public Health Agency of Canada. Canadian immunization registry functional standards 2020 to 2024: Recommendations from the Canadian Immunization Registry and Coverage Network [Internet]. Ottawa, ON: Government of Canada; 2021 [modified 2021 Jan 06; cited 2024 Jun 11]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-registry-functional-standards-2020-2024.html

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