IIS and HIE:
Is there a Future Together?

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This purpose of this paper is to describe the developing health information exchange (HIE) landscape, including current HIE collaboration with IIS, and to provide some insight about the future of IIS-HIE collaboration. After briefly defining and discussing IIS development with a focus on interoperability, the paper will go on to define HIE functionality, including the benefits to public health and the contributions public health can make to HIE efforts. The paper will continue with a description of some current research on IIS-HIE collaboration before concluding with a discussion of the key question: Do IIS and HIEs have a future together?

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.

Health Information Exchanges (HIEs) are collaborative efforts that focus on sharing health data in a community, county, or even on a state-wide basis. They can provide new and efficient ways for public health agencies (PHAs) and IIS projects to receive and send data, especially from the clinical community. Yet HIEs are quite diverse and have yet to provide a pervasive or consistent set of services that can be leveraged by public health.

Immunization Information Systems

Nearly every US state and territory has an IIS, defined by the Centers for Disease Control and Prevention (CDC) as, "...confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area."[2] IIS have been around for nearly twenty years. 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 agency[3] will continue to grow, captured in Figure 1 (which was inspired by the pop-culture posters of the

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

[2] http://www.cdc.gov/vaccines/programs/iis/about.html

[3] 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>

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).[4]
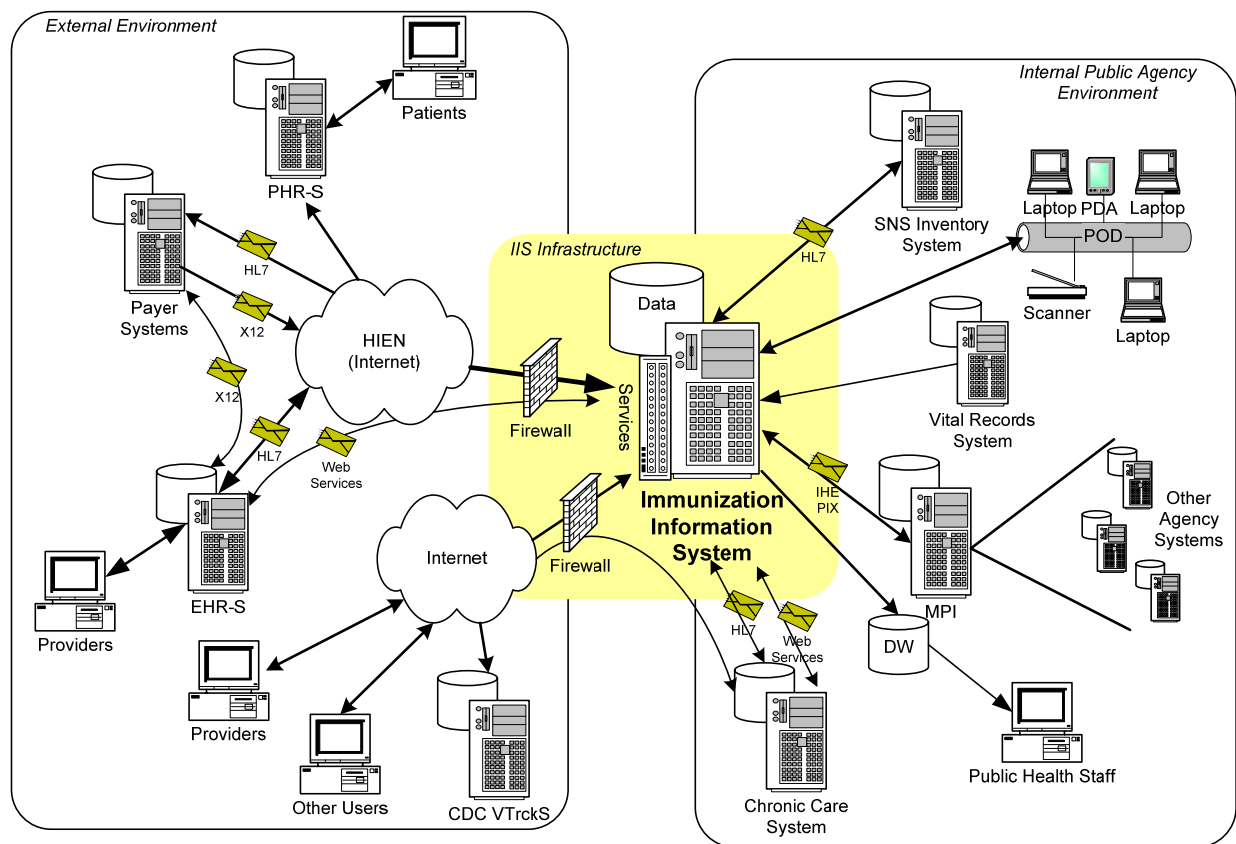

Figure 1 – IIS of the Future

IIS provide a rich set of data for both providers and public health. Here are some of the sources and uses depicted in the diagram above. For public health, 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 delivery of services (either agency-wide or jurisdiction-wide). Because most IIS are population-based they typically have strong

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[4] 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>
A more thorough discussion of the IIS of the Future can be seen in Arzt, Noam H., *Towards a National IIS Strategy: Options for Developing a National Immunization Information System Architecture,* October 2013.
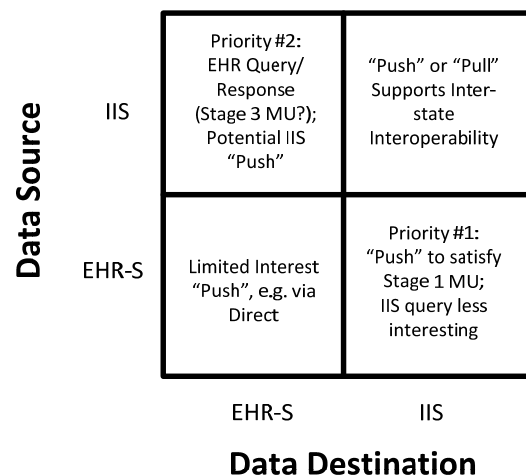[5] http://www.cdc.gov/phpr/stockpile/stockpile.htm

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). Finally, 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.

For providers, access to IIS has always been a key objective to support clinical care, support quality measures, 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. 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. And as more immunization administration moves to retail pharmacies, their interactions with IIS will increase accordingly both to provide data and query.

As interoperability becomes paramount, IIS projects need to consider how they will meet these data exchange requirements effectively. Given the bi-directional nature of interoperability, IIS have to consider themselves both a destination and a source of data (Figure 2). Not all targets of opportunity for interoperability can be satisfied at the same time, especially given limitations of funding as well as

		Data Destination	
		EHR-S	IIS
Data Source	IIS	Priority #2: EHR Query/ Response (Stage 3 MU?); Potential IIS "Push"	"Push" or "Pull" Supports Inter-state Interoperability
	EHR-S	Limited Interest "Push", e.g. via Direct	Priority #1: "Push" to satisfy Stage 1 MU; IIS query less interesting

Figure 2

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[6] http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx
[7] http://www.cdc.gov/vaccines/programs/vtrcks/index.html

variations in technical preparedness among data exchange partners. For IIS, their top priorities are first and foremost receipt of immunization reports to satisfy the immediate requirements of the CMS EHR Incentive Programs (bottom right in Figure 2) which can be enabled by a variety of technologies that allow providers to "push" data to IIS. The second priority – supply of IIS data back to provider systems (upper left in Figure 2) is best satisfied by query/response capabilities that many IIS are enabling, in part with an expectation that Stage 3 Meaningful Use will require this. Most IIS are not focused on either IIS-to-IIS interoperability (upper right in Figure 2) or EHR-S-to-EHR-S interoperability (lower left in Figure 2).

The National IIS Landscape

IIS exist in all states and US territories but one, and that last state is in the final stages of selecting an IIS product for deployment. Functionality, completeness, and usefulness of IIS have all steadily increased over the years.[8] IIS have worked steadily to meet the requirements of CDC Functional Standards which were revised in 2013.[9] The American Immunization Registry Association (AIRA), in conjunction with CDC, continues to provide needed support and a strong environment for collaboration among IIS projects.[10] The commercial market for IIS products has consolidated over the years with three products dominating (two commercial off-the-shelf, one public health developed) and a smattering of other solutions (some commercial, some custom developed) rounding out the field. IIS projects seem more willing to work together to achieve common goals, and a new "joint development" initiative was launched by AIRA in the Fall of 2013.

State and local governments continue to go through changes as well. Many jurisdictions have reacted to funding limitations by consolidating and centralizing IIS technical staff and operations either at the agency or even the State level. While this type of organizational change tends to go in cycles, the current swing pulls technical staff away from IIS program staff and often limits the technical resources available to support IIS projects. In the worst-case scenario, IIS projects can be marginalized within agencies as overall priorities shift the focus to other efforts and activities.

With shrinking resource bases, IIS continue to look for ways to sustain their projects. Most states do not support IIS with state funds but instead rely on Federal funding from the CDC either through the Immunization Grant Program (Section 317[11]) and other grant programs with various Federal agencies. As state (and Federal) budgets continue to suffer from a sluggish economy, some IIS projects look to other related public health projects to enhance the usefulness of the IIS, including integration with childhood lead poisoning prevention programs,

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[8] For the most recently available data on this see the *Progress in Immunization Information Systems - United States, 2011*, Morbidity and Mortality Weekly Report (MMWR), CDC: January 25, 2013 / 62(03);48-51.
 < http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a2.htm>
[9] http://www.cdc.gov/vaccines/programs/iis/func-stds.html
[10] http://www.immregistries.org/
[11] http://www.cdc.gov/vaccines/programs/vfc/downloads/grant-317.pdf

obesity management programs, various newborn screening programs, and others. In addition, states have taken on additional program management burdens such as the need to manage vaccine orders by participating in the Vaccine Management Business Improvement Project (VMBIP[12]) and the deployment of the Vaccine Tracking System (VTrckS[13]).

Health Information Exchange

So where does health information exchange (HIE) enter the picture? One of the challenges with interoperability is providing robust, reliable, and cost effective connections between practice sites and IIS, and HIE supports these new ways of sharing data. HIEs are collaborative efforts that focus on health data exchange in a community, county, or even on a state-wide basis (Figure 3). They have a wide and varied set of participants (providers, labs, hospitals, health plans, public health agencies, pharmacies, and patients/citizens). Note that the term "HIE" can be used as both a *verb* and a *noun*: As a verb, HIE refers to the *act* of exchanging data through whatever means and using whatever technology that is selected. As a noun, HIE refers to the physical network or organization that enables the data exchange to take place (sometimes the organizations are call Health Information Organizations, or HIOs).

Primarily driven by private-sector participants, HIEs may involve public health agencies as a key player in their formation and operation. While the emphasis is typically on exchanging clinical data to support patient care, some health data exchanges focus on health services data instead of—or in addition to—their clinical needs. HIEs have begun to intermediate in public health reporting services, including provider-IIS interoperability. Today, HIEs typically rely on existing means of connectivity which often use proprietary vendor protocols delivered over virtual private network (VPN) connections. Some HIEs provide value-added services (such as semantic coding or message filtering), while others simply transport the data from source to destination.
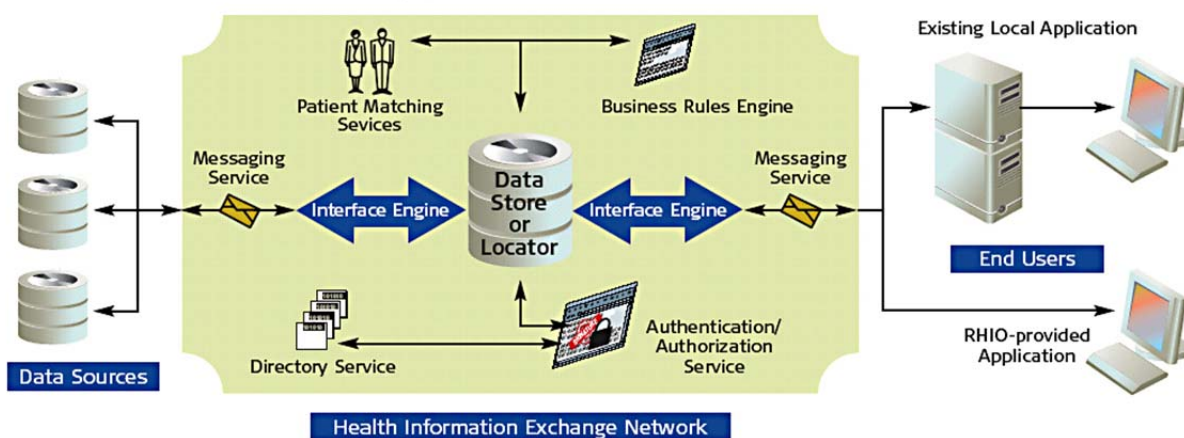

Figure 3

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[12] http://www.cdc.gov/vaccines/programs/vmbip/default.htm
[13] http://www.cdc.gov/vaccines/programs/vtrcks/index.html

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 4). 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 d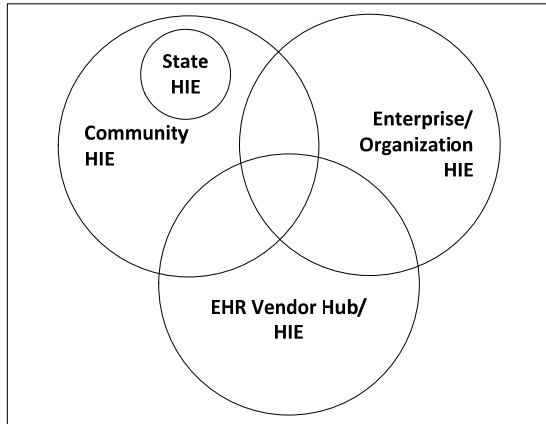eployment of lighter strategies such as directed exchange. Most community HIEs continue to work hard on developing an appropriate business model and sustainability plan as the spike of government funding over the last several years is subsiding.

Figure 4

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 agencies (PHA). 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**.** Public health agencies – including IIS – have a lot to gain by participating in HIE activities, including:

- **Achieve Public Health Goals** of increased data collection and dissemination.

- **Support meaningful use** and other objectives of the CMS EHR Incentive Program since many of the interoperability objectives and measures involve public health.

- **Connectivity:** Many of public health's data trading partners will choose to interoperate with an HIE and reduce (or eliminate!) what they may perceive to be superfluous, and perhaps costly, additional connections, even to public health.

- **New Sources of Data:** Public health can gain access to data and trading partners who previously might not have participated in its initiatives.

- **Inclusion:** It's better to be an insider than an outsider: As the healthcare community moves in this direction, public health should be an active participant—or risk being left out of the network.

And similarly, public health has a lot to contribute to health information exchange, including:

- **"Quick start":** By leveraging existing public health interoperability activities, including interfaces to labs and providers, HIEs can move ahead more quickly with interface deployment.

- **Existing data:** PHAs already have systems and applications that have consolidated and population-based data, including master person index systems, that can be leveraged by and HIE for broader access.

- **Expertise:** PHAs have experience in key technical areas that are critical to HIE operations and success, including patient matching and de-duplication, database management, web-based portal development and support, and HL7 messaging.

- **Existing relationships:** For years PHAs have developed coalitions of stakeholders, including providers, payers, professional associations, and even citizens. These are often the same stakeholders who need to be involved in HIE activities.

- **Governance:** PHAs have experience in negotiating and implementing data sharing agreements.

Current HIE Landscape

Since its inception, HIE has taken some unpredictable turns. Statewide HIE projects differ greatly across the country and include many models, including single, consolidated, statewide HIEs (*e.g.,* DE, VT); regionalized HIEs with some statewide coordination (*e.g.,* NY, MI); and state HIEs with little infrastructure and varying levels of coordination (*e.g.,* CA). In addition, significant HIE activity occurs in the private sector within complex organizations (*e.g.,* internal networks in hospital systems comprised of multiple hospitals, ambulatory clinics, specialty facilities and affiliated practices) as well as within "hubs" provided by EHR system vendors for their clients. e-Prescribing continues to take place largely outside of traditional HIE settings (usually via the Surescripts network). Finally, some independent state HIE projects have ceased

to operate and been folded back into State government (*e.g.,* KS, TN) or completely ceased operations (*e.g.,* Carespark).

While Federal HIE initiatives (including the State HIE Cooperative Agreement Program) focused largely on Meaningful Use requirements of the CMS EHR Incentive Programs, the specific requirements for *HIE* in Stage 1 (and somewhat in Stage 2) are rather meager , though they do include immunization data submission by eligible professionals and hospitals.[14] Stage 3 purports to have more HIE requirements but the final rule is pushed off into 2014 at minimum. The ONC State HIE Cooperative Agreement Program shifted a large portion of its emphasis away from query-based exchange to "push" transactions largely focused on use of the Direct protocol. Uptake of Direct has been mixed across the country as the basic technology seems sound but the governance mechanisms needed for it to roll out securely across the country was lacking.

Public health data submission continues to evolve, with immunization, electronic laboratory reporting, and syndromic surveillance taking center stage, with cancer reporting poised to make its move with Stage 2 Meaningful Use. Stage 3 MU should bring immunization query/response and, though that is still several years away, IIS are preparing now for this capability.

As Federal funding for HIE diminishes and is eliminated by the spring of 2014, the ensuing period will be "sink or swim" time for HIEs. While there has been some activity on the issue of HIE sustainability, precious little best practice has been published in this area. From a state funding standpoint, Medicaid continues to be the most viable source of grant funding through its 90/10 matching program for HIE activities. Of course, only the proportion of a project budget that corresponds to the proportion of citizens who are eligible for the Medicaid program can be requested, and the 10% matching funds cannot be Federal in origin. As HIEs become more desperate, they will look for newer and different lines of business where they might add value to their members and customers.

IIS-HIE Collaboration

A 2013 unpublished CDC study examined the current status of IIS-HIE interactions, documenting both success stories and challenges.[15] After interviewing eight IIS and HIE projects, the study concluded that:

- Effective partnership is the key determinant to success
- No "one size fits all" technical solution exists for successful HIE-IIS data exchange

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[14] For more details on Meaningful Use and public health see http://www.hln.com/expertise/hit/hie/mu-ph.php

[15] See Noam H. Arzt and Danielle Reader-Jolley, *Building Effective IIS-HIE Relationships: Findings from a Nationwide Telephone Survey,* American Immunization Registry Association (AIRA) 2013 National Meeting, Denver, CO, October 8, 2013. < http://www.immregistries.org/resources/iis-meetings/1.Building_Effective_HIE-IIS_Relationships_Results_of_Nationwide_Study.pdf>

- IIS are seen as the authoritative source of immunization information
- True bi-directional exchange through an HIE is not yet generally a reality
- Both HIEs and IISs are challenged to meet on-boarding demand

The study went on to identify a number of opportunities for IIS-HIE collaboration (including benefits to IIS in provider HIE participation, shared responsibility for provider onboarding for IIS interoperability, and benefits to HIEs in gaining immunization expertise from IIS) as well as a number of challenges ("turf wars" that interfere with productive collaboration, legislative barriers to effective collaboration, and technology challenges relating to standards and misalignment of priorities). Finally, the study made a number of recommendations for IIS and HIE projects, including:

- When mutual value can be demonstrated, develop consistent and shared messages to providers of how the HIE and IIS are working together to support information exchange and enhance quality of care.
- Agree upon the respective areas of expertise.
- Don't compromise IIS *or* HIE functionality when partnering.
- Identify mutually agreeable and appropriate roles for on-boarding providers.
- Involve public health in HIE at both governance and technical levels.
- Carefully review the respective laws, policies and regulations related to health information disclosure and mandatory reporting requirements.
- Future IIS/HIE partnerships should prioritize comprehensive messaging strategies to minimize the impact on provider practices.

Though the sample for this study was limited, the observations are encouraging. Interoperability is not always a balanced activity, however. Today's focus is on provider *submission* of data to an IIS (data senders), but tomorrow's focus will be on provider *query* of IIS data (data receivers). In any data exchange relationship, a variety of roles are possible (Figure 5). Participants – including IIS – hope that data exchange partners will become full participants: both sending data (in this case, immunization histories received from patients and immunization information from doses administered), and receiving data back from the IIS (complete immunization history as well as forecast). But some participants may only supply data (perhaps due to a technical limitation) and are characterized as "good Samaritans." Still others may only desire to *receive* data but not contribute data: they are characterized as "opportunists." And, of course, there may also be non-participants who neither send nor receive data. How will HIEs and IIS position themselves in this matrix?

As HIEs become more hard-pressed to offer value to their customers and sustain themselves financially, they

		Receive Data	
Send Data		**No**	**Yes**
Yes		Good Samaritan	Full Participant
No		Non-Participant	Opportunist

Figure 5

may look to their ability to aggregate data more strategically. Already some HIEs see data analytics as one key to their sustainability. The more HIEs collect and store data on its way to IIS the less they may perceive a need to rely on IIS to get data back. This may have some profound effects on IIS projects, including potentially a reduction in the *quality* and *timeliness* of immunization data reaching IIS as HIEs and their provider-customers can access more of the data locally within the HIE. This may be especially significant in jurisdictions without a mandatory immunization reporting law to help enforce timely submissions (Meaningful Use leaves the definition of "ongoing submission" largely up to the IIS[16]). Another risk is that HIE-based immunization repositories may continue to have gaps in information which will result in incomplete immunization histories, and HIEs may not have the clinical decision support (CDS) capabilities to accurately predict on an ongoing basis when immunizations are due (or overdue) for the patients in their databases.

Emerging IIS program changes also jeopardize the future of IIS-HIE collaboration. Increasing requirements for accountability for use of vaccine acquired by providers through the Vaccines for Children Program (VFC) is leading IIS to demand even more detailed data from providers on vaccines administered which are funded through this program.[17] This usually takes the form of requiring not only lot number and manufacturer to be submitted to IIS along with the rest of the data, but also with VFC program eligibility information to be certified with each dose administered. Most EHR-S are simply not yet able to store every piece of required information, or if they can, they find it challenging to include all this data in HL7 messages being sent to IIS.[18] Some IIS are taking a different tact: they are encouraging providers to use the *IIS* web interface as the primary means of entering new doses administered and providing a mechanism for providers to query the IIS and download the newly-entered doses into the local EHR-S. While this does provide a rich graphical user interface (GUI) for accurate entry of immunizations closely coupled with VFC accountability through the IIS, it also is *counterproductive* to the CMS EHR Incentive Programs which measure public health data submission by whether the data *originates* in electronic form from the certified EHR system itself.[19] The tension between the requirements of these two programs may affect EHR-S-IIS interoperability and by extension IIS-HIE collaboration.

Is There a Future Together?

IIS have been around for quite some time and have been quite resilient over the years in maintaining their purpose and activity. HIEs, though, have had a profound effect on the larger healthcare ecosystem as data *sharing* becomes more and more important. Both activities have

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[16] http://www.hln.com/expertise/hit/hie/mu/mu-iz.php

[17] http://www.cdc.gov/vaccines/programs/vfc/index.html

[18] Note that currently commonly-used clinical document specifications (like CCD and C-CDA) do not include all these data points either.

[19] One possible solution is to *resend* the new doses back to the IIS but this seems wasteful and has potential implications for IIS capacity and data quality.

shown themselves to be quite resilient. How should IIS and HIE projects view each other in the coming years? We offer the following advice, purposely aimed at *both* IIS and HIEs together:

- **Communicate whether you collaborate or not.** Whether projects decide to collaborate or not, they need to have open, honest, ongoing channels of communication. Both IIS and HIE need to recognize the changing nature of the healthcare landscape – a decision today might not be the same decision that might be made tomorrow.
- **Know when to compromise, and when to stick to your guns.** Both IIS and HIE have primary, somewhat overlapping missions, but they do approach healthcare from different perspectives, with different drivers, and different constraints. IIS need to protect the data within their care, and provide information and services for which they are uniquely qualified. HIEs need to continue to satisfy their entrepreneurial instincts as they look for long-term sustainability. But cannibalizing each other's primary activities serves no one well.
- **Leverage where it's sensible.** Though IIS and HIEs have evolved quite differently, they share some common objectives and often have differing capabilities. No organization likes to be unduly dependent on another for mission critical activities, but in today's environment of resource constraint organizations cannot afford needless redundancy. HIE and IIS projects should look hard for ways to meaningfully leverage each other capabilities even in unlikely places.
- **Strive for coherence from the customer's point of view.** Nothing is worse than a confused client. IIS and HIE projects are largely working with the same customers – whether they are hospitals, clinics, practices, or even patients. While organizations work hard at understanding the differences between them and other service providers, the average customer simply does not recognize the nuance of these differences. IIS and HIE projects – whether they are collaborating closely or not in the delivery of services – should craft service portfolios that are complimentary and coherent from the customer's point of view.
- **Be civil and respectful.** Everyone thinks they are the best; everyone thinks their approach is superior. There is a place for confidence, but it must be coupled with respect for other organizations and individuals who are operating within a project's sphere of influence. One need not always agree, but behavior must be civil at all times. You never know when today's competitor will be tomorrow's collaborator.