The digital immunization system of the future: imagining a patient-centric, interoperable immunization information system

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Abstract: To ensure the effectiveness of increasingly complex immunization programs in upper-middle and high-income settings, comprehensive information systems are needed to track immunization uptake at individual and population levels. The maturity of cloud systems and mobile technologies has created new possibilities for immunization information systems. In this paper, we describe a vision for the next generation of digital immunization information systems for upper-middle and high-income settings based on our experience in Canada. These systems center on the premise that the public is engaged and informed about the immunization process beyond their interaction with primary care, and that they will be a contributor and auditor of immunization data. The digital immunization system of the future will facilitate reporting of adverse events following immunization, issue digital immunization receipts, permit identification of areas of need and allow for delivery of interventions targeting these areas. Through features like immunization reminders and targeted immunization promotion campaigns, the system will reduce many of the known barriers that influence immunization rates. In light of the global COVID-19 pandemic, adaptive digital public health information systems will be required to guide the rollout and post-market surveillance of the SARS-CoV-2 vaccine.

Keywords: health technology, health information systems, immunization, public health practice

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Introduction

It is widely recognized that immunization is one of the most successful public health interventions in medical history. Immunization programs have been credited with reducing morbidity and mortality from several pathogens, including the complete or near eradication of infectious diseases such as smallpox and polio.[1] However, to continue making progress in the face of an increasingly complex immunization reality in upper-middle and high-income settings, effective systems are needed for tracking immunization uptake at individual and population levels.

Immunization Information Systems (IISs) are centralized repositories of personally identifiable vaccination information for individual members of a served population.[2,3] Many jurisdictions have developed and implemented IISs over the past few decades, but despite international guidance and defined standards, the features and functionality of these systems vary.[4–8] The original vision of an IIS was to function as a database used by public health officials to calculate population coverage rates. However, with advances in technology, they can now serve a variety of functions. Jurisdictions should be viewing their IIS as a tool
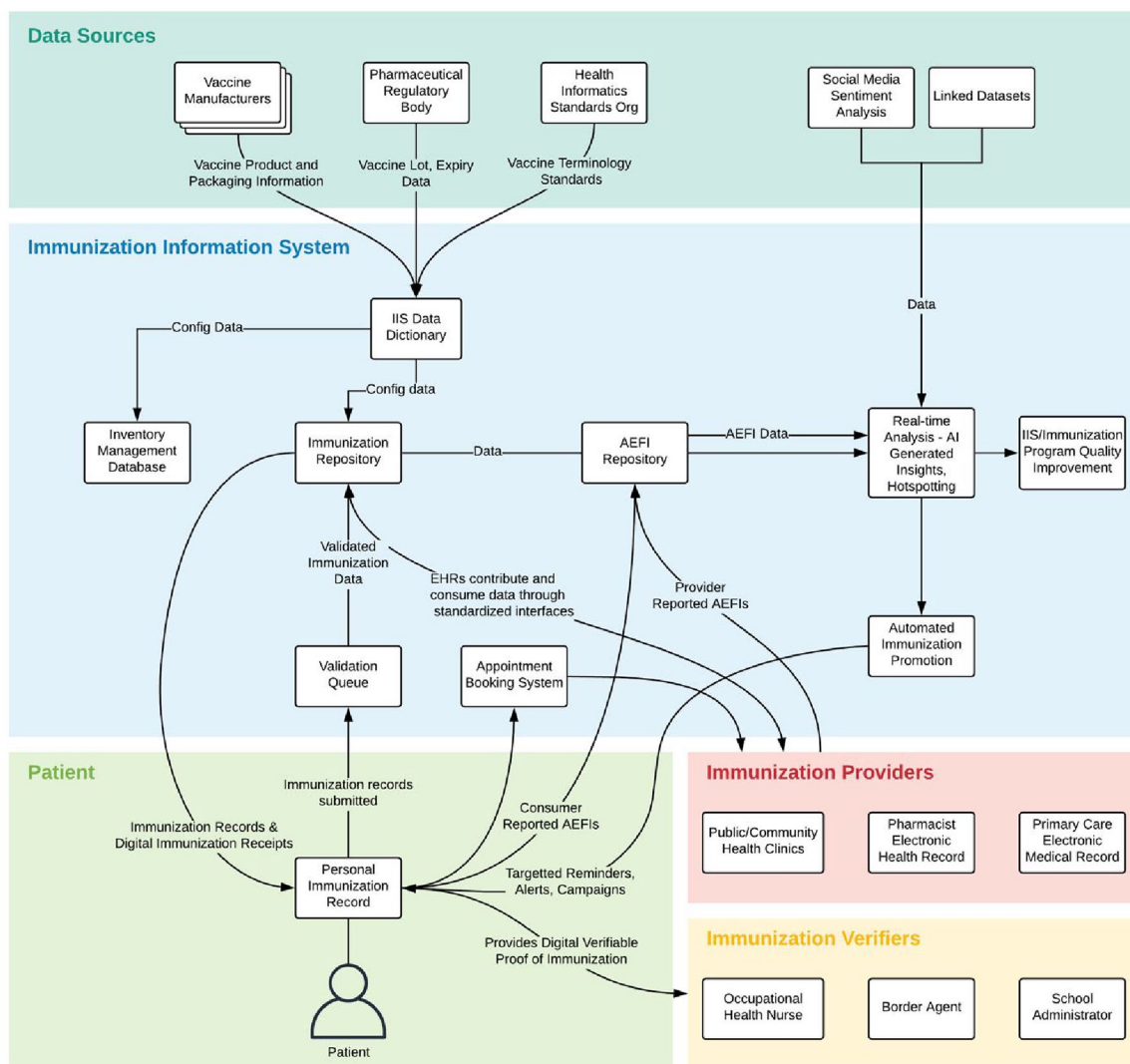
Figure 1. Data sources and components of a modern immunization information system.
AEFI, adverse events following immunization; AI, artificial intelligence; IIS, immunization information system.

to evaluate vaccine effectiveness and safety, as well as an instrument to improve coverage rates and combat vaccine hesitancy.[9,10] IISs can identify certain populations by geographic, demographic or behavioral characteristics who are at risk for under-immunization. This is particularly useful at local levels (i.e. state or provincial), as overall coverage rates may not identify pockets of suboptimal coverage in smaller geographical regions.[11]

In this paper, we describe a vision for the next generation of digital IISs (Figure 1) for upper-middle and high-income settings based on our experience developing solutions for Canada.[12–17] These systems will provide a centralized immunization record that is accessible to the patient, healthcare providers, and the responsible public health authority in real time. Each immunization will be tracked through the supply chain and into the arm of the patient. They will be built on the premise that the public is engaged and informed about the immunization process beyond their interaction with primary care, and that they will be a contributor and auditor of the immunization data contained in the repository. Digital IISs will enable novel ways to track the safety and effectiveness of vaccines by leveraging real-time data

analysis and artificial intelligence (AI) to detect issues as they arise. The system will automatically identify areas or populations with suboptimal vaccine uptake and will prompt public health officials to intervene through both traditional health promotion campaigns and modern digital marketing techniques. These systems will incorporate comprehensive consent management frameworks that track consent for immunization, exemptions, and disclosure of immunization records. Through features like immunization reminders and targeted promotion campaigns, the system will make immunization easier for people to navigate and reduce many of the known barriers that influence immunization rates. By issuing digital verifiable immunization receipts, they will help patients attest to their vaccination status throughout the course of their lives, which may be required in pandemic scenarios, when registering for school, starting with a new employer, or crossing international borders. These systems will inevitably be built into broader population health management platforms that become ingrained into how public health authorities perform their duties and interact with the public. Ultimately, these systems will improve immunization practice by automating and streamlining the role of public health and by providing the public with tools that empower and engage them in the immunization process.

Challenges faced by existing IISs

IISs are core components of any immunization program, and reflecting their importance, several guidance documents have been published on the design and structure of these systems.[6,18–22] However, today's IISs face many challenges that systems of the future will need to address, including the ability to capture quality data, enhancing interoperability, and logistical and policy issues.

Capturing quality data

For an IIS to be effective, it must contain high quality and comprehensive data. This process starts at the time the immunization is administered and is usually the responsibility of the vaccine provider, which has traditionally included public health workers, nurses, or physicians. However, delivery of immunizations has become highly fragmented, with multiple providers administering vaccines.[23,24] This includes family physicians, pharmacists, workplace and school-based programs, travel medicine clinics, and, increasingly, dentists.[25]

Studies have shown that 10–60% of immunization records lack important information or contain errors.[26–29] One source of error is when vaccination details, such as patient demographics or the small print on vaccine vials for lot numbers, have to be manually entered into an IIS. As the number of providers administering vaccines grows, so do the challenges.

There are several challenges at the data capture phase. First, healthcare providers must be aware of what data they are required to record, as well as have access to tools that make it easy for them to adhere to these requirements that fit into their existing workflows. This requires the governing body of the IIS to decide upon a set of minimum core immunization data elements and ensure that these requirements are built into the electronic medical record (EMR) software that is used by providers.

Tools like 2D barcoding have been leveraged to help streamline and improve data entry for providers, but the practice has been sparsely adopted in primary care in Canada and the United States (US).[26,30–32] In settings where barcode scanning is widely adopted, like hospitals and pharmacies, it should be used as a means for data entry into the IIS. Barcode scanning of vaccination vials offers the opportunity to limit missing data and transcription errors by directly uploading product information into the IIS.

Interoperability

The concept of interoperability, defined as computer systems or software products that seamlessly exchange and make use of stored data, is still nascent in healthcare settings.[33] The siloed nature of health data repositories today will quickly become outdated as standards and infrastructure evolve to facilitate the free flow of data while maintaining the privacy and security of patient data. Challenges to enable widespread access to health data include developing trustworthy digital identities for patients and establishing consent management infrastructure to support online access to health data.

Enabling interoperability among IISs requires the adoption of standards and processes that can be easily communicated to other systems. IISs require a large amount of configuration data that is used to key the immunization records they contain. For instance, an IIS will often need to be configured with clinical terms for immunizing agents (vaccine products), antigens, diseases, routes of administration, anatomical sites, as well as with vaccine product information such as available lot numbers, expiry dates, and vaccine packaging identifiers like Global Trade Item Numbers (if the IIS is also responsible for vaccine inventory management). This data is dynamic as new vaccines enter and leave the market, requiring IIS administrators to be constantly updating this information. This task is further complicated by the variety of sources from which this configuration data originates. The information about lot numbers and vaccine product status is often made available by the pharmaceutical regulator, while clinical terminology is most often governed by a health informatics entity. Meanwhile, vaccine packaging information needs to be aggregated from each vaccine manufacturer. In order for IISs to be interoperable with each other, downstream clinical systems, or consumer applications, this information needs to be aggregated and published on a regular basis.

Logistical and policy challenges

Increasing population mobility, both domestic and foreign, presents challenges for capturing comprehensive immunization data and understanding vaccine coverage. Those related to domestic mobility of individuals within and between jurisdictions (particularly among certain populations such as those who are homeless, undocumented or move frequently)[11] are both a product of the lack of interoperability between systems described above, and the fact that we are still in the period of transition from paper to digital. Challenges associated with foreign mobility can be more complex. Particularly among undocumented migrants and refugee populations, determining accurate vaccination coverage can be difficult in cases where they are hesitant to register with health authorities, or there is a lack of coordination in recording multiple doses that are often administered by multiple providers.[34] Public health authorities may also encounter difficulties interpreting immunization records that are in foreign languages, contain unfamiliar vaccine products, or have different vaccine terminology.[35] Alternatively, migrants may not have any record of vaccination upon arrival to a new country despite being previously immunized. Not only is this a common source of confusion for healthcare providers, who must determine an appropriate catch-up schedule, it may also lead to over-immunization. IISs of the future can assist in these challenges by enhancing interoperability among jurisdictions and automating many of these tasks using AI.

Repositories often rely on historically reported immunization records either directly from the public or from providers. This leads to the challenge of determining what constitutes a legitimate or trustworthy record, especially in the context of patient-reported data.[36] In some IIS systems, like the Digital Health Immunization Repository (DHIR) in Ontario, Canada, this has led to the creation of a validation queue, where a public health nurse reviews all patient submitted immunization records prior to including them in the repository.

Further complicating matters are increasingly complex immunization schedules and changes to these schedules, the broader number of available vaccines, and the introduction of vaccines targeted at populations besides children (i.e. adolescents, pregnant women, adults, seniors), which can vary from nation to nation, and even region to region (e.g. states, provinces, cantons). Overlaying this is the spectre of vaccine hesitancy, which is an ongoing threat to the success of population-based immunization programs.[37–39] Simultaneously, expectations of the public are changing where citizens want to have access to their health data.[40] This, in combination with the digital health revolution, creates opportunities to transform immunization systems by creating digital citizen access and virtual connections between the public and health systems.

A digital immunization system of the future

Connecting the public, healthcare providers, and public health: simultaneous access to immunization records

At present, IIS development has focused on meeting the needs of public health officials with

the objective of calculating coverage rates. Often, this data remains only accessible to public health authorities. We believe a modern IIS should facilitate simultaneous access by the public, healthcare providers and public health, which would maximize the collection and utilization of these data.[2,5,41,42] This would be achieved through a set of interoperable systems (Figure 1), rather than a single monolithic system. Each stakeholder (healthcare providers, public health, and individuals) would be using a system specifically designed to meet their workflow. For example, this could be an EMR in a healthcare provider clinic, a database for public health, and a personal immunization record for patients on the web or a mobile app. Through application program interfaces, information would flow between these systems such that the information is available to all stakeholders, digitally, and in real time. If a vaccine is administered by a physician and entered into a clinic EMR, it would flow to both public health officials and the recipient of the vaccine through their personal immunization record. The source of the information would be visible to all parties and un-editable (view only) in the recipient system. Thus, your family physician could be digitally informed that you received your influenza vaccine at a connected pharmacy. Reporting from both healthcare providers and the public would provide a more accurate and complete dataset for public health officials to examine population coverage, vaccine safety, and vaccine effectiveness.

Citizen access to medical data is becoming popular, and the most common approach to providing access is through a consumer health portal or viewer. While this is an improvement over the status quo, real interoperability and patient-centered technology will give the patient ownership and custodianship of the record in an unlimited sense. With a personal immunization record, patients will be free to store the record where they choose, in the format they choose, and to provide this record to applications of their choice that may provide additional services beyond what can be provided by public health authorities.

Consent directives. With the storage of personal health information and consent for immunization in an IIS comes the importance of developing processes and procedures to manage consent directives across the various systems. A consent directive is a "patient's instruction to block or access to their personal health information".[43] While consent directives are a simple concept, numerous scenarios in immunization practice can present challenges for system design and governance. They should account for information sharing among systems as well as within family units, such as between guardian and child. For example, under the Family Educational Rights and Privacy Act (FERPA) in the US, school-reported immunization records are separate from medical record systems and generally cannot be imported into an IIS; therefore, capturing consent directives from parents to report school-based immunizations to the IIS would be an important issue to address. As another example, if a parent does not consent for their teenager to receive an HPV vaccine, but the adolescent (who would be acting as a mature minor) provides consent themselves, both the consent for service and the HPV dose should be blocked from being communicated back to the parent from the IIS. However, a sudden and full revocation of the record from the parent would likely draw attention to the mature minor's action and result in unintended negative consequences. The IIS should be able to manage consent directives at the level of record, dose, and accessor. In circumstances where a child's custody arrangement changes, the system must be able to block information from flowing to the non-custodial parties on the date that the arrangement changes but leave the information available to the custodial parties.

Building suites of interoperable systems has traditionally been challenging.[44] The migration to cloud-based platforms will accelerate interoperability and real-time data transmission.

As the immunization data would exist in several systems simultaneously, it is crucial that clinical terminology standards are employed. This would preserve data integrity (i.e. this dose of MMR is still the same dose of MMR in each system) while allowing for "viewer customized" terms in each system. For example, the consumer solution could display "patient friendly" terminology, while the IIS would show much more detailed information on the dose. In Canada, we have developed the Canadian Vaccine Catalogue (Box 1) which provides standards for systems, as well as the mapping between standards and variable product data.

Box 1. The Canadian vaccine catalogue..

The Canadian Vaccine Catalogue
The Canadian Vaccine Catalogue provides access to up-to-date vaccine terminology standards and vaccine product information. This content is needed by electronic health record vendors and immunization system implementers to build and configure systems that capture and exchange immunization records across health care domains and jurisdictional borders, in compliance with the standards and core data elements that have been set by the Canadian Immunization Committee. The CVC content also facilitates vaccine barcode scanning for both inventory management and immunization administration.

Objectives of the CVC
- **Improve the data quality of immunization records captured in digital systems**
- **Improve the interoperability of immunization records across Canada**
- **Facilitate the use of standardized pick-lists for the collection of vaccine identifiers and product data**
- **Facilitate vaccine barcode scanning**

What is the CVC?
The CVC is a dataset that is aggregated from a number of different data sources to provide a comprehensive list of vaccine products in Canada, as well as information about those products, and standardized terminology to represent those products in digital systems. Each month, the following data is aggregated from its respective source, and published in a new version of the catalogue.

Health Canada
Health Canada provides lot numbers and expiry dates of all vaccine lots that are approved by the Biologics and Genetic Therapies Directorate. The CVC also leverages data available in the Health Canada Drug Product Database.

Public Health Agency of Canada
The Public Health Agency of Canada provides product information which it obtains through its relationships with vaccine manufacturers as a bulk purchaser of vaccines. This product information is submitted by vaccine manufacturers to the Public Health Agency *via* the GS1 ECCnet database. This information includes fields like Global Trade Item Number (GTIN), Drug Information Number, and other packaging specific fields.

Canada Health Infoway
Canada Health Infoway maintains the Pan-Canadian Immunization Reference Sets which are SNOMED CT terms for vaccine related concepts. The reference sets include subsets for historically reported vaccines, administered tradename vaccines, vaccine preventable diseases, and antigens. These terms are included in the CVC and mapped to the product data received from Health Canada and the Public Health Agency.
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Needs analysis, hot-spotting, and vaccine messaging to combat vaccine hesitancy

In addition to providing simultaneous access to data, the next generation of IISs will be an important tool in the fight against vaccine hesitancy and under-vaccination. Vaccine hesitancy was identified by the World Health Organization (WHO) as a top threat to global health in 2019.[45] Reductions in vaccine coverage for a variety of reasons have resulted in the resurgence of vaccine-preventable diseases – most notably measles – with important health consequences.[46–51] Given the breadth and complexity of factors at play, public health officials need to find innovative ways to address individual immunization knowledge, attitudes, and beliefs, which are intrinsically linked to their healthcare providers and surrounding environment.[52–54] The European Vaccine Action Plan 2015–2020 etches this sentiment as it identifies tailored, innovative strategies as critical in reaching population groups with suboptimal vaccination coverage.[55]

More accurate, real-time immunization coverage data, as well as the opportunity to conduct enhanced surveillance of IIS data, creates a path to address declining immunization coverage rates and tackle emerging vaccine hesitancy. It should be noted that not all relevant data may be present in the IIS, particularly in contexts without centralized national databases and where the IIS only contains information on immunization receipt. Therefore, linking additional sources to IIS data, such as other health and demographic data, may be required to enhance national representativeness and identify pockets of need. For example, data linkages identifying unimmunized children would be important to capture in the IIS to allow for immunization coverage "hot spotting." This would permit public health officials to detect

early trends in immunization sentiment or coverage (or lack thereof) in a specific region or population that could result in loss of herd immunity and predispose populations to vaccine-preventable disease outbreaks. Furthermore, the potential to link immunization repositories to disease testing results would permit correlating these results with vaccination status, allowing for better assessments of vaccine effectiveness.

Using machine learning, AI and social media sentiment analysis, we envision an automated system that can identify and analyze pockets of need (using geographic, demographic or gathering place information stored in the IIS). Upon identifying a pocket of need, health officials would design an intervention tailored to address the causes underlying suboptimal vaccine coverage.

While identifying pockets of need based on gathering place has traditionally been very challenging outside of schools and child care centers, the increasing use of contact tracing technology, as demonstrated by the response to COVID-19, may provide additional data regarding events or places of worship for public health to leverage in the future. Mobile digital contact tracing apps could mitigate issues associated with manual contact tracing, such as notification delay and recall errors, by allowing public health authorities to instantaneously and automatically notify individuals of possible exposure and ask them to self-isolate.[56] However, it is important to note the caveats to this approach, including privacy and security concerns, suboptimal sensitivity and specificity, and the need for widespread uptake in order to be effective.[57] Pending the resolution of these concerns, digital contact tracing has the potential to be integrated in IISs of the future to swiftly manage outbreaks of vaccine-preventable diseases and identify pockets of under-immunized populations. It is currently recommended, however, that digital contact tracing be used as a complement to traditional contact tracing methods.[57]

Sentiment analysis. Significant progress has been made in developing methods and a body of knowledge regarding sentiment analysis. For example, the Vaccine Confidence Project built an information surveillance system to detect emerging public concerns around vaccines.[58] They also apply a diagnostic tool to the data they collect to determine the risk level to vaccination programs. Using interviews, surveys, registries and social media content, their publications have summarized research on the impact of various vaccination initiatives on coverage rates and vaccine confidence.[59–61] They have also characterized important relationships between vaccine confidence and contextual factors, such as geographical proximity to vaccine-preventable outbreaks and political trends.[62,63] Findings have also reinforced early impressions that while social media and other Web 2.0 tools are promising to disseminate accurate information on vaccines, they have also become a tool that has been leveraged more effectively by anti-vaccinationists than public health.[64,65]

A recent analysis of Facebook responses to a South African HPV vaccination campaign found that while the majority of reactions (97%) on the page were favorable towards the vaccine, 33% of the comments were categorized as vaccine hesitant, "suggesting that people with negative reactions though few in numbers, were more likely to be vocal deniers".[61] This pattern has also been observed on Twitter and YouTube,[66,67] making social media particularly vulnerable to amplifying the voices of some through an echo chamber, or homophily, which is the idea that individuals tend to connect more with people of similar mindset.[68,69]

Overall, vaccine confidence is highly complex and specific to local circumstances. Given the breadth of data available and the highly complex nature of analyzing this information, there is considerable work underway in developing automated, scalable machine, and deep learning methods for conducting these analyses.[70–72] Once completed, this work will be central to powering public health's response to vaccine hesitancy.

Digital consent for immunization

Collecting informed consent prior to any intervention is a key ethical principle in medicine. A patient's right to autonomy and informed consent for any medical treatment was popularized as a legal doctrine in the Schloendorf case where it was proposed that "every human being of adult years and sound mind has a right to determine what shall be done with his own body".[73,74] However, digitally capturing informed consent prior to vaccination has been scarcely implemented in IISs.

In cases such as pediatric immunization, the limitation of this approach is not obvious. Consent is implied when the parent brings their child in for the immunization appointment. In other settings, the limitations are numerous. For example, in school-based immunization programs, collecting consent from parents or guardians can be burdensome. Once consent forms are initially sent home with children and returned, nurses must physically visit each school to collect them and identify missing consent forms so that the chain of custody is not broken. Then, a second round of consent forms are sent home with children prior to the nurses returning to schools to administer the vaccine. These repeat visits introduce risk and increase the cost of administering the program overall, especially over long distances in rural areas. With the introduction of new vaccines, particularly in pandemic scenarios, capturing informed consent prior to immunization is also important as there will be increased uncertainty around the adverse event profile of a novel vaccine. A system that allows individuals to access comprehensive information about a vaccine prior to the appointment and provides a platform to give consent digitally could enhance the efficiency of this process and promote more effective care between healthcare providers and patients. For those not comfortable providing consent ahead of time, it would prompt the individual to catalogue their concerns and prepare for a conversation with their provider. Furthermore, collecting consent for service digitally would streamline workflows without compromising the integrity of data collection. Real-time dashboards could be available to public health in advance of the immunization clinic, allowing them to remotely track which consents have been returned and administer a second round of consents without leaving their office.

Adverse event following immunization reporting

Poor vaccine surveillance systems can create a wave of distrust amongst people regarding vaccinations and aid in spreading misinformation.[75] Pharmacovigilance is essentially a "hypothesis generating activity whereby suspicions of harm spontaneously reported by manufacturers, healthcare providers, and patients in reporting systems give rise to questions of causality between medicines or vaccines and adverse events".[76] One of the four steps of pharmacovigilance is signal detection, whereby the potential causal relationship between a vaccine and the adverse effect can be identified. Signals can be detected from different types of data sources, but the most common ones are large databases of adverse event reports that undergo routine screening. Furthermore, newer approaches such as machine learning and systems immunology may allow us to develop better solutions for monitoring of vaccine safety.[76,77] Efforts to improve vaccine pharmacovigilance can prove to be essential in maintaining or regaining public trust in vaccine policy.[76]

The guidance report on Vaccine Safety issued by the WHO in 2012 regarded vaccine safety as a global priority.[78] An updated version of the report further emphasized the need to enhance vaccine safety communication, improve the coordination of safety systems, and strengthen frameworks in fragile states and crisis situations.[79]

A critical component of any IIS is the capacity to monitor the safety of vaccines. Typically, reporting of adverse events following immunization (AEFIs) is performed by healthcare providers and administrators of vaccines in a standardized manner. In the US, public reporting of potential AEFIs is enabled through the Vaccine Adverse Event Reporting System (VAERS) system, which is a passive reporting system that relies on individuals to report their symptoms to the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA).[80] Soliciting public data on AEFIs is particularly useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. While public reporting is controversial and has recognized disadvantages, it does provide an opportunity for novel signal detection. For example, VAERS is used to detect possible safety problems – called "signals" – that may be related to vaccination.[81] If a vaccine safety signal is identified through VAERS, scientists may conduct further studies to investigate if the signal represents an actual risk.

Mobile reporting of an AEFI using SMS and web-based reporting has been examined previously in several settings, including Australia and Cambodia, and has demonstrated high response rates and provided real-time reporting.[14] A study

in Cameroon also showed a significant response rate in reporting adverse events through telephone "beep",[82] a cost-effective way to identify the incidence of AEFIs. AEFI reporting using mobile applications could also leverage other functionality in smartphones. Assessment of local reactions or rash could be facilitated if individuals are able to photograph lesions and transmit them with their reports. Using smartphone cameras to scan the 2D barcodes on vaccine vials can permit the integration of lot number and global trade identification number with the AEFI report. This would help to improve the quality of information received by public health officials and assist in the identification of lot-specific issues, as well as assist individuals by automating the identification of the product.

A personal immunization record solution would also provide a channel for public health officials to send notifications to individuals who received a vaccine from a lot determined to be defective. Educational information could be rapidly shared with individuals, explaining that they may need to be revaccinated against the antigens covered by the defective lot and how they could access services for that. By allowing public health to query the IIS for all individuals who received a vaccine from this lot, public health would rapidly understand how many people were affected and in what geographical areas. In addition to accelerating understanding of the impact of the defective lot on herd immunity, it would allow for the appropriate allocation of resources for catch-up clinics or programs to revaccinate affected individuals. Together, this could potentially decrease the overall cost of performing lot recalls and improve the population protection against vaccine-preventable diseases in the event of a defective lot.

This mechanism for reporting AEFIs comes with potential disadvantages. The ease of being able to report adverse events can result in a high number of reports of mild reactions (e.g. short-term rash, soreness, and fever), which may not be of clinical relevance.[14] This could lead to potentially unnecessary spending of public health resources invested in follow up.[14] This reporting system may also be vulnerable to exploitation by individuals or groups harbouring anti-vaccination sentiment if mild reactions are flagged and amplified on social media as serious safety concerns. Therefore, further studies are required to evaluate the impact of an app that facilitates mobile AEFI reporting on vaccine hesitancy. Mobile AEFI reporting allowing direct reporting by individuals would resemble the VAERS in several ways and may reflect the advantages and disadvantages of this system. Given that we have determined that the technology is functional and secure, a more comprehensive study is warranted to examine these questions.

Digital verifiable immunization receipts

The IISs of the future will have an important role to play in providing patients with the ability to prove that they have received an immunization. Through the course of an individual's life, there may be several instances where one is required to prove that they have been immunized, like when registering for primary and post-secondary school, starting a new job in certain fields (especially healthcare), and when crossing international borders. At present, there are few standards for the international exchange of proof of immunization, and those that do exist are paper-based, like the International Certificate of Vaccination or Prophylaxis.[83] We expect that it will become common for IISs to issue patients with digital verifiable claims to immunization and that standards will be created for verifying these claims and for establishing trust relationships between issuers and verifiers. For example, a country could integrate the verification of digital immunization records into their border control procedures.[84] Using a barcode scanner, the border agent could scan a barcode presented by a traveller that contains a verifiable immunization claim, signed with the digital signature of the issuing IIS. The verifier's software would then cross-reference the digital signature of the issuing IIS against a list of IIS signatures that it has decided to trust. This list of trusted IISs could be made available through a federated network, and the IISs that participate in the network would need to provide proof or attestation that the immunization records, for which they issue verifiable claims, are of sufficient quality and accuracy. The standard would likely need to incorporate the notion of levels of assurance with respect to the veracity of a record. For example, a record in a repository that was reported from a historical record by a patient would have a lower level of assurance than one recorded by a provider and entered directly into a repository. Verifiers could then use the level of assurance to

determine whether the immunization claim is sufficient for their use case.

The economic argument for digitally transforming immunization information systems

Any transformation of a health system has the potential to create costs. However, there is a strong argument to be made that investment in improving IISs could be potentially cost-saving.

Using a measles outbreak example, responding to a single case of measles can be as high as $142,000 USD.[85] Total costs vary based on the number and location of contacts, the amount of post-exposure prophylaxis and the number of people quarantined. Moreover, further costs are incurred from the laboratory testing for suspected cases, healthcare personnel's increased work hours and efforts for public outreach/communication.[85] In 2011, the US experienced 16 outbreaks of measles with 107 confirmed cases. The average duration of an outbreak was 22 days, resulting in 42,635–83,133 personnel hours with an estimated $2.7 million to $5.3 million USD total economic burden on local and public health institutions.[85]

From July 2016 to January 2017, two single, unrelated measles cases were diagnosed in Denver, Colorado, each exposing hundreds of people. This required public health to act in a prompt and coordinated manner.[86] With 2525 hours of personnel time expended on contacting exposed passengers, setting up vaccination clinics, phoning people exposed, and the miles driven by healthcare staff, the estimated cost of this was $142,452 USD.[85] The use of novel digital contact tracing apps as employed in the COVID-19 pandemic, which can potentially be linked with IISs, can further improve the efficiency of an outbreak response.

There are also indirect costs related to loss of productivity and parents having to devote time caring for sick children. For example, in the most recent measles outbreak in Washington state, 800 children were kept out of school for up to 3 weeks.[87] This sudden reallocation of resources could weaken the structures of health systems and create vulnerabilities elsewhere in the community's public health infrastructure. This can result in

substantial disturbances in the progress of other programs. Thus, the cost of developing and implementing new IISs could be offset by preventing a single case of measles based on some estimates.

Future directions and conclusion

Implementation of the solutions we have described will help create a state-of-the-art IIS that will have the capacity to meet the needs of public health officials, healthcare providers and citizens. Such a system will provide real-time, geographical data on immunization coverage, a more comprehensive assessment of vaccine safety, and higher quality data for vaccine effectiveness assessments. Importantly, it will connect citizens digitally to their healthcare providers and public health officials and permit the creation of lifelong digital immunization records.

To enable these solutions, there are some important obstacles that need to be overcome. As IISs of the future become more sophisticated, they will benefit from tracking increasingly granular detail about the immunization event and the vaccine product used. While public health epidemiologists will always seek to err on the side of collecting more data, this will need to be balanced with the need to keep the provider's workflow simple. Public health will need to look to technology to get the data they want without interfering with the providers' interaction with the patient. Today, while it is common for the lot number of the vaccine to be tracked by the provider or appended to the patient's paper record as a sticker, the practice is far from ubiquitous. This will be complicated further by the trend towards serialization and the interest of public health and the vaccine industry in capturing individually unique identifiers for each unit of vaccine throughout the supply chain.

Technological barriers to the solutions we describe are surmountable and models to address issues related to privacy and security are maturing. Perhaps the foremost barrier is establishing and authenticating the identity of citizens who are accessing the system. Technological advances will permit further enhancements of digital immunization systems of the future. The incorporation of machine learning and AI into immunization surveillance techniques may help identify individuals at high risk of falling off schedules or missing

immunization appointments, permitting interventions to increase immunization coverage. The technology now exists to implement solutions that can greatly enhance what is one of the most important advances in medicine. The IIS of the future will be one component of a much larger digital ecosystem where data flows freely between providers and is always accessible to patients. Aggregating immunization records from across the health system's digital fabric will be key to its success. These solutions will permit the ongoing protection of the public and the world from vaccine-preventable diseases.

Importantly, as the world prepares for a potential pandemic vaccine for SARS-CoV-2, effective immunization systems will be essential. The digitization of the pandemic response is evident with the use of novel contact tracing apps as well as the development of digital immunity passports.

Digital IISs, as we have described, will be needed to obtain consent more efficiently, provide a mechanism for early detection of adverse events and provide real-time geographical dashboards of coverage, effectiveness, and safety. These features are also key to supporting the unique challenges of pandemic and mass immunization campaigns – including the need to identify hard to reach populations, rapidly collect and report on coverage rates and adverse event prevalence. Due to the large number of doses administered over a short time, managing safety and effectiveness data during mass immunization campaigns is crucial to reducing infection and maintaining public confidence in the program.[88,89] The participation of the public in these systems *via* digital technology will enhance their effectiveness for what will be one of the most complicated mass vaccination programs in history. However, it is important to recognize that these systems will largely be implementable in high-income settings. Analogous solutions that leverage technology more readily available in lower-resource settings should be urgently explored as the safe and effective roll-out of a pandemic vaccine, as well as the ongoing monitoring of existing immunization campaigns, is critical.

Conflict of interest statement

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