CNI
Advantage, LLC

HIMSS IMMUNIZATION INTEGRATION PROGRAM:

IMMUNIZATION-RELATED CAPABILITIES AND GUIDANCE

JANUARY 23, 2017

VERSION HISTORY

CNIADV will update Deliverable 10a to reflect changes that incorporate CDC's review and feedback, as well as any new requirements or changes to the business environment in which the project exists. The table below tracks these changes and updates 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 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	CDC	January 23, 2017
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	CDC	January 23, 2017

			to publish as a single capability and guidance document.		
3	CNI Advantage and HIMSS	December 21, 2016	Update with input from Technical Advisory Panel to address guidance and capabilities.		

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1 OVERVIEW

1.1 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 a truly integrated system that promotes full vaccine compliance, a process to include 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 also general guidance.

Immunization-Related Clinical Software Guidance provides the following information:

- **Section 1. Overview**
- **Section 2. Background** — Background regarding the origin and goals of the guidance.
- **Section 3. Immunization-Related Conceptual Model** – The end-to-end clinical workflow to manage immunizations in a clinical setting and the related software requirements.
- **Section 4. Functional Test Development** – The methods used to evaluate existing software capabilities and develop tests to evaluate performance.
- **Sections 5-12. Functional capabilities and guidance** – Information to help vendors and providers consider fulfilling each requirement.

CNI Advantage, LLC (CNIADV) 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 strong advocates by providing vaccine education. 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.

1.2 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.[4] 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.[5,6,7] 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
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
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.[8] The Task Force on Community Preventive Services has recommended the use of IIS' based on such evidence.[9] 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.[10]

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[11]	How EHRs Support Intervention
Provider reminders	Provider reminder interventions inform those who administer vaccinations that	Vaccine reminders can be programmed in EHRs through

Intervention	Description[11]	How EHRs Support Intervention
	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.	Clinical Decision Support rules. Outcomes show positive results in improved vaccine rates through the use of reminders.[12]
Standing orders	Standing orders authorize nurses, pharmacists, and other health care personnel 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.	Like reminders, standing orders can be programmed in EHRs to enable clinicians 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.[13]
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 by various methods, such as email, text, telephone, letter, 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.	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.

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.[14]

1.3 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.

1.3.1 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.
Enhanced ability to achieve Meaningful Use requirements under the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Program	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 school 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

1.3.2 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.[15] 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; and
- Promoting vaccine safety.

1.3.3 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 Certification criteria required for Meaningful Use; and
- Reduced burden associated with coding and supporting the transmission of data to multiple IIS', provided that IIS' requirements are also standardized.

1.3.4 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.

1.3.5 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 school 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 patient and the provider. Additionally, connectivity has the

potential for decreasing the cost of School Immunization System (SIS) immunization data management

Section 2 provides 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.

2   BACKGROUND

HIMSS and CNI Advantage, LLC (CNIADV) present this EHR Immunization-Related Capabilities 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.[16,17,18] 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.

2.1   Literature Review and Requirement Definition

In 2014 and 2015, CNIADV 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; and

- 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*[19]

- HL7 EHR Functional Model[20]

- HL7 Child Health Profile[21]

- HL7 EHR-System Public Health Functional Profile[22]

- HL7 Personal Health Record Functional Profile[23]

- Agency for Healthcare Research and Quality (AHRQ) Children's Electronic Health Record Format.[24]

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

- Sue Kressley, MD, Pediatrics, Kressley 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 Department of Biomedical Informatics, 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.

2.2   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 CNIADV 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 CNIADV 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 CNIADV team developed the test using the NIST software which is also used for the ONC EHR 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.

Subsequent to the pilot work, CNIADV 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 Immunization Integration Program also established a Technical Advisory Panel (TAP) beginning with a public call for participation. Exhibit 4 provides the Panel membership, 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.

Immunization Integration Program Technical Advisory Panel

Public Health Perspective:
- Eric Larson – Senior Technical Project Manager, American Immunization Registry Association (AIRA)
- Jenne McKibben, Director, Alert IIS, Oregon Immunization Program
- Beth English, Associate Director, Immunization Program, Massachusetts Department of Public Health

Healthcare Provider Organization and/ or Medical Group
- Donna Mazyck, RN – Executive Director, National Association of School Nurses
- Stuart Weinberg, MD – Associate Professor, Department of Biomedical Informatics, Vanderbilt University Medical Center

EHR Vendor:
- Kristin Glaza – Strategist, Cerner
- Richard Loomis, MD – VP, CMO, Practice Fusion

Clinicians [including pediatricians, family physicians, internists, nurses pharmacists]
- Susan Kressly, MD – Kressly Pediatrics
- Feliciano Yu, MD – St. Louis Children's Hospital
- Jennifer Russo, RN – Barnabas Health
- Shaun Grannis, MD, Associate Director, Center for Biomedical Informatics, Regenstrief Institute

Retail Clinics
- Brandy Altstadter – Scientific Technologies Corporation

Consumers
- Donald Hackett – Precision Vaccines (consumer vaccine registry)

Exhibit 4. HIMSS Immunization Integration Program Technical Advisory Panel Membership

The HIMSS IIP TAP reviewed the public input and the test findings from early 2016 in a series of four meetings and recommended additional updates to the tests, capabilities and guidance. This document reflects those changes to the capabilities and guidance.
The HIMSS Immunization Integration Program has now progressed to encourage clinical software testing and validation, and provide recognition for EHR vendors successfully completing the testing process. The HIMSS IIP TAP will continue to review public input in order to inform and improve the program and its testing, validation and recognition processes to ensure success.

3 OVERVIEW OF CONCEPTUAL MODEL FOR REQUIREMENTS: GENERAL USER WORKFLOWS

The immunization-specific functional requirements and the related guidance in this document are based on a conceptual model of clinical workflow process. 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 shows the end-to-end workflow for providing immunizations to patients. In most settings, software assists with some tasks but not all. Exhibit 5 presents the actions performed by providers and public health immunization registries (also called Immunization Information Systems, or IIS) to provide immunizations to patients.

Conceptual Model: General User Workflows
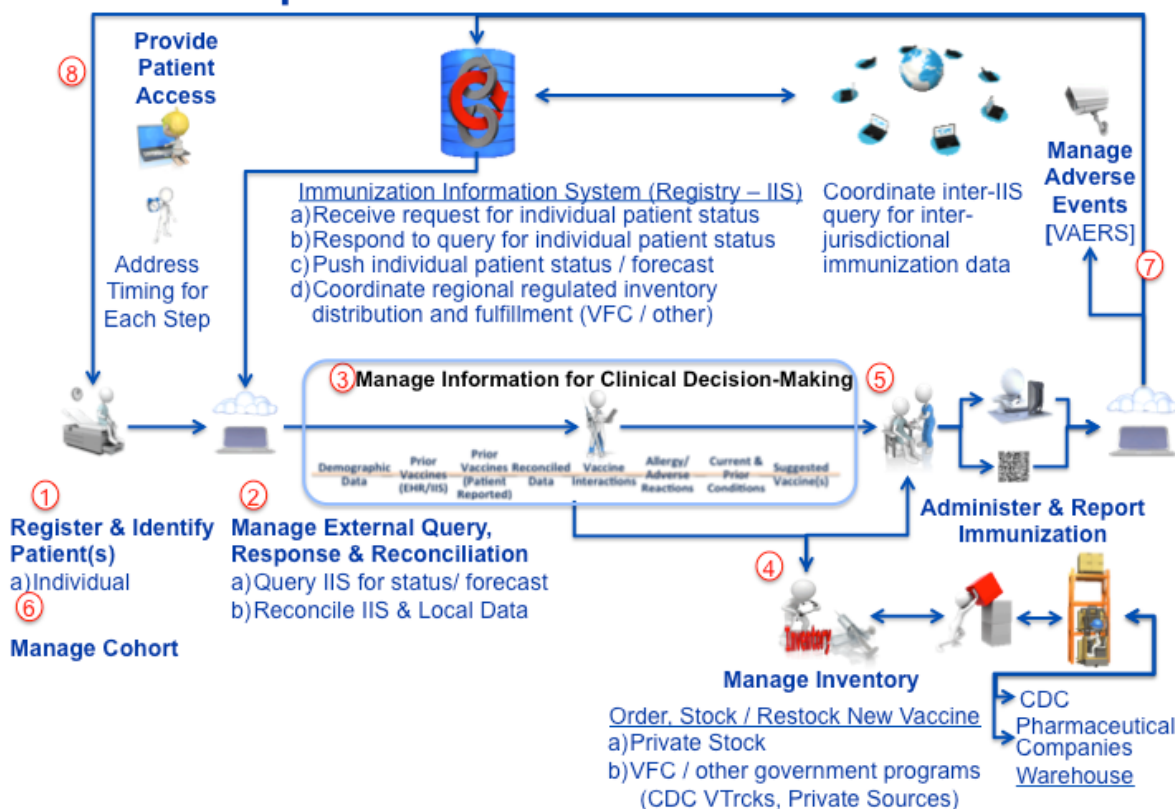
Exhibit 5: Conceptual Model: EHR Immunization Management Activities Comprising Eight General User Workflows, (1) Register and Identify a Patient, (2) Manage External Query, Response and Reconciliation, (3) Manage Information for Clinical Decision Making, (4) Manage Inventory, (5) Administer and Report 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;

Immunization-Specific Actions Categorized Within Eight Distinct General User Workflows		
		· Allergy and adverse reaction history; · Current and prior clinical conditions; and · Forecasted (recommended) immunizations based on the general 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:
		  - Vaccine recall (manufacturer and lot number);
		  - All patients past due for immunizations; and
		  - Notify patients for appropriate care management.

7	Manage Adverse Events	· Document adverse event. · Report adverse event to reporting agency (e.g., VAERS).
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 47 distinct immunization-related requirements.

4   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 LLC	Greenway
Allscripts	eMDs
NextGen	Practice Fusion
Cerner	PCC

EHR Vendors Participating in Ambulatory Clinical Software Assessment	
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 CNIADV, 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, ICSA Labs submitted observations regarding the test tool and test plans via the surveys found on the HIMSS CDC Immunization Integration Program website at http://www.himssinnovationcenter.org/immunization-integration-program. Section 5 presents the results of the pilot testing, recommended tests where applicable, and general guidance related to each requirement.

4.1   Use of NIST Tool for Test Development and Processing

The National Institute for Standards and Testing (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 CNI 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 was input into TCAMT, NIST executed a utility within TCAMT to make the test plan and test data available on the NIST Immunization Test Suite (Beta) platform, which is publicly available at http://hl7v2-iz-r1.5-testing.nist.gov.

NIST makes the Immunization Test Suite available (a) for testing whether public health immunization information systems (IIS') conform to standards and (b) to prepare for proposed Meaningful Use 3 testing requirements. Coordination of the EHR functional testing using the NIST Immunization 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 Meaningful Use 3 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 NIST Immunization 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 test tool still plans to add test data specifications and message content tabs.
3. The validation engine is still being tested.

In order to use the NIST Immunization Test Suite Beta to run the EHR Functional testing, the vendor would do the following:

1. Access the NIST Immunization Test Suite Beta http://hl7v2-iz-r1.5-testing.nist.gov.
2. Select option (5) Isolated Testing 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.

5.1   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 (sometimes called an immunization information system, or IIS).

5.2   Examples of Work in This Area

Anyone using an EHR to review or enter information for any reason must be able to find a patient. This ability is not unique to providing or reviewing immunizations. Some suggest a need for a unique, national patient identifier.[25] Others recommend common matching procedures, or algorithms.[26,27] Considerable effort is underway in other settings to address unique patient identification.[28] 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.

5.3   Requirement 1.1 Register New Patients

The 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. EHRs or other clinical software 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 also helps ensure a match when the EHR send the patient's information to external systems such as an immunization registry.

5.3.1   Example of Scenario "Register New Patients"

Joanna Gonzales Morales, age 32, arrives in the office with her twin daughters Juana Maria Gonzales Morales and Mariela Gonzales Morales, age 3 years and 4 months. 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 Gonzales. However, Juana Mariana Gonzales 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 Morales 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.

5.3.2   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, Section 13.1 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.

5.3.2.1   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.

5.3.2.2 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.

5.3.3 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.

5.3.3.1 Data Elements

See Appendix A

5.4 Requirement 1.2 Select New Patient

The 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. 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). A new element added in 2016 is 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. The provider should be aware of how often the protection indicator information must be updated based on local rules.

5.4.1 Example of Scenario "Select New Patient"

Joanna Gonzales Morales, age 32, presents at the office with her twin daughters, Juana Maria Gonzales Morales and Mariela Gonzales Morales, age 3 years and 4 months. 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 Morales" into the system to locate her record. The system returns three potential matches: 1) Juana Maria Gonzales Morales (multiple birth indicator = yes, birth order = 1); 2) Mariela Gonzales Morales (multiple birth indicator = yes, birth order =2); and 3) Juana Mariana Gonzales (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. A new element added in 2016 is to assure 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. The provider should be aware of how often the protection indicator information must be updated based on local rules.

5.4.2 Guidance

Identical to Requirement 1.1 (Section 5.1).

5.4.2.1 Focus on Vendor Perspective

Identical to Requirement 1.1 (Section 5.1).

5.4.2.2 Focus on Provider and Implementer Perspective

Identical to Requirement 1.1 (Section 5.1).

5.4.3 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.

5.4.3.1 Data Elements

See Appendix A

5.5 Requirement 1.3 Select One or More Patients

The 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.

5.5.1 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.

5.5.2 Guidance

Identical to Requirement 1.1 (Section 5.1).

5.5.2.1 Focus on Vendor Perspective

Identical to Requirement 1.1 (Section 5.1).

5.5.2.2 Focus on Provider and Implementer Perspective

Identical to Requirement 1.1 (Section 5.1).

5.5.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

5.5.3.1 Data Elements

See Appendix A, Section 13.1

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 does 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.

6.1.1 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*.[29] 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 is currently developing an Interoperability Roadmap.[30,31,32] Earlier efforts addressed communication among EHRs and specialized or public health registries.[33,34,35]The Meaningful Use program, Stage 2, specifically addressed immunization registries requiring submission of information to public health registries. It did not require the EHR to receive patient immunization history from such registries.[36] 2015 Edition CEHRT 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, the American Immunization Registry Association (AIRA) and the Association of Immunization Managers (AIM), address requirements for immunization registries and enable collaboration among registry organizations and managers.[37,38,39,40] 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.

6.2 Requirement 2.1 Batch Request / Receive Patient Immunization History

The EHR or other clinical software system sends a single request (a "batch" request) to the public health immunization registry for each of several patients. Reasons for a batch request may

be (a) to obtain updated immunization histories for all patients with upcoming appointments, or (b) to receive complete immunization histories for all patients new to the provider's practice. The request includes identifying information that the immunization registry needs to match each patient in the request with those in the registry. The request also is sent in a pre-determined format the registry can read and interpret (Query by Parameter (QBP) – HL7 version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5).

6.2.1.1 Example of Scenario "Batch Request/Receive Patient Immunization History(s)"

Every Friday evening, Dr. Smith's office uses the EHR to create a query to the public health immunization registry (IIS) requesting immunization history for each patient scheduled for an appointment in the coming week. Dr. Smith's EHR puts each patient's information into the correct format so it can be read and processed by the registry. The registry receives and processes the request, and sends Dr. Smith's office a response that includes the latest vaccine history and forecast for each of the patients in the batch request, with the exception of two patients for whom the registry has no information. Dr. Smith's EHR receives and processes the response from the registry, and presents the information to a system user (e.g., the office manager, intake worker, etc.) who can ensure the correct immunization history and forecast is associated with the correct patient. The EHR also lists patients for whom the registry returned no matches or multiple matches and assists the user in resolving potential conflicts.

6.2.2 UPDATE

October 2016 Update: Responses to the capabilities during Phase 3 of the project suggest that batch queries may be problematic. Most sites send multiple or sequential single queries to the IIS' for information to allow more direct matching 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.

This requirement is considered obsolete.

6.2.2.1 Focus on Vendor Perspective

Not applicable.

6.2.2.2 Focus on Provider and Implementer Perspective

Not applicable.

6.2.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

6.2.3.1 Data Elements

Not applicable.

6.3 Requirement 2.2 Real Time Request / Receipt of Patient Immunization History

The system sends a request to the public health immunization registry "on demand" (e.g., those without 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).

6.3.1 Example of Scenario "Real Time Request/Receive Patient Immunization History"

On Wednesday, Dr. Smith's office manager uses the EHR to select Juana Mariana Gonzales (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.

6.3.2 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, Section 13.2.. 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 in Section 13.2 may also provide benefit for patient follow up. Further feedback is invited regarding which additional elements to address.

6.3.2.1 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.

6.3.2.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

6.3.3 Test

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

6.3.3.1 Data Elements

See Appendix A.

6.4 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 he or she

chooses 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. As we move toward greater interoperability communication between IIS's and EHRs becomes increasingly important. Efforts are underway to advance IIS standardization as well.

6.4.1 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 Mariana Gonzales. 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.

6.4.2 Guidance

The immunization history that the registry returns to the provider may include some or all of the data elements listed in Appendix A, Section 13.2Most 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 in Section 13.2 may also provide benefit for patient follow up. Further feedback is invited regarding which additional elements to address.

6.4.2.1 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.

6.4.2.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

6.4.3 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.

6.4.3.1 Data Elements

See Appendix A.

6.5 Requirement 2.4 Request/Receive Patient Immunization Data and Identify Source

The EHR 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 manually as patient-reported, and which were accepted electronically from the public health registry.

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

Dr. Smith's EHR maintains Juana Mariana Gonzales' 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 that 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.

6.5.2 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 those used to capture information received from the IIS referenced in section 6.5.2 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 other 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.).

6.5.2.1 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.

6.5.2.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

6.5.3 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.

6.5.3.1 Data Elements

See Appendix A, Section 13.2

6.6 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.

6.6.1 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 a future audit.

6.6.2 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. 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 the EHR should carefully address usability.

6.6.2.1 Focus on Vendor Perspective

Not applicable.

6.6.2.2 Focus on Provider and Implementer Perspective

Not applicable.

6.6.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

6.6.3.1 Data Elements

Not applicable.

6.7 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 report to the public health registry listing such inconsistencies (e.g., past immunizations missing from the registry report, incorrect CVX codes and incorrect vaccine administration dates).

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

The immunization history maintained in Dr. Smith's EHR for Juana Mariana Gonzales, age 6, includes the three-dose meningococcal B vaccine (CVX code 162). The public health immunization registry history shows the two-dose meningococcal B vaccine (CVX code 163). Dr. Smith's staff confirms they provided the vaccine with a three-dose schedule. The EHR then prepares and submits a report to the public health registry that lists the discrepancy and indicates that the CVX code 162 is the correct information.

6.7.2 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. Added October 2016: If IIS' do not update information based on provider updates future queries to the IIS' will continue to return the same discrepancies resulting in repeated conflicts and needing provider reconciliation. The challenge is that some IIS' have jurisdictional restrictions about what types of data they can accept and store in their registries.

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

6.7.2.1 Focus on Vendor Perspective

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

6.7.2.2 Focus on Provider and Implementer Perspective

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

6.7.3 Test

The HIMSS Immunization Integration Program did not test this requirement.

6.7.3.1 Data Elements

Not applicable.

7 USER WORKFLOW 3: MANAGE INFORMATION FOR CLINICAL DECISION MAKING

7.1 Background

7.1.1 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 physician 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 (IIS), 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.

7.1.2 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 (IIS) 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 clinical decision support web service also participate in the process.

7.1.3   Examples of Work in This Area

- The Advisory Committee on Immunization Practices, an Advisory Committee to the CDC Director, develops recommendations about how to use vaccines to control diseases in the United States.[41] CDC publishes the recommendations regularly as public health advice.[42] 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 clinical decision support.[43] 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 clinical decision support 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 clinical decision support engine can also indicate if individual doses already given are not valid because they were administered inappropriately (e.g., too soon, too young, incorrect product, etc.) per ACIP recommendations. A clinical decision support 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.

7.2   Requirement 3.1 View Immunization Forecast

The system provides a view of the immunization forecast provided by the IIS. The display includes the forecast from the registry and includes recommended vaccination dates, earliest date, the due date and the latest date for each vaccine included in the forecast.

7.2.1   Example of Scenario "View Immunization Forecast"

Marcel Manuel Gonzales, age 2 (birth date 12/24/2014), 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 06/25/2014 and the second dose of Hepatitis A vaccine is recommended to be administered 03/24/2015.

7.2.2   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.

October 2016 Updates:

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.

3. A model for local or state specific variation in forecast recommendations would be helpful. A model for such variation is currently under development by CDC/OPHS/CSELS for electronic case reporting.

7.2.2.1   Focus on Vendor Perspective

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

7.2.2.2   Focus on Provider and Implementer Perspective

Providers should collaborate with public health immunization registries and EHR vendors in the HIMSS Immunization Integration program to harmonize requirements and determine workflow.

7.2.3   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.

7.2.3.1   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;
- Dose number in a series.

7.3   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.

7.3.1   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.

7.3.2   Guidance

The American Immunization Registries of Association 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.[44]

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

7.3.2.1   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 the Advisory Committee on Immunization Practices, an Advisory Committee to the CDC Director.[45] CDC publishes the recommendations regularly as public health advice.[46] 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 clinical decision support.[47] 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 clinical decision support engine can recommend the earliest and latest acceptable dates for providing each vaccine as well as the appropriate intervals between individual vaccines. The clinical decision support engine can also indicate if individual doses already given are not valid because they were given ahead of the prescribed vaccination schedule. A clinical decision support 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.

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 (IIS) 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.

7.3.2.2   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) processes.

7.3.2.3 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.

7.3.2.4 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.

7.3.3 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).

7.3.3.1 Data Elements

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

7.4 Requirement 3.3 Modify Antigen Recommendations Based on Allergy History

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

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

The system notifies the provider that Marcel Manuel Gonzales, age 2 (birth date 12/24/2012) is allergic to diphtheria CRM 197 protein, although the forecast included DTaP in the recommended vaccines. The provider, therefore, can select alternate vaccines.

7.4.2 Guidance

All systems 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:[48]

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.

7.4.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

7.4.2.2 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.

7.4.3 Test

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

7.4.3.1 Data Elements

Not tested.

7.5 Requirement 3.4 Modify Antigen Recommendations Based on Active Diagnosis

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

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

Marcel Manuel Gonzales, age 2 comes to the provider's office for a scheduled appointment. The forecast received from the health department registry indicates that Marcel is due for the influenza vaccine. The provider's EHR system finds a diagnosis of asthma and recommends injectable attenuated influenza vaccine rather than live attenuated nasal vaccine administration.

7.5.2 Guidance

All systems 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.

7.5.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

7.5.2.2 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.

7.5.3 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.

7.5.3.1 Data Elements

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

7.6 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.

7.6.1 Example of Scenario "Update Patient Immunization Schedule"

If hypothetically, the Advisory Committee for Immunization Practices 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.

7.6.2 Guidance

This requirement addresses the ability of the forecasting logic to remain current. Hypothetically, if the Advisory Committee for Immunization Practices 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 8 describes general principles to address effective clinical decision support include the "Ten Commandments of Effective Clinical Decision Support."[49]

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 8. Ten Commandments of Elective Clinical Decision Support

7.6.2.1   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.

7.6.2.2   Focus on Provider and Implementer Perspective

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

7.6.3   Test

The HIMSS Immunization Integration Program does not test this requirement.

7.6.3.1   Data Elements

Not applicable.

7.7   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 are 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.

7.7.1   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 five months.

7.7.2   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.

7.7.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

7.7.2.2 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.

7.7.3 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.

7.7.3.1 Data Elements

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

7.8 Requirement 3.7 Receive Dose Not Indicated Alert Upon Vaccine Administration

The 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 should the provider order a vaccine dose that is inconsistent with appropriate timing intervals.

7.8.1 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 two months.

7.8.2 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.

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.

7.8.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

7.8.2.2 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.

7.8.3 Test

The HIMSS Immunization Integration Program test does not evaluate this requirement.

7.8.3.1 Data Elements

Not tested.

7.9 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.

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

The system administrator in a medical practice reviews all recommendations provided by clinical decision support 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 have no value.

7.9.2 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.

7.9.2.1 Focus on Vendor Perspective

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

7.9.2.2 Focus on Provider and Implementer Perspective

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

7.9.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

7.9.3.1 Data Elements

Not applicable.

8 USER WORKFLOW 4: MANAGE INVENTORY

8.1 Background

8.1.1 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 Vaccine for Children's (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.

8.1.2 Who Performs User Workflow 4: Manage Inventory

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

8.1.3 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 systems, most systems offer drop-down lists that staff members can use to order vaccines and document the vaccine administered more quickly.
- The American Immunization Registry Association has established requirements for inventory management.[50] Some public health registries provide inventory management software that help providers manage guarantee program inventory, as well as private stock. Participating providers enter and manage this information in the public health registry software manually. 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 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 85651), 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.

8.2 Requirement 4.1 Display Available Vaccine Antigens

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

8.2.1 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 Vaccine for Children, and which products are from local/private stock.

8.2.2 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 Vaccines for Children (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 bar code technology to load vaccine stock into the EHR instead of manual entry. Other products allow use of bar code 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 CDC's Vaccine Tracking System (VTrckS) to place orders for additional stock and VFC vaccine is shipped to the provider.[52,53] 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. The American Immunization Registry Association published guidance for inventory management to support the ExIS systems.[54]

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 American National Standards Institute (ANSI) standard, Advanced Ship Notification (EDI 85655), 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 thought the HIMSS Immunization Integration Program 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.

8.2.2.1   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 User Centered Design (UCD) to evaluate how the system manages inventory.

8.2.2.2   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.

8.2.3   Test

The HIMSS Immunization Integration Program does not test this requirement.

8.2.3.1   Data Elements

Not applicable.

8.3   Requirement 4.2 Update Vaccine Inventory from Patient Dosage Administration

The system updates the vaccine inventory to ensure the correct count of remaining available vaccine inventory.

8.3.1   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 Vaccine for Children (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.

8.3.2   Guidance

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

8.3.2.1   Focus on Vendor Perspective

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

8.3.2.2 Focus on Provider and Implementer Perspective

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

8.3.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

8.3.3.1 Data Elements

Not applicable

8.4 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.

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

The nurse manager uses a bar code reader to enter new IPV vaccine stock when it is received. Once she reads in all of the bar codes, 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).

8.4.2 Guidance

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

8.4.2.1 Focus on Vendor Perspective

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

8.4.2.2 Focus on Provider and Implementer Perspective

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

8.4.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

8.4.3.1 Data Elements

Not applicable.

8.5 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.

8.5.1 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).

8.5.2 Guidance

Those products that include 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.

8.5.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

8.5.2.2 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.

8.5.3 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.

8.5.3.1 Data Elements

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

8.6 Requirement 4.5 Produce Vaccine History Report

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.

8.6.1 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-Vaccine For Children) patients will expire in two weeks. The report also indicates that private Varicella vaccine is nearly out of stock.

8.6.2 Guidance

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

8.6.2.1 Focus on Vendor Perspective

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

8.6.2.2 Focus on Provider and Implementer Perspective

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

8.6.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

8.6.3.1 Data Elements

Not applicable.

9 USER WORKFLOW 5: ADMINISTER AND REPORT IMMUNIZATION

9.1 Background

9.1.1 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.

9.1.2 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)

9.1.3 Examples of Work in the Area

- Two vendors interviewed for this effort have evaluated 2D bar coding to document vaccine administration into their EHR systems. Bar code readers for linear and 2D bar codes are readily available at relatively low cost. To date, testing the use of bar codes in administering vaccinations has not identified an ideal workflow for implementing bar code assisted documentation of vaccine administration. Some work has found scanning bar codes 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 bar code on packaging for the lowest unit of sale. Most vaccines contain linear bar codes on the vial containing the vaccine (the unit of use), as well as on the packaging. Linear bar codes 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 bar code no later than 2017, but only at the level of packaging (unit of sale). 2D bar codes 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 bar code. 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 bar coded. Most practices were interested in implementing bar coding to document vaccine administration if a threshold of 76 to 99% of vaccines had 2D bar codes. No vendor identified has yet included incorporation of the Vaccine Information Statement (VIS) and its issue date into the software.[56]

■ 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.[57]

■ 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 electronic clinical quality measures (eCQMs) in EHRs.[58,59] A more usable mechanism to document deferrals is needed.

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

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

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

The nurse planning to administer a DTaP vaccine to Juana Maria Gonzales Morales, age 3 years 4 months, accesses the appropriate DTaP Vaccine Information Statement 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.

9.2.2 Guidance

CDC updates VIS statements periodically and posts them in PDF and Word format for download.[60] Some vendors provide Vaccine Information Statements (VIS) 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 establish an API to pull the most up-to-date VIS form into the EHR as needed.

9.2.2.1 Focus on Vendor Perspective

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

9.2.2.2 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 learn the vendor's process to keep them current. If the practice uploads the VIS statements into the EHR or provides paper or electronic copies to patients directly, develop a process to routinely check for VIS statement updates to remain current.

9.2.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

9.2.3.1 Data Elements

Not applicable.

9.3 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.

9.3.1 Example of Scenario "Record Vaccine Administration Deferral"

Mrs. Morales refuses to allow her daughter Maria to receive DPT 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.

9.3.2 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.[61]

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

9.3.2.1 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.

9.3.2.2 Focus on Provider and Implementer Perspective

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

9.3.3 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.

9.3.3.1 Data Elements

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

9.4   Requirement 5.3 Record Past Immunization

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.

9.4.1   Example of Scenario "Record Past Immunizations"

Juana Mariana Gonzales, age 6, received 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).

9.4.2   Guidance

The requirement addresses recording immunization history obtained from external sources or history provided by the patient or patient's caregiver. All vendors 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.

9.4.3   Perspective

9.4.3.1   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.

9.4.3.2   Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

9.4.4   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.

9.4.4.1   Data Elements

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

9.5   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.

9.5.1   Example of Scenario "Notify of Vaccine Dose Ineligibility"

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

9.5.2 Guidance

Programming vaccine dose ineligibility (or eligibility) requires clearer documentation and specification of the requirement. All vendors evaluated provide the ability for providers to specify VFC eligibility at each visit and most when documenting administration of each vaccine. All also support including 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.

The American Immunization Registry Association (AIRA) publishes a number of guidance documents about VFC eligibility.[62,63]

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.

   a. Dependency: Electronically accessible eligibility criteria in each state, or a compendium of all state criteria in a central source.
   b. Direct the InfoButton 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 US 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 American National Standards Institute 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.

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.[64,65,66]

9.5.2.1 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.

9.5.2.2 Focus on Provider and Implementer Perspective

Providers participating in VFC programs should be familiar with VFC eligibility requirements to document dose level eligibility appropriately in the EHR. Providers may also want to address VFC requirements for vaccine handling and storage issues discussed in the Guidance section (5.2.6.1). EHRs do not assist with management or documentation of such vaccine handling and storage issues.

9.5.3 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.

9.5.3.1 Data Elements

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

9.6 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.

9.6.1 Example of Scenario "Document Vaccine Ineligibility Override Reason"

Dr. Smith has no remaining VFC stock of MMR vaccine. Mason Williams, a 15-month-old child, is present for his visit and has not previously received MMR. Dr. Smith writes an order to give Mason his MMR vaccine from private stock and documents the reason for not using VFC vaccine (override).

9.6.2 Guidance

Refer to the guidance discussion for Section 5.26 (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 generally occurs external to the EHR.

9.6.2.1 Focus on Vendor Perspective

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

9.6.2.2 Focus on Provider and Implementer Perspective

Same as Focus on Vendor Perspective.

9.6.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

9.6.3.1 Data Elements

Not applicable.

9.7 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.

9.7.1 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).

9.7.2 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).

9.7.2.1 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.

9.7.2.2 Focus on Provider and Implementer Perspective

Discuss preferences for vaccine ordering with the software vendor.

9.7.3 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.

9.7.3.1 Data Elements

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

9.8 Requirement 5.7 Review Patient Immunization History

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

9.8.1 Example of Scenario "Review Patient Immunization History"

When ordering vaccines for her patient, Dr. Smith is able to view Juana Mariana Gonzales' 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.

9.8.2 Guidance

All vendors 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.

9.8.2.1 Focus on Vendor Perspective

Usability evaluation such as UCD may benefit more efficient workflow.

9.8.2.2 Focus on Provider and Implementer Perspective

Discuss preferences for documenting vaccine administration with the software vendor.

9.8.3 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.

9.8.3.1 Data Elements

Not applicable.

9.9 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, CVX for immunizations) to discrete data elements associated with an immunization.

9.9.1 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 EHR check for diagnoses, which should help providers know to avoid specific vaccines.

9.9.2 Guidance

All vendors evaluated support CVX codes for immunizations and SNOMED-CT or ICD for conditions.

9.9.2.1 Focus on Vendor Perspective

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

9.9.2.2 Focus on Provider and Implementer Perspective

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

9.9.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

9.9.3.1 Data Elements

Not applicable.

9.10 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, site of administration (e.g., left arm), immunization type, product, lot number, manufacturer, Vaccine Information Statement date, and quantity of

vaccine/dose size. The system also assures data quality, i.e., data entered are appropriate (e.g., avoid "oral" route for IM vaccines, and assure dose is appropriate for the vaccine).

9.10.1 Example of Scenario "Record Vaccine Administration"

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

9.10.2 Guidance

All products evaluated can record expected information for vaccines the provider administers. The data set used for evaluation include elements listed in the HL7 2.5.1 implementation guide version 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.

9.10.2.1 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 product can capture the superset of data to support the variation.

9.10.2.2 Focus on Provider and Implementer Perspective

There are a limited set of known locally required (R) fields for immunization reporting that are not required (R) fields in the HL7 2.51 version 1.5 standard 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'.

9.10.3 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.

9.10.3.1 Data Elements

See Appendix A.

9.11 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.

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

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

9.11.2 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.

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

Usability evaluation such as a UCD process may inform the content and presentation of such a "standard" form.

9.11.2.1 Focus on Vendor Perspective

Usability evaluation such as a UCD process may inform the content and presentation of such a "standard" form.

9.11.2.2 Focus on Provider and Implementer Perspective

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

9.11.3 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.

9.11.3.1 Data Elements

Not applicable.

9.12 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 immunization history to public health immunization registries.

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

The nurse administering vaccines to Juana Maria Gonzales Morales 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.

9.12.2 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 version 1.4 (used for Meaningful Use 2) 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 version 1.5 requires NCIT body site codes rather than the HL7 Table 0162 allowed by the version 1.4.

The implementation guide version 1.5 requires the code ER (return only on error) for the field "Accept Acknowledgement Type" (MSH.15). The test tool does not accept ACK (acknowledgement).

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.

9.12.2.1 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 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.

9.12.2.2 Focus on Provider and Implementer Perspective

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

9.12.3 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.

9.12.3.1 Data Elements

See Appendix A.

9.13 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.

9.13.1 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.

9.13.2 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.

9.13.2.1 Focus on Vendor Perspective

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

9.13.2.2 Focus on Provider and Implementer Perspective

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

9.13.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

9.13.3.1 Data Elements

Not applicable.

9.14 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.

9.14.1 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.

9.14.2 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.

9.14.2.1 Focus on Vendor Perspective

Vendor feedback is invited on this requirement.

9.14.2.2 Focus on Provider and Implementer Perspective

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

9.14.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

9.14.3.1 Data Elements

Not applicable.

9.15 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 time frame.

9.15.1 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 Morales. 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.

9.15.2 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 include *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.

9.15.2.1 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.

9.15.2.2 Focus on Provider and Implementer Perspective

Refer to the provider perspective discussion for requirement 4.2.

9.15.3 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.

9.15.3.1 Data Elements

Not applicable.

10 USER WORKFLOW 6: MANAGE COHORT OF PATIENTS

10.1 Background

10.1.1 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.

10.1.2 Who Performs User Workflow 6: Manage Cohort of Patients

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

10.1.3 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.[67] 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 (IIS) support this functionality. The independence of the health department service helps to ensure accuracy of the results.

10.2 Requirement 6.1 Produce Population-Level Report

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

10.2.1 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.

10.2.2 Guidance

Most products evaluated support customers to create patient lists based on basic criteria. The function is a requirement for Meaningful Use 2014 certification. 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.

10.2.2.1 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).

10.2.2.2 Focus on Provider and Implementer Perspective

Discuss preferences for the specific immunization-related population-level (cohort) reports with the software vendor.

10.2.3 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.

10.2.3.1 Data Elements

Not applicable.

10.3 Requirement 6.2 Notify Patients of Immunization Status

The EHR or other clinical software system notifies patients based on specific known immunization data.

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.

10.3.1 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.

10.3.2 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 (expected for Meaningful Use 2014 certification). 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.

10.3.2.1 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).

10.3.2.2 Focus on Provider and Implementer Perspective

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

10.3.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

10.3.3.1 Data Elements

Not applicable.

11 USER WORKFLOW 7: MANAGE ADVERSE EVENT REPORTING

11.1 Background

11.1.1 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.

11.1.2 Who Performs User Workflow 7: Manage Adverse Event Reporting

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

11.1.3 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.[68] 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.[69]
- 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.[70]
- Many EHRs provide a link for providers to access the VAERS or MedWatch sites.
- The ONC Standards and Interoperability Framework initiative, Structured Data Capture, is developing standard mechanisms to report directly using information already captured in the

EHR.[71] VAERS is one of the reports addressed by the Structured Data Capture initiative (although listed as a low priority example).

11.2 Requirement 7.1 Identify Adverse Event

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

11.2.1.1.1 Example of Scenario "Identify Adverse Event"

Dr. Smith examines Juana Maria Gonzales Morales 24 hours after she receives a live, attenuated influenza 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 specific influenza vaccine.

11.2.2 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.

11.2.3 Perspective

11.2.3.1 Focus on Vendor Perspective

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

11.2.3.2 Focus on Provider and Implementer Perspective

Discuss preferences for documenting adverse events with the software vendor.

11.2.4 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.

11.2.4.1 Data Elements

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

11.3 Requirement 7.2 Initiate and Submit a VAERS Report

The EHR or other clinical software initiates and submits a Vaccine Adverse Event Reporting System (VAERS) report.

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

Dr. Smith examines Juana Maria Gonzales Morales 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.

11.3.2 Guidance

Providers generally report adverse reactions to the Vaccine Adverse Reporting System (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 clinical decision support system called Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP-VAERS) to assist clinicians with adverse event detection and reporting.[72] 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.

11.3.2.1 Focus on Vendor Perspective

Vendors should evaluate opportunities to incorporate the new CDC ESP-VAERS clinical decision support 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.

11.3.2.2 Focus on Provider and Implementer Perspective

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

11.3.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

11.3.3.1 Data Elements

Not applicable.

11.4 Requirement 7.3 Notify of Previous Adverse Event

EHRs and other clinical software systems alert providers to previous adverse events for a specific patient, in order to inform clinical decision-making when providers view an existing immunization record.

11.4.1 Example of Scenario "Notify of Previous Adverse Event"

In 2013, 24 hours after she received a live, attenuated influenza vaccine, Juana Maria Gonzales Morales 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.

11.4.2 Guidance

All systems 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:[73]

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.

11.4.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

11.4.2.2 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.

11.4.3 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.

11.4.3.1 Data Elements

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

11.5 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.

11.5.1 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 Morales 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).

11.5.2 Guidance

Some of the products evaluated will submit an updated immunization record to an immunization registry (IIS) 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 also 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.

11.5.2.1 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.

11.5.2.2 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.

11.5.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

11.5.3.1 Data Elements

Not applicable.

12 USER WORKFLOW 8: PROVIDE PATIENT ACCESS

12.1 Background

12.1.1 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.

12.1.2 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 personal health record (PHR) or through external access to the provider's EHR (for example, a portal).

12.1.3 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. 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,[74] and for daycare facilities and schools.[75] These searchable web sites are helpful to determine individual requirements, but highlight the differences among the states for employee, daycare, 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.

12.2 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).

12.2.1 Example of Scenario "Provide Access to Patient Immunization Record

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

12.2.2 Guidance

All products evaluated provide access for patients to view immunization histories on the patient portal. The method for displaying the information on 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.

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how the system handles notifications and alerts.

12.2.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how to provide patients access to their immunization records.

12.2.2.2 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.

12.2.3 Test

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

12.2.3.1 Data Elements

Not applicable.

12.3 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.

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

Juana Maria Gonzales Morales' 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 Vaccine Information Statements for each of the upcoming vaccines so she can be informed before taking Juana Maria to the doctor's office.

12.3.2 Guidance

Few of the products evaluated 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.

12.3.2.1 Focus on Vendor Perspective

Vendors should consider usability evaluation such as User Centered Design (UCD) to evaluate how to provide patients access to their future immunization requirements.

12.3.2.2 Focus on Provider and Implementer Perspective

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

12.3.3 Test

The HIMSS Immunization Integration Program test requires that the system displays the forecast created after the office visit (during which vaccines are administered). The test does not include provision of VIS forms based on the feedback from vendors and providers.

12.3.3.1 Data Elements

Not applicable.

12.4 Requirement 8.3 Provide Access to Printable Immunization Record

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

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

Juana Maria Gonzales Morales' 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.

12.4.2 Guidance

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

12.4.2.1 Focus on Vendor Perspective

No specific recommendations.

12.4.2.2 Focus on Provider and Implementer Perspective

No specific recommendations.

12.4.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

12.4.3.1 Data Elements

Not applicable.

12.5 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.

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

Mariela Gonzales Morales' mother logs onto to Dr. Smith's EHR portal to view Mariela's immunization record. Mariela received an influenza vaccine 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.

12.5.2 Guidance

One-quarter of the products 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.

12.5.2.1 Focus on Vendor Perspective

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

12.5.2.2 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.

12.5.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

12.5.3.1 Data Elements

Not applicable.

12.6 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.

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

Dr. Smith receives notification about information Mariela Gonzales Morales' 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.

12.6.2 Guidance

Many products evaluated 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.

12.6.2.1 Focus on Vendor Perspective

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

12.6.2.2 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.

12.6.3 Test

The HIMSS Immunization Integration Program does not test this requirement.

12.6.3.1 Data Elements

Not applicable.

13 APPENDIX A: DATA ELEMENTS FOR FUNCTIONAL TESTING

13.1 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 9 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
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

PATIENT DEMOGRAPHIC INFORMATION		
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 9: Patient Demographic Information included in the HL7 2.5.1 Implementation Guide (R = Required, RE = Required if Exists, O = Optional)

13.2 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 10 lists the immunization history data element.

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)		C (R- if administered amount NOT '999'/O)
Administering Provider	The person who administers the dose to the patient	C (RE - New Administrations/O - Historical)

IMMUNIZATION HISTORY DATA ELEMENTS		
Administered-at Location		C (RE - New Administrations/O - Historical)
Lot Number		C (RE - New Administrations/O - Historical)
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 10: 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)

13.3 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 11 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
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

ADMINISTER AND RECORD VACCINE		
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 11: Administer and Record Vaccine – captured data elements (R = Required, RE = Required if Exists, O = Optional, C = Conditional)

13.4 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 12 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

TRANSMIT STANDARD PATIENT IMMUNIZATION HISTORY REPORT	
	Administered/O)
Entering Organization	RE
Vaccine Type	R
Date/time Vaccine Administered	R
Dose Number in Series	O
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 12: Transmit Standard Patient Immunization History Report (R = Required, RE = Required if Exists, O = Optional, C = Conditional)

14 APPENDIX B: CROSS-WALK OF CAPABILITIES TO TEST SCRIPT

Cross-walk of Capabilities to Test Scripts, December 20, 2016

The full test plan including detailed Test Case Groups and Test Cases are available at: http://75.101.155.161:8080/iztool/#/cb.

Exhibit 13 provides an overview of the test steps, organized by capability. The exhibit abbreviates the Test Case Groups as follows:

- Group 1: Initial Data Load
    - Patient1: Juana Mariana Vazquez
    - Patient2: Juan Marcel Marina
    - Patient3: Mariela Gonzales Morales
    - Patient4: Juana Maria Gonzales Morales
- Group 2: Juana Mariana Vazquez Visit

- Group 3: Juan Marcel Marina Visit
- Group 4: Mariela Gonzales Morales Visit
- Group 5: Juana Maria Gonzales Morales Visit
- Group 6: Cohort Report

User Workflow	Immunization-Related Capabilities	Bi-Directional Exchange Test Plan Test Case Group/ Test Case/ *Test Step*
1. Register and Identify a Patient	1.1 Register new patients	Group 1 (Initial Data Load) / Patients1-4/ Enter Initial Demographic Data
	1.2 Select new patient	Groups 2-5/ Query the Registry/ *Select Patient*
	1.3 Select one or more patients	n/a
2. Manage External Query, Response, and Reconciliation	2.1 Batch Request/Receive Patient Immunization History(ies)	n/a
	2.2 Real Time Request/Receive Patient Immunization History	Group 2/ Query the Registry/ *Query Registry for vaccination history and forecast* **and** *View and Compare response* **AND** Group 3-5/ Query the Registry/ *Query Registry for vaccination history and forecast and View and Import response* Group 5/ Query the Registry/ *Query Registry for vaccination history and forecast* **and** *Error Handling - Too many matches found Error Handling - No persons found View and Import response*
	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* **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* **AND** Group2/ Query Registry/ *Reconcile and import vaccinations from Evaluated History and Forecast* **AND** Group2/ Enter Orders and Immunizations *Enter Immunization Data for MMR Given 2 Weeks Prior* **AND** Groups 3-5/ Query Registry/ *Query Registry for vaccination history and forecast and View and import response to request for vaccination history*

User Workflow	Immunization-Related Capabilities	Bi-Directional Exchange Test Plan Test Case Group/ Test Case/ *Test Step*
	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	Groups 2-5/ Query the Registry/ *View the updated vaccination forecast*
	3.3 Modify Antigen Recommendations Based on Allergy History	n/a
	3.4 Modify Antigen Recommendations Based on Active Diagnoses	Group 1 (Initial Data Load)/Patient2/ *Enter Clinical History* **AND** Group 3/ Enter Orders and Immunizations/ *Orders meningococcal vaccine for congenital asplenia indication* **AND** Group 4/ Enter Orders and Immunizations/ *Enter Initial Clinical Information*
	3.5 Update Patient Immunization Schedule	n/a
	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 **AND** 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* **AND** Group3/ 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	Note: Formal Deliverable 10a indicates 3.7 is tested while Immunization-Related Test Processing document dated 2/24/16 indicates that it is not tested
	3.8 Save History of Clinical Decision Support Recommendations	n/a

User Workflow	Immunization-Related Capabilities	Bi-Directional Exchange Test Plan Test Case Group/ Test Case/ *Test Step*
4. Manage Inventory	4.1 Display Available Vaccine Antigens	n/a
	4.2 Update Vaccine Inventory from Patient Dosage Administration	n/a
	4.3 Update Vaccine Inventory from Stock Receipt	n/a
	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	n/a
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/ *Enter Initial Immunization Data: Immunizations from practice* *Enter Initial Immunization Data from Another Practice* *Enter Initial Immunization Data Reported by Parent* **AND** 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** Group 3/ Enter Orders and Immunizations/ *Orders meningococcal vaccine for congenital asplenia indication contraindication* **and** *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*

User Workflow	Immunization-Related Capabilities	Bi-Directional Exchange Test Plan Test Case Group/ Test Case/ *Test Step*
		Reconcile and import vaccinations from Evaluated History and Forecast **AND** Group 3-5/Query the Registry and Group/ *View and import response to request for vaccination history*
	5.8 Link Standard Codes to Immunization Data	n/a
	5.9 Record Vaccine Administration	Group 2/ Enter Orders and Immunizations/ *Records Influenza Vaccine administration route with data validation checking* **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* *Record Meningococcal Vaccine administration* **AND** Group 5/ Enter Orders and Immunizations/ Record Combo Vaccine administration
	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/ Transmit Immunization Report/ Transmit the immunization report/ *Transmit the immunization report to the Immunization Registry* **and** *Receive ACK Z23 from Immunization Registry* **AND** Group 2/ Transmit the immunization report/ *Record an adverse reaction* **and** *Transmit the updated vaccination report with adverse reaction to the registry* **AND** Group 3/ Transmit the immunization report/ Transmit Delete from Bad Lot **AND** Group 5/ Transmit Immunization Report/ Transmit Immunization Report - Error Handling / *Transmit the immunization report to the Immunization Registry – Fatal Error* **and** *Receive ACK Z23 Fatal Error - CVX Code* **and** *Transmit the Immunization Report for Juana Maria Gonzales Morales - warning handling* **and** *Receive ACK Z23 Warning - Invalid Value* **and** Transmit the Immunization Report for Juana Maria Gonzales Morales - 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

User Workflow	Immunization-Related Capabilities	Bi-Directional Exchange Test Plan Test Case Group/ Test Case/ *Test Step*
	5.14 Produce Immunization Forecast Report	Groups 2-4/ Display Immunization Report/ *Produce an immunization report*
6. Manage Cohort of Patients	6.1 Produce Population-Level Report	Group 6 (Cohort Report)/ Overdue Immunizations/*Produce Overdue Immunizations Cohort Report*
	6.2 Notify Patient of Immunization Status	n/a
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*
	7.4 Notify IIS of Update from Adverse Event	Group 2/ Transmit the immunization report/ *Record an adverse reaction* **and** *Transmit the updated vaccination report with adverse reaction to the registry*
8. Provide Patient Access	8.1 Provide Access to Patient Immunization Record	Group 2/ Provide Patient Access to Immunization Report
	8.2 Provide Access to Recommendations and Vaccine Information Statement(s)	n/a
	8.3 Provide Access to Printable Immunization Record	n/a
	8.4 Provide Access to Update Immunization Information	n/a
	8.5 Review Patient-Provided Immunization Information	n/a

Exhibit 13. Cross-walk of capabilities to test script

15 APPENDIX C: END NOTES

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