

**Gaining Input from Stakeholders
Immunization-Related Capabilities for Electronic Health Records and Other
Clinical Software**

**For the Centers for Disease Control and Prevention (CDC)
National Center for Immunization and Respiratory Diseases (NCIRD)**

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1 OVERVIEW OF THE PROJECT

1.1 Overview

Under two contracts for the Centers for Disease Control and Prevention (CDC) National Center for Immunization and Respiratory Diseases (NCIRD), CNI Advantage, LLC (CNIADV) is developing immunization-related requirements and related testing and certification processes for electronic health records (EHRs) and other clinical software to increase vaccine coverage.

1.2 Why is This Important?

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. EHRs and other clinical software also have the potential of improving vaccine tracking, vaccine safety, and the ease by which patients can gain access to their immunization histories.

Due to nearly \$28 billion in federal health IT investments, a majority of hospitals and clinicians in the U.S. now use EHRs to improve the quality, safety, and cost of care. CDC believes that embedding immunization-related capabilities in EHRs will (1) improve immunization rates by making it easy for clinicians to administer appropriate vaccines, (2) increase knowledge and acceptance of immunizations among patients and their caregivers, and (3) improve the tracking and safety of vaccines.

1.3 How Were the Software Requirements Developed?

The initial draft immunization-related capabilities and requirements were developed based on the following:

- A literature review;
- Interviews with more than 60 individuals and organizations representing clinicians and other immunization providers, EHR and other clinical software developers, the immunization information system (IIS) community, certification and testing bodies, and others who are in a position to provide incentives for adoption of such requirements;
- Initial requirement-specific feedback and a working session involving approximately 20 stakeholders including clinicians and other immunization providers, EHR developers, the IIS community, certification and testing bodies, and CDC.
- Insights from a team of subject matter experts with expertise in clinical informatics, clinical workflow, and public health informatics.

1.4 How the Input Received From this Process Will be Used

CNIADV is now gaining additional input on the draft immunization-related capabilities and requirements through this website and through stakeholder meetings convened by collaborating non-profit organizations representing clinicians and other immunization providers, EHR and other software developers, and the IIS and public health community.

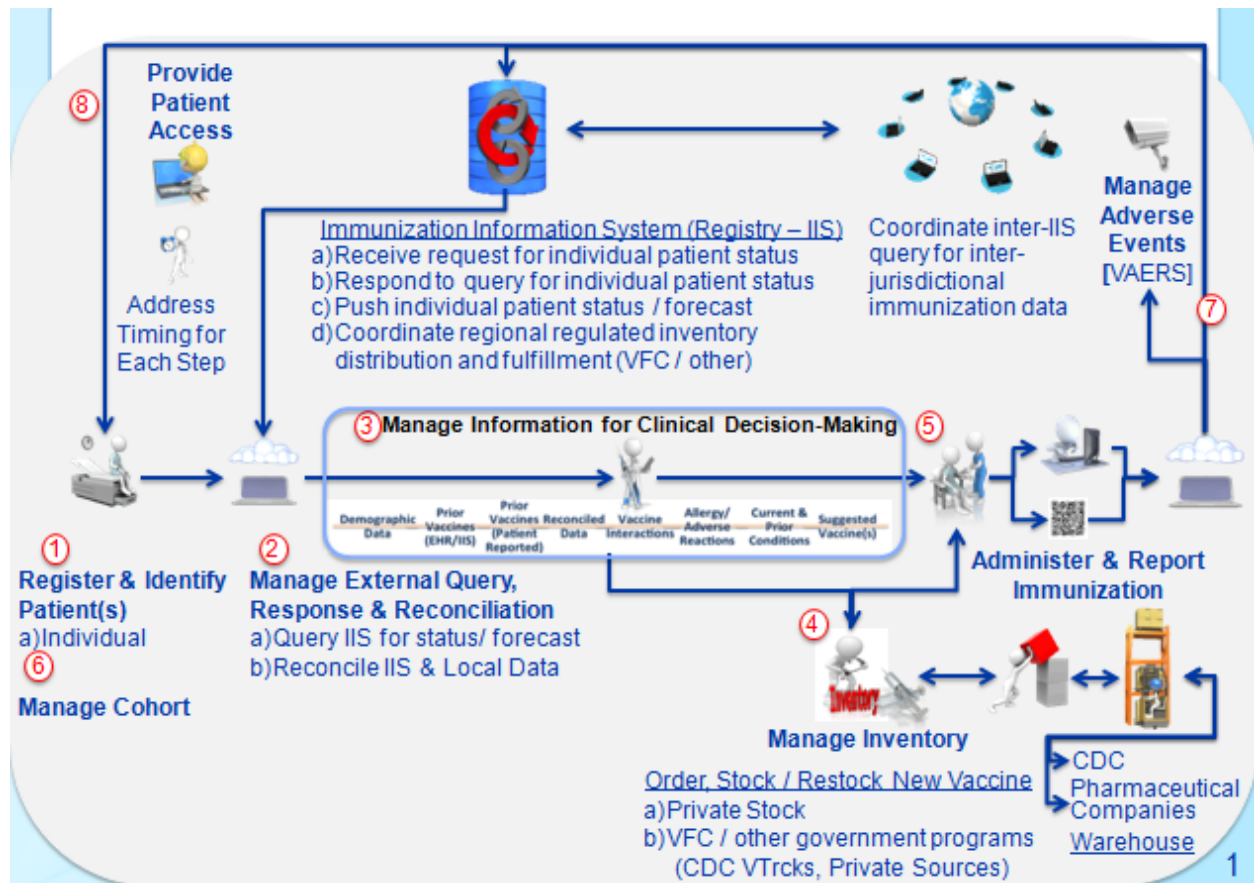
The final set of immunization-related capabilities and requirements—integrating input received through the website—will be inform the following deliverables to CDC.

- A final set of immunization-related software capabilities (including scenarios and examples) that will be published in a guidance document to support users and developers of clinical software
- Voluntary testing processes for a critical subset of the requirements that can be used to support validation of the existence of such requirements in clinical software within voluntary, market-based testing and/or certification programs

2 ABOUT THE WORKFLOWS

The immunization-related requirements are organized within eight general user workflows, which together constitute the end-to-end workflow for providing immunizations to patients.

Providing the right immunization(s) to a patient at the right time requires actions by people and information sharing among software systems. The following diagram shows the end-to-end workflow for providing immunizations to patients. Some tasks are performed exclusively by people, such as immunization providers; other tasks incorporate EHRs and/or other clinical software. The Exhibit below presents the actions performed by providers and IIS' to provide immunizations to patients.



Immunization-related requirements were developed for each workflow, that can be used to evaluate and demonstrate the inclusion of such capabilities within EHRs or other clinical software. Usability considerations associated with immunizations were also developed.

The following sections describe each workflow, a list of the actors who perform activities within each workflow, examples of work related to the workflow area, and requirements associated with each workflow. Usability considerations are also described.

3 WORKFLOW 1: REGISTER AND IDENTIFY A PATIENT

3.1 General Description

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.

3.2 Who Performs This Workflow

- 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).

3.3 Examples of Work Related to this Workflow

Anyone using an EHR or PHR 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.¹ Others recommend common matching procedures, or algorithms.^{2,3} Considerable effort is underway in other settings to address unique patient identification.⁴ Note that the process assumes privacy and security is managed for all users of the EHR. This workflow does not include any specific immunization-related privacy and security requirements.

3.4 Requirements Within Workflow 1

Requirement 1.1: Register New Patients

Overview of Scenario

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 for identifying patients in immunization registries, if it is available, specifically the mother's maiden name, whether the patient was part of a multiple birth, and if so, the order of birth. This information allows the provider to correctly identify the patient and also helps assure a match when the EHR send the patient's information to external systems such as an immunization registry.

Example of Scenario

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.

Requirement 1.2: Select New Patient

Overview of Scenario

The system must allow a user to distinguish information about patients with similar sounding names or identifying information in order to select the right patient from the providers EHR or other clinical software. For example, twins living in the same household will have similar dates of birth, addresses, and may have similar sounding names. Specifically for immunizations, 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. This information allows the provider to correctly identify and select the correct patient. This information also helps assure a match when the EHR send the patient's information to external systems such as an immunization registry.

Example of Scenario

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.

Requirement 1.3: Select Multiple Patients

Overview of Scenario

The system must allow a provider to specify all patients scheduled for appointments 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.

Example of Scenario

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.

3.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a "guidance" document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to warrant inclusion in the subset for which testing and certification processes will be developed.

4 WORKFLOW 2: MANAGE EXTERNAL QUERY, RESPONSE, AND RECONCILIATION

4.1 General Description

This workflow 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.

4.2 Who Performs This Workflow

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

4.3 Examples of Work Related to this Workflow

Exchanging health information among two or more systems, and the ability of those systems to use the information, is defined as *interoperability*.⁵ 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.^{6,7,8} Earlier efforts addressed communication among EHRs and specialized or public health registries.^{9,10,11} 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.¹²

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.^{13,14,15,16} 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.

4.4 Requirements Within Workflow 2

Requirement 2.1: Batch Request/Receive Patient Immunization History(s)

Overview of Scenario

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).

Example of Scenario

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 assure 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.

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

Overview of Scenario

The system sends a request to the public health immunization registry “on demand” for walk-in patients (i.e., 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 (Query Response Grammar (RSP) – HL7 version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5).

Example of Scenario

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 be process and present to Dr. Smith when she sees the patient.

Requirement 2.3: Compare IIS Immunization History to EHR Immunization History

Overview of Scenario

The public health immunization registry has returned the requested immunization history for a patient. The EHR is able to display the 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.

Example of Scenario

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.

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

Overview of Scenario

The EHR or other clinical software is able to store immunization history accepted from other sources (such as a public health immunization registry) or entered directly by a clinician based on information provided by the patient. 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 from the public health registry.

Example of Scenario

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.

Requirement 2.5: Request/Receive Patient Vaccine Forecast and Store Audit Data

Overview of Scenario

The system stores the vaccine forecast as it was received from the public health immunization registry. The forecast can be used for any later quality assurance activities that may be required.

Example of Scenario

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.

Requirement 2.6: Notify IIS of Differences Between EHR Data and IIS Response

Overview of Scenario

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.

Example of Scenario

The immunization history maintained in Dr. Smith's EHR for Juana Mariana Gonzales, age 6, includes the three-dose meningococcal vaccine (CVX code 163). The public health immunization registry history shows the two-dose meningococcal vaccine (CVX code 162). 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 163 is the correct information.

4.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a "guidance" document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to

warrant inclusion in the subset for which testing and certification processes will be developed.

5 WORKFLOW 3: MANAGE INFORMATION FOR CLINICAL DECISION MAKING

5.1 General Description

This workflow 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.

5.2 Who Performs This Workflow

- 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.

5.3 Examples of Work Related to this Workflow

- 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.¹⁷ CDC publishes the recommendations regularly as public health advice.¹⁸
- 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.¹⁹ 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.

- 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.

5.4 Requirements Within Workflow 3

Requirement 3.1: View Immunization Forecast

Overview of Scenario

The system provides a view of the immunization forecast provided by the public health immunization registry (IIS). The forecast includes recommended vaccination dates, minimum (earliest) date, ideal date, and maximum (latest) date for each vaccine included in the forecast.

Example of Scenario

Marcel Manuel Gonzales, age 2 (birth date 12/24/2012), 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.

Requirement 3.2: View Reconciled Immunization Forecast

Overview of Scenario

The EHR or other clinical software system has the ability to re-evaluate the immunization forecast using a patient's newly updated immunization history, where the updated history results from the 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.

Example of Scenario

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.

Requirement 3.3: Modify Antigen Recommendations Based on Allergy History

Overview of Scenario

The EHR or other clinical software system compares the vaccines recommended in the updated forecast from the public health immunization registry with the patient's allergy history and then notifies the provider of any conflicts with the recommended vaccines.

Example of Scenario

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.

Requirement 3.4: Modify Antigen Recommendations Based on Active Diagnoses

Overview of Scenario

The system compares the vaccines recommended in the updated forecast from the public health immunization registry with the patient's active diagnoses and then notifies the provider of any conflicts with the recommended vaccines.

Example of Scenario

Marcel Manuel Gonzales, age 2 (birth date 12/24/2012) 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.

Requirement 3.5: Update Patient Immunization Schedule

Overview of Scenario

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.

Example of Scenario

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 update all patients' vaccine schedules to include the newly required MMR dose.

Requirement 3.6: Receive Dose Not Indicated Alert for Single Vaccine Order

Overview of Scenario

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.

Example of Scenario

The minimum valid date (earliest date) for the fourth dose of pneumococcal conjugate (PCV13) vaccine is at 9 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 two months.

Requirement 3.7: Receive Dose Not Indicated Alert Upon Vaccine Administration

Overview of Scenario

The system notifies the individual administering a vaccine that the vaccine is inconsistent with expected timing intervals as suggested by the vaccine forecast. This requirement is a “failsafe” mechanism should the provider order a vaccine dose that is inconsistent with appropriate timing intervals.

Example of Scenario

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.

Requirement 3.8: Save History of Clinical Decision Support Recommendations

Overview of Scenario

The EHR or other clinical software system saves a history of all recommendations provided to a clinician, including the information accessed and used to arrive at the recommendation.

Example of Scenario

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.

5.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a “guidance” document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to warrant inclusion in the subset for which testing and certification processes will be developed.

6 USER WORKFLOW 4: MANAGE INVENTORY

6.1 General Description

This workflow 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 provider'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.

6.2 Who Performs this Workflow

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

6.3 Examples of Work Related to this Workflow

- 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 such 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.²⁰ 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 85621), 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.

6.4 Requirements Within Workflow 4

Requirement 4.1: Display Available Vaccine Antigens

Overview of Scenario

The system presents a list of vaccine antigens available for administration to patients.

Example of Scenario

Through her 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.

Requirement 4.2: Update Vaccine Inventory from Patient Dosage Administration

Overview of Scenario

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

Example of Scenario

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.

Requirement 4.3: Update Vaccine Inventory from Stock Receipt

Overview of Scenario

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 and for private stock.

Example of Scenario

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).

Requirement 4.4: Notify of Vaccine Dose Expiration

Overview of Scenario

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

Example of Scenario

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).

Requirement 4.5: Produce Vaccine History Report

Overview of Scenario

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

Example of Scenario

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.

6.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

-
1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
 2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
 3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a “guidance” document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to warrant inclusion in the subset for which testing and certification processes will be developed.

7 USER WORKFLOW 5: ADMINISTER AND REPORT IMMUNIZATION

7.1 General Description

This workflow 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:

- Providing patient education to help the patient understand the immunization about to be administered
- Documenting reasons why a recommended immunization is not given (e.g., patient refusal, fever on the day of the visit, etc.)
- Administration of the vaccine to the patient
- Documenting all of the information about the process (i.e., which vaccine, lot number and expiration date, body site of the injection, etc.)
- Submitting the report to the public health registry, and
- Providing the patient with a summary of vaccine status.

7.2 Who Performs This Workflow

- 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)

7.3 Examples of Work Related to this Workflow

- 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 expiration date into the software.²²
- 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.²³
- 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.^{24,25} A more usable mechanism to document deferrals is needed.

7.4 Requirements Within Workflow 5

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

Overview of Scenario

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.

Example of Scenario

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

Requirement 5.2: Record Vaccine Administration Deferral

Overview of Scenario

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.

Example of Scenario

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.

Requirement 5.3 Record Past Immunizations

Overview of Scenario

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.

Example of Scenario

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).

Requirement 5.4: Notify of Vaccine Dose Ineligibility

Overview of Scenario

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.

Example of Scenario

Juana Maria G. Morales is not covered by the Vaccine for Children's 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.

Requirement 5.5: Document Vaccine Ineligibility Override Reason

Overview of Scenario

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.

Example of Scenario

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).

Requirement 5.6: Enter Vaccination Order

Overview of Scenario

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

Example of Scenario

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).

Requirement 5.7: Review Patient Immunization History

Overview of Scenario

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.).

Example of Scenario

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.

Requirement 5.8: Link Standard Codes to Immunization Data

Overview of Scenario

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

Example of Scenario

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.

Requirement 5.9: Record Intent to Administer Vaccine

Overview of Scenario

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.

Example of Scenario

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 she works allows this information to be entered manually or using bar codes.

Requirement 5.10: Produce Standard Patient Immunization History Report

Overview of Scenario

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.

Example of Scenario

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.

Requirement 5.11: Transmit Standard Patient Immunization History Report

Overview of Scenario

The EHR or other clinical software system creates and transmits a report of a patient's immunization history to public health immunization registries.

Example of Scenario

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.

Requirement 5.12: Produce Configurable Patient Immunization History Report

Overview of Scenario

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.

Example of Scenario

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.

Requirement 5.13: Transmit Configurable Patient Immunization History Report

Overview of Scenario

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.

Overview of Example

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.

Requirement 5.14: Produce Immunization Forecast Report

Overview of Scenario

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

Example of Scenario

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.

7.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a "guidance" document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to warrant inclusion in the subset for which testing and certification processes will be developed.

8 USER WORKFLOW 6: MANAGE COHORT OF PATIENTS

8.1 General Description

This workflow describes how EHRs and other clinical software system 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. There are many reasons for identifying a cohort of patients. Some examples include identifying all patients who are up to date with respect to immunization coverage, those with missed appointments and who are therefore at risk for exceeding the maximum time for immunizations, and those who received a specific medication (or immunization) that has been recalled.

8.2 Who Performs this Workflow

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

8.3 Examples of Work Related to this Workflow

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.²⁶ 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.

8.4 Requirements Within Workflow 6

Requirement 6.1: Produce Population-Level Report

Overview of Scenario

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

Example of Scenario

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.

Requirement 6.2: Notify Patients of Immunization Status

Overview of Scenario

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

Example of Scenario

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.

9 USER WORKFLOW 7: MANAGE ADVERSE EVENT REPORTING

9.1 General Description

This workflow 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.

9.2 Who Performs this Workflow

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

9.3 Examples of Work Related to this Workflow

- 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.²⁷ 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.²⁸

- 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.²⁹
- 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.³⁰ VAERS is one of the reports addressed by the Structured Data Capture initiative (although listed as a low priority example).

9.4 Requirements Within Workflow 7

Requirement 7.1: Identify Adverse Event

Overview of Scenario

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

Example of Scenario

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.

Requirement 7.2: Initiate and Submit a VAERS Report

Overview of Scenario

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

Example of Scenario

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 asks Dr. Smith if she wanted to submit a report to VAERS and, if so, the EHR formats and submits a report.

Requirement 7.3: Notify of Previous Adverse Event

Overview of Scenario

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.

Example of Scenario

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

Requirement 7.4: Notify IIS of Update from Adverse Event

Overview of Scenario

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

Example of Scenario

24 hours after her live, attenuated influenza vaccine, Juana Maria Gonzales Morales had 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).

9.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a “guidance” document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to warrant inclusion in the subset for which testing and certification processes will be developed.

10 USER WORKFLOW 8: PROVIDE PATIENT ACCESS

10.1 General Description

This workflow 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.

10.2 Who Performs this Workflow

- 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).

10.3 Examples of Work Related to this Workflow

- 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.

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- 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,³¹ and for daycare facilities and schools.³² 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.

10.4 Requirements Within Workflow 8

Requirement 8.1: Provide Access to Patient Immunization Record

Overview of Scenario

The EHR or other clinical software system provides patients and their authorized representatives with electronic access to immunization records.

Example of Scenario

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

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

Overview of Scenario

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

Example of Scenario

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.

Requirement 8.3: Provide Access to Printable Immunization Record

Overview of Scenario

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

Example of Scenario

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.

Requirement 8.4: Provide Access to Update Immunization Information

Overview of Scenario

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

Example of Scenario

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.

Requirement 8.5: Review Patient-Provided Immunization Information

Overview of Scenario

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.

Example of Scenario

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.

10.5 Gaining Input on Requirements

We seek the following input on each of the above-identified requirements.

1. **Value and Impact.** Does the requirement have a positive impact on any of the following: quality, safety, cost-effectiveness, patient experience of care, health outcomes, or workflow?
2. **Readiness for Implementation.** Are individuals and organizations in your stakeholder group generally ready to implement this requirement?
3. **Identifying a Critical Subset for Testing and Certification.** While all final requirements will be included in a "guidance" document to support software developers and users, testing and certification processes will also be developed for a critical subset of the requirements. We therefore also seek your opinion on whether this requirement is important enough to warrant inclusion in the subset for which testing and certification processes will be developed.

11 USABILITY

11.1 Immunization-Related Function and Usability

Usability of EHRs and other clinical software systems receives considerable attention from health care stakeholders and in the lay press. While usability is a fundamental issue for any EHR's functionality, there is no existing program or set of standards that address usability and which is specifically focused on immunization management. The purpose of this section is to

provide a path to addressing usability evaluation for Electronic Health Record (EHR) and other clinical software systems from an immunization perspective.

Software product usability and related topics such as user experience (UX), user-centered design (UCD), user “friendly,” human factors, and human-system interaction have been studied by standards organizations and academia for many years. The International Organization for Standardization (ISO) defines usability as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.”³³ This ISO 9241 standard has been maintained and updated many times.

Many other initiatives and organizations have crafted and asserted their point of view on the “open field” of usability and EHR certification.^{34,35,36,37} EHR vendors and others have raised concerns that usability evaluation should not be prescriptive or limit innovation in software design.³⁸ This section describes approaches to evaluating usability for EHR systems relative to immunization and patient safety.

11.2 Usability Definition and Background

Getting stakeholders to agree on how to evaluate usability for the purposes of EHR certification has always been difficult. Even establishing a common definition for the term “usability” has been a serious challenge. A different definition may be used depending on the organization or the focus of the study conducted. This difference has served to support healthy debate among members of the health IT community, and each variation has represented a step toward the eventual specification and standardization of usability for EHRs.

Building upon established literature, we propose the following definition of usability,:

- The ability of the user to **safely** and **efficiently** obtain what is needed from the system to assure patient safety; and
- The ability of the system to provide information and functionality in a way that allows the user to make the most informed clinical decisions in a **safe** and **effective** manner.

For the purposes of this document, the following informs the overall EHR immunization usability definition:

- **Effectiveness:** Ability to achieve an intended goal/outcome,
- **Efficiency:** Ability to achieve an intended goal/outcome within appropriate time and resource constraints, and
- **Satisfaction:** Ability to achieve an intended goal/outcome in a way that delights the user.

NIST uses the ISO 9241 standard to define usability as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use [ISO 9241].” Immunization-related EHR usability specifies immunization workflow as the context of use and adds to it the dimension of patient safety.

This definition informs the suggested approach to immunization-related usability guidance, testing, and evaluation.

11.3 Guidance, Testing, and Evaluation

There are multiple ways to improve usability and impact workflow and safety outcomes of EHR immunization-related capabilities. The approach recommended here builds upon industry best

practices and standards (Jakob Nielsen’s “10 Usability Heuristics for User Interface Design”)³⁹ and NIST EHR-specific usability efforts that build upon Nielsen’s in “NISTIR 7804: Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records”.⁴⁰ The intent is to create guidance that ensures the patient’s safety through advisement on how to accommodate usability throughout the workflow of all providers involved in the immunization process. The challenge is to provide such assistance without providing an overly prescriptive system design.

Exhibit 3 presents the scope of the current effort to address usability in the context of immunization-related EHR evaluation. The effort focuses on usability dimensions that are more quantifiable and objective. Usability also addresses the more subjective user experience (UX), which is valid and important, yet more subjective and therefore more challenging to evaluate as part of a certification process. Utility, a term describing the functionality present in the EHR system that enables a user to complete a needed or desired task, is a foundation for usability, but does not alone qualify as usability.

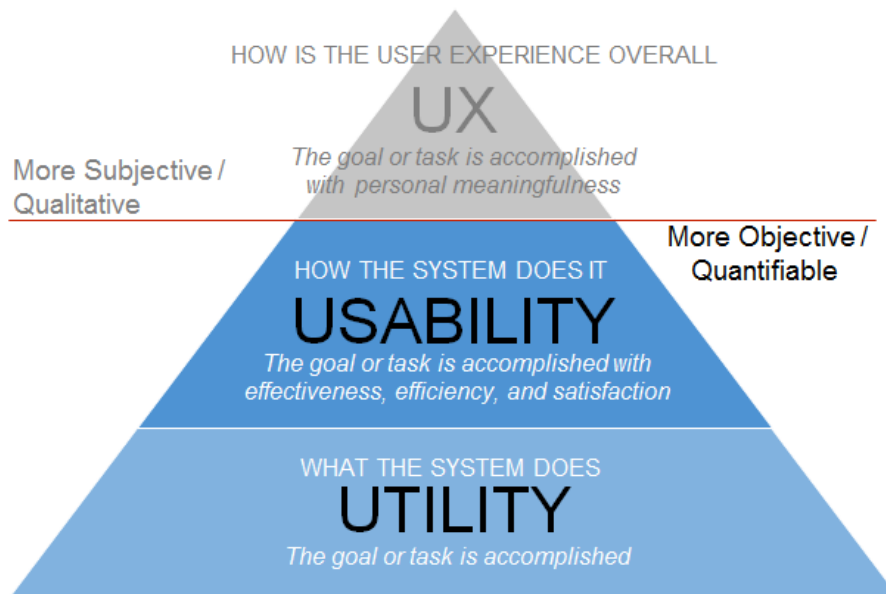


Exhibit 3. Comparison of Utility and Usability Including Dimensions of Usability

Distinguishing utility from usability, NIST published a set of critical user interactions that should be addressed to support EHR usability for pediatric patient care (2012).⁴¹ That report listed five specific interactions that directly or indirectly affect immunizations:

1. Allow ordering vaccination via reminder,
2. Allow data entry for vaccinations given at other institutions,
3. Support display and tracking of components of combination vaccines,
4. Display the days prior vaccinations were given and support alerts for recommended minimum, ideal, and maximum intervals between vaccinations, and
5. Allow sorting of vaccination data by multiple fields.

EHR software can address *utility*; i.e., implementation of each of these critical functions. Safety and efficient workflow are the desired outcomes of improving software's usability (efficiency, effectiveness, and satisfaction).

11.4 Usability Criteria (Heuristics) for Evaluation

The NIST EHR Usability Protocol (EUP)⁴² defines the following criteria (heuristics) to measure usability:

1. Error Handling and Prevention – Even better than good error messages is careful design that prevents a problem from occurring in the first place.
 - a. Patient identification error – Actions are performed for one patient or documented in one patient's record that were intended for another patient.
 - b. Mode error – Actions are performed in one mode that were intended for another mode (e.g., medication ordering by direct dose vs. weight dose, same units, same measurement system, etc.).
 - c. Data accuracy error – Displayed data are not accurate.
 - d. Data availability error – Decisions are based on incomplete information because related information requires additional navigation, access to another provider's note, taking actions to update the status, or is not updated within a reasonable time.
 - e. Interpretation error – Differences in measurement systems, conventions, and terms contribute to erroneous assumptions about the meaning of information.
 - f. Recall error – Decisions are based on incorrect assumptions because appropriate actions require users to remember information rather than recognize it.
 - g. Feedback error – Decisions are based on insufficient information because lack of system feedback about automated actions makes it difficult to identify when the actions are not appropriate for the context.
 - h. Data integrity error – Decisions are based on stored data that are corrupted or deleted.
2. Visibility of System Status – The system should always keep the user informed about what is going on, through appropriate feedback within reasonable time.
3. Match Between System and the Real World – The system should speak the users' language, with words, phrases, and concepts familiar to the user, rather than system-oriented terms. The system also should follow real-world conventions, making information appear in a natural and logical order.
4. User Control and Freedom – Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. The system should provide undo and redo functionality.
5. Consistency and Standards – Users should not have to wonder whether different words, situations, or actions mean the same thing. The system should follow platform conventions.
6. Help Users Recognize, Diagnose and Recover from Errors – Error messages should be expressed in plain language and not use confusing or ambiguous code.
7. Recognition Rather than Recall – Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part

of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.

8. Aesthetic and Minimalist Design – Dialogues should not contain information that is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.
9. Help and Documentation – Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.
10. Pleasurable and Respectful Interaction with the User –The user's interactions with the system should enhance the quality of her or his worklife. The user should be treated with respect. The design should be aesthetically pleasing- with artistic as well as functional value.
11. Privacy – The system should help the user to protect personal or private information belonging to the user or his/her patients.

11.5 Gaining Input on Usability

Please list the top three critical immunization-related functions that should be tested for usability.

12 VALUE OF GUIDANCE AND TESTING/CERTIFICATION FOR IMMUNIZATION-RELATED SOFTWARE CAPABILITIES

12.1 Overview

Improved immunization rates have been linked to better health outcomes, reductions in health care costs, and higher levels of productivity.^{43,44,45}

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. EHRs and other clinical software also have the potential of improving vaccine tracking, vaccine safety, and the ease by which patients can gain access to their immunization histories.

This section—which is stakeholder-specific—is designed to gain input on the value of immunization-related software guidance and/or testing and certification processes.

12.2 Gaining Input from Clinicians and Other Immunization Providers

We seek your input on the extent to which immunization-related capabilities—such as those outlined in this document—will:

1. Enable you to deliver better care to my patients
2. Reduce burden associated with reporting to immunization registries
3. Reduce burden associated with the Vaccines for Children Program
4. Reduce burden associated with reporting on immunization-related performance measures
5. Enhance my ability to meet Meaningful Use requirements under the CMS Medicare and Medicaid EHR Incentive Programs
6. Reduce burden associated with providing immunization-related information to my patients or their caregivers
7. Provide other benefits (please describe).

We also seek your input as to whether you would be willing to consider immunization-related software capabilities—such as the ones described in this document—when making your next EHR or other clinical software purchasing decision.

12.3 Gaining Input from Immunization Information Systems (IIS')

We seek your input on the extent to which immunization-related capabilities—such as those outlined in this document—will:

1. Enable you to receive more immunization-related information from clinicians and other immunization providers
2. Improve the timeliness of receipt of immunization-related information from clinicians and other immunization providers
3. Improve the data quality of immunization-related information received from clinicians and other immunization providers
4. Reduce the burden associated with the receipt of immunization-related information from clinicians and other immunization providers
5. Reduce the burden associated with the transmission of immunization-related information to clinicians and other immunization providers
6. Provide other benefits (please describe).

12.4 Gaining Input from EHR and Other Clinical Software Developers

We seek your input on the extent to which immunization-related capabilities—such as those outlined in this document—will:

1. Enable your customers who are clinicians and other immunization providers to deliver better care to their patients
2. Reduce the burden associated with developing and implementing software changes associated with reporting to immunization registries (as required under the CMS Medicare and Medicaid EHR Incentives Programs and related Standards and Certification Criteria)
3. Provide other benefits (please describe).

We also seek your input as to whether you would be willing to consider pursuit of a voluntary testing and/or certification program to demonstrate software adherence to immunization-related software capabilities or requirements.

12.5 Gaining Input From Those Who Pay for Health Care

We seek your input on the extent to which immunization-related capabilities—such as those outlined in this document—will:

1. Enable clinicians and other immunization providers to deliver better care to their patients
2. Improve the accuracy and timeliness of reporting on immunization-related performance measures
3. Improve the quality and safety of health care and/or health outcomes
4. Improve the cost of care
5. Improve the patient experience of care

6. Provide other benefits (please describe).

14 END NOTES

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