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The Office of the National Coordinator for
Health Information Technology

**Consumer Access to Immunization
Information System (IIS) Data:
A Guide for EHR and PHR System Vendors**

December 16, 2013

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1 Introduction

1.1 Project Background

For over twenty years, states and other jurisdictions have been collecting immunizations in a centralized database originally referred to as Immunization Registries but more commonly referred to as Immunization Information Systems (IIS). The Centers for Disease Control and Prevention (CDC) defines an IIS as, “confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.”¹

Individual/consumer access to immunization registry data has recently been identified as a priority initiative of the Office of the National Coordinator for Health Information Technology (ONC), the CDC, and many state immunization programs. However, there are a number of challenges to overcome to allow individual access to IIS data. These include policy, technology, identity proofing, communication and outreach. The response by some states has been to grant access by creating a duplicate database for access. Some other states are investigating portals or EHR/PHR solutions. While it is clear that there are as many options as there are challenges to consumer access, the goal of providing access to consumers to enhance their health care engagement is a priority. The ONC strongly encourages the development of tools and applications to make this actionable.

Nearly twenty states use IIS applications based on the Wisconsin Immunization Registry (WIR) software application. WIR is a web-based system that provides documentation and access to information about immunization records for patients. Updates to the system can be done by providers through numerous methods. These include manual entry through the web-based client, through HL7 standard messaging, or through a flat or delimited file batch. WIR collects data about immunizations and offers providers an immunization history and forecast for each patient. The forecast lays out a treatment plan to assist providers in administering immunizations.

A group of WIR states worked together to identify common approaches and best practices that could be used to provide individual access to IIS data in support of Federal consumer health data initiatives. This work built upon an earlier study conducted by the State of Minnesota, one of the participating states in this effort. After compiling a report detailing the information known to date, the project team conducted a series of internal webinars and surveys, as well as external interviews, to identify business requirements and options for consumer access to immunization information. A set of guiding principles was also developed to help the team narrow the set of possible options for IIS direct access, and access through EHRs/PHRs.

The laws, policies, and technical standards of the participating jurisdictions differ, so no “one size fits all” solution to IIS access was defined. The project described a wide variety of potential

¹ <http://www.cdc.gov/vaccines/programs/iis/about.html>

solutions – some feasible today, some less so – as a way to spur discussion and consider all possibilities. The proposed IIS direct-control solution leverages HL7 web services for IIS query/response that are aggressively being deployed around the country and was not specific to WIR-based projects; solutions using this technology are already becoming available in the market.² The proposed EHR/PHR indirect-control solution leverages patient view/download/transmit requirements of Stage 2 Meaningful Use as a way to encourage providers to offer access to these data.

1.2 Federal Context

The CMS EHR Incentive Programs provide another backdrop for consumer access to immunization data.³ Established in 2010, the incentive programs encourage eligible professionals and hospitals to implement health information technology. The primary focus of this program is the implementation of electronic health record systems and their "meaningful use" (MU). This multi-year program will roll out in several phases, or "stages." A critical component of the programs is a set of public health objectives related to reporting, with corresponding measures and standards, which eligible professionals and hospitals will be expected to support if the public health agencies in their jurisdictions are capable of exchanging data electronically. Immunization reporting was established as an optional, or "menu set" item, in Stage 1 of the program, before being elevated to a required, "core set" item in Stage 2 which begins in 2014.

The Stage 2 Eligible Professional (EP) MU Core Measure 7 outlines the Patient Electronic Access. The objective states that the provider must "Provide patients the ability to view online, download and transmit their health information within four business days of the information being available to the EP."⁴ It further defines the meaning of access, view and transmission as stated below.

"View/Download/Transmit" represents a new, more formal requirement for patients to access their own health data ostensibly through the provider's EHR system. Blue Button/Blue Button+ may become one strategy for providing this access. As IIS contemplate strategies for providing data access directly to consumers, these initiatives may provide strong points of leverage in accomplishing this goal.

National IIS policy originates with the National Center for Immunization and Respiratory Diseases (NCIRD), a branch of the CDC. As stated above, the CDC echoed the sentiments of several states HLN interviewed that the demand for direct access to immunization records does not appear to be coming directly from the consumer at this time. The demand for this service is coming from the top: the Secretary of Health and Human Services and the National Coordinator for Health Information Technology at ONC as a function of their consumer empowerment

² For a good example, see <https://myir.net/>

³ <http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2>

⁴ <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf#12>

initiative. This initiative is part of a large Federal initiative related to consumer access to data that transcends health care.⁵

1.3 Purpose of this document

The purpose of this document is to provide a guide for EHR system vendors to consider/implement effective strategies to providing access to immunization data from IIS to patients through the patient portal capabilities included with most EHR systems (EHR-S) as well as independent PHR systems. The goal is not to provide details specific to any particular product, but rather to offer guidelines for consideration from both the IIS and patient point of view. IIS have been specializing in providing and displaying immunization data for more than twenty years and have refined effective strategies that are often not drawn upon by EHR and PHR products.

2 Requirements for Consumer Access

Based on the research and discussion conducted by the Project the following core requirements were identified:

1. **Support for Federal consumer health data access initiative** as referred to above. This is an evolving set of initiatives and may or may not imply specific strategies.
2. **Query access is provided for a patient's record.** While this may sound obvious, it is at the core of what this project is intended to address.
3. **Query returns one and only one target record.** When providers access an IIS, they can typically enter search criteria that may yield multiple, potential patients' records. For consumers, however, they must know enough about a unique record to establish a single match in response to a query.
4. **Query response does not return demographic data that was not originally supplied in the query parameters.** The project is very sensitive to the need to provide immunization data but little else back to a consumer that might prove to be a violation of patient privacy.
5. **Only authorized users can see data for a particular patient.** User relationship to patient is either established reliably before the query or user knows enough data about the patient to substantiate the relationship with the patient.
6. **If the solution requires authentication then single-factor authentication is sufficient for this project.** ONC indicates that two-factor authentication is recommended, and perhaps required, for access to patient records, but this may not be practical in this scenario.
7. **User can view consolidated, de-duplicated immunization history** (at a minimum, series, vaccine, and date), indicator of validity for each dose, and, potentially, **a forecast of doses due** (and overdue if algorithm provides this distinction). This view of the data may be simpler than what a provider sees currently through their IIS, or through their local EHR system, but is sufficient for a patient.

⁵ <http://www.data.gov/>

8. **User can generate or download a report with vaccine history suitable for school, camp, or child care admission.** This is a key requirement, and is often the reason why parents and adult students want access to these data in the first place.

These items were viewed by the project as *minimum*, or core requirements; additional requirements may be imposed by particular jurisdictions.

3 Principles for Option Selection

The project considered a number of deployment options before selecting EHR/PHR access as the appropriate long-term strategy. The following principles were used by the project in selecting options and should be upheld to the degree possible within any solution that is deployed:

- **Meet Requirements:** Recommended options should meet all the core requirements and as many of the other requirements as possible (see section 2 above).
- **High leverage:** Recommended options should leverage existing (and planned) IIS and non-IIS activities wherever possible.
- **Consistency with National Standards:** Recommended options should be consistent with national standards and directions both within and outside of the IIS community. It is recognized that some elements of the national scene may not yet be certain.
- **Recognize Diversity:** We need to recognize the diversity in both IIS implementation and state and local laws/regulations. There is no “one size fits all” solution, so multiple recommended strategies are expected. On the other hand, too many options will degrade our focus and distract progress.
- **Feasibility:** Recommended options should be investigated if the state has the resources to feasibly implement the solution within one year of project commencement.
- **Cost:** Recommended options should be cost-effective, especially since it may be an interim solution. Cost should include total cost of ownership, including ongoing maintenance, and transition to longer-term solutions.
- **Incremental Steps:** We should recognize that it will likely take incremental steps to move us in the direction we want to go. But, there may be a tension between short-term and long-term strategies.

4 Solution Description

4.1 Introduction

The indirect-access option preferred by the work group involves relying on EHR and PHR systems to provide individual access to IIS data based on queries that these systems would do to the IIS itself. There are a number of advantages to this approach, including:

- Allows authoritative immunization data in IIS to be accessed by authorized systems.

- IIS can accommodate the interoperability requirements described below with little or no additional effort.
- Leverages current national interoperability standards, including likely MU Stage 3 requirements.
- Relies on querying systems which have preexisting relationship with the patient to provide patient access control.
- Consistent with MU requirements for View/Download/Transmit of patient records which is required of EHR systems.
- Encourages query of IIS and incorporation of more complete records into EHR systems.
- Provides easy to fulfill “carrot” for patients to use provider-based portals for records access
- Can easily be expanded to incorporate PHR-S Query simultaneously; can co-exist with untethered PHR access
- In some implementations, this may allow for the potential for patients to consolidate patient records from multiple sources.

For the purpose of describing this solution, the term *tethered PHR* is used to identify a patient portal or any other type of web-based system provided by a provider or hospital for patients to use to access some or all of the data contained in the EHR. Typically, these tethered PHRs are provided to patients and legal guardians and offer a structured window into the EHR system data. The term *untethered PHR* is used to identify a system accessed by a patient that is not under the control of an EHR and not tied exclusively to a particular EHR implementation at a provider site or hospital. Typically, these systems are independent web-based or mobile products offered by other service providers, sometimes requiring a subscription fee and sometimes offered without charge to consumers. In our context, an untethered PHR may rely only on data received from an IIS (or more than one IIS), or it may also rely on data received from other clinical sites or even directly from the patient (these sources are out of scope for this document). It is possible that a tethered or an untethered PHR can be offered by a Health Information Exchange as a service to its members or the general public. The unqualified term “PHR” is used to include both tethered and untethered PHRs.

4.2 Work Flow

The basic work flow for access by either a tethered or untethered PHR to IIS data is displayed in Figure 1. There are several preconditions for this work flow:

- The patient (or legal guardian) has already received access credentials to the PHR system.
- The PHR system has negotiated and signed a data sharing agreement with one or more IIS to query for data.
- The PHR system has ensured that the IIS is abiding by any consent requirements before sharing adolescent health data.
- The IIS receives one query per patient data request. Batch queries are not supported.
- The PHR system follows appropriate privacy and security best practice once identifiable health data is presented to the patient.

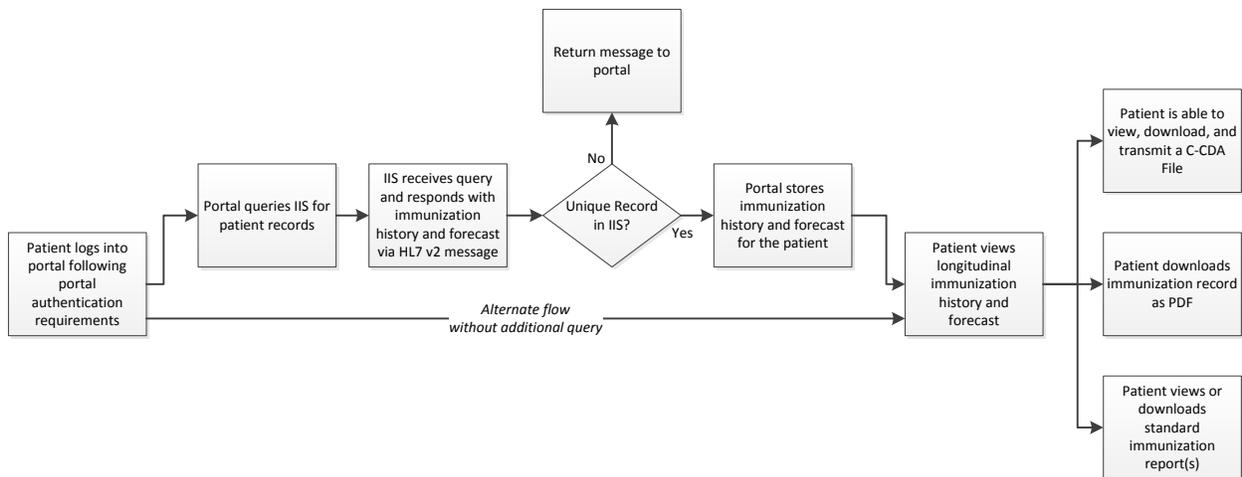


Figure 1 – Work Flow

- The patient (or legal guardian) logs on to the portal using whatever access control credentials or methods have been provided by the system administrator.
- At this point, one of two work flows can occur:
 - Upper work flow:
 - The portal sends an HL7 v2.5.1 QBP message to query the IIS for the patient.
 - The IIS receives the query, and assuming a unique match is found responds via HL7 v2.5.1 RSP message with the immunization history and forecast. Even though the requirements call for only one record match to be returned by the IIS, it is possible that if a unique match is not found, the IIS *may* return an HL7 v2.5.1 RSP message with a list of possible matches or an indication that the patient was not found. In this work flow, this message should be ignored since there is no clinical user to choose among possible matches.⁶
 - The portal receives the response and stores the immunization history and forecast. In some cases, the PHR may not be able to or may choose not to store the forecast.
 - The patient then views the immunization history and forecast through the portal.
 - The patient can then download or transmit the immunization history through a series of standard (*e.g.*, C-CDA, state-defined Parent Report suitable for a school or camp) or non-standard reports or file formats. The portal is in complete control over the types of output that are presented to the user.
 - Lower work flow:
 - The portal does not execute an additional query, but the patient views the immunization history and forecast through the portal based on data already stored in the PHR database. The portal might want to warn the user about when the last data update from the IIS took place, and provide some additional clarifications about why the data might be out of date.

⁶ This would likely only be possible in the case of an EHR system query, not an untethered PHR system query. The IIS might not want to change its standard query response technique for this use case.

4.3 Issues to Consider

There are a number of important issues and choices that EHR systems and their IIS partners need to make in order for a solution to be effective in a given settings:

	Issue/Key Question	Suggested Guidance
Technical	EHR/PHR systems and IIS must support HL7 query/response. Some IIS implementations differ across the country.	Encourage use of CDC WSDL ⁷ for more consistent implementations.
	IIS may experience performance issues as volume of queries increases.	Work closely with IIS partners to understand constraints and capacity of IIS system.
Privacy and Security	Some patients may not have routine access to a primary care provider and thus might not have access to the data (public health agencies may need to provide access).	Encourage use of untethered PHRs for these patients, or consider using public health agencies (local or state) and surrogate medical homes.
	Potential exposure of personally-identifiable health information in electronic form in patients hands may be increased as immunization data may be combined with more sensitive health information.	Educate patients about information privacy and security and the risks that come from even possessing unencrypted copies of electronic health information.
	Jurisdictional law may prevent patient access to IIS data.	Work with public health agencies to change legislation to allow this access.
	Access by untethered PHRs to IIS data requires extension of trust domain to PHR systems which may require new or different data sharing agreements and use of legal services.	This may be a particularly difficult issue for some IIS projects, as untethered PHRs have no provider organization to intermediate and to hold accountable for data queries. Over time, security models will evolve that include this type of access control. In the meantime, legal counsel may need to be consulted to determine how to craft an appropriate data sharing agreement.
Functional	States that have “official” parent reports need to consider whether vendors can generate these according to specifications provided by the jurisdiction.	EHR systems may have to be modified to include these specific report formats in their patient portals. Untethered PHR systems should have less trouble meeting

⁷ Web Services Definition Language – See <http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html#technical>

	Issue/Key Question	Suggested Guidance
		these requirements.
	PHR systems vary in the data about immunization events that are displayed, and IIS project differ in the data they would <i>like</i> PHR systems to display.	See below for suggested best practice for immunization data display. Generally speaking, it is best for PHR systems to display immunizations in a longitudinal record rather than an encounter-based record. Some patients might also find it useful to identify the source of each immunization, though some IIS may be concerned about the potential to share this information inappropriately (<i>e.g.</i> , with a non-custodial parent).
	If the tethered PHR does not query the IIS for records (alternative/lower work flow above), the patient risks seeing an incomplete immunization history and potentially an inaccurate forecast.	There is a tradeoff between the risk of an incomplete record and the potential for error and duplication without clinical review of immunizations received by an EHR system in response to an IIS query. The concern is somewhat mitigated by a strong patient medical home where most/all of the immunizations are likely administered by the provider and captured locally in the EHR system. This is a greater concern with patients who have no consistent medical home, have moved locations, or who receive immunizations in pharmacy locations.
	If a tethered PHR queries the IIS for records but does not provide clinical review, or if an untethered PHR has no clinical review of immunizations received, there is the potential for duplicate and/or near-duplicate immunizations to be stored especially if the immunization history is received from multiple sources. This can lead to a confusing display for the patient and potentially to an inaccurate forecast.	Untethered PHR systems should consider using best practices for de-duplicating immunizations and presenting a cleaner, filtered display for the patient. ⁸ Display of duplicate immunizations is less risky to the patient than potentially missing some immunizations altogether, and a good immunization forecast system will ignore duplicate immunizations in its evaluation of immunization history. ⁹
	PHR does not show a forecast of	The absence of a forecast still satisfies an

⁸ See *MIROW Best Practice Guidelines Chapter 2: Vaccine Level Deduplication in Immunization Information Systems*, American Immunization Registry Association (AIRA), 2006.

<http://www.immregistries.org/resources/AIRA-BP_guide_Vaccine_DeDup_120706.pdf>

⁹ For an example see <http://www.hln.com/ice>

	Issue/Key Question	Suggested Guidance
	immunizations due.	important need for the patient: provision of an immunization history for school, camp, or child care admission. However, absence of a forecast represents an important missed opportunity to inform a patient about immunizations due or overdue.

Appendix: Suggestions for Immunization Display

IIS have, for many years, provided consolidated immunization displays for clinical users that emulate the “face sheets” that pediatricians commonly keep in the front of a patient’s paper chart, and that some EHR systems duplicate electronically. This handy summary allows the clinician to get an instant view of the history, though the paper version cannot dynamically change to provide a forecast. Only an electronic presentation – enabled by accurate immunization evaluation and forecasting software – will be able to predict the immunizations due.

Patients, when they access immunization records, should also be able to see a coherent display of their immunization history and forecast (when available) through their tethered or untethered PHR portal. The most effective display is typically in a grid, with vaccines types or series down the side and different doses displayed across the rows. Figure 2 shows a sample display from the Citywide Immunization Registry (CIR) in New York City:

Event	1	2	3	4	5	Next Due
Influenza 4 Events	09/15/2010 Influenza-injectable, 14m Dose	10/11/2011 Influenza-injectable, 2y 3m	09/21/2012 Influenza-injectable, 3y 1m			09/01/2014 INFLUENZA
HepB 3 Events	07/11/2009 Hep B Peds <20 yrs 0a 1d	09/21/2009 Hep B Peds <20 yrs 5a 5d	07/12/2010 Hep B Peds <20 yrs 12m Dose			Completed Vaccine Series
Rotavirus 2 Events	08/21/2009 Rotavirus RV1 (RotaTeq), 3 doses 5a 5d	01/08/2010 Rotavirus RV1 (RotaTeq), 3 doses 2a 5d				Not recommended after 33 weeks
DTP 3 Events	08/21/2009 DTaP-IPV/Hib (PENTACEL) 0a 5d	01/08/2010 DTaP-IPV/Hib (PENTACEL) 2a 5d	01/10/2011 DTaP-IPV/Hib (PENTACEL) 15m Dose			DUE NOW DTaP
Hib 3 Events	08/21/2009 DTaP-IPV/Hib (PENTACEL) 0a 5d	01/08/2010 DTaP-IPV/Hib (PENTACEL) 2a 5d	01/10/2011 DTaP-IPV/Hib (PENTACEL) 15m Dose			Completed Vaccine Series
Pneumo, Conjugate 3 Events	08/21/2009 Pneum Conj (PCV7) 0a 5d	01/08/2010 Pneum Conj (PCV7) 2a 5d	07/12/2010 Pneum Conj (PCV13) 12m Dose			Completed Vaccine Series
Polio 3 Events	08/21/2009 DTaP-IPV/Hib (PENTACEL) 0a 5d	01/08/2010 DTaP-IPV/Hib (PENTACEL) 2a 5d	01/10/2011 DTaP-IPV/Hib (PENTACEL) 15m Dose			DUE NOW IPV
MMR 2 Events	10/11/2010 MMR-Varicella 15m Dose	07/19/2013 MMR-Varicella 4y 5m				Completed Vaccine Series
Varicella 2 Events	10/11/2010 MMR-Varicella 15m Dose	07/19/2013 MMR-Varicella 4y 5m				Completed Vaccine Series
HepA 2 Events	07/11/2011 HepA-pediatric/adolescent (D 0a) 2y 5m	02/22/2012 HepA pediatric 2-dose 2y 7m				Completed Vaccine Series
Meningococcal 0 Events						Recommended for high risk groups, otherwise 07/10/2020 MENING CONJ (MCV4P MENACTRA 9MO-55YRS.)
Human Papillomavirus 0 Events						07/10/2020 HUMAN PAPILLOMAVIRUS
Pneumo, Polysaccharide 0 Events						Recommended for high risk groups, otherwise 07/10/2014 PNEUMOCOCCAL POLYSACCHARIDE (PNEUMOVAX)

Figure 2 – Citywide Immunization Registry Immunization Summary

A few attributes are worth noting:

- Dose numbers are typically calculated and not assigned by the individual entering the data.
- Invalid immunizations are so noted but usually appear alongside valid immunizations.
- The “Next Due” column provides the forecast.
- Some de-duplication is done of the immunization history to avoid cluttering the screen with redundant events (see earlier reference to AIRA MIROW best practice).
- Different vaccines that satisfy similar vaccine series requirements are grouped together (*e.g.*, a DTP and a DTaP, or two different flu vaccines from different flu seasons).
- Combination vaccines may be duplicated on different rows if they satisfy multiple vaccine series requirements.

A simple chronological list of immunizations is less useful to the patient, and certainly less useful to a recipient of the information in a school, camp, or day care center who needs to evaluate if a child’s history is compliant. Similarly, immunizations available to a patient embedded in multiple encounter summaries (and not grouped together across encounters in a longitudinal history) is also of limited usefulness to the patient and requires a fair amount of effort to compile.