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A COMPARATIVE ANALYSIS OF
IMMUNIZATION DATA
TO GAUGE INTEROPERABILITY
AND DATA QUALITY

BY
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Degree to be awarded: M.P.H.
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M.P.H, Emory University, 2016
B.A., Temple University, 2008

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An abstract of
A Thesis submitted to the Faculty of the
Rollins School of Public Health of Emory
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2016

Abstract

A COMPARATIVE ANALYSIS OF
IMMUNIZATION DATA
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Dannelle Hauser-Saslo

Abstract
CONTEXT:
Immunization information systems are used by most states to maintain registries of immunization data for monitoring population-level adherence as well as for use in clinical practice and research. Data exchange between said systems and electronic health record systems presents an opportunity to improve the completeness and quality of information available using appropriate messaging technology to enhance interoperability and data quality.
OBJECTIVE:
The goal of this study is to evaluate and compare HL7 messaging versions 2.4; 2.5.1 and FHIR to determine if interoperability and data quality improve with version enhancements in an effort to contribute to the discussion of standards and interoperability of state-run immunization information systems and data exchange with electronic health record systems.
DESIGN:
Sample immunization data from version 2.4 and 2.5.1 were collected from the Washington State Immunization Information System, analyzed and compared to FHIR based on literature review and tests completed in Grahame Grieves test server environment. Personal health information found in immunization messages were removed using HL7Scrubber, a Scientific Technologies Corporation (STC) product, to remove all personal identifiers.
RESULTS:
Data quality analysis of sample immunization data determined that poor semantic interoperability of standardized concepts were the primary reason for data fields in both HL7 v2.4 and v2.5.1 to fall below the required 95% threshold expected at the state level for what is considered high data quality. Improvement in v2.5.1 was found in select fields but is not a significant improvement from v2.4. Literature review and testing of HL7 FHIR and its capacity for immunization data suggests that platform specification Structured Data Capture would resolve provider barriers to semantic interoperability by pre-defining data element definitions to which providers can map.
CONCLUSION:
This study highlights issues related to data exchange, data quality, and interoperability of immunization information to state registries and suggests that there is some degree of deficiency in data quality in immunization data submitted using earlier versions of HL7 due to issues providers face in maintaining updated concept codes. This study indicates that there is a need to strengthen messaging requirements while maintaining flexibility between electronic health record systems and immunization information systems.

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Chapter 1: Introduction

Introduction and Rationale

Immunization information systems (IIS) are electronic, confidential, population-based systems that collect vaccination data from vaccination providers that can be used in designing and sustaining effective immunization strategies aimed to minimize the occurrence of vaccine preventable diseases within a community. Prior to the use of interface software technologies, vaccination data was submitted manually with providers increasingly sending data via different transport methods as new technologies were adopted. Currently, in Washington State, nearly 98% of data exchange occurs through interface software established between the provider's electronic health record (EHR) product and the Washington State Immunization Information System (WAIIS). This enables providers to transport vaccination data in real-time or batch, expediting the receipt of data which provides the Office of Immunization and Child Profile (OICP) a volume of vaccination data never before seen (Washington State Department of Health, 2014). However, due to variations in data standards, providers' and electronic health record products among others, interoperability and data quality remain a challenge to attain. In Washington State, increased data exchange through established interface work between the WAIIS and provider EHR products aided in improving vaccination coverage data. As measured by the IIS, the percentage of kids ages 19–35 months old who completed the 4:3:1:3:3:1:4 immunization series increased from 11% in 2012 to 56% in 2014. The increases in coverage data are due in part to improved reporting of immunization data to the IIS through an increase in active interfaces and an adoption of technologies that support interoperability (Washington State Department of Health, 2014). The value added to the IIS in the adoption of transport software and communication methods can be measured by the volume of data submitted, gradual improvement of immunization data quality, and providers improved ability to use the IIS data to support clinical decision making. In addition, timeliness of data submission adds value, which has increased with the adoption of improved transport methods, according to the CDC IIS Annual Report, 53% of administered vaccinations were received within one day in 2012 and 67% by 2014.

A recent study conducted in New York state using similar transport methods and communication technologies found value through a cost savings analysis whereby increased interoperability of systems would reduce redundant administrative processes and streamline workflow saving the state an estimated $2.50 billion in laboratory savings and $1.51 billion in radiology savings annually after full implementation of the technology ((Hook, Pan et al. 2006). While the business goals in clinical settings differ from those of state immunization programs, the technology used to exchange data is applicable and can be utilized in a variety of business settings. The value lies in the improved transport of data and reduction of administrative processes that would be a benefit to any business.

The benefits and cost savings that increased interoperability of systems provides are grounds for public health decision makers to make revisions to their legacy systems and update functional requirements. While transition to newer technologies requires resources and funding which states may not have readily available, there are, federal programs to aid in the uptake of technologies geared towards implementing and maintaining interoperability.

The CDC annually surveys immunization program grantees using the IIS Annual Report (IISAR). Results from the 2013 IISAR, completed by 54 of 56 grantees, indicate that 86% (19.5 million) of U.S. children aged <6 years, and 25% (57.8 million) of U.S. adults participated in IIS. Eight of twelve minimum functional standards for IIS published by the National Vaccine Advisory Committee (NVAC) have been met by >/=90% of grantees. During 2011-2012, progress was also made in meeting three additional functional standards, including the presence of core data element fields, timeliness of vaccine records, and Health Level 7 (HL7) messaging. Several new and ongoing initiatives, including interoperability between IIS and electronic health records systems (EHR), application of emerging technologies, collaboration with pharmacies, federal agencies, and other stakeholders, will support further progress in meeting functional standards and enhance data exchange of vaccinations to IIS (Centers for Disease and Prevention (2013). While value has been placed on interoperability initiatives and support is being garnered at a national level, the need for public health decision makers to be able to accurately adopt appropriate technologies across jurisdictions is increasingly important. With significant variations in data standards affecting national agencies, public health and EHR vendors there is a growing need for a common platform to unite these stakeholders to facilitate interactions and exchange data in a meaningful way, thereby creating value for all involved. The development of messaging standards grew out of this need to create a common platform for data exchange and nullify the need for custom built interfaces.

This research seeks to contribute to the existing body of work supporting interoperability specifically within the immunization community, by conducting comparative data quality analysis on sample immunization data on HL7 versions 2.4 and 2.5.1 against the immunization resource structure in HL7 FHIR to determine the impact on interoperability and data quality among versions. This analysis will aid public health decision makers in determining if there is value added in adopting HL7 FHIR as an emerging technology to support the development of interoperable solutions into a state IIS.

This research aims to conduct four tasks:

1. Identify current, common data standards used within the IIS community.
2. Identify challenges and current issues impeding interoperability and data quality with sample immunizations data analysis results from WAIIS.
3. Evaluate emerging messaging standard HL7 FHIR for appropriateness and capacity for immunization data.
4. Compare data quality results across HL7 versions analyzed.

Problem Statement

The Immunization community has an array of tools and technologies used to accomplish their business goals at local and state jurisdictional levels. While the technologies used enable public health and clinical partners to accomplish their work, there are interoperability challenges in communicating data across systems due to variations in data standards, differences in “providers” electronic health record products, clinical workflow practices, data messaging standards, and interface types. This issue is also at a national scale, as most states run an IIS with some states using multiple registries to accommodate larger urban areas.

The need for a flexible solution to streamline how data is submitted, either through an established interface or improved messaging technology has become increasingly important not only for cost savings and quality improvement as mentioned previously, but also for the most recent release of meaningful use stage 3 requirements published by Centers for Medicare & Medicaid Services (CMS) indicating the need for participating providers to focus on the advancement of EHR technology to promote health information exchange and improved outcomes for patients.

In a recent study to gauge the current state of interoperability between states, researchers analyzed over 7 million electronic laboratory reporting (ELR) messages between 2010 and 2011 for reported test results. Analysis focused on the applicable data fields where LOINC and SNOMED CT values are expected, which according to Health Level 7 (HL7) version 2 specifications are OBX-3 (identifies the test performed) and OBX-5 (identifies the result of the test performed). Using data from each state, researchers calculated the proportion of field values that appropriately contained either LOINC or SNOMED CT codes in cases where a semantically interoperable code was expected.

Less than 17% of incoming Indiana ELR messages contained a standardized LOINC code identifying the test performed, and none of the results contained a standardized SNOMED identifier. Of the Wisconsin messages, none contained a standardized LOINC code for identifying the test performed, and less than 13% of the test results contained a standardized SNOMED identifier. Their analysis demonstrated that very few real-world ELR messages sent from operational laboratory systems contain standardized codes, even post-meaningful use regulations (Dixon, Vreeman et al. 2014). This study did not review or consider data submitted in incorrect fields or unstructured data submissions but is emblematic in that other systems which transport and exchange data share similar issues in semantic interoperability or the exchange of data with an unambiguous, shared meaning.

While meaningful use is aimed to incentivize and bolster activity promoting interoperability it may be that requirements for meeting stage 3 criteria require more resources and technical expertise than providers can allocate. The aforementioned study aids in explaining the real world challenges of making these changes and the effort required to orchestrate standards even across state lines. A flexible solution, poised to alleviate the challenges associated with constant changes in technology and ease of implementation is therefore ideal for both end users of the system and public health practitioners alike.

Specific Aims

The goal of this project is to contribute to the existing body of work supporting interoperability specifically within the immunization community, by conducting comparative data quality analysis sample immunization data submitted through existing messaging versions to the WAIIS (Health Level 7 2.4-2.5.1) and evaluation of immunization resources in HL7 FHIR/SDC (Fast Healthcare Interoperability Resources/ Structured Data Capture) to determine the impact on interoperability and data quality. This analysis will inform public health decision makers to decide if there is value added in adopting HL7 FHIR/SDC as an emerging technology that benefits both public health and participating healthcare providers.

The research for this thesis takes place in four stages:

1. Identify current, common data standards used within the IIS community.
2. Identify challenges and current issues impeding interoperability and data quality with sample immunizations data analysis results from WAIIS.

3. Evaluate emerging messaging standard HL7 FHIR for appropriateness and capacity for immunization data.
4. Compare data quality results across HL7 versions analyzed.

Data quality analysis has been performed on de-identified immunization HL7 message data to ascertain variance in data quality and interoperability against existing state data quality thresholds and compared to evaluation of HL7 FHIR/SDC to ascertain differences in versions and improvements to semantic interoperability. Additionally, common barriers and limitations within existing data standards and solutions will be addressed to fully inform an optimal strategy for public health decision-making.

Purpose Statement

The purpose of this research is to identify and analyze an improved technology to enhance the state of interoperability and data exchange within the immunization community and support public health decision makers in determining what value is added to an early adoption. The most flexibility among the data standards relevant to immunizations is in messaging standards, which allows providers to develop clinical workflows independent from the requirements of the messaging standard. This enables a vaccination provider to send a representation of the clinical information captured in their EHR without standardizing how they provide care to their patients. A solution, which promotes accurate transport of clinical information while lending flexibility to the end user may have a positive impact on interoperability and the end user's perception of adopting a new technology as changing technology often means adjusting to new requirements and revising workflows (Raths 2014).

Chapter 2: Literature Review

Introduction

This research aims to build upon existing bodies of work dedicated to expanding interoperability within the IIS community. This section is organized as follows:

1. Overview of current data standards common within the IIS community.
2. Review of challenges and common issues impeding interoperability via sample immunization data analysis.
3. Evaluation of HL7 FHIR for appropriateness and capacity for immunization data.
4. Comparative data quality analysis of immunization data submitted via multiple versions of HL7.

Current Data Standards

Data standards are "documented agreements on representations, formats, and definitions of common data. Data standards provide a method to codify invalid, meaningful, comprehensive, and actionable ways, information captured in the course of doing business (Public Health Data Standards Consortium, 2013)." Data standards are at the core of interoperability, without data standards and data quality, issues preventing interoperability will persist. There are several types of standards that are of particular importance for IIS data exchange:

1. Standard Vocabularies enable transparent and consistent content to be understood across disparate databases. Vocabularies common in the immunization community include code sets for vaccine type, manufacturer and billing data that are standardized to communicate the same concept contained within a given code (See Appendix A & B).
2. Message Structure Standards enable the concepts sent between disparate systems to agree on the grammar and organization of the data being submitted/received. Health Level 7 (HL7) versions 2.4-2.5.1 are the most commonly used versions to send/receive immunization data where messages are being submitted via an established interface.
3. Transport Level Standards refer to the security protocols set on data in motion. This will vary among state IIS; however, in WA, HTTPS is used to secure data in motion.

Variability among any of the previously mentioned standards causes either invalid data submission or the loss of a message entirely. As an example, the WAIIS has a profile for each provider type (VFC, pharmacy, primary provider) and within that profile certain fields tolerate certain levels of complete or incompleteness. If a message submitted is missing a critical field the system will reject the message. If it's not critical the system might accept part of the message. If it's non critical then the system will accept the message even with some missing or incorrect data. Therefore, in addition to nationally recognized data standards, there may be local/ state requirements as well, complicating the goal of interoperability further.

Version Review

According to the literature review, Health Level 7 (HL7) is a Standards Developing Organization accredited by the American National Standards Institute to author consensus-based standards representing a broad view from healthcare system stakeholders. What this definition means from a practical standpoint is that HL7 has developed a collection of messaging formats and related clinical standards that generally define an ideal presentation of clinical information, and together the standards provide a format/ framework in which data may be exchanged. Despite being a 'standard', HL7 is flexible in that it does not require a standardized clinical or business workflow to use, which allows some variability in the presentation of clinical information being submitted. For purposes of this analysis, HL7 versions that are most commonly used in the immunization community will be reviewed for the sake of brevity, namely HL7 v 2.4; 2.5.1, which will also be the messaging versions used to analyze the sample immunization as well as an evaluation of HL7 FHIR SDC.

According to Corepoint Health, HL7 V2 was developed by application users in the early 1990's with the intent to remove custom interfaces from their workflow and enable systems to exchange data more fluidly. In order for this to gain acceptance among stakeholders, the developers intentionally built the model to be vague in terms of standards and flexible to increase adoption. The early versions at the time only needed to specify 80 percent of the interface in the framework, which gradually led to its acceptance in 1998, when enough healthcare providers had implemented the version. The HL7 community began to release V3 in mid 2000's with the intent of refining the data model and creating tighter standards with 90 percent of the interface predefine. This was toted as a way to make interface easier for users, but with more rigid standards came challenges to meet those requirements, and continue to exchange data. To date, V3 has not been widely implemented in the United States because of its stark

differences in standards requirements and complexity in comparison to V2. The images below are examples of messages in V2 and V3 complexity.

HL7 V2.X message (below)

```
MSH|^~\&|AcmeHIS|StJohn|ADT|StJohn|20060307110111||ADT^A04|MSGID20060307110111|P|2.4
EVN|A04
PID|||12001||Jones^John||19670824|M|||123 West St.^^Denver^CO^80020^USA
PV1||O|OP^PAREG^||||2342^Jones^Bob|||OP|||||||2|||||||||||||||||||||20060307110111|
AL1|1||3123^Penicillin||Produces hives~Rash~Loss of appetite
```

HL7 V3 message (right)

Figure 1. Sample HL7 version comparison

HL7 version 2.4 and 2.5.1 are similar in that they are both a departure from the complexities presented in V3 but incorporate many new fields in their framework that encourage the standardization of data. V2.5.1 is more consistent and supplies more functionality than previous versions. Below are sample profiles highlighting the core data items in each segment for each version with required recommendations, which will be used as a guide during sample version analysis with FHIR. The table represents IIS system behavior and response to incoming HL7 messages by version, the left hand columns represents version 2.4 and the right hand column represents version 2.5.1. Under each version the IIS can respond in three unique ways: Ignore, meaning that the system will accept data from a message even if the field is missing data or if data is incorrect. This is typical for fields that are non-critical to the patient's immunization record, for example if a nickname is submitted rather than a full first name, the system will ignore that and accept the message as it is submitted. Records that the system cannot reconcile due to inconsistent data (IE Patient name: Rebecca and Becky) will return the records to a table for manual deduplication. Warnings are generated on fields that are expected to contain correct data but do not. The provider will receive an acknowledgement message if any data fields generate a warning against the IIS profile. Lastly, Error signifies a message with poor data or missing data in a required field. Critical fields are more frequently found in the vaccination segment as that data directly

affects vaccine forecasting for patients, for this reason messages submitted that generate an error are not accepted into the IIS.

Figure 2. Issue Resolution Version Comparison

		2.4					2.5.1		
Issue Resolution	**IIS Standard Template**	Ignore	Warn	Error			Ignore	Warn	Error
Patient First Name - PID-5.2									
	is invalid	x						x	
	is truncated	x					x		
Patient Last Name - PID-5.1									
	is invalid	x							x
	is possibly a test-name			x					x
Patient Address City - PID-11.3									
	is missing			x					x
Patient Address County - PID-11.9 - (Code Table: County)									
	is missing	x					x		
	is invalid	x						x	
	is unrecognized	x						x	
Patient Address State - PID-11.4 - (Code Table: State)									
	is missing			x					x
	is invalid	x						x	
	is unrecognized	x						x	
Patient SSN - PID-3, PID-19									
	is missing		x		is unwanted			x	
	is invalid	x					x		

Patient Primary Facility Id - PD1-3.3 - (Code Table: Facility ID)									
	is missing			x					x
	is invalid		x						x
	is unrecognized		x						x
Patient VFC Status - PV1-20.1 - (Code Table: VFC Status)									
	is missing			x					x
	is invalid			x					x
	is unrecognized			x					x
Vaccination Administration Units - RXA-7									
	is missing			x					x
Vaccination Facility ID - RXA-11.1, RXA-11.4 - (Code Table: Facility ID)									
	is missing		x						x
	is invalid		x					x	
	is unrecognized		x		Historical vs. Admin				x
	exceeds maximum length		x						x
Vaccination Information Source - RXA-9									
	is missing			x				x	
Vaccination Lot - RXA-15 - (Code Table: Lot Number)									
	is missing		x					x	
	is invalid		x					x	

	is unrecognized		x					x	
	does not match manufacturer code		x					x	
	does not match funding source	x					x		
	does not match expiration date		x					x	
	does not match vaccine group	x					x		
Vaccination Manufacturer - RXA-17 - (Code Table: MVX)									
	is missing			x					x
	is invalid			x					x
	is unrecognized			x					x
Vaccination VFC Status - OBX - (Code Table: VFC Status)									
	is missing			x					x
	is invalid			x					x
	is unrecognized			x					x
Vaccination Route - RXR-1 - (Code Table: Route)									
	is missing			x				x	
	is invalid	x						x	
	is unrecognized	x						x	
Vaccination Anatomical Site - RXR-2 - (Code Table: Anatomical									

Site)									
	is missing	x						x	
	is invalid	x						x	
	is unrecognized	x						x	
Insurance Company - IN1-3 - (Code Table: Insurance Company ID)									
	is missing	x					x		
	is invalid	x					x		
	is unrecognized	x					x		

Regardless of the version in use, CDC has issued guidelines for core data items to be included in HL7 immunization messages, which are listed in Appendix C. In addition to these items, there are additional requirements set by the state for data items that are required by provider type (I.E. Pharmacy, Primary Care, Vaccine For Children (VFC) Program Status) as some data items may not be known or available depending on the provider type. Developing separate provider profiles to distinguish between provider types and adjust data items to be accepted is managed differently across states. Variability in how data items are accepted is another barrier to interoperability and obtaining high quality data. Local variability, while offering customizable solutions for the locale, creates complications for interoperable data exchange when scaled to higher levels such as national reporting or multi-state reporting. Similarly, variability at higher levels impacts data exchange to lower levels such as local or state health departments. It is for this reason that reasonable agreement on standards should be accepted across stakeholders exchanging data with embedded flexibility for data standards that are not standardized or vary in format or structure. A solution that maintains clinical flexibility while enforcing standardization of data collected from HL7 immunization messages would promote interoperability and improve data quality for both participating providers and immunization information systems alike.

HL7 FHIR

Messaging standards are a means to communicate concepts across systems for purposes of data exchange. Since HL7 messaging standards are commonly accepted in clinical and public health communities and because the need for increased interoperability requires a baseline of common standards to succeed, emerging HL7 messaging standards are ideal to review for purposes of this study. HL7 FHIR/SDC (Fast Healthcare Interoperability Resources/ Structured Data Capture) is an emerging technology among messaging standards that has been hailed for benefiting various stakeholders including immunization registries as well as EHR vendors, which are the focus groups for this study. FHIR (Fast Healthcare Interoperability Resources) is the next generation of standards framework created by HL7, which offers various specifications adapted for particular use cases including immunizations. The SDC

specification is the platform which most closely aligns with the current needs of the immunization community, namely improving semantic interoperability in key fields for patient and vaccination segments while minimizing the burden of upgrading and implementing a new technology to do so. This soon to be normative standard combines the best features of HL7 V.2, V.3, and CDA (Clinical Document Architecture) while leveraging current web standards with a concentrated focus on improved implementation. This version has also been identified by the Office of the National Coordinator (ONC) as a recommended standard in the agency's 10-year interoperability roadmap largely due to its capacity for end users to implement easily, its increased flexibility, and seamless compatibility with existing legacy standards.

Structured data capture aims to link clinical data, captured from the EHR system, to supplemental systems that collect structured patient data within forms such as immunization registries. SDC requires that the question/answer (data element) structure of EHR forms be specified in a standardized, interoperable and reproducible way. As a consequence, SDC requires the definition of metadata for forms and data elements, in a manner relevant to EHRs and entities using EHR data. Therefore SDC aims to leverage synergistic government and health care industry efforts underway related to standards definition, and representation to facilitate capture, reporting, and analysis. The standards and guidance incorporated in the HL7 implementation guide are based on the requirements defined in the Structured Data Capture Use Case document. When designing studies, constructing questionnaires, building profiles or performing other tasks that involve determining what data will be captured or exchanged and how, users can query to find pre-defined data element definitions they can leverage or map to. By encouraging consistency around data element definitions, data types, value sets, string lengths and other constraints, data becomes more easily exchangeable and comparable across systems (HL7 SDC Implementation Guide, 2015).

Chapter 3: Methods

Introduction

The goal of this project is to identify and analyze an emerging technology to enhance the state of interoperability and data exchange within the immunization community and support public health decision makers in determining what value is added to an early adoption. This will be accomplished through a general review of the current variations in data standards within a state IIS, followed by an evaluation of messaging standard HL7 FHIR as a potential technology to improve interoperability and data quality within the immunization community, and a comparative data quality analysis across HL7 versions to determine if HL7 FHIR adds value by increasing interoperability and quality of data among participating vaccination providers and the WAIIS. The analysis for this thesis will therefore take place in three stages: 1. A review of existing messaging standards of interest in the immunization community; 2. An evaluation of HL7 FHIR for appropriateness and capacity for immunization data; 3. A comparative data quality analysis of sample HL7 data to gauge current status of interoperability and data quality.

Research Design

The study will be conducted using a three-stage approach involving objectivist approaches for each stage of the study:

Stage 1: Version Analysis

An objectivist, decision-facilitation based approach will be utilized to evaluate sample immunization HL7 data. The decision-facilitation based approach will allow the study to resolve issues critical to decision makers and support future decisions about messaging version implementation within the IIS. Analysis of current standards will aid decision makers in determining where data quality and interoperability challenges lie and provide a starting point for determining the best solution to resolve said challenges. This stage of the study will involve identifying versions of interest, which are commonly used in the immunization community and data quality analysis of each version using sample immunization data to gauge semantic interoperability. Results from this portion of the evaluation will be integral in the third stage of the study for comparative analysis with HL7 FHIR.

Stage 2: HL7 FHIR Evaluation

Similarly, an objectivist, decision-facilitation approach will be utilized to evaluate HL7 FHIR and its capacity for interoperable data exchange with an IIS. Evaluation results from this stage will help inform Stage 3 for comparative analysis.

Stage 3: Comparative Data Quality Analysis

An objectivist, comparison-based approach will be used to evaluate data quality analysis results of sample HL7 messages analyzed in different versions of the standard to elicit differences in data quality and semantic interoperability. The comparison-based approach will allow the study to identify the messaging standard with the highest capacity for interoperability as well as the quality of data based on data quality analysis and state data threshold requirements. This stage requires the most significant time commitment of the study. Analysis will involve the generation of sample HL7 immunization messages in multiple versions with common errors and warnings. Once generated, data will be validated to ensure data does not contain personal identifiers, parsed for analysis and reviewed for errors and warnings based on the Washington State Issue Resolution profile by organizations (for purposes of this analysis the standard provider profile will be used). The analysis will generate the calculated proportion of field values that appropriately contain data anticipated with a minimum threshold of 95% of data submitted accurately. Results from this portion of the evaluation will be compared to analysis results from previous versions and evaluation of immunization resources in HL7 FHIR.

Instruments & Analysis

All research data collected through the literature review of data standards and emerging messaging technology were collected and organized for interpretation in the final stage of the study and were tracked using Google Docs Spreadsheet web service. Additionally, all HL7 sample data was generated from PHC-Hub, a Scientific Technologies Corporation (STC) application used to aid in validation and export of HL7 data, and de-identified of all sensitive personal health information via HL7Scrubber prior to analysis. Microsoft excel spreadsheet software was used to calculate proportions of data in required fields to determine if data met the minimum threshold of 95%. After

parsing and validating patient and vaccination segments, messages were analyzed to ensure data quality in addition to meeting issue resolution requirements. This analysis was repeated for sample HL7 data in V2.4 (N=710); V 2.5.1(N=1259), variations in sample size are due to the volume of messages submitted by providers in each version, for brevity, samples were taken throughout the month of December 2015. Due to the volume of messages being analyzed, existing validation tools such as the National Institute for Standards & Technology's Edge Testing Tool (Certified by the Office of the National Coordinator) will not be used as batch HL7 messages cannot be analyzed with this tool at this time. FHIR immunization resource has been evaluated and compared for structural similarities to v2.4 and v2.5.1 to establish its capacity for immunization data and inform comparative analysis of all three versions.

Stage 1: Version Analysis

Version analysis was conducted on a sample of data pulled from the Washington State Immunization Information System for the same time period and scrubbed for personal health information using HL7Scrubber. Both versions (V.2.4 / N=710; V2.5.1 / N=1259) were analyzed to determine the proportion of fields that accurately contained data with a 95% threshold.

HL7 V.2.4 Sample Data
Demographic Data: Total Patients: 710 | Unique Patients: 284

	All Patients	
Patient Demographic Data N=710	**Count (%)**	**Pass/Fail**
MRN (PID-3)	710 (100%)	Pass
First Name (PID-5)	710 (100%)	Pass
Last Name (PID-5)	710 (100%)	Pass
Date of Birth (PID-7)	710 (100%)	Pass
Gender (PID-8)	710 (100%)	Pass
Race (PID-10)	0 (0%)	Fail
Ethnicity (PID-22)	0 (0%)	Fail
SSN	0 (0%)	Pass
Address Street (PID-11)	710 (100%)	Pass
City (PID-11)	710 (100%)	Pass
State (PID-11)	710 (100%)	Pass
Zip (PID-11)	710 (100%)	Pass
Phone Number (PID-13)	88 (12%)	Fail
Primary Facility Name (PD1-3.1)	710 (100%)	Pass

Primary Facility ID (PD1-3.3)	710 (100%)	Pass

Required Data for Children: Total Patients <19 years: 632

Guardian Data N= 632	**Children (<19 years)**	
	Count (%)	**Pass/Fail**
Guardian Name (NK1-2)	632 (100%)	Pass
Next of Kin Type (NK1-3)	632 (100%) 0 (0%)	Pass

Total Patients <19 years imported with a vaccine administered: 632
367 New Immunizations |265 Historical Immunizations

Data	**Children (<19 years)**	
	Count (%)	**Pass/Fail**
Patient-Level VFC Status (PV1-20)	68 (10%)	Fail
	V01	12 (1%)
	V02	29 (5%)
	V10	27 (4%)

Vaccination Data:
Total Vaccinations: 710 (442 New Immunizations | 268 Historical Immunizations)
Vaccinations for Children <19 years: 632 (367 New Immunizations |265 Historical Immunizations)
Vaccinations for Adults ≥19 years: 78 (75 New Immunizations |3 Historical Immunizations)

Total Vaccination Data	**Children (<19 years) N=632**		**Adults (≥19 years) N=78**	
	Count (%)	**Pass/Fail**	**Count (%)**	**Pass/Fail**
Vaccination Date (RXA-3)	367 (100%)	Pass	78 (100%)	Pass
CVX Code (RXA-5)	0 (0%)	Fail	0 (0%)	Fail
CPT Code (RXA-5)	367 (100%)	Pass	78 (100%)	Pass
Vaccine Name (RXA-5)	367 (100%)	Pass	78 (100%)	Pass

Vaccinations for Children <19 years: 632 (367 New Immunizations |265 Historical Immunizations)
Vaccinations for Adults ≥19 years: 78 (75 New Immunizations |3 Historical Immunizations)

New Vaccination Data	**Children (<19 years) N=367**		**Adults (≥19 years) N=75**	
	Count (%)	**Pass/Fail**	**Count (%)**	**Pass/Fail**
Vaccinating Facility (RXA-11)	367 (100%)	Pass	75 (100%)	Pass
Lot Number (RXA-15)	16 (4%)	Fail	4 (5%)	Fail

Manufacturer (RXA-17)	16 (4%)	Fail	4 (5%)	Fail
Dose Size Volume (RXA-6)	367 (100%)	Pass	75 (100%)	Pass
Dose Measurement (RXA-7)	0 (0%)	Fail	0 (0%)	Fail
Route of Administration (RXR-1)	367 (100%)	Pass	75 (100%)	Pass
Anatomical Administration Site (RXR-2)	367 (100%)	Pass	75 (100%)	Pass

HL7 V.2.5.1 Sample Data
Demographic Data: Total Patients: 1259 | Unique Patients: 746

	All Patients	
Patient Demographic Data N=1259	**Count (%)**	**Pass/Fail**
MRN (PID-3)	1259 (100%)	Pass
First Name (PID-5)	1259 (100%)	Pass
Last Name (PID-5)	1259 (100%)	Pass
Date of Birth (PID-7)	1259 (100%)	Pass
Gender (PID-8)	1259 (100%)	Pass
Race (PID-10)	1167 (92%)	Fail
Ethnicity (PID-22)	104 (8%)	Fail
SSN	0 (0%)	Pass
Address Street (PID-11)	1259 (100%)	Pass
City (PID-11)	1259 (100%)	Pass
State (PID-11)	1259 (100%)	Pass
Zip (PID-11)	1259 (100%)	Pass
Phone Number (PID-13)	1245 (98%)	Pass
Primary Facility Name (PD1-3.1)	1138 (90%)	Fail
Primary Facility ID (PD1-3.3)	1138 (90%) 710 (100%)	Fail

Required Data for Children: Total Patients <19 years: 562

	Children (<19 years)	
Guardian Data N= 562	**Count (%)**	**Pass/Fail**
Guardian Name (NK1-2)	452 (80%)	Fail
Next of Kin Type (NK1-3)	452 (80%)	Fail

Vaccination Data:
Total Vaccinations: 1259 (925 New Immunizations | 334 Historical Immunizations)
Vaccinations for Children <19 years: 562 (357 New Immunizations |205 Historical Immunizations)
Vaccinations for Adults ≥19 years: 697 (568 New Immunizations | 129 Historical Immunizations)

Total Vaccination Data	Children (<19 years) N=562		Adults (≥19 years) N=697	
	Count (%)	Pass/Fail	Count (%)	Pass/Fail
Vaccination Date (RXA-3)	562 (100%)	Pass	697 (100%)	Pass
CVX Code (RXA-5)	562 (100%)	Pass	697 (100%)	Pass
CPT Code (RXA-5)	0 (0%)	Fail	0 (0%)	Fail
Vaccine Name (RXA-5)	562 (100%)	Pass	697 (100%)	Pass

Vaccinations for Children <19 years: 562 (357 New Immunizations \|205 Historical Immunizations)
Vaccinations for Adults ≥19 years: 697 (568 New Immunizations \| 129 Historical Immunizations)

New Vaccination Data	Children (<19 years) N=357		Adults (≥19 years) N=568	
	Count (%)	Pass/Fail	Count (%)	Pass/Fail
Vaccinating Facility (RXA-11)	357 (100%)	Pass	568 (100%)	Pass
Lot Number (RXA-15)	357 (100%)	Pass	567 (99%)	Pass
Manufacturer (RXA-17)	356 (99%)	Pass	565 (98%)	Pass
Dose Size Volume (RXA-6)	356 (99%)	Pass	567 (99%)	Pass
Dose Measurement (RXA-7)	356 (99%)	Pass	567 (99%)	Pass
Route of Administration (RXR-1)	357 (100%)	Pass	568 (100%)	Pass
Anatomical Administration Site (RXR-2)	357 (100%)	Pass	568 (100%)	Pass

Stage 2: HL7 FHIR Evaluation

HL7 FHIR as a current draft holds significant promise in the way of increasing flexibility while offering adaptations to improve standards adherence. Based on research and evaluation of specification guidelines, this version is platform specific, meaning that a specification is adaptable to a specific purpose such as immunizations. FHIR adheres to RESTful architecture using standardized resources that can be combined and reused in different ways. It mirrors previous versions but introduces 'resources' as a new way of organizing data elements. Resources are the exchange model of FHIR, which are small, discrete units of exchange that define a concept, much like segments in HL7 v2 and Common Message Element Types (CMETS) in HL7 v3 but are human readable, an improvement for non-technical, clinical stakeholders who find themselves responsible for data exchange. In addition, FHIR's resources are already pre-defined, allowing developers and analysts to stick to their roles thereby negating the need for them to know the healthcare side of messaging and are easily extended and capable of real-time interactions (API exchange protocol), which support increasingly demanding MU criteria for interoperability. Enabling stakeholders to stick to their roles and expertise and pre-defining resources holds significant promise to address semantic interoperability issues found in the data quality analysis of sample immunization data in HL7 v2.4 and HL7 2.5.1.

In addition to FHIR as a promising solution to enhance interoperability and data quality for immunization data exchange, a comparison of version message structure indicates that the immunization resource in FHIR provides fields for all critical fields expected based on the WAIIS issue resolution profile as comparison criteria with increased flexibility in fields and new ways to organize data. Greater improvements were found in HL7 FHIR SDC specification whereby users can query to find pre-defined data element definitions they can leverage or map to thereby encouraging consistency in data exchange for fields where standardized codes are expected. Below is a comparison

chart between HL7 FHIR immunization resource structure and HL7 v2 demonstrating FHIR's capacity for immunization data as it's currently exchanged.

Figure 3. FHIR Mapping for HL7 v2

Immunization	VXU_V04
identifier	
status	
date	RXA-3
vaccineCode	RXA-5
patient	PID-3
wasNotGiven	
reported	RXA-9
performer	RXA-10
requester	ORC-12
encounter	PV1-19
manufacturer	RXA-17
location	RXA-27 (or RXA-11, deprecated as of v2.7)
lotNumber	RXA-15
expirationDate	RXA-16
site	RXR-2
route	RXR-1
doseQuantity	RXA-6 / RXA-7.1
note	
explanation	
reason	
reasonNotGiven	RXA-18
reaction	OBX-3
date	OBX-14 (ideally this would be reported in an IAM segment, but IAM is not p OBX segments if at all)
detail	OBX-5
reported	(no such concept seems to exist for allergy/adverse reaction in HL7 v2)
vaccinationProtocol	(HL7 v2 doesn't seem to provide for this)
doseSequence	
description	
authority	
series	
seriesDoses	
targetDisease	

doseStatus	
doseStatusReason	

Stage 3: Comparative Data Quality Analysis

Comparative Data Quality Analysis has been conducted on HL7 immunization messages that have been scrubbed of personal health information by HL7 Scrubber, a product of Scientific Technologies Corporation to de-identify HL7 messages. Analysis includes sample messages from HL7 versions 2.4; 2.5.1; and evaluation of immunization resources of HL7 FHIR and SDC. Samples has been scrubbed, parsed using Microsoft Excel, proportions calculated per segment/ field and compared against a minimum threshold of 95% to gauge data quality and interoperability.

The analysis of HL7 FHIRs immunization resource was completed through a comparison of fields in v2.4 ,v2.5.1 and FHIRs immunization resource structure to establish FHIRs capacity for immunization data. Additional review of HL7 FHIR includes literature review of implementation guides as well as Structured Data Capture specification guides to inform the study.

Barriers & Limitations

The immunization community, despite sharing the same business goals and in many cases the same processes, is unique from state to state. Thus, as this study was conducted using the Washington State Immunization Information System and PHC-Hub, a data validation application, it is limited in that the results of this analysis may not be representative of results from other states due to variations in standards and legacy systems involved in data exchange; however, other states that use the same product and adhere to standard guidance as recommended by the CDC should be able to benefit from results founds through this analysis.

In addition, exploratory data analysis of HL7 FHIR was restricted in that the environment for generating sample immunization data from the WAIIS was not available to the author in this version. Therefore similar data quality analysis was not possible for immunization data in FHIRs messaging structure. Results based upon comparison of message structure inform the study that FHIR has the capacity and improved flexibility to manage immunization data. The analysis of FHIR, while limited, still supports full use for IIS users and improved flexibility, specifically when using structured data capture specification, which is also supported by research findings. However, full analysis of each version would have been ideal to fully inform public health decision makers considering early adoption of emerging messaging technologies.

Chapter 4: Results

Introduction

The products of this thesis are separated into three stages: Version Analysis Results, Comparative Data Quality Analysis Results and HL7 Version Recommendations.

Findings

Stage 1: Version Analysis Results

The data quality analysis of versions 2.4 and 2.5.1 enabled the review of key data fields of importance and those that have fallen short of meeting the 95% minimum threshold. Common issues were found in field PID-10, PID-22, PD1-3.1-3.3 in the patient demographic segments indicating patient race, ethnicity, and facility as well as RXA-5, RXA-7, and RXA-17 in the vaccination segment indicating vaccine type, dose volume and manufacturer concept codes. These errors are common on both segments, although improvements to the vaccination segments were observed in version 2.5.1 messages. There is an observed issue with fields that require a standardized code to represent a concept whereby fields where a specific code is expected is either incorrect or missing with exception to state assigned codes for provider facility. The standardized codes are made publicly available through the Center for Disease Control and Prevention (CDC) and are the responsibility of the participating provider to update should changes be made. While changes are uncommon for the bulk of vaccines, there are a few which change seasonally, primarily influenza vaccine. This observed issue suggests that the provider in both versions has not made updates to their workflow to correct errors related to standardized codes submitted that received an error or warning acknowledgement message. Acknowledgement messages, in addition to state run data quality checks are two ways in which providers are notified of quality issues, which are critical to resolve if providers are to utilize vaccine-forecasting functionality to support their clinical decision-making. In addition, there are differences between the versions in location of VFC Status in v2.4 and v2.5.1. In v2.4, VFC Status was accepted in PV1-20 and in version 2.5.1 the same data was reported in OBX-5, the provider who adopted v2.5.1 had made the transition using OBX-5 the field for reporting, sending VFC Status in the observation segment only. Fields, which are consistently missing data or contain incorrectly reported data are those that require a standard code for communicating a concept. Therefore, the data that is missing is due to workflow challenges at the clinic level, where data input may be incorrectly mapped, old code may be used, or miss entered. These barriers at the clinical level are the cause for poor data quality and prevent complete patient and vaccination data from transferring seamlessly from the provider's EHR system to the IIS thereby impacting the quality of vaccine data to inform clinical decision-making through vaccine forecasting functionality as well as vaccine inventory management and correct vaccine lot decrementing. Despite its increased functionality and improvement from previous versions, the HL7 versions commonly used do not fully address clinical barriers to interoperability and data quality.

Stage 2: Comparative Data Quality Analysis Results

Challenges found from the data quality analysis in versions 2.4 and 2.5.1 include errors associated with missing or incorrect submission of standardized concept codes for fields found in both the patient demographic segments as well as the vaccination segments. These errors are rooted in clinical workflow practices, which require providers to update or modify their existing workflow to accommodate IIS requirements for standardized concept codes. Review of HL7 FHIR indicates that the version itself, while an improvement from previous versions in terms of flexibility, usability and ease of

implementation is not sufficient to address clinical workflow issues preventing standardized codes from being submitted incorrectly. Although, after review of FHIR's Structured Data Capture specification, it is possible to establish the SDC profile and map to pre-defined data elements to enhance semantic interoperability. Data quality efforts to support improvements to semantic interoperability can be addressed through improved communication of standard expectations and limitations to IIS acceptance of insufficient data.

Stage 3: HL7 Version Recommendations

Based upon results of the data quality analysis conducted on HL7 v2.4; 2.5.1 and the literature review and evaluation of HL7 FHIR, it is recommended that the immunization community consider adopting HL7 FHIR using the SDC specification to improve interoperability and data quality of immunization data submitted from participating providers. This version and specification aligns well with the immunization community's goal of improving data quality as well as MU Stage 3 criteria to improve interoperability.

Chapter 5: Conclusion

Summary of study

Immunization information systems are used by most states to maintain registries of immunization data for monitoring population-level adherence as well as for use in clinical practice and research. Data exchange between said systems and electronic health record systems presents an opportunity to improve the completeness and quality of information available using appropriate messaging technology to enhance interoperability and data quality.

The goal of this study is to evaluate and compare HL7 messaging versions 2.4; 2.5.1 and FHIR to determine if interoperability and data quality improve with version enhancements in an effort to contribute to the discussion of standards and interoperability of state-run immunization information systems and data exchange with electronic health record systems.

Sample immunization data from version 2.4 and 2.5.1 were collected from the Washington State Immunization Information System, analyzed and compared to FHIR based on literature review and immunization resource evaluation.

Data quality analysis of sample immunization data determined that poor semantic interoperability of standardized concepts were the primary reason for data fields in both HL7 v2.4 and v2.5.1 to fall below the required 95% threshold expected at the state level for what is considered high data quality. Improvement in v2.5.1 was found in select fields but is not a significant improvement from v2.4. Literature review and evaluation of HL7 FHIR and its capacity for immunization data suggests that platform specification Structured Data Capture would resolve provider barriers to semantic interoperability by pre-defining data element definitions to which providers can map.

Conclusion

This study highlights issues related to data exchange, data quality, and interoperability of immunization information to state registries and suggests that there is some degree of deficiency in data quality in immunization data submitted using earlier

versions of HL7 due to clinical workflow issues providers face in maintaining updated concept codes and the messaging standards inability to map to where that data may be located elsewhere in the providers EHR. Based upon the analysis conducted through this study and the research found from similar comparative analysis in other systems, this study indicates that there is a need to strengthen messaging requirements while maintaining flexibility between electronic health record systems and immunization information systems. The literature review and evaluation of HL7 FHIR and platform specification SDC suggest that this emerging technology would support and improve the immunization communities need to improve interoperability among stakeholders and overall data quality.

Recommendation

To improve upon this study, it would be advisable that state or local health jurisdictions that are considering adopting an emerging technology develop an evaluation process by which they can compare and analyze the differences of technologies in a real environment prior to adoption. In this study, HL7 FHIR could not be tested in a live environment, which may have produced different results had the state IIS used the version in their production environment. In addition, based on these results, it is recommended that the immunization community take a close look into what HL7 FHIR has to offer, specifically Structured Data Capture specification and evaluate the messaging technology compared with their current HL7 version and state/local requirements.

Appendix A

IIS CPT Codes Mapped to CVX Codes

This table cross-references Current Procedural Terminology (CPT™) codes that are related to vaccines, toxoids and immune globulins with their corresponding CVX codes (vaccine administered) (CDC, 2016).

CPT_CODE	CPT_description	CVX Short Description	CVX Code	CPT_code_ID
90281	Immune globulin (IG), human, for intramuscular use	IG	86	169
90283	Immune globulin (IGIV), human, for intravenous use	IGIV	87	170
90287	Botulinum antitoxin, equine, any route	botulinum antitoxin	27	171
90291	Cytomegalovirus immune globulin (CMV-IGIV), human, for intravenous use	CMVIG	29	172
90296	Diphtheria antitoxin, equine, any route	diphtheria antitoxin	12	173
90371	Hepatitis B immune globulin (HBIG), human, for intramuscular use	HBIG	30	174
90375	Rabies immune globulin (RIG), human, for intramuscular and/or subcutaneous use	RIG	34	175
90376	Rabies immune globulin, heat-treated (RIG-HT), human, for intramuscular and/or subcutaneous use	RIG	34	176
90378	Respiratory syncytial virus immune globulin (RSV-IgIM), for intramuscular use, 50 mg, each	RSV-MAb	93	177
90379	Respiratory syncytial virus immune globulin (RSV-IGIV), human, for intravenous use	RSV-IGIV	71	178
90389	Tetanus immune globulin (TIG), human, for intramuscular use	TIG	13	179
90393	Vaccinia immune globulin, human, for intramuscular use	vaccinia immune globulin	79	180
90396	Varicella-zoster immune	VZIG	36	150

	globulin, human, for intramuscular use			
90470	H1N1 immunization administration (intramuscular, intranasal), including counseling when performed	Novel Influenza-H1N1-09, all formulations	128	297
90476	Adenovirus vaccine, type 4, live, for oral use	adenovirus, type 4	54	151
90477	Adenovirus vaccine, type 7, live, for oral use	adenovirus, type 7	55	152
90581	Anthrax vaccine, for subcutaneous use	anthrax	24	153
90585	Bacillus Calmette-Guerin vaccine (BCG) for tuberculosis, live, for percutaneous use	BCG	19	154
90620	Meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B, 2 dose schedule, for intramuscular	meningococcal B, OMV	163	314
90621	Meningococcal recombinant lipoprotein vaccine, serogroup B, 3 dose schedule, for intramuscular use	meningococcal B, recombinant	162	313
90630	Influenza virus vaccine, quadrivalent (IIV4), split virus, preservative free, for intradermal use	influenza, intradermal, quadrivalent, preservative free	166	316
90632	Hepatitis A vaccine, adult dosage, for intramuscular use	Hep A, adult	52	155
90633	Hepatitis A vaccine, pediatric/adolescent dosage-2 dose schedule, for intramuscular use	Hep A, ped/adol, 2 dose	83	156
90634	Hepatitis A vaccine, pediatric/adolescent dosage-3 dose schedule, for intramuscular use	Hep A, ped/adol, 3 dose	84	157
90636	Hepatitis A and hepatitis B (HepA-HepB), adult dosage, for intramuscular use	Hep A-Hep B	104	158
90644	Meningococcal conjugate vaccine, serogroups C & Y and	Meningococcal C/Y-HIB PRP	148	317

	Hemophilus influenza B vaccine (MenCY-Hib)			
90645	Haemophilus influenza b vaccine (Hib), HbOC conjugate (4 dose schedule), for intramuscular use	Hib (HbOC)	47	159
90646	Haemophilus influenza b vaccine (Hib), PRP-D conjugate, for booster use only, intramuscular use	Hib (PRP-D)	46	160
90647	Haemophilus influenza b vaccine (Hib), PRP-OMP conjugate (3 dose schedule), for intramuscular use	Hib (PRP-OMP)	49	161
90648	Haemophilus influenza b vaccine (Hib), PRP-T conjugate (4 dose schedule), for intramuscular use	Hib (PRP-T)	48	162
90649	Human Papilloma virus (HPV) vaccine, types 6, 11, 16, 18 (quadrivalent) 3 dose schedule, for intramuscular use	HPV, quadrivalent	62	163
90650	Human Papilloma virus (HPV) vaccine, types 16, 18, bivalent, 3 dose schedule, for intramuscular use	HPV, bivalent	118	164
90651	Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (HPV)	HPV9	165	318
90654	Influenza virus vaccine, split virus, preservative free, for intradermal use	influenza, seasonal, intradermal, preservative free	144	302
90655	Influenza virus vaccine, split virus, preservative free, for children 6-35 months of age, for intramuscular use	Influenza, seasonal, injectable, preservative free	140	165
90656	Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years of age and above, for intramuscular use	Influenza, seasonal, injectable, preservative free	140	166
90657	Influenza virus vaccine, split virus, for children 6-35 months of age, for	Influenza, seasonal, injectable	141	167

	intramuscular use			
90658	Influenza virus vaccine, split virus, for use in individuals 3 years of age and above, for intramuscular use	Influenza, seasonal, injectable	141	168
90659	Influenza virus vaccine, whole virus, for intramuscular or jet injection use	influenza, whole	16	181
90660	Influenza virus vaccine, live, for intranasal use	influenza, live, intranasal	111	182
90661	Influenza virus vaccine, derived from cell cultures, subunit, preservative and antibiotic free, for intramuscular use	Influenza, injectable, MDCK, preservative free	153	310
90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use	Influenza, high dose seasonal	135	292
90663	Influenza virus vaccine, pandemic formulation, H1N1	Novel Influenza-H1N1-09, all formulations	128	293
90664	Influenza virus vaccine, pandemic formulation, live, for intranasal use	Novel Influenza-H1N1-09, nasal	125	294
90665	Lyme disease vaccine, adult dosage, for intramuscular use	Lyme disease	66	183
90666	Influenza virus vaccine, pandemic formulation, split-virus, preservative free, for intramuscular use	Novel influenza-H1N1-09, preservative-free	126	300
90668	Influenza virus vaccine, pandemic formulation, split-virus, for intramuscular use	Novel influenza-H1N1-09	127	296
90669	Pneumococcal conjugate vaccine, polyvalent, for children under five years, for intramuscular use	pneumococcal conjugate PCV 7	100	184
90670	Pneumococcal conjugate vaccine, 13 valent, for intramuscular use	Pneumococcal conjugate PCV 13	133	185
90672	Influenza virus vaccine, quadrivalent (LAIV), live, intranasal use	influenza, live, intranasal, quadrivalent	149	319
90673	Influenza virus vaccine, trivalent, derived from recombinant DNA (RIV3),	influenza, recombinant, injectable, preservative free	155	311

	hemagglutnin (HA) protein only, preservative and antibiotic free, for intramuscular use			
90675	Rabies vaccine, for intramuscular use	rabies, intramuscular injection	18	186
90676	Rabies vaccine, for intradermal use	rabies, intradermal injection	40	187
90680	Rotavirus vaccine, pentavalent, 3 dose schedule, live, for oral use	rotavirus, pentavalent	116	188
90681	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use	rotavirus, monovalent	119	189
90685	Influenza virus vaccine, quadrivalent, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular us	Influenza, injectable,quadrivalent, preservative free, pediatric	161	305
90686	Influenza virus vaccine, quadrivalent, split virus, preservative free, when administered to individuals 3 years of age and older, for intramuscular use	influenza, injectable, quadrivalent, preservative free	150	306
90687	Influenza virus vaccine, quadrivalent, split virus, when administered to children 6-35 months of age, for intramuscular use	influenza, injectable, quadrivalent	158	312
90688	Influenza virus vaccine, quadrivalent, split virus, when administered to individuals 3 years of age and older, for intramuscular use	influenza, injectable, quadrivalent	158	308
90690	Typhoid vaccine, live, oral	typhoid, oral	25	190
90691	Typhoid vaccine, Vi capsular polysaccharide (ViCPs), for intramuscular use	typhoid, ViCPs	101	191
90692	Typhoid vaccine, heat- and phenol-inactivated (H-P), for subcutaneous or intradermal use	typhoid, parenteral	41	192
90693	Typhoid vaccine, acetone-killed, dried (AKD), for subcutaneous use (U.S.	typhoid, parenteral, AKD (U.S. military)	53	193

	military)			
90696	Diphtheria, tetanus toxoids, acellular pertussis vaccine and poliovirus vaccine, inactivated (DTaP-IPV), when administered to children 4 years through 6 years of age, for intramuscular use	DTaP-IPV	130	194
90698	Diphtheria, tetanus toxoids, and acellular pertussis vaccine, haemophilus influenza Type B, and poliovirus vaccine, inactivated (DTaP - Hib - IPV), for intramuscular use	DTaP-Hib-IPV	120	195
90700	Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), for use in individuals younger than seven years, for intramuscular use	DTaP, 5 pertussis antigens	106	301
90700	Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), for use in individuals younger than seven years, for intramuscular use	DTaP	20	196
90701	Diphtheria, tetanus toxoids, and whole cell pertussis vaccine (DTP), for intramuscular use	DTP	01	197
90702	Diphtheria and tetanus toxoids (DT) adsorbed for use in individuals younger than seven years, for intramuscular use	DT (pediatric)	28	198
90703	Tetanus toxoid adsorbed, for intramuscular use	tetanus toxoid, adsorbed	35	199
90704	Mumps virus vaccine, live, for subcutaneous use	mumps	07	200
90705	Measles virus vaccine, live, for subcutaneous use	measles	05	201
90706	Rubella virus vaccine, live, for subcutaneous use	rubella	06	202
90707	Measles, mumps and rubella virus vaccine (MMR), live, for subcutaneous use	MMR	03	203
90708	Measles and rubella virus vaccine, live, for	M/R	04	204

	subcutaneous use			
90710	Measles, mumps, rubella, and varicella vaccine (MMRV), live, for subcutaneous use	MMRV	94	205
90712	Poliovirus vaccine, (any type(s)) (OPV), live, for oral use	OPV	02	206
90713	Poliovirus vaccine, inactivated, (IPV), for subcutaneous or intramuscular use	IPV	10	207
90714	Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, for use in individuals seven years or older, for intramuscular use	Td (adult) preservative free	113	208
90714	Typhoid vaccine	typhoid, unspecified formulation	91	209
90715	Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), for use in individuals 7 years or older, for intramuscular use	Tdap	115	210
90716	Varicella virus vaccine, live, for subcutaneous use	varicella	21	211
90717	Yellow fever vaccine, live, for subcutaneous use	yellow fever	37	212
90718	Tetanus and diphtheria toxoids (Td) adsorbed for use in individuals seven years or older, for intramuscular use	Td (adult), adsorbed	09	213
90720	Diphtheria, tetanus toxoids, and whole cell pertussis vaccine and Hemophilus influenza B vaccine (DTP-Hib), for intramuscular use	DTP-Hib	22	214
90721	Diphtheria, tetanus toxoids, and acellular pertussis vaccine and Hemophilus influenza B vaccine (DTaP-Hib), for intramuscular use	DTaP-Hib	50	215
90723	Diphtheria, tetanus toxoids, acellular pertussis vaccine, Hepatitis B, and poliovirus vaccine, inactivated (DTaP-HepB-IPV), for intramuscular use	DTaP-Hep B-IPV	110	216

90724	Influenza virus vaccine	influenza, unspecified formulation	88	217
90725	Cholera vaccine for injectable use	cholera	26	218
90726	Rabies vaccine	rabies, unspecified formulation	90	219
90727	Plague vaccine, for intramuscular use	plague	23	220
90728	BCG vaccine	BCG	19	221
90730	Hepatitis A vaccine	Hep A, unspecified formulation	85	222
90731	Hepatitis B vaccine	Hep B, unspecified formulation	45	223
90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, for use in individuals 2 years or older, for subcutaneous or intramuscular use	pneumococcal polysaccharide PPV23	33	224
90733	Meningococcal polysaccharide vaccine (any group(s)), for subcutaneous use	meningococcal MPSV4	32	225
90734	Meningococcal conjugate vaccine, serogroups A, C, Y and W-135 (tetravalent), for intramuscular use	meningococcal MCV4P	114	226
90734	Meningococcal conjugate vaccine, serogroups A, C, Y and W-135 (tetravalent), for intramuscular use	Meningococcal MCV4O	136	285
90735	Japanese encephalitis virus vaccine, for subcutaneous use	Japanese encephalitis SC	39	227
90736	Zoster (shingles) vaccine, live, for subcutaneous injection	zoster	121	228
90737	Hemophilus influenza B	Hib, unspecified formulation	17	229
90738	Japanese encephalitis virus vaccine, inactivated, for intramuscular use	Japanese Encephalitis IM	134	230
90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use	Hep B, dialysis	44	231
90741	Immunization, passive; immune serum globulin,	IG, unspecified formulation	14	232

	human (ISG)			
90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use	Hep B, adult	43	233
90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use	Hep B, adolescent or pediatric	08	234
90745	Hepatitis B vaccine, adolescent/high risk infant dosage, for intramuscular use	Hep B, adolescent/high risk infant	42	235
90746	Hepatitis B vaccine, adult dosage, for intramuscular use	Hep B, adult	43	236
90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use	Hep B, dialysis	44	237
90748	Hepatitis B and Hemophilus influenza b vaccine (HepB-Hib), for intramuscular use	Hib-Hep B	51	238

Appendix B

MVX Code Set - Manufacturers of Vaccines

The table below is the most up to date value set for this table. It includes both active and inactive manufacturers of vaccines in the US. Inactive MVX codes allow transmission of historical immunization records. When MVX code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated (CDC,2016).

MVX_CODE	Manufacturer_name	Status	manufacturer_id
AB	Abbott Laboratories	Active	1
ACA	Acambis, Inc	Inactive	2
AD	Adams Laboratories, Inc.	Active	3
ALP	Alpha Therapeutic Corporation	Active	4
AR	Armour	Inactive	5
AVB	Aventis Behring L.L.C.	Inactive	6
AVI	Aviron	Inactive	7
BA	Baxter Healthcare Corporation-inactive	Inactive	8
BAH	Baxter Healthcare Corporation	Active	9
BAY	Bayer Corporation	Inactive	10
BP	Berna Products	Inactive	11
BPC	Berna Products Corporation	Active	12
BTP	Biotest Pharmaceuticals Corporation	Active	13
MIP	Emergent BioDefense Operations Lansing	Active	14
CSL	bioCSL	Active	15
CNJ	Cangene Corporation	Inactive	16
CMP	Celltech Medeva Pharmaceuticals	Inactive	17
CEN	Centeon L.L.C.	Inactive	18
CHI	Chiron Corporation	Inactive	19
CON	Connaught	Inactive	21
DVC	DynPort Vaccine Company, LLC	Active	22
EVN	Evans Medical Limited	Inactive	23
GEO	GeoVax Labs, Inc.	Active	24
SKB	GlaxoSmithKline	Active	25
GRE	Greer Laboratories, Inc.	Active	26
IAG	Immuno International AG	Inactive	27
IUS	Immuno-U.S., Inc.	Active	28
INT	Intercell Biomedical	Active	29
KGC	Korea Green Cross Corporation	Active	30
LED	Lederle	Inactive	31
MBL	Massachusetts Biologic Laboratories	Active	32
MA	Massachusetts Public Health Biologic Laboratories	Inactive	33

MED	MedImmune, Inc.	Active	34
MSD	Merck and Co., Inc.	Active	35
IM	Merieux	Inactive	36
MIL	Miles	Inactive	37
NAB	NABI	Active	38
NYB	New York Blood Center	Active	39
NAV	North American Vaccine, Inc.	Inactive	40
NOV	Novartis Pharmaceutical Corporation	Active	41
NVX	Novavax, Inc.	Active	42
OTC	Organon Teknika Corporation	Active	43
ORT	Ortho-clinical Diagnostics	Active	44
PD	Parkedale Pharmaceuticals	Inactive	45
PWJ	PowderJect Pharmaceuticals	Inactive	46
PRX	Praxis Biologics	Inactive	47
JPN	The Research Foundation for Microbial Diseases of Osaka University (BIKEN)	Active	48
PMC	sanofi pasteur	Active	49
SCL	Sclavo, Inc.	Active	50
SOL	Solvay Pharmaceuticals	Inactive	51
SI	Swiss Serum and Vaccine Inst.	Inactive	52
TAL	Talecris Biotherapeutics	Active	53
USA	United States Army Medical Research and Material Command	Active	54
VXG	VaxGen	Inactive	55
WA	Wyeth-Ayerst	Inactive	56
WAL	Wyeth	Active	57
ZLB	ZLB Behring	Inactive	58
OTH	Other manufacturer	Active	59
UNK	Unknown manufacturer	Active	60
AKR	Akorn, Inc	Active	61
PFR	Pfizer, Inc	Active	62
BRR	Barr Laboratories	Active	64
JNJ	Johnson and Johnson	Active	65
PSC	Protein Sciences	Active	66
IDB	ID Biomedical	Active	67
GRF	Grifols	Active	68
CRU	Crucell	Active	69
KED	Kedrion Biopharma	Active	70
PAX	PaxVax	Active	71
MCM	MCM Vaccine Company	Active	72

Appendix C

HL7 Data Requirements Status

This table represents the recommended status for data fields in HL7 messages transporting immunization data (CDC, 2016).

Label	Status (Required/Optional)
Patient name: first, middle, last	Required
Patient alias name: first, middle, last	Optional
Patient address, phone number	Optional
Birthing facility	Optional
Patient Social Security number (SSN)	Optional
Patient birth date	Required
Patient sex	Required
**Patient race	Required
**Patient ethnicity	Required
Patient Primary language	Optional
**Patient birth order	Required
Patient birth registration number	Optional
Patient birth State/country	Required
Patient Medicaid number	Optional
Mother's name: First, middle, last, maiden	Required
Mother's SSN	Optional
Father's name: first, middle, last	Optional
Father's SSN	Optional
Vaccine Type	Required
Vaccine Manufacturer	Required
Vaccine dose number	Optional
Vaccine expiration date	Optional
Vaccine injection site	Optional
Vaccination date	Required
Vaccine lot number	Required
Vaccine provider	Optional
**Historical vaccination flag indicator	Optional
**VFC eligibility	Optional
**History of varicella disease indicator	Optional
**Patient status indicators that include active, inactive, MOGE, and other classifications	Optional

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