IMMUNIZATION INTEGRATION PROGRAM: IMMUNIZATION-RELATED CAPABILITIES & GUIDANCE

UPDATED – JANUARY 2022

VERSION HISTORY

The Immunization Integration Program (IIP) updates this Immunization-related Capabilities and Guidance document to reflect new testing requirements, updates and changes and incorporates CDC's review and feedback. The table below tracks these changes to the document.

Version #	Implemented by	Revision Date	Description	Approved by	Approval Date
Draft v.01	CNI Advantage	September 20, 2015	1st Draft	F Eisenberg	September 20, 2015
1	CNI Advantage		Version 1	CDC	October 30, 2015
1.01	CNI Advantage	October 6, 2016	Update based on public and Technical Advisory Panel Feedback during Phase 3: 1. Remove unidirectional exchange test script; retain bidirectional exchange test script (page 1 and Section 5.41, page 14) 2. Section 5.2 (page 12) – add protection indicator to patient demographics 3. Section 5.81 (page 17) – Remove the term "audit" 4. Section 5.91 (page 17) – Discuss IIS acceptance of update from provider post-immunization reconciliation	CDC	January 23, 2017

			5. Section 5.10.1 (page 18) – Saving post-reconciliation forecast 6. Section 5.29 (page 33) – Address vaccine series 7. Section 5.38 (page 39) – Patient's preferred methods for notification 8. Section 5.41.1 (page 42) Adverse event terminology		
2	CNI Advantage and HIMSS	November 27, 2016	Add capability examples and update for publication in HIMSS Immunization Integration Program. 1. Change test references to direct readers to the testing tool where the script can be downloaded. 2. Add capability examples to publish as a single capability and guidance document.	CDC	January 23, 2017
3	CNI Advantage and HIMSS	December 21, 2016	Update with input from Technical Advisory Panel to address guidance and capabilities.		
4	Chickasaw Health Consulting and HIMSS	October 23, 2017	Update based on input from public comments, implementation testing and the Technical Advisory Panel to address guidance and capabilities.		
5	Chickasaw Health	March 26, 2018	Update based on input from the Technical Advisory Panel and	CDC	March 26, 2018

	Consulting and HIMSS		findings from HIMSS IIP Testing Program to address guidance and capabilities. Added Change Log (Appendix C)		
6	Chickasaw Health Consulting and HIMSS	September 2018	Update based on input from testing, program feedback and the Technical Advisory Panel to address guidance and capabilities.		September 30, 2018
7	Chickasaw Health Consulting and HIMSS	October 2019	Update based on input from testing, program feedback and the Technical Advisory Panel to address guidance and capabilities.		October 15, 2019
8	Chickasaw Health Consulting and HIMSS	March 2020	Update based on quality review and update of test plan.	CDC	May 4, 2020
9	Chickasaw Health Consulting and HIMSS	May 2020	Removal of test pursuant to guidance from CDC received on April 29, 2020 and discussed April 30, 2020		
10	Chickasaw Health Consulting and HIMSS	September 2020	Update based on input and agreed upon recommendations from the Technical Advisory Panel to address guidance and capabilities. Details to Methods in Section 5.		September 14, 2020
11	AIRA and HIMSS	January 2022	Update based on approved new capabilities and other recommendations from the Technical Council to enhance the IIP Testing		

			and Recognition Program		

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1 OVERVIEW

Project Overview

This document is intended for electronic health record (EHR) vendors and developers of clinical software to present clinical workflow requirements, self-tests, suggestions for managing clinical workflow, and software usability addressing immunization management. It is also intended for end-users of clinical software, including clinical care providers, to encourage understanding about how software might enhance workflow efficiency and patient safety. Providers also may find value in the content to help evaluate and differentiate clinical software products. This document should provide value for software developers and providers to increase attention to immunization-specific functionality and usability. It should also encourage greater collaboration among the public health registries, vendors, and providers to harmonize requirements for patient care and clinical workflow. For truly integrated systems that promote comprehensive vaccine compliance, processes to include additional immunization data exchange partners such as pharmacies, long term care facilities and student information systems (SIS) should be considered. The document presents immunization-related software requirement focused on end-to-end clinical workflow, functional and usability tests, and general guidance.

The Immunization Integration Program (IIP) presents this EHR Immunization-Related Guidance document on behalf of the Centers for Disease Control and Prevention (CDC), Office of Infectious Diseases (OID), National Center for Immunization and Respiratory Diseases (NCIRD), Office of the Director. Improved immunization rates have been linked to better health outcomes, reductions in health care costs, and higher levels of productivity.[1,2,3] EHRs have been shown to increase the effectiveness of various interventions that improve immunization rates, such as provider reminders, standing orders, provider assessment and feedback processes, and patient reminders. School requirements are also primary drivers of vaccine compliance – school nurses are important immunization data consumers and strong advocates for vaccination. CDC believes that improving immunization-related functions and usability of EHRs and other clinical software will improve the level of appropriate immunizations, thereby positively impacting public health.

IIP Technical Council

When the American Immunization Registry Association (AIRA) assumed an IIP leadership role in October 2020, the IIP governance structure was assessed, and the Technical Advisory Panel (TAP) evolved to the IIP Technical Council which currently provides technical expertise to both the IIP Testing and Recognition initiative and the IIP Collaborative. The Technical Council considers changes in the environment, immunization community input and test findings through a series of meetings and recommends additional updates to the tests, capabilities, and guidance to ensure success. This document reflects those changes to the capabilities and guidance.

Technical Council Membership

Chair:

- *Shaun Grannis*, Regenstrief Institute

Technical Council Members:

- *Noam Arzt,* HLN Consulting
- *Kevin Brimer*, Cerner
- *Cheryl Lee Eberting,* AZOVA
- *Kristin Glaza*, Cerner
- *Terrie Hamlin*, Professional Software for Nurses, Inc.
- *Joe Kelly*, STChealth
- *Susan J. Kressly*, MD, Pediatric Health IT SME
- *Becky Learn,* Indiana Health Information Exchange
- *Jon Reid,* Utah Department of Health
- *Ron Shapiro,* Qvera
- *Stuart Weinberg*, MD, Clinical Informaticist

Ex-Officio Members:

- *Kafayat Adeniyi*, CDC
- *Stuart Myerburg*, CDC
- *Chrissy Miner*, CDC
- *Katie Tully*, HHS/ONC

- *Johnny Bender*, HHS/ONC

Capability Category Definitions

Each IIP Testing &Recognition capability maps to the individual testing requirement section within this document. The capabilities are organized by four categories:

Required – This is the base set of IIP capabilities that must be supported, including the ONC 170.315 (f)(1) required capabilities, to pass the IIP test plan.

90% Required – Systems are required to pass 90% of these capabilities. This means that the electronic health record (EHR) vendor may choose to not implement some of these capabilities. If vendors have implemented at least 90% of these capabilities (21 or more), in addition to the Required Capabilities, they will pass the IIP test plan.

Trial - Capabilities that are in the process of being vetted to promote them as part of the 90% Required as either stand-alone or part of existing capabilities.

Discovery – Capabilities which are considered Discovery and included for the IIP to gather information on additional capabilities or features to determine if, how, where and when they should be required in the IIP test plan.

2 SUMMARY OF CHANGES

This section provides a summary of major changes found in the current version of the document. Appendix D – Change Log includes the details to each change highlighted in the summary. The summary of changes is archived after each major update.

Summary of changes to this version include:

- Revising the Capabilities Category Definitions
- Upgrading the Requirement 5.15 Record Vaccine Information by Scanning 2D Barcode Found on Unit-of-Use for Vaccine Administration from an Optional Category to the 90% Required Category
- Adding two new Discovery Capabilities to Section 13 - Configuration and Operational Management –
    - Requirement 9.4 Add Jurisdiction-Specific Vaccine Eligibility Code
    - Requirement 9.5 Acknowledgment Data Reporting

- Deprecating Requirement 7.4 Notify Public Health Immunization Registry (IIS) of Update from Adverse Event
- Updated Appendix B – Crosswalk of Capabilities to 2021/2022 test script updates
- Updated Appendix C – 2D Barcode Example to provide an example 2D barcode and list of encoded data elements

3 OVERVIEW OF GENERAL USER WORKFLOWS

The immunization-specific functional requirements and the related guidance in this document are based on a conceptual model of clinical workflows. Providing the right immunization(s) to a patient at the right time requires actions by people, interactions between people and software systems, and information sharing among software systems. Exhibit 5 lists the workflows for providing immunizations to patients and exchanging data with IIS.

Exhibit 5: EHR Immunization Management Activities Comprising Eight General User Workflows, (1) Register and Identify a Patient, (2) Manage External Query, Response and Reconciliation, (3) Manage Information for Clinical Decision-Making, (4) Manage Inventory, (5) Administer and Report Immunization, (6) Manage Cohort, (7) Manage Adverse Events, and (8) Provide Patient Access.

Exhibit 6 presents the eight general user workflows identified in Exhibit 5, as well as specific immunization-related actions conducted within each general user

workflow. Appendix A provides a full description of each workflow and related work in the area.

Immunization-Specific Actions Categorized Within Eight Distinct General User Workflows		
General User Workflows		**Immunization-Specific Actions**
1	Register and Identify a Patient	▪ Register and identify an individual patient.
2	Manage External Query, Response and Reconciliation	▪ Query/request data from the IIS (Ideally, the IIS can consolidate information about the same patient from other IIS to be a complete source of information). ▪ Receive a response with vaccine history and forecast. ▪ Reconcile IIS and local immunization data. ▪ Incorporate reconciled data into the vaccine administration record.
3	Manage Information for Clinical Decision-Making	Determine the appropriate immunization to provide to the individual patient based on: ▪ Demographic data. ▪ Prior vaccine history (available from the EHR/IIS and from patient reported immunizations). ▪ Vaccine interaction history and potential. ▪ Allergy and adverse reaction history. ▪ Current and prior clinical conditions. ▪ Forecasted (recommended) immunizations based on the general Advisory Committee on Immunization Practices (ACIP) recommended schedule.
4	Manage Inventory	▪ Access local inventory based on patient eligibility for special programs or private vaccine stock. ▪ Assure adequate stock is available in the provider setting (order, stock/restock) from guarantee programs (e.g., CDC VFC) or private sources.
5	Administer and Report Immunization	▪ Provide patient education. ▪ Document deferrals. ▪ Administer immunization. ▪ Document administration of immunization. ▪ Report – provide message to IIS. ▪ Report – provide patient summary.
6	Manage Cohort	▪ Identify a cohort of patients based on defined criteria. ▪ Examples:

Immunization-Specific Actions Categorized Within Eight Distinct General User Workflows		
		- Vaccine recall (manufacturer and lot number). - All patients past due for immunizations. - Notify patients for appropriate care management.
7	Manage Adverse Events	▪ Document adverse event.
8	Provide Patient Access	▪ Provide patient portal. ▪ Allow download or transmit of validated immunization summary to meet external requirements (school entry, summer camp, employment).

Exhibit 6: General User Workflows and Immunization-Related Actions

Each general user workflow and immunization-related action is associated with requirements that can be used to develop and evaluate EHRs or other clinical software. Sources for developing the requirements include existing consensus-based efforts to define EHR requirements from the Agency for Healthcare Research and Quality (AHRQ) Children's Electronic Health Record Format (CEHRF, 12/2013), and the Health Level 7 Electronic Health Record Functional Model (EHR-FM) Release 2 (4/2014). Requirements from these industry efforts were mapped to the eight general user workflows and related functional activities and consolidated into 43 distinct immunization-related requirements.

4 COLLABORATION WITH NIST

NIST makes the HIMSS Immunization Integration Test Suite available for (a) testing whether public health immunization information systems (IIS) conform to standards and (b) to prepare for ONC Certified EHR Technology (CEHRT) 2015 requirements. Coordination of the EHR functional testing using the HIMSS Immunization Integration Test Suite means that the scenarios include the same detailed data requirements expected of the IIS. Also, NIST has provided the scenario developed for this project as an expanded test set for EHR vendors choosing to self-evaluate their products for comprehensive immunization capabilities under Option 5 of the Test Suite, 'Isolated Testing'. The expectation is that vendors successfully completing evaluation with the expanded test set may pass certification for CEHRT 2015 in addition to the voluntary portion of the test.

Vendors may test the validity of HL7 Request/Return Evaluated Immunization History and Forecast Query (Z44/Z42) messages, the Send Unsolicited Immunization Update Using a VXU (Z22) messages, and other associated messages using the option (3) HL7 Context-Free.

Note that the HIMSS Immunization Integration Test Suite is a work in progress. It does not include all functionality. Some specific items to consider:

1. The tool also requires that HL7 transactions occur as consecutive steps (i.e., a query must be followed by a response, VXU/ACK). Either the test plans will need modification, or the tool can be modified to support non-consecutive transactions, or both.
2. The validation engine is continually tested.

In order to use the HIMSS Immunization Integration Test Suite 1.7.3 to run the EHR Functional testing, the vendor would do the following:

1. Access the HIMSS Immunization Integration Test Suite 1.7.3 https://hl7v2-iz-cdc-testing.nist.gov/iztool/#/cb.
2. Select option (4) 'Context-based' from the top menu bar.
3. Once the test plan is selected, a more detailed menu is available with the test categories that make up the full scenario set. These are intended to be executed in order top-to-bottom as there are data dependencies.
4. Open the test categories to reveal the test cases. There are 4 test patients that together fulfill each of the EHR Functional testing requirements. The test step descriptions and data requirements are listed by selecting the arrow to the left of the test case. Select each test step to obtain the test data and description of each step. Test steps involving transactions are indicated by arrows (←, →) rather than checkboxes (☑).

The following sections review the functional capabilities and guidance for each of the requirements. EHR vendors should consider the tests as methods to evaluate their own products' ability to meet the requirements. Clinical providers may use this information to help evaluate differences among clinical software products and to identify topics they should discuss with their EHR vendors.

5 GENERAL DESCRIPTION OF USER WORKFLOW 1: REGISTER AND IDENTIFY A PATIENT

Using the EHR, the provider identifies the patient either by locating the patient's record in the EHR or other clinical software system or by adding a new patient.

Who Performs User Workflow 1: Register and Identify a Patient

- Clinicians (physicians, nurses, and other personnel who assist with providing immunizations)
- Patients or caregivers with permission to access an individual's information in a personal health record (PHR) or through external access to the provider's EHR (e.g., a portal).

Patient information may also be sent to other approved providers or public health organizations, such as the immunization registry (also called an immunization information system, or IIS).

Examples of Work in This Area

Anyone using an EHR to review or enter information for any reason must be able to find a specific patient. This ability is not unique to providing or reviewing immunizations. Some suggest a need for a unique, national patient identifier.[4] Others recommend common matching procedures, or algorithms.[5,6] Considerable effort is underway in other settings to address unique patient identification.[7] Note that the process assumes that privacy and security is managed for all users of the EHR. This workflow does not include any specific immunization-related privacy and security requirements.

Requirement 1.1 Register New Patients

The EHR or other clinical software system must allow a user to enter distinguishing information about patients so that providers can uniquely identify patients who have similar sounding names or other similar identifying information. For example, twins living in the same household will have similar dates of birth, addresses, and may have similar names. The EHR or other clinical software system must be able to store information to successfully match with patients in immunization registries if the information is available. Specific to immunization registries, that information includes the mother's maiden name, whether the

patient was part of a multiple birth, and the birth order (i.e., ordinal number of birth, first, second, etc.). This information allows the provider to correctly identify the patient and helps ensure a match when the EHR sends the patient's information to external systems such as an immunization registry.

5.1.2 Example of Scenario "Register New Patients"

Joanna Gonzales Morales, age 32, arrives in the office with her twin daughters Juana Maria Gonzales and Mariela Gonzales, age 1 years. Juana Maria is 15 minutes older than Mariela. There is no record for either sibling in the provider's EHR. The intake worker in the provider's office collects information from Mrs. Morales and enters Juana Maria and Mariela as new patients. The intake worker first determines if either child is already registered by searching for each child's information in the EHR. In conducting the search, the intake worker locates a patient with similar information, who is named Juana Mariana Vasquez. However, Juana Mariana Vasquez is 6 years of age, which enables the intake worker to validate that this is a different patient, and that Juana Maria and Mariela Gonzales are new patients whose information is not yet entered in the EHR. The intake worker then registers Juana Maria and Mariela in the EHR by entering the necessary patient information. As part of this process, the intake worker enters the mother's maiden name (Gonzales), checks the multiple birth indicator for each, and enters birth order for each child in the appropriate field.

5.1.3 Guidance

The HL7 Version 2.5.1 Implementation Guide: Immunization Messaging (Release 1.5) 10/1/2014 lists data elements usable for patient identification. Appendix A lists the full set of demographic data elements. When provided with such information, systems should store and submit it. The fields most likely to be absent in existing software the project evaluated include multiple birth indicator and birth order. These fields are helpful in immunization registries to differentiate children from multiple births, especially when other differentiating data are not available from the birth facility. Capturing complete data (e.g., a full middle name rather than a middle initial) is preferable to differentiate patients with similar names. A new data element was added in 2016 to ensure the patient's information includes a "protection indicator" identifying whether the patient's information may be shared with others. The indicator specifically conveys

information about whether the patient has opted in or opted out of reporting in jurisdictions that require such information.

Immunization Registries (IIS) have a concept of "Active" or "Inactive" within a provider organization (see Exhibit 13, Patient Demographics). The American Immunization Registry Association (AIRA) published a document on this topic for the IIS community.[8] However, the issue of patient inactivation in provider organizations varies and IIS suggest inactivation is rare in EHRs and it is even rarer for providers to document it. Further, if patient inactivation is documented, it's unclear what the triggering event should be to send this information to the IIS since the event wouldn't coincide with a vaccination event. The IIP TAP listed the following challenges regarding how active status might be determined in a clinical practice and potentially shared with an IIS:

- Ambulatory practices do not necessarily have a consistent workflow to record patients who expire or who become inactive in the practice.
- Pediatricians have a standard practice to manage transitioning patients as they approach adulthood and marking patients as transferred.
- EHRs may have the ability to allow administrative roles to indicate a status in the record as "moved or gone elsewhere" but the process requires communication from the patient or caregiver; it is not part of the clinical workflow.
- Identification of deceased patients is standardized only in the inpatient setting as discharge status or disposition.
- Workflow to address this issue is important with respect to immunizations as well as other preventive care and care coordination activities; and to support work with other registries.

Resolution for determining and sharing active or inactive status requires definition of workflow considerations for both the clinician and the IIS. Such information is best attained by convening all stakeholders to review scenarios and apply potential workflow models identified.

5.1.3.1 Focus on Vendor Perspective

Products with the ability to store all elements listed as *required* (R), *required if exist* (RE), and *conditional* (C) may more commonly match patients with those in

public health registries by allowing capture of a superset of demographic elements to manage the variation in statutory requirements.

5.1.3.2 Focus on Provider and Implementer Perspective

Capturing more demographic data elements for each patient helps match patients within the practice and especially when communicating with immunization registries. Better matching increases the likelihood that queries sent to the registry for information will identify unique patients and return data to the practice.

Regarding use of the "protection indicator" (i.e., should the information be protected – Yes or No), each jurisdiction determines how an individual's immunization status may be shared with the IIS and with other providers. In some cases, the IIS may require the provider to send immunization data even if the protection indicator is set to "Yes" but the IIS will not share it with others; in other cases, the IIS may not accept immunization messages with a protection indicator set to "Yes". The clinician should be aware of local rules for sharing as they may be different for adults and for children. For reference, guidance regarding use of the protection indicator is copied below from the latest HL7 version 2.8.2 Implementation Guide for Immunization Messaging provides guidance Section 2.3.6.3 – Sending Protection Indicator) In the VXU "Messaging Capabilities":

> The protection indicator identifies whether a person's information may be shared with others. The indicator conveys the current patient state in the system constructing the message. Local laws, regulations and IIS policy may significantly impact the collection and exchange of patient protection indicators including, but not limited to:
>
> - Method of collecting protection indicator (electronic versus paper)
> - Who data is collected for (adults versus minors)
> - Whether individuals opt in or opt out of data sharing
> - Filtering of data for protected individuals
>
> More information on consent can be found in the AIRA Confidentiality and Privacy Considerations document: (http://www.immregistries.org/AIRA_Confidentiality_and_Privacy.pdf)

Some jurisdictions require that submitters not transmit events for patients who have not consented to share their data. In this case, no HL7 message is constructed by the submitter's system. The remaining discussion of the protection indicator in this use case assumes that the submitter is allowed to generate and transmit an HL7 message.

The protection state must be explicitly captured in the system documenting the immunization. If it is not actively determined, then the protection indicator shall be empty.

The protection indicator and associated effective date are messaged in the Protection Indicator (PD1-12) field and the
Protection Indicator Effective Date (PD1-13) field.

In the description of PD1-12, the Implementation Guide states:
This field identifies whether a person's information may be shared with others (local policies determine how data are protected). The protection state must be explicitly captured in the system documenting the immunization. If it is not actively determined, then the
protection indicator shall be empty.

There are 3 states:

Protection State	Code
Yes, protect the data. Patient (or guardian) has indicated that the information shall be protected. (Do not share data)	Y
No, it is not necessary to protect data from other clinicians. Patient (or guardian) has indicated that the information does not need to be protected. (Sharing is OK)	N
No determination has been made regarding patient's (or guardian's) wishes regarding information sharing	PD1-12 is empty

Notes on use of Y for Protection Indicator starting in version 2.5.1 Guides

Note that Implementation Guides based on HL7 versions less than 2.5 stated that Y meant that a person's information could be shared. This was an incorrect interpretation of the use of this field. The meaning now aligns with the base definition of HL7, that is, Y means data must be protected. Existing systems that use the old meaning will need to determine how they will send the correct value in messages based on version 2.5.1 or beyond.

Note that the value sent in a message that is based on the 2.3.1 or 2.4 version of the HL7 standard shall continue to follow the old guidance. That is, Y means sharing is allowed and N means sharing is not allowed. A system receiving a message containing a PD1 segment must process the protection indicator in a way consistent with the HL7 version the message is based on. [9]

Implementation sites should contact their respective IIS to determine the local policy regarding protection indicator.

Options for local configuration (contingent upon local IIS policy):

1. Turn on "Opt-in" and send data only on patients who opt in with a protection indicator "N" (no protection).
2. Turn on "Opt-in" and send data on all patients (with the "Y", "N", or absent indicator) and the IIS will determine from the indicator if the data can be further shared with other providers.
3. Turn on "Opt-out" and send data only on patients who don't opt out (those with protection indicator set to "N").
4. Turn on "Opt-out" and send data on all patients with the "N" or "Y" or absent indicator and the IIS will determine from the indicator if the data can be further shared with other providers.

In general, the absent indicator is problematic, and a value of "N" or "Y" is preferred.
Note that some jurisdictions have different policies regarding "Opt-in" and "Opt-out" for children, adolescents, and adults.

5.1.4 Test

Attachment B provides a test script scenario that includes the requirement Register New Patients. The script also indicates successful performance for each of the test sections. When provided with a patient's full middle name, a mother's maiden name, multiple birth data and birth order, the system will store and transmit all of the information, including the full middle name in queries and reports sent to the immunization registry.

5.1.4.1 Data Elements

See Appendix A

Requirement 1.2 Select New Patient

The EHR or other clinical software system must allow a user to distinguish information about patients with similar names or identifying information in order to select the right patient from the providers' EHR or other clinical software system. This information is crucial for identifying and selecting the correct patient. For example, twins living in the same household will have similar dates of birth, addresses, and may have similar sounding names. In order to match patients with those already in the immunization registry, the EHR or other clinical software should have the ability to record the mother's maiden name, whether the patient was part of a multiple birth, and if so, the order of birth (when such information is available). The provider should be aware of how often the protection indicator information must be updated based on local rules.

5.1.5 Example of Scenario "Select New Patient"

Joanna Gonzales Morales, age 32, presents at the office with her twin daughters, Juana Maria Gonzales and Juana Mariela Gonzales, age 1 year. Neither child has received any MMR vaccine. The provider (e.g., doctor, nurse, etc.) must administer the vaccine to each child and then record the immunization information in each child's record in the EHR or other clinical software system. To accomplish this, the intake clerk enters the name "Juana Maria Gonzales" into the system to locate her record. The system returns three potential matches: 1) Juana Maria Gonzales (multiple birth indicator = yes, birth order = 1); 2) Mariela Gonzales (multiple birth indicator = yes, birth order =2); and 3) Juana Mariana Vasquez (multiple birth order = no). In this instance, the

multiple birth indicator and birth order information provides sufficient information for the intake clerk to quickly determine which patient to select. The provider should be aware of how often the protection indicator information must be updated based on local rules.

5.1.6 Guidance

Identical to Requirement 1.1 (Section 5.1).

5.1.6.1 Focus on Vendor Perspective

Identical to Requirement 1.1 (Section 5.1).

5.1.6.2 Focus on Provider and Implementer Perspective

Identical to Requirement 1.1 (Section 5.1).

5.1.7 Test

Attachment B provides a test script scenario that includes the requirement Select New Patients. The script also indicates successful performance for each of the test sections. When provided in the script with a patient's full middle name, a mother's maiden name, multiple birth data and birth order, the system will be able to distinguish among test patients with similar sounding names and twins.

5.1.7.1 Data Elements

See Appendix A

Requirement 1.3 Select One or More Patients

The EHR or other clinical software system must allow a provider to specify one or more patients in real time or those scheduled for appointment(s) in the future (e.g., the next day, week, month, etc.) so that a request can be sent to the public health immunization registry for each patient's complete immunization history.

5.1.8 Example of Scenario "Select One or More Patients"

Doctor Smith is a pediatrician. Via the EHR Dr. Smith's office uses, her office manager sends requests to the local public health immunization registry every Friday to retrieve immunization histories for all patients scheduled for appointments during the next week. On Tuesday afternoon, Dr. Smith's office

manager wants to identify all patients added to the schedule since the request was sent on the prior Friday. She wants to view the list of all patients scheduled for appointments, identify those that were added to the schedule, and send a new request to the registry for immunization histories that does not include any duplicate requests for patients included in the request sent the previous Friday.

5.1.9 Guidance

Identical to Requirement 1.1 (Section 5.1).

5.1.9.1 Focus on Vendor Perspective

Identical to Requirement 1.1 (Section 5.1).

5.1.9.2 Focus on Provider and Implementer Perspective

Identical to Requirement 1.1 (Section 5.1).

5.1.10 Test

Refer to the test script scenario that includes the requirement Select One or More Patients. The script also indicates successful performance for each of the test sections.

5.1.10.1 Data Elements

See Appendix A

6 GENERAL DESCRIPTION OF USER WORKFLOW 2: MANAGE EXTERNAL QUERY, RESPONSE, AND RECONCILIATION

General User Workflow 2: Manage External Query, Response, and Reconciliation includes sending a request for immunization information to a public health registry (IIS) for one or more patients, receiving past immunization history, and comparing and reconciling history with what is already present in the EHR or other clinical software system.

This workflow assumes the ability to distinguish among multiple patients in the EHR. However, it specifically addresses include the ability for an EHR or other clinical software system to communicate with the public health registry if there are no patient matches, incorrect matches, or multiple matches result from the request.

Who Performs User Workflow 2: Manage External Query, Response, and Reconciliation

- Clinicians (physicians, nurses and other personnel who assist with providing immunizations)

6.1.2 Examples of Work in This Area

Exchanging health information among two or more systems, and the ability of those systems to use the information, is defined as *interoperability*.[10] Much work in this area is already underway. The Office of the National Coordinator for Health IT (ONC) has applied considerable effort to address interoperability among EHRs and between EHRs and registries. ONC has published an Interoperability Roadmap.[11,12,13] Earlier efforts addressed communication among EHRs and specialized or public health registries.[14,15,16] The earlier CEHRT requirements specifically addressed immunization registries requiring submission of information to public health registries. They did not require the EHR to receive patient immunization history from such registries.[17] The CEHRT 2015 requirement for "Immunization History and Forecast" requires the EHR to "enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at §170.205(e)(4)."

Two organizations, AIRA and the Association of Immunization Managers (AIM), address requirements for immunization registries and enable collaboration among registry organizations and managers.[18,19,20,21] Although the vision and goals are aligned, the level to which each registry currently achieves those goals may be addressed on different time schedules. Differences in funding and state regulations also may affect the extent to which each registry can support query and response with EHRs and other clinical software for citizens of all ages. Some registries do not yet accept immunization information for adults (individuals 19 years of age or greater); others allow opt-out for adults. While common standards exist that address methods to send and receive electronic information, all are not yet using those standards due to funding or state regulatory requirements.

DEPRECATED Requirement 2.1 Batch Request / Receive Patient Immunization History

This requirement has been deprecated as it is no longer recommended to batch request/receive patient immunization history. This section is retained as a reference for historical references.

Requirement 2.2 Request / Receipt of Patient Immunization History

The EHR or other clinical software system sends a request to the public health immunization registry "on demand," or in advance for those with scheduled appointments. The request includes the identifying information the immunization registry needs to match each patient with those in the registry including, if present, the mother's maiden name, a multiple birth indicator, and the birth order. The request also is sent in a pre-determined format the registry can read and interpret (Request Evaluated Immunization History and Forecast (Z44) – HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5).

6.1.3 Example of Scenario "Request / Receipt of Patient Immunization History"

On Wednesday, Dr. Smith's office manager uses the EHR to select Juana Maria Vasquez (age 6), who is a late addition to the appointment schedule for the same day. The EHR allows the office manager to create a query to the public health immunization registry (IIS) requesting the patient's immunization history. The EHR formats the request, including the patient's information, into a format that can be read and processed by the registry. The registry returns a response in real-time that includes Juana's latest vaccine history and forecast in a standard format that the EHR can process and present to Dr. Smith when she sees the patient.

6.1.4 Guidance

Information required for matching patients with those known to the immunization registry is identical to Requirement 1.1 (Section 5.1). The immunization history that the registry returns to the provider may include some or all of the data elements listed in Appendix A. Most of the products evaluated had fields for historical vaccine information for all except the fields: *ordering provider, entering organization, administering provider* and *entered by*. Specifically valuable for reconciling the vaccine history with the information in

the EHR were *date/time of administration, vaccine administered, lot number, substance manufacturer name*. The additional fields may also provide benefit for patient follow up. Further feedback is invited regarding which additional elements to address.

6.1.4.1 Focus on Vendor Perspective

Products with the ability to store additional data elements about historical vaccines may assist providers to perform reconciliation. Additional data (such as administered at location) may also allow providers to obtain additional information as needed for vaccine recalls.

6.1.4.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

6.1.5 Test

Refer to the test script scenario that includes the requirement Request / Receipt of Patient Immunization History. The script also indicates successful performance for each of the test sections.

6.1.5.1 Data Elements

See Appendix A.

Requirement 2.3 Compare Public Health Immunization Registry (IIS) Immunization History to EHR Immunization History

The public health immunization registry has returned the requested immunization history for a patient (Return Evaluated Immunization History and Forecast (Z42) – HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5). The EHR is able to display the evaluated immunization history received from the registry as well as the immunization history already present in the EHR so that a user can compare them. The EHR provides a way for the provider to view both histories, determine what is different (if anything), and update the existing EHR immunization history with new information from the public health registry if they choose to do so. The system must store the new information as structured data as part of the patient's local immunization history and include the time of the update and the source of the new information.

6.1.6 Example of Scenario "Compare Public Health Immunization Registry (IIS) Immunization History to EHR Immunization History"

Dr. Smith's EHR system receives immunization information from the registry for the existing patient, Juana Maria Vasquez. The immunization history in the EHR indicates that the patient has not received any doses of MMR vaccine. The history received from the registry indicates that Juana was given an MMR vaccine at age 15 months by another provider. The EHR allows Dr. Smith to accept the history received from the registry, save it in Juana's record, and indicate that the source of the information is the public health registry.

6.1.7 Guidance

The immunization history that the registry returns to the provider may include some or all of the data elements listed in Appendix A. Most of the vendors evaluated had fields for historical vaccine information for all except the fields: *ordering provider, entering organization, administering provider, and entered by*. Specifically valuable for reconciling the vaccine history with the information in the EHR were *date/time of administration, vaccine administered, lot number, substance manufacturer name*. The additional fields may also provide benefit for patient follow up. The AIRA Management and Improvement Initiative is also exploring assessment and standardization of IIS (http://www.immregistries.org/initiatives/measurement-and-improvement-initiative). Further feedback is invited regarding which additional elements to address.

6.1.7.1 Focus on Vendor Perspective

Products with the ability to store additional data elements about historical vaccines may assist providers perform reconciliation. Additional data (such as administered at location) may also allow providers to obtain additional information as needed for vaccine recalls.

6.1.7.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

6.1.8 Test

Refer to the test script scenario that includes the requirement Compare Public Health Immunization Registry (IIS) Immunization History to EHR Immunization History. The script also indicates successful performance for each of the test sections.

6.1.8.1 Data Elements

See Appendix A.

Requirement 2.4 Request/Receive Patient Immunization Data and Identify Source

The EHR or other clinical software system stores immunization history accepted electronically from other sources (such as a public health immunization registry consistent with HL7 Version 2.5.1, Implementation Guide for Immunization Messaging Release 1.5) or communicated by the patient and manually entered by the clinician. When viewing such information, the provider can determine which immunizations were administered by the practice, which were entered historically as patient-reported, and which were accepted electronically from the public health registry.

6.1.9 Example of Scenario "Request/Receive Patient Immunization Data and Identify Source"

Dr. Smith's EHR maintains Juana Maria Vasquez' immunization history and clearly identifies the source of all information about Juana's immunizations. The EHR indicates that two of Juana's immunizations were not administered in Dr. Smith's office. Specifically, the EHR shows that the public health immunization registry provided information about Juana's first dose of Hepatitis B vaccine, which was administered in the hospital on the day after her birth. The EHR also shows the registry provided information that Juana received an MMR vaccine at age 15 months from a public health clinic. In addition, the EHR shows that a parent provided a report from the local pharmacy that Juana received a live, attenuated influenza vaccine on November 9, 2014. All other vaccines were administered at Dr. Smith's office. Dr. Smith can easily see the organization that administered each vaccine and the source of the information when viewing the patient's immunization history.

6.1.10 Guidance

The requirement addresses recording immunization history obtained from external sources or history provided by the patient or patient's caregiver. The available fields for capturing the information should be the same as those used to capture information received from the IIS referenced in section 6.4.2 requirement 2.3 with an entry in the field (RXA-9) indicating the source of the historical information (HL7 Version 2.5.1 Implementation Guide: Immunization Messaging (Release 1.5) 10/1/2014, page 48):

00 – New immunization record
01 – historical information – source unspecified
02 – historical information – from another provider
03 – historical information – from parent's written record
04 – historical information – from parent's recall
05 – historical information – from other registry
06 – historical information – from birth certificate
07 – historical information – from school record
08 – historical information – from public agency

The additional field indicates the source of the information (i.e., the registry, the patient, etc.).

6.1.10.1 Focus on Vendor Perspective

Products with the ability to identify the source of historical information may assist providers to perform reconciliation. Additional data (such as administered at location) may also allow providers to obtain additional information as needed for vaccine recalls.

6.1.10.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

6.1.11 Test

Refer to the test script scenario that includes the requirement Request/Receive Patient Immunization Data and Identify Source. The script also indicates successful performance for each of the test sections.

6.1.11.1 Data Elements

See Appendix A.

DEPRECATED Requirement 2.5 Store Immunization Registry Vaccine History and Forecast

This requirement has been deprecated as it is no longer recommended to store immunization registry vaccine history and forecast. This section is retained as a reference for historical references.

DEPRECATED Requirement 2.6 Notify Public Health Immunization Registry (IIS) of Differences between EHR Data and IIS Response

This requirement has been deprecated as it is no longer recommended notify public health immunization registry (IIS) of differences between EHR data and IIS response. This section is retained as a reference for historical references.

7 GENERAL DESCRIPTION OF USER WORKFLOW 3: MANAGE INFORMATION FOR CLINICAL DECISION-MAKING

Background

7.1.2 General Description of User Workflow 3: Manage Information for Clinical Decision-Making

General User Workflow 3: Manage Information for Clinical Decision-Making describes how EHRs use information to support clinical decision-making. The information begins when the provider receives a vaccine forecast from the public health immunization registry. The forecast lists the appropriate immunizations for a patient based on his or her known history and the most up-to-date immunization schedule. The forecast provides important information that helps providers make the appropriate decisions regarding which vaccines to administer and when. In addition, the provider must assess if the patient has any conditions or laboratory test findings that would alter the decision about which vaccine to provide. The forecast addresses vaccine-vaccine interactions,

but immunization registries do not have individual patient diagnoses or results that might impact which vaccine should be given and when.
Once the vaccine history in the EHR is reconciled with the history from the public health immunization registry, the forecast must be re-checked. The information may be processed directly by the EHR, a public health immunization registry, a third-party web service, or other clinical decision support (CDS) resource. The provider must use the information provided along with information known about the patient to make the final decision about what immunization to give the patient (if any) and enter any orders appropriate to that decision.

7.1.3 Who Performs User Workflow 3: Manage Information for Clinical Decision-Making

- Clinicians (physicians, nurses, and other personnel who assist with providing immunizations).
- Patients or caregivers who participate in the decision-making about which of several vaccine options to choose, and who may decline a vaccine once they are appropriately informed about the risks and benefits.
- Public health immunization registries that provide the patient's initial vaccine forecast and may also re-process the forecast with new information a provider submits from his or her EHR or other clinical software system.
- The EHR and registry software, and/or a third party CDS web service also participate in the process.

7.1.4 Examples of Work in This Area

- The Advisory Committee on Immunization Practices (ACIP), an Advisory Committee to the CDC Director, develops recommendations about how to use vaccines to control diseases in the United States.[22] CDC publishes the recommendations regularly as public health advice.[23] States also have advisory committees that may modify such recommendations or legal requirements that dictate specific timing of a vaccine.
- CDC also provides the Clinical Decision Support for Immunization (CDSi) logic specification as an authoritative, implementation-neutral foundation for technical and non-technical immunization-related CDS.[24] CDSi includes business rules logic, test cases, and supporting data to determine if the vaccine doses a patient received are appropriate (valid) when compared

to the ACIP recommended schedule. Based on the logic, a CDS engine can recommend the earliest, recommended, past due and latest dates for providing each vaccine as well as the appropriate intervals between individual vaccines. The CDS engine can also indicate if individual doses already given are not valid because they were administered inappropriately (e.g., too soon, patient too young, incorrect product, etc.) per ACIP recommendations. A CDS engine that incorporates CDSi content requires a mechanism to capture patient information and send results to a clinician for review and reconciliation with all known patient information.

- Some EHR vendors indicate they have started to evaluate use of CDSi content within CDS engines in their software. Most vendors express a preference for an external service to provide such decision support for their products.

Requirement 3.1 View Immunization Forecast

The EHR or other clinical software system provides a view of the immunization forecast provided by the IIS. The display includes the recommended vaccines and their associated dates (e.g., earliest, recommended, past due, latest) for each vaccine included in the forecast.

7.1.5 Example of Scenario "View Immunization Forecast"

Juan Marcel Marina, age 3 (birth date 12/24/2015), comes to the provider's office for a scheduled appointment. The doctor's office receives a forecast from the public health immunization registry indicating that the fourth dose of DTaP vaccine is overdue as of 06/25/2016 and the second dose of Hepatitis A vaccine is recommended to be administered 03/24/2017.

7.1.6 Guidance

Feedback from EHR vendors and providers suggest that the value of the history from the immunization registry is to update patients' vaccination records in the EHR. During the reconciliation process, the provider determines which information to accept or which to reject as a duplicate. The value of displaying the initial forecast received from the registry is unclear since reconciliation of the vaccine history may cause an update to the forecast. The initial forecast may have value in cases of persistent conflict between IIS and EHR data about

individual vaccine doses; the information may help providers avoid the need to re-reconcile the same information each time. Further feedback is invited about the value of this requirement, noting the following principles:

1. The post-reconciliation forecast should be displayed to drive immunization administration decisions.
2. The CDS provided to the clinician should indicate if a dose given prior to the earliest recommended date is valid for completion of the recommended immunization schedule. For example, a provider may consider an early dose of a vaccine as appropriate for the patient due to known exposure to a viral agent. The subsequent forecast reference to that vaccine should be based on ACIP recommendations to help determine if the dose should be considered part of the immunization series.

7.1.6.1 Focus on Vendor Perspective

Vendors should collaborate with public health immunization registries and providers in the HIMSS IIP to harmonize requirements and determine workflow.

7.1.6.2 Focus on Provider and Implementer Perspective

Providers should collaborate with public health immunization registries and EHR vendors in the HIMSS IIP to harmonize requirements and determine workflow. Consider the scenario in which a provider receives a message from an IIS that a patient has received the new Varicella vaccine with an NDC and CVX codes but the EHR codes have not been updated. The EHR needs to understand how to handle these new valid codes.

7.1.7 Test

Refer to the test script scenario that includes query, response, and reconciliation. The script also indicates successful performance for each of the test sections.

Feedback from some members of the IIS community suggests that some providers are sending incorrect vaccine codes (CVX), manufacturer codes (MVX) and NDC codes because they are not aware of updates to the code systems (CVX, MVX, NDC). Some EHR vendors have similarly indicated that some IIS do not recognize updated codes when they receive them. CDC should make

new codes available when they are needed (CVX, VIS, MVX, NDC, etc.). The AIRA testing program now includes testing for current codes on a monthly basis as of July 2018.

The HIMSS IIP test plan now requires a vendor to demonstrate or minimally document that they are configured to use the latest release of CVX, MVX and NDC code systems. The IIP TAP also suggests that the AIRA testing program include a similar requirement.

7.1.7.1 Data Elements

Data elements required include:

- Vaccine (CVX and NDC codes);
- Immunization schedule used;
- Earliest date to administer;
- Recommended date vaccine due;
- Past due date;
- Latest date next dose may be administered; and,
- Dose number in a series.

Requirement 3.2 View Reconciled Immunization Forecast

The EHR or other clinical software system has the ability to re-evaluate and update the immunization forecast using a patient's newly updated immunization history. Forecasts are updated following reconciliation of immunization data contained in the public health immunization registry with immunization data contained in the EHR. Processing the new forecast can be internal to the EHR or it can use an external forecasting service, but should reference the most recent recommendations.

7.1.8 Example of Scenario "View Reconciled Immunization Forecast"

The EHR record for Juana Maria Gonzales, age 6, includes an inactivated polio vaccine that was administered in Dr. Smith's office 3 months prior to the date of Juana's office visit. Due to an EHR system upgrade, the polio vaccine was not reported to the public health registry history. Therefore, the original forecast received from the registry had recommended a fourth dose of inactivated polio vaccine. The EHR system sends the updated vaccine history to a third-party

forecaster and receives a new forecast that does not include the recommendation for a fourth dose of inactivated polio vaccine, as it was already given.

7.1.9 Guidance

AIRA defines immunization forecasting as:

> …the result of the process of applying rules to determine dates for the next vaccine dose(s) to be administered to a Patient. Vaccination Forecast may also include a reason why the next dose in a series is or is not recommended and recommended Trade Name for the next vaccine in a series.[25]

Discussion about immunization forecasting includes two areas of concern. The first is addressing the accuracy of forecasting logic, i.e., that the recommendation is correct. The second is the provider's view of the forecast presentation.

7.1.9.1 Immunization Forecasting Logic

The logic used to develop a vaccine forecast originates with recommendations about how to use vaccines to control diseases in the United States from ACIP.[26] CDC publishes the recommendations regularly as public health advice.[27] CDC also provides the CDSi logic specification as an authoritative, implementation-neutral foundation for technical and non-technical immunization-related CDS.[28] CDSi includes business rules logic, test cases, supportive data, workflow descriptions, and describes methods to determine if the vaccine doses a patient received are appropriate (valid) when compared to the ACIP recommended schedule. Based on the logic, a CDS engine can recommend the earliest and latest acceptable dates for providing each vaccine as well as the appropriate intervals between individual vaccines. The CDS engine can also indicate if individual doses already given are not valid because they were given ahead of the prescribed vaccination schedule. A CDS engine that incorporates CDSi content requires a mechanism to capture patient information and send results to a clinician for review and reconciliation with all known patient information. Note: The ACIP immunization schedule is not universally implemented in every jurisdiction. States may have their own advisory committees that review ACIP

recommendations and make alterations based on state law, local practice or norms. States may have their own advisory committees that review ACIP recommendations and make alterations based on state law, local practice or norms. In addition, state mandated vaccines for schools may not include all ACIP recommended vaccines for children and adolescents.
Some EHR vendors indicate they have started to evaluate use of CDSi content within CDS engines in their software. Many vendors express a preference for an external service to provide such decision support for their products. The requirement is purposely not prescriptive about how the software should process the forecasting logic. The post-reconciliation forecast may be processed by logic provided by the vendor, by accessing an external web service, or by requesting a new forecast from the registry after the EHR sends an immunization history update to the registry. Refer to Section 5.9 (requirement 2.6) for discussion about historical updates submitted to registries.

7.1.9.2 Immunization Forecast Presentation

This requirement (3.2) addresses display of an immunization forecast after reconciliation of the EHR data with updated historical information from the registry or from other sources, including the patient. The intent of the forecast is to help providers make real-time decisions. Display of both the pre- and post-reconciliation forecasts may cause confusion and affect system usability. Since usability issues can inhibit the system's effectiveness vendors should consider forecasting an important area to address using a User Centered Design (UCD) process.

7.1.9.3 Focus on Vendor Perspective

Accurate and timely vaccine recommendations are essential to address efficient, effective, and safe use of clinical software. Usability is integral to encourage appropriate interpretation and use of the information provided.

7.1.9.4 Focus on Provider and Implementer Perspective

The logic used for immunization forecasting is complex. Users should expect their software to provide or access the most recent vaccine recommendations and provide feedback to software vendors regarding questions about forecasting logic and the presentation.

7.1.10 Test

Refer to the test script scenario that includes the requirement View Reconciled Immunization Forecast. The script also indicates successful performance for each of the test sections. The data included in the test is limited to vaccine due and timing, i.e., it addresses vaccines given too early or those that are administered late and thus require recalculation of the next dose in a series. Further work should address administration of specific antigens in proximity to others (e.g., acceptable interval between live virus and inactivated vaccines).

7.1.10.1 Data Elements

There is no specific standard set of data elements to evaluate immunization forecast presentation.

DEPRECATED Requirement 3.3 Modify Antigen Recommendations Based on Allergy History

This requirement has been deprecated as it is no longer recommended to modify antigen recommendations based on allergy history. This section is retained as a reference for historical references.

Requirement 3.4 Modify Antigen Recommendations Based on Active Diagnoses

The EHR or other clinical software system notifies the provider of any conflicts between recommended vaccines in the updated forecast and the patient's current or historical diagnoses.

7.1.11 Example of Scenario "Modify Antigen Recommendations Based on Active Diagnoses"

Juan Marcel Marina, age 3 comes to the provider's office for a scheduled appointment. The forecast received from the health department registry indicates that Juan has never received MMR or Varicella vaccine. The provider's EHR CDS engine might suggest MMRV vaccine, but it finds a diagnosis of Varicella at age 18 months. Therefore, the EHR immunization forecast recommends MMR vaccine rather than MMRV.

7.1.12 Guidance

All products reviewed allow entry of diagnoses or conditions on the patient's problem list. Less clear is the ability to ensure a user is aware of a potential condition-related indication or contraindication. Section 7.4 (requirement 3.3.) describes methods for feedback to users about potential patient risks related to allergies.
Notification in this context indicates that the system provides indication, so the user is aware of a potential problem. Notification should include information, if available, about prior decisions, e.g., if a provider documented a reason to override notification about allergy or diagnosis in the past. The method for fulfilling the requirement is not prescriptive. Examples of notification include visual clues.

The method for sharing information about evidence of prior immunity with the IIS and with other providers represents another factor to consider in managing CDS as well as aligned with reporting requirements. The ONC Interoperability Standards Advisory, suggests that all vendors should be able to support CVX codes and NDC numbers for immunizations, SNOMED CT for laboratory tests and SNOMED CT or numerical values for test results. Specific to immunization-related clinical workflow, there are several reasons for using standard terminology:

1. Assure that the immunization is properly identified to enable tracking, alignment with inventory and to support future immunization forecasting using local, external or IIS forecasting engines.
2. Assure that conditions identified as evidence of immunity are properly coded to allow appropriate forecasting decisions.
3. Assure that laboratory evidence of serologic immunity is adequately coded to allow appropriate forecasting decisions.
4. Assure that allergies and prior adverse reactions are coded in a manner that allows CDS checks that inform future immunization decisions.

Prior iterations of this Capabilities and Guidance document focused primarily on the first issue, coding of vaccine products (section 9.9.2). However, the requirement to use standard codes also impacts the use of terminology to address conditions, laboratory tests and allergies or adverse reactions. This

section discusses clinical conditions and laboratory test coding. Refer to section 11.2.2 for a discussion about allergy and adverse event coding.
Note: There are three possible scenarios for which the EHR might recommend a change in vaccine antigen based on disease history:

1. The patient has a clinical condition where a usually recommended vaccine should not be given at all; for example, a severely immunocompromised person should not be given a live-virus vaccine like MMR.
2. The patient has a clinical condition where a usually recommended vaccine is 'replaced' with an alternative; the MMR vaccine is suggested instead of MMRV due to prior history of varicella disease.
3. The patient has a clinical condition where a usually recommended vaccine is given on a different (i.e., earlier) schedule; for example, patients who need to receive Pneumovax earlier than usual because of Sickle Cell Disease or other chronic conditions: https://www.cdc.gov/pneumococcal/about/risk-transmission.html

7.1.12.1 Clinical Disease as Evidence of Immunity

The current HL7 2.51 Implementation Guide for Immunization Messaging Release 1.5 provides a value set of SNOMED CT concepts for use to indicate history of disease as evidence of immunity (Exhibit 8).

History of Disease as Evidence of Immunity[29]	
SNOMED CT Concept	**Description**
398102009	Acute poliomyelitis (disorder)
409498004	Anthrax (disorder)
397428000	Diphtheria (disorder)
18624000	Disease due to Rotavirus (disorder)
91428005	Haemophilus influenzae infection (disorder)
240532009	Human papilloma virus infection (disorder)

History of Disease as Evidence of Immunity[29]	
SNOMED CT Concept	**Description**
6142004	Influenza (disorder)
52947006	Japanese encephalitis virus disease (disorder)
14189004	Measles (disorder)
23511006	Meningococcal infectious disease (disorder)
36989005	Mumps (disorder)
27836007	Pertussis (disorder)
16814004	Pneumococcal infectious disease (disorder)
14168008	Rabies (disorder)
36653000	Rubella (disorder)
76902006	Tetanus (disorder)
66071002	Type B viral hepatitis (disorder)
4834000	Typhoid fever (disorder)
111852003	Vaccinia (disorder)
38907003	Varicella (disorder)
40468003	Viral hepatitis, type A (disorder)
16541001	Yellow fever (disorder)
398102009	Acute poliomyelitis (disorder)

Exhibit 8. History of Disease as Evidence of Immunity

Value sets have several purposes. For the context of this immunization-related software capabilities and guidance, two such purposes should be considered:

1. Convenience, or Subset: A compilation of concepts that contain all possible terms that might be used to encode the majority concepts captured in clinical documentation for a specific purpose, for example

a set of values that encompass 80% of all clinical problems for problem lists.

2. Value Sets: Concepts used to define the limited set of allowable concepts to meet the definition of a data element for data entry and/or clinical software data retrieval for electronic clinical quality measures (eCQMs) and CDS artifacts within the clinical workflow.

Some of the value sets described in the HL7 Version 2.5.1 Implementation Guide v1.5 meet the second definition, as examples, the limited set of options to specify the site of immunization administration, or the route of administration. Other value sets meet the first definition, all possible choices that might be included in submitting information to a public health immunization registry. The PHVS HistoryOfDiseaseAsEvidenceOfImmunity is an example of such a convenience value set. It includes a single code for each condition that might be submitted to a public health registry such that individual jurisdictions can use the terms appropriate for their specific use cases. However, some of the concepts in the referenced value sets are inconsistent with existing clinical guidelines for clinically diagnosed conditions that substitute for the need to vaccinate. Some examples of such conditions in the existing value set include:

- Human Papilloma Virus infection (due to multiple serotypes)
- Meningococcal disease (due to multiple serotypes)
- Pneumococcal disease (due to multiple serotypes)
- Rubella (since there are similar presentations that might be confused with Rubella)

Note that these examples do not represent an exhaustive list of conditions in the value set that would still require administration of a vaccine.
To implement the guidelines correctly, the CDS rules need to use a comprehensive and limited set of appropriate values to address only those conditions that represent exclusions from the requirement to administer a vaccine. A convenience value set as referenced in the HL7 Version 2.5.1 Implementation Guide Release 1.5 (Exhibit 8) requires CDS providers to make decisions about which concepts from the convenience value set are appropriate for the CDS logic (i.e., vendors developing forecasting software whether web-based, standalone or incorporated directly into the EHR). This

process can lead to variation in CDS output and impact clinical decision-making. Therefore, a more effective approach is to reference a focused, standardized value set maintained regularly as required by clinical evidence. Also note that the PHVS_HistoryOfDiseaseAsEvidenceOfImmunity value set (Exhibit 8) references a single SNOMED CT concept for each of 23 vaccine-preventable diseases. Clinicians have other options for documenting conditions in clinical records using SNOMED CT. Exhibit 9 shows eight such SNOMED CT concepts that reference one of these 23 diseases, Hepatitis A. A clinician may enter the concept in Exhibit 9 that best fits a patient's presentation with Hepatitis A disease. Since the Implementation Guide limits the acceptable concepts to one per disease, the clinician must re-select the concept required by the IIS to reference evidence of clinical disease or the clinical software must map the codes to assure successful transmission of acceptable information to the IIS. The same is true for each of the other 22 diseases referenced by the HL7 Version 2.5.1 Implementation Guide Release 1.5.

SNOMED CT Concepts for Hepatitis A Disease (Disorder) [Code System Search - National Library of Medicine Value Set Authority Center)[30]		
SNOMED CT Concept	**Description**	Type
111879004	Viral hepatitis A without hepatic coma	Disorder
18917003	Acute fulminating type A viral hepatitis	Disorder
206373002	Congenital hepatitis A infection	Disorder
25102003	Acute type A viral hepatitis	Disorder
310875001	Hepatitis A - current infection	Disorder
40468003	Viral hepatitis, type A	Disorder
43634002	Relapsing type A viral hepatitis	Disorder
79031007	Anicteric type A viral hepatitis	Disorder

Exhibit 9. SNOMED CT Concepts for Hepatitis A Disease

Thus, if the EHR meets a standard requirement for use of terminology, the HL7 Version 2.5.1 Implementation Guide Release 1.5 reporting requirements necessitate a workflow mapping step and decisions about such mapping are

made at the local level. EHR vendors now have experience using similar value sets when implementing CMS eCQMs rather than a single code for required data unless only one code exists to represent the required concept. The difference in clinical documentation and public health reporting requirements could be simplified if the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging referenced a value set of concepts rather than a single code for each allowable condition. Using a value set instead of a single code remains agnostic with respect to how the sending system captures data. However, the value set provides greater assurance that mapping will not exclude codes that should be mapped and will not inadvertently map codes that are not relevant.

7.1.12.2 Serologic Evidence of Immunity

The HL7 Version 2.5.1 Implementation Guide Release 1.5 references a set of six codes used to report evidence of serology immunity (i.e., laboratory evidence of immunity). Exhibit 10 lists these six SNOMED CT concepts.

Serologic Evidence of Immunity[31]	
SNOMED CT Concept	**Description**
278971009	Hepatitis A immune (finding)
271511000	Hepatitis B immune (finding)
371111005	Measles immune (finding)
371112003	Mumps immune (finding)
278968001	Rubella immune (finding)
371113008	Varicella immune (finding)

Exhibit 10. Serologic Evidence of Immunity (IIS)

The existing value set for serologic immunity includes a SNOMED CT clinical *finding* which requires an interpretation of a laboratory test result that provides evidence of past infection. Clinicians generally determine such immunity by ordering laboratory tests and reviewing the results. Exhibit 11 references 27 laboratory tests or laboratory panels for which positive results provide evidence of immunity to Hepatitis A, one of the six conditions referenced in the value set listed in Exhibit 10. The codes in Exhibit 11 are from LOINC®, the terminology

commonly used in interoperability standards to reference laboratory tests. To successfully report serologic immunity in the message to the IIS, the clinician must review and interpret the results of one of the tests noted in Exhibit 11 and enter a finding indicating the present of immunity, or the software must be programmed to map results to the code required by the IIS.

Laboratory Tests for Hepatitis A[32]			
LOINC Code	Description	LOINC Code	Description
13950-1	Hepatitis A virus IgM Ab [Presence] in Serum or Plasma by Immunoassay	5183-9	Hepatitis A virus Ab [Units/volume] in Serum or Plasma by Immunoassay
13951-9	Hepatitis A virus Ab [Presence] in Serum by Immunoassay	5184-7	Hepatitis A virus Ab [Units/volume] in Serum by Radioimmunoassay (RIA)
20575-7	Hepatitis A virus Ab [Presence] in Serum	53775-3	Hepatitis A virus Ab panel - Serum
22312-3	Hepatitis A virus Ab [Units/volume] in Serum	53776-1	Hepatitis A virus IgM and total [Interpretation] in Serum
22313-1	Hepatitis A virus IgG Ab [Units/volume] in Serum	78444-7	Hepatitis A virus IgG+IgM Ab [Units/volume] in Serum or Plasma by Immunoassay
22314-9	Hepatitis A virus IgM Ab [Presence] in Serum	7904-6	Hepatitis A virus RNA [Presence] in Serum by Probe and target amplification method
22315-6	Hepatitis A virus IgM Ab [Units/volume] in Serum	LP38316-3	Hepatitis A virus Ab
40724-7	Hepatitis A virus IgG Ab [Presence] in Serum by Immunoassay	LP38317-1	Hepatitis A virus Ab.IgG
42191-7	Hepatitis A and B and C 7a panel – Serum	LP38318-9	Hepatitis A virus Ab.IgM
51660-9	Hepatitis A virus IgM Ab [Presence] in Body fluid	LP38319-7	Hepatitis A virus RNA
51661-7	Hepatitis A virus Ab [Presence] in Body fluid	LP66852-2	Hepatitis A virus | Bld-Ser-Plas
5179-7	Hepatitis A virus IgG Ab [Units/volume] in Serum by Immunoassay	LP71324-5	Hepatitis A virus Ab panel

Laboratory Tests for Hepatitis A[32]			
5180-5	Hepatitis A virus IgG Ab [Units/volume] in Serum by Radioimmunoassay (RIA)	LP71325-2	Hepatitis A virus Ab.IgM & total
5181-3	Hepatitis A virus IgM Ab [Units/volume] in Serum by Immunoassay		

Exhibit 11. LOINC® Codes for Laboratory Tests for Hepatitis A

The difference in clinical workflow and documentation and public health reporting requirements could be simplified if the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging referenced a value set of appropriate serologic studies and acceptable results for each allowable condition. With such information, EHR vendors or local implementers can map the results of appropriate tests to the required SNOMED CT finding or submit the laboratory test results directly without requiring interpretation. The result would limit concerns about interpretation and also enable more effective and re-usable and sharable CDS artifacts for EHR implementation.

7.1.12.3 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system handles notifications and alerts.

7.1.12.4 Focus on Provider and Implementer Perspective

Notifications and alerts can be a significant usability issue in EHRs. Providers should consider participating in vendor activities to address timely and appropriate notification.

7.1.13 Test

Attachment B provides a test script scenario that includes the requirement Modify Antigen Recommendations Based on Active Diagnosis. The script also indicates successful performance for each of the test sections. The notification must be visible directly on the ordering and the documentation screens specific to the vaccine ordered or documented. Note that notification based on the patient's condition may require more advanced functionality.

7.1.13.1 Data Elements

The data elements include the condition specific to the clinical scenario in the test script.

Requirement 3.5 Update Patient Immunization Schedule

The EHR or other clinical software system displays a patient's anticipated immunization schedule routinely and updates the patient's schedule when immunization guidelines change.

7.1.14 Example of Scenario "Update Patient Immunization Schedule"

If hypothetically, ACIP adds a third dose of MMR vaccine at age 15, the EHR or other clinical software system provides a mechanism to compare the patient's vaccine history with the most current immunization schedule and includes the new dose in patients' vaccine schedules.

7.1.15 Guidance

This requirement addresses the ability of the forecasting logic to remain current. Hypothetically, if AHIP were to add a recommendation to add an additional dose of a vaccine antigen to an existing series, the system should provide a mechanism to evaluate each patient's vaccine history with the most current vaccine schedule so the EHR can include the newly required dose in the schedule displayed to the user. Section 7.3.2.1 presents information about vaccine forecasting logic. This requirement adds the dimension of timeliness for incorporating updates to the logic. Many variables affect the timeliness of updates. Exhibit 12 describes general principles to address effective CDS include the "Ten Commandments of Effective Clinical Decision Support."[33]

Ten Commandments of Effective Clinical Decision Support[50]
1. Speed is Everything.
2. Anticipate Needs and Deliver in Real Time.
3. Fit into the User's Workflow.
4. Little Things Can Make a Big Difference.
5. Recognize that Physicians will Strongly Resist Stopping.

6.	Changing Direction is Easier than Stopping.
7.	Simple Interventions Work Best.
8.	Ask for Additional Information Only When You Really Need It.
9.	Monitor Impact, Get Feedback, and Response.
10.	Manage and Maintain Your Knowledge-based Systems.

Exhibit 12. Ten Commandments of Effective Clinical Decision Support

7.1.15.1 Focus on Vendor Perspective

Vendors should have governance principles and processes to manage currency of clinical knowledge in general, and specifically for immunization-related activities.

7.1.15.2 Focus on Provider and Implementer Perspective

Providers should understand vendor processes and timeliness for keeping clinical knowledge current, and specifically address immunization-related content.

7.1.16 Test

Refer to the test script scenario that includes the requirement Update Patient Immunization Schedule. The script also indicates successful performance for each of the test sections.

7.1.16.1 Data Elements

Not applicable.

Requirement 3.6 Receive Dose Not Indicated Alert for Single Vaccine Order

The EHR or other clinical software system notifies the provider in instances when there is single or combination vaccine orders that are inconsistent with the expected timing intervals included in the vaccine forecast. Inconsistencies include suggestion of different date(s) for ordering the vaccine(s) or indication the vaccine(s) is/are no longer required.

7.1.17 Example of Scenario "Receive Dose Not Indicated Alert for Single Vaccine Order"

The minimum valid date (earliest date) for the fourth dose of pneumococcal conjugate (PCV13) vaccine is at 12 months. The provider orders a dose of PCV13 for a 7-month-old patient who has received three prior doses. The EHR or other clinical software system notifies the provider that the dose is not indicated and should be delayed by five months.

7.1.18 Guidance

This requirement addresses the EHR's ability to make the provider aware that a vaccine being ordered is not yet due. EHRs have various methods for encouraging the provider to take the expected path, i.e., only order or document administration vaccines currently due. One method is to organize the workflow directly from the vaccine schedule screen. However, providers may still attempt to order or document vaccine through other screen flows. The decision support logic is presented in Section 5.11.1.1. Section 5.12.1 (requirement 3.3) describes methods for feedback to users about potential patient risks. These methods apply to vaccines not yet due as well as known allergies, adverse reactions or specific clinical conditions.
Notification in this context indicates that the system provides indication, so the user is aware the vaccine timing is inconsistent with the decision support logic. Examples of notification include visual clues. Notification should allow the provider to proceed to order or document clinically relevant vaccines even if the timing may not be considered valid according to the routine vaccination schedule. Such clinically relevant vaccines might include urgent public health recommendations due to disease outbreaks.

7.1.18.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system handles notifications and alerts.

7.1.18.2 Focus on Provider and Implementer Perspective

Notifications and alerts can be a significant usability issue in EHRs. Providers should consider participating in vendor activities to address timely and appropriate notification.

7.1.19 Test

Refer to the test script scenario that includes the requirement Receive Dose Not Indicated Alert for Single Vaccine Order. The script also indicates successful performance for each of the test sections. The data included in the test is limited to timing, i.e., it addresses vaccines given too early.

7.1.19.1 Data Elements

The data elements include the vaccines specific to the clinical scenario in the test script.

Requirement 3.7 Receive Dose Not Indicated Alert upon Vaccine Administration

The EHR or other clinical software system notifies the individual administering a vaccine that the vaccine is inconsistent with expected timing intervals as suggested by the vaccine forecast. The method and timing of notification can be specified to meet local clinical workflow. This requirement is a "failsafe" mechanism in case the provider orders a vaccine dose that is inconsistent with appropriate timing intervals.

7.1.20 Example of Scenario "Receive Dose Not Indicated Alert upon Vaccine Administration"

The minimum valid date (earliest date) for the fourth dose of DTaP vaccine is at 15 months. However, a provider ignores the EHR system-issued alert and orders a dose of DTaP for a 13-month-old patient who has received three prior doses. In this case, the EHR notifies the person administering the vaccine that the dose is not indicated and should be delayed by two months.

7.1.21 Guidance

This requirement addresses the EHR's ability to make the provider aware that a vaccine about to be administered is not yet due. EHRs have various methods for encouraging the provider to take the expected path, i.e., only order or document administration vaccines currently due. One method is to organize the workflow directly from the vaccine schedule screen. However, providers may still attempt to order or document vaccine through other screen flows. The decision support logic is presented in Section 5.11.1.1. Section 5.12.1 (requirement 3.3)

describes methods for feedback to users about potential patient risks. These methods apply to vaccines not yet due as well as known allergies, adverse reactions or specific clinical conditions. Note that the earliest date provided with a forecast is a "forecasting concept." A CDS engine may accept an immunization given earlier as valid based on the "evaluation concept." For example, the earliest date for when Measles vaccine may return in a forecast as 15 months of age, but a vaccine given as of the first birthday (i.e., 12 months) may return as a valid vaccine based on the "evaluation concept" in the CDS engine. Thus, the EHR may only use "forecasting concepts" to provide recommendations to clinicians.

Notification in this context indicates that the system provides indication, so the user is aware the vaccine timing is inconsistent with the decision support logic. Examples of notification include visual clues. Notification should allow the provider to proceed to order or document clinically relevant vaccines even if the timing may not be considered valid according to the routine vaccination schedule. Such clinically relevant vaccines might include urgent public health recommendations due to disease outbreaks.

7.1.21.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system handles notifications and alerts.

7.1.21.2 Focus on Provider and Implementer Perspective

Notifications and alerts can be a significant usability issue in EHRs. Providers should consider participating in vendor activities to address timely and appropriate notification.

7.1.22 Test

Refer to the test script scenario that includes the requirement Receive Dose Not Indicated Alert Upon Vaccine Administration. The script also indicates successful performance for each of the test sections. The data included in the test is limited to timing, i.e., it addresses vaccines given too early.

7.1.22.1 Data Elements

Not tested.

DEPRECATED Requirement 3.8 Save History of Clinical Decision Support Recommendations

This requirement has been deprecated as it is no longer recommended to save history of clinical decision support recommendations. This section is retained as a reference for historical references.

8 GENERAL DESCRIPTION OF USER WORKFLOW 4: MANAGE INVENTORY

Background

8.1.2 General Description of User Workflow 4: Manage Inventory

General User Workflow 4: Manage Inventory describes how EHRs, and other clinical software systems use available information to assist with managing the immunization inventory available in the provider's setting.
Patients eligible for special guarantee programs, such as VFC, should receive the doses provided by the program. Those patients not eligible for VFC or similar programs should receive private vaccine stock. This user workflow enables the provider to determine patient eligibility for special guarantee programs and whether the patient's vaccine dose is eligible for the program. The goals of this process are to: 1) identify the appropriate vaccine stock to provide to the patient, based on the patient's eligibility for guarantee programs, and 2) document when vaccine doses from one program are borrowed and assure that stock is replenished.

8.1.3 Who Performs User Workflow 4: Manage Inventory

- Clinicians (physicians, nurses and other personnel who assist with providing immunizations)

8.1.4 Examples of Work in This Area

- Most providers interviewed for this project stated that specific personnel in their offices manage their vaccine inventory using paper logs or electronic spreadsheets. In most practices, an individual staff member then enters the inventory into the practice's EHRs manually, including the vaccine lot number and expiration date. Once this information is entered into the EHR or other

clinical software system, most systems offer drop-down lists that staff members can use to order vaccines and document the vaccine administered more quickly.

- AIRA has established requirements for inventory management.[34] Some public health registries provide inventory management software that helps providers manage guarantee program inventory, as well as private stock. Participating providers enter and manage this information manually in the public health registry software. As vaccine doses for the guarantee programs are used and reported to the registry, the software updates the amount of available stock. The provider can also order more vaccine from CDC's Vaccine Tracking System (VTrckS) for the guarantee program. Ordering to replenish private stock is the responsibility of the provider.
- Some hospital software vendors produce inventory applications that allow customers to order all materials the office needs, including examination gloves, syringes, alcohol wipes, medications, and vaccinations. These inventory software products use an existing American National Standards Institute (ANSI) standard, Advanced Ship Notification (EDI 85635), to transmit data from the warehouse to the inventory software. However, there is no known connection of such applications to clinical software used to order and administer vaccines.

Requirement 4.1 Display Available Vaccine Antigens

The EHR or other clinical software system presents a list of vaccine antigens available for administration to patients (i.e., private stock vs. specific guarantee program).

8.1.5 Example of Scenario "Display Available Vaccine Antigens"

Through the EHR or other clinical software system, Dr. Smith is able to access a list of vaccine products that are available to order and administer to an individual patient. The list displays which products are restricted to specific guarantee programs, such as VFC, and which products are from local/private stock.

8.1.6 Guidance

The intent of this requirement is to allow providers to order or document vaccines administered by selecting vaccines from the appropriate inventory.

The inventory chosen (i.e., government guarantee program such as VFC or private stock) should be consistent with the patient's eligibility for the related guarantee program.

Most providers interviewed for this project stated that specific personnel in their offices manage their vaccine inventory using paper logs or electronic spreadsheets. In most practices, an individual staff member then enters the inventory into the practice's EHR manually, including the vaccine lot number and expiration date. Some, but not all software provides fields that providers can use to document the source of the vaccine products (e.g., VFC or private), list the number of available doses, and decrement that number each time a clinician documents administering a dose from the respective vaccine lot. Some products allow use of barcode technology to load vaccine stock into the EHR instead of manual entry. Other products allow use of barcode readers to document administration of vaccine doses instead of requiring manual entry. Most vendors indicate their customers differentiate private vaccine stock from that provided by guarantee programs such as VFC using mechanisms other than the EHR.

Some public health registries provide inventory management software that help providers manage guarantee program inventory, as well as private stock. Providers manually enter inventory information and orders and into these External Information Systems (ExIS), reporting all vaccine doses the guarantee programs that are used, wasted, expired and returned. The ExIS software updates the amount of available stock. The registry coordinates inventory data with VTrckS to place orders for additional stock and VFC vaccine is shipped to the provider.[36,37] Some registries allow providers to document their private vaccine inventory in the ExIS software as well, but the provider is responsible to order private stock through other mechanisms. AIRA published guidance for inventory management to support the ExIS systems.[38]

There is currently no interface between ExIS programs and EHRs providing inventory capabilities. Some hospital software vendors produce inventory applications that allow customers to order all materials the office needs, including examination gloves, syringes, alcohol wipes, medications, and

vaccinations. These inventory software products use an existing ANSI standard, Advanced Ship Notification (EDI 85639), to transmit data from the warehouse to the inventory software. However, there is no known connection of such applications to clinical software used to order and administer vaccines. Feedback from EHRs vendors and providers suggests that providers who only treat adults see limited value in EHR inventory capabilities. However, vaccine inventory capabilities generate greater interest to pediatricians and family physicians who manage a complex series of childhood immunizations as a core practice competency.

Collaboration among providers, EHR vendors and public health immunization registries through the HIMSS IIP will more clearly define the requirements and allow the workflow to be streamlined. Accountability in VFC programs is a critical issue. Inventory and order management have been the cornerstone of accountability efforts for over a decade.

Note: Feedback suggests that the term "vaccine dose-level eligibility" is confusing to clinicians; the public health community should consider modifying the concept to "vaccine program eligibility."

8.1.6.1 Focus on Vendor Perspective

A decision to provide inventory functionality depends on the product's intended market. Collaboration with public health registries and providers should help to further define requirements and develop capabilities needed to fulfill those requirements. Vendors should consider usability evaluation such as UCD to evaluate how the system manages inventory.

8.1.6.2 Focus on Provider and Implementer Perspective

Providers should understand vendor processes and timeliness for managing inventory. Participation in discussions with public health registries and software vendors should help to further define requirements that meet the needs of providers and public health.

8.1.7 Test

Refer to the test script scenario that includes the requirement Display Available Vaccine Antigens. The script also indicates successful performance for each of the test sections. The test requires the system display the Manufacturer, NDC, Product Name, Lot#, Expiration Date, GTIN Vaccine source (VFC or non-VFC), and Quantity.

8.1.7.1 Data Elements

Not applicable.

Requirement 4.2 Update Vaccine Inventory from Patient Dosage Administration

The EHR or other clinical software system updates the vaccine inventory to ensure the correct count of remaining available vaccine inventory.

8.1.8 Example of Scenario "Update Vaccine Inventory from Patient Dosage Administration"

The EHR or other clinical software system maintains the number of doses of inactivated polio vaccine (IPV) available from the VFC program at a specific site. The system then decreases that number when one of the IPV doses is administered to a patient. The updated list can be displayed to Dr. Smith, so that she can write orders for vaccines available for administration.

8.1.9 Guidance

Refer to the guidance discussion for Section 5.18 (requirement 4.2) for a general discussion of inventory functionality.

8.1.9.1 Focus on Vendor Perspective

Refer to the Focus on Vendor Perspective discussion for Section 5.18 (requirement 4.2).

8.1.9.2 Focus on Provider and Implementer Perspective

Refer to the provider perspective discussion for Section 5.18 (requirement 4.2).

8.1.10 Test

Refer to the test script scenario that includes the requirement Update Vaccine Inventory from Patient Dosage Administration. The script also indicates successful performance for each of the test sections. The test requires the system display the Manufacturer, NDC, Product Name, Lot#, Expiration Date, GTIN Vaccine source (VFC or non-VFC), and Quantity. The test script includes the ability to scan the inventory data using a 2-D Data Matrix.

8.1.10.1 Data Elements

Not applicable

Requirement 4.3 Update Vaccine Inventory from Stock Receipt

The EHR or other clinical software system updates the vaccine inventory when new stock is received at the site and updates the correct count of each vaccine, including those for use in guarantee programs (such as Vaccines for Children) and for private stock.

8.1.11 Example of Scenario "Update Vaccine Inventory from Stock Receipt"

The nurse manager uses a barcode reader to enter new IPV vaccine stock when it is received. Once she reads in all of the barcodes, the system updates the count of available IPV doses. The update includes information about the program for which the lot is to be used (for example, guarantee program such as VFC or patients who are not part of such programs).

8.1.12 Guidance

Refer to the guidance discussion for Section 5.18 (requirement 4.2) for a general discussion of inventory functionality.

8.1.12.1 Focus on Vendor Perspective

Refer to the Focus on Vendor Perspective discussion for Section 5.18 (requirement 4.2).

8.1.12.2 Focus on Provider and Implementer Perspective

Refer to the provider perspective discussion for Section 5.18 (requirement 4.2).

8.1.13 Test

Refer to the test script scenario that includes the requirement Update Vaccine Inventory from Stock Receipt. The script also indicates successful performance for each of the test sections. The test requires the system display the Manufacturer, NDC, Product Name, Lot#, Expiration Date, GTIN Vaccine source (VFC or non-VFC), and Quantity. The test script includes the ability to scan the inventory data using the 2-D Data Matrix.

8.1.13.1 Data Elements

Not applicable.

Requirement 4.4 Notify of Vaccine Dose Expiration

The EHR or other clinical software system notifies the provider administering a vaccine if the dose chosen for administration is expired.

8.1.14 Example of Scenario "Notify of Vaccine Dose Expiration"

The EHR alerts the RN entering the dT vaccine about to be administered to an adult patient if the expiration date of the planned dose has passed (i.e., the dose is expired).

8.1.15 Guidance

Those products that include an inventory function generally allow clinicians to choose only non-expired vaccine lots when ordering immunizations or documenting administration. Some products that do not provide inventory function also provide an indication in the user interface if a clinician documents an expiration date that is in the past.
Notification in this context indicates that the system provides indication, so the user is aware of a potential problem. The system should allow the user to proceed as a clinician must be able to document an expired dose inadvertently administered. The method for fulfilling the requirement is not prescriptive. Examples of notification include visual clues.

8.1.15.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system handles notifications and alerts.

8.1.15.2 Focus on Provider and Implementer Perspective

Notifications and alerts can be a significant usability issue in EHRs. Providers should consider participating in vendor activities to address timely and appropriate notification.

8.1.16 Test

Refer to the test script scenario that includes the requirement Notify of Vaccine Dose Expiration. The script also indicates successful performance for each of the test sections. The notification must be visible directly on the ordering and the documentation screens specific to the vaccine ordered or documented. Note: The test assures the provider is aware the dose has expired. It does not test that the EHR allows entry of a historical vaccine inadvertently administered after it expired.

8.1.16.1 Data Elements

The data elements include the vaccine dose and expiration date specific to the clinical scenario in the test script.

Requirement 4.5 Produce Vaccine History Report

The EHR or other clinical software system generates inventory reports of remaining stock. The reports can be sorted by expiration date and source (e.g., private or guarantee program).

8.1.17 Example of Scenario "Produce Vaccine History Report"

The nurse manager views a report of all existing vaccine stock. She is able to quickly identify that the available MMR vaccine for private (non-VFC) patients will expire in two weeks. The report also indicates that private Varicella vaccine is nearly out of stock.

8.1.18 Guidance

Refer to the guidance discussion for Section 5.18 (requirement 4.2) for a general discussion of inventory functionality.

8.1.18.1 Focus on Vendor Perspective

Refer to the Focus on Vendor Perspective discussion for Section 5.18 (requirement 4.2).

8.1.18.2 Focus on Provider and Implementer Perspective

Refer to the provider perspective discussion for Section 5.18 (requirement 4.2).

8.1.19 Test

Refer to the test script scenario that includes the requirement Produce Vaccine History Report, which is within the test steps 'Produce Stock Inventory Report - Expiration Date Sort' and 'Produce Stock Inventory Report - Funding Source Sort.' The script also indicates successful performance for each of the test sections.

8.1.19.1 Data Elements

Not applicable.

9 GENERAL DESCRIPTION OF USER WORKFLOW 5: ADMINISTER AND REPORT IMMUNIZATION

Background

9.1.2 General Description of User Workflow 5: Administer and Report Immunization

General User Workflow 5: Administer and Report Immunization describes how EHRs, and other clinical software systems can use information to assist with administering and reporting immunizations given to patients in the provider setting. This includes: (1) providing patient education to help the patient understand the immunization about to be administered, (2) documenting reasons why a recommended immunization is not given (e.g., patient refusal, fever on the day of the visit, etc.), (3) administration of the vaccine to the patient, (4) documenting all of the information about the process (i.e., which vaccine, lot number and expiration date, body site of the injection, etc.), (5) submitting the report to the public health registry, (6) supporting the patient's ability to opt in or opt out of reporting, and (7) providing the patient with a summary of vaccine status.

9.1.3 Who Performs User Workflow 5: Administer and Report Immunization

- Clinicians (physicians, nurses, and other personnel who assist with providing immunizations)

- Patients or caregivers with permission to access an individual's information
- Public health immunization registry (as a receiver of the immunization report)

9.1.4 Examples of Work in the Area

- Two vendors interviewed for this effort have evaluated 2D barcoding to document vaccine administration into their EHR systems. Barcode readers for linear and 2D barcodes are readily available at relatively low cost. To date, testing the use of barcodes in administering vaccinations has not identified an ideal workflow for implementing barcode assisted documentation of vaccine administration. Some work has found scanning barcodes on individual vaccine doses after vaccine administration may be easier for the provider's staff. However, such a practice is contrary to the patient safety initiatives that encourage bar coding prior to vaccine administration.
- The Drug Quality Security Act (9/27/2014) requires all pharmaceuticals to have human readable or barcode on packaging for the lowest unit of sale. Most vaccines contain linear barcodes on the vial containing the vaccine (the unit of use), as well as on the packaging. Linear barcodes allow 48 alphanumeric characters and include NDC numbers to identify the drug, but not lot number and expiration date. The Act requires adding a 2D barcode no later than 2017, but only at the level of packaging (unit of sale). 2D barcodes allow 2335 alphanumeric characters allowing room for the NDC number plus expiration date and lot number.
- A study of 215 practices – using 24 EHR vendor products – evaluated 2D barcode. The study found significant satisfaction regarding the accuracy of documentation and the ease of entering vaccine stock into the EHR to allow ordering from inventory. Most practices included in the study experienced additional burden, since only some of the vaccine products in the testing were barcoded. Most practices were interested in implementing bar coding to document vaccine administration if a threshold of 76 to 99% of vaccines had 2D barcodes. No vendor identified has yet included incorporation of the Vaccine Information Statement (VIS) and its issue date into the software.[40]
- When a clinician does not administer a vaccination based on clinical guidelines, it is important that the reason for the deferral is available, so that other clinicians can use this information to guide subsequent decision-making regarding vaccinations. The core data elements for reporting immunizations

to public health registries include contraindications, exemptions/parent refusals, and history of vaccine preventable disease, all of which may represent deferral reasons that should be documented.[41]

- Reporting for clinical quality measures for hospitals and ambulatory physicians also requires documentation and reporting of deferrals. Managing such documentation is one of the reasons for difficulty implementing eCQMs in EHRs.[42,43] A more usable mechanism to document deferrals is needed.

DEPRECATED Requirement 5.1 Provide Access to Vaccine Information Statement(s)

This requirement has been deprecated as it is no longer recommended to provide access to Vaccine Information Statement(s). This section is retained as a reference for historical references.

Requirement 5.2 Record Vaccine Administration Deferral

The EHR or other clinical software system allows a user to enter a reason or reasons why a specific immunization was not given to a patient (e.g., due to contraindication, refusal, etc.). The system also stores that information in a structured way so it can be reported and analyzed as needed.

9.1.5 Example of Scenario "Record Vaccine Administration Deferral"

Mrs. Morales refuses to allow her daughter Maria to receive a DTaP vaccine. Dr. Smith's entry of the refusal is stored in her EHR system as coded information. Thus, the EHR system can access it for the immunization report that is sent to the public health registry. The information also is available to Dr. Smith and her staff as part of Maria's record.

9.1.6 Guidance

When a clinician does not administer a vaccination, it is important that the reason for the deferral is available to guide other clinicians who might order or administer the same antigen. Core data elements for reporting immunizations to public health registries include contraindications, exemptions/parent refusals, and history of vaccine preventable disease, all of which may represent deferral reasons that should be documented.[44]

All products evaluated support documentation of immunization deferrals, including the reason for the deferral (medical or patient request) and the expected duration of the deferral. Deferral information should be included in the field (RXA-18) indicating the substance refusal reason (HL7 Version 2.5.1 Implementation Guide: Immunization Messaging (Release 1.5) 10/1/2014, page 49):

00 – Parental decision
01 – Religious exemption
02 – Other (must add text component of the CE field with description)
03 – Patient decision

9.1.6.1 Focus on Vendor Perspective

Usability evaluation such as UCD may help address mechanisms to capture deferrals and to make the information available to other providers when addressing the same vaccine antigens.

9.1.6.2 Focus on Provider and Implementer Perspective

Review with your EHR vendor how the system manages vaccine deferrals.

9.1.7 Test

Refer to the test script scenario that includes the requirement Record Vaccine Administration Deferral. The script also indicates successful performance for each of the test sections.

9.1.7.1 Data Elements

The data elements include the vaccine deferral reasons specific to the clinical scenario in the test script.

Requirement 5.3 Record Past Immunizations

The EHR or other clinical software system allows providers to enter information about immunizations given elsewhere (e.g., by another doctor, at a public health clinic, pharmacy, etc.) with incomplete details.

9.1.8 Example of Scenario "Record Past Immunizations"

Juana Mariana Vasquez, age 6, received a live, attenuated influenza vaccine on November 9 at a local pharmacy. His mother brought a copy of the vaccination information to the office and Dr. Smith entered it directly into the EHR system even though the vaccine lot number and expiration date were missing. Reviewing Juana Mariana's record one month later, Dr. Smith's associate is able to see that the November 9 influenza vaccine was manually entered and identify the source of the information (in this case, the patient's mother).

9.1.9 Guidance

The requirement addresses recording immunization history obtained from external sources or history provided by the patient or patient's caregiver. All products evaluated consistently supported the historical vaccine name, CVX, date, and lot number. Section 6.5.2 provides the field and the entry codes to document the immunization information source.

9.1.10 Perspective

9.1.10.1 Focus on Vendor Perspective

Products with the ability to identify the source of historical information may assist providers to perform reconciliation. Additional data (such as administered at location) may also allow providers to obtain additional information as needed for vaccine recalls.

9.1.10.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

9.1.11 Test

Refer to the test script scenario that includes the requirement Record Past Immunization. The script also indicates successful performance for each of the test sections.

9.1.11.1 Data Elements

The data elements include the immunization history data specific to the clinical scenario in the test script.

Requirement 5.4 Notify of Vaccine Dose Ineligibility

The EHR or other clinical software system provides a method for alerting a provider if a vaccine is selected for a patient who is not eligible for the inventory item selected.

9.1.12 Example of Scenario "Notify of Vaccine Dose Ineligibility"

Juana Maria Gonzales is not covered by the VFC program. When Dr. Smith tries to order Varicella vaccine from VFC stock, the EHR informs her that Juana is not eligible for a vaccine from the VFC stock.

9.1.13 Guidance

Programming vaccine dose ineligibility (or eligibility) requires clearer documentation and specification of the requirement. All products evaluated provide the ability for providers to specify VFC eligibility at each visit and most when documenting administration of each vaccine. All products also include VFC eligibility in the vaccine administration report.
Vendors support providers to document VFC eligibility in two ways: (1) Expect the provider's practice to evaluate each patient's VFC eligibility at each visit and update the status in the patient's demographics. Therefore, the system does not require a check box with each vaccine administered. (2) Expect the provider to select the VFC eligibility reason when documenting each vaccine administered.
AIRA publishes a number of guidance documents about VFC eligibility.[45,46]
To automate VFC eligibility evaluation additional information must be readily available. Potential mechanisms for developing automated eligibility checks include:

1. A link to the CDC VFC Eligibility Criteria URL (https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html) may be useful to verify and document eligibility; however, variation may exist across state programs. Note that state / jurisdictional programs vary from state to state. Standardizaion of such state and jurisdictional requirements would assist EHRs, or a centralized source of information about such differences would assist EHRs and IIS in complying with national and local requirements.

a. Dependency: Electronically accessible eligibility criteria in each state, or a compendium of all state criteria in a central source.
b. Direct the Info Button to the eligibility rules to enable processing within the EHR.

2. Use EHR eligibility/authorization capabilities to electronically determine each patient's eligibility at each visit.

   a. Dependency: Each state can set up an electronic access point to criteria or an electronic hub can provide a central source for real-time eligibility/ authorization checks directly from an EHR. Third party vendors that manage similar capabilities for e-prescribing across the U.S. may also manage such capability. Some states are using eligibility checks for referrals to human services. However, VFC eligibility information is already gathered and verified at intake (insurance status) and the option would represent a significant change in processing.
   b. Most EHRs currently perform eligibility and benefit checks as an administrative function at the beginning of each visit using ANSI Accredited Standards Committee (ANSI ASC X12) messaging. ANSI ASC X12 is used for electronic data interchange (EDI). EHRs currently use the EDI Eligibility, Coverage and Benefit Inquiry (EDI 270) to determine eligibility and benefits. The process currently accesses the patient's insurance plan to evaluate eligibility.
   c. The ANSI ASC X12 EDI 270 standard would need to be updated to include the VFC eligibility related vocabularies.

9.1.13.1 Focus on Vendor Perspective

Currently, the software must be able to capture and store VFC eligibility and include the information in each vaccine administration report sent to the public health immunization registry.

9.1.13.2 Focus on Provider and Implementer Perspective

Providers participating in VFC and other guarantee programs should be familiar with eligibility requirements to document dose level eligibility appropriately in the EHR. Vaccine guarantee programs are those that provide vaccines to eligible

patients at no cost. Some guarantee programs are national VFC; others are local or regional. The individual program defines patient eligibility requirements. Providers should confirm eligibility at each patient visit to assure administration of the appropriate guarantee program vaccine product(s). In addition, many guarantee programs only cover routine childhood vaccines and not travel-related vaccines such as yellow fever vaccine, typhoid vaccine, etc. However, some programs may cover specific vaccine products that are not included in other programs. In order for a vaccine to be eligible for a vaccine guarantee program, both the patient and the vaccine must meet the program requirements. That means (1) the patient must meet criteria for the guarantee program and (2) the vaccine must be supported by the specific guarantee program. If either fails, then the outcome is "ineligible" at the dose level.

Some examples:
Patient John Smith is a 5-year-old Alaska native. During a provider encounter, John is administered a dose of DTaP. John meets the VFC requirements as an Alaska native and DTaP is a vaccine included in the VFC program, therefore an eligibility code of V04 (VFC Eligible – American Indian/Alaska native) is transmitted to the registry as part of the VXU message.

Patient Joe Jackson is a 20-year-old male. During a provider encounter, Joe is administered a dose of HPV. HPV is a vaccine included in the VFC program, but Joe exceeds the maximum age for the VFC program, therefore an eligibility code of V01 (not VFC eligible) is transmitted to the registry as part of the VXU message.

Jane Miller is an uninsured 6-year-old female. During a provider encounter, Jane is administered a dose of Yellow Fever vaccine as she will be travelling internationally. Because of her uninsured status, Jane is eligible for the VFC program, but Yellow Fever vaccine is not included in the VFC program, therefore an eligibility code of V01 (not VFC eligible) is transmitted to the registry as part of the VXU message.

Providers have additional vaccine handling and storage responsibilities in the VFC program that EHRs do not currently support. Providers may want to review

the 2012 Department of Health and Human Services (HHS) Office of the Inspector General report addressing these vaccine handling and storage responsibilities and review their state requirements in this area.[47,48,49] EHRs do not assist with management or documentation of such vaccine handling and storage issues.

9.1.14 Test

Refer to the test script scenario that includes the requirement Notify of Vaccine Dose Ineligibility. The script also indicates successful performance for each of the test sections.

9.1.14.1 Data Elements

The data elements include the condition specific to the clinical scenario in the test script.

DEPRECATED Requirement 5.5 Document Vaccine Ineligibility Override Reason

This requirement has been deprecated as it is no longer recommended to document vaccine ineligibility override reason. This section is retained as a reference for historical references.

Requirement 5.6 Enter Vaccination Order

The EHR or other clinical software system allows providers to order immunizations for a patient using filters for type of vaccine, including combination vaccines.

9.1.15 Example of Scenario "Enter Vaccination Order"

Dr. Smith accesses the available vaccine list and can search by type of vaccine, such as all products containing Varicella (i.e., Varicella vaccine and MMRV vaccine).

9.1.16 Guidance

All products evaluated allowed entry of a vaccination order by selecting from a list of vaccines. Vendors do not consistently limit access to only those vaccines present at the practice site. The requirement must be more clearly defined to evaluate if providers can filter the vaccines by antigen (i.e., look for all vaccines

that contain a specific antigen even if the vaccine name does not clearly identify all of the antigens it contains).

9.1.16.1 Focus on Vendor Perspective

The requirement indicates a user should be able to search for all vaccines containing a specific antigen. Usability evaluation using UCD may improve approaches to vaccine ordering.

9.1.16.2 Focus on Provider and Implementer Perspective

Discuss preferences for vaccine ordering with the software vendor.

9.1.17 Test

Refer to the test script scenario that includes the requirement Enter Vaccination Order. The script also indicates successful performance for each of the test sections.

9.1.17.1 Data Elements

The data elements include the orders specific to the clinical scenario in the test script.

Requirement 5.7 Review Patient Immunization History

The EHR or other clinical software system displays vaccine history by vaccine series.

9.1.18 Example of Scenario "Review Patient Immunization History"

When ordering vaccines for her patient, Dr. Smith is able to view Juana Mariana Vasquez' immunization history, complete with Juana Mariana's age at each recorded vaccine dose, reasons specific doses were not given as planned, and an indicator if Juana Mariana had any adverse reactions.

9.1.19 Guidance

All products allow review of the patient's immunization history during the ordering and administration workflow process. Most have providers start at the immunization history / forecasting screen that displays those vaccines currently due and then take action to order or document administration directly from that screen.

9.1.19.1 Focus on Vendor Perspective

Usability evaluation such as UCD may benefit more efficient workflow.

9.1.19.2 Focus on Provider and Implementer Perspective

Discuss preferences for documenting vaccine administration with the software vendor.

9.1.20 Test

Refer to the test script scenario that includes the requirement Review Patient Immunization History. The script also indicates successful performance for each of the test sections.

9.1.20.1 Data Elements

Not applicable.

Requirement 5.8 Link Standard Codes to Immunization Data

The EHR or other clinical software system links standard codes (i.e., LOINC for lab tests or evaluation tools, SNOMED CT for conditions or observations, NDC codes for current immunizations, CVX for historical immunizations, appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization.

9.1.21 Example of Scenario "Link Standard Codes to Immunization Data"

A patient's record in Dr. Smith's EHR displays all vaccines, lab tests, and diagnoses with common names. The EHR can translate these items to appropriate codes to allow reporting to public health registries. The coding also helps the software improve data quality by assuring the data entered and shared in reports to the IIS are consistent with expected codes referenced in the HL7 Version 2.5.1 Implementation Guide Release 1.5.

9.1.22 Guidance

All products evaluated support NDC and CVX codes for immunizations. The concepts used to express administration site, device, method, and site should align with the HL7 Version 2.5.1 Implementation Guide Release 1.5 and also align with clinical documentation standards for EHR interoperability. Specific

examples for clinical diagnosis and serologic evidence of disease are discussed in section 7.5.2.

9.1.22.1 Focus on Vendor Perspective

Vendors should collaborate with public health immunization registries and providers to harmonize requirements and determine workflow.

9.1.22.2 Focus on Provider and Implementer Perspective

Providers should collaborate with public health immunization registries and EHR vendors to harmonize requirements and determine workflow.

9.1.23 Test

The HIMSS IIP includes testing for this requirement in all transmission steps.

9.1.23.1 Data Elements

Not applicable.

Requirement 5.9 Record Vaccine Administration

The EHR or other clinical software system records information about each vaccine administered. The EHR records this information as structured data elements, including, at a minimum: date administered, administering clinician, route of administration (e.g., intramuscular), site of administration (e.g., left arm), immunization type, lot number, manufacturer, Vaccine Information Statement date, quantity of vaccine/dose size and ordering clinician. The system also assures data quality i.e., data entered are appropriate (e.g., avoid "oral" route for IM vaccines, and assures dose is appropriate for the vaccine).

9.1.24 Example of Scenario "Record Vaccine Administration"

The nurse about to administer a vaccine to Juana Maria Gonzales first enters the date, the nurse's name, the site of administration, immunization type, lot number, manufacturer, VIS date, and the amount of vaccine to be administered. The EHR in the practice where he works allows this information to be entered manually or by using barcodes.

9.1.25 Guidance

All products evaluated can record expected information for vaccines the provider administers. The data set used for evaluation includes elements listed in the HL7 2.5.1 Implementation Guide Release 1.5 for immunizations as required (R), required if exist (RE), optional (O), and conditional (C) to ensure the products could capture and store all data if it is available.

9.1.25.1 Focus on Vendor Perspective

Due to state statutory requirements and local variation, some public health immunization registries require more data elements in immunization reports. The ability to capture all potential data elements listed in the HL7 Implementation Guide ensures that the product can capture the superset of data to support the variation.

9.1.25.2 Focus on Provider and Implementer Perspective

There is a limited set of known locally required (R) fields for immunization reporting that are not required (R) fields in the HL7 2.51 Version Implementation Guide Release 1.5 that is applied nationally. Such fields include Patient Address, Responsible person address or phone, etc. Providers who are able to provide such information will be better prepared to submit immunization information to the IIS in the field. This Capability and Guidance document addresses such data fields to assure EHRs and other clinical software can accommodate the data entry and support submission of the information to IIS.

Note: A completed vaccine administration generally references a "potent" vaccine, i.e., the vaccine has not expired, and it has been properly stored and administered. However, several issues may occur that render the dose administered sub-potent (or less than completely potent). Once such information is known, the immunization records should be updated to indicate the administration was "sub-potent," representing only partial administration:

a) Known at the time of vaccine administration:
   - The child pulls away from the injection and an unknown quantity was administered (i.e., partial dose).

b) Known subsequent to vaccine administration:

- Review of office storage practices determines that during some time interval, the storage refrigerator temperature was incorrect, and any vaccines administered during that time interval may, therefore, not be potent.
- A manufacturer recall of a specific vaccine lot indicates any vaccine administered from the referenced lot may not be potent.

Providers may not consistently document such incomplete or sub-potent administration events. For product recalls and incorrect storage issues, providers need to recall patients to be revaccinated and provide an update message to the IIS that the previous administration is sub-potent.

The Vaccine Record Update (VXU message) records an incompletely administered dose or a sub-potent dose. Statement from the Immunization Messaging Implementation Guide version 2.8.2 release 1 September 2018 section 2.3.6.10:

> There are occasions when a dose is not completely effective. For example, a child may jump away during injection and an unknown quantity was administered or a dose of vaccine may be considered sub-potent due to a cold-chain break or manufacturing issue. In this case, the dose needs to be recorded to support accurate inventory management and to allow for notification of the patient if there is a recall of the vaccine. This is accomplished using a Completion Status of "PA" in RXA-20. The remainder of the RXA segment is populated as usual. If more details are of interest, then by local agreement additional information may be sent as a comment or using locally defined observations identifiers.[50]

9.1.26 Test

Refer to the test script scenario that includes the requirement Record Vaccine Administration. The script also indicates successful performance for each of the test sections. The test also includes the ability to scan the vaccine information using 2-D Data Matrix.

9.1.26.1 Data Elements

See Appendix A.

Requirement 5.10 Produce Standard Patient Immunization History Report

The EHR or other clinical software system produces a report of a patient's immunization history that is appropriate for various entities, such as schools and day-care centers.

9.1.27 Example of Scenario "Produce Standard Patient Immunization History Report"

The nurse administering vaccines to Juana Mariana Gonzales prints a report of Juana Mariana's complete immunization history, which Juana Mariana's mother can share with her day care center.

9.1.28 Guidance

This requirement is to produce an immunization history report that a patient can use to share with other entities. The term "standard" refers to the report the EHR creates without additional configuration or effort. The requirement is not prescriptive with respect to the report's content or its presentation. Comparison of all local and state requirements for compliant, conditional and exempt data elements with the national reporting requirements would be a valuable exercise to assist EHR vendors and providers in creating such report templates. The information would also provide schools and day care centers with clear information regarding national and local compliance. Note that in some jurisdictions, the IIS must produce the official report as defined by a state department (e.g., education). In these sites, the jurisdiction defines the look, feel, fields, and other factors that must be met to qualify as an official report.

Documentation of sub-potent vaccines most often occurs after the administration event, often by a considerable period of time for manufacturer recalls or storage temperature issues. Resolution requires definition of workflow considerations for both the clinician and the IIS. Such information is best attained by convening all stakeholders to review scenarios and apply potential workflow models identified. To be considered by such convening:

- There is no consistent manner to document previously administered vaccine doses as sub-potent; most methods are manual and represent free-text addenda to the administration record.
- If sub-potent vaccine information is available, it can be submitted to the IIS as an update in the RXA-20 field (with the value PA) and the IIS usually can store it as a coded concept and include the code when sending vaccine history to other providers. AIRA is actively working to assure all IIS capture such information.
- IIS need the sub-potent vaccine data because it impacts the waiting period before the same antigen, or another live antigen can be administered.
- CDSi includes information about how to address sub-potent vaccines. If the vaccine information is coded as sub-potent, a forecasting engine should be able to calculate forecasts consistent with the vaccine potency information.

All products evaluated provide an updated immunization history for patients whether by printing or by sending the information to the patient's portal.

9.1.28.1 Focus on Vendor Perspective

Usability evaluation such as a UCD process may inform the content and presentation of such a "standard" form. Vendors should work with standards organizations to explore a standard allowing EHRs to request official vaccine history reports from IIS rather than attempt to reproduce each jurisdiction's requirements and maintain multiple report formats over time.

9.1.28.2 Focus on Provider and Implementer Perspective

Discuss preferences for the EHR patient immunization history report with the software vendor.

9.1.29 Test

Refer to the test script scenario that includes the requirement Produce Standard Patient Immunization History Report. The script also indicates successful performance for each of the test sections.

9.1.29.1 Data Elements

Not applicable.

Requirement 5.11 Transmit Standard Patient Immunization History Report

The EHR or other clinical software system directly or indirectly through an intermediary creates and transmits a report of a patient's newly administered or newly identified immunization history to public health immunization registries.

9.1.30 Example of Scenario "Transmit Standard Patient Immunization History Report"

The nurse administering vaccines to Juana Maria Gonzales completes the session by submitting a report to the public health immunization registry. The EHR system formats all of the information in the report consistent with HL7 version 2.5.1, Implementation Guide for Immunization Messaging Release 1.5.

9.1.31 Guidance

All products evaluated provide an HL7 2.5.1 patient immunization report to the immunization registry. Vendors should take care to avoid conformance errors with respect to HL7 Implementation Guide for Immunization Messaging release 1.4 (used for CEHRT 2015) and the newer version 1.5. Here are some potential conformance errors seen in pilot testing of the available tests:

1. Syntax (formatting) errors in the message.
2. Content errors:
    a. Failure to include content provided in the test script for some elements required by the standard if content exists (RE); and
    b. Use of a value or value set different from the one expected by the standard and the NIST test tool.

The HL7 V2.5.1 Implementation Guide for Immunization Messaging Release 1.5 requires NCIT body site codes rather than the HL7 Table 0162 allowed by the release 1.4.
Greater collaboration among the public health registries, vendor, and providers should help to address areas of workflow conflicts and lead to more efficient standards development.
Some registries require more "RE" elements in the vaccine report than others. Enabling the EHR report to transmit any of the data elements listed in the

standard, or the "super set" should decrease the need for local configuration at customer sites.

To address receipt of the immunization message, IIS respond with an acknowledgement (ACK) message. IIS have worked to standardize ACK messages as indicated in the Implementation Guide over the last 2+ years. There is still work to assure compliance with the new standard messages, but how EHRs might triage the ACK messages is not clear. Ideally, provider sites would take actions to correct transmission errors and resubmit the message.[51] However, providers may not be able to see acknowledgement messages and thus they may not be aware if and why messages are rejected. Some issues are missing or inconsistent content in the message, other issues represent message formatting concerns. AIRA has published guidance for IIS regarding use of Acknowledgement (ACK) codes: http://repository.immregistries.org/files/resources/5835adc2add61/guidance_for_hl7_acknowledgement_messages_to_support_interoperability_.pdf. AIRA has also developed a standard set of ACK codes for use by the IIS to describe the type of error (http://wiki.hl7.org/index.php?title=FHIR_Connectathon_Track_Process). Potential issues include:

a. ACK messages include codes that providers may not understand
b. Providers have limited ability to mitigate the issues identified in some ACK messages (i.e., they might be able to add data where it is missing but they are not able to change the message configuration developed by the IT implementers)
c. When messages go through Health Information Exchanges, the ACK messages may not reach the provider

The IIP TAP reviewed the issue, recommending that resolution requires definition of workflow considerations for both the clinician and the IIS. The IIP Collaborative is addressing acknowledgements and further considering workflow approaches for EHRs, IIS and clinicians. Such information is best attained by convening all stakeholders to review scenarios and apply potential workflow models identified. To be considered by such convening:

- Differentiating acknowledgement messages that indicate a technical error from those representing missing/inconsistent information in patient demographics or clinical data
- The role within an organization that is most appropriate to review and correct ACK issues varies within organizations
- Determining the timeliness required for responses to ACK messages; real-time responses (i.e., send corrected messages to the IIS) are not necessary
- Evaluating some clinical software methodology to facilitate review of ACK messages
- Addressing user workflow as a critical factor to resolve this issue to avoid burden and to assure the availability of actionable information for the appropriate role
- Managing ACK messages is a significant uniformity and usability concern. Software that provides ACK message information should also include information to help the user understand the message and what actions might be taken to mitigate the issue.

The ability to address ACK messages is one of the critical factors affecting onboarding cues.

Note: The test evaluates EHR receipt of ACK (acknowledgement) messages from the IIS. It does not expect or address any ACK messages from the EHR to the IIS (i.e., EHR acknowledging receipt of the immunization history or forecast).

9.1.31.1 Focus on Vendor Perspective

Due to state statutory requirements and local variation, some public health immunization registries require more data elements in immunization reports. The ability to capture and submit all potential data elements listed in the HL7 implementation guide assure that the product can capture the superset of data to support the variation, though it does not address custom local requirements that may be imposed beyond those defined in the standard.

9.1.31.2 Focus on Provider and Implementer Perspective

Customization requirements for non-standard localization can be costly and cause implementation delays.

9.1.32 Test

Refer to the test script scenario that includes the requirement Transmit Standard Patient Immunization History Report. The script also indicates successful performance for each of the test sections.

9.1.32.1 Data Elements

See Appendix A.

DEPRECATED Requirement 5.12 Produce Configurable Patient Immunization History Report

This requirement has been deprecated as it is no longer recommended to produce configurable patient immunization history report. This section is retained as a reference for historical references.

9.1.32.2 Data Elements

Not applicable.

DEPRECATED Requirement 5.13 Transmit Configurable Patient Immunization History Report

This requirement has been deprecated as it is no longer recommended to transmit configurable patient immunization history report. This section is retained as a reference for historical references.

Requirement 5.14 Produce Immunization Forecast Report

The EHR or other clinical software system creates a list of immunizations to be administered within a specified timeframe.

9.1.33 Example of Scenario "Produce Immunization Forecast Report"

Dr. Smith is able to view a schedule of immunizations due over the next 3 years for Juana Maria Gonzales. The schedule includes the recommended dates, minimum (earliest) date, ideal date, and maximum (latest) date for each vaccine. The report can be viewed and printed to share with Juana Maria's mother.

9.1.34 Guidance

This requirement is to provide a new immunization forecast after administering a vaccine or a number of vaccines to a patient. The purpose of the new forecast is to advise the provider and the patient about the timing of future immunizations. The requirement is specifically vague about the amount of information to provide since clinical practice should decide the most appropriate content. Some feedback suggests that too much information can be confusing. For example, a forecast for a one-year-old child may not need to include all vaccine doses due through age 18. If the next dose in the series is administered late, the timing for all subsequent doses may need to be modified. Therefore, some suggest that only the next dose of each vaccine should be included and that the forecast should cover only a limited age range. Also, the updated forecast report has two audiences. First, the physician and the office staff will use it to advise the patient and to arrange future appointments and set reminders. Secondly, the provider may share the forecast report with the patient as part of care planning activities.

Only 25% of products evaluated included *future* immunization requirements in the immunization history report (requirement 5.10) provided to patients. Usability evaluation such as a UCD process may inform the content and presentation for this forecast report. Such a UCD process should address the various users as the content and presentation will likely vary depending on the user.

9.1.34.1 Focus on Vendor Perspective

Usability evaluation such as a UCD process may inform the content and presentation for an updated forecast report. Such a UCD process should address the various users as the content and presentation will likely vary depending on the user.

9.1.34.2 Focus on Provider and Implementer Perspective

Refer to the provider perspective discussion for requirement 4.2.

9.1.35 Test

Refer to the test script scenario that includes the requirement Produce Immunization Forecast Report. The script also indicates successful performance for each of the test sections.

9.1.35.1 Data Elements

Not applicable.

Requirement 5.15 Record Vaccine Information by Scanning 2D Barcode Found on Unit-of-Use for Vaccine Administration

The EHR or other clinical software system allows users to record vaccination information from 2D barcodes (GS1 DataMatrix) found on unit of use (vial or prefilled syringe) for each vaccine administered. This 2D barcode contains: the Global Trade Item Number (GTIN), expiration date and lot number. The GTIN contains the National Drug Code (NDC) and manufacturer data elements. Implementers can use mapping tables to determine the manufacturer from this NDC. The software system records these elements as structured data elements so the immunization administration message can use them to include the NDC and manufacturer in the message to the IIS.

9.1.36 Example of Scenario Record Select Vaccine Information for Vaccine Administration by Scanning 2D Barcode Found on Unit-of-Use

The clinician administers a vaccine to Juana Maria Gonzales. When recording the vaccine administration using a compatible scanning device, the clinician scans the vaccine vial's 2D barcode to automatically populate the immunization type (product NDC and manufacturer), lot number, and expiration date.

9.1.37 Guidance

All products evaluated for this requirement can record expected information for vaccines the clinician administers. The CDC offers information and resources to assist with 2D barcode scanning, and Appendix C provides an example 2D barcode.

9.1.37.1 Focus on Vendor Perspective

The ability to capture all potential data elements listed in the HL7 Implementation Guide using 2D barcodes and scanners ensures products used by immunization providers enable high data entry accuracy and promote patient safety. Vendors may wish to consult CDC's EMR/IIS 2D Barcode Functional Capabilities Guide for more information.

9.1.37.2 Focus on Provider and Implementer Perspective

The ability to capture all potential data elements listed in the HL7 Implementation Guide using 2D barcodes and scanners ensures high data entry accuracy, promotes interoperability, reduces time required to document vaccination, promotes patient safety, and enables a more efficient workflow for the clinician. Providers and implementers may wish to consult CDC's Workflow Determination Tool "that includes activities, tips, and process maps to support the incorporation of 2D barcode scanning into the vaccine administration workflow. The Lessons Learned supplement provides key tips and data from the 2D Vaccine Barcode Scalability Pilot (2015-2017)."

9.1.38 Test

For 2021/2022 and beyond, vendors must successfully scan and input data for the following: the National Drug Code (NDC) and manufacturer derived from the scanned Global Trade Item Number (GTIN), expiration date, and lot number. All of these data elements are expected to be in transmission test.
Refer to the test script scenario that includes the requirement Record Vaccine Information by Scanning 2D Barcode Found on Unit-of-Use for Vaccine Administration. The script also indicates successful performance for each of the test sections. The test requires the ability to scan 2D barcodes to input the required vaccine information.

9.1.38.1 Data Elements

See Appendix C for an example unit of use 2D barcode and the encoded data elements.

10 GENERAL DESCRIPTION OF USER WORKFLOW 6: MANAGE COHORT OF PATIENTS

Background

10.1.2 General Description of User Workflow 6: Manage Cohort of Patients

General User Workflow 6: Manage Cohort of Patients describes how EHRs, and other clinical software systems use information to assist with managing groups (cohorts) of patients. While there are many examples of cohorts, common ones include those who received vaccines which were later recalled, those who may be overdue for immunizations, and those who are up to date with immunizations, and many others.

10.1.3 Who Performs User Workflow 6: Manage Cohort of Patients

- Clinicians (physicians, nurses, and other personnel who assist with providing immunizations)

10.1.4 Examples of Work in the Area

Healthcare providers need to evaluate how well they deliver care and how their patients are progressing. Providers with the ability to assess their own performance can institute improvements that result in better scores when they are reviewed by external organizations. One such external review is CDC's Assessment, Feedback, Incentives, and eXchange (AFIX) program.[52] The program includes assessment of the healthcare provider's vaccination coverage levels and immunization practices, feedback of results to providers with recommended quality improvement strategies, incentives to recognize and reward improved performance, and exchange of information with providers to follow up on their progress to improve immunization services and coverage levels. All public vaccine providers have an AFIX assessment and many public health registries support this functionality. The independence of the health department service helps to ensure accuracy of the results.

Requirement 6.1 Produce Population-Level Report

The EHR or other clinical software system generates aggregate, population-level reports based on known patient immunization data.

10.1.5 Example of Scenario "Produce Population-Level Report"

Dr. Smith uses her EHR to produce immunization-specific reports that help her manage her practice. Two such reports are: (1) all patients who received a specific lot number of a vaccine that has been recalled, and (2) all patients who have no scheduled appointments and are overdue for required vaccines.

10.1.6 Guidance

Most products evaluated support customers to create patient lists based on basic criteria. The function is a requirement for CEHRT 2015. Some products include immunizations as one of the options that providers can select to create specific patient lists. Thus, providers can directly create a list of all patients who are late for expected administration of specific immunizations, or all patients receiving a specified vaccine lot number. Other products require providers to configure their systems to include immunizations in the patient list (cohort) function. Some products require providers to acquire additional software to perform such cohort function.

10.1.6.1 Focus on Vendor Perspective

Vendors should work with customers to determine effective "model" cohort reports useful for immunization management. Some options include (a) all patients overdue for immunizations, and (b) all patients who received a specific vaccine lot number (to manage recalls).

10.1.6.2 Focus on Provider and Implementer Perspective

Discuss preferences for the specific immunization-related population-level (cohort) reports with the software vendor. The HIMSS IIP seeks guidance regarding additional examples of immunization-related cohorts that would assist clinicians and patients. Some feedback suggested the ability to provide a patient-centered cohort, e.g., immunizations due for all children in a family as a single report. Feedback on additional information regarding cohort examples and their relative value is appreciated. Other new considerations include:

- all children who should receive reminder notices of vaccines due.
- all children at risk for a new outbreak of disease based on demographics, and the subset of those children without known immunity based on clinical disease, serologic evidence of disease or prior vaccination.

- all children who are about to enter school and still need state required vaccines for entry.
- all children who's yearly check-up falls outside of the flu season and are more likely to not be reminded of the need for a flu vaccine.
- all patients with asthma who have not received an influenza vaccine this season.
- all patients receiving Flovent who have not received an influenza vaccine this season (to assure patients without an asthma diagnosis but on treatment for asthma are protected from influenza).

Comments can be submitted to: IIP@himss.org

10.1.7 Test

Refer to the test script scenario that includes the requirement Produce Population-Level Report. The script also indicates successful performance for each of the test sections.

10.1.7.1 Data Elements

Not applicable.

Requirement 6.2 Notify Patients of Immunization Status

The EHR or other clinical software provides the ability to notify patients of recommendations based on their individual preferences for receiving notification.

10.1.8 Example of Scenario "Notify Patients of Immunization Status"

Dr. Smith needs to notify a significant number of her patients about new information and actions they may need to take. Two examples of such notification include: (1) that a patient received a vaccine that has been recalled and there is a specific action that needs to be taken (e.g., receive another vaccine, etc.), and (2) that a patient is overdue for required vaccines and needs to schedule appointments to catch up with their vaccine schedules.

October 2016 Update: The EHR or other clinical software provides the ability to notify patients of recommendations based on their individual preferences for receiving notification.

10.1.9 Guidance

Many products evaluated support notifying all patients identified in a population-level report (cohort) of actions they should take. These vendors support capturing a patient's preferred method for communication as part of the demographics. The products subsequently use these notification preferences to allow providers to notify patients in a cohort of required information. Three-quarters of the products allow such notification; many require the provider to configure the process to support immunization-related notices.

10.1.9.1 Focus on Vendor Perspective

Vendors should work with customers to determine preferences for individual and cohort-based patient notification (i.e., send notification to all patients identified in the population-level report).

10.1.9.2 Focus on Provider and Implementer Perspective

Discuss preferences for the individual patient and cohort notification with the software vendor.

10.1.10 Test

Refer to the test script scenario that includes the requirement Notify Patients of Immunization Status. The script also indicates successful performance for each of the test sections.

10.1.10.1 Data Elements

Not applicable.

11 GENERAL DESCRIPTION OF USER WORKFLOW 7: MANAGE ADVERSE EVENT REPORTING

Background

11.1.2 General Description of User Workflow 7: Manage Adverse Event Reporting

General User Workflow 7: Manage Adverse Event Reporting describes how EHRs, and other clinical software systems use information to assist with documenting, reporting, and storing adverse event information. General User Workflow 7 also describes how systems make adverse event information available in settings where providers administer immunizations to patients.

11.1.3 Who Performs User Workflow 7: Manage Adverse Event Reporting

- Clinicians (physicians, nurses, and other personnel who assist with providing immunizations)

11.1.4 Examples of Work in the Area

- There are numerous reporting forms for various types of adverse events. In some cases, there are standard forms for such reporting.
- Providers voluntarily report adverse events to patient safety organizations, with protections for such reporting offered to providers through The Patient Safety and Quality Improvement Act of 2005. In accordance with the Patient Safety and Quality Improvement Final Rule.[53] The Agency for Healthcare Research and Quality (AHRQ) has developed Common Formats for such reporting.
- The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide mechanism by which adverse events following immunization may be reported, analyzed, and made available to the public. Providers can access the reporting form online and submit adverse event information either electronically through the VAERS website or via fax or mail.[54]
- MedWatch, the FDA's Safety Information and Adverse Event Reporting Program, enables clinicians and consumers to report serious medical product problems, either through an online submission form or by completing a standard form and sending it to the FDA via fax or mail.[55]
- Many EHRs provide a link for providers to access the VAERS or MedWatch sites.

Requirement 7.1 Identify Adverse Event

The EHR or other clinical software system enables capture of structured data regarding adverse events.

11.1.5 Example of Scenario "Identify Adverse Event"

Dr. Smith examines Juana Maria Gonzales 24 hours after she receives the MMR vaccine. She had fever and diarrhea and, therefore, Dr. Smith entered her

observations indicating a possible adverse event. The EHR stored the observations associated with the MMR vaccine.

11.1.6 Guidance

All products reviewed allow entry of allergy and adverse reactions in the allergy list and/or on the patient's problem list. Some allowed providers to specify the type of reaction (e.g., type of allergy or adverse reaction) and its severity. In some situations, the causative agent of an adverse event can be clearly identified. In other cases, the provider may not be able to unambiguously differentiate the cause of a reaction (e.g., the reaction occurred after administering multiple vaccines in the same visit). The system should provide a mechanism to record the reaction and the potential causative agents with an indication of level of certainty. In either case, the system should provide a mechanism such that the provider is aware of the previous reaction and certainty level during the subsequent immunization ordering or administration workflow. Such detailed information can support decision-making by other providers involved in the patient's subsequent care. If a provider chose to include detailed information about reactions in immunization messages to the IIS it is generally in a comment, or text field. Standards are evolving for modeling adverse event and allergy information in EHRs directly and when sharing information with other clinical software. Public Health is seeking input for better code sets for data exchange regarding adverse events and allergies. Current efforts include HL7 Messaging Standard Version 2.8.2 (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=403), and Fast Healthcare Interoperability Resources (FHIR) clinical resources (https://www.hl7.org/fhir/). Participation in such efforts will enhance mutual understanding for clinicians and public health. CDC is also in the process of updating the 2018-2022 CDC-Endorsed Data Elements" which will not include adverse events. The update will be available in the same location as the 2013-2017 Data Elements site (https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html). Functional standards include adverse event information (https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-2018-2022.html).

Some IIS accept adverse event information only if it meets the codes identified in the HL7 2.51 Version Implementation Guide Release1.5. Thus, the IIS may not store information the provider considered relevant to immunization decisions and, therefore, the information is not shared with providers subsequently involved in the patient's care. By accepting such historical information and including it in responses to data queries for immunization histories, IIS may be able to improve subsequent decision-making by providers, patients, and care givers.

11.1.7 Perspective

11.1.7.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system documents and stores adverse event data.

11.1.7.2 Focus on Provider and Implementer Perspective

Discuss preferences for documenting adverse events with the software vendor. Providers should also collaborate with public health to determine effective ways to capture and share adverse event data such that it enables more effective clinical decision-making. Providers need to document adverse events in a way that allows the next provider to be aware of it when they are reviewing the immunization record and/or ordering immunizations.
Note: Having the prior reaction on the allergy or problem list may not fulfill this requirement. The mechanism of reporting the adverse event to the appropriate entities should be as painless as possible.

11.1.8 Test

Refer to the test script scenario that includes the requirement Identify Adverse Event. The script also indicates successful performance for each of the test sections.

11.1.8.1 Data Elements

The data elements include the adverse reaction specific to the clinical scenario in the test script.

DEPRECATED Requirement 7.2 Initiate and Submit a VAERS Report

This requirement has been deprecated as it is no longer recommended to initiate and submit a VAERS report. This section is retained as a reference for historical references.

Requirement 7.3 Notify of Previous Adverse Event

The EHR or other clinical software system alerts providers to previous adverse events for a specific patient, in order to inform clinical decision-making when providers view an existing immunization record.

11.1.9 Example of Scenario "Notify of Previous Adverse Event"

In 2013, 24 hours after she received a live, attenuated influenza vaccine, Juana Maria Gonzales had a fever and diarrhea. When Dr. Smith's associate sees Juana Maria in 2015, he can view her possible adverse event as part of the immunization record.

11.1.10 Guidance

All products reviewed allow entry of allergy and adverse reactions in the allergy list and/or on the patient's problem list. Less clear is the ability to ensure a user is aware of an adverse reaction to the antigen recommended by a forecast or an antigen about to be ordered or administered. Feedback to users about potential patient risks can be provided specific to the level of risk. Types of feedback defined in the context of software usability include:[56]

1. Notification: A notification is a visual clue or displayed message that informs a user but does not require any action (examples include visual clues such as a persistent banner, color change, bolding, etc. (E.g., "This patient is allergic to ___").
2. Alert: An alert or warning is displayed when user action may result in unintended consequences, for example loss of data, etc. These types of messages shall require the user to acknowledge the message before they can move on (e.g., click ok)
3. Errors: Error message should be displayed in plain language describing specific error condition and instructions what steps a user need to take.

This condition requires the user to fix something before they can move on (e.g., fix this date, it is invalid).

Notification in this context indicates that the system provides indication so the user is aware of a potential problem including the severity of previous reactions. Notification should include information, if available, about prior decisions, e.g., if a provider documented a reason to override notification about allergy or diagnosis in the past. The method for fulfilling the requirement is not prescriptive. Examples of notification include visual clues.
Update October 2016: Clinicians often document allergies or adverse reactions using local terminology or SNOMED CT. IIS generally accept reports based on ACIP criteria for reportable adverse events from vaccines; such reports use PHIN-VADS coding. Collaboration among public health immunization registries and clinicians may help resolve these differences.

11.1.10.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system handles notifications and alerts.

11.1.10.2 Focus on Provider and Implementer Perspective

Notifications and alerts can be a significant usability issue in EHRs. Providers should consider participating in vendor activities to address timely and appropriate notification.

11.1.11 Test

Refer to the test script scenario that includes the requirement Notify of Previous Adverse Event. The script also indicates successful performance for each of the test sections. The notification must be visible directly on the ordering and the documentation screens specific to the vaccine ordered or documented.

11.1.11.1 Data Elements

The data elements include the adverse reaction specific to the clinical scenario in the test script.

DEPRECATED: Requirement 7.4 Notify Public Health Immunization Registry (IIS) of Update from Adverse Event

This requirement has been deprecated as it is no longer recommended to notify the public health immunization registry (IIS) of adverse events. This section is retained as a reference for historical references.

12 GENERAL DESCRIPTION OF USER WORKFLOW 8: PROVIDE PATIENT ACCESS

Background

12.1.2 General Description of User Workflow 8: Provide Patient Access

General User Workflow 8: Provide Patient Access describes how EHRs, and other clinical software systems use information to provide patients or their caregivers with access to immunization histories via a patient portal within an EHR or other consumer-facing application. Ideally, immunization histories can be printed or electronically transmitted to support a user's need for sending information to schools, day care centers, summer camps, employers, and others. This workflow is not intended to be the exclusive mechanism for patient access to immunization reports. For example, direct access also may be provided from a public health immunization registry. It is included here to address requirements defined by providers.

12.1.3 Who Performs User Workflow 8: Provide Patient Access

- Clinicians (physicians, nurses, and other personnel who assist with providing immunizations)
- Patients or caregivers with permission to access an individual's information in a PHR or through external access to the provider's EHR (for example, a portal).

12.1.4 Examples of Work in This Area

- Providers and representatives from public health immunization registries indicate that consumers have significant interest in accessing and printing their own up-to-date immunization records.

- Providers indicate that there is a large seasonal influx of requests for immunization records in late spring – to meet summer camp requirements – and late summer – to meet school requests or requirements. Employers impose similar requirements for immunization records from their prospective or current employees.
- CDC provides references to find specific state-required forms for reporting immunization histories for healthcare workers and patients by employee type,[57] and for day care facilities and schools.[58] These searchable web sites are helpful to determine individual requirements, but highlight the differences among the states for employee, day care, and school criteria. As examples, some provider report formats are provided in PDF format and others in Excel. Schools must further report they have complied with state regulations for vaccines required for school entry. Providers that practice near state borders are, therefore, required to use various formats for the complete patient immunization history report.

Requirement 8.1 Provide Access to Patient Immunization Record

The EHR or other clinical software system provides patients and their authorized representatives with electronic access to immunization records (either directly or by interacting with an external system such as a patient portal).

12.1.5 Example of Scenario "Provide Access to Patient Immunization Record"

Juana Maria Gonzales' mother logs into Dr. Smith's EHR patient portal to view Juana Maria's immunization record.

12.1.6 Guidance

All products reviewed provide access for patients to view immunization histories in the patient portal. The method for displaying the information in a portal varies by product. Some products include a defined immunization section. Others include the immunization data as part of complete patient summary information, mixing immunizations provided with other health maintenance activities.

12.1.6.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how to provide patients access to their immunization records.

12.1.6.2 Focus on Provider and Implementer Perspective

Providers should consider participating in vendor activities to address the workflow and challenges of providing patients access to their own immunization records.

12.1.7 Test

The HIMSS IIP tests this requirement by requiring the immunizations provided during the test are presented for patient access (e.g., through a portal).

12.1.7.1 Data Elements

Not applicable.

Requirement 8.2 Provide Access to Recommendations and Vaccine Information Statement(s)

The immunization record displays immunization recommendations to be discussed with a provider, displaying the relevant Vaccine Information Statement (VIS).

12.1.8 Example of Scenario "Provide Access to Recommendations and Vaccine Information Statement(s)"

Juana Maria Gonzales' mother logs into Dr. Smith's EHR patient portal to view Juana Maria's immunization record. At the same time, she also views an immunization schedule that helps her plan for Juana Maria's future doctor visits. Mrs. Morales also reads the VIS's for each of the upcoming vaccines so she can be informed before taking Juana Maria to the doctor's office.

12.1.9 Guidance

Few of the products reviewed provide future immunization recommendations. Those that do provide future recommendations do not generally include VIS statements for patients to read prior to their next visit. Vendors and providers indicated challenges with providing recommendations on patient portals. Many cite a concern about a need to review each recommendation before it is displayed. Others note uncertainties about how much information is appropriate.
Feedback about this requirement is invited.

12.1.9.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how to provide patients access to their future immunization requirements.

12.1.9.2 Focus on Provider and Implementer Perspective

Refer to the provider perspective discussion for Section 5.18 (requirement 4.2).

12.1.10 Test

The HIMSS IIP requires that the system displays the forecast created after the office visit (during which vaccines are administered) and VIS's.

12.1.10.1 Data Elements

Not applicable.

Requirement 8.3 Provide Access to Printable Immunization Record

The EHR or other clinical software system provides a printable version of the immunization record.

12.1.11 Example of Scenario "Provide Access to Printable Immunization Record"

Juana Maria Gonzales' mother logs into Dr. Smith's EHR portal to view Juana Maria's immunization record. She is able to print the record and the immunization schedule.

12.1.12 Guidance

All products reviewed that include a patient's immunization history on a portal also allow patients to print the information directly from the screen.

12.1.12.1 Focus on Vendor Perspective

No specific recommendations.

12.1.12.2 Focus on Provider and Implementer Perspective

No specific recommendations.

12.1.13 Test

The HIMSS IIP tests this requirement by requiring the immunizations provided during the test are presented for patient access (e.g., through a portal) with the ability to print.

12.1.13.1 Data Elements

Not applicable.

Requirement 8.4 Provide Access to Update Immunization Information

The patient is able to add or request an update to immunization information for review by the provider.

12.1.14 Example of Scenario "Provide Access to Update Immunization Information"

Juana Mariela Gonzales' mother logs into Dr. Smith's EHR portal to view Mariela's immunization record. Mariela received an influenza vaccination at a local pharmacy. Mrs. Morales enters the information into Mariela's record including lot number and expiration date indicated on the slip she received from the pharmacy. The information is presented to Dr. Smith for review.

12.1.15 Guidance

One-quarter of the products reviewed allow patients to enter specific information about immunizations they received in other settings and store the information as immunizations. All such products require providers to confirm the information entered by patients before it is included in the EHR immunization record, mostly using the reconciliation function. Other products allow patients to enter any information in a comment field that practices can review. These comments are neither specific to immunizations nor are they structured in any way.

12.1.15.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how to provide patients with the ability to annotate or update immunization information.

12.1.15.2 Focus on Provider and Implementer Perspective

Providers should consider participating in vendor activities to address the workflow and challenges of patients annotating or updating immunization information.

12.1.16 Test

The HIMSS IIP tests this requirement by verifying that the patient is able to provide immunization information electronically (through any electronic means e.g. patient portal) that will later be reviewed by the provider for consideration to be added to the EHR or other clinical software system.

12.1.16.1 Data Elements

Not applicable.

Requirement 8.5 Review Patient-Provided Immunization Information

The EHR or other clinical software system provides a mechanism for the provider to review patient-generated immunization data. It also provides a mechanism for the provider to update or annotate the immunization history, indicating the source of the information.

12.1.17 Example of Scenario "Review Patient-Provided Immunization Information"

Dr. Smith receives notification about information Juana Mariela Gonzales' mother entered into Mariela's immunization record. Dr. Smith reviews the information and can accept and/or annotate the information into the EHR immunization record as patient reported.

12.1.18 Guidance

Many products reviewed provide some mechanism for patients to provide information from the patient portal. Most products limit patient-provided information to a general comment section on the portal. Only a few products allow patients to enter their own vaccine information directly into a vaccine record.

Management of patient-provided information is a general issue; it is not limited to immunization information. Capabilities should evolve as general efforts for shared decision-making and patient generated data evolve.

12.1.18.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how to provide providers with ability to review and update or annotate the immunization records based on patient-provided information.

12.1.18.2 Focus on Provider and Implementer Perspective

Providers should consider participating in vendor activities to address the workflow and challenges of reviewing and annotating information based on patient-provided immunization data.

12.1.19 Test

The IIP tests this requirement by requiring that the provider is able to access and review within the EHR or other clinical system immunizations electronically provided by the patient (through any electronic means e.g., patient portal) during the test, and documenting within the EHR or other clinical software system the information as historical immunization information from the patient.

12.1.19.1 Data Elements

Not applicable.

13 CONFIGURATION AND OPERATIONAL MANAGEMENT

Background

13.1.2 General Description of Configuration and Operational Management

The Configuration and Operational Management describes configuration and acknowledgment reporting requirements for EHRs and other clinical software systems to enable communications and semantic interoperability. These requirements are generally not end-user-facing requirements but are requirements applicable to setting up and maintaining connection and content to enable optimal interoperability with the IIS. This set of requirements also includes acknowledge reporting requirements which addresses data content

issues. Such issues are handled by a variety of staff depending upon the organization size and staffing but are typically not handled within the clinical aspects of the EHRs or other clinical software systems.

13.1.3 Who Performs Configuration and Operational Management

- Interface analysts
- Clinical or administrative support staff
- EHR or other clinical software system customer support

13.1.4 Examples of Work in This Area

- EHRs and other clinical systems need to support annual new influenza vaccine updates.
- CDC has published a SOAP-based CDC WSDL which has been adopted by more than 75% of the IIS community in the US.
- AIRA has published a list of data quality related error codes, some of which can inform data quality checks within the EHR or other clinical system.
- The IIP Collaborative has produced a white paper offering guidance for Acknowledgment Reporting: *Aggregate Immunization Acknowledgment Message Reports Guidance White Paper.*

Requirement 9.1 Add New Vaccine Codes

Add codes to support new vaccines. This includes vaccine codes (CVX), National Drug Codes (NDC), and Vaccine Information Statement codes (VIS).

13.1.5 Example of Scenario "Add New Vaccine codes"

A new vaccine is available to combat a new virus. A CVX code is released, and one or more vaccine products are available for vaccine administration. A VIS is available for this new vaccine, with the associated VIS fully encoded text string that is used for reporting to the IIS. The individual responsible for configuring the EHR or other clinical system configures the system to recognize these new vaccine CVX, NDC, and VIS information.

13.1.6 Guidance

Significant challenges exist with regularly updating, accurately cross-walking and consistently storing all variations across vaccine code sets. NDCs, in particular, present challenges between unit of use and unit of sale NDCs, 10- and 11-digit NDCs, hyphens vs. no hyphens, etc. Timely updates are also critical. This is especially challenging with influenza codes, as they change annually, and information about new codes may not be available as early as needed. There are also issues related to trial vaccines not being assigned codes until they move out of the trial period.

Inconsistent or less than timely code sets coded into and/or stored by the IIS can adversely affect an individual's consolidated record and forecast, as well as the IIS vaccine inventory and accountability.

CDC maintains the tables and crosswalks across vaccine code sets (NDC, CVX, MVX, and CPT) and has also released new functionality (or management service) to access and download these code sets.

13.1.6.1 Focus on Vendor Perspective

Similar to IIS, inconsistent or less than timely storage and messaging of vaccine code sets entered and/or queried by EHRs can adversely affect the completeness and accuracy of an individual's clinical record. Submitting incorrect codes can also affect inventory and accountability for those providers receiving publicly funded vaccine, an issue which could put their access to publicly funded vaccine into jeopardy, or even result in fraud charges in the most extreme cases.

While currently a largely manual process, further advancements toward a more automated availability and system synchronization with new code availability will be an area for future enhancements.

13.1.6.2 Focus on Provider and Implementer Perspective

Providers should encourage optimization of these new vaccine update capabilities by their vendor to improve optimal documentation of new vaccine information.

13.1.7 Test

Refer to the test script scenario that includes the requirement New Vaccine Requirements. The script also indicates successful performance for each of the test sections. This introductory test anticipates manual data entry, but opportunities to improve automation and synchronization will be monitored through the HIMSS IIP Collaborative, and this test may be updated as such solutions evolve.

13.1.7.1 Data Elements

CVX Code, CVX Description, NDC Code, NDC Description, VIS Fully Encoded Text-String, VIS Publication Date. Additional maintenance attributes and detailed description information may also be documented but are not prescribed at this time by this requirement.

Requirement 9.2 Configure SOAP-based CDC WSDL for Transport

The EHR or other clinical software system configures connectivity using the SOAP-based CDC WSDL and demonstrates compliance with the transport standard.

13.1.8 Example of Scenario "Configure SOAP-based CDC WSDL for Transport"

Dr. Smith needs her EHR configured to connect to the state IIS. Using the SOAP-based CDC WSDL transport standard, the individual responsible for configuring the interface establishes the connection between the EHR and the IIS.

13.1.9 Guidance

Although standardization among EHRs and IIS has increased in the last several years, considerable variability in the use of transport protocols still exists. This variability may involve differences in the transport methods supported by each system (e.g., SOAP vs. REST) or specifics around how the method is implemented. Variability results in considerable burden for health care providers, EHR developers, and IIS as it creates the need to establish custom interfaces in order to effectively exchange immunization data. Customization increases costs, prolongs the onboarding process to establish data sharing connections, and ultimately contributes to incomplete immunization data for clinical and public health decision-making.

For nearly a decade, SOAP Web Services has been identified as the transport standard for immunization data for the IIS community. In 2011, the CDC and AIRA convened an expert panel to recommend a transport protocol for exchanging immunization data. The panel of 41industry experts representing CDC, ONC, AIRA, EHRA, IHS, IIS, IIS technology partners, and EHR companies - selected SOAP Web Services as the preferred standard. In addition, CDC developed a common Web Services Definition Language (WSDL) to aid IIS and EHRs developers with adoption and implementation of the standard. Together, they represent the standard for transport of immunization messages put forth by the CDC to facilitate immunization information sharing.

13.1.9.1 Focus on Vendor Perspective

The majority of US IIS systems (75%+) have adopted this SOAP-based CDC WSDL for transport. In order to optimize interoperability and minimize variability, EHRs or other clinical software systems should support this transport standard.

13.1.9.2 Focus on Provider and Implementer Perspective

Providers will benefit from improved onboarding with the majority of the IIS by using an EHR or other clinical software system that supports the SOAP-based CDC WSDL.

13.1.10 Test

Refer to the test script scenario that includes the requirement Configure SOAP-based CDC WSDL for Transport. The script also indicates successful performance for each of the test sections. This test leverages the same NIST tool capabilities used for testing the IIS support of this standard transport.

13.1.10.1 Data Elements

Not applicable.

Requirement 9.3 Support Data Quality Checks

The EHR or other clinical software system integrates additional data quality checks into IIP Testing & Recognition to improve data quality and reduce rejections.

13.1.11 Example of Scenario "Support Data Quality Checks"

Dr. Smith attempts to document vaccination information with inconsistent clinical content (e.g., route is inconsistent with the vaccine administered). The EHR notifies Dr. Smith of the inconsistency before the record is saved such that when the information is transmitted to the IIS, the inconsistency will not trigger a warning or error from the IIS.

13.1.12 Guidance

After a vaccine is administered, a health care provider records the vaccine administration information in their EHR. EHR products often include functionality to promote data quality like drop-down menus and logic or checks. The EHR then submits the immunization data to the IIS.
Following receipt of this immunization data, the IIS reviews the information for data quality before incorporating the information into the IIS. For submissions containing errors, all or part of the submission may be rejected by the IIS depending on the error. To ensure the immunization data is accepted into the IIS, the health care provider would need to investigate the errors and take action to correct and/or resubmit as necessary.

In order to minimize data quality related rejections, data quality check can be incorporated into the workflow steps where the potential data entry issues occur. AIRA has published a set of National Error Codes. The goal of this guidance document is to reduce variability in the use of error codes in acknowledgement messages, particularly the ERR-5 code set for Application Errors. Specifically, this guidance expands the list of national error codes to address common error scenarios encountered during implementation by multiple jurisdictions but not represented in the original list of standard error codes. Among the error codes defined to-date, some may be mitigated at the point of care or data entry.

13.1.12.1 Focus on Vendor Perspective

Vendors should consider incorporating data quality verification to minimize the potential burden on the provider clinical and support staff that may be responsible for resolving data quality rejections.

13.1.12.2 Focus on Provider and Implementer Perspective

Providers will find that minimizing errors at the point of care or data entry can minimize follow-up efforts and data corrections resulting from rejected messages submitted to the IIS. While this will address only a subset of prospective errors, it will minimize the burden associated with error correction and resubmission to the IIS. Improved successful transmissions to the IIS will also result in improved comprehensive data returned from the IIS when querying for the vaccine history and forecast.

13.1.13 Test

Refer to the test script scenario that includes the requirement Data Quality Checks. The script also indicates successful performance for each of the test sections. These data quality checks are incorporated into the clinical workflows where documentation of the relevant information occurs. Among these are the following that have mitigations that are incorporated into the test plan:

- 2002: Indicates that the date of birth messaged in PID-7 is after the date of death messaged in PID-29.
- 2008: Indicates that either a refusal reason was messaged in RXA-18 when the completion status in RXA-20 was not RE or a valid refusal reason was not messaged when the completion status was RE.
- 2013: Indicates that the funding source code in an OBX segment conflicts with other data in the message (eligibility, age etc.).
- 2014: Indicates that the administration amount is inconsistent with the vaccine administered.
- 2016: Indicates that the administration route is inconsistent with the vaccine administered.
- 2100: Indicates that any date field is in the future. Specific errors for date transmitted in an OBX are also provided.
- 2101: Indicates that a contraindication effective date messaged in OBX-5 is in the future.
- 2102: Indicates that a VIS given date messaged in OBX-5 is in the future.
- 2103: Indicates that a VIS publication date messaged in OBX-5 is in the future.

- 2104: Indicates that a historical dose is being reported for the current date.
- 2202: Indicates individual components of the address are valid, but overall, the address is invalid (conflict between elements, non-existent address, etc.)
- 2204: Indicates that the administration being reported occurred too far in the past.
- 2207: Indicates a conflict between PID-29 and PID-30 or between PD1-16 and either PID field. In other words, one element indicates the patient is deceased and another element indicates the patient is not deceased.
- 2306: Indicates that the patient found is too old.

13.1.13.1 Data Elements

Not applicable.

Requirement 9.4 Add Jurisdiction-Specific Vaccine Eligibility Code

For the 2021/2022 IIP test plan update, this capability is introduced as a Discovery requirement. Developers will be requested to walk through "desktop testing" to identify current or prospective approaches. They will demonstrate the capability if the functionality exists. The IIP observer will record the process to evaluate whether this capability should be included in future testing.

The EHR or other clinical software system demonstrates the ability to configure publicly funded dose level vaccine eligibility codes per jurisdictional requirements. This includes tracking and exchanging jurisdiction-specific dose level eligibility code(s) for administered vaccines. This capability only applies to newly administered doses, not historical doses.

13.1.14 Example of Scenario "add jurisdiction-specific vaccine eligibility code"

The EHR is reporting to a jurisdiction with a unique jurisdiction-specific vaccine eligibility code. The individual responsible for configuring the EHR or other clinical system configures the system to support recording and submitting this new

code. A patient presents who is eligible for the jurisdiction-specific program. The clinician selects the vaccine product funded by that program, documents the eligibility for the jurisdiction-specific product in the patient's record, and administers the dose using the vaccine product funded by this program. When the visit is completed, the EHR or other clinical system transmits the vaccination record to the IIS, reporting the vaccine eligibility code for the program under which the product was administered.

13.1.15 Guidance

Participation in a jurisdiction-specific vaccine program requires accountability for each dose of vaccine administered. This is often accomplished through submission of a dose level eligibility code via data exchange or when adding immunizations via the IIS user interface.

Dose level eligibility describes the reason the patient is eligible to receive a vaccine provided through a jurisdiction-specific vaccine program. For example, in 2017 the Florida Department of Health funded hepatitis A vaccines for residents without private insurance. Providers participating in the program were required to indicate a patient was eligible for the program in the VXU messages sent to the IIS.

The immunization program will use this data to ensure that participating provider organizations are accountable for all federally or jurisdiction-supplied vaccines. Additionally, IIS and providers may use this data to inform future vaccine needs and ordering activities. Dose level eligibility may also be used in IIS to support other processes during data exchange, such as monitoring utilization. IIS teams may work closely with immunization program managers and VFC managers to ensure that requirements for eligibility coding and data submission are clear and shared with provider organization partners as well as EHR partners.

It is important to note that, depending on the vaccine supply model implemented by an immunization program, dose level eligibility may be managed differently. Jurisdictions with a universal vaccine supply model may have different dose level coding requirements from jurisdictions that operate as VFC-only.

13.1.15.1 Focus on Vendor Perspective

EHRs should be flexible and configurable to allow for jurisdiction-specific eligibility codes to be documented in the patient record and submitted to the IIS. Submitting incorrect codes can affect monitoring utilization and accountability for those providers receiving publicly funded vaccines, an issue which could put their access to publicly funded vaccines into jeopardy, or even result in fraud charges in the most extreme cases.

13.1.15.2 Focus on Provider and Implementer Perspective

To ensure accountability for vaccines, providers should be able to record and submit the accurate code to ensure dose level reporting and appropriate inventory decrementing, where relevant.

13.1.16 Test

Refer to the test script scenario that includes the requirement for the Add Jurisdiction-Specific Vaccine Eligibility Code. The script also indicates successful performance for each of the test sections. This Discovery test anticipates manual data entry, but opportunities to improve automation and synchronization will be monitored through the IIP, and this test may be updated as such solutions evolve.

Data Elements

Dose level vaccine eligibility code and description are required. Additional maintenance attributes and detailed description information may also be documented but are not prescribed at this time by this requirement.

Requirement 9.5 Acknowledgment Data Reporting

For the 2021/2022 IIP test plan update, this capability is introduced as a Discovery requirement. Developers will be requested to walk through "desktop testing" to identify current or prospective approaches. They will demonstrate the capability if the functionality exists. The IIP observer will record the process to evaluate whether this capability should be included in future testing. The EHR or other clinical software system is able to generate an Aggregate Error Report using the acknowledgment error message data returned in the ACK response to

a vaccine update message (VXU/Z22). The report data must include the following data elements:

- Clinic code and name
- Patient identifier
- Vaccination date
- IIS error severity
- IIS error code and description

The aggregate report functionality should include grouping and sorting by error code, clinic, and vaccination date. Drill-down capability by error or date should also be supported as it is important to support identifying the source of the data errors and to correct the issue.

There are two options to meet this requirement:

- Creation of an aggregate error report by leveraging reporting functionality to produce an Aggregate Error Report provided by the EMR or other clinical software system
- ACK data export as described in the IIP *Aggregate Immunization Acknowledgment Message Reports Guidance White Paper*[1]:

Software developers who do not intend to incorporate aggregate acknowledgment report functionality must be able to support ACK data export functionality. This allows ACK messages received from an IIS to be downloaded in a common electronic format, including raw HL7, which can also be accessed by data analysts and/or third-party tools. The export functionality should allow the user to select a specified period and could have additional filtering capabilities.

Developers should note which option is selected and need not demonstrate both approaches. Whichever requirement is selected will be noted if a product achieves IIP recognition.

[1] Health Information and Management Systems Society Immunization Integration Program. Aggregate Immunization Acknowledgment Message Reports Guidance White Paper. Available at: https://www.himss.org/resources/aggregate-immunization-acknowledgment-message-reports-guidance-white-paper . Accessed 1 November 2021.

13.1.17 Example of Scenario "Acknowledgment Data Reporting"

Igor Inquirer, a clinical quality manager at Huge Health System is contacted by Sally State, the Vaccines for Children program manager. Sally informs Igor that as calculated by the State Public Health Agency's IIS, Huge Health Systems Pediatrics' childhood series immunization completion rates have plummeted from 98% to 0%.

Igor contacts his colleague Allison Analyst and asks if she can take a look at the issue.

Using Native Reporting Features

Allison is able to use Huge Health Systems EMR Acknowledgment Data Reporting system to generate an aggregate report of all errors reported in the Acknowledgment messages received from the IIS during the past seven days which is grouped by error code and is sorted by date. The drill-down functionality is used to drill down by vaccine product.

Using Data Extract Features

Allison is able to use Huge Health Systems data extractor to create a structured file noting errors reported in the acknowledgment messages received from the IIS during the past seven days.

The file includes the following data elements:

- clinic code and name
- patient identifier
- vaccination date
- IIS error severity
- IIS error code and description

As a post-condition, she can load the data file into her business intelligence and report creator which is then accessible to Igor. The report lists fatal errors that prevent State Public Health Agency's IIS from accepting data sent by Huge Health Systems Pediatrics during the past seven days.

Using the report within Huge Health System's Report Viewer Portal, Igor is able to determine that all 100 submissions indicating patients were administered rotavirus vaccine doses have been rejected by the IIS. The report indicates 100 instances of the same error from the IIS: "2010 Product/manufacturer not in agreement: RXA-5=00006-4047-2^ROTATEQ^NDC & RXA-17=SKB^GlaxoSmithKline^MVX".

Igor checks with Clara Clinical-Manager at Huge Health System Pediatrics who indicates that the clinic uses ROTATEQ made by Merck and Company. Igor also checks with Phillip Pharmacist, who tells Igor that Huge Health System exclusively uses ROTATEQ which is the only rotavirus vaccine available from Huge Health System's drug distributor. Phillip also notes that GlaxoSmithKline makes a rotavirus vaccine product called "ROTARIX," but it is not used by Huge Health System. Igor now understands there is the problem with the EHR-IIS interface: ROTATEQ is made by Merck and Company, but the interface indicates GlaxoSmithKline is the manufacturer. Igor then checks with Tina Techie who notes a recent change by Erin Errormaker. Tina discovers Erin made an error when mapping the interface's vaccine code set. Tina Techie consults with Igor and Phillip and then updates the code tables. Tina also updates routine table maintenance to leverage downloadable tables in order to prevent the error from occurring again. Tina is also able to correct the errors by sending delete messages for all records with the error and then sends add messages to the IIS.
Igor and Allison work together on an automated process that will extract the data needed for the report and load it into Huge Health System's Report Viewer Portal each week. Igor is now able to review updated versions of the report weekly without having to ask Allison.

13.1.18 Guidance

EHR and other clinical software systems should provide a mechanism to generate reports to enable the clinical site to review, evaluate, and correct the underlying issues surrounding fatal errors noted by IIS through ACK messages in aggregate. If this functionality is not provided within the EHR or other clinical software systems, to improve data quality, these same products should provide users with the ability to export ACK data so it may be used by third-party tools to enable users to evaluate fatal errors noted by IIS.

13.1.18.1 Focus on Vendor Perspective

Vendors should work with customers to determine effective ACK data reporting functionality needed for user generated reports. For example, the ERR-5 code and description, date, and segment/field to be available for reporting, along with a mechanism to identify the facility, and patient identifier to allow for drill-down. The aggregate report functionality should include grouping and sorting by error code, clinic, and vaccination date. Drill-down capability by error or date is important to support identifying the source of the data errors and to correct the issue. Additionally, vendors may work with customers to determine effective aggregate error reports useful for immunization interface management.

13.1.18.2 Focus on Provider and Implementer Perspective

Providers should encourage optimization of these capabilities by their vendor to improve IIS data quality. This functionality may be reserved for administrative, and analyst EHR users. This functionality may not be appropriate for end-user or clinician roles.

13.1.19 Test

Refer to the test script scenario that includes the requirement Acknowledgment Data Reporting. The script also indicates successful performance for each of the test sections.

13.1.20 Data Elements

To facilitate effective report development the following data elements must be available to users for report data, whether used for reporting within the EHR or other clinical software system or as exported content to be used in a reporting tool:

- Meta information including: the organization, clinical facility or clinician that the report describes; the time period covered by the report
- IIS error severity
- IIS error message

Additional data elements may be included if desired but are not required for IIP recognition.

14 APPENDIX A: DATA ELEMENTS FOR FUNCTIONAL TESTING

Data Elements for Patient Demographics

The HL7 2.5.1 Immunization Implementation Guide lists 39 data elements for patient demographic information for use to identify unique patients. 7 Required (R), 22 Required if Exist (RE), 1 Conditional (C), 8 Optional (O) and 1 Not Applicable (NA). Exhibit 13 lists these data requirements.

PATIENT DEMOGRAPHIC INFORMATION		
Concept Name	Description	R/RE/O
Patient ID	Medical Record number, or other identifier (HL7 2.5.1 previously listed as "Medicaid Number")	R
Patient ID Assigning Authority:	Assigning Authority ID (i.e., owning source)/Facility Name. The name may be vendor supplied.	R
Patient ID: Type (e.g., medical record number, IIS ID)		R
Patient Name: First		R
Patient Name: Middle		RE
Patient Name: Last		R
Patient Date of Birth		R
Birth Time		O
Patient Gender (Administrative Sex)	Looking for "Administrative Sex" - Statement in HL7 2.5.1 standard 'Gender' may be inconsistent with MU	R
Patient Multiple Birth Indicator		RE
Patient Birth Order	If multiple birth indicator is checked - Conditional	C
Responsible Person Name: First		RE
Responsible Person Name: Middle		RE
Responsible Person Name: Last		RE
Responsible Person Name: Relationship to Patient		RE
Mother's Name: First		RE

PATIENT DEMOGRAPHIC INFORMATION		
Mother's Name: Middle		RE
Mother's Name: Last		RE
Mother's Name: Maiden Last		RE
Patient Address: Street		RE
Patient Address: City		RE
Patient Address: State		RE
Patient Address: Country		RE
Patient Address: Zip code		RE
Patient Address: County of Residence		O
Preferred Contact Information		NA
Race		RE
Ethnicity		RE
Birthing Facility Name		RE
Birthing Facility Location Address		RE
Patient Birth State		RE
Patient Primary Language	Important to Registry for managing follow-up	O
Patient Telephone Number		RE
Patient Telephone Number Type (e.g., home, cell)		RE
Patient E-mail Address		O
Publicity Code	Level of privacy for recall (parent, family, patient only, etc.)	O
Protection Indicator	Whether the information can be shared with others including registry (opt-in, opt-out) and other clinicians – often state dependent	O
Protection Indicator Effective Date	Date of the decision about the protection level	O
Immunization Registry Status	Indication the patient is active or inactive in the practice	O

Exhibit 13: Patient Demographic Information included in the HL7 2.5.1 Implementation Guide (R = Required, RE = Required if Exists, O = Optional)

Data Elements for Sharing Immunization History Information

The HL7 2.5.1 Immunization Implementation Guide lists data elements for transmitting immunization information, whether the data is historical or part of a report for an immunization recently provided. Each element is Required (R), Required if Exists (RE), Conditional (C), Optional (O) or Not Applicable (NA). Exhibit 14 lists the immunization history data elements.

IMMUNIZATION HISTORY DATA ELEMENTS		
Concept Name	Description	R/RE/O
Entered BY		RE
Ordering Provider		RE/O-Historical
Entering Organization		RE/O-Historical
Administration Notes (Vaccine Event information source)	Can be structured using HL7 2.5.1 options for vaccine event information source, or equivalent text	C (R-status is Completed or Partially administered/O if Non-administration)
Date/Time of Start of Administration		R
Vaccine Administered	Can be generic name or equivalent text (e.g., brand name of vaccine product)	R
Administered Amount (of Vaccine)		R
Administered Units (of Measure)		'R' if administered amount NOT '999'/O)
Administering Provider	The person who administers the dose to the patient	C (RE - New Administrations/O - Historical)
Administered-at Location		C (RE - New Administrations/O — Historical)
Lot Number		C (RE - New Administrations/O - Historical)

IMMUNIZATION HISTORY DATA ELEMENTS		
Substance Expiration Date		C (RE - New Administrations/O - Historical)
Substance Manufacturer Name	Manufacturer Name and MVX code; can be equivalent text	C (RE - New Administrations/O - Historical)
Completion Status	CP – Complete, RE – Refused, NA – Not administered, PA – Partially administered	RE
Route of Administration		RE
Administration Site		RE

Exhibit 14: Immunization History Data Elements included in the HL7 2.5.1 Implementation Guide Send Unsolicited Immunization Update Using a VXU (Z22) message (R = Required, RE = Required if Exists, O = Optional)

Data for Administer and Record Vaccine

Exhibit 6, Administer and Record Vaccine, provides the list of data elements used to test documentation of vaccine administration. The HL7 2.5.1 Immunization Implementation Guide informed the list since the system subsequently transmits the data in a report to the public health immunization registry. [Each element is Required (R), Required if Exists (RE), Conditional (C), Optional (O).] Exhibit 15 lists the data elements required to record immunizations.

ADMINISTER AND RECORD VACCINE		
Concept Name	Description	R/RE/O
Entered by		RE
Ordering Provider		RE
Vaccine Event Information Source	New or historical immunization (and source of history, e.g., patient reported, etc.)	C (R - Vaccine is Completed or Partially Administered/O)
Entering Organization		RE
Vaccine Type	Can be structured or equivalent text (i.e., narrative text with the expected information)	R

ADMINISTER AND RECORD VACCINE		
Date/time Vaccine Administered		R
Dose Number in Series		O
Number of Doses in Primary Immunization Series		O
Vaccine Administered	Can be structured or equivalent text (i.e., narrative text with the expected information)	R
Vaccine Lot Number		R
Vaccine Expiration Date		R
Vaccine Manufacturer Name		R
Dose – Administered Amount of Vaccine		R
Administered Units (of Measure)		C
Administering Provider		R
Administered-at Location		R
Completion Status	CP – Complete, RE – Refused, NA – Not administered, PA – Partially administered	RE
Route of Administration		RE
Administration Site		RE
VFC/grantee program vaccine eligibility at dose level		R
VIS Type & Publication Date		C (R for certain vaccines)
VIS Date given to patient		C (R for certain vaccines)
Adverse Reaction From This Dose		O

Exhibit 15: Administer and Record Vaccine – captured data elements (R = Required, RE = Required if Exists, O = Optional, C = Conditional)

Data Elements for Reporting Vaccine Administration to Registries

Exhibit 7, Transmit Standard Patient Immunization History Report, provides the list of data elements used to transmit vaccine administration information to the registry. The HL7 2.5.1 Immunization Implementation Guide informed the list. Each element is Required (R), Required if Exists (RE), Conditional (C), Optional (O). Exhibit 16 lists data elements used in transmission of the patient immunization history to the IIS.

TRANSMIT STANDARD PATIENT IMMUNIZATION HISTORY REPORT	
Concept Name	R/RE/O
Patient Identifier Number	RE
Assigning Authority	RE
Patient Identifier Type Code	RE
Patient Name	RE
Mother's Maiden Name	RE
Date/Time of Birth	RE
Sex	RE
Patient Address	RE
Phone	RE
Multiple Birth Indicator	RE
Birth Order	RE
Entered by	RE
Ordering Provider	RE
Vaccine Event Information Source	C (R - Vaccine is Completed or Partially Administered/O)
Entering Organization	RE
Vaccine Type	R
Date/time Vaccine Administered	R
Dose Number in Series	O

TRANSMIT STANDARD PATIENT IMMUNIZATION HISTORY REPORT	
Number of Doses in Primary Immunization Series	O
Vaccine Administered	R
Vaccine Lot Number	R
Vaccine Expiration Date	R
Vaccine Manufacturer Name	R
Dose – Administered Amount of Vaccine	R
Administered Units (of Measure)	C (R - administered amount NOT '999'/O)
Administering Provider	R
Administered-at Location	R
Completion Status	RE
Route of Administration	RE
Administration Site	RE
VFC status	R
VIS type and Date	R
Adverse Reactions	O
Vaccination Contraindications	O
Vaccine Refusal	O
Dose Number in Series	O
Number of Doses in Primary Immunization Series	O

Exhibit 16: Transmit Standard Patient Immunization History Report (R = Required, RE = Required if Exists, O = Optional, C = Conditional)

15 APPENDIX B: CROSS-WALK OF CAPABILITIES TO TEST SCRIPT, FEBRUARY 2022

The full test plan including detailed Test Case Groups and Test Cases are available at: https://hl7v2-iz-cdc-testing.nist.gov/iztool/#/cb.
Exhibit 17 abbreviates the Test Case Groups follows:

- Group 1: Initial Data Load

  - Patient1: Juana Mariana Vazquez
  - Patient2: Juan Marcel Marina
  - Patient3: Juana Mariela Gonzales
  - Patient4: Juana Maria Gonzales
  - Patient5: Anita Francesca Marina
  - Inventory6: Enter Inventory
  - Configure7: Manage Configuration
- Group 2: Juana Mariana Vazquez Visit
- Group 3: Juan Marcel Marina Visit
- Group 4: Juana Mariela Gonzales Visit
- Group 5: Juana Maria Gonzales Visit
- Group 6: Reporting
- Group 7: Anita Francesca Marina Visit
- Group 8: Review Inventory

User Workflow	**Immunization-Related Requirements**	**Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step***
1. Register and Identify Patient(s)	1.1 Register new patients	Group 1 (Initial Data Load) / Patients1-5, / Enter Initial Demographic Data
	1.2 Select new patient	Groups 2-5/ Query the Registry/ *Select Patient*
	1.3 Select one or more patients	Group 7/ Query the Registry for Anita Francesca Marina/*Select the Set of Patients to be Seen in the Vaccination Clinic*
2. Manage External Query, Response, and Reconciliation	2.1 Batch Request/Receive Patient Immunization History(ies)	N/A
	2.2 Request / Receipt of Patient Immunization History	Group 2/ Query the Registry/ *Query Registry for*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		vaccination history and forecast **and** *Group 3-5,7 Query the Registry/ Query Registry for vaccination history and forecast* Group 5 Query the Registry/ *Query Registry for Vaccination History and Forecast Too Many Matches Found Response* **and** *Query Registry for Vaccination History and Forecast No Persons Found Response* **and** *Query Registry for Vaccination History and Forecast*
	2.3 Compare IIS Immunization History to EHR Immunization History	Group 1 (Initial Data Load)/Patient1/ *Enter Initial Immunization Data: Immunizations from practice* *Enter Initial Immunization Data from Another Practice* *Enter Initial Immunization Data Reported by Parent*Group 1 (Initial Data Load)/Patient5/ *Provider Review and Entry of*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Immunization Data for Anita Francesca Marina Provided by Patient **and** Group 2: Query Registry/ *View and Compare response*
	2.4 Request/Receive Patient Immunization Data and Identify Source	Group 1(Initial Data Load)/Patient1 *Enter Initial Immunization Data: Immunizations from practice* *Enter Initial Immunization Data from Another Practice* *Enter Initial Immunization Data Reported by Parent* Group 1 (Initial Data Load)/Patient5/ *Provider Review and Entry of Immunization Data for Anita Francesca Marina Provided by Patient* **and** Group2/ Query Registry/ *View and Compare Response to Request for Vaccination History* **and** *Reconcile and import vaccinations from Evaluated History and Forecast* **and** Group2/ Enter Orders and Immunizations

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Enter Immunization Data for MMR Given 2 Weeks Prior **and** Groups 3-5: Query Registry/ *View and import response to request for vaccination history* –**and** Group 5: Query Registry/ *Error Handling – Too Many Matches Found* **and** *Error Handling - No Persons Found*
	2.5 Store Immunization Registry Vaccine History and Forecast	N/A
	2.6 Notify IIS of Differences Between EHR Data and IIS Response	N/A
3. Manage Information for Clinical Decision-Making	3.1 View Immunization Forecast	Groups 2/ Query the Registry/ *View the vaccination forecast*
	3.2 View Reconciled Immunization Forecast	Group 1 (Initial Data Load)/Patient5/ *Enter Clinical History* Groups 2-5,7: Query the Registry/ *View the updated vaccination forecast*
	3.3 Modify Antigen Recommendations	N/A

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
	Based on Allergy History	
	3.4 Modify Antigen Recommendations Based on Active Diagnoses	Group 1 (Initial Data Load)/Patient2/ *Enter Clinical History* **and** Group 3/ Query the Registry for Juan Marcel Marina/ *View the vaccination forecast for Juan Marcel Marina* **and** Group 4/ Enter Orders and Immunizations/ *Enter Initial Clinical Information*
	3.5 Update Patient Immunization Schedule	Group 1 (Initial Data Load)/ Configuration7/Update Vaccine Schedule Information
	3.6 Receive Dose Not Indicated Alert for Single Vaccine Order	Group 1 (Initial Data Load)/ Patient 1/Enter Initial Immunization Data: Immunizations from practice Group 2/ Query the Registry/ *View and Compare response to request for vaccination history* *Query Registry for vaccination history and forecast* **and** *Reconcile and import vaccinations from Evaluated History and Forecast*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		and Group 3/ Query the Registry/ *View and import response to request for vaccination history* **and** Group 2/Enter Orders and Immunizations/ *Enter Immunization Data for MMR Given 2 Weeks Prior Attempt to order Varicella Dose* **and** Group 3/ Enter Orders and Immunizations/ *Orders administration of DTaP vaccine and alerted that the dose is too early*
	3.7 Receive Dose Not Indicated Alert Upon Vaccine Administration	Group 3/Enter Orders and Immunizations/*Attempt to administer DTaP vaccine and alerted that the dose is too early*
	3.8 Save History of Clinical Decision Support Recommendations	N/A
4. Manage Inventory	4.1 Display Available Vaccine Antigens	Group 1 (Initial Data Load)/ Inventory/View Inventory/
	4.2 Update Vaccine Inventory from Patient Dosage Administration	Group 1 (Initial Data Load)/ Inventory/Enter Vaccine Inventory/

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
	4.3 Update Vaccine Inventory from Stock Receipt	Group7/View Inventory/View updated vaccine inventory
	4.4 Notify of Vaccine Dose Expiration	Group 3/ Order and Immunize Patient/ *Records Hepatitis B Vaccine lot number with expired lot alert*
	4.5 Produce Vaccine History Report	Group 7/ Produce Inventory Report of Remaining Stock / *Produce Stock Inventory Report - Expiration Date Sort* *Produce Stock Inventory Report - Funding Source Sort*
5. Administer and Report Immunization	5.1 Provide Access to Vaccine Information Statement(s)	N/A
	5.2 Record Vaccine Administration Deferral	Group 2/ Enter Orders and Immunizations/ *Order IPV and view prior reaction* **and** *IPV Parental Refusal* **and** Group 4/ Enter Orders and Immunizations/ *Enter Initial Clinical Information* **and** *Enters a deferral for the vaccines due*
	5.3 Record Past Immunizations	Group 1 (Initial Data Load)/Patient1/

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Enter Initial Immunization Data: Immunizations from practice *Enter Initial Immunization Data from Another Practice* *Enter Initial Immunization Data Reported by Parent* Group 1 (Initial Data Load)/Patient5/ *Provider Review and Entry of Immunization Data for Anita Francesca Marina Provided by Patient* Group 2/ Enter Orders and Immunizations *Enter Immunization Data for MMR Given 2 Weeks Prior*
	5.4 Notify of Vaccine Dose Ineligibility	Group 3/ Enter Orders and Immunizations/ *Records Influenza Vaccine administration with VFC eligibility checking*
	5.5 Document Vaccine Ineligibility Override Reason	N/A
	5.6 Enter Vaccination Order	Group 2/ Enter Orders and Immunizations/ *Order IPV and view prior reaction **and** order influenza vaccine* Group 3/ Enter Orders and Immunizations/

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Orders administration of Hepatitis B vaccine **and** *Orders administration of DTaP vaccine and alerted that the dose is too early*
	5.7 Review Patient Immunization History	Group 2/Query the Registry and Group/ *View and Compare response to request for vaccination history* *Reconcile and import vaccinations from Evaluated History and Forecast* Group 3-5,7/Query the Registry and Group/ *View and import response to request for vaccination history*
	5.8 Link Standard Codes to Immunization Data	Group 2-4, 7/ Transmit Immunization Report/ *Transmit the immunization report to the Immunization Registry* **and** Group 3/ Transmit the immunization report/ *Transmit Delete for Vaccine Recorded in Error* **and** Group 5/ Transmit Immunization Report - Error Handling /

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Transmit the immunization report to the Immunization Registry – Fatal Error **and** *Transmit the Immunization Report for Juana Maria Gonzales - warning handling* **and** *Transmit the Immunization Report for Juana Maria Gonzales - Multiple warning handling*
	5.9 Record Vaccine Administration	Group 2/ Enter Orders and Immunizations/ *Vaccine Dosing and Administration route with Data Quality Checks* **and** *Record Influenza Vaccine Administration* Group 3/ Enter Orders and Immunizations/ *Attempt to record HepB Vaccine administration route with data validation checking* **and** *Record Hepatitis B Vaccine administration* **and** *Record Influenza Vaccine administration* Group 5/ Enter Orders and Immunizations/

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Record Combo Vaccine administration Group 7/ Enter Orders and Immunizations/ *Record Vaccine Administration for Hepatitis B* **and** *Record Vaccine Administration for New Vaccine*
	5.10 Produce Standard Patient Immunization History Report	Groups 2/ Display Immunization Report/ *Produce an immunization report*
	5.11 Transmit Standard Patient Immunization History Report	Group 2-4, 7/ Transmit Immunization Report/ Transmit the immunization report/ *Transmit the immunization report to the Immunization Registry* **and** *Receive ACK Z23 from Immunization Registry* **and** Group 3/ Transmit the immunization report/ *Transmit Delete for Vaccine Recorded in Error* **and** Group 5/ Transmit Immunization Report/ Transmit Immunization Report - Error Handling /

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Transmit the immunization report to the Immunization Registry – Fatal Error **and** *Receive ACK Z–3 Fatal Error - CVX Code* **and** *Transmit the Immunization Report for Juana Maria Gonzales - warning handling* **and** *Receive ACK Z23 Warning - Invalid Value* **and** *Transmit the Immunization Report for Juana Maria Gonzales - Multiple warning handling* **and** *Receive ACK Z23 Multiple Warnings*
	5.12 Produce Configurable Patient Immunization History Report	N/A
	5.13 Transmit Configurable Patient Immunization History Report	N/A
	5.14 Produce Immunization Forecast Report	Groups 2-4/ Display Immunization Report/ *Produce an immunization report*
	5.15 Record Vaccine Information by Scanning 2D Barcode Found on Unit-of-Use	Group 2/Enter Orders and Immunizations/*Vaccine Dosing and Administration Data Quality Checks* **and**

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
	for Vaccine Administration	*Record Influenza Vaccine administration* Group 3/ Order and Immunize Patient/ *Records Hepatitis B Vaccine lot number with expired lot alert* **and** *Record Hepatitis B Vaccine administration* **and** *Records Influenza Vaccine administration with VFC eligibility checking* **and** *Record Influenza Vaccine administration for Juan Marcel Marina* Group 5/Enter Orders and Immunizations/*Record Combo Vaccine administration* Group 7/ Enter Orders and Immunizations/ *Record Vaccine Administration for Hepatitis B* **and** *Record Vaccine Administration for New Vaccine*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
6. Manage Cohort of Patients	6.1 Produce Population-Level Report	Group 6 (Reporting)/ Due and Overdue Immunizations *Produce Overdue Immunizations Cohort Report*
	6.2 Notify Patients of Immunization Status	Group 7/Notify Patients of Immunization Status */Notify New Vaccine Candidate Patients*
7. Manage Adverse Event Reporting	7.1 Identify Adverse Event	Group 1 (Initial Data Load)/Patient1/ *Enter Initial Immunization Data for Juana Mariana Vazquez from Another Practice* **and** Group 2/ Transmit Immunization Report/ *Record an adverse reaction*
	7.2 Initiate and Submit a VAERS Report	N/A
	7.3 Notify of Previous Adverse Event	Group 1(Initial Data Load))/Patient1/ *Enter Adverse Reaction to the Polio Vaccine* **and** Group 2/Enter Orders and Immunizations/ *Order IPV and view prior reaction*
8. Provide Patient Access	8.1 Provide Access to Patient Immunization Record	Group 2/ Provide Patient Access to Immunization Report/ *Produce an immunization report for*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Juana Mariana Vazquez including all history Group 2/ Provide Patient Access to Immunization Report/ *Provide access to Printable Immunization Record for Juana Mariana Vazquez*
	8.2 Provide Access to Recommendations and Vaccine Information Statement(s)	Group 2/ Provide Patient Access to Immunization Report/ *Produce an immunization report for Juana Mariana Vazquez including all history* Group 2/ Provide Patient Access to Immunization Report/ *Provide access to Vaccine Information Statements*
	8.3 Provide Access to Printable Immunization Record	Group 2/ Provide Patient Access to Immunization Report/ *Provide access to Printable Immunization Record for Juana Mariana Vazquez*
	8.4 Provide Access to Update Immunization Information	Group 1 (Initial Data Load)/Patient 5/ *Anita Francesca Marina Electronically Submits Prior Immunization to Provider*
	8.5 Review Patient-Provided	Group 1 (Initial Data Load)/Patient 5/ *Provider Review and Entry of*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
	Immunization Information	*Immunization Data for Anita Francesca Marina Provided by Patient*
9. Configuration Management	9.1 Add New Vaccine Codes	Group 1 (Initial Data Load)/Configure7 /*Add New Vaccine Information*
	9.2 Adopt SOAP-based CDC WSDL for Transport	Group 1 (Initial Data Load)/Configure7 /*Configure SOAP-based CDC WSDL*
	9.3 Support Data Quality Checks	Group 1 (Initial Data Load)/Patient1/*Attempt to enter vaccination too long ago for Juana Mariana Vazquez* Group 1 (Initial Data Load)/Patient1/*Attempt to enter historical vaccination for current date for Juana Mariana Vazquez* Group 1 (Initial Data Load)/Patient5/*Demographic Data Quality Checks for Anita Francesca Marina* Group 2/Enter Orders and Immunizations/*Vaccine Refusal Data Quality Checks* Group 2/Enter Orders and Immunizations/*Vaccine Dosing and Administration Data Quality Checks* Group 4/Enter Orders and Immunizations/*Vaccine Deferral Data Quality Checks*

User Workflow	Immunization-Related Requirements	Bi-Directional Exchange Test Plan TestCaseGroup/ Test Case/ *Test Step*
		Group 7/Enter Orders and Immunizations/*Vaccine Administration Data Quality Checks*
	9.4 Add Jurisdiction-Specific Vaccine Eligibility Code	Group 1 (Initial Data Load)/Configure7 /*Configure Jurisdiction-Specific Vaccine Eligibility Code* Group 3/ Enter Orders and Immunizations/ *Record Hepatitis B Vaccine administration* Group 3/ Transmit the immunization report/ *Transmit the Immunization Report for Juan Marcel Marina* Group 3/ Transmit the immunization report/ *Transmit Delete for Vaccine Recorded in Error*
	9.5 Acknowledgment Data Reporting	Group 6 (Reporting)/ Acknowledgment Error Reporting / *Produce Acknowledgments Report*

Exhibit 17. Crosswalk of capabilities to test script

16 APPENDIX C: 2D BARCODE EXAMPLE

For the 2021/2022 test plan update, 2D barcode scanning has been added as a 90% Required capability. An example 2D barcode for a Hepatitis B vaccine, ENGERIX-B®, is provided below. The IIP test plan includes the actual unit of use 2D barcodes for the vaccines that are used during vaccine administration steps.

1. Example 2D barcode for ENGERIX-B® manufactured by GlaxoSmithKline:

2. Data encoded in the 2D barcode:
    a. Lot Number: 6332FK26
    b. Expiration Date: 12/31/2022
    c. GTIN: 10358160820431

17 APPENDIX D: DEPRECATED CAPABILITIES

17.1 Requirement 2.1 Batch Request / Receive Patient Immunization History

Most sites send multiple or sequential single queries to the IIS (rather than batch queries) for information to allow more direct matching of the response to the patient referenced in the EHR. Commenters suggested challenges matching the information returned from batch queries. In general, IIS are moving to sequential (or parallel) transactions in a synchronous manner.

17.2 Requirement 2.5 Store Immunization Registry Vaccine History and Forecast

The system stores the vaccine forecast and the vaccine history as they were received from the public health immunization registry or other sources. The information can be used for any later quality assurance activities that may be required.

17.2.2 Example of Scenario "Store Immunization Registry Vaccine History and Forecast (Audit Data)"

The vaccine history from the public health immunization registry did not include some vaccines that had been administered by Dr. Smith's practice. The original forecast suggests a schedule to administer some of the vaccines that were missing in the registry. After Dr. Smith reconciles the vaccine history, the additional doses suggested by the forecast are no longer needed. The EHR stores the original forecast in case there is ae audit.

17.2.3 Guidance

Feedback from EHR vendors and providers suggests that the value of the history from the immunization registry is to update patients' vaccination records in the EHR. During the reconciliation process, the provider determines which information to accept or which to reject as a duplicate. Once reconciliation has occurred (requirement 2.3) and the EHR presents an updated forecast (requirement 3.2), the value of storing the original

data set (history and forecast) received from the registry is not clear. Further feedback is invited about the value of this requirement.

October 2016 Addition: The term "audit" has been removed. The EHR should store the forecast used by the clinician to make decisions about which vaccines to give a patient at each visit. If the forecast received from the IIS is updated with a new forecast after immunization reconciliation, then the latter (updated) forecast is the one that should be stored as it drove the subsequent vaccine decisions. Clinicians need to view the most active forecast indicating the next dose(s) of vaccine to administer. The benefit of storing historical forecasts is to support quality assurance and medico-legal issues. Consideration about how to provide such information in should carefully address usability.

17.2.4 Vendor Perspective

Not applicable.

17.2.5 Focus on Provider and Implementer Perspective

Not Applicable.

17.2.6 Test

The IIP does not test this requirement.

17.2.7 Data Elements

Not applicable.

17.3 Requirement 2.6 Notify Public Health Immunization Registry (IIS) of Differences between EHR Data and IIS Response

After reconciling immunization history maintained in a provider's EHR and with immunization history from the public health registry, a provider may determine that some EHR-maintained information may be more correct than what is in the registry's history. The EHR should provide a mechanism to identify previously reconciled information so that the clinician does not need to reconcile the same information again. For example, the historical CVX code for a vaccine administered locally may be more specific in the EHR immunization record than the CVX code recorded by the IIS and included in the vaccine history received. Once the clinician has decided to retain the local CVX code for the vaccine administered, the EHR should have a mechanism such that it does not present the difference as a new variance requiring specific attention during the reconciliation process. New information available to the clinician and recorded in the EHR about historical immunizations that are absent from the IIS

history should be reported to the IIS using the standard HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.5 format.

17.3.2 Example of Scenario "Notify Public Health Immunization Registry (IIS) of Differences between EHR Data and IIS Response"

17.3.2.1 Example 1

The immunization history maintained in Dr. Smith's EHR for Juan Marcel Marina, age 3, includes the meningococcal MCV4P vaccine (Meningococcal A, C. Y and W135 – CVX code 114). The public health immunization registry history does not include this vaccine. The EHR then prepares and submits a report to the public health registry that lists the historical vaccine that was missing from the IIS record received.

17.3.2.2 Example 2

The diagnosis history maintained in Dr. Smith's EHR for Juan Marcel Marina, age 3, includes a clinical diagnosis of Hepatitis A disorder (SNOMED CT code 40468003) at age 18 months. Due to the diagnosis as evidence of immunity, the EHR does not include Hepatitis A vaccine in the vaccine recommendations (sometimes referenced as the EHR immunization schedule).

17.3.2.3 Example 3

The EHR contains laboratory evidence of immunity in Dr. Smith's EHR for Juan Marcel Marina, age 3. The evidence includes a SNOMED CT finding (278971009). Due to the serologic evidence of immunity, the EHR does not include Hepatitis A vaccine in the vaccine recommendations (sometimes referenced as the EHR immunization schedule).

17.3.3 Guidance

Experience reported by some EHR vendors and providers suggests that IIS routinely accept requests to update a record, but local and state business rules may prevent them from accepting the updates. IIS data represent the collection of all providers' submitted records. Examples include:

1. Some registries reportedly accept updated information only from the provider that administered the vaccine. However, registries are bound by local and state rules regarding what may be included.
2. Some providers indicate receiving documentation of historical vaccines that include inexact dates, indicating registries will not accept such information without an exact date.
3. Some providers indicate discrepancies between the specific CVX codes they record for vaccines they administer and the CVX code recorded by the registry (the registry using a more generic CVX code). These providers report that registries may

not accept the update with the correct code. The result is the discrepancy shows up every time the patient has an appointment, and a new query is sent to the registry.

4. The current interoperability standard does not include an indicator to identify that the provider considers a discrepancy in the data regarding administered vaccines. Feedback suggests that most IIS update information only if it is provided by the administering clinician, and the ability to modify immunization records is governed by jurisdictional restrictions about what types of data they can accept and store in their registries. However, to enhance usability, EHRs should have the ability to recognize differences in metadata that have been reviewed and rejected during the reconciliation process to improve usability and workflow.

The IIS community asked the IIP TAP to address a scenario in which a provider might incorrectly reconcile immunization data received from an IIS with data already present in the EHR. Consider the following scenario:

a. A provider accepts all IIS immunization data into the EHR, creating duplicate entries rather than updating existing information with that received from the IIS. The EHR now has two immunizations (duplicates) and the IIS has one immunization. Once the EHR user realizes the issue, the user deletes the duplicate record in the EHR, triggering a delete message to the IIS. The IIS subsequently deletes the only immunization it has. This leaves the EHR with one immunization and the IIS with none.
b. This scenario happened to at least one state IIS causing deletion of at least 11,000 immunizations. The investigation to track down legitimate versus accidental deletions required an enormous number of staff hours. At this time, the IIS turned off automatic deletions.
c. The IIS community is seeking advice regarding anything the HIMSS IIP can do to develop requirements to prevent such accidental deletion.

Note – In some cases, the immunization reconciliation activity results in retaining information in the EHR for which the IIS had different information. For example, the EHR includes a specific CVX code for an immunization administered at the local site and the CVX has assigned that administration a more generic CVX code. The HIMSS IIP test does not expect the provider to resend the original CVX code. However, if a clinician corrects an error in the local EHR documentation about an immunization administration, the correction should be sent to the IIS.

The IIP TAP addressed this concern, presenting the following considerations to manage the reconciliation process:

- De-duplication may occur in a number of scenarios, and it is not limited to the reconciliation process step.
- Specifying and documenting a full set of scenarios is a valuable first step to help address this issue.
- Adding a step to the text script prematurely may lead to unintended consequences and not fix the underlying issues.
- There are times when two immunization administration events for the same antigen on the same day are both appropriate (e.g., if the first administration was sub-potent since the patient pulled away from the needle).
- Differences in dates, CVX codes, etc. may also represent duplicates and the clinician site that administered the vaccine should be the arbiter of which is the best record to keep.

Feedback is invited about the value of Requirement 2.6. Further, collaboration among providers, software vendors, and public health registries through the HIMSS IIP may help identify the source of the discrepancies and recommend solutions.

17.3.4 Focus on Vendor Perspective

Vendors should collaborate with providers and public health immunization registries to harmonize requirements and determine workflow.

17.3.5 Focus on Provider and Implementer Perspective

Providers should collaborate with public health immunization registries and EHR vendors to harmonize requirements and determine workflow.

17.3.6 Test

The IIP does not test this requirement.

17.3.7 Data Elements

Not applicable.

17.4 Requirement 3.3 Modify Antigen Recommendations Based on Allergy History

The EHR or other clinical software system notifies the provider of any conflicts between recommended vaccines in the updated forecast and the patient's active allergies.

17.4.2 Example of Scenario "Modify Antigen Recommendations Based on Allergy History"

The system notifies the provider that Juan Marcel Marina, age 3 (birth date 12/24/2014) is allergic to latex. Therefore, the system recommends Rotavirus pentavalent (Rotateq) rather than Rotavirus monovalent (Rotarix) vaccine.

17.4.3 Guidance

All products reviewed allow entry of allergy and adverse reactions in the allergy list and/or on the patient's problem list. Less clear is the ability to ensure a provider is aware of an allergy or potential adverse reaction to the recommended vaccine product. Feedback to users about potential patient risks can be provided specific to the level of risk. Types of feedback defined in the context of software usability include:[59]

1. Notification: A notification is a visual clue or displayed message that informs a user but does not require any action (examples include visual clues such as a persistent banner, color change, bolding, etc. (E.g., "This patient is allergic to ___").
2. Alert: An alert or warning is displayed when user action may result in unintended consequences, for example loss of data, etc. These types of messages shall require the user to acknowledge the message before they can move on (e.g., click ok).
3. Errors: Error message should be displayed in plain language describing specific error condition and instructions for what steps a user needs to take. This condition requires the user to fix something before they can move on (e.g., fix this date, it is invalid).

Notification in this context indicates that the system provides indication, so the user is aware of a potential problem including the severity of previous reactions. Notification should include information, if available, about prior decisions, e.g., if a provider documented a reason to override notification about allergy or diagnosis in the past. The method for fulfilling the requirement is not prescriptive. Examples of notification include visual clues.

17.4.4 Focus on Vendor Perspective

Vendors should consider usability evaluation such as UCD to evaluate how the system handles notifications and alerts.

17.4.5 Focus on Provider and Implementer Perspective

Notifications and alerts can be a significant usability issue in EHRs. Providers should consider participating in vendor activities to address timely and appropriate notification.

17.4.6 Test

Updated ACIP recommendations put less emphasis on modifying immunizations based on allergy. Therefore, the current HIMSS IIP does not include a test to modify antigen recommendations based on allergy.

17.4.7 Data Elements

Not tested.

17.5 Requirement 3.8 Save History of Clinical Decision Support Recommendations

The system saves a history of information used to provide information to the provider as well as the recommendation presented (or no recommendation if none was provided), and any actions subsequently taken by the provider for later analysis.

17.5.2 Example of Scenario "Save History of Clinical Decision Support Recommendations"

The system administrator in a clinical practice reviews all recommendations provided by CDS system, with particular emphasis on those recommendations that have been ignored by the provider. From the review and discussion with the staff, the administrator is able to eliminate alerts that no value.

17.5.3 Guidance

The requirement addresses two of the "ten commandments of effective clinical decision support" presented in Section 5.14.1: Monitor Impact, Get Feedback, and Response, and Manage and Maintain Your Knowledge-based Systems. Such generic EHR capability is not yet commonplace. The capability could allow organizations to address those recommendations that have been ignored by the provider to change processes or to eliminate notifications and alerts that have no value. Any potential changes to existing systems would require evolution over time.

17.5.4 Focus on Vendor Perspective

Vendors should have governance principles and processes to manage CDS effectiveness in general, and specifically for immunization-related activities.

17.5.5 Focus on Provider and Implementer Perspective

Providers should understand vendor processes and timeliness for managing CDS effectiveness, and specifically address immunization-related content.

17.5.6 Test

The IIP does not test this requirement.

17.5.7 Data Elements

Not applicable.

17.6 Requirement 5.1 Provide Access to Vaccine Information Statement(s)

The EHR or other clinical software system provides the VIS sheets, as required by federal law, so that patients can review them prior to receiving a vaccination.

17.6.2 Example of Scenario "Provide Access to Vaccine Information Statement(s)"

The nurse planning to administer a DTaP vaccine to Juana Maria Gonzales, age 3 years 4 months, accesses the appropriate DTaP VIS in the EHR and provides it to the patient's mother. Mrs. Morales is able to review the VIS statement prior to giving consent for Juana Maria to receive the vaccine.

17.6.3 Guidance

CDC updates VIS statements periodically and posts them in PDF and Word format for download. Some vendors provide VIS statements with their products. Others allow customers to upload or link to the VIS forms. One-third of those evaluated do not support the VIS forms. All products support documenting the VIS statement and its issue date on the vaccine administration record. A future consideration might be to develop an API to pull the most up-to-date VIS form into the EHR as needed.

17.6.4 Focus on Vendor Perspective

The provision of VIS statements requires a vendor to routinely check for VIS statement updates, upload new statements and implement a distribution mechanism to customers.

17.6.5 Focus on Provider and Implementer Perspective

Current practice requires providers to review the most recent VIS statement with patients prior to administering a vaccine. If the EHR provides VIS statements, the provider should learn the vendor's process to keep current. If the practice uploads the VIS statements into the EHR or provides paper or electronic copies to patients directly, it should develop a process to routinely check for VIS statement updates to remain current.

17.6.6 Test

The IIP does not test this requirement.

17.6.7 Data Elements

Not Applicable.

17.7 Requirement 5.5 Document Vaccine Ineligibility Override Reason

The EHR or other clinical software system prompts the provider to document the reasons for selecting a vaccine from inventory if the patient is not eligible.

17.7.2 Example of Scenario "Document Vaccine Ineligibility Override Reason"

Dr. Smith has no remaining private stock of Prevnar vaccine. Juana Maria Gonzales, an infant, is present for her visit and has not previously received her 2nd Hepatitis B, DTaP, or Polio. Dr. Smith writes an order to give Juana Maria a combination vaccine, Pediarix, vaccine from VFC stock and documents the reason for borrowing from VFC vaccine (override).

17.7.3 Guidance

Refer to the guidance discussion for Section 9.5.2.2 (requirement 5.4) for a general discussion of VFC eligibility. Documentation of an override reason (e.g., vaccine borrowed from VFC stock) associated with inventory may occur externa EHR.

17.7.4 Focus on Vendor Perspective

Documentation of VFC eligibility override reasons is generally associated with inventory capabilities.

17.7.5 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

17.7.6 Test

Not tested.

17.7.7 Data Elements

Not applicable.

17.8 Requirement 5.12 Produce Configurable Patient Immunization History Report

The EHR or other clinical software system allows users to modify and save a template that produces a patient's immunization history to meet the needs of the populations served by the practice.

17.8.2 Example of Scenario "Produce Configurable Patient Immunization History Report"

Dr. Jones is an internist whose practice covers patients aged 19 and above. A large number of his patients work for a large local healthcare provider. To avoid receiving duplicate vaccinations, Dr. Jones' patients require documentation of specific vaccines that are required for employment and are administered by their individual physicians. Therefore, Dr. Jones wants to create an immunization report listing only those required vaccines to give to his patients.

17.8.3 Guidance

Some EHRs allow a provider to modify the "standard" patient immunization history report to meet the needs of local populations. Others will provide specific custom report configurations on request. Usability evaluation such as a UCD process may inform the content and functionality for immunization report configuration capabilities. Feedback about this requirement and expectations for the EHR is invited.

17.8.4 Focus on Vendor Perspective

Usability evaluation such as a UCD process may inform the content and functionality for immunization report configuration capabilities.

17.8.5 Focus on Provider and Implementer Perspective

Discuss preferences for a configurable patient immunization history report with the software vendor.

17.8.6 Test

The IIP does not test this requirement.

17.9 Requirement 5.13 Transmit Configurable Patient Immunization History Report

The EHR or other clinical system transmits a locally configured report of a patient's immunization history to meet the needs of the populations served by the practice.

17.9.2 Example of "Transmit Configurable Patient Immunization History Report"

Dr. Jones configured a specific immunization report for his patients who work at a local large healthcare provider. The report includes only those immunizations the employer requires for healthcare workers. With permission from a patient, Dr. Jones wants to transmit the report directly to the patient's employer.

17.9.3 Guidance

The requirement is to transmit the locally configured immunization report discussed in Section 5.35 (requirement 5.13) to an entity the patient selects. This capability raises patient privacy and confidentiality concerns. The products evaluated can fax reports at patient request. However, more input is needed on the value and privacy concerns related to this requirement. Feedback is invited.

17.9.4 Focus on Vendor Perspective

Vendor feedback is invited on this requirement.

17.9.5 Focus on Provider and Implementer Perspective

Provider feedback is invited about the import, feasibility, and risks associated with this requirement.

17.9.6 Test

The IIP does not test this requirement.

17.9.7 Data Elements

Not applicable.

17.9.1 Requirement 7.2 Initiate and Submit a VAERS Report

The EHR or other clinical software initiates and submits a VAERS report.

17.9.8 Example of Scenario "Initiate and Submit a VAERS Report"

Dr. Smith examines Juana Maria Gonzales 24 hours after she receives a live, attenuated influenza vaccine. She had a fever and diarrhea and, therefore, Dr. Smith entered her observations indicating a possible adverse event. Ideally, the EHR would ask Dr. Smith if she wants to submit a report to VAERS and, if so, the EHR would format and submit the report. At present, the EHR could provide a template consistent with the VAERS reporting form. However, direct electronic reporting is not available.

17.9.9 Guidance

Providers generally report adverse reactions to the VAERS directly on the VAERS website (https://vaers.hhs.gov/index). The VAERS site does not accept electronic report submission. Therefore, EHRs can provide a link to the site but further integration has not occurred.

CDC has developed an open-source CDS system called Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP-VAERS) to assist clinicians with adverse event detection and reporting. The system monitors the EHR for new diagnoses, changes in laboratory values and new allergies following vaccine administration. The ESP-VAERS sends the physician a secure electronic message if it identifies a suggestive event and invites the physician to affirm or refute the message, add comments and submit an automated prepopulated electronic report to VAERS. Such reporting was only available within the ESP-VAERS program pilot.

17.9.10 Focus on Vendor Perspective

Vendors should evaluate opportunities to incorporate the new CDC ESP-VAERS CDS system to help identify and report potential adverse events. Vendors should also consider the system as a method to identify vaccine-related adverse events as part of the clinical workflow.

17.9.11 Focus on Provider and Implementer Perspective

Providers should review needs to identify and report vaccine-related adverse events with their vendors.

17.9.12 Test

The IIP does not test this requirement.

17.9.13 Data Elements

Not applicable.

17.9.2 Requirement 7.4 Notify Public Health Immunization Registry (IIS) of Update from Adverse Event

The EHR or other clinical software system notifies the public health immunization registry (IIS) of an update due to an adverse event.

17.9.14 Example of Scenario "Notify Public Health Immunization Registry (IIS) of Update from Adverse Event"

24 hours after her live, attenuated influenza vaccine, Juana Maria Gonzales had a fever and diarrhea. The potential adverse event occurred 24 hours after the vaccine was administered. Dr. Smith updates the report to the public health immunization registry (IIS).

17.9.15 Guidance

Some of the products reviewed submit an updated immunization record to an immunization registry if the provider updates the vaccine administration record to include the adverse event either as a structured data attribute or as an administration note. Some of the vendors indicated their customers report some IIS do not accept these updated reports or reports of adverse events in the HL7 Send Unsolicited Immunization Update Using a VXU (Z22). The vocabularies used to record an adverse event within the products differ from the vocabularies identified for reporting adverse events in the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging.

The purpose of updating the IIS is to ensure public health is aware of events related to specific vaccines and also so other providers receiving the patient's immunization history from the registry are aware of the previous reaction. This is a patient safety issue to make providers aware of the adverse events to reduce the risk of repeat events. Some vendors report that registries will only accept updated reports containing adverse events if the match one of nine specific adverse events based on a value set (http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3289). The vendors also report that when providers submit updated reports containing comments about adverse events not in the value set, the reports are often rejected. Further, previous adverse events are not generally included in immunization histories returned to providers in response to queries (Section 5.5, requirement 2.2).

Collaboration among public health immunization registries, EHR vendors and providers will help to harmonize expectations and improve communications.

17.9.16 Focus on Vendor Perspective

Vendors should consider collaborating with providers and public health immunization registries to harmonize needs and workflow for adverse event notifications to the registry.

17.9.17 Focus on Provider and Implementer Perspective

Providers should consider collaborating with EHR vendors and public health immunization registries to harmonize needs and workflow for adverse event notifications to the registry.

17.9.18 Test

As this requirement has been deprecated, there are no tests associated with this historical requirement.

17.9.19 Data Elements

Not applicable.

18 APPENDIX E: CHANGE LOG

Changes in 2018 Edition

- Section 2.2 – Exhibit 4 – Update Technical Advisory Panel
- Section 6.7 – Requirement 2.6 Notify Public Health Immunization Registry (IIS) of Differenced between EHR Data and IIS Response
- Updated to reference: Feedback suggests that most IIS update information only if it is provided by the administering clinician, and the ability to modify immunization records is governed by jurisdictional restrictions about what types of data they can accept and store in their registries. However, to enhance usability, EHRs should have the ability to recognize differences in metadata that have been reviewed and rejected during the reconciliation process to improve usability and workflow.
- Section 7.2.2 – Updated text: The CDS provided to the clinician should indicate if a dose given prior to the earliest recommended date is valid for completion of the recommended immunization schedule. For example, a provider may consider an early dose of a vaccine as appropriate for the patient due to known exposure to a viral agent. The subsequent forecast reference to that vaccine should be based on ACIP recommendations to help determine if the dose should be considered part of the immunization series.
- Section 7.3.2.1 – Updated text: Note: The ACIP immunization schedule is not universally implemented in every jurisdiction. States may have their own advisory committees that review ACIP recommendations and make alterations based on state law, local practice or norms. In addition, state mandated vaccines for schools may not include all ACIP recommended vaccines for children and adolescents.
- Section 7.4.1 – Updated example: The system notifies the provider that Juan Marcel Marina, age 3 (birth date 12/24/2014) is allergic to latex. Therefore, the system recommends Rotavirus pentavalent (Rotateq) rather

than Rotavirus monovalent (Rotarix) vaccine. [Removed example of CRM 197 allergy since it is unrealistic to find in an EHR.]

- Section 7.5.1 – Updated example to reference history of clinical varicella disease such that the EHR recommends MMR instead of MMRV.
- Section 7.5.2 – Updated Guidance discussion about capturing and evaluating clinical conditions as evidence of prior immunity using SNOMED CT. The new discussion also addresses the use of LOINC for laboratory studies that provide serologic evidence of immunity.
- Section 7.8.2 Updated guidance for "receive dose not indicated alert upon vaccine administration" – updated description of "earliest date" in vaccine forecasting.
- Section 8.2.2 Updated guidance statement: that provides further clarification and definition for "dose-level eligibility."
- Section 9.2.2 Updated reference link for VIS statements.
- Section 9.9 Link Standard Codes to Immunization Data – Updated Guidance to address immunization-specific data quality. Section 7.5.2 updated to discuss the use of SNOMED CT and LOINC to reference evidence of prior disease.
- Section 9.10 Record Vaccine Administration - Updated text to indicate minimum data quality requirements: date administered, administering clinician, site of administration (e.g., left arm), immunization type, lot number, manufacturer, Vaccine Information Statement date, quantity of vaccine/dose size and ordering clinician.
- Section 10.2.2 Produce Population-Level Report (Cohort) – Updated examples of useful cohorts and request for additional examples from clinicians and public health professionals.
- Section 11.2.2 Guidance for Identify Adverse Event – Expanded description of the issues in identifying, documenting and reporting adverse events, in additional to assuring the information is available to the next clinician managing the patient.
- Appendix B – Crosswalk of capabilities to 2018 test script updates.
- Appendix C – Barcode supplement for evaluation, listing barcodes the can be used to evaluate the process but not included in the recognition testing performance calculation.

Changes in 2019 Edition

- Section 2.2 – Exhibit 4 – Updated Technical Advisory Panel Members
- Section 4.0 Updated HIMSS Immunization Integration Program website
- Section 4.1 Use of NIST Tool for Test Development and Processing – updated links, name, and version of the NIST tool used for testing to reflect the updated website (https://hl7v2-iz-cdc-testing.nist.gov/iztool/#/cb), Name (HIMSS Immunization Integration Test Suite), and Version (1.7.3)
- Section 8.2.3 Test, 8.2.4 Test, and 8.2.6 Test – Updated to point to the test plan sections where these are tested in the test plan (previously listed as not tested).
- Section 8.3 Requirement 4.2 Update Vaccine Inventory from Patient Dosage Administration
- Section 8.4 Requirement 4.3 Update Vaccine Inventory from Stock Receipt
- Section 8.6 Requirement 4.5 Produce Vaccine History Report – Corrected the requirement description from the redundant description 'The EHR or other clinical software system updates the vaccine inventory when new stock is received at the site and updates the correct count of each vaccine, including those for use in guarantee programs (such as Vaccines for Children) and for private stock.' to the correct description: 'The EHR or other clinical software system generates inventory reports of remaining stock. The reports can be sorted by expiration date and source (e.g., private or guarantee program). Updated test to document the newly added capability tested.
- Section 9.10 Requirement 5.9 Record Vaccine Administration - Updated Test section to indicate that the test also includes the ability to scan the vaccine information using 2-D Data Matrix.
- Section 9.6.1 Example of Scenario "Document Vaccine Ineligibility Override Reason" – Updated example: 'Dr. Smith has no remaining VFC private stock of Prevnar vaccine. Juana Maria Gonzales, an infant, is present for her visit and has not previously received her 2nd Hepatitis B, DTaP, or Polio. Dr. Smith writes an order to give Juana Maria a combination vaccine, Pediarix, from VFC stock and documents the reason for borrowing from VFC (override).'

- Section 9.6.2 Guidance – Updated to indicate that Documentation of an override reason (e.g., vaccine borrowed from VFC stock) associated with inventory MAY occur external to the EHR. (previously 'generally occurs external to the EHR')
- Section 9.9.3 Test – Updated statement to indicate that the HIMSS Immunization Integration Program includes testing for this requirement in all transmission steps.
- Section 11.5 Requirement 7.4 Notify Public Health Immunization Registry (IIS) of Update from Adverse Event - Updated to reflect the testing of this capability which had already been in the test plan, introduced in version 5.
- Appendix B – Crosswalk of capabilities to 2019/2020 test script updates, including update to the table to document the new capability tested: Produce Vaccine History Report
- Appendix C – Updated Barcode supplement for evaluation, listing barcodes that can be used to evaluate the process but not included in the recognition testing performance calculation.

Changes in 2020 Edition

- Section 2.2 – Exhibit 4 – Updated Technical Advisory Panel Members
- Section 4.1 Use of NIST Tool for Test Development and Processing – updated version of the NIST tool used for testing to reflect the updated tool Version (1.7.6)
- Section 5.5.3 Test, 7.6.3 Test, 7.8.3 Test, 10.3.3 Test, 12.4.2 Test, 12.5.3 Test, 12.6.3 Test – Updated to point to the test plan sections where these are tested in the test plan (previously listed as not tested):
    - 5.5.3 (5.5 Requirement 1.3 Select One or More Patients)
    - 7.6.3 (7.6 Requirement 3.5 Update Patient Immunization Schedule)
    - 7.8.3 (7.8 Requirement 3.7 Receive Dose Not Indicated Alert upon Vaccine Administration)
    - 10.3.3 (10.3 Requirement 6.2 Notify Patients of Immunization Status)
    - 12.4.2 (12.4 Requirement 8.3 Provide Access to Printable Immunization Record)
    - 12.5.3 (12.5 Requirement 8.4 Provide Access to Update Immunization Information)

  - 12.6.3 (12.6 Requirement 8.5 Review Patient-Provided Immunization Information)
- Section 6.3.1 - Corrected title for example to "Example of Scenario "Request / Receipt of Patient Immunization History"
- Section 6.3.3 corrected reference from 'Real Time Request / Receipt of Patient Immunization History' to 'Request / Receipt of Patient Immunization History'
- Section 6.4 Removed note: from requirement description in 6.4 Requirement 2.3 Compare Public Health Immunization Registry (IIS) Immunization History to EHR Immunization History'. As we move toward greater interoperability, communication between IIS and EHRs becomes increasingly important. Efforts are underway to advance IIS standardization as well.'
- Section 7.5 editorial correction of requirement name from '7.5 Requirement 3.4 Modify Antigen Recommendations Based on Active Diagnosis' to '7.5 Requirement 3.4 Modify Antigen Recommendations Based on Active Diagnoses'
- Sections 9.2.1, 9.5.1, 9.10.1, 9.12.1, 9.15.1, 11.2.1, 11.3.1, 11.4.1, 11.5.1, 12.2.1, 12.3.1, 12.4.1 Editorial correction - Remove 2nd last name from instances of Juana Maria Gonzales Morales
- Section 9.4 editorial correction of requirement name from '9.4 Requirement 5.3 Record Past Immunization' to '9.4 Requirement 5.3 Record Past Immunizations'
- Section 9.8 remove old description from requirement description 'To assist with the ordering process, the EHR or other clinical software system allows a user to specify standard views of patient immunization information for each vaccine dose administration, including patient-specific data (e.g., age on dates of administration, etc.). October 2016 Update:'
- Section10.3 remove old description from requirement description 'The EHR or other clinical software system notifies patients based on specific known immunization data. October 2016 Update:'
- Section 12.3.3 updated Test description to add reference to vis: 'The HIMSS IIP test requires that the system displays the forecast created after the office visit (during which vaccines are administered) and Vaccine Information Statements. '

- Section 13: Added Configuration management Requirement 9, to address new requirements from the IIP Collaborative:
  - 13.1 Background
  - 13.2 Requirement 9.1 Add New Vaccine Codes
  - 13.3 Requirement 9.2 Adopt SOAP-based CDC WSDL for Transport
  - 13.4 Requirement 9.3 Support Data Quality Checks
- Appendix B – Crosswalk of capabilities to 2020/2021 test script updates, including updates to the table to document the new capabilities tested
- Appendix C – Updated Barcode supplement for evaluation, listing barcodes and associated data that can be used to evaluate the process but not included in the recognition testing performance calculation.

Changes in 2021 Edition

- Added Section 2 Summary of Changes
- Section 13: Added Configuration management Requirements 9.3 and 9.4, to address new requirements from the IIP Collaborative and project team:
  - Updated section heading and description to 'Configuration and Operational Management' in order to accommodate the addition of the Acknowledgment Data Reporting requirement under this category.
  - 13.5 Requirement 9.4 Add Jurisdiction-Specific Vaccine Eligibility Code
  - 13.6 Requirement 9.5 Acknowledgment Data Reporting
- Section 9: Added new requirement to address new requirement for 2D Barcodes from project team:
  - 9.16: Requirement 5.15 Record Vaccine Information by Scanning 2D Barcode Found on Unit-of-Use for Vaccine Administration
- Appendix B – Crosswalk of capabilities to 2021/2022 test script updates, including updates to the table to document the new capabilities tested
  - Updated reference to Group 6 which is now generalized to accommodate both Cohort and Acknowledgment related reports
  - Updated 5.8 Link Standard Codes to Immunization Data: removed reference to test step that was removed to report adverse reactions to the registry

  - Updated 5.11 Transmit Standard Patient Immunization History Report: removed reference to test step that was removed to report adverse reactions to the registry
  - Corrected the test step reference previously labelled as 'Transmit Delete from Bad Lot' to 'Transmit Delete for Vaccine Recorded in Error'
- Appendix C – Updated barcode supplement for evaluation, listing barcodes and associated data that are used for 2D Barcode related testing and inventory.
- Deprecated Requirement 7.4 Notify Public Health Immunization Registry (IIS) of Update from Adverse Event: Language added to indicate the requirement is deprecated but information regarding the requirement is retained for historical reference.

19 APPENDIX F: BACKGROUND

The Link Between Immunization-Related Capabilities Within EHRs and Improved Immunization Rates

The goal of "a nation without vaccine-preventable disease, disability, and death" within CDC's Global Immunization Registry Framework highlights the role that immunization plays in improving morbidity and mortality rates within the United States.[60] The value of vaccination and immunization is well established. Improved immunization rates have been linked to better health outcomes, reductions in health care costs, and higher levels of productivity.[61,62,63] Exhibit 1 highlights some of the key benefits that improved immunization rates bring to various stakeholders.

Stakeholder	Value of Immunization
Clinicians	• Ability to deliver better care to patients • The benefit of lower costs (for those operating in risk-sharing arrangements) and better health outcomes

Stakeholder	Value of Immunization
Consumers	• Improved quality of life • Better outcomes • Reduced costs (given increased responsibility for health care costs)
Employers	• Reduced health care spending • Better outcomes • Increased productivity
Health Plans	• Lower health care costs • Better outcomes
Public Health Community	• Achieve public health goals associated with reducing vaccine-preventable diseases in this population
Schools	• Improved attendance • Safety of medically vulnerable children • Support compliance for children without medical homes, interstate travel, refugees and immigrants

Exhibit 1. Benefits of Immunizations

There is also considerable evidence that the use of Immunization Information Systems (IIS) increases vaccination rates and reduces vaccine-preventable disease.[64] The Task Force on Community Preventive Services has recommended the use of IIS based on such evidence.[65] Recognizing the importance of IIS, one of the Healthy People 2020 goals calls for 95 percent of children under six years of age to have their immunizations recorded in an IIS.[66]

To a large extent, IIS rely upon those who provide immunizations to fulfill their general functions, which include (1) providing consolidated immunization histories for use by immunization providers at the point of clinical care and (2) providing aggregate data on vaccinations for use in surveillance and program operations and in guiding public health action. Both of these functions help improve vaccination rates and reduce vaccine-preventable disease. EHRs provide the opportunity for immunization providers to directly transmit

immunization-related information to IIS, thereby supporting their general functions.

In addition to their role of providing information to support IIS functions, the use of EHRs also has the potential to increase immunization rates, although evidence of their direct contribution to improvements in immunization rates is not well documented. However, the use of provider reminders, standing orders, provider assessment and feedback, and patient reminders has been shown to increase immunization rates and EHRs have been shown to support and increase the effectiveness of such interventions. IIS have been shown to support these functions; incorporating them into the EHR clinical workflow will add significant efficiencies.

Exhibit 2 presents an overview of how EHRs support evidence-based interventions that have been shown to improve immunization rates.

Intervention	Description[67]	How EHRs Support Intervention
Provider reminders	Provider reminder interventions inform those who administer vaccinations that individual clients are due for specific vaccinations. Techniques by which reminders are delivered vary but can include: notes prepared in advance and posted in client charts, alerts in electronic medical records, and letters sent by mail.	Vaccine reminders can be programmed in EHRs through Clinical Decision Support rules. Outcomes show positive results in improved vaccine rates through the use of reminders.[68]
Standing orders	Standing orders authorize nurses, pharmacists, and other health care personnel,	Like reminders, standing orders can be programmed in EHRs to enable clinicians

Intervention	Description[67]	How EHRs Support Intervention
	where allowed by state law, to assess a patient's immunization status and administer vaccinations according to an approved protocol. The protocol enables assessment and vaccination without the need for examination or direct order from the attending provider at the time of the interaction.	to assess immunization status and administer vaccinations according to approved protocols.
Provider assessment and feedback	Provider assessment and feedback involves retrospectively evaluating provider performance in delivering one or more vaccinations to a client population and giving them feedback on their performance. Assessment and feedback can also involve other activities (e.g., incentives, benchmarking, etc.).	Quality and outcomes-based reporting in EHRs can be used to assess individual patient and provider outcomes. Studies have shown improvements in tracking and documentation of immunization information through the use of the EHR.[69]
Client reminders and recalls	Client reminders and recalls involve reminding members of a target population that vaccinations are due (reminders) or late (recall). Reminders and recalls differ in content and are delivered	Office staff can run reports from the EHR to generate a list of patients that require follow-up for any number of health conditions, including immunizations, lab testing, or screenings.

Intervention	Description[67]	How EHRs Support Intervention
	by various methods, such as email, text, telephone, letter, patient portal, or postcard. Most reminder systems involve a specific notification for a specific client, and may be accompanied by educational messages regarding the importance of immunization for the targeted vaccine.	

Exhibit 2. EHR Support for Interventions Improving Immunization Rates

In addition to supporting interventions that have been shown to improve immunization rates, EHRs generally have been shown to play a role in improving the quality, cost-effectiveness, and patient experience of care. One comprehensive review of the literature showed that 92 percent of recent peer-reviewed articles on the effects of health IT used in clinical practice reached positive conclusions overall, addressing such areas as efficiency of care, effectiveness of care, provider satisfaction, and patient safety.[70]

Other Types of Value Derived from Immunization-Related Capabilities in EHRs
This section presents an overview of the other types of value that stakeholders experience from enhanced immunization-related capabilities of EHRs.

19.1.2 Other Types of Value for Providers

In addition to improving health outcomes for patients by increasing immunization rates, EHRs with immunization-related capabilities offer other types of value to clinicians and other providers. Exhibit 3 summarizes these types of value.

Value	Description
Reduced burden associated with mandatory reporting to IIS	Many states require vaccine reporting by all immunization providers. Using an EHR or other clinical software to report vaccines to an IIS can reduce a provider's burden of manual entry.
Reduced burden associated with required reporting under the Vaccines for Children (VFC) Program	Providers administering vaccines received from their state or locality under the VFC Program are required to screen and record patient eligibility. Providers can use EHRs or other clinical software to electronically capture and transmit information through HL7 messages sent to an IIS.
Reduced burden associated with reporting on performance measures	Many health plans and public and private sector purchasers require reporting on immunization rates. While ordinarily such measures rely on administrative or claims data, increasingly performance specifications enable the use of clinical data from EHRs to support the calculation of such measures.

Value	Description
Enhanced ability to achieve the Centers for Medicare and Medicaid Services (CMS) requirements associated with the Promoting Interoperability Program for hospitals and critical access hospitals, and the Merit-Based Incentive Payment Systems (MIPS) Program for clinicians. Such programs require health care providers to attest that they are in active engagement to submit data for at least two of six public health-related purposes, one of which represents immunization reporting to IIS.[71,72] Health care providers must use ONC-certified EHR technology for such reporting.	Enhanced immunization-related EHR capabilities enable eligible professionals to more easily achieve the immunization reporting-related requirements of Meaningful Use.
Reduced burden associated with providing immunization records to patients	Immunizations are often required for enrollment in schools, camps, and athletic activities, resulting in patient and caregiver calls to provider offices—often around the same period of time—to request such documents. Having immunization-related capabilities within EHRs that connect to student information systems and patient portals or other consumer-facing applications reduces the burden on clinicians to provide such information to patients upon request.

Exhibit 3. Value for Clinicians Associated with Enhanced EHR Capabilities

19.1.3 Other Types of Value for IIS

Immunization-related capabilities in EHR systems and other clinical software enable IIS to receive more accurate information on a timely basis, thereby supporting their mission to increase immunization coverage within local jurisdictions. This information also provides situational awareness with respect to citizens who are protected (immunized), those at-risk, and the available vaccine stock.[73] Over time, provider access to IIS information also will support this mission.

Such capabilities also improve the ability of IIS to meet CDC functional standards, including those related to:

- Delivering services at the point of administration.
- Supporting activities and requirements of VFC Program, including accountability.
- Maintaining data quality.
- Promoting vaccine safety.

19.1.4 Other Types of Value for EHR and Other Clinical Software Developers

EHRs and other clinical software with immunization-related capabilities provide the following types of value to vendors:

- Support for the needs of customers who value such capabilities.
- Enhanced ability to meet the ONC 2015 Edition Health IT Certification criteria.
- Reduced burden associated with coding and supporting the transmission of data to multiple IIS, provided that IIS requirements are also standardized.

19.1.5 Other Types of Value for Those Who Pay for Health Care

In addition to improving health outcomes through improved immunization rates, having immunization-related capabilities within EHRs used by all immunization providers enables those who pay for health care to improve the accuracy of measurement of such immunization rates. Currently such rates are largely determined through the review of claims data, which do not always provide an

accurate measurement, given that immunizations are often provided under circumstances in which claims are not generated.

Examples of instances in which claims are not generated for immunizations provided include the following:

- Situations in which individuals pay for immunizations out-of-pocket; and
- Settings in which claims are not generated, such as free onsite clinics offered by employers or in some cases, public health clinics.

Access to immunization data within the EHR can also reduce rates of over-immunization, including children without medical homes, which can be both costly and inconvenient for patients.

19.1.6 Other Types of Value for Individuals

In addition to reducing vaccine-preventable disease through improved immunization rates, having immunization-related capabilities within EHRs enables individuals to more efficiently access immunization records to support both reporting requirements and improvements in health. Immunizations are often required to enroll in schools, colleges, camps, and athletic activities. Accessing such information through a student information system, patient portal or other consumer-facing application connected to the EHR can be much more convenient than visiting or calling the office—for both the individual and the provider. Additionally, connectivity has the potential for decreasing the cost of SIS immunization data management

Section 2 provides the background and history of the project. Section 3 provides the conceptual model for immunization-related workflow that drove these requirements. Sections 4 through 11 detail each of the requirements, organized by workflow component.

The IIP presents this EHR Immunization-Related Capabilities and Guidance document on behalf of the Centers for Disease Control and Prevention (CDC), Office of Infectious Diseases (OID), National Center for Immunization and Respiratory Diseases (NCIRD), Office of the Director. Improved immunization

rates have been linked to better health outcomes, reductions in health care costs, and higher levels of productivity.[74,75,76] EHRs have been shown to increase the effectiveness of various interventions that improve immunization rates, such as provider reminders, standing orders, provider assessment and feedback processes, and patient reminders. CDC believes that improving immunization-related functions and usability of EHRs and other clinical software will improve the level of appropriate immunizations, thereby positively impacting public health.

19.1.7 Literature Review and Requirement Definition

In 2014 and 2015, Chickasaw Health Consulting (CHC) performed a literature review to identify capabilities required to manage immunizations including data requirements, clinical and administrative workflow issues, usability and information sharing needs. The literature review evaluated over 150 references covering the following topics:

- Value of immunization.
- The capabilities and interventions that have been shown to improve immunization rates.
- The role of health IT in improving immunization rates and enhancing immunization-related capabilities and interventions.
- Current and ideal clinician and other immunization provider workflows and requirements associated with immunizations.
- Immunization information system (IIS) requirements of immunization providers.
- Incentives that ordinarily drive the adoption of health care and/or IT-related capabilities.
- Accreditation and certification-related governance, processes, and systems.

Specific consensus-based standards reviewed and addressed in these efforts included:

- CDC's *Immunization Information System Functional Standards, 2013-2017*[77]
- HL7 EHR Functional Model[78]
- HL7 Child Health Profile[79]

- HL7 EHR-System Public Health Functional Profile[80]
- HL7 Personal Health Record Functional Profile[81]
- Agency for Healthcare Research and Quality (AHRQ) Children's Electronic Health Record Format.[82]

The next step was to consolidate 113 requirements gleaned from the existing standards and literature review to handle the end-to-end clinical workflow for clinicians and address patient needs. A panel of clinicians, consumer, immunization registry and usability subject matter experts guided this effort:

- Greg Anderson, CEO, Connexion Software (Office Practicum)
- Craig Newman, EPIC (subsequently, CDC)
- Justin Elliot, EDI Project Manager, NextGen Healthcare Information Systems
- Mark Segal, Vice President, Government and Industry Affairs, GE Healthcare IT
- Michael Chaney, Former Immunization Program Manager
- Eric Daub, Senior Public Health Advisor, Scientific Technologies Corporation
- Allison Chi, Program Director, American Immunization Registry Association
- Shaun Grannis, MD, Family Physician, Medical Informatics Research Scientist, Indiana Center for Excellence for Public Health Informatics, Regenstrief Institute, Indiana University School of Medicine
- Susan Kressly, MD, Pediatrics, Kressly Pediatrics
- Peter Basch, MD, Internal Medicine, Senior Director, Health IT Quality and Safety, Research and National Health IT Policy, Medstar Health
- Stuart Weinberg, MD, Pediatrics, Associate Professor, Departments of Biomedical Informatics and Pediatrics, Vanderbilt School and Medicine
- Feliciano (Pele) Yu, MD, Pediatrics, Chief Medical Informatics Officer, Arkansas Children's Hospital
- David Bar-Shain, MD, Pediatrics, Associate Director of Medical Informatics, Metro Health Medical Center
- Stephen Palmer, State Health IT Coordinator and Director, Office of e-Health Coordination, Texas Health and Human Services Commission
- Svetlana Lowry, NIST Usability Expert
- James Daniel, Public Health Coordinator, Office of the National Coordinator for Healthcare IT
- Cindy Dye, VP, Executive Partner, Gartner, Inc.

- Ian Heiman, Senior Director, Gartner, Inc.
- Kathryn Cornelius, Associate Director, Gartner, Inc. (Usability Expert)
- Lori Fourquet, eHealthSign (Health IT standards expert)
- Warren Williams, Acting Branch Chief, National Center for Immunization and Respiratory Disease, CDC
- Kafayat Adeniyi, Public Health Project Manager, National Center for Immunization and Respiratory Disease, CDC

The effort led to a workflow-based conceptual model for health IT immunization-related capabilities. Section 3 provides details on that model and the eight distinct subcomponent workflows that define the overall process.

19.1.8 Evaluating EHR Software and Piloting a Testing Process

Having defined the conceptual model and clinical workflow, the next step included evaluating existing clinical software to determine the extent to which the defined capabilities existed in available EHR products. The CHC team identified the EHRs with the highest market share overall and also in the Pediatric market. Twelve of these vendors agreed to a web-based demonstration to evaluate existing immunization-related capabilities. The vendors were provided only one week to review the capabilities and asked to demonstrate existing software that was then currently in use by customers. One clinician, one standards expert and two usability experts from the CHC project team participated in the demonstrations to evaluate what capabilities existed. This clinical software assessment provided significant input to the subject matter expert team to subsequently recommend a scenario-based software test to evaluate immunization capabilities of clinical software. The CHC team developed the test using the NIST software which is also used for the ONC Health IT Certification Program as it is somewhat familiar to EHR vendors. Four of the vendors that participated in the clinical software assessment process agreed to voluntarily pilot the new scenario-based test. The information gained from this pilot led to significant improvements in the test scripts.

19.1.9 Launch of the IIP and the Technical Advisory Panel

Subsequent to the pilot work, CHC collaborated with HIMSS to launch the HIMSS Immunization Integration Program (IIP), making the resulting test script available for voluntary testing in early 2016. The HIMSS IIP also established a Technical Advisory Panel (TAP) beginning with a public call for participation. TAP membership was specifically intended to address a broad spectrum of stakeholders – public health (the immunization registry community), healthcare provider organizations, EHR vendors, clinicians, retail clinics and consumers.

Functional Test Development

Twelve vendors participated in an initial clinical software assessment, an activity in which each vendor demonstrated how its product might meet each of the 47 requirements. Exhibit 7 lists the vendors participating in the clinical software assessment of ambulatory EHR products.

EHR Vendors Participating in Ambulatory Clinical Software Assessment	
Epic	Athenahealth
eClinicalWorks	Greenway
Allscripts	eMDs
NextGen	Practice Fusion
Cerner	PCC
Connexin	McKesson

Exhibit 7: Vendors Participating in Ambulatory Clinical Software Assessment

The result of the clinical software assessment was a subset of requirements for pilot testing based on clinical importance and covering an end-to-end clinical workflow scenario. Four vendors volunteered to evaluate the tests based on these requirements. In addition, ICSA Labs, in collaboration with HIMSS, and utilizing test tools and test plans developed by CHC, comprehensively evaluated developer compliance with workflows designed to advance the integration of immunization-related capabilities within EHRs and other clinical software. In preparation for these assessments, the Drummond Group submitted

observations regarding the test tool and test plans via the surveys found on the HIMSS IIP website at https://www.himss.org/library/immunization-integration-program. Section 5 presents the results of the pilot testing, recommended tests where applicable, and general guidance related to each requirement.

19.1.10 Use of NIST Tool for Test Development

The National Institute of Standards and Technology (NIST) developed a Test Case Authoring and Management Tool (TCAMT) to facilitate the development of test cases and test plans for domains such as immunization. The CHC team used this tool to create two test plans. The team developed the first test plan for use with vendors that support bi-directional communications with the immunization registries to allow for a standard HL7 Request/Return Evaluated Immunization History and Forecast Query (Z44/Z42). Vendors supporting this standard HL7 transaction set were asked to import the test patients' vaccine history through their reconciliation functions. The second test plan for vendors that did not perform bi-directional communications used the same test data, but the vendors needed to manually enter the patients' vaccine history data. Once the test plan and test data were input into TCAMT, NIST executed a utility within TCAMT to make the test plan and test data available on the HIMSS Immunization Integration Test Suite 1.7.6 platform, which is publicly available at https://hl7v2-iz-cdc-testing.nist.gov/iztool/#/cb. There is now a single test plan that includes the bi-directional communications.

20 APPENDIX G: END NOTES

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