CASE STUDY

Application Programming Interface (API) for Immunization Information Interoperability

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Abstract

Public health agencies established immunization registries - now called Immunization Information Systems (IIS) - to consolidate records across provider locations to support more effective immunization of patients and public health surveillance. While initially collecting data through interactive client-server and then web-based interfaces, IIS now collect the vast majority of their data through automated interfaces to electronic health record (EHR) systems using standard application programming interfaces (API). IIS have sophisticated processing rules for the incoming data to ensure data accuracy and completeness. This paper will review the existing workflow, standards, and processes used by IIS to accept, process, and make immunization data available. This will include a review of emerging standards - Fast Healthcare Interoperability Resources (FHIR) - which will likely become dominant over the next few years.

Keywords: immunization, immunization registries, immunization information systems, Health Level Seven, public health, electronic health records

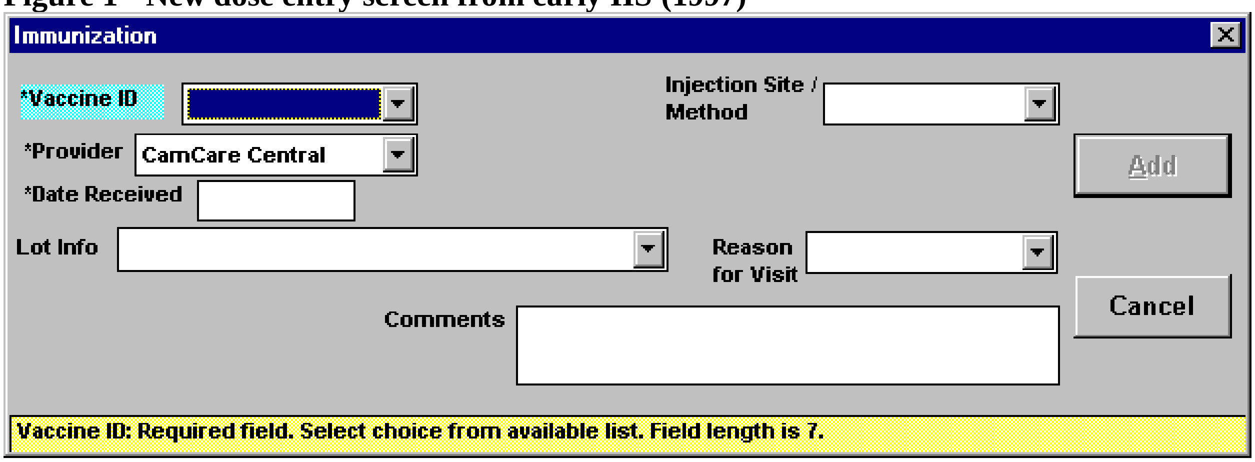
Introduction

Immunization Information Systems (IIS) are defined as "...confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area."[i] They support both point-of-care services for the administration and recording of vaccine doses as well as population level data management and the practice and jurisdiction levels.

Central to the effectiveness of IIS is the collection of accurate immunization information, both for newly-administered doses as well as historical doses for a patient. IIS have existed in one form or another for nearly thirty years. In that time they have employed a variety of means to harvest data, consolidate it, and make it available for clinical care and surveillance. Early IIS were deployed as client/server applications - often using private networks or remote desktop sharing tools - and users were expected to type patient and immunization data into a user interface (see Figure 1). As the Internet matured these user interfaces evolved into web-based applications that still by and large exist today.

In these early days, clinical sites did not have electronic health records (EHR) so often the IIS was the only electronic system to store immunization data. Other techniques were employed to speed up the process of entering historical records (especially for children) and in ensuring that lack of information technology was not a barrier to collecting records. Some jurisdictions supported submission of paper forms with both historical and administered doses, even employing FAX services with optical character recognition (OCR) to speed up data entry. In some cases, where electronic records did exist, batch extract files were used to bulk load data.[ii]

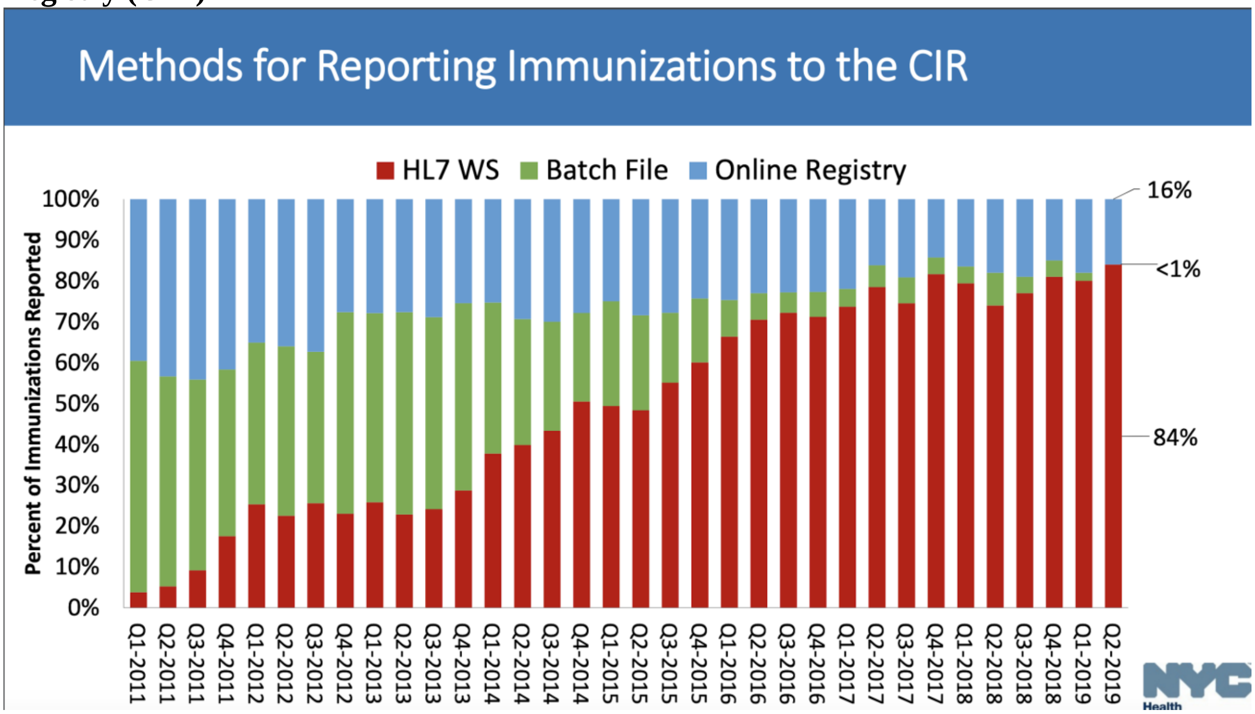
Figure 1 - New dose entry screen from early IIS (1997)



As EHRs became more prevalent, clinical sites began to resist "double data entry" where they were required to enter data in their local systems and then re-enter it into the IIS via the web interface. IIS began to develop more standardized methods for receiving and processing immunization data which typically involved use of Health Level Seven (HL7) Version 2 messaging standards deployed over web services.[iii] With the passage of the HITECH Act and the institution of the Centers for Medicare and

Medicaid Services (CMS) EHR Incentive Programs (now referred to as the Promoting Interoperability Programs) there was a rapid increase in the number of EHRs deployed.[iv, v] One of the core measures was the ability of EHRs to submit data to IIS electronically through standards-based techniques. Over the next several years, the proportion of data received by IIS via HL7-based web services increased dramatically over legacy, non-standard batch file formats and key-entered data through a web-based application (see Figure 2). Paper record submission was eliminated.

Figure 2 - Change in Methods for Reporting Data to the NYC Citywide Immunization Registry (CIR)[vi]



Application Programming Interfaces

As interoperability with IIS has steadily replaced data access and submission through web-based applications, application programming interfaces (API) have been the primary vehicle for implementation of system-to-system data sharing. At its most fundamental level, an API is a specification that allows two software applications to talk to one another.[vii] The 21st Century Cures Act placed requirements with respect to APIs on Certified EHR Technology (CEHRT) that falls under the purview of the Act and the Centers for Medicare and Medicaid Services Promoting Interoperability Program (formerly known as Meaningful Use).[viii] Dellabh *et al* do a nice job of reviewing literature for references to APIs and applying a socitechnical model to understanding their character.[ix]

APIs are more powerful when they are *shared*, not negotiated privately between two trading partners. They are even more successful when developed collaboratively by a community of users.[x] Publicly available and transparent APIs also help with their utility, acceptance, and adoption.[xi] Increasingly, APIs are being used for patient-facing applications to be able to access data from clinical systems, sometimes with no intermediation by the clinical data source other than authentication of the user and authorization to appropriately access the data. A recent study that identified a set of forty-five personal help apps showed that a third of these offered public websites that described the APIs they used.[xii] Woody et al describe API implementation to support life sciences research at Duke. They conclude that standard APIs make it easier to both develop and maintain complex applications.[xiii]

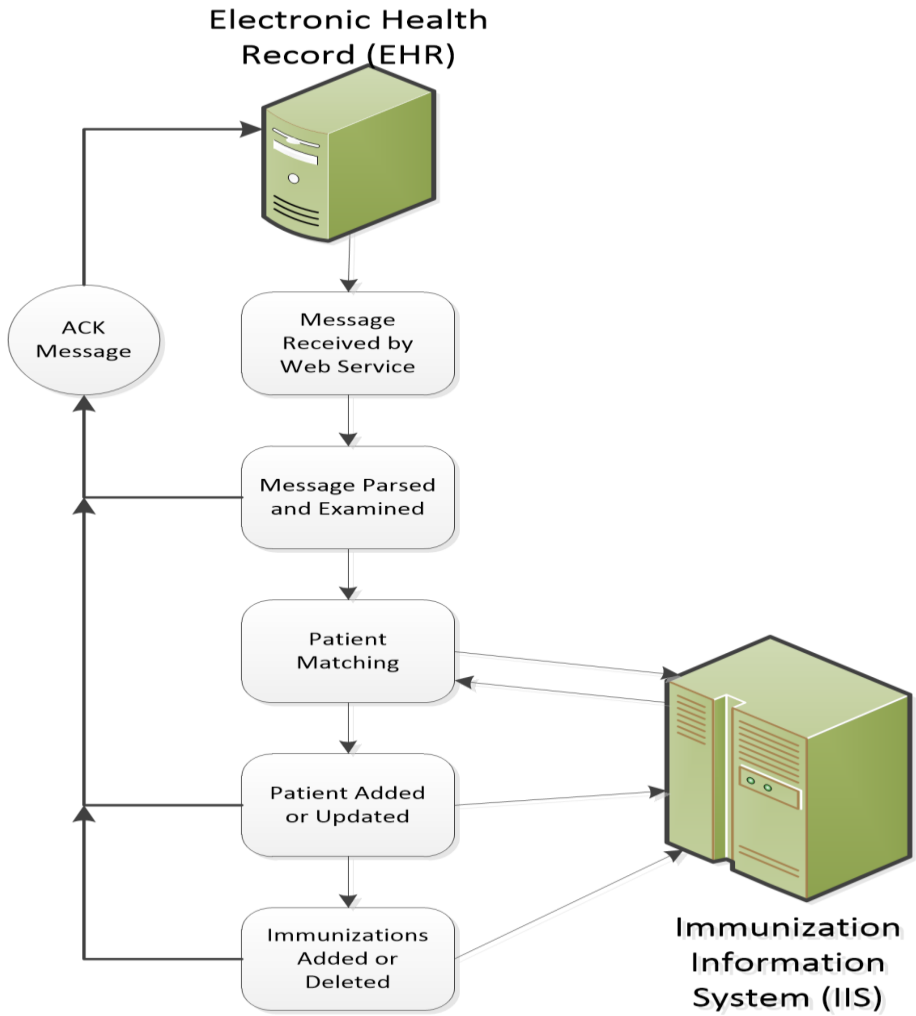
In the case of IIS, their interoperability with EHRs especially is fundamental to how they acquire and provide data, and supports their core mission of consolidating immunization data and making it available at the point of care. Through the collaborative efforts of the American Immunization Registry Association (AIRA) and the Centers for Disease Control and Prevention (CDC), and Health Level Seven (HL7), the API for IIS interoperability was widely discussed before implementing and evolved over a number of years. Currently, it is implemented via Health Level Seven (HL7) Version 2 messaging delivered over SOAP Web Services using a standard Web Services Definition Language (WSDL) file. To date there has been no substantive move to migrate this implementation to HL7's newer Fast Healthcare Interoperability Resources (FHIR).[xiv]

Basic Incoming Record Processing

IIS and the systems with which they interact (usually EHRs but other types of systems as well) are fairly loosely coupled. They rely on the details specified in their APIs to define the behavior they should exhibit in processing new incoming data or responding to queries for data retrieval. The processes that trigger data submission or query from a partner system can be complex, as can the processes that are employed by the IIS to accept (or reject) that incoming data or respond to a query.

The basic workflow for processing incoming records to an IIS is displayed in Figure 3.

Figure 3 - EHR to IIS Message Processing Flow



Here is a brief explanation of the steps involved, recognizing that each IIS is free to implement nuances in its own process based on jurisdictional law or policy, or technical capabilities and constraints.

Electronic Health Record (EHR) sends the message. It is the responsibility of the EHR to trigger the transmission of a record to the IIS. The current standards define HL7 version 2.5.1 VXU (Unsolicited Immunization Update) messages as the required format.[xv]

Message received by web service. We specify web services here because that is the transportation standard promoted by the Centers for Disease Control and Prevention for these communications.[xvi] Other transports could certainly be used; if these transactions migrate to FHIR in the future they would most likely use REST.[xvii]

Message parsed and examined. A pre-processor examines each incoming HL7 message to look for errors in format, coding and value sets, and completeness. The rules are established by each IIS through conformance with the national implementation guide (IG) usually supplemented by a jurisdiction-specific addendum (in some cases, jurisdictions prepare a complete IG that supersedes the national IG and incorporates jurisdiction-specific requirements. Errors which prevent the message from further processing, or warnings that indicate a non-fatal problem with the message, are generated and returned to the sending EHR via HL7 Acknowledgement (ACK) messages as defined in the IG.

Patient Matching. Once a message has been validated by the parser, an attempt is made to determine if the patient has a record in the IIS already. This can be a quite complicated process (discussed more thoroughly in Basic Record Processing above and Record Matching below). Needless to say most IIS are conservative when it comes to patient matching but often employ quite sophisticated tools to improve their matching quality.

Patient added or updated. If a reliable match is not made in the previous step the patient whose data is contained in the incoming message is added to the IIS database as a new patient. If a reliable match is made with a record in the database the patient record is updated. IIS have sophisticated rules about how to update demographic records since, unlike other types of clinical systems, records are coming in for the same patient from multiple sources often simultaneously. Just because a record is processed *later* does not mean that the data contained within it is necessarily the most recent. In addition, some sources (like birth records from a Vital Records database) are considered more reliable than others and even immutable. If the message does not contain any immunization events an HL7 Acknowledgement (ACK) "success" message is returned immediately to the EHR as defined in the IG.

Immunizations added or deleted. Based on the contents of the message, immunization records are added to the associated patient's record. Many IIS also support the *deletion* of immunization records added in error by an EHR message previously, but this deletion is usually restricted to immunization records representing doses administered by a clinician from that message source only and not historical records from other sources. Though the HL7 IG permits messages that *modify,* or update, rather than delete existing immunization records, these have not been implemented in practice. Some IIS instruct clinical sites to send a "deletion" message followed immediately by an "add" message to effectively achieve a "modify." Once immunizations are added or deleted an HL7 Acknowledgement (ACK) "success" message is returned to the EHR as defined in the IG.

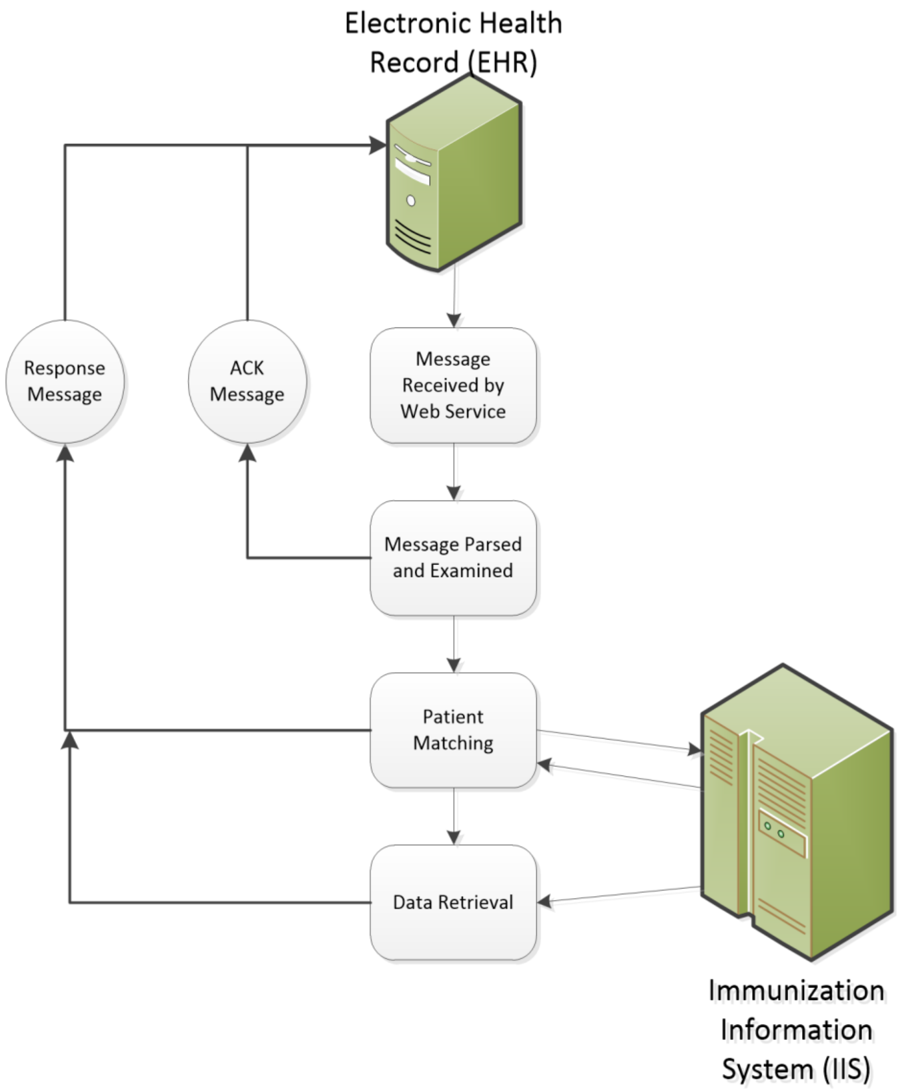
It is worth noting that the IG for immunization does recognize the notion of "action codes" to be used by the sender to stipulate whether the message is intended for record addition, deletion or update. The IG, however, goes on to say that many IIS do not utilize these codes and local IGs need to be inspected for specific instructions. Still others *only* abide by a "delete" action code and ignore the action code for other types of messages and simply process those messages regardless.

Record Query

Another important part of the immunization API is record query. With authorization from the IIS, an EHR (or other system) can query for a patient's demographic and/or immunization record. Here is a brief explanation of the steps involved, recognizing that each IIS is free to implement nuances in its own process based on jurisdictional law or policy, or technical capabilities and constraints.

The basic workflow for processing incoming query requests to an IIS is displayed in Figure 4.

Figure 4 - EHR to IIS Query Processing Flow



Here is a brief explanation of the steps involved, recognizing that each IIS is free to implement nuances in its own process based on jurisdictional law or policy, or technical capabilities and constraints.

Electronic Health Record (EHR) sends the message. It is the responsibility of the EHR to trigger the query for a record to the IIS. The current standards define Health HL7 version 2.5.1 QBP (Query by Parameter) messages as the required format.[xviii]

Message received by web service. As before, we specify web services here because that is the transportation standard promoted by the Centers for Disease Control and Prevention for these communications. Other transports could certainly be used; if these transactions migrate to FHIR in the future they would most likely use REST.

Message parsed and examined. A pre-processor examines each incoming HL7 message to look for errors in format, coding and value sets, and completeness. The rules are established by each IIS through conformance with the national implementation guide (IG) usually supplemented by a jurisdiction-specific addendum (in some cases, jurisdictions prepare a complete IG that supersedes the national IG and incorporates jurisdiction-specific requirements. Errors which prevent the message from further processing, or warnings that indicate a non-fatal problem with the message, are generated and returned to the sending EHR via HL7 Acknowledgement (ACK) messages as defined in the IG.

Patient Matching. Once a message has been validated by the parser an attempt is made to determine if the patient has a corresponding record in the IIS. This can be a quite complicated process (discussed more thoroughly in Basic Record Processing above and below). The HL7 standard supports the notion that an IIS might not be able to determine a single reliable match within its database for an incoming message, and allows an IIS to respond to an EHR with multiple matches from which the EHR user might choose one based on additional data supplied.

Data retrieval. A query is made to the IIS database based on the patient match achieved, and the necessary data is retrieved and formatted into the appropriate HL7 v2 RSP (Response) message. The exact contents of the response may differ from IIS to IIS, but usually the response include patient demographics, immunization history (evaluated for valid and invalid doses), and an immunization forecast based on the evaluation as stipulated in the IG and/or jurisdiction-specific addendum. The RSP message is then returned to the EHR.

Record Matching

Record matching is always a challenge between systems. The very purpose of IIS is to consolidate records from disparate sources, so IIS place a high value on their record matching capabilities and strategies. A wide variety of approaches are used, including deterministic and probabilistic techniques, which will not be discussed here.[xix] IIS generally use, at minimum, first name, last name, date of birth, and gender to match records. Some IIS use additional data elements when available, including mother's maiden name, various address elements, medical record number (including an identifier for the patient previously and uniquely assigned by the IIS in a prior transaction), and insurance identification number. Social security number is highly discouraged and in some jurisdictions is even illegal for transmission and use in healthcare records.

Availability of these additional fields vary, especially as IIS move from the realm of being childhood registries (where most began) to be lifelong registries (to which most are evolving). The advent of a COVID-19 immunization will likely spur that evolution in jurisdictions where adult immunizations have not yet been stored in the IIS in large quantity.

As described above, the API does define a mechanism for supporting a workflow that allows systems querying for data (for QBP messages) to "dialogue" with the IIS over possible matches that need to be resolved by a human being due to ambiguity in the data being submitted or a multiplicity of possible matches due to common names and even dates of birth. The Integrating the Healthcare Enterprise (IHE) Patient Data Query (PDQ) profile describes similar normative workflow.[xx] In reality, most IIS are not permitted to return additional data not found in the original message for matching purposes, and most EHRs do not support the workflow or technical solution for this type of determination.

Authentication and Authorization

Consistent with SOAP-based web services, the immunization API uses a shared, private key to authenticate a system sending information (or requesting information) to the IIS. This typically consists of a username and password assigned by the IIS, often coupled with a Facility ID that identifies the sending system organization also assigned by the IIS. Communication is secured by digital certificates which protect these credentials (and the data in transit) from inappropriate disclosure.

Considerations for FHIR

HL7's Fast Healthcare Interoperability Resources (FHIR) API is beginning to grow in popularity driven by a number of factors. As noted above, the 21st Century Cures Act placed requirements with respect to APIs on Certified EHR Technology (CEHRT) that falls under the purview of the Act and the Centers for Medicare and Medicaid Services Promoting Interoperability Program. The API selected by the Office of the National Coordinator for Health Information Technology (ONC) to satisfy this requirement is FHIR. Over a relatively short period of time, EHRs will need to expose their data using FHIR APIs, publish the end points, and secure connectivity to their systems to be compliant with new regulations. Though public health reporting transactions do not appear to be directly impacted (that is, they are not explicitly called out in the final rule), as FHIR becomes more pervasive in the clinical community, some public health registry activities (*e.g.*, IIS query/response) may come under pressure to support FHIR.[xxi]

Another effort, this time being promulgated by CDC, is the "Making EHR Data More Available for Research and Public Health," or MedMORPH, project.[xxii] Still under development, this project will leverage the expected availability of FHIR within EHRs to build an architecture that will enable easier flow of information from clinical care to public health and research. Mishra, et al describe a system called PACER (Public Health Automated Case Event Reporting) which leverages FHIR to query EHRs for case reporting of sexually transmitted diseases.[xxiii] As more CDC programs build upon this architecture, FHIR will become more prominent within public health.

A third initiative, the Trusted Exchange Framework and Common Agreement (TEFCA), is a new initiative funded by ONC aimed at promoting the development of a *national* network infrastructure for the exchange of health data. Managed by the Sequoia Project as ONC's Recognized Coordinating Entity (RCE), TEFCA is first and foremost building on existing networks which do not yet use FHIR pervasively. Still not operational, the initial implementation of this new network may have more of a dampening effect on the deployment of FHIR.

With respect to interoperability for immunizations, the API described above is mature and pervasively implemented within both clinical care and public health. Public health will need additional funding to re-architect its systems, most notably IIS, to support a FHIR API. Other major public health reporting initiatives, like electronic laboratory reporting (ELR), syndromic surveillance reporting (SS), and cancer registry reporting, all rely on older HL7 standards and are mature and widely deployed.[xxiv, xxv, xxvi] Electronic Case Reporting (eCR) is fairly new - spurred on by the COVID-19 pandemic - and straddles the old (currently deployed using HL7 Clinical Document Architecture) and the new (there is a FHIR profile defined but not yet implemented).[xxvii]

While FHIR does support a "push," versus a "pull" query/response operation, more emphasis is being placed on pull, or query, transactions.[xxviii] While that serves clinical care transactions, and even query/response for immunizations as described above well, it does not serve public health reporting (the incoming record processing example above) very effectively.

Regardless, the immunization domain continues to have active development within HL7 related to FHIR. There are Immunization, ImmunizationEvaluation, and ImmunizationRecommendation resources defined, but they have not been well tested or exercised.[xxix] Active work is also being done on an implementation guide for immunization-related clinical decision support.[xxx]

Conclusion

Immunization data interoperability has been around for more than twenty-five years. It began as non-standard data extracts from early clinical systems transmitted (sometimes via floppy disk!) to public health registries to reduce the amount of data entry that might be required through online systems. Over the years these interfaces have become more pervasive and standards-based. But entrenched standards can be hard to replace, especially when they appear to serve their purpose. Only time will tell whether FHIR will offer either sufficiently-enticing benefits over current standards or whether perpetuation of existing standards will extract a high enough cost to warrant migration. HL7 announced a "revisioning" activity in September 2020 which has certainly put FHIR front and center while reducing emphasis on development of other standards.[xxxi] While their use is wide-spread, current standards for immunization data exchange are far from easy to implement. As Marsolo points out, we need to make data access from clinical care much easier and sustainable than it currently is.[xxxii] Perhaps a migration to FHIR will be able to satisfy that imperative.

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