Immunization Information Systems (IIS) as Sources of Vaccine Credential Information in the US

March 7, 2021

HLN Consulting, LLC®
9 Pemberly
Mission Viejo, CA 92692
858/538-2220 (Voice)
858/538-2209 (FAX)
info@hln.com
http://www.hln.com/

There are many possible sources of immunization data scattered across many systems. Identifying the most complete, accurate and easily accessible data source is critical. Some sources aggregate data that is collected from distributed systems and locations. They are generally preferable to these more distributed sources as they provide record consolidation (assembling a whole record from fragments found in different places) and quality assurance services to ensure that the combined record is accurate and coherent.

Immunization Information Systems (IIS) consolidate data from many sources, mostly EHRs and other clinical records, and they provide clinical decision support to determine vaccine doses due now or in the future. IIS contain a mixture of data from administering sites as well as historical data provided by clinical users for doses administered at other sites. In many jurisdictions, they are considered authoritative for such purposes as school compliance, daycare and camp admission. Some limitations to this data source include: Variability in statutory restrictions on who can access immunization data and for what purposes; Incomplete adult records; Low participation of adults in some IIS (and in some cases no participation); And, inconsistency in the inclusion of travel vaccines in IIS.

IIS began primarily with a focus on childhood immunizations spurred by the measles outbreaks of the early 1990s. Only later did adult immunization become a focus as more adolescent and adult vaccines became available (including flu). Some IIS historically were even required to purge their systems of records from children as they reached adulthood. But now, nearly twenty-five years since the earliest IIS came online, childhood records are retained and "roll over" into adult records. Note that only in 2020 did the last jurisdiction that had a prohibition against storing adult immunizations in the IIS modify its law to now allow itI

IIS in the US are deployed on a jurisdiction-by-jurisdiction basis, essentially all US states and territories as well as a small number of remaining county/municipal systems. Most of their funding comes from CDC with some supplemental funding from state and local sources, as well as occasionally from grant/foundation funding and even public-private partnerships. There is no comprehensive process by which IIS exchange data with one another, nor any easy way for clinicians to access IIS in a jurisdiction out of where they practice. Some IIS exchange data through bi-lateral agreement, and the American Association of Immunization Registries has promulgated a Memorandum of Agreement (MOU) which many jurisdictions have signed to enable the legal/policy framework for inter-IIS data sharing. CDC has funded an Immunization Gateway Project to facilitate this sharing technically.

There are two primary use cases related to data interoperability with IIS. The first use case supports submission of immunization data from clinical sites to IIS for record consolidation. The data submitted may relate to doses administered by that clinical site or historical doses reported to that site by the patient or another healthcare provider. The work flow is detailed in Figure 1 (for a fuller description see Arzt, NH, "Application Programming Interface (API) for Immunization Information Interoperability," *Medical Research Archives*, 8(11), Dec. 2020.):

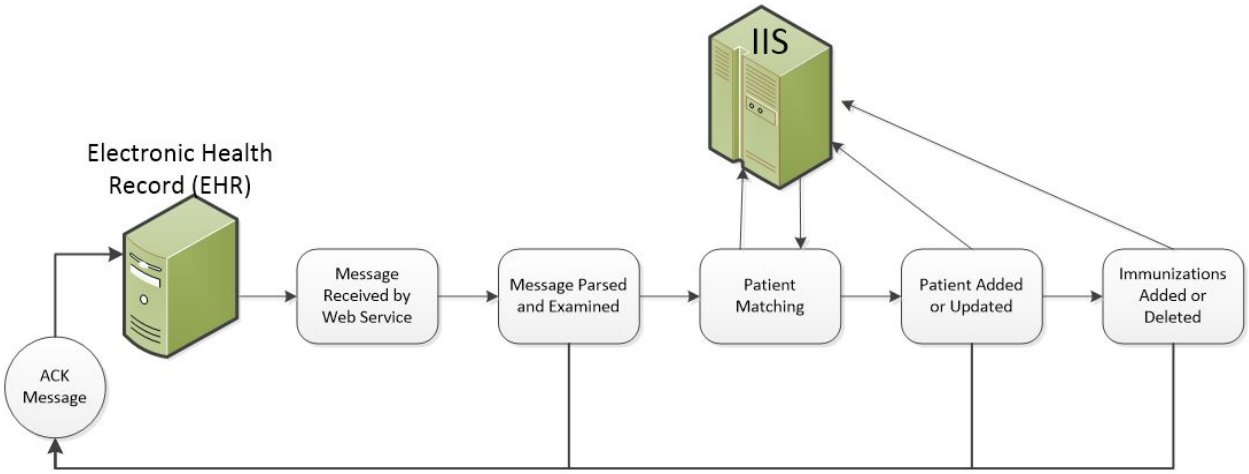

Figure 1 - EHR to IIS Data Submission

This workflow is typically achieved using Health Level Seven (HL7) v2 Unsolicited Immunization Update (VXU) messages most often transported over web services using a Web Service Definition Language (WSDL) file promulgated by the Centers for Disease Control and Prevention (CDC). HL7 data submission and processing are very much dependent on trusting the provider sites to submit data that is appropriate. IIS implement extensive data quality assurance programs to ensure that the data they receive is matched to the correct patient, consolidated properly, and contains as little duplication of vaccination events as possible. In order to establish a data submission relationship with an IIS a data source must not only accept one or more data use agreements developed by the jurisdiction but also conform to an extensive process of testing referred to as “onboarding” by IIS. Once onboarding is complete the interface between the clinical system and the IIS is monitored actively by IIS staff. EHR vendors are often active participants in the onboarding process and may facilitate interoperability with IIS through vendor “hubs” which provide connectivity between their clinical clients and the IIS (especially in the case of web-based EHR products).

The second use case supports query of patient and immunization data from an IIS for many purposes, including clinical decision support at the point of care; reminders for patients who are coming due for an immunization in the near future; recall of patients who have missed an immunization that is due or overdue; support for school or daycare immunization compliance; support for supplemental school, summer camp, or extracurricular activities compliance; workplace immunization requirements; payer quality assurance programs like HEDIS; and public health surveillance at all levels. The workflow is detailed in Figure 2:

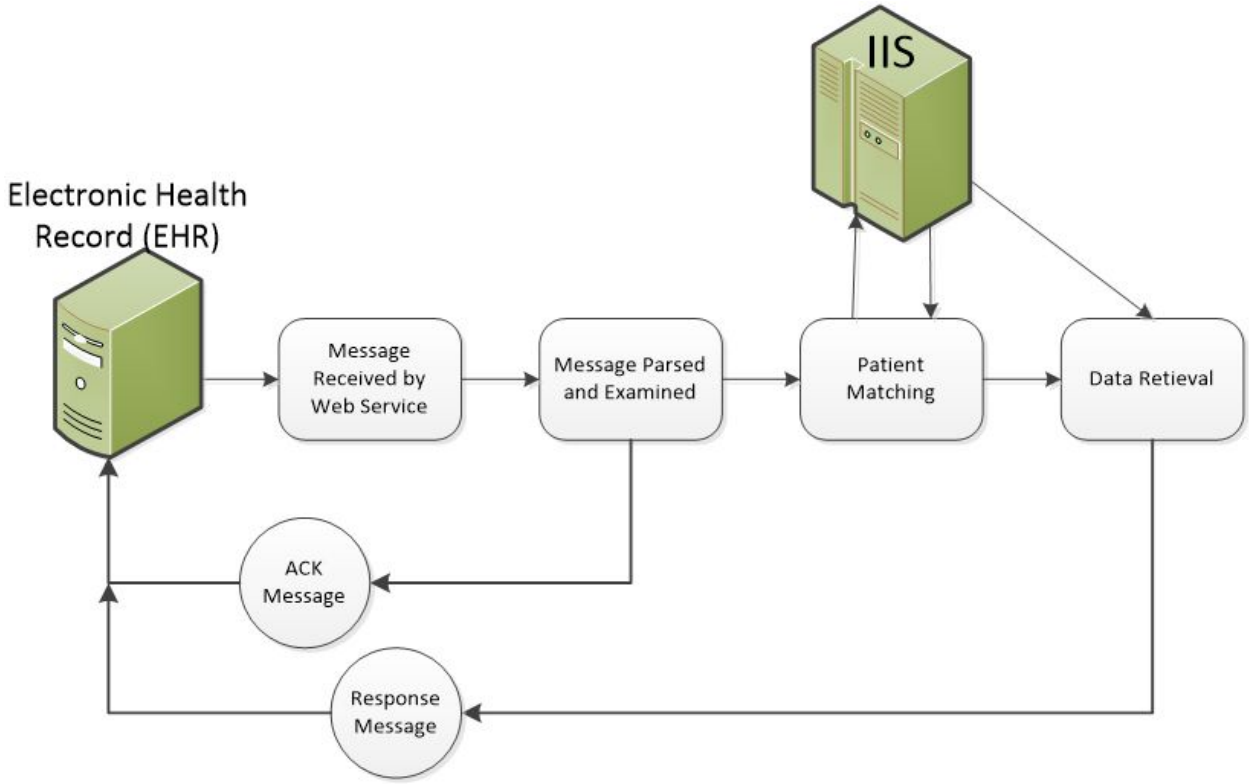

Figure 2 - IIS Query

This workflow is typically achieved using Health Level Seven (HL7) v2 Query by Parameter (QBP) and corresponding Response (RSP) messages most often transported over web services using a Web Service Definition Language (WSDL) file promulgated by the Centers for Disease Control and Prevention (CDC). The response from an IIS contains both the immunization history for the patient with any *invalid* doses noted along with a forecast of doses due now or in the future based on that history and the patient's age. Typically, provider organizations onboarded for data submission are automatically enabled for query/response as well since the business requirements for clinical care for vaccinating sites requires both data submission as well as data query.

Conformance by IIS to uniform technical standards supporting the messages and transport requirements of these use cases varies to some degree. While all IIS support HL7 v2 data submission (the first use case) to some degree, there are some IIS that do not currently support query/response (the second use case) at all. Some support earlier versions of the HL7 v2 message standards and/or outmoded forms of data transport. Still others enforce more stringent message content requirements usually based on requirements in jurisdictional law or policy (see this third-party State Connection Guide for one example of cataloging these differences but the accuracy of this data cannot be easily verified).

While the primary IIS query/response use case is targeted at clinical care providers, there are some limited cases where IIS have permitted other types of systems to query, including student

information systems (SIS) to support school compliance, payer-based systems for clinical quality measures, and consumer-oriented systems. Patients and their proxies originally accessed IIS data through their providers in the form of paper patient reports that were provided at the time of care or beforehand. Over time, as clinical providers supported patient portals, immunization data from the EHR and IIS was often provided through that interface.

A small number of IIS provide direct access to patients to their data but this has historically been both a low priority and a challenge to IIS. The primary barrier to wider patient access has been the limited ability of IIS to verify the identity of the patient who wishes to query based on the information the IIS typically knows about a patient (name, address, date of birth) which is often widely-known by a patient's family and even friends. Many IIS do not yet store email address or cell phone number reliably enough to use these to verify identity but that situation is improving slowly but surely (for a more extensive discussion of these issues see the series of white papers located on the lower section of this page). Some jurisdictions rely on the clinician to provide an access code to the patient (or proxy) to enable access to their IIS data much as is done with some patient portals attached to EHRs

The Vaccine Credential relies on the *second* use case described above: query/response. The credential holder should be able to query an IIS for the up-to-date record which may be expressed (as it is now) as a clinical record rather than as a more limited vaccine credential. IIS could be modified to provide a vaccine credential when such a standard exists, but there are a number of other barriers to implementation that also need to be addressed including:

- **Lack of support for FHIR**: As described above, IIS support HL7 v2 messages over web services and are not currently architected to support FHIR queries over REST. Direction (and funding) from CDC can mitigate this over time.
- **Regulatory barriers to consumer access**: Some IIS have explicit prohibitions, in law or policy, to direct consumer access. Many others, however, simply have not addressed the issue and have perceived it (at least until now) as a low priority. US CDC has only recently begun to fund consumer access projects and encourage IIS to consider it in their implementation plans.
- **Patient identification limitations:** As noted above, there are significant issues related to properly identifying patients who wish to access IIS data. Over time strategies will develop to mitigate this concern.
- **Potential Philosophical Issues:** IIS typically provide clinical data to clinical users. While they will likely accept the need to provide this data to patients, the notion that they might provide a more limited vaccine credential may encounter some resistance. The dominant view in the vaccine credential community is that the issuer should provide only the data related to vaccine events and not the conclusions that might be reached about immunization status based on that data, leaving that to the verifier. This has driven the standards development and reference implementations to as minimal a set of data from the issuer as can be tolerated. IIS may be more accepting of providing the same set of data they provide now and place the burden on the recipient to glean what is needed from the data.

- **Scalability:** The infrastructure supporting IIS is aging and may be insufficient to handle the increased load that may come from additional queries to their databases. IIS have seen a steady increase in queries over the past several years. Many have moved into the cloud to allow a more scalable infrastructure with a more nimble ability to adapt to changing requirements. But the actual load is often hard to predict, and funding for IIS platforms and services is often fixed and can only be expanded when periodic funding is available. The current COVID-19 vaccination campaign's reliance on IIS (including some unintended side effects) has heightened the awareness within government for the need for continuing attention to their well-being.