



**Towards a National IIS Strategy:
Options for Developing a National
Immunization Information System
Architecture**

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Immunization Information Systems (IIS) have been under development for over twenty years in the US with systems deployed in nearly every state and territory. Yet no national IIS exists, and no serious discussion is underway for a national strategy for IIS data access. This white paper will describe the enablers and barriers for creating a national IIS strategy, as well as various potential models for its development, including the attributes, strengths, and challenges for each proposed option. Finally, suggestions will be made for informing US policy in this area moving forward.

Introduction

Immunization Information System (IIS) projects are increasingly becoming interoperability projects. The desire to collect a consolidated record of a patient's immunizations from all sources has always been a primary functional imperative for IIS. The advent of electronic health records – and the pressure on the entire healthcare system to reduce its cost and increase its efficiency – has led to the development of electronic health record systems (EHR-S). The CMS EHR Incentive Programs have lit an even stronger fire under both the clinical and vendor communities to develop and implement EHR-S.¹ Providers have always resisted “double data entry” – keying immunization data into *both* local systems *and* centralized IIS. The more local systems that pop up, the less providers want to use the web-based IIS client. So the activity switches to interoperability – harvesting records from EHR-S to populate IIS databases and return complete immunization histories and forecasts back to providers.

IIS of the Future

The *vision* for the IIS of the future is one centered around interoperability: the requirements for IIS to interoperate with other IIS across the country as well as other public health programs within an agency² will continue to grow, captured in Figure 1 (which was inspired by the pop-culture posters of the world from the top of the Empire State Building: this is the world from the point of view of the IIS, but not the only view possible).³

With the IIS at the center, a variety of interoperability opportunities are available – for many IIS these have already flourished into operational interfaces, though rarely all at the same time. Opportunities within government include (right side of Figure 1):

¹ <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html>

² For a more thorough discussion of this notion see Arzt, Noam H., *Evolution of Public Health Information Systems: Enterprise-wide Approaches*, July 2007. <<https://www.hln.com/assets/pdf/UT-White-Paper-Final.pdf>>

³ A more thorough discussion of the role of public health registries can be seen in Arzt, Noam H., *Revisiting Public Health Registries*, September, 2013. <<https://www.hln.com/assets/pdf/8-revisiting-registries.pdf>>

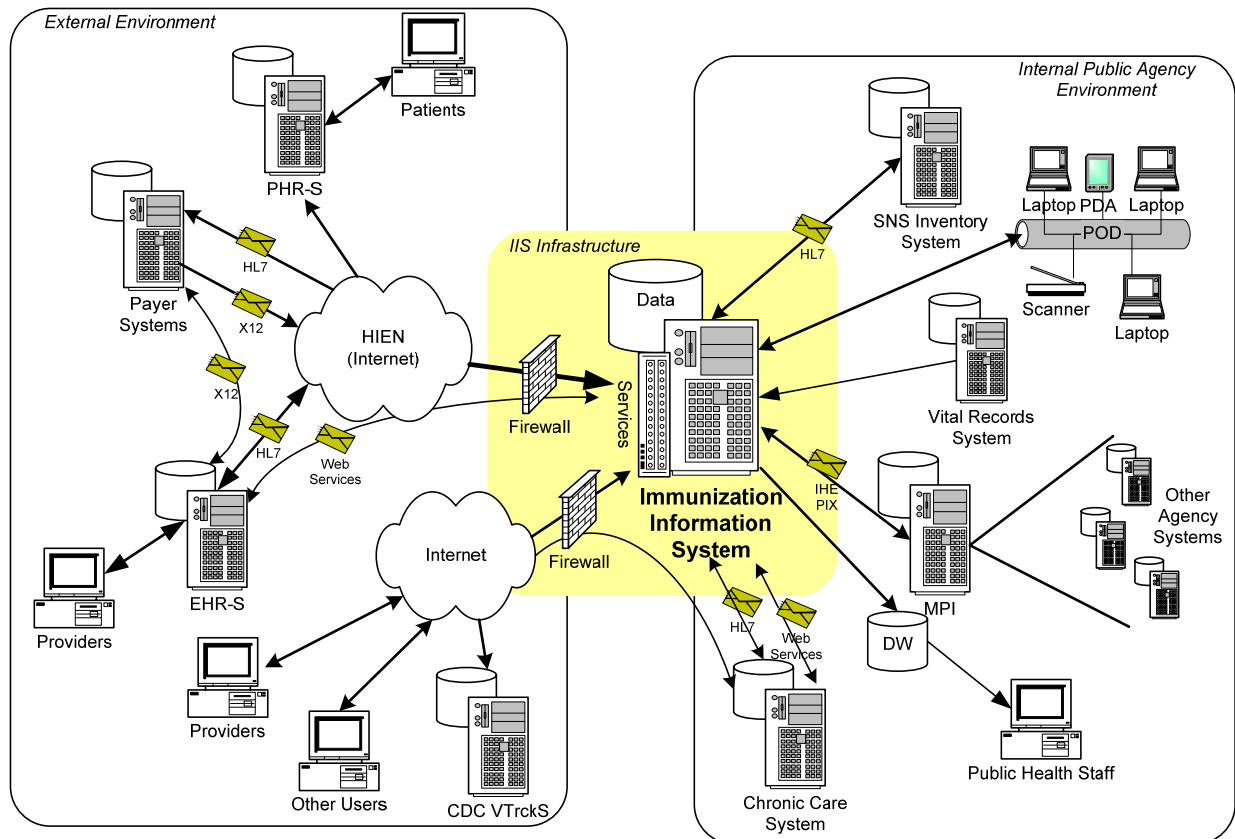


Figure 1 – IIS of the Future

- Vital Records Systems⁴** are a key supplier of information to IIS which strive to be population-based: IIS count on Vital Records Systems to seed their databases with birth records and establish the “denominator” for population-based statistics. Note that in some jurisdictions the Vital Records Agency is *not* within public health. This may introduce additional political or bureaucratic obstacles to data integration. In addition, some jurisdictions have data privacy or consent laws which also may present obstacles to data sharing.
- Emergency Preparedness Systems** cover a wide variety of areas, but the ones most relevant to IIS involve support for mass vaccination campaigns and management of the Strategic National Stockpile.⁵ Planning for these efforts varies across jurisdictions and thankfully there have been few if any reasons to activate these capabilities. Yet the threats are real and IIS can play a key role in data management for these activities.
- Many **other internal systems** exist within public health agencies that are good candidates for interoperability with IIS. Some agencies build and maintain **data warehouse systems** to provide management data often across public health domain areas. Some agencies support a **master person index (MPI)** to facilitate interoperability between systems or to support a consolidated “client” view for a more coherent

⁴ <http://www.cdc.gov/nchs/nvss.htm>

⁵ <http://www.cdc.gov/phpr/stockpile/stockpile.htm>

delivery of services (either agency-wide or jurisdiction-wide). Because most IIS are population-based they typically have strong MPI functionality of their own which can contribute well to an agency or jurisdiction-wide approach. For some states, their Medicaid Management Information Systems (MMIS) are a target of this MPI integration; for other jurisdictions other types of systems may be driving this (for example, some jurisdictions use IIS as the cornerstone of a child health system by integrating other child health domain area information with the IIS).

- **Chronic disease/care systems** are maintained by some jurisdictions to support community care initiatives for some chronic conditions. As accountable care organizations (ACOs) and patient-centered medical homes increase in their presence these systems will start to work together. IIS can be major contributors to documenting “well care” activities in these scenarios.

Some opportunities for interoperability are found outside of the public health agency, including:

- **Provider access** to IIS has always been a key objective to support both clinical care and provide coverage information required by public health agencies to perform their population-level monitoring and assurance functions. Providers access IIS directly through web-based clients, but increasingly they access indirectly through local EHR systems (EHR-S). The CMS EHR Incentive Programs have accelerated the deployment of EHR systems and promoted standards-based interoperability via HL7 messaging. Increasingly, immunizations are being administered at retail pharmacies so these sites are becoming more and more relevant for IIS interoperability.
- **Patient access** to IIS is a relatively recent phenomenon, spurred on by the Federal initiatives related to consumer access to health data. Access could be provided directly via web client (some IIS are already doing this), or indirectly through Personal Health Records systems (either tethered to provider EHR systems or untethered and independent). The challenge is ensuring that patients or their guardians only access records for which they are authorized.
- **Health plans/payers access** to IIS is for a number of purposes, including support for claims adjudication and as source of data to support the Healthcare Effectiveness Data and Information Set (HEDIS).⁶ Many of the interfaces that support these processes are becoming increasingly automated, replacing manual report generation.
- **Other users and processes** increasingly require automated interfaces to IIS, including CDC’s vaccine ordering through VTrckS.⁷ Other systems, such as those in schools and elsewhere, can make good use of IIS data.

But there is a difference between vision and architecture: embedded in the Interoperability Model is a technical architecture for the IIS of the future that enables this functionality.⁸ And to

⁶ <http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx>

⁷ <http://www.cdc.gov/vaccines/programs/vtrcks/index.html>

⁸ For a brief explanation of technical architecture methodology see <http://www.hln.com/hln/ta.html>

truly determine an appropriate architecture requires an examination of *various* architectural models and the strengths/challenges of each.

Role of HIEs

Health information exchanges are emerging as a key component in this interoperability model. While they come in many shapes and sizes, their primary purpose is to reduce the number of point-to-point interfaces between healthcare organizations – including public health agencies – to make interoperability more cost effective and more standardized.

The HIE landscape continues to get more complex as different styles of HIE have developed and in some cases are vying for their position in the interoperability “marketplace” (see Figure 2). Community HIEs are supported within a medical trading area, community, or state and can be the most challenging to sustain. Some states – particularly smaller ones – have single, state-level HIEs while others pursue a “hub and spoke” model where they provide interconnection between sub-state HIEs. Still others merely facilitate HIE through selection of standards or deployment of lighter strategies such as directed exchange. Most community HIEs continue to work hard on developing an appropriate business model and sustainability plan as the spike of government funding over the last several years is subsiding.

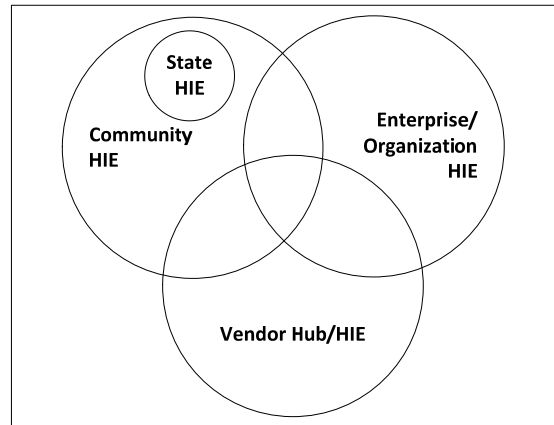


Figure 2 – Types of HIE

Enterprise or organization HIEs are deployed and supported within a single organization or integrated delivery network (IDN) and may or may not interoperate beyond organizational boundaries. Many IDNs have become complex organizations connecting hospitals, clinics, tertiary care centers, and small practices together. The movement to Accountable Care Organizations (ACO) will further promote the development of these HIEs to serve the information exchange needs of medical homes and their supporting clinical locations. Finally, a third type of HIE, the EHR vendor hub, has emerged as many EHR system vendors offer interoperability between installations of their products and often will provide less expensive external interfaces to/from these “hubs.” For the EHR system vendor this is a matter of strategic leverage. For providers, this becomes a matter of lower cost. For communities, these hubs may or may not make interoperability more efficient as the hub is focused less on interconnecting a logical set of data trading partners as it does on the idiosyncrasies of who happens to be using a particular EHR system.

While compatibility with *de facto* or emerging standards is important, HIEs are in a good position to provide the necessary gateways and translations for their members, including public health. Many states are also focusing their connectivity options through a single state gateway

or portal, providing leveraged connections for simpler, less costly, and less redundant data exchange.

Challenges with Inter-jurisdictional Information Exchange

Public health is essentially a *local* activity, even though much of the *funding* for public health is Federal in origin. In some cases, the Federal government facilitates the collection, aggregation, and even sharing of public health data (e.g., Biosense 2), but there is no such program for immunization data. States and other jurisdictions are on their own in terms of sharing immunization data with each other. This historical absence of national policy and facilitation in this area has led to the development of a number of challenges and barriers to exchange:

- **Patient Matching:** While challenging enough within a single system, matching patients across systems is even more challenging in the US especially due to a lack of a universal patient identifier.⁹ Jurisdictions need to be very careful about both false positive and false negative matches that compromise the building of a comprehensive, longitudinal immunization record across jurisdictions.
- **Privacy laws:** State and local privacy laws – such as those regarding consent to share records, access to adolescent sexual health records, and others – are incompatible across many jurisdictions. This makes it very difficult to share data consistently and transparently. While several efforts, including the Health Information Privacy and Security Collaboration (HISPC¹⁰) and other more recent efforts have attempted to reconcile these differences, most states simply have been unwilling to compromise on their local regulations.
- **Governance issues:** When jurisdictions work together they usually do so within a governance framework that either is pre-existing or that is created to support the new activity. So long as local law does not prohibit the activity, jurisdictions typically enter into agreements memorialized in memoranda of understanding (MOU, though there are many names for these types of agreements) to clearly delineate the responsibilities and expectations of the parties. In this context, these agreements are essentially data sharing agreements but often require special negotiation and legal review before being signed.¹¹
- **Technical differences:** While most jurisdictions follow published HL7 implementation guides to support interoperability, there are still subtle (and not so subtle) differences from jurisdiction to jurisdiction that can make data exchange more difficult to implement. Differences in message content can sometimes be small but significant; occasionally message transport differences also exist. As the CMS EHR Incentive

⁹ See Section 516, Title V, Omnibus Consolidated and Emergency Supplemental Appropriations for FY 1999, H.R. 4328 (P.L. 105-277), October 21, 1998.

¹⁰ <http://www.healthit.gov/policy-researchers-implementers/health-information-security-privacy-collaboration-hispc>

¹¹ Some sample data sharing agreements can be viewed at <http://www.immregistries.org/resources/data/data-sharing-agreements>

Programs mature there will be increasing pressure from the EHR vendor community and Federal agencies for IIS around the country to standardize more and more on their interface specifications.

Despite these challenges, some sharing of immunization information across jurisdictional lines does take place. The States of Washington and Oregon have been exchanging immunization information for a number of years,¹² and the New York City Citywide Immunization Registry (CIR) has begun to exchange immunization and birth data with the upstate New York State Immunization Information System (NYSIIS) for children who live and receive care on either side of the municipal border. Another more ambitious effort between New York State, New York City, New Jersey, and Pennsylvania never quite moved passed the discussion stage.

Options for a National IIS Architecture

Based on national policy, the Centers for Disease Control and Prevention (CDC) is prevented from pursuing activities that may create a unified, consolidated, national IIS.¹³ Much of the focus has therefore shifted to interoperability between State (or local) IIS instead. The advent of the CMS EHR Incentive Programs has shifted that focus more recently towards EHR-IIS interoperability at the expense of inter-jurisdictional considerations: public health funds are limited and not all functionality can be implemented based on current funding levels. The development of Health Information Exchanges (HIE) at all levels, and especially the national HealtheWay eHealth Exchange, has raised both the need and expectation that immunization information be available across jurisdictional lines. The combination of these factors has made a national IIS strategy into a strong imperative for sharing this data broadly and maintaining the public's health in this domain.

A range of options should be considered, including:

- **The current *ad hoc* means of inter-jurisdictional IIS interoperability:** Currently, jurisdictions negotiation bi-lateral agreements to facilitate inter-jurisdictional exchange. The progress has been slow, so a number of steps can be taken to bring more coherence to this process including development of a more standardized inter-jurisdictional agreement (AIRA and others have done some work on this already); reduction in the variability between technical interfaces for services-based query/response; and the establishment of a voluntary governance process to facilitate ongoing discussion and deployment.
- **Regionalized clusters for multi-jurisdictional IIS to reduce the number of end points for connections:** Medical practice tends to be local, with some regional extensions that are more important in some parts of the country. In addition, many metropolitan areas sit on state borders (New York City, Philadelphia, Cincinnati, St. Louis, Kansas City to

¹² See http://www.immregistries.org/resources/WA_OR_MOU.pdf

¹³ While we are aware of no specific policy preventing this, the foundation of these concerns comes from a 1998 Congressional prohibition of even discussing a national patient identifier (see footnote above).

name a few). While point-to-point inter-jurisdictional connectivity may be a practical necessity, it may be possible to develop regional consolidation of immunization information (physically, or in a federated/distributed model) to position IIS data to serve extended medical trading areas more efficiently than via queries to individual, multiple, state-level IIS. HIEs are one possible consolidation point for regional data.

- **An EHR-centric model for querying across jurisdictional lines:** The current trajectory of Meaningful Use is for EHR systems to be able to query IIS directly (or via HIEs). If the primary purpose of IIS data is to serve the point of care, it would be possible for EHR systems to be able to query *multiple* IIS to retrieve complete patient records. As with the *ad hoc* model, reduction in the variability between technical interfaces for services-based query/response across IIS would greatly enable this strategy. Additional governance would likely not be required if standards are followed more rigorously. Of course, providers might still not know exactly which IIS to query, and might not create a complete record if they miss a particular data source or if it was not available during the time of the query. A variation of this approach would focus on emerging EHR “vendor hubs” which utilize out-of-the box *vendor*-centric interfaces for users of the *same* EHR system which are often supplemented by interfaces between these product hubs and other data trading partners.
- **The use of a single national hub or network:** In many ways, this represents the simplest strategy. Surescripts already provides a multi-IIS interface engine (at last count supporting more than forty IIS) into which daily submissions from large pharmacy chains are submitted, then parsed, processed, and sent to the appropriate IIS as standard HL7 v2 messages based on patient’s zip code. Another potential way to interconnect IIS in a standardized way would be to ensure that all IIS are nodes on HealtheWay’s eHealth Exchange (directly or indirectly, *e.g.*, through their public health agencies). The standards and specifications already exist, and the eHealth Exchange is already a going concern with an established governance structure that would not need to be re-invented. On the other hand, the eHealth Exchange has been rather slow to develop, and relies on a set of fairly “heavy-duty” technical specifications which might be challenging for IIS to implement.
- **A consumer-mediated model:** An alternative model would be one where the responsibility for records consolidation would fall to the patient (or guardian) and not the provider or the public health infrastructure. By collecting data into PHRs patients can be sure to include all relevant immunizing sites from their past. Through publish and subscribe capabilities such as those supported by Blue Button+ these records can be “pushed” to patients as they are created (or modified). Though these core technologies are available, current deployments are quite limited, especially in public health agencies. But this strategy may be a good bet for the future.

Each option has strengths and challenges, and can be rated as to its feasibility in the current technical and political/policy environment. And these strategies may not be mutually exclusive. Finally, the options can be compared and suggested strategy choices identified. Let’s look at these options a little more closely.

Current Ad-hoc Means of Inter-jurisdictional Interoperability

There are only slightly more than 50 jurisdictions that operate IIS in the US,¹⁴ and far fewer IIS products in use.¹⁵ In some cases, neighboring jurisdictions have already agreed and implemented bi-lateral agreements to enable system-to-system sharing.¹⁶ An additional case was the aftermath of Hurricane Katrina where the Louisiana IIS provided access to its data by any state that requested it.¹⁷ While the process of negotiating and implementing agreements between jurisdictions can be tedious, there are a limited number of such agreements to be entered into and many jurisdictions do not often share patients with many others.¹⁸ Developing a more sophisticated national approach to IIS interoperability may prove to be an unneeded distraction from other important IIS and public health activities.

The strengths, weaknesses, opportunities, and threats (SWOT¹⁹) of the current approach include:

Strengths	Weaknesses
<ul style="list-style-type: none"> • Individual jurisdictions can proceed with plans to interoperate without the burden of national coordination • Implementation can proceed incrementally. • More realistic given current funding constraints. • Does not require any more governance than agreement between the trading partners. 	<ul style="list-style-type: none"> • Progress to date has been slow and haphazard. • Data sharing agreements not standardized making every negotiation a unique experience. • Jurisdictional differences in privacy/security laws continue to hinder data sharing.
Opportunities	Threats
<ul style="list-style-type: none"> • Development of model standardized inter-jurisdictional data sharing agreements will not take a lot of effort but would greatly facilitate the process. • Early adopters can provide strong models for later adopters. • Health Information Exchanges (HIEs) could fill the void and play a more prominent role in inter-jurisdictional data sharing which, if done collaboratively with IIS, could free up IIS to pursue other core activities. 	<ul style="list-style-type: none"> • Variability in technical approaches continues to hamper progress. • No strong incentives for more standardized technical approaches. • Patient and vaccination-level de-duplication will be an even larger issue across jurisdictions than it is within IIS projects now. • HIEs may take a more prominent role in inter-jurisdictional data sharing which may reduce the role and impact of the IIS in this process.

¹⁴ The CDC includes several major cities and US territories in addition to the 50 states as its funding grantees.

¹⁵ The IIS software market has consolidated somewhat in the past few years, with the majority of the jurisdictions using just three products, two commercial and one public health developed.

¹⁶ See <http://jphit.org/wp-content/uploads/2013/09/jphit-inter-jurisdictional-data-exchange-guidance-0913.pdf>

¹⁷ <http://www.healthit.gov/providers-professionals/louisiana-health-care-quality-forum-case-study>

¹⁸ Though there are exceptions: officials in Florida are fond of saying that they have thirty-five bordering states given the large number of snow birds and visitors who frequent the state from all over the country.

¹⁹ http://en.wikipedia.org/wiki/SWOT_analysis

Regionalized Clusters

While a single, national immunization information system with a consolidated database is not feasible, it may be feasible to think about more regionalized clusters of consolidated immunization information around the country. There are several well-established models for this type of interoperability which range from more centralized, warehouse models to more distributed, “federated” models.²⁰ There are other contexts in which clusters of states (in particular) work together across jurisdictional lines to promote a regional approach to solving a public health necessity: disease surveillance, bioterrorism preparedness and response, and broader disaster planning and recovery.²¹ The HIE marketplace has been experimenting with the deployment of many of these models and proving their efficacy. As HIEs look for new models and value propositions to secure their sustainability as Federal grant funds diminish, IIS interoperability may prove to be one avenue of new business for these organizations.

The strengths, weaknesses, opportunities, and threats (SWOT) of a regionalized approach include:

Strengths	Weaknesses
<ul style="list-style-type: none"> • Regions can proceed with plans to interoperate without the burden of national coordination • Implementation can proceed incrementally. • Somewhat more realistic given current funding constraints. • Allows for regional differences to be recognized and exploited. • Inter-regional interoperability still possible by mutual agreement. 	<ul style="list-style-type: none"> • Requires regional cooperation and consensus around policies and technical implementation. • Data sharing agreements not standardized nationally which potentially hampers inter-region interoperability. • Differences in jurisdictional privacy/security laws still have to be reconciled in any data sharing agreements. • Requires a somewhat formal governance structure to set policy and to adjudicate unexpected consequences of interoperability.
Opportunities	Threats
<ul style="list-style-type: none"> • Early adopter regions can provide strong models for later adopters. • One or more regional approaches may prove to be useful models of a future national approach. 	<ul style="list-style-type: none"> • Regional participants may not be able to reconcile policy and legal differences between jurisdictions. • Health Information Exchanges (HIEs) may take a more prominent role in regional

²⁰ For a discussion of these models, see *Response to Request for Information, Development and Adoption of a National Health Information Network*, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, January 18, 2005.
<<http://www.hln.com/noam/ONCHIT-RFI-HLNConsulting.pdf>>

²¹ For a case study on how the Southeastern States planned for health data sharing during a regional emergency see the ONC State Health Policy Consortium Project: Health Information Exchange in Disaster Preparedness and Response, *Southeast Regional HIT-HIE Collaboration (SERCH): Final Report*, July 2012.
< <http://www.healthit.gov/sites/default/files/pdf/SERCH-White-Paper.pdf>>

Strengths	Weaknesses
<ul style="list-style-type: none"> Health Information Exchanges (HIEs) could fill the void and play a more prominent role in regional data sharing which, if done collaboratively with IIS, could free up IIS to pursue other core activities. 	<ul style="list-style-type: none"> data sharing which may reduce the role and impact of the IIS in this process. No strong incentives for nationally-standardized technical approach.

An EHR-centric Model

While IIS projects are working to protect the public at large against vaccine-preventable diseases, individual providers are most concerned about their own patients. EHR-S serve providers at the point of care and need to provide current, accurate information about the patient in the exam room.²² Providers have always resisted “double data entry” – keying immunization data into *both* local systems *and* centralized IIS. The greater the use of local EHR systems, the less providers want to use the web-based IIS client. HIEs have also provided patient portals as points of integration for patient data. But this is understood by most to be a stopgap measure until EHR systems become more universal and until they are better able to query other data sources and present the results in a consolidated way through the local EHR system.

But if the EHR-S is the clinician’s window to the world, it can serve as the integration point for immunization data as well. Under this model, the EHR-S queries *multiple* IIS to retrieve complete patient records. This might be done directly to the various IIS, through an EHR vendor hub (which would already have these IIS interoperability relationships established), or both. IIS would continue to operate independent of one another.

The strengths, weaknesses, opportunities, and threats (SWOT) of an EHR-centric model include:

Strengths	Weaknesses
<ul style="list-style-type: none"> Individual jurisdictions need not worry about interoperability with other IIS directly. Individual jurisdictions can support this strategy with little or no change to their infrastructures. Implementation can proceed incrementally. Consistent with focus of CMS EHR Incentive Programs on EHRs. Does not require any more governance than agreement between the trading partners. Individual provider sites not hampered by limitations in particular jurisdictions of interest. 	<ul style="list-style-type: none"> Places the burden of record consolidation on the provider. Access to data limited by capabilities of multiple IIS of interest to a provider. EHR-S may need to be enhanced to able to perform queries to multiple IIS and integrate the results. Providers will have to negotiate data sharing agreements with each jurisdiction in the absence of a national model or agreement. Providers would become even more responsible for patient and especially vaccination-level de-duplication of data

²² This is not to diminish the importance of population health and clinical quality measures from the clinician’s point of view, but for most providers these are secondary concerns.

Strengths	Weaknesses
	<p>as the point of integration is their EHR-S.</p> <ul style="list-style-type: none"> • Integration/de-duplication of results from multiple sources now needs to be done by the provider and not the IIS causing a potential delay in the availability of the information to the clinician. • EHR-S may have insufficient clinical decision support (CDS) to assess consolidated record locally. • IIS performance capacity may be adversely impacted by an increase in query requests.
Opportunities	Threats
<ul style="list-style-type: none"> • Health Information Exchanges (HIEs) could take a prominent role in onboarding providers for inter-jurisdictional data sharing to simplify the process for IIS projects already overwhelmed with onboarding requirements <i>within</i> their jurisdictions. • HIEs could reduce the number of end-points for IIS connectivity. • Strong incentives for standardized technical approaches to develop. 	<ul style="list-style-type: none"> • Variability in technical approaches to interoperability may continue to hamper progress. • IIS may push providers from other jurisdictions lower in the onboarding queue which will hamper access to data.

Leverage Emerging National Networks

With the number of IIS in the US limited, an existing or emerging national network could provide the interconnection between them, especially if PHAs have other drivers for connecting to the network anyway. Surescripts is the near-universal provider of ePrescribing services in the US so nearly all EHR vendors have a relationship with the company. Surescripts already provides a multi-IIS interface engine (at last count supporting more than forty IIS) into which daily submissions from large pharmacy chains are submitted, then parsed, processed, and sent to the appropriate IIS as standard HL7 v2 messages based on patient's zip code. While these services are provided for a fee, Surescripts has already invested a significant amount in developing and maintaining the profiles of all the IIS interfaces that they feed, and this knowledge could be leveraged for IIS to IIS interoperability. It is worth noting that Surescripts primarily supports data submission to IIS and only supports query/response in a limited fashion.

Another good candidate for this network is the eHealth Exchange which emerged out of the Nationwide Health Information Network (NwHIN) Limited Production Exchange into a self-standing national network operated by HealthWay.²³ Nodes on the eHealth Exchange interoperate through services developed to be compliant with a set of open specifications

²³ <http://www.healthwayinc.org/>

based on IHE Profiles.²⁴ All participants (without exception) agree to abide by a common Data Use and Reciprocal Support Agreement (DURSA) and that is one of its strength. The eHealth Exchange was designed primarily to connect whole *networks* together, not individual sites or systems. While it is therefore not likely appropriate for the many provider-to-IIS connections necessary to support interoperability, it is likely a good fit for the smaller number of IIS-to-IIS connections. PHAs may be considering joining the eHealth Exchange to satisfy larger agency objectives and IIS may be able to gain access to the network with no marginal cost or action. While the eHealth Exchange uses technologies that are similar to other IIS interoperability technologies (*e.g.*, web services) the specifications differ somewhat significantly from those used for EHR to IIS interfaces. However, only *one* eHealth Exchange connection would be required for each IIS to be connected to *all others* who choose to join the network.

The strengths, weaknesses, opportunities, and threats (SWOT) of leveraging a national network include:

Strengths	Weaknesses
<ul style="list-style-type: none"> • Implementation can proceed incrementally as each IIS joins the network. • All IIS use a consistent technical approach for interoperability between them. • All jurisdictions agree to common DURSA and pre-established governance. Jurisdictional differences in privacy/security laws can be accommodated within this process. • May provide point of leverage for existing (or pending) PHA connection to the national network. 	<ul style="list-style-type: none"> • Cost to join national network may not be affordable for PHAs. • Technical expertise may not exist within PHAs to support connections to national network. • May require different technical implementation than IIS-to-provider interoperability.
Opportunities	Threats
<ul style="list-style-type: none"> • Leverage of commercial services may speed up the implementation timetable significantly. • Health Information Exchanges (HIEs) could assist in inter-jurisdictional data sharing by providing network connectivity for IIS/PHAs. 	<ul style="list-style-type: none"> • National network may not prove in the long run to be a viable interoperability platform. • Patient and vaccination-level de-duplication of data will be an even larger issue across jurisdictions than it is within IIS projects now.

A Consumer-mediated Approach

At the end of the day, it's the patient (as well as the provider) who needs the consolidated immunization information. And the patient knows where s/he has received care. Personal Health Records are developing quickly as patient-accessible (if not patient-controlled) repositories for health data. There are two kinds of PHRs (Figure 3): "tethered" PHRs are

²⁴ <http://www.healthwayinc.org/index.php/in-the-news/2-uncategorised/44-exchange-specifications-manifest>

patient portals that provide access to data from an EHR system within a single healthcare organization. Usually, the patient portal uses a simpler interface than the EHR-S itself and provides only a subset of data. An “untethered” PHR is controlled completely by the patient and is not connected to any particular EHR-S or healthcare organization. The patient decides what data to store and who should have access to it. Use of tethered PHRs should increase in the short run as Stage 2 Meaningful Use requires providers and hospitals to allow patients to view, download, and transmit their data relevant to treatment at the site. Over time, untethered PHRs should increase in popularity as patients discover the limitations of the tethered approach and seek solutions that allow integration of their data *across* provider sites.

Tethered PHRs are really extensions of EHR systems. Often they present data in an encounter-based format rather than longitudinally. For immunization data this is a critical distinction: it is of limited usefulness for a patient to pick through multiple encounter summaries to pluck out immunization events – they simply won’t do it. A PHR needs to present a consolidated, longitudinal immunization record display much as an IIS web interface does for providers. If done well, though, a tethered PHR could certainly provide a consolidated view (as Epic’s MyChart does, for example), but of course its data will only be as complete as the data in the EHR-S from which it is drawing. For this approach to be viable (and distinguished from the EHR-centric model above), it is the *untethered* PHR that is relevant here since *patients* should have the right to receive their own data and they have a strong interest in consolidating it. Several IIS already provide access to patient data through a number of mechanisms, some via web-based portals directly into the IIS database²⁵ and some through third-party portals.^{26,27}

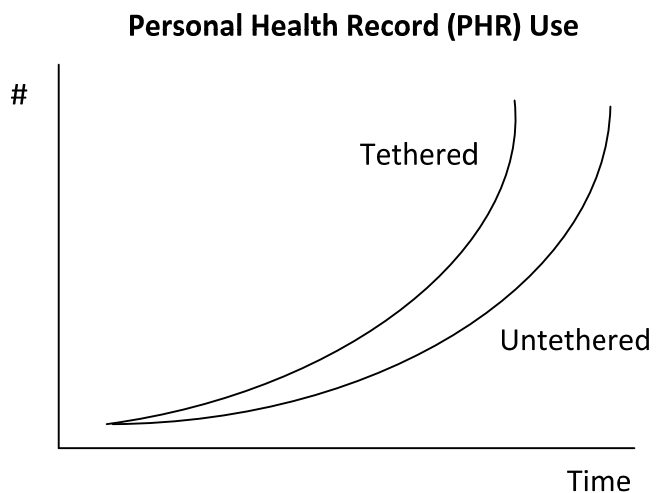


Figure 3 – Types of PHRs

This approach would require interoperability between IIS and untethered PHRs. Patients would need to have a way to request data from multiple IIS and have that data consolidated in their PHR. If implemented, this would be breaking fairly new ground, as there are a number of issues relating to authentication of the legitimacy of a patient-initiated query. Technologies and standards to support this type of access are currently developing, though it is less clear how successful they will be in the marketplace.

²⁵ For example, see <https://myvaxindiana.in.gov/>

²⁶ For example, see <https://myir.net/>

²⁷ HLN Consulting, LLC and Deloitte Consulting, *Consumer Access to Immunization Information System (IIS) Data: Synthesis of Work to Date*, August 2013. <<http://www.health.state.mn.us/e-health/consumeraccessdata.pdf>>

The strengths, weaknesses, opportunities, and threats (SWOT) of a patient-mediated approach include:

Strengths	Weaknesses
<ul style="list-style-type: none"> • No issues of consent management as the patient ultimately should have the right to request his/her own records. • Individual jurisdictions need not worry about interoperability with other IIS directly. • Individual jurisdictions can support this strategy with little or no change to their infrastructures. • Implementation can proceed incrementally. 	<ul style="list-style-type: none"> • Places the burden of record consolidation on the PHR. • Access to data limited by capabilities of multiple IIS of interest to the patient. • PHR-S may need to be enhanced to able to perform queries to multiple IIS and integrate the results. • PHRs will have to negotiate data sharing agreements with each jurisdiction in the absence of a national model or agreement. • PHRs would become even more responsible for patient and especially vaccination-level de-duplication of data as the point of integration is their PHR-S. • Integration/de-duplication of results from multiple sources now needs to be done by the PHR and not the IIS causing a potential delay in the availability of the information to the patient. • PHR-S may have insufficient clinical decision support (CDS) to assess consolidated record locally. • IIS performance capacity may be adversely impacted by an increase in query requests.
Opportunities	Threats
<ul style="list-style-type: none"> • Leverages strong patient incentive to consolidate and control his/her own record. • This provides a potential mechanism for IIS to provide patient access to immunization data with little marginal effort or cost. 	<ul style="list-style-type: none"> • Variability in technical approaches to interoperability may continue to hamper progress. • IIS may push PHRs lower in the onboarding queue which will hamper patient access to data. • Patient and vaccination-level de-duplication of data will be an even larger issue across jurisdictions than it is within IIS projects now.

These approaches can be examined relative to one another against a number of potential objectives and measures. The weight of the circle in each cell indicates the strength of that attribute for each approach. The unweighted total score is calculated by assigning a value of 1 to the lowest score (○), a value of 2 to the middle score (◐), and a value of 3 to the highest score (●). They are unweighted because each measure is considered equally with all other measures:

Measure	Current Approach	Regionalized Approach	EHR-Centric	National Network	Patient-mediated
Will achieve universal interoperability more quickly	○	◐	◐	●	○
Builds on/promotes compliance with national standards	◐	◐	◐	●	◐
Ease of governance	○	◐	◐	●	●
Builds on/consistent with existing IIS technical implementation	●	●	●	◐ ²⁸	●
Provides an accurate consolidated immunization history	●	●	◐	●	◐
Provides an accurate vaccine forecast	●	●	◐	●	◐
Opportunity to Leverages HIEs	●	●	●	●	○
Likelihood of ultimate success	◐	◐	◐	◐	○
Lower overall cost	◐	◐	●	◐	●
Unweighted Total Score (1, 2, 3)	20	22	21	24	18

Notice that no one strategy stands out head and shoulders above any other and even the unweighted scores are remarkably similar across the options.

Conclusion: Towards a National IIS Strategy

It is not likely that a purposeful national strategy will emerge anytime soon, since it will take strong leadership and funding to make such an event a reality. But that does not mean progress cannot – and will not – be made towards greater cross-IIS interoperability. And it is possible that several strategies will take hold simultaneously, perhaps even converging over time on one approach, or continuing a compatible multi-approach strategy.

²⁸ Depends on strategy selected.

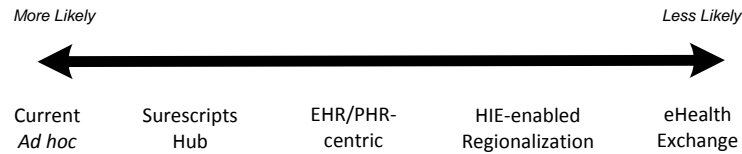


Figure 4 – Likely Outcome Choices

The likely scenarios over the next five years include (Figure 4):

- **The path of least resistance.** The current approach is clearly the path of least resistance. Projects will continue to forge bi-lateral agreements with neighboring jurisdictions as it suits their needs and available funding. Interoperability technologies being used for provider to IIS interfaces will be used for inter-IIS functionality as well. As more pressure builds for greater uniformity in IIS HL7 specifications, this strategy may enable greater participation between IIS and may flourish into a truly national strategy over time.
- **Commercial solution.** The most practical solution might not come from the public health community at all, but rather from a commercial solution already well on its way to becoming the *de facto* hub for submission of data to IIS, initially just from pharmacies. While these services are currently provided for a fee, Surescripts has already invested a significant amount in developing and maintaining the profiles of all the IIS interfaces that they feed, as well as the infrastructure and staffing to support these connections, and this knowledge could be leveraged for IIS to IIS interoperability. A commercial partnership with significant experience to leverage may be the quickest and potentially cheapest way to implement more pervasive immunization data sharing.
- **EHR- and PHR-centric access.** Meaningful Use is just picking up steam. We will continue to see several years of “shake out” among EHR systems in terms of the number of ONC certified systems that can feasibly continue and the functionality they offer. Tethered PHRs will become quick common, likely pushing open the market PHRs in the next two to three years for untethered to help patients make sense of their EHR across providers – in this scenario, tethered and untethered PHRs will co-exist and interoperate. IIS in this scenario will find that they are supplying data at both ends – to the EHR systems to support Stage 3 Meaningful Use query *and* to untethered PHR systems to meet consumer demand. The data streams will converge at the patient’s point of access and produce either a complete record or an incoherent jumble of duplicated events.
- **HIE-enabled regionalization.** There does not appear to be the political will or financial ability to launch independent regionalized inter-IIS projects at this time, however HIEs are continuously looking for new sources of revenue and sustainability. Given the frequency with which medical trading areas span jurisdictional lines, HIEs are well positioned to provide regionalized services to public health. We may begin to see HIEs encroaching on historical IIS territory: IIS can either try to benefit from (and even work to craft) the new services, or risk potential marginalization by HIEs and the communities they serve.

- **eHealth Exchange.** It is possible that the eHealth Exchange will indeed gain traction among HIEs, large provider organizations, ACOs and public health agencies. If PHAs find themselves becoming nodes on the Exchange, it becomes much easier (and cost effective) for IIS to leverage these connections to interoperate with each other. This would not happen in a well-coordinated or purposeful way (for IIS, that is), but will emerge as circumstances permit. Brave early adopters will implement the different technologies necessary to use this network, potentially through an interface engine deployed at the agency level. But it would take an extreme set of events to make this approach universal. In a variation of this scenario, HIEs could be a major enabler of the use of the Exchange either in a regionalized solution (see above) or otherwise.

This discussion is meant to begin the conversation of a national IIS strategy, not necessarily provide a definitive answer to this complex problem. An analysis of options can be presented, but clearly other options will emerge from the discussion that should follow.