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CASE STUDIES IN MEANINGFUL USE

Meaningful Use and Public Health

An Immunization Information System Case Study

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ABSTRACT

Submission of immunization information from a certified electronic health record (EHR) to state/local immunization information systems (IIS) is one of three meaningful use public-health data submission objectives. Eligible healthcare providers can choose this objective if the public-health agencies in their jurisdictions are capable of accepting data electronically. Since 2009, New York City's IIS, the Citywide Immunization Registry (CIR), has supported standards-based submission of immunization data via a real-time, bi-directional Health Level 7 (HL7) web service. The advent of meaningful use requirements in 2010 presented the opportunity for the New York City Department of Health and Mental Hygiene to leverage the HL7 web service to improve the quality of data reported to the CIR, as well as the completeness and timeliness of reporting. To accommodate the changes brought about by meaningful use, the CIR expanded its capability to accept immunization data using the HL7 web service, and increased its ability to perform data quality assurance and management of data received through this method. This article will describe the purpose and function of IIS; review the requirements for meaningful use for immunization; describe the modifications made to the CIR processes, tools and systems to support testing, certification, and increased level of bi-directional data exchange; and provide data on the initial uptake of the web service in the provider community.

KEYWORDS

Meaningful use, public health, EHR, EMR, health information exchange, nationwide health information network, Health Level 7, immunization information systems.

CUTTING-EDGE PUBLIC health technology initiatives that require large investments on the part of healthcare providers will not entice—unless you help pay for them. The New York City (NYC) Department of Health and Mental Hygiene's (DOHMH) immunization information system (IIS), the Citywide Immunization Registry (CIR), released its “cutting edge technology” almost two years ago.

This technology, a standards-based real-time, bi-directional Health Level 7 (HL7) web service, allows healthcare providers to report immunizations to the CIR and query the CIR for immunization histories directly from their own electronic health record (EHR).

Nevertheless, developing an interface to connect to the web service requires resources, and initial interest in the technology from the health care community was limited. The advent of the Centers for Medicare and Medicaid Services' (CMS) meaningful use incentive payments in 2010 completely changed this landscape.

With a focus on EHRs and their meaningful use, CMS established a monetary incentive program to encourage eligible professionals and hospitals to adopt health information technology. This multi-year program is rolling out in several stages

FOCUS: MEANINGFUL USE AND PUBLIC HEALTH

and requires eligible professionals or hospitals to meet specific objectives in order to receive incentive payments. Stage 1 meaningful use is defined by the CMS Electronic Health Record Incentive Program Final Rule (July, 2010).^{1,2}

Three public health objectives related to reporting to public health agencies from an EHR were identified for Stage 1: reporting of immunizations, submission of laboratory results for reportable conditions, and reporting of syndromic surveillance information. Meaningful use participants must select at least one of these public health objectives for Stage 1, if the public-health agencies in their jurisdiction are capable of exchanging data electronically.

Development of Stage 2 and Stage 3 criteria are underway, and no new public health measures are expected. Since IIS in many jurisdictions are well-prepared to support meaningful use testing, submission of immunizations will likely remain a leading public health objective for meaningful use. It is also worth noting that meaningful use participants must select from a list of clinical quality measures on which to report, and may select childhood immunization status as one of these measures.

Use of the CIR's HL7 web service as a means to report immunizations to the IIS meets one of the Stage 1 meaningful use public health objectives. This presents the healthcare community with new resources and incentives to use the web service, which DOHMH expects will improve the quality of data reported to the CIR, as well as the completeness and timeliness of reporting.

To meet the anticipated increase in demand for the web service, CIR needed to expand its capacity to work with healthcare providers to develop interfaces between the web service and their EHRs. CIR also needed to increase its ability to perform data quality assurance and management of data received through this method. To understand the context in which these developments occurred more fully, this article will present a general background on IIS, the CIR and interoperability; describe the modifications made to CIR process, tools and systems; and provide data on the initial uptake of the web service.

PURPOSE AND FUNCTION OF IMMUNIZATION INFORMATION SYSTEMS

IIS, or registries, are defined as, "...confidential, population-based, computerized information systems that... collect vaccination data about all residents within a geographic area."³

They help providers and families by consolidating immunization information into one reliable source, making the information readily available during the physician visit, and offering decision support, i.e., flagging immunizations due based on recommendations of the Advisory Committee on Immunization Practices.

IIS also saves money by avoiding unnecessary or duplicate immunizations, and improve office efficiency by reducing the time needed to gather and review immunization records. Public health agencies use IIS to monitor and promote increased immunization coverage rates for the population, control disease outbreaks, manage publicly purchased vaccines and respond to emergencies.⁴

IIS exist in 49 states and the District of Columbia, eight territories and five cities.⁵ In some states, participation by healthcare providers in IIS is mandated by law; in other states participation is voluntary. While they began as a repository for childhood immunizations, IIS initial focus on pre-school children has expanded (within applicable state/local law) to encompass lifelong immunization and/or emergency preparedness and response. IIS have also begun to focus more on data integration across public health programs, including lead poisoning prevention and newborn hearing screening.

BENEFITS OF INTEROPERABILITY BETWEEN EHRs AND IIS

Exchanging data electronically between IIS and other systems—especially an EHR—is desirable for a number of reasons. Probably the most compelling reason is to establish more accurate and complete immunization records for individuals and populations, which are then used to support interventions to improve immunization coverage. Evidence-based interventions facilitated

by IIS at the provider level include patient reminder-recall and provider coverage assessment and feedback. IIS reminder and recall functions facilitate physician outreach to patients to encourage them to receive needed immunizations. Improving the accuracy and completeness of reporting in combination with retrieval of more complete records from the IIS, may also reduce over- and under-immunization in the clinical setting. At the population level, improved reporting will enhance the capacity of the public health agency to conduct accurate population-based surveillance of immunization coverage.

A second important benefit of interoperability involves improved workflow for clinical staff. As more immunization providers (practices, hospitals, and clinics) adopt EHRs, more immunization data will exist in electronic form, ready to be sent to an IIS. Yet in many jurisdictions, providers are currently required to key-enter immunization data twice (or more): once in their own system, and then again in a Web-based IIS application. This duplicative activity can be eliminated through implementation of electronic data exchange.

In New York City, the CIR's web service is poised to provide a means to achieve both of these important benefits, and meaningful use has established the incentives and resources required for the healthcare community, in service of public health, to take advantage of this new and exciting technology.

REQUIREMENTS FOR MEANINGFUL USE

There are two federal rules that govern the EHR incentive program and its corresponding technology requirements. The CMS Final Rule contains the following objective and measure for IIS in its Stage 1 (beginning in 2011) criteria for meaningful use:

- **Eligible Professional (EP)/Eligible Hospital (EH) Objective:** Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice.⁶

- **Eligible Professional (EP) /Eligible Hospital (EH) Measure:** Performed at least one test of certified EHR technology's

THE INTRODUCTION OF meaningful use presented an opportunity for the CIR to leverage its recently deployed HL7 web service to improve the timeliness, quality and quantity of data reported. However, this new opportunity also introduced a number of challenges.

capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP or EH submits such information have the capacity to receive the information electronically).⁷

- This objective is only relevant to EP/EH's who administer one or more immunizations during the reporting period.

The second federal rule, the ONC Final Rule for Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology (July 2010) identified two standards for immunization data exchange (HL7 2.3.1 and HL7 2.5.1)⁸⁻⁹ and functions as a companion document to the CMS Final Rule.¹⁰

The Centers for Disease Control (CDC), with the approval of the National Vaccine Advisory Committee (NVAC), encouraged IIS to comply with a set of functional standards well before the meaningful use initiative was announced. One of these standards (#7) is exchange of immunization records via the HL7 protocol.¹¹ As a result of this standard, IIS were well poised to work with the healthcare community to capitalize on the meaningful use requirements following the official announcement of the final rule.

Electronic movement of health data for meaningful use can be achieved through a number of mechanisms, from less formal direct exchange between individuals who know and trust each other (similar to how FAX is used today), to more sophisticated

health information exchanges (HIE) which provide the technical infrastructure for whole communities to interoperate.

Though the CMS Final Rule recognizes that the infrastructure to support HIEs is still developing, there is an expectation that, as the meaningful use program proceeds, submission of immunization information to public health agencies via HIE will increase. Retrieval of immunization records from an IIS to an EHR may also play a more prominent role as Stage 2 and Stage 3 of meaningful use become defined. This function will add value and efficiency for healthcare providers by enabling access from the provider's own EHR to a patient's complete immunization history, including immunizations and decision support from the local IIS.

For developers, it is important to note that transactions do not meet meaningful use unless generated from a certified EHR system or module in one of the two accepted HL7 formats. So, for example, a provider who sends a clinical document (Continuity of Care Record or Continuity of Care Document) containing immunization information to a public health agency is not meeting meaningful use, but a provider who generates an HL7 v2 message which is transformed into a clinical document by a health information exchange before it reaches a public health agency is meeting meaningful use.

If the IIS available to an EP/EH does not accept the version of HL7 generated by an EHR system the EP/EH can claim

exemption from this objective. Batch or real-time transmissions in HL7 format are both acceptable.¹²

THE CIR AND THE IMPACT OF MEANINGFUL USE IN NYC

Background. The CIR is a population-based IIS operated by the NYC DOHMH to track the immunization status of children and adolescents in NYC and monitor immunization coverage levels in the population. The CIR has more than 4.4 million individuals and approximately 51 million immunizations in its database.

The CIR is accessible to licensed healthcare providers, parents and agencies authorized by the DOHMH for the retrieval of immunization records for the purpose of ensuring that individuals receive all required immunizations and are thereby protected from vaccine-preventable diseases. The two principal sources of CIR data are birth certificates (loaded weekly) and data supplied by providers who are required by the NYC Health Code and New York State Public Health Law to report immunizations administered to children from birth through 18 years of age.¹³⁻¹⁴

As of April 2011 there were 241 public immunization facilities and 1,574 private immunization sites in New York City reporting vaccinations administered to children and adolescents to the CIR. More than 90 percent of enrolled New York City childhood immunization providers report regularly and an estimated 88 percent of immunizations given in NYC are reported

FOCUS: MEANINGFUL USE AND PUBLIC HEALTH

within 30 days of administration.¹⁵

Currently, providers have three means of reporting immunizations to the CIR:

The Online Registry. The Online Registry, the CIR's Web-based application, is used by more than 70 percent of the childhood immunization providers in New York City to either report to the CIR, obtain children's immunization records, or both. About 42 percent of all immunizations reported to the CIR are received via the Online Registry.

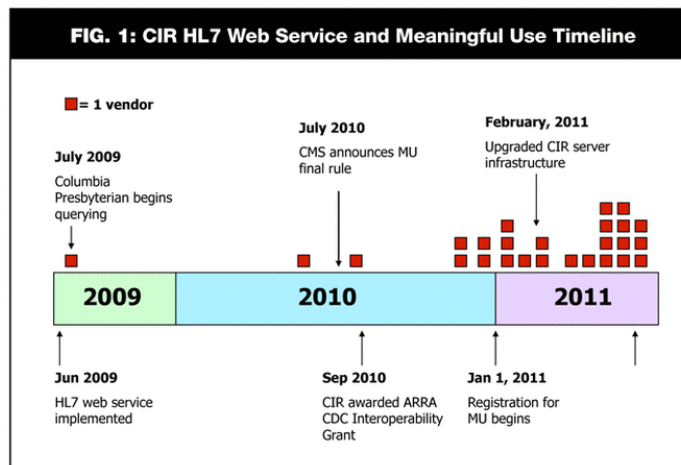
File Transfer. Batch files are sent to the CIR either via EHRs or billing systems. Currently about 57 percent of all immunizations reported to CIR are received via electronic file transfer. Reporting through file transfer is utilized by 620 sites (34 percent of total CIR sites). While the majority of these sites are sending files containing information in a CIR-developed non-standard format, four are sending HL7 batch files.

CIR's HL7 Real-Time Web Service. In the spring of 2007, the CIR partnered with HLN Consulting LLC (HLN) and the Primary Care Information Project, which would later become the Regional Extension Center for New York City, to implement a secure, real time, bi-directional HL7 web service for immunization transactions, in accordance with the HL7 implementation guide.¹⁴ The CIR deployed the HL7 v. 2.3.1 web service in the summer of 2009. Immunizations received through the web service make up just over 1 percent of all immunizations reported; however, this number is expected to increase rapidly given that many large hospitals and private provider facilities are working to connect to the web service.

CIR PROCESS: CHANGES TO ACCOMMODATE MEANINGFUL USE

The introduction of meaningful use presented an opportunity for the CIR to leverage its recently deployed HL7 web service to improve the timeliness, quality and quantity of data reported. However, this new opportunity also introduced a number of challenges, including increased workload for CIR staff and the need for additional computing infrastructure.

Furthermore, it necessitated the development of new processes and protocols for interface development, testing and



certification as well as ongoing data quality assurance. In November 2010, the CIR was awarded an American Recovery and Reinvestment Act (ARRA) grant: Enhancing the Interoperability of Electronic Health Records (EHR) and Immunization Information Systems (IIS), Grant Number: 1U66IP000449-01.

This grant allowed the CIR to hire new staff to work on EHR-IIS interoperability, to increase server capacity and to implement a tool for sustainable administration and quality assurance of bi-directional data exchange. These changes enhanced the CIR's capacity to accommodate rapid adoption of the web service by healthcare providers participating in meaningful use. The timeline for the meaningful use work and the changes made to CIR systems are shown in Figure 1.

TECHNICAL DECISIONS

When the CIR began researching the development of a technology to support HL7 interoperability (to meet CDC's functional standard #7 for IIS), the first step involved the selection of the technology over which this data exchange would occur.

After careful review of several options, a Simple Object Access Protocol (SOAP) web service was selected. Several considerations were taken into account when making this decision. One of the primary con-

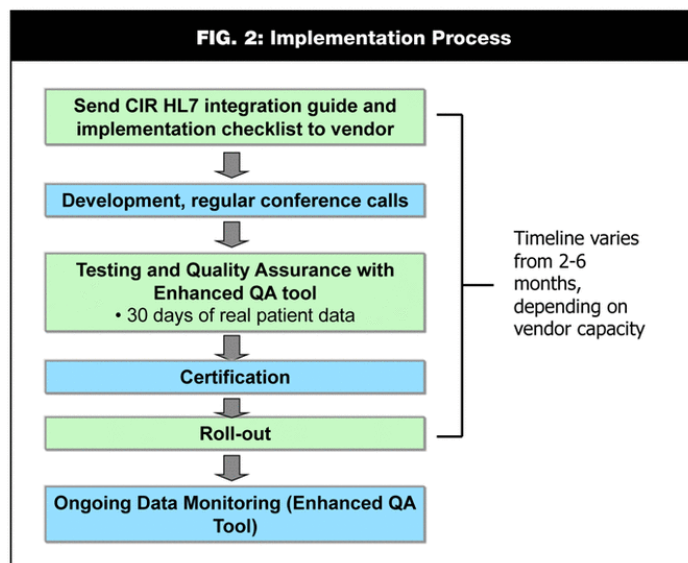
siderations was the ease with which EHR systems could integrate with and utilize the communication technology. The CIR found SOAP web services to be well suited to meet this requirement, as it integrates easily with Microsoft's .NET framework and Java, the software development environments used by nearly all EHR vendors.

The CIR also determined that a SOAP Web Service would integrate easily with CIR's own technologies, such as the Online Registry. An additional benefit was that there are free, open source implementations of the SOAP specification, an important consideration at a time when budgets continue to decline.

As the web service was being developed, HLN and CIR staff recognized two important needs. The first was the need for a web service test environment that could be used by EHR vendors and providers to review and correct their submissions before going into production.

The second was the need for a technical specifications document that would set forth CIR-specific interface requirements for the EHR vendors and hospital IT staff programming an interface between their system and the web service. Intended as a supplement to the CDC's Implementation Guide for Immunization Data Transactions using v. 2.3.1 of the HL7 Protocol⁸, the CIR HL7 2.3.1 Integration Guide¹⁶ provides CIR-

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specific requirements for connecting to the registry's HL7 web service and for creating messages with the proper structure and content. The CIR's HL7 Integration Guide also includes a set of detailed examples, in which sample HL7 messages are listed in their entirety and then analyzed and discussed along with the sample message that the CIR HL7 web service would send in response.

INTERFACE DEVELOPMENT, TESTING AND CERTIFICATION

The CIR HL7 integration guide is the key document that the CIR uses to initiate the development process with EHR vendors and hospitals interested in connecting to the HL7 web service.

After giving partners time to review this document, the CIR works closely with vendor and hospital IT teams during their development and implementation phases (see Figure 2) to ensure compliance with CIR-specific standards. During bi-weekly conference calls, CIR staff review many aspects of design and implementation decisions with vendors, including the data fields that will be sent, how immunization histories and decision support information

returned from queries will be displayed and stored, and how errors will be handled.

After development is completed, vendors can begin the testing process. The minimum standard for the meaningful use Stage 1 immunization reporting objective requires a provider to send at least one test immunization to the state/local IIS.

However, CIR encourages vendors to go well beyond this minimum criterion, and requires a formal and rigorous quality assurance process for those vendors planning to implement regular, production reporting and querying for their clients. Each vendor must undergo an official test in which they select a pilot site from which to send a large volume of real immunization data—usually one month's worth.

The data is sent to the web service test environment as a series of HL7 messages, and is reviewed by CIR staff within 48 hours. CIR staff provide feedback on the message statistics (how many were successful, partially successful or failed), explanations of the observed errors and suggestions for correcting those errors. After the vendor makes corrections, they are asked to send another large volume of data to the test environment to confirm

that all known issues were resolved and that no new errors were introduced. If this test is successful, they are certified to begin rolling out the production interface to their clients, which will allow clients to report immunizations in real-time to the CIR and query for immunization histories if that feature has been included in the interface; if the test is not successful, the testing process is repeated until all outstanding errors are resolved.

DATA QUALITY ASSURANCE

Reviewing the large volume of messages received during the testing process is labor intensive if done manually, as the messages are difficult to decipher without a high degree of familiarity with HL7 message structure. To accommodate the increased workload associated with reviewing messages for data quality, and to make such review accessible to non-technical staff, the CIR worked with HLN to develop a tool to automate much of the process. This tool, called the CIR Administrative Tool (CAT), is a web-based data exchange management application that enables CIR staff to perform both administrative tasks and data quality assurance.

On the administrative side, CAT allows CIR staff to register and create new provider facilities in the CIR database and grant them the account credentials necessary to use the web service to perform real-time bi-directional data exchange. On the data quality side, CAT allows CIR staff to search for and display a list of all of the HL7 messages sent by a particular facility during a specified time period. The user can see whether individual messages were accepted, rejected, or partially rejected, and can review the specific errors that caused any message rejections (Figure 3). CIR staff can compile aggregate statistics on error types and message success/failure rates and view the individual HL7 messages that contributed to the selected statistic. Staff can also use CAT to drill down to the message level and view each of the field values, making it possible to pinpoint errors or missing data at the field level (Figure 4).

While CAT is currently used by CIR staff exclusively, it will eventually be available to

FOCUS: MEANINGFUL USE AND PUBLIC HEALTH

EHR vendors during the testing process as well as the provider community to enable them to monitor their own messages for data quality on an ongoing basis.

ADOPTION OF HL7 WEB SERVICE

Feedback from the Provider Community. Providers have been very receptive to connecting to the CIR's HL7 web service. Those moving from Online Registry reporting (requiring manual key entry of individual immunizations) to reporting via the web service from their own EHR eliminate double data entry, and therefore, experience a significant time savings.

One facility that migrated from the Online Registry to the real-time web service was regularly entering upwards of 1,000 immunizations per month online, each of which had to be keyed in by a clinic nurse or staff person. Those providers who have implemented the web service query functions also benefit from the ability to obtain CIR data without logging into and searching the Online Registry to view patient immunization histories. These query functions allow physicians to import patient immunizations into their EHRs with the click of a button, rather than keying in the historical immunizations manually.

Successes. New York Presbyterian Hospital's sites, the first group to connect to the web service, began querying the web service in July 2009, and as of April 2011 had sent close to 700,000 queries for patient immunization histories.

As a result, their documented coverage for the 4:3:1:3:3:1 childhood immunization series (adjusted for age), based on a random sample of children receiving immunizations during the twelve month period immediately prior to analysis, increased from 79.3 percent to 85.6 percent for seven- to 23-month-olds, and from 78.6 percent to 86.1 percent for 24-36-month-olds.¹⁷

Documented coverage for the adolescent immunization series increased from 74.5 percent to 79.3 percent for Tdap; 69.8 percent to 76.4 percent for MCV4; and 61.1 percent to 68 percent for HPV1, showing that integration with the CIR can increase patient documented up-to-date rates by several percentage points.

FIG. 3: CIR Administration Tool

Facility Name	Facility Code	Account Name	Contact Name	Contact Number	Contact Email	Error Stats
NYC-DOH Bureau of Child Health	8000N70	HLNHL7				

All Messages	Success (No Errors)	Success (Non-Fatal Errors)	Partial Success	Failed
2	2	2	0	0

Successes (Fatal Errors)						
M	Message Control ID	Received	Admin Facility	Message Status	Fatal Errors	Non-Fatal Errors
238517	200707311223198436N70	04/05/2011 10:11 PM	8000N70	SUCCESS_NONFATAL		UNKNOWNIDENTIFIER (L) VIA LUMESING (L) BADNUMBER (S)...

FIG. 4: C.A.T Message-Level Screenshot

Fatal Error	Non Fatal Error	Segment	Name	Value
		MDH-9.1	Message Type: Message Type	V00U
		MDH-9.2	Message Type: Trigger Event	V004
		MDH-10	Message Control ID	200707311223198436N70
		MDH-1.1	Processing ID: Processing ID	T
		MDH-1.2	Version ID/Version ID	2.3.1
		MDH-16	Application Acknowledgment Type	AE
		PD-3.1 (I)	Patient Identifier List ID	86564
		PD-3.5 (I)	Patient Identifier List Identifier Type Code	SR

VNU Message

MDH-9.1 (PATIENTS) (T) (8000N70) (1) (2007090612147) (V00U) (MDH-10) (200707311223198436N70) (T) (2.3.1) (346) (1) (AE)

New York Presbyterian Hospital was the only partner to connect to the web service prior to the announcement of the meaningful use final rule. Subsequent to the official establishment of the meaningful use incentive program, there has been a surge

of interest among both EHR vendors and healthcare providers to connect to the CIR via the HL7 real-time web service.

The CIR is currently engaged with more than 25 EHR vendors, and many of the large hospital networks in New York City

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are actively participating in the development of web service interfaces. As of April 2011, one EHR vendor had completed CIR's testing and quality assurance process and had rolled out the interface to 27 of their private provider facilities. Since February 2011, these facilities have used the HL7 web service to report more than 68,000 immunizations and perform more than 9,000 queries. New York City Health and Hospitals Corporation, New York City's large public hospital and healthcare facility network, has completed the testing process and is slated to begin rolling out their interface at individual facilities in May. While their initial interface is unidirectional, they plan to implement bi-directional communication shortly after the reporting function is in place. This partnership is critical, as HHC facilities alone reported close to 650,000 immunizations in 2010, accounting for almost 10 percent of the total immunizations added to the CIR that year.

Challenges. While meaningful use has provided a powerful impetus for EHR vendors to work with the CIR and IIS nationally, progress in New York City has been hindered by the limitations of the meaningful use requirement for immunization reporting. EHR vendors are eager to comply with the meaningful use criteria, which at this stage only require unidirectional communication (immunization reporting) from the provider's EHR to the CIR.

Fewer EHR vendors at this time are

prepared to undertake the extra work required to implement bi-directional communication. This is unfortunate, as much of the value of the interface for healthcare providers lies in the provider's ability to receive immunization histories and decision support back from an IIS.

An additional challenge is the sheer number of EHR vendors and products utilized by New York City providers. As more providers begin the process of adopting EHRs in order to meet meaningful use requirements, they have an ever widening array of products to choose from. The ONC is certifying new products continuously, and as of April 2011, there were more than 400 ambulatory care EHR products and close to 200 inpatient care EHR products certified by ONC for meaningful use. Keeping informed of the constantly changing landscape of EHR products used by New York City providers is a challenge in and of itself, in addition to the challenge of engaging each of these vendors in development.

Each vendor requires a separate development effort and a significant investment of time and resources, whether the vendor has 500 clients that will connect to the IIS or just five. The investment of resources at this level would not have been possible without the additional funding provided by the CDC/ARRA grant.

Finally, EHR vendors have many responsibilities related to meaningful use and may have many jurisdictions to

work with; as such, it can be a challenge for them to prioritize development and testing of the immunization reporting interface for each jurisdiction in which they operate. This results in widely variable time frames for completion of a CIR interface, as the process can take anywhere from two to nine months and is largely dependent on the priority level and the resources an EHR vendor devotes to developing this capacity.

Next steps. Going forward, the CIR will continue to build on the foundation that MU has established. In particular, as meaningful use Stage 1 has only had a significant impact on the development of unidirectional communication from providers' EHRs to the CIR, CIR staff will focus on supporting implementation of bi-directional communication at sites that are currently unidirectional.

By August of this year, the CIR expects to have 200 facilities interoperable, with an additional 300 facilities interoperable by the end of 2012. As more facilities connect, the CIR will continue to monitor increases in the timeliness and completeness of reporting, as well as increases in provider and population up-to-date immunization coverage rates.

Future enhancements to CIR services and networks will include expanding the web service to support HL7 2.5.1 standards and working with the Universal Public Health Node (UPHN), part of the state of New York's HIE plan. In addition, CIR

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plans to update its web service to comply with CDC's upcoming national standard for web service interfaces for bi-directional HL7 communication.

CONCLUSION

The introduction of meaningful use requirements has precipitated a significant movement towards interoperability between EHRs and IIS nationwide. The New York City case study has shown that a jurisdiction which was already moving towards interoperability by developing widely accepted technology solutions could leverage the meaningful use incentives and requirements to make rapid progress towards real-time unidirectional interoperability.

While the CIR began work on HL7 bi-directional communication in 2007, it was not until the announcement of the financial incentives in 2010 that many outside partners became interested in engaging with the CIR to utilize this new technology. The anticipated benefit is an improvement in timeliness, completeness and quality of data reported, with the goal of achieving increased immunization coverage overall. The DOHMH is hopeful that the objectives and measures for future stages of meaningful use will require bi-directional interoperability between EHRs and IIS, as this will bring about the greatest gains for healthcare providers, their patients and IIS.

This is a moment for public health to speak to the rest of the healthcare community. The healthcare system operates in an economic landscape where financial resources often drive decision making.

Public health is part and parcel of the healthcare ecosystem and can be a strong partner in improving health by improving the flow of information. By putting money behind public health information sharing efforts already underway, the CMS' meaningful use initiative is bringing together public health and the rest of the healthcare system, financing what could be a significant step forward for healthcare information systems, healthcare providers and patient care in the United States today. **JHIM**

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