



AIRA

AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

Literature Review

**An Environmental Scan on
Progress, Challenges, and Opportunities:
Expanding Immunization Information Systems
for Adults in the United States**

July 2020

I. INTRODUCTION

In response to concern over low immunization rates in preschool children and the measles resurgence of the late 1980s, the United States, largely through early efforts of the Robert Wood Johnson Foundation (1,2) and the US Centers for Disease Control and Prevention (CDC), invested in the development of monitoring and follow-up systems for vaccination. Initially known as immunization registries, immunization information systems (IIS) offered a centralized repository of consolidated records to reduce record fragmentation. Initial IIS predated the world wide web and were installed on local servers or networks. These confidential, web- and population-based computerized databases have the ability to record all vaccine doses administered by all participating providers to all persons residing within a given geopolitical area. IIS were initially designed for the following purposes:

- Identify children due or past due for immunizations and notify their parents or guardians
- Serve as a provider outreach tool and a means to monitor immunization status
- Provide immunization information to program planners to target interventions and evaluate program efforts

In recent years, national focus on expanding IIS beyond data capture and use in pediatric populations to adults across the life span has increased (3, 4). The National Adult Vaccination Plan, a national plan for coordinated action to increase adult coverage rates, calls upon partners to strengthen the adult immunization infrastructure. Increasing the use of electronic health records (EHRs) and IIS to collect and track adult immunization data is a key objective in supporting a stronger infrastructure for adult immunization (4).

The effectiveness of IIS in increasing vaccination rates is well established (1,2, 4-6). The Community Preventive Services Task Force recommends the use of IIS and their functionalities, based on strong evidence of effectiveness, to increase vaccination rates and reduce vaccine-preventable diseases (5,6). IIS functions that support immunization delivery include:

1. Determining vaccination status, using vaccine evaluation and forecasting, to identify vaccines due, past due, or due in the future and to guide vaccination decisions at the point of care, including during outbreaks of vaccine-preventable diseases (VPDs)
2. Determining vaccination rates, missed vaccination opportunities, and invalid dose administration to enable reporting for performance and quality measures (e.g., HEDIS)¹

¹ HEDIS® is a widely used set of performance measures in the health care industry, developed and maintained by the National Committee for Quality Assurance. Over 191 million people are enrolled in plans that generate HEDIS reports, which are used as performance improvement tools. HEDIS includes measures for physicians, preferred provider organizations, and other organizations.

3. Creating or supporting effective interventions (such as reminders or recalls to patients for upcoming or past due vaccinations), provider assessment and feedback, and provider reminders
4. Generating and evaluating public health responses to outbreaks of vaccine-preventable disease
5. Facilitating vaccine management and accountability, including under epidemic or pandemic conditions

The focus at the time IIS emerged was on childhood vaccination, and few vaccines were routinely recommended by the Advisory Committee for Immunization Practices (ACIP) for adults. There are now more vaccines recommended for adults (7) and an increased public health focus on increasing adult vaccination coverage (2,3). VPDs take a heavy toll on adults age 19 and older, and low rates of vaccine uptake lead to costs to individuals and society (e.g., death and disability, hospital costs, lost income) (8,9). The health and productivity costs of influenza alone are estimated to be as high as \$87 billion per year (9). While immunizations are well recognized as an essential preventive service, vaccination coverage for adults is low (10), leaving many disproportionately vulnerable to infectious vaccine-preventable diseases.

Unlike children, who receive vaccinations in their medical home, adults often receive care from a wide range of practitioners (e.g., primary care and specialty providers, pharmacists) and at various locations (e.g., pharmacy, workplace, provider office), making consolidation of immunization data through IIS especially important for efforts to increase adult vaccination rates. Unique challenges that limit the capacity of IIS to capture adult records include:

- Identifying and enrolling the diverse providers that serve adults
- State and federal immunization program priorities and laws, including the lack of adult immunization reporting mandates
- Competing priorities for state and local immunization resources to support increased adult provider participation

IIS are also critical systems providing vital information during an outbreak and pandemic response when near real-time data for decision making are vital to managing a public health emergency. IIS have evolved to include additional functionalities, unique to outbreaks. These functionalities are often included either as part of current IIS capabilities or as separate mass vaccination modules that may or may not connect to the IIS. Functionalities important to the conduct of mass vaccination campaigns include the ability to manage increased enrollment of new patients and new providers, incorporate new data fields, and process increased volume of data requests under a rapid time frame, typically from state, local, and federal partners and providers.

Challenges to adult immunization

All jurisdictions that operate an IIS do so with set functional components prescribed by the CDC (11). All systems have the technical capability to capture adult data. The challenge is that doctors' offices across the nation are currently using different individual EHR systems to manage adult patient care in their own jurisdictions and pharmacies and pharmacy chains are using their pharmacy system to manage patient information at point of care. While these systems are making connections to the IIS in their respective jurisdictions, many providers who see adults are not connected to their IIS, and in turn, doses administered to their adult patients are not captured (i.e., adults are not participating) in the IIS. Additionally, providers and pharmacies that are connected to their jurisdiction's IIS may have chosen not to establish bidirectional exchange of information between their EHR system and pharmacy system and the IIS; in turn, information flows only one way: unidirectionally into the IIS. This means that an individual's medical home might not have complete vaccination records if additional vaccine doses are administered in another setting and the provider does not solicit updates from the IIS. Notably, at the time users initially established an interface and connected to the registry, the IIS itself may not have had functionality for bidirectional exchange. Currently, approximately three quarters of IIS in place have the ability to establish bidirectional exchange with new interfaces (12).

To enable expanded use of adult data means aligning standards for interoperability between EHR systems at provider offices that see adults and pharmacy dispensing systems. Establishing electronic Health Level 7 (HL7) interfaces—the standard specification for immunization messages—between EHRs and pharmacy systems and the IIS is a top priority for many IIS programs. Many pediatric providers have established these interfaces, which may be unidirectional or bidirectional; however, many providers who see adult patients have not yet connected.

In a unidirectional interface, the EHR simply reports all doses administered to the IIS. In a bidirectional interface, the EHR can query the IIS for patient and vaccination records and then report any doses administered or recorded in the EHR back to the IIS for the selected patient. A bidirectional interface can be more complicated, as it requires work from both the EHR vendor and the IIS; however, a bidirectional interface is more robust and provides greater insight into the full immunization workflow for each patient. Bidirectional interfaces ensure that both the EHR and the IIS contain the most complete records possible for the patient. Establishing a bidirectional interface may be cost prohibitive for small to midsize providers, and not all EHR systems are capable of bidirectional data exchange. As such, unidirectional reporting is currently the most common type of reporting interface. Progress toward establishing electronic interfaces—and the proportion of unidirectional to bidirectional interfaces—is assessed annually in the CDC's Immunization Information System Annual Report (IISAR) administered to all CDC jurisdictions within the National Immunization Program.

Efforts to expand IIS capture of adult demographic and immunization data, increase the use of IIS by adult care providers, and leverage the IIS for population level information are critical to increasing adult immunization coverage rates (3-6, 13). Concerted focus is needed:

- To address state laws and policies (14,15) unique to each jurisdiction that increase and require adult reporting and provider participation and that enable cross-jurisdictional data exchange
- To support technical and operational solutions needed for EHRs to interface with IIS in a standard way (i.e., interoperability)²
- To address programmatic capacity challenges to prioritizing and staffing adult immunization efforts, including addressing gaps in dedicated funding for adult expansion of data capture in IIS

There are administrative steps involved in connecting to and reporting adult doses to the IIS. While providers may perceive these as a participatory burden (16), supporting a fuller view of vaccinations across patient life spans plays an important role in public health and a critical role in mass vaccination.

Addressing challenges in these three domains—state laws and policies, technical and operational solutions for interoperability, and programmatic challenges—is critical to optimizing IIS capabilities and capacities for clinical care, public health reporting, and consumer engagement. Ideally every IIS would serve as a lifetime registry widely used by practitioners, including pharmacists who vaccinate adults, facilities that care for residents like long-term care, public health agencies that manage population health and respond to emergencies, and the public who access their secure data for documentation.

This literature review captures challenges facing federal, state, tribal, and local public health officials, health care providers, and consumers, as well as current strategies and opportunities to guide and unify efforts to improve awareness and use of IIS among providers in the context of providing ACIP-recommended adult vaccines and responding to pandemic challenges.

II. BACKGROUND

Currently, a single national IIS does not exist. Funding to develop independent systems has resulted in a network of IIS independently governed by state and local jurisdictions and designed to solve uniquely local challenges rather than a national centralized repository of immunization information (1,2).

² The goal of interoperability is for electronic health records systems and pharmacy dispensing systems to be able to communicate, exchange data, and use the information that has been exchanged. The standard implementation specification for immunization messages is HL7 2.5.1, Release 1.5.

Creation of IIS within the National Immunization Program

IIS were initially developed in the early 1990s and emerged within the boundaries of the 64 jurisdictions that comprise the formalized nationwide National Immunization Program, established through the Vaccination Assistance Act (Section 317 of the Public Health Service Act) in 1962 (17). The 64 jurisdictions include all 50 states, the District of Columbia, cities (Chicago, Illinois; Houston, Texas; New York, New York; Philadelphia, Pennsylvania; San Antonio, Texas), and islands (American Samoa, Guam, Marshall Islands, Micronesia, Northern Mariana Islands, Puerto Rico, Republic of Palau, and the US Virgin Islands). The Vaccination Assistance Act created a mechanism to provide ongoing financial support to state and local health departments to support immunization activities, especially for all preschool children (17). While the initial intent of this law was to allow CDC to support mass, intensive vaccination campaigns for a limited period of time, the focus of the program has evolved into a permanent system that provides comprehensive immunization services to the birth cohort of over four million children born each year in the United States. IIS initially sought to capture children from birth through age 18 years.

Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. For over 50 years, Section 317-purchased vaccine has been directed toward meeting the needs of priority populations, including uninsured adults. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels. This includes significant investments in supporting IIS. Funding to support IIS varies across jurisdictions and includes assistance from Section 317, state and local sources, the Centers for Medicare & Medicaid Services (CMS)³ (18), nonprofit organizations, and other sources upwards of more than \$40 million nationwide (CDC, unpublished data, 2012). To date, there has not been a specific IIS grant program enacted to fund IIS expansion to adults, as recommended by the National Vaccine Advisory Committee in 2001 (19).

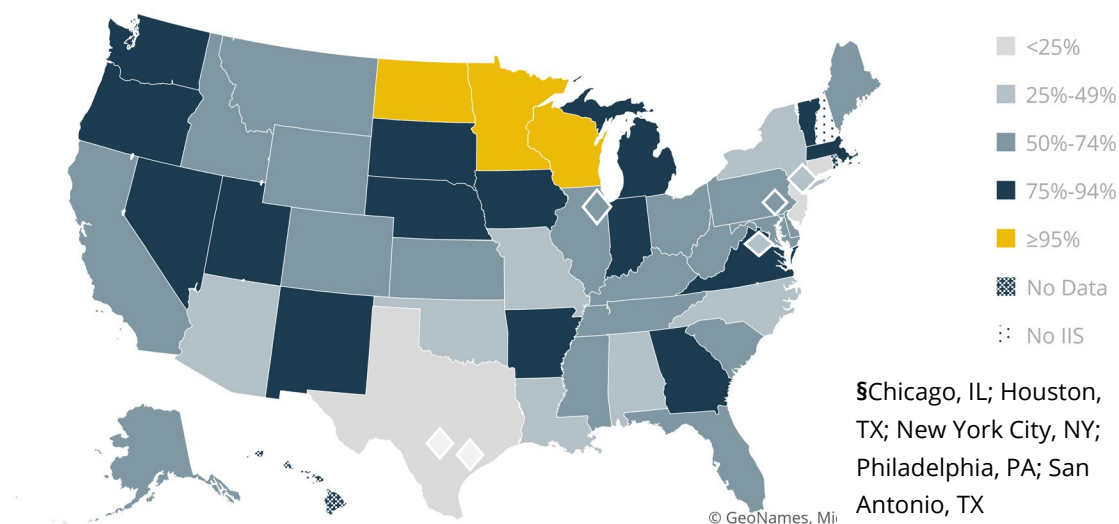
Currently there are 61 IIS in place that exist within the jurisdictional boundaries of the National Immunization Program. Of the 64 CDC immunization program awardees that comprise the National Immunization Program, one state (New Hampshire) and two cities (Houston and San Antonio) do not currently have IIS, though they have had one in the past. New Hampshire is in the process of implementing an IIS, which should be in place by the end of 2020. The Houston and San Antonio systems were decommissioned, and data

³ CMS allows states to submit funding requests to obtain 90 percent Federal Financial Participation (FFP) to plan, design, develop, and implement (DDI) immunization information systems that connect health care providers to a state's public health immunization registry if a 10 percent match is allocated from non-federal funds. Health Information Technology for Economic and Clinical Health Act (HITECH) funding is available at the 90 percent match FFP rate for the DDI of technologies or programs that support Medicaid through 2021. Public health and state Medicaid agencies may jointly request and gain federal approval for increased federal dollars for reporting immunization data.

within these IIS were rolled into the respective state IIS.⁴ Chicago, a separate CDC grantee from Illinois, utilizes the Illinois IIS but operates its immunization program as a separate jurisdiction. While not a CDC grantee, San Diego County maintains its own IIS as a legacy from when California had multiple regional systems.

National goals and milestones to strengthen the adult immunization infrastructure prioritize efforts to increase use of EHRs and IIS (3,4). As of December 31, 2018, 95 percent of children aged less than 6 years and 80 percent of adolescents age 7-19 were enrolled in an IIS with at least two vaccinations recorded, and 56 percent of adults age 19 years and older were represented with at least one vaccination recorded (**Figure 1**) (12). Adult participation rates vary widely across jurisdictions. For example, five jurisdictions capture less than 25 percent of adults while three jurisdictions have achieved 95 percent participation and above. Adult participation has significantly improved since 2010 (12), when only 25 percent or less of adults were represented, and has surpassed the 2010 National Vaccine Plan target of 50 percent (20).

Figure 1: Percentage of adults aged ≥19 years participating in an immunization information system—United States, five cities§, and D.C., 2018



Source: CDC 2018 IIS Annual Report (12)

⁴ When the San Antonio IIS was decommissioned and consumer records were migrated to the Texas IIS, only data with explicit consent (permission) from consumers was migrated. The legislative basis of Texas as a home-rule state also means that, if the county-level policies differ or contradict state policies, the county policies overrule state policies. In this case, the county-level policy required explicit consent despite Texas state policy to the contrary. Differences in policies across jurisdictions reflect the lack of uniformity in the basis of IIS, which in turn affect how IIS are developed and their performance.

Significant gaps in adult immunization data capture remain, particularly in contrast to children and adolescents. The proposed new National Vaccine Plan target is to achieve at least 75 percent by 2025 (21); 18 states currently achieve at least 75 percent (12). All IIS are now life span IIS, with recent legislation passed in Rhode Island that now allows for inclusion of adult vaccination information (22). Despite the ability of all IIS to capture life span vaccination data and progress being made each year, the low level of adult representation in IIS indicates that there are other barriers or challenges to the capture of this data.

When children age into adulthood, depending on state laws (e.g., consent mandates for IIS participation), one of the following scenarios may apply with regard to the disposition of childhood immunization data:

- **Opt-out all ages.** The individual's record continues to exist as an adult as it did as a minor. Opt-out requires an individual signature to "opt out" of inclusion in the IIS.
- **Opt-out child.** The child record exists until the age of adulthood (age 18 or 19 as dictated by state's mandate for reporting); however, at the age of adulthood, the record becomes locked and archived until the adult individual opts himself or herself back into the IIS.
- **Opt-in all age, with consent.** The individual's record exists across the life span as an adult as it existed as a minor. Opt-in requires an individual's or guardian's signature for inclusion in the IIS.
- **Opt-in child.** The child record exists with the consent of the parent, but at the age of adulthood, as determined by state mandate for reporting. The record becomes locked and archived until the adult person provides his or her own express consent.

In most jurisdictions, an individual's record in the IIS continues to exist—when children age into adulthood—in some form as it did before or in the IIS as a locked and archived record until a new round of consent is authorized. Records may also be permanently deleted; however, a skeleton of an individual's record may remain, providing a means to reactivate an individual's record at a future date. The extent of data that resides within the record exists to varying degrees. A better understanding is needed of what happens to these records when children age into adulthood.

Additionally, state mandates on provider and pharmacist reporting impact the nature of these immunization records. Specifically, if more practitioners are required to report adult data into the IIS, more information resides in the system. As larger volumes of adult data populate IIS, the more robust and complete the data is in the system.

Development of systems

Most IIS were developed either as "homegrown" systems or commercial off-the-shelf (COTS) systems offered by commercial vendors. There are currently two COTS IIS solutions (Envision and STC), one public domain platform (Wisconsin Immunization Registry) commonly but not exclusively maintained by DXC Technologies, and a handful of homegrown, locally developed applications (**Figure 2**). Homegrown systems may leverage

system support from vendors providing support to multiple homegrown jurisdictions. Each jurisdiction customizes its IIS to meet the needs of its own jurisdiction; however, how IIS were developed is important because that provides insight into the base functionality of the product. Additionally, a consortium of states that have a common platform can pool funds and try to evolve certain pieces of functionality.

Figure 2: Map of primary immunization information platforms as of June 2020

Map of Primary IIS Platforms/Systems Utilized

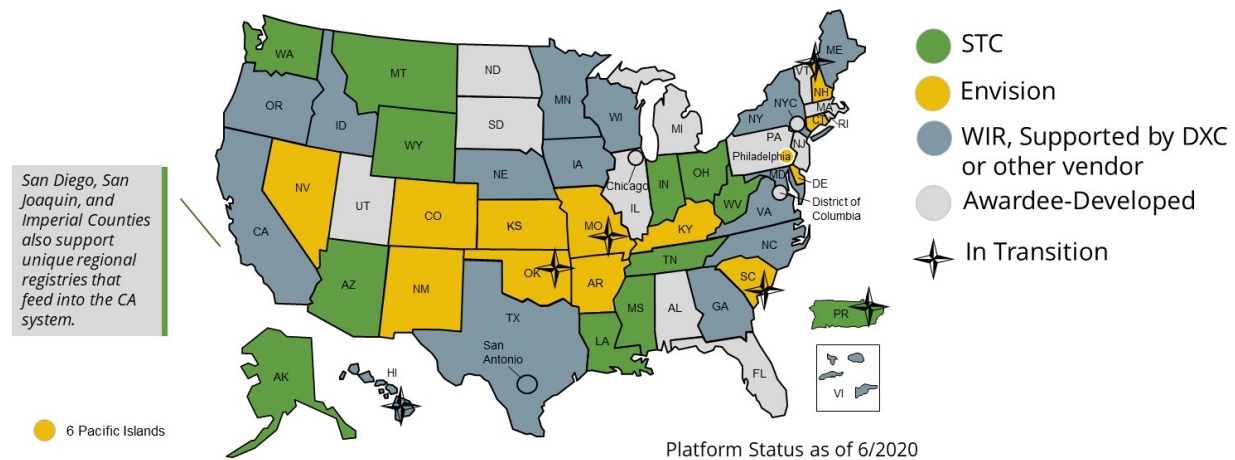


Figure 2, updated as of June 2020, shows the current state of primary platforms or systems in each jurisdiction. Jurisdictions can and do change platforms, which can be costly in time and finances. Changes occur particularly among states with homegrown awardee-developed systems that shift to commercial vendors. As the number of states on a common platform increases, the ability to pool funds to support needed functionality increases.

Interjurisdictional exchange: talking state to state

At the national level, sharing of information across IIS remains a challenge, often because of differing state laws that preclude interjurisdictional data exchange. An interjurisdictional community of practice (CoP), facilitated by the American Immunization Registry Association (AIRA) and the Association of State and Territorial Health Officials (ASTHO), works to address common IIS-to-IIS data exchange barriers and solutions, focusing primarily on technical barriers (23). This CoP also supports all jurisdictions signing the Public Health Interjurisdictional IIS Memorandum of Understanding, an agreement that serves as a means for secure, electronic exchange of immunization information among governmental entities that operate an IIS (24). While interjurisdictional exchange is of growing importance given the mobility of individuals and families across state lines, the current priority is to get more providers connected to IIS and, thereby, capture more adult immunization data.

Consumer access

At the individual level, some work has been piloted to develop real-time consumer access to immunization records online. Consumer portals empower consumers with information on their own health records and reduce administrative burden in obtaining records for school, daycare, camp entry, and travel (25). Consumer access portals connect to the IIS and provide information to the consumer on immunization doses received; if a consumer finds an error or an incomplete immunization record in the portal, the consumer can contact his or her provider office to update or add records.

My Immunization Record (MyIR), a program initiated in 2013 and piloted in a handful of states by the US Department of Health and Human Services, is an example of a free consumer access portal that gives patients access to their own and their family's official immunization records online. MyIR account registration has continued to increase over time and has proven particularly useful for families in outbreak and back-to-school situations. During the 2019 Washington state measles outbreak, there was a 476 percent increase in new user accounts created in MyIR compared to the month prior (25). Consumers were able to confirm their measles, mumps, and rubella (MMR) vaccination status and reported taking actions such as scheduling an appointment, calling their provider, and getting vaccinated. Additionally, a handful of jurisdictions have developed, or are in the process of developing, local IIS portals for consumer access. The extent to which these systems are being developed and the extent to which consumers are participating are yet to be determined.

Implementation of the adult standards

The National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice (Adult Standards) call on all health care professionals—whether they provide vaccinations or not—to take steps to help ensure that their adult patients are fully immunized (26). IIS play a central role in the four main steps of the Adult Standards:

1. *Assess* immunization status of all patients at every clinical encounter
2. Strongly *recommend* vaccines that patients need
3. *Administer* or *refer* patients to a vaccination provider
4. *Document* vaccines received by patients, including follow-up from vaccines given by other immunization providers

Providers rely on IIS as a tool to implement the adult standards (e.g., view patient vaccine history, document vaccines received, follow up with patients to ensure all vaccines that were referred out to another immunization provider were documented to complete a vaccination record). In addition to supporting the NVAC adult standards of practice, IIS can also be used to provide official immunization records to comply with state laws for school and daycare entry and health care worker compliance with workplace requirements.

The goal of the network of IIS across the nation is to improve the overall health of the population through the optimal use of vaccines across the life span. The ways in which the

various IIS across jurisdictions connect with providers to serve consumers and public health differ. IIS operations are influenced by their legislative base, the means by which they were developed (e.g., homegrown or commercial), the nature and extent of connections to other data systems, and the improvements and functionalities supported through and dictated by the needs of each jurisdiction.

III. STANDARDS FOR IIS DEVELOPMENT, FUNCTIONALITY, AND OPERATION

Progress of policies supportive of IIS participation

Over the last three decades, states made progress in enacting legislation and policies that protect privacy, confidentiality, and security of information or rules to address sharing of immunization information (27). The legal and regulatory framework for IIS has changed considerably in a way to improve the ability of IIS to perform their public health functions while maintaining strict confidentiality controls. All IIS are now authorized to capture data across the patient's life span, compared to 96 percent of IIS in 2012, just under half of states (n=24) in 2000, and only nine states with any IIS authorization in 1995 (15, 28). As of a 2012 review of progress in law and policy, 31 jurisdictions (59 percent) had mandates for at least one type of provider to report immunizations, compared to only 12 states with mandates in 2000 (15). Of the 31 programs in 2012 with some sort of mandate, only 12 (39 percent) included mandates for all ages including adults. The remainder were focused on children and adolescent immunization reporting. Many jurisdictions also require providers participating in Vaccines for Children (VFC) to report to the IIS as part of policies for program participation in the VFC program; 41 of 61 jurisdictions that receive CDC immunization funding and participate in the VFC program have such a requirement, with an additional 5 awardees that require all providers to report all doses, VFC or private, to the IIS for children through age 18 (12). Current efforts are under way to better understand reporting requirements and state-specific legislation for adults.

Since 2000, the number of jurisdictions requiring explicit consent (i.e., opt-in) to be included into the IIS has declined, most programs rely on implied consent (i.e., inclusion in the IIS) with a right to "opt out" with a signature (15). Higher levels of participation are seen in opt-out programs (29) leading to more complete patient and vaccination data available in the IIS. With a more complete vaccination record, there will be more accurate vaccine forecasting, fewer duplicate doses administered, and fewer missed opportunities. The goal is to achieve complete data saturation to the degree that the IIS has collected all patient and vaccination records within a jurisdiction. Despite the variation in policies across jurisdictions, the CDC and partners have made large strides in guiding IIS to capture standardized data elements, become more uniform, and improve interoperability through the development of IIS Functional Standards.

Standards for IIS development, functionality, and operation

In 1997, NVAC undertook an initiative on immunization registries, which resulted in a report that defined immunization registries and identified a vision guiding its recommendations for a “nationwide network of community or state population-based registries that are capable of sharing information while maintaining privacy and confidentiality”(30). Four primary objectives were identified, and recommendations and action steps were developed for each:

1. Ensure appropriate protections of privacy and confidentiality for individuals and security for information included in the registry
2. Ensure participation of all immunization providers and recipients
3. Ensure appropriate functioning of registries
4. Ensure sustainable funding for registries

IIS Functional Standards, first developed and issued in 1997 by CDC in collaboration with immunization program managers and endorsed by NVAC in 2001, define operational, programmatic, and technical capabilities that all IIS should achieve in order to capture complete, accurate, secure, and confidential data in a timely manner. In 2012, CDC and IIS stakeholders (31) restructured the 2013–2018 IIS Functional Standards into three parts (general considerations, programmatic goals, and functional standards) and increased focus of the Functional Standards on quality of care and support of public health programs; core data elements were also added (32). All IIS are required to store each of the core data elements listed in the Functional Standards as requirements. The CDC-endorsed data elements represent the core data fields needed by an IIS to record patient demographic information (e.g., patient name, address, gender) and vaccination event information, including vaccination data elements, provider data elements, and facility identifier data elements (33).

The most recent version 4.1 of the IIS Functional Standards was released in 2020 (34). There are eight essential infrastructure functional standards; the remaining 18 standards sit within the framework of four overarching goals: (1) to support health care providers in delivering age- and risk-appropriate immunization services, (2) to support the control and management of vaccine-preventable disease outbreaks, (3) to support and inform stakeholder efforts to improve immunization rates, and (4) to support health care providers in meeting the requirements of the VFC program and state and local vaccine programs.

To encourage IIS to implement functionality in a consistent manner across jurisdictions, operational and technical guidance have been developed to help guide this process. Many partners such as AIRA, the Association of Immunization Managers (AIM), Public Health Informatics Institute (PHII), and others in collaboration with CDC have worked to develop and implement standards-based functionality for issues such as data quality, technical data exchange, accuracy of data, real-time data access and input, vaccination-level deduplication, management of patient active/inactive status, and adverse event reporting.

However, it is up to the jurisdictions to implement these standards. Central among these efforts are the following:

- **CDC and AIRA’s Modeling of Immunization Registry Operations Workgroup (MIROW).** This collaborative expert working group seeks to identify and prioritize functional areas of IIS that can benefit from a collective approach and to develop best practice recommendations toward achieving functional standards regardless of the IIS operational platform. MIROW has developed “micro” guides, providing recommendations for specific and significant IIS operational areas, such as lot number validation (35). The group has developed recommendations for IIS for assuring incoming data quality, deduplicating vaccination-level data, assigning patient active/inactive status, conducting reminder/recall activities, patient eligibility status, and vaccine inventory management.
- **AIRA’s Measurement and Improvement (M&I) Initiative.** This current voluntary initiative, conducted as a third-party evaluation of IIS in achieving alignment with national standards, connects with IIS pre-production systems to measure the IIS response to test messages. The M&I Initiative has significantly helped IIS improve interoperability and standards-based functionality by providing actionable information and technical assistance to the IIS community and continues to focus on areas such as clinical decision support and data quality (36). This initiative serves as a model to standardize measures of success and data-sharing capabilities largely by demonstrating that the IIS objectively meets recognized standards.
- **The Public Health Informatics Institute (PHII), CDC, and AIRA’s Technology Requirements Project.** Despite the availability of national IIS functional standards and other best practice and guidance resources aimed at standardizing and improving the performance of all IIS, there is variation in baseline system capabilities and IT support services across the IIS community (37). In 2020 PHII, together with CDC and AIRA, began updating previous 2012 work to develop a baseline set of functional and nonfunctional system requirements and sample information technology support service expectations to assist immunization programs and IIS program staff in the procurement process for a wide range of IIS needs (e.g., a new system, module, maintenance and support of an IIS, enhancements to a current system).

Adult vaccine providers and IIS reporting practices

IIS are widely used by practitioners administering ACIP-recommended vaccines in primary care and pediatric settings for children. Representation of children and adolescent populations in IIS is further supported by school and daycare entry requirements. Furthermore, providers ordering public vaccine as VFC providers are more likely to participate in IIS (38). This is primarily driven by two factors: (1) requirements that VFC providers account for and order VFC vaccine through the IIS user interface and (2) local enforcement of policies that require providers participating in the VFC program to report

all doses administered to the IIS if they want to administer publicly supplied vaccine. In addition, CDC's national Immunization Quality Improvement for Providers (IQIP) program, formerly AFIX, promotes and supports the implementation of strategies, including the utilization of IIS, for VFC providers to improve child and adolescent vaccination rates (39). No such widespread program or requirements exist for adults.

A large benefit IIS offer adults and the providers caring for them is the ability to consolidate records into an IIS for patients who may see multiple providers for varying reasons (e.g., patients with multiple chronic comorbid conditions). For adults who do not have a primary care physician, vaccines may be given in other settings, such as the workplace, pharmacy, local health department, community health center, or travel clinic (40).

Chain pharmacies, hospitals, local public health departments, and large health systems are largely connected to and routinely report to the IIS. Many family physicians are reporting to the IIS, although less so than the pediatric primary care provider audience (41). Only 53.4 percent of clinicians, including internists, obstetricians and gynecologists (OB/GYNs), and other specialists, who were surveyed on their implementation of the NVAC Adult Standards reported they document administered vaccines in the IIS (42). OB/GYNs have increasingly improved efforts to vaccinate women during pregnancy (43) and women against human papilloma virus (HPV), although barriers remain related to EHR interoperability to ensure vaccines being provided are being recorded in the IIS (44). While the large majority (83.8 percent) of local public health departments utilize IIS (45), capacity is sometimes more limited in smaller, rural jurisdictions (46, 47). Other settings for capturing adult vaccines that have variability in IIS documentation practices include long-term care facilities, workplaces, home health, federally qualified health centers, rural health clinics, migrant health centers, military settings, and correctional facilities.

Pharmacies have increasingly become a central site for vaccination services. Pharmacies are uniquely positioned to improve vaccine access and coverage, as all pharmacists are allowed to administer vaccines to adults (48-50). Almost 100 percent of chains and approximately 70 percent of independent pharmacies provide immunization services (51). While it is known that pharmacies have contributed to improved vaccination coverage and play a substantial role in addressing suboptimal adult vaccination rates, approximately half of pharmacists (53.2 percent) document vaccines administered in the IIS (42).

Measuring progress

To monitor progress toward achieving IIS program goals, CDC uses the IIS Annual Report to survey all immunization program awardees (i.e., the 64 National Immunization Program jurisdictions). The most recent 2018 IISAR questionnaire included extensive revisions to reflect updates and capture responses related to the Functional Standards version 4.0 mainly regarding themes of timeliness, completeness, participation of providers, and the proportion of the population that is represented in an IIS (12). In 2020, Functional Standards version 4.1 was released. IISAR data has also been utilized to analyze the association with and impact of jurisdictional consent policies on adult IIS participation.

2015 IISAR data showed that jurisdictions with opt-in consent policies have lower IIS adult enrollment and participation (28). Similar assessments of more recent policy and participation data may help to demonstrate the need for further policy changes in support of adult IIS capture.

Select IIS received supplemental funding to participate in CDC's IIS Sentinel Sites Project (52) based on their ability to achieve high data-quality standards for the use of their IIS for program evaluation and vaccine use assessments. From 2013 to 2017, six participating jurisdictions—Michigan, Minnesota, New York City, North Dakota, Oregon and Wisconsin—participated in multiple data quality improvement and IIS evaluation activities to further enhance the use of IIS data to monitor vaccination trends; to improve IIS data quality, system functionality, and analytic capacity; and to disseminate findings for the IIS community. Supplemental project funding included focus on increasing adult provider outreach, enrollment, and reporting to the IIS. States implemented strategies including adult provider outreach and enrollment, development of provider group-specific recruitment strategies and targets, proposing legislation to strengthen adult provider reporting requirements, collaborating with providers and vendors to increase HL7 reporting capabilities, and developing new tools to monitor adult participation (53, 54). Sites that participated are among those with the highest adult participation rates and include the three states that have achieved 95 percent or above adult capture as of 2018 (12). More investments in these efforts are needed across IIS jurisdictions.

IV. INTEROPERABILITY, DATA UTILIZATION, QUALITY IMPROVEMENT

The American Recovery and Reinvestment Act (ARRA) was enacted in 2009 to modernize national infrastructure and included the Health Information Technology for Economic and Clinical Health (HITECH) Act. Under HITECH, the CMS and the Office of the National Coordinator for Health IT (ONC) established the Medicare and Medicaid EHR Incentive Program to encourage providers and hospitals to adopt, implement, and upgrade to certified electronic health record (CEHR) systems and demonstrate meaningful use (MU). In this context of health IT, meaningful use defines minimum government standards for EHRs, outlining how patient data should be exchanged between health care providers, between providers and insurers, and between providers and patients.

In an effort led by both CMS and ONC, MU was phased into practice and divided into three stages over the years 2001–2015⁵ in compliance with their criteria to improve health outcomes and quality of care through the exchange of electronic health information (55–58). Requirements that meet MU address five main objectives: to improve quality, safety, and efficiency and reduce disparities; to increase patient engagement; to improve care coordination; to expand population and public health; and to ensure adequate privacy and

⁵ Meaningful Use (MU) Criterion Stage 1 (2011-2012) focused on data capture and sharing, Stage 2 (2014) on advance clinical processes, Stage 3 (2016) on improved outcomes.

security protection for personal health information. If CMS determines that a successful demonstration of MU applied, parties were considered eligible for federal funds.

Reporting to an IIS is a measure within the Public Health Registry and Clinical Data Exchange objective of the EHR Incentive Program⁶ and is accomplished through the implementation of HL7 2.5.1 standards (59) to guide compatible information exchange of uniform data elements. HL7 message transmission from health care systems to IIS has been shown to improve timeliness and completeness of immunization data over manual entry (60-62). As a result of MU, vaccinating Medicare providers who reported data electronically to the IIS (in Meaningful Use Stage 2) increased from 51 percent in 2011 to 72 percent in 2014 (63). However, providers were financially incentivized to adopt certified EHR technology (CHERT). Public health was not funded to meet the demands of providers wanting to onboard to the IIS, creating long onboarding queues in jurisdictions across the nation. IIS had to prioritize providers to be onboarded, and because most of the vaccine administered in the United States is on the pediatric and adolescent schedules in many jurisdictions, providers who see children and adolescents were prioritized first, resulting in fewer adult providers being onboarded. Further, many VFC program policies required reporting into the IIS.

Meaningful Use significantly enhanced interoperability of EHRs with IIS, allowing public health to exchange vaccination records and reduce the need for duplicate data entry by providers, as well as improving data completeness and accuracy in IIS (64-66). Further requirements for meaningful use Stage 3 are included in the highlights box below. IIS have been preparing for MU3 and the use of 2015 CHERT as systems and providers ease into MU Stage 3. The public health reporting aspects of the CMS rules for meaningful use continue to push local and state public health agencies to enhance their informatics capabilities and establish new—or review existing—processes by which they will receive MU public health reporting data from providers (i.e., eligible professionals, eligible hospitals, or critical access hospitals, as defined by CMS) (67).

⁶ In 2018 CMS renamed meaningful use from the EHR Incentive Programs to the Promoting Interoperability Programs, with the intent of reflecting a focus on improving interoperability, flexibility, and patient access to information. These changes align with the shift to the Merit-Based Incentive Payment System (MIPS), in part due to the introduction of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which consolidated a number of programs, including existing CMS quality programs like meaningful use, all with an eye toward improving quality of care. All these efforts hinge on the meaningful exchange of health information.

Meaningful Use Stage 3

Beginning in 2018, MU Stage 3 requirements were mandated for providers and include a consolidated public health report containing an optional immunization measure for the electronic exchange of immunization administration data and bidirectional patient history and forecast. This means they will be required to meet at least two of the available five measure options from the Public Health Reporting Objectives, such as immunization registry reporting.

In 2018, as part of Modified Stage 2 Objectives and Measures, providers needed to meet Objective 10 related to immunization registry reporting. This objective contains a measure that ensures that the eligible professional is actively engaged with a public health agency to submit immunization data. The public health immunization measure and the 2015 EHR certification regulations spotlight the technical requirements of using HL7 to exchange immunization related data (68).

Interoperability with other health information systems

IIS are among the most mature health information systems that bridge clinical care and public health practice. However, their singular purpose is to focus on immunizations, so in the broader health care context their utility is limited. Past efforts to integrate IIS with other child information systems, most notably Vital Records, newborn dried bloodspot screening (NDBS), and early hearing and detection (EHDI), were selected because these interventions were universally recommended or mandated, began shortly after birth, involve both the public and private sectors, and are time-sensitive interventions where poor outcomes may be associated with delays (69, 70). In contrast, integration for adults has been more challenging.

Strategies to integrate IIS with these external data sources have been attempted with varying levels of success. For example, some states allow health plans, insurers, and Medicaid programs to query the IIS (71). According to the 2019 AIM Annual Survey, at least 37 states reported they share data between their IIS and state Medicaid agency, and/or their state Medicaid agency uses IIS data for Medicaid reporting (72). Recent adoption of two new adult quality measures—one for pregnant women and one for adults—into the 2019 HEDIS dataset utilizes a new electronic clinical data system (ECDS) architecture to inspire innovative use of electronic clinical data, including use of IIS, to document HEDIS measures while encouraging sharing and interoperability of health data systems (73).

Efforts to better populate adult demographic and vaccination information in IIS have been successful in some jurisdictions, but progress has been uneven, with no single one-size-fits-all model to replicate these strategies. Leveraging additional data sources can help to improve IIS data saturation and may serve as a good source of adult demographic and vaccination data records with careful consideration of data quality issues (74). Such sources include Medicaid (74-80), all-payer health insurance claims data (80), vital records including birth registries (80, 81), and less commonly, communicable and reportable disease records,

cancer registries (54), body mass index (BMI) surveillance systems (82), CDC's overseas electronic disease notification system (EDN) that captures health information on refugees and immigrants (83-84), sexually transmissible disease clinics, syringe services programs (85), Women in Children (WIC) programs, and the Department of Motor Vehicles. Challenges regarding broader scalability for implementation across the IIS community require further study to identify and remove barriers, including exchange with health information exchanges, which share information among health care providers, health care institutions, and health departments.

Quality improvement and quality measurement

Akin to national efforts that focus on improving immunization practices to increase vaccination coverage in children and particularly VFC providers, a number of efforts to focus on adult practices have also improved the use of IIS among adult providers (44, 86-92). Provider professional organizations, national advocacy groups, and public health organizations have focused efforts on increasing adult vaccination rates through the better use of IIS. Many groups have extended their official endorsement (e.g., American Medical Association, America's Health Insurance Plans, National Medical Association, National Association of School Nurses, US Department of Education) (31) of IIS. National and advocacy organizations, like the Adult Vaccine Access Coalition (AVAC), champion adult immunization issues by informing and educating policymakers and other decision makers to increase funding in support of IIS (93).

Provider organizations also play a central role in improving awareness and use of IIS in adult provider settings by creating resources, implementing educational initiatives, and issuing technical guidance to improve awareness and use of IIS in adult provider settings (94-99). For example, the American College of Obstetricians and Gynecologists' efforts to increase coverage of ACIP-recommended vaccines for pregnant women (43) rely on the use of IIS to ensure complete vaccination records because many women in the United States see an OBGYN for care during pregnancy (rather than their family physician or other provider in their medical home). Therefore, ACIP-recommended vaccinations (i.e., Tdap and influenza) may be more likely administered by a woman's OBGYN. IIS are fundamentally important in tracking these doses among different providers as women transition across provider types in their continuity of care. Notably, the new Prenatal Immunization Status (PRS), adopted into the 2019 HEDIS measure set and recently in 2020 endorsed for inclusion in the 2021 Medicaid core set, highlights the importance of ensuring pregnant women receive ACIP-recommended vaccinations and underscores the role that IIS can play in coordinating care and documenting adherence to the HEDIS measure (100, 101).

A second quality measure, the Adult Immunization Status (AIS) measure, became available in 2019. The AIS captures the administration of seasonal influenza, pneumococcal, herpes zoster, and a tetanus booster in adults. Unique to these measures is that they are reported through the National Committee for Quality Assurance's Electronic Clinical Data System (ECDS). This new reporting method is a standard designed to leverage health information

technology to increase the efficiency of quality reporting, while also providing an incentive to connect data across data systems (e.g., EHRs, clinical registries, health information exchanges, administrative claims, immunization information systems, electronic pharmacy systems, and disease and case management registries). It is the hope that more measures in the future are converted to ECDS measures (102).

V. IIS USE FOR OUTBREAK AND PANDEMIC RESPONSE

IIS are critical tools used in support of outbreak response of vaccine-preventable diseases, which can vary in size and magnitude from localized outbreaks of measles and hepatitis to global pandemic response such as the 2009 H1N1 pandemic. States prepare for pandemics by anticipating the potential need for mass vaccination activities. Emphasis is placed on updating and enhancing functionality of their IIS by first ensuring messaging practices are standards based.⁷ Additional efforts include enhancing data capture and technical and functional capabilities by (1) swiftly onboarding⁸ new and non-traditional immunization providers through automated and streamlined processes such as pre-registration and online registration; (2) expanding the number of adults with demographic data in the IIS; and (3) supporting ways to identify and manage priority groups for vaccination and to support vaccine allocation and distribution strategies.

Experience from recent and current experience with outbreaks across various states (e.g., Washington, New York, Oregon, Tennessee) and from previous mass vaccination experiences validate these common priority activities (103, 104). Common functional needs and uses of IIS in emergencies include:

1. **Rapid data entry and input feature.** To facilitate entry of data and accommodate increased volume of new users and new patients, most likely adult patients.
2. **Enhanced reporting capabilities at the local level and high volume of information requests.** From patients, providers, and public health at state, local, and federal levels. Public health and providers often query the IIS for information such as proportion of under-vaccinated individuals and coverage status. Patient access to IIS information remains a significant issue.
3. **Ability to create new fields and functionalities.** To accommodate information needs. For example, specific scheduling functionalities to stage appointment times in 15-minute intervals and capture of priority tier group screening tools.

⁷ HL7 V2, SOAP/Web Services and the CDC WSDL are in full compliance with CDSi specifications.

⁸ Onboarding refers to the testing and validation process that providers and public health programs engage in prior to ongoing submission of production data from certified electronic health record technology. Electronic interfaces enable providers and hospitals to connect with local public health department systems to electronically send immunization data to the IIS.

4. **Technical support for enrolling new clinics and users.** To accommodate increased volume of new users for onboarding of more and non-traditional providers (e.g., long-term care).
5. **Removing “opt-in” consent barriers that exist in some jurisdictions.** To facilitate faster processing of new patients, specifically adults.
6. **Vaccine management.** To track and account for all vaccine doses down to the local level, differentiated by vaccine formulation, including doses transferred among jurisdictions and providers, and to capture doses administered to consumers across provider types, particularly for series vaccines where series completion may occur at different provider locations.

Some states meet the unique needs of an outbreak or pandemic through the use of mass vaccination modules rather than relying only on the use of IIS and other systems (e.g., reportable disease registries). A recent 2020 AIRA survey (105) revealed that, for a mass vaccination event, most jurisdictions plan to leverage their IIS to facilitate the event and capture doses administered. Most jurisdictions assume that patients seeking vaccination will likely come to their primary care provider, pharmacies, or a local health department to receive vaccination services. Many of these provider types have existing reporting relationships with their respective IIS through a real-time electronic interface or direct entry through the IIS user interface. It is likely that the majority of vaccinations will be captured and reported using these existing reporting relationships.

When a relationship does not exist between a provider and the IIS, or when an alternative setting is needed to facilitate a high-volume vaccination event, many jurisdictions also support a mass vaccination module. Mass vaccination modules are strategically designed to maximize throughput at pop-up clinics or points of dispensing, known as PODs, (e.g., a high school gymnasium) or a closed POD such as an onsite vaccination effort for health care workers or a local police department. These mass vaccination modules are typically a hybrid version of the jurisdiction’s IIS or a stand-alone tool that interfaces with the IIS in either a bidirectional or unidirectional manner. The primary goal of a mass vaccination module is to facilitate rapid data entry of patient demographics and the details of the vaccination encounter. This typically includes the ability to reduce the number of fields required for data entry, use defaulted values to populate common fields, and leverage barcode scanning technologies. Some mass vaccination modules can also be configured to support multi-station clinic workflows (registration, vaccination, and possibly even billing). Mass vaccination modules are intended to facilitate real-time (or near real-time) recording and reporting of vaccinations to help inform command center decisions related to available inventory, vaccination activity, and population coverage.

Progress since and lessons learned from 2009 H1N1 pandemic response

Since 2009 when the United States responded to the H1N1 influenza pandemic, the technology and systems of IIS have evolved (12), the use of HL7 interfaces is much more commonplace, and more online systems are in place for data entry (i.e., less paper-based entry of immunization data). These developments provide some insight into how IIS might perform in responding to the current public health response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19).

The use of IIS in 2009 H1N1 pandemic response varied widely by state. About a quarter of states required patient-level reporting through IIS. States that did not require reporting through IIS and did not have an electronic interface had to rely on the laborious and costly effort of manual data entry. Some jurisdictions took special measures. Virginia, for example, provided a grant to help offset provider costs for training, to establish an interface, and to connect to new IIS users to encourage use of the IIS. Washington used billing data and an interface with its health promotion and immunization registry to obtain data from private providers (106).

The benefits of using IIS in H1N1 were both short- and long-term in nature. Immediate benefits included having more data earlier for decision making in shaping public health response activities, tracking progress, evaluating results, demonstrating accountability, and informing policies valuable to improving plans for the response. It was extremely difficult to develop methods for collecting accurate, reliable, and meaningful data. Moreover, data collection requirements were perceived as a burden for providers (i.e., some providers did not order vaccine or vaccinate because of registry reporting requirements),⁹ as training of new practitioners and ensuring data collection and entry for the IIS require time and resources. Additionally, important data were not available for informing mass vaccination campaigns (**Table 1**) (106).

In the long term, more providers became familiar with the IIS. Such familiarity could be leveraged in routine immunization and for use in other public health emergencies. However, it has been a challenge to retain these data and continue use of the IIS by providers who established an interface (103). Considerations in future pandemic efforts should include strategies to retain data rather than support direct data entry, which can occur without an established user interface to the IIS. Efforts to encourage providers who do establish an interface to continue entry to IIS should be a priority.

⁹ During the 2009 H1N1 campaign, once states relaxed IIS requirements for reporting, more providers ordered vaccine, though other factors may have also led to increased provider orders.

Table 1: Important data elements cited as missing during H1N1 mass vaccination campaigns

Table 1: Important data elements cited as missing during H1N1 mass vaccination campaigns

- Accurate data on doses administered (especially to target groups)
- Disease incidence by target group
- Prior immunity in target group
- Rapid assessment of reasons why people are or are not being vaccinated by risk group
- Demographic information
- Data on the impact and effectiveness of messaging campaigns
- Clear and early determination of severity of illness

Source: Institute of Medicine Forum on Medical and Public Health Preparedness for Catastrophic Events (106)

In general, the tracking of vaccine administration was considered poor in most jurisdictions, making it difficult to determine in near or real time whether vaccination activities were successful (106). This problem was exacerbated by challenges in reporting for pharmacies. Each jurisdiction had different reporting requirements, adding huge administrative challenges for the pharmacy chains that had to report to multiple health departments in a variety of formats. Also, not all retail pharmacies had convenient internet access, so multiple reporting pathways were needed, such as fax or paper forms (106).

Innovations such as consumer portals and mobile apps appear promising for patients and providers. They have been pilot tested in other countries (107-113) and may be useful to support data collection in pandemic response. In 2009, some states were innovative with data collection at mass vaccination clinics. One state used a personal digital assistant device to scan a patient's driver's license upon entry into and exit from a clinic to provide real-time information on the timeliness of vaccination. Another used fully electronic data collection by leveraging an interface with the Bureau of Motor Vehicles to download all driver's license data into IIS (106). The extent to which these interfaces still exist is unknown.

Lastly, IIS have the potential to increase and track countermeasure distribution, beyond vaccines, and many do. The question, however, is if the IIS should do so, as the implications of this practice expand beyond an IIS's initial purpose; legal issues could also be raised if IIS were used to target vaccination groups based on health status to differentiate individuals into risk groups (106). IIS are not typically designed to function like an EHR where health status (underlying medical conditions, health care worker status), and occupation are recorded.

Impact of COVID-19 on maintaining immunization services

The primary purpose of IIS is not related to pandemics. In a pandemic, the purpose of the IIS is to provide data to guide actions (103, 104, 106, 115). The central function of the IIS is to consolidate records and to monitor and maintain coverage of routine vaccinations. Current public health response amid the COVID-19 pandemic has led to dramatic declines in vaccine uptake (116-117), largely driven by “stay at home” orders that have shut down communities and interrupted immunization services. Additional concerns arise during fall months when influenza vaccination campaigns begin, as well as back-to-school campaigns to ensure children are up to date with immunization requirements. Strategies to address missed vaccination may be centered on the use of individual EHR systems or centrally through a jurisdiction’s IIS for reminder and recall. Using the IIS as a centralized way to conduct reminder/recall has the benefit of reducing the burden on individual practices (118, 119). The functionality (i.e., coverage assessments, reminder/recall) exists both in office-based EHRs and centrally in an IIS; the current unknowns are the extent to which some of these functions are used for adults and the effectiveness of these functionalities in various health care delivery settings (120).

VI. MOVING FORWARD

The use and operational aspects of IIS reside within an immunization program and have specific system requirements. How the system is designed, developed, and implemented in alignment with specifications for information technology determines how well high-quality, trusted data that supports the immunization information needs of an immunization program flows. Beyond the technical steps required to ensure data exchanges occur, the central challenge to adult expansion in IIS is centered on enrolling providers who care for adults to exchange information among different information systems, including across state lines. Ensuring sustainable financing for this expansion is also needed because capturing and monitoring more data and connecting more users (interfaces) comes with a cost.

Other factors including state laws and policies (e.g., lack of mandates for adult provider IIS participation); technical and operational variability (EHR variability); and capacity and program challenges (e.g., staffing to onboard new adult providers) in addition to perceived provider burden in participation (e.g., lack of incentives to report adult vaccination data to IIS) inhibit the expansion and use of IIS. Efforts to fully realize the use of IIS to meet needs of public health immunization programs require finding meaningful ways to:

1. Identify all providers who are administering vaccinations to adults and either incentivize them to report to IIS or enforce existing reporting mandates
2. Communicate the value of IIS to adult providers, in part by making reporting to the IIS easier, to support timely, routine use
3. Identify and address policy barriers that inhibit the expansion and use of IIS for adults and providers who see adults
4. Close data gaps in IIS to ensure records are timely, accurate, and complete

The most important value of the IIS comes from providers' ability to query the IIS at the point of care and to locate and use the information about additional immunizations administered elsewhere, providing a complete picture of a patient's vaccination history. The challenge facing IIS use in adult immunization programs does not primarily rest in the technology, which exists to seamlessly and efficiently exchange (i.e., capture, report, and use) data. The gap is that providers who see adult patients do not report adult vaccinations in a routine and timely manner. When providers leverage data in the IIS through their EHR, the system becomes more complete and more useful to all users: providers, public health, and consumers.

The challenge in expanding IIS is a causality problem analogous to the classic "chicken and egg" dilemma. In order for the IIS to be more complete, more practitioners need to be enrolled, submitting more adult vaccination doses; in order for more practitioners to be enrolled and using the IIS, they need to value the IIS as a means to manage the coordinated care of their patients. As more information increases the robustness of IIS across jurisdictions, the more useful IIS are in driving public health decisions. This literature review documents the tremendous progress in the development and expansion of IIS. As increased and focused attention and strategic financial investments are infused into these systems, the promise and the value of IIS to public health practice can come closer to being fully realized.

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